Ping Xiong

# An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement

## *An Interpretation of the TRIPS Agreement in Relation to the Right to Health*

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## An Interpretation of the TRIPS Agreement in Relation to the Right to Health

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PART TWO

## INTERPRETATION OF TRIPS

# Abstract

Intellectual property protection has entered into the global trading era. This is the consequence of the conclusion of the Marrakesh Agreement Establishing the World Trade Organization (WTO) and the inclusion in it of the intellectual property protection law known as the TRIPS Agreement. Intellectual property protection is a system which is based on a balance between the protection of private rights and public interests. The minimum standard of patent protection under the TRIPS Agreement requires all WTO members to make their respective patent laws comply with those minimum standards.

The TRIPS Agreement requires pharmaceutical patent protection in all member States. As a result of this patent protection under the TRIPS Agreement, pharmaceutical patent holders enjoy a strong monopoly position and can control the price of medicines by taking advantage of this position. If patent holders inflate drug prices, this will impact on the access to medicines. Therefore, pharmaceutical patent protection under the TRIPS Agreement regime is potentially in conflict with the right to health. The right to health, as a basic human right, entails access to medicine as its essential element, and it requires the parties to human rights treaties to respect, to protect and to fulfil the right.

This book analyses the relationship between the TRIPS Agreement and the right to health and relevant human rights norms by using the tools of treaty interpretation of public international law. It explores how the TRIPS regime, and ultimately the whole WTO regime, relates to the relevant human rights norms. Further, it examines the specific relevant provisions of the TRIPS Agreement to determine how far the TRIPS regime relates to the right to health. It ends with an analysis of the TRIPS-plus regime to explore its relationship with the right to health. This book concludes that the TRIPS Agreement should be interpreted with reference to the right to health. This method of interpretation should be applied so that the TRIPS Agreement and the right to health will not be in conflict.

# Preface

In this book Dr Xiong makes a cogent argument for the relevance of human rights – specifically the right to health – into the general discourse, and ultimately into the corpus of law to be generated by the dispute resolution procedures of the World Trade Organisation (WTO), regarding trade-related intellectual property rights (TRIPS). A key example is presented by the protected patents of life saving drugs, held by large pharmaceutical companies, and the desperate need of poor people in developing countries to access those drugs.

I come to this subject without a specialised knowledge of trade law or intellectual property law. I am a general international lawyer, and my comments must be understood in that light. I cannot offer a critique of all of the points made by Dr Xiong in her book. However, I join with Dr Xiong in believing that the subject of her book needs to be subjected to examination in a wider context. It seems to me that new areas of international law run the danger of attracting a following of enthusiastic labourers in each vineyard who are unaware of what is happening over the hill. In other words, new bodies of law such as international environment law and international trade law, and even older bodies of law such as intellectual property law, can be treated by some as closed systems insulated against outside influences, and maintained as the preserves of specialised and elite priesthoods. I do not count Dr Xiong among their number. She has indeed made a strong case in her book that one should look over the hill and see that human rights law, and other principles of international law, have a strong claim to a place in the structure and implementation of international trade law.[1]

The notion of international law as an "open" system has been expounded by Professor James Crawford in the collection of his essays entitled "International Law as an Open System".[2] Crawford considers international law to

[1] See e.g. D. Kinley, S. Joseph and J. Waincymer (eds), The World Trade Organisation and Human Rights: Interdisciplinary Perspectives (Elgar Publishing, UK, 2009); D. Kinley, Civilising Globalisation: Human Rights and the Global Economy (Cambridge UP, 2009).

[2] Cameron May Publishers, London, 2002.

be both "open", in the sense of open to new areas of legal activity, and a "system" in that those new areas are accommodated within a stable structure. He writes:

> By contrasting the current situation in a number of fields of international law with the situation as it was, say, in the first third of the twentieth century, it is possible to see two things clearly enough: first, that the present is a period of comparative openness and reformation; and secondly, that the sense of fluidity, opportunity and uncertainty characteristic of the present period coexists with a systematic sub-structure of international law which is recognisably the same as that of, say, the 1920s. Institutions have been created, have changed and developed, many new rules and arrangements have come into existence. But, in principle, the foundations do not appear to have changed (statehood, treaty, custom, consent, acquiescence…). Thus we have the apparent paradox of rapidly expanding horizons and a simple, not to say, elemental set of underpinnings. Our system is one which international lawyers of four generations ago would have had no particular difficulty in recognising or working with, once they had got over its bulk.

I am struck by Crawford's phrase "expanding horizons but a simple…set of underpinnings". I think this neatly captures the main point Dr Xiong makes in urging that human rights, as an underpinning of the international legal system, must not be lost sight of in such new horizons as the TRIPS Agreement.

I turn now to a brief exploration of a few other avenues prompted by Crawford and by the issues raised by Dr Xiong in her excellent book.

First, I point to the underpinnings of international law in treaty and in custom. Both are at play in the debate about TRIPS and human rights. Treaties, such as the various instruments constituting the World Trade Organisation, including the TRIPS Agreement, require implementation by the parties in good faith. No State is required to become a party to any treaty. But if it does so, it is then bound by its terms. A State is not bound by a treaty to which it is not a party, but it may be bound in cases where a particular right or obligation, expressed in a treaty, has become so widely observed that it has entered into a parallel existence as a rule of customary international law. Examples include the prohibition of aggression and of torture. In every case, one has to be careful in analysing the precise extent of the right or obligation in question. In the case of treaties, customary international law provides principles and rules, confirmed in the Vienna Convention on the Law of Treaties, 1969, for the interpretation and application of treaty provisions. These include the literal meaning of the words used, their context and their purpose (allowing also for the use of the negotiating history).

Dr Xiong has rightly invoked the Vienna Convention rules in her argument regarding the interpretation of TRIPS. She also rightly recognises that

the right to health is not expressed in terms as peremptory as some of the "negative" human rights expressed in the field of civil and political rights. We begin with the Universal Declaration of Human Rights, adopted by the UN in 1948 as a non-treaty document but as a proclamation of "a common standard of achievement for all peoples and all nations." Article 25 of the Declaration states that:

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services. . . .

In time the Declaration has come to be regarded as customary international law, and recognised as such.[3] But it was always intended that the bare bones of the rights contained in the Declaration should be elaborated in a form that would be formally binding on States as a treaty. In fact, in 1966 there emerged two treaties built on the Declaration: the International Covenant on Economic, Social and Cultural Rights, and the International Covenant on Civil and Political Rights. This division took account of the reality that some rights depended for their fulfilment on the different levels of development to be found among States, whereas others, such as the prohibition of arbitrary killing, or torture, or the right to a fair trial, allowed for no such differentiation. The right to health belongs to the former category. The International Covenant on Economic, Social and Cultural Rights (ICESCR) allows for the progressive achievement of these rights for its peoples. Article 2 of the Covenant provides:

> Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.

The right to health is expressed as follows in the ICESCR, article 12:

1. The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:

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[3] See e.g. T. Meron, Human Rights and Humanitarian Norms as Customary Law (Clarendon, Oxford, 1989).

(a) …;
(b) …;
(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

It is noticeable that the general right, echoing the Universal Declaration, is stated first in article 12 as a right of the individual. The obligations of States are stated afterwards in paragraph 2. It is thus arguable on the basis of the language and context of these provisions, and of the previous Universal Declaration, that the right of individuals to the highest attainable standard of health is a general right antecedent to the particular steps to implement the right that are the obligation of States Parties to take progressively on the basis of their abilities. I take it that this is the argument that Dr Xiong is making in contending for the balancing of this right against the rights of patent holders of medicines. Attention has mostly focused in the past on the obligations of States to implement human rights, expressed in the typology "to respect, to protect, and to fulfil".[4] The invocation of human rights in disputes with third parties is relatively novel. Can the right to health be invoked against a patent holder by a developing State to manufacture or license pharmaceuticals for its own peoples facing a public health crisis?

The second avenue I would like to note briefly is the emergence of new forms of dispute resolution. It is especially relevant in the context of the subject of this book since many would wonder why there has not yet been a definitive judgment of some court, or other competent body, resolving the conflict between BigPharma on the one hand and the victims, for example, of the HIV-Aids pandemic in southern Africa on the other.

States have been traditionally cautious of accepting the compulsory jurisdiction of international courts and tribunals. States have also been reluctant to allow standing to non-State entities before international courts and tribunals created by them. The International Court of Justice stands foremost among dispute resolution bodies at the international level. However, only about one third of the UN membership has accepted its compulsory jurisdiction, and even then, many acceptances have been hedged by exceptions and qualifications. Moreover, only States may appear before the Court; the interests of individuals/corporations may be addressed by the Court only if "espoused" by their national States. Arbitration has long been a frequent means by which States settle their disputes, but again resort to arbitration is

[4] O. De Schutter, International Human Rights Law: Cases, Materials, Commentary, 242–257 (Cambridge University Press, 2010).

essentially voluntary, either ad hoc or by reason of a compromissory clause in a treaty. The parties to arbitration have a degree of autonomy in the selection of the arbitrators and in the conduct of the proceedings. In some forms of international arbitration, individuals may be parties, such as before the International Centre for the Settlement of Investment Disputes (ICSID). In recent years, arbitration has assumed considerable importance in international investment disputes under ICSID, a facility of the World Bank, and in maritime disputes under the United Nations Convention on the Law of the Sea. In relation to the latter, a remarkable – and unexpected – achievement of the UN Third Conference on the Law of the Sea, 1973–82, was to provide for compulsory resort to arbitration in a range of maritime disputes.

These developments towards greater acceptability of the ideal of compulsory dispute settlement have not been matched within the World Trade Organisation. An extremely cautious approach has prevailed. The Dispute Settlement Understanding (DSU) of the World Trade Organisation, in effect since 1 January 1995, provides for panels of three experts to consider disputes between States. Individuals, including corporations, do not have standing. A panel can only issue a report which is not binding until endorsed by a superior organ called the Dispute Settlement Body (DSB). An Appellate Body exists, consisting of seven members, reflective of the general membership of WTO. The Appellate Body does allow for individuals/corporations to have their say, but only as *amici curiae*, not as parties. The ultimate authority for settling disputes thus rests with the WTO Member States acting through the DSB. This is a very top heavy and creaky system. It tends to explain why difficult issues such as the one discussed by Dr Xiong in this book, have not been dealt with, or rather have been reserved for discussion and possible future resolution within the WTO at the political level.[5] The author refers to the Doha Declaration of 2001 and to a proposal for clarification of the issue of public health-related pharmaceuticals by the General Council of WTO, consideration of which has been deferred twice and is now due for acceptance by Members by the end of 2011.

The proliferation of international tribunals in recent years (including also the International Criminal Court) has led to concern regarding the possible fragmentation of international law. Unlike national systems of law, that recognise a supreme court capable of binding all courts lower in the judicial hierarchy, international law knows no such system. Even the International

[5] A limited exception to this view appears to be a single case before a WTO dispute settlement panel in *Canada-Patent Protection of Pharmaceutical Products* (17 March 2000) WT/DS114/R. However, this case did not address the issues covered by Ping in her paper.

Court of Justice has only a title of honour as the supreme organ of international justice. (Famously, the International Criminal Tribunal for the Former Yugoslavia did not follow a ruling by the ICJ in the Nicaragua case.) Is there a danger that tribunals, especially arbitral tribunals under various instruments, or panels under the DSU, may operate in a cocoon of their own making, with little or no regard to the jurisprudence of other international bodies?[6]

Finally, I wish to make a plea for consideration of public international law as a foundational subject for study in our law schools. Students who are genuinely – and rightly – enthused by such fields as environment law, human rights law, natural resources law, intellectual property law, and trade law ought not to embark on these studies without background preparation. Without a foundation in principles of public international law, they are likely to go seriously astray and in time, if they become significant players in these fields, perhaps unwittingly they may work for the undermining of the integrity of the international legal system.

The present book is an antidote to such isolationist thinking. I commend it.

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[6] Tim Stephens, "Multiple international courts and the 'fragmentation' of international environmental law" (2006) 25 Australian Yearbook of International law 227–271.

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Writing a book involves an individual responsibility and at times is a lonely task, but now that the task is complete I would like to acknowledge the encouragement assistance and support I have received from friends and colleagues during the process.

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Finally I thank my dear parents. This book is dedicated to them as a small symbol of my recognition of the great part they have played in my life and my everlasting gratitude for their love and all that they have done to advance my education and my well being.

# Chapter 1

# Introduction

## I. The Issue

International law has seen a recent proliferation of multilateral treaties. This proliferation reflects the ongoing development of traditional areas of international law that deal with instruments which create and facilitate various forms of global order and structure; but it also signals an important shift from "inter-state relations" to "global trading patterns".[1] Newly developed areas, ranging from climate change to corporate social responsibility, have emerged as significant influences impacting upon the traditional areas of international law, changing the international order and affecting the international treaty process. New synergies will emerge from this process and sometimes conflicts will arise between the different areas, requiring new responses. An example is the conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[2] by the World Trade Organization (WTO) and its impact on human rights protection, specifically on the right to health.

The field of intellectual property protection was formally incorporated into the international trade treaty framework with the establishment of TRIPS in 1995. The protection of intellectual property rights has gone through several stages.[3] Initially it was offered at the level of national laws and then a process

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[1] See Sanford R. Silverburg, '(Review of) *The Impact of International Law on International Cooperation: Theoretical Perspectives*, by Eyal Benvenisti and Moshe Hirsch (eds) (2006) 16 *Law & Politics Book Review* 50.

[2] *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) ('*Marrakesh Agreement*') annex 1C ('*Agreement on Trade-Related Aspects of Intellectual Property Rights*').

[3] See John Braithwaite and Peter Drahos, *Global Business Regulations* (Cambridge University Press, 2000) 59 and 63–64. The author is of the view that the development of intellectual property protection has undergone nationalism, bilateralism, regionalism and global stages, with different features at different stages.

of internationalisation expanded and reformed the nature and functions of the field, at first through bilateral and then through multilateral treaties. The conclusion of TRIPS is a product of this process moving towards a global protection era.[4] This process has not only brought intellectual property protection to a global level, but the incorporation into the international trade arena has also caused an evolution in the justification of intellectual property protection.

At differing times, justifications for intellectual property protection were based upon notions of natural rights, disclosure for reward, incentives for innovation, and the economic analysis of innovation. However, the inclusion of intellectual property protection in the WTO regime has given rise to a change from the traditional justifications to one that stresses the goal of promotion of international trade and the furtherance of international economic policy. This international process is driven by the belief that not only is adequate intellectual property protection necessary for world-class innovation and creativity, but that it will also promote technology imports and foreign direct investment (FDI).[5]

The TRIPS regime has itself undergone several phases during the process of challenges and discussion.[6] The various phases, according to Gervais, are informed by "*addition narratives*", "*subtraction narratives*" and "*calibration narratives*" respectively.[7] These phases require a deeper understanding of TRIPS. In particular, the understanding of the TRIPS regime needs to be developed for implementation by the member countries in the light of their national policy considerations and of the criticisms of TRIPS. The TRIPS Agreement is said to include "a significant degree of built-in policy flexibility that developing economies can use,"[8] and it is most important for developing economies to make full use of this flexibility to overcome the negative impact of higher intellectual property protection and to achieve more benefits. This

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[4] Ibid.

[5] See Daniel Gervais, 'TRIPS and Development' in Daniel Gervais (ed), *Intellectual Property, Trade and Development* (Oxford University Press, 2007) 3–4.

[6] See Daniel Gervais, 'Introduction' in Gervais (ed), above n. 5, xv–xvii.

[7] Ibid. According to Gervais, the first phase of TRIPS started with a well-documented push by the United States, later supported by the European Commission and the Japanese, to link intellectual property rules and trade rules in the WTO as part of the Uruguay Round of Multilateral Trade Negotiations, which ended in Marrakesh in April 1994. The second phase began during the new millennium and is characterised by highly critical analyses of the TRIPS negotiation process, arguing that it is based on coercion of, and/or ignorance on the part of, the developing world, leading to poor outcomes. The third phase focuses on the differences among developing countries and on the calibration of the TRIPS implementations with their national innovation policies.

[8] Daniel Gervais, 'TRIPS and Development' in Gervais (ed), above n. 5, 3–4.

will require a greater understanding of the intellectual property protection policy contained in TRIPS.

One area that requires consideration is the apparent conflict between the need to provide affordable access to essential medicines and the higher level of pharmaceutical patent protection required by TRIPS at the global level.

On the one hand, serious epidemic disease poses a global threat to human health,[9] and without adequate medication many people may die.[10] With access to appropriate drugs, many kinds of diseases are controllable. The right to health is a basic human right.[11] The acknowledgment of, and giving effect to, the right to health entails access to essential drugs as a matter of major concern.[12] The right to health may also be related to the right to life[13] when the denial of access to life-saving drugs occurs in a medical context. Therefore, the threat to human health can give rise to the invocation of the right to health and related human rights protections to justify access to medicines.

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[9] WHO [World Health Organization] Secretariat, *More Equitable Price for Essential Drugs: What Do We Mean and What Are the Issues*? Executive Summary, Background Paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, 8–11 April 2001 (30 March 2001).

[10] According to the Joint United Nations Programme on HIV/AIDS ('*UNAIDS*'), "by the end of 2007, the estimated number of people living with Human Immunodeficiency Virus ('*HIV*') worldwide in 2007 was 33.2 million (30.6–36.1 million)." In 2007, 2.5 million people were newly infected with HIV, and 2.1 million people died of Acquired Immunodeficiency Syndrome ('*AIDS*'). "Every day, more than 6800 people become infected with HIV and more than 5700 people die from AIDS, mostly because of inadequate access to HIV prevention and treatment services." Joint United Nations Programme on HIV/AIDS, *07 UNAIDS Annual Report. Knowing your Epidemic* (March 2008) <http://data.unaids.org/pub/Report/2008/jc1535_annual_report07_en.pdf>. According to UNAIDS, in 2008 there were 33.4 million people living with HIV and the estimated number of HIV-related deaths was two million. Every day, 1200 children are infected with HIV, 2500 young people (15–24) are infected and 3700 adults (25+) are infected. See UNAIDS, *UNAIDS Annual Report 2009: Uniting the World Against AIDS* (June 2010) <http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/report/2010/2009_annual_report_en.pdf>.

[11] *International Covenant on Economic, Social and Cultural Rights* ('*ICESCR*'), opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) art 12. See also *Universal Declaration of Human Rights* ('*UDHR*'), GA Res 217A (III), UN GAOR, 3rd sess, 183rd plen mtg, UN Doc A/810 (10 December 1948) art 25.

[12] UN Commission on Human Rights Sub-Commission on the Promotion and Protection of Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 52nd sess, UN Doc E/CN.4/Sub.2/2001/13 (27 June 2001) [42]. ('*The Impact of TRIPS Agreement*'). The UN Commission on Human Rights ceased to exist on 19 June 2006 and its function has been replaced by the Human Rights Council.

[13] *International Covenant on Civil and Political Rights* ('*ICCPR*'), opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) art 6.

On the other hand, TRIPS, as part of the WTO package, is an agreement that sets minimum standards for intellectual property protection at the global level. Under that minimum standard protection, non-discrimination provisions require that inventions should not be excluded from the ambit of the patent system due to their field of technology or place of invention, or whether products are imported or locally produced.[14] Pharmaceutical inventions are prima facie eligible for patent protection in accordance with this non-discrimination requirement. The members of TRIPS are obliged to provide a minimum level of patent protection for pharmaceutical inventions. This minimum level of patent protection is very high, and requires the member countries, despite their various economic and historical situations, to give the patent holders the same level of protection in each member's market.[15]

Patents involve a bargain in which the state grants a certain period of monopoly protection in exchange for the disclosure of the invention. The possibility of patent protection provides incentives for investment in innovation and creates conditions favourable for technology transfer for the development of the local economy.[16] It has some positive impacts.

However, the monopoly created by a pharmaceutical patent also means that patent holders can take advantage of their position in the market to prevent the introduction of competitive generic products during the term of the patent.[17] As a result, patent holders can control the price of drugs in the market and can even charge higher prices for drugs and the transfer of a drug's technology.[18]

When the ability of drug companies to control the drug price is combined with the market monopoly guaranteed by TRIPS, high prices may result, meaning that many poor countries cannot afford essential medicines.[19] In this way, pharmaceutical patent protection has an impact upon access to

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[14] TRIPS art 27.1.

[15] See Frederick M. Abbott, 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005) 393, 408–10. Abbott is of the view that patent protection for pharmaceuticals under the "one-size-fits-all" TRIPS Agreement can restrict access to the essential drugs for the poor.

[16] See, for example, David Bainbridge, *Intellectual Property* (Longman Publishing, 5th ed, 2002) 313–7; Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, 2004) 327–9.

[17] Abbott, above n. 15, 408–410.

[18] *The Impact of TRIPS Agreement*, UN Doc E/CN.4/Sub.2/2001/13, [42].

[19] For example, drugs for HIV/AIDS. According to UNAIDS, most poor sub-Saharan countries are suffering from AIDS. UNAIDS, *07 UNAIDS Annual Report. Knowing your Epidemic* (March 2008) <http://data.unaids.org/pub/Report/2008/jc1535_annual_report07_en.pdf>.

medicines. From a public health perspective, this is problematic, because it puts limitations on access to affordable medicines developed by multinational pharmaceutical corporations.[20] In addition, the commercial motivation of intellectual property protection also has the potential to divert medical research to "profitable" diseases that affect people in markets where the return is likely to be greater. It has left the "unprofitable" diseases that mainly affect people in poor countries under-researched.[21]

One criticism of this minimum standard setting in TRIPS is that it defies economic analysis and historical experience and has "deleterious effects on global welfare".[22] Abbott has argued that TRIPS is an example of a flawed bargain because developing countries were under great pressure to establish private stakeholder interests and did not adequately evaluate public interest consequences from a developmental perspective.[23] This has become a central controversy.

This negative impact of TRIPS on access to medicines has raised concern whether the TRIPS regime is in conflict with the right to health.[24] In its Resolution 2000/7, the UN Sub-Commission on the Promotion and Protection of Human Rights recognises that "TRIPS could affect the enjoyment of the right

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[20] Jamie Crook, 'Balancing Intellectual Property Protection with the Human Right to Health,' (2005) 23 *Berkeley Journal of International Law* 524, 525.

[21] *The Impact of TRIPS Agreement*, UN Doc E/CN.4/Sub.2/2001/13, [38].

[22] See Susan K. Sell, *Private Power, Public Law – The Globalization of Intellectual Property* (Cambridge University Press, 2003) 13. According to Sell, this minimum standard agreement advances a "one-size-fits-all" approach, and this approach and the concept of intellectual property have had deleterious effects on global welfare.

[23] Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections,' in Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights – Foundations and Conceptual Issues* (The University of Michigan Press, 2006) 145, 165. Abbott refers to Daniel Kennedy and James Southwick (eds), *Contributions on TRIPS in the Political Economy of International Trade Law: Essays in Honor of Robert Hudec* (Cambridge University Press, 2002). This view is also expressed in Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPS Agreement* (Routledge, 2002), 7–28.

[24] In dealing with intellectual property rights and human rights, the Sub-Commission on the Promotion and Protection of Human Rights has discussed the actual or potential conflicts between TRIPS and the realisation of economic, social and cultural rights. These may restrict access to patented pharmaceuticals and have implications for the right to health. In 2001, the Sub-Commission on the Promotion and Protection of Human Rights raised the issue of the role of the TRIPS Agreement with regard to the promotion and protection of the right to health. UN Commission on Human Rights Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property Rights and Human Rights* Resolution 2000/7 (25th meeting) (17 August 2000) Preamble and [1] ('*Resolution 2000/7*'). Also see CESCR, *The Impact of TRIPS Agreement*, UN Doc E/CN.4/Sub.2/2001/13, [1]–[2].

to health – in particular through its effect on access to pharmaceuticals".[25] Some argue that the right to health includes the right to access medical treatment, and that the denial of affordable drugs due to the impact of patent protection for pharmaceuticals under TRIPS constitutes a violation of the right to health.[26]

It has been proposed that a human rights approach should be introduced to analyse intellectual property protection. The notion of intellectual property protection is also underpinned by certain aspects of the human rights regime,[27] with the entrenchment of the right to property in the UDHR,[28] and the right to fruits of creation contained both in UDHR and in ICESCR.[29] These references establish links between the protection of intellectual property and human rights, and establish grounds for the recognition of intellectual property protection as a basic human right.

When viewed against this background, international law seems to be in potential conflict. On the one hand, there is more and more overlap and inter-connection between each of the areas of international law. On the other hand, the various areas of international law preserve their own central identity, and the relationships between these areas need to be clarified. This results in a more serious issue of whether there is fragmentation or integration of international law. The argument of this book is developed against this background. Its purpose is to make a specific examination of how, and

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[25] UN Commission on Human Rights Sub-Commission on the Promotion and Protection of Human Rights, *Resolution 2000/7*, (25th meeting) (17 August 2000). Also see *The Impact of TRIPS Agreement*, UN Doc E/CN.4/Sub.2/2001/13, [2]. Also see UN Commission on Human Rights, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, 60th sess, UN Doc E/CN.4/2004/49/Add 1 [43].

[26] For this view, see Amit Gupta, 'Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?' (2004) 2 *Buffalo Intellectual Property Law Journal* 127, 151–153; Lissett Ferreira, 'Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations,' (2002) 71 *Fordham Law Review* 1133, 1165.

[27] This has been preliminarily discussed in Peter Drahos, 'Intellectual Property and Human Rights,' (1999) 3 *Intellectual Property Quarterly* 349, 358–65.

[28] UDHR Art 17 provides: "(1) Everyone has the right to own property alone as well as in association with others. (2) No one shall be arbitrarily deprived of his property." Art 17.1 states that "Everyone has the right to own property". Art 17.2 states that "No one shall be arbitrarily deprived of his property." The implications of this Article are that the right to property should be recognised by states; and that states have a right to regulate the property rights of individuals, but that they must do so according to the rule of law. See Drahos, above n. 27, 358.

[29] Art 15.1 of ICESCR and art 27 of UDHR. The term "the right to fruits of creation" may be found in the literature, such as Abbott, above n. 23, 148.

to what extent, the TRIPS regime relates to the right to health and related human rights norms.

TRIPS is under the umbrella of WTO laws. Each part of the WTO forms an integral part of the whole and is consistent with the other parts.[30] TRIPS has been incorporated into the global trade area, and has become one of the three major pillars of the WTO.[31] According to the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU), any dispute arising from the WTO agreements is subject to the WTO dispute settlement system.[32] The WTO dispute settlement system is a central instrument for providing security and predictability to the multilateral trading system.[33] As one of the pillars of the WTO, TRIPS is also subject to the dispute settlement procedures of the WTO laws; these settlement procedures arm TRIPS with teeth to safeguard intellectual property at a global level. In case of any dispute concerning compliance with TRIPS, the WTO dispute settlement Panel will interpret the provisions of TRIPS and issue a report.[34] A decision made by the Panel may be appealed to the Appellate Body (AB).[35] The decision is of binding effect and allows the successful party in a dispute, upon authorisation by the Dispute Settlement Body (DSB), to impose trade sanctions upon the unsuccessful party in case of non-compliance by the losing party. In the course of hearing a dispute, the Panel or the AB will necessarily have to interpret TRIPS provisions. Whether pharmaceutical patent protection has restricted access to medicines under TRIPS, thereby constituting a violation of the right to health, is a relevant matter that may also be considered by the Panel or the AB.

The seeming conflict between the right to health and pharmaceutical patent protection has become an issue, not only in relation to TRIPS, but for all WTO laws. It has also become an issue in relation to human rights laws, specifically the human rights norms of the right to health, the right to property and the right to fruits of creation. This has the potential for conflict in the various international law regimes, including trade, intellectual property

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[30] *Marrakesh Agreement* art II.2 provides: "The agreements and associated legal instruments included in Annexes 1, 2 and 3 are integral parts of this Agreement, binding on all Members."

[31] *General Agreement on Tariffs and Trade* (**'***GATT***'**) (30 October 1947) 55 UNTS 187, *General Agreement on Trade in Service* (**'***GATS***'**) (15 April 1994) 1869 UNTS 183; 33 ILM 1167 (1994) and TRIPS are said to be the three major pillars of WTO.

[32] *Understanding on Rules and Procedures Governing the Settlement of Disputes* (*'DSU'*) (15 April 1994) 1869 UNTS 401, art 1.1.

[33] Ibid., art 3.2.

[34] Ibid.

[35] Ibid.

protection and human rights protection. This overlapping effect leads to the need to deal with the issue of the access to medicines and pharmaceutical patent protection, both inside TRIPS and WTO laws, and outside WTO laws.

Intellectual property law is a system based on a delicate balance between the private interests of intellectual property owners, and the public interest in having access to the creations and their benefits.[36] In order to achieve a fine balance between the users and owners of intellectual property rights, private interests and the public interest, and the interests of developing countries and developed countries, TRIPS contains a series of Articles which form its own balance mechanism. Many of the Articles contained in the balance mechanism are said to offer flexibilities in the field of patent protection to cope with the public health problem.[37]

In November 2001, the WTO Ministerial meeting was held in Doha and adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).[38] This Declaration recognises a WTO member's right to protect public health and to promote access to medicines for all. In December 2005, the WTO Ministerial Conference was held in Hong Kong and the General Council proposed an amendment of Article 31 of TRIPS with clarifications for the "importing countries" and "exporting countries" and measures to prevent diversion of the public health-related pharmaceuticals. This adds more flexibility to deal with the problem of access to medicines.

This raises a number of questions. Can human rights norms be introduced into TRIPS and the whole WTO laws? How can such human rights norms be introduced? To what extent can TRIPS introduce such norms external to WTO law into its own regime? Can all of these flexibilities adequately respond to the right to health? How, and to what extent, can they respond to the right to health? Or will attempts to recognise a positive interrelationship between TRIPS requirements and human rights norms cause fragmentation to the human rights law?

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[36] Sell, above n. 22, 14; also see Jill McKeough, Andrew Stewart and Philip Griffith, *Intellectual Property in Australia*, (LexisNexis Butterworths, 3rd ed, 2004) 25–26.

[37] For a full range of flexibilities offered by TRIPS, see Abbott, above n. 23, 151.

[38] *Ministerial Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (20 November 2001).

## II. Approach to the Argument of this Book

One of the most important consequences of incorporating intellectual property protection rules into the WTO is the more effective enforcement of intellectual property protection through a powerful dispute settlement system. The major responsibility of the WTO Panels and Appellate Body is to interpret the WTO agreements, including the TRIPS Agreement.[39] How will the Panels and the Appellate Body interpret the TRIPS Agreement flexibilities? Will they also take the human rights norms into consideration while interpreting TRIPS? How can these human rights norms be introduced into the interpretation of TRIPS flexibilities, and to what extent?

This book will analyse these issues from the perspective of how the WTO Dispute Settlement Body should interpret the TRIPS provisions. Article 3.2 of the DSU requires WTO laws to be interpreted in accordance with the customary rules of interpretation of public international law.[40] Paragraph 5 of the Doha Declaration reaffirms that TRIPS should be interpreted in accordance with customary rules of interpretation of public international law and emphasises the reference of the object and purpose of TRIPS for the interpretation.[41] In addition, WTO jurisprudence shows that the customary rules of interpretation of public international law have been applied in WTO dispute resolution.

This book will consider the established rules of public international law followed in WTO jurisprudence to find the meaning and "built-in policy" of the relevant TRIPS provision. It is intended to determine whether there is conflict or cohesion between the TRIPS regime and human rights regime, and how far the TRIPS regime can relate to the right to health.

The book begins with an overview of the TRIPS regime and the human rights regime, and presents the apparently conflicting relationship between

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[39] Laurence R. Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale Journal of International Law* 1, 75.

[40] DSU art 3.2 provides: "The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements."

[41] Doha Declaration para. 5(a) provides: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

the two regimes to find whether there is integration or fragmentation between them. It then goes from the general to the specific to examine the two regimes by specifically applying the right to health to the TRIPS regime by means of treaty interpretation in international law.

## III. Focus of this Book

This book is limited to an examination of the right to health and the related human rights norms, including the right to life, and intellectual property protection-related human rights norms, such as the right to property and the right to fruits of creation. The examination of the right to life will be limited to the scope that overlaps with the right to health, and the examination of the right to property and the right to fruits of creation will be limited to the relationship with intellectual property protection. It does not examine the relationship between TRIPS and other human rights norms, such as the right to development, the right to food, the right to freedom of expression, and the right to education. Further, the examination of TRIPS is limited to the patent protection required in TRIPS and does not cover other areas of intellectual property protection, such as copyright, trademark and geographical identification protection. Another limitation is that this book uses only treaty interpretation to deal with the relationship between the TRIPS regime and the human rights regime, and does not go into the implementation of TRIPS in national laws. Nor does it extend the examination to other related regimes, such as WHO. In summary, the argument of this book focuses on the relationship between TRIPS and the right to health and the intellectual property rights-related human rights norms.

## IV. Scheme of this Book

In order to discuss how, and to what extent, TRIPS relates to the right to health, this book starts by clarifying the right to health and the related human rights norms in the human rights regime. Then it examines the TRIPS regime to find out how that relates to the right to health, and the specific TRIPS provisions to find out how far they can relate to the right to health. Finally, it continues with an examination of the TRIPS-plus regime to find out how far that can relate to the right to health.

Part One presents the international context of the human rights regime and the apparent conflict between the human rights regime and TRIPS. The purpose of this Part is to clarify the related human rights norms, including their content and scope and their relationship with each other, to present

the apparent conflict, and to establish an approach to deal with the apparent conflict. Part One consists of Chapters 2 and 3.

Chapter 2 locates the right to health within the human rights regime. The purpose of this Chapter is to investigate the content and scope of each human rights norm. The Chapter begins by observing that the right to health is well recognised in human rights law as a way to ensure access to medicine as one of the people's health rights, and further that the right to fruits of creation and the right to property in human rights law are different from intellectual property protection in private law. The relationship between the right to health and the right to life is analysed to show the status of the right to life in the health context. This section also provides an analysis of the right to health and the right to life, since the denial of life-saving drugs in the health context can give rise to consideration of the right to life, and the right to life is always used to make an argument that TRIPS has the potential to violate the right to life on health matters. The individually-based human rights regime may be found to be incompatible with the group-based concept of public health. However, TRIPS uses language that explicitly recognises the need to protect public health. Accordingly, this Chapter examines the relationship between the right to health and public health. Under certain circumstances, the right to life may achieve *jus cogens* status, that is, having a special character in international law which allows for no derogation. It is therefore crucial to clarify the relationship between the right to health and the right to life in order to define the right to health. Since TRIPS is central to human health rights concerning access to medicines, it is important to clarify whether a denial of access to a life-saving drug can amount to a breach of the right to life. After the examination of these two human rights norms, the other human rights norms – the right to property and the right to fruits of creation – are clarified. A human rights approach to patent protection is introduced to identify the scope of the two human rights norms in terms of intellectual property rights. In this analysis, the changing justification from a territorial to regional and global protection underlying patent protection is introduced to identify the human rights approach to patent protection.

Chapter 3 continues the examination by starting to raise the nature of the challenge from the human rights regime to the TRIPS regime to delineate the apparent conflict between the right to health and TRIPS. The purpose of this Chapter is to identify the approach required to respond to the challenges presented. An examination follows of the grounds for the limitation and derogation of human rights norms within the human rights regime itself, to find out how the differing human rights norms can relate to each other. Analogously, the similar grounds in WTO jurisprudence are introduced to make a comparison with the human rights regime. After this examination, a further question on how the TRIPS regime can relate to the human rights

regime is introduced. The approach of treaty interpretation proposed by Joost Pauwelyn is discussed to examine whether there is conflict or cohesion between the two regimes.[42] The example of the right to health in the human rights regime is used for the examination of fragmentation or integration in the two regimes in international law.

Part Two of the book starts the examination of the two regimes from the perspective of the WTO dispute settlement to give an interpretation of the related TRIPS provisions to discuss how TRIPS relates to the right to health. Part Two includes Chapters 4, 5 and 6.

Chapter 4 starts with an attempt to locate the proper approach used by WTO jurisprudence for interpretation of WTO laws. The chapter continues with analysis of the interpretation of WTO laws, with reference to WTO dispute settlement cases and jurisprudence, examining the evolutionary approach of interpretation of WTO laws. Particular attention is paid to the manner in which international rules and principles can be introduced into WTO jurisprudence. In addition, the interpretation relationship between WTO covered agreements, and the interpretation relationship between the covered agreements and the incorporated agreements are examined.

Chapter 5 provides specific analysis of the related TRIPS regime to investigate how it relates to the right to health and the human rights regime. The related Articles 27, 28, 30 and 31 are given special attention, with an intensive study of the Preamble and Articles 7 and 8 to reveal the object and purpose of TRIPS.

Chapter 6 addresses the way the TRIPS regime introduces human rights norms and gives an analysis of the application of the relevant human rights norms in the TRIPS regime. The specific provisions of TRIPS are analysed to discern how far the TRIPS regime relates to the right to health and the human rights regime.

Part Three consists of Chapter 7, which continues the examination of the TRIPS-plus regime to investigate how the TRIPS-related regime can relate to the right to health through interpretation.

Chapter 8 sets out the conclusion of the book.

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[42] See Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 244–74.

# Part One

## Preliminary

# Chapter 2

## The International Human Rights Context

### I. The Right to Health in International Law

The right to health is a stand-alone right in international human rights law and is generally regarded one of the economic, social and cultural rights. Various terms are used to address the right to health as a human right. Usually, the term employed is "the right to health", but it can also be "the right to health care" or "the right to health protection", and in a broader sense "health rights".[1] The right to health is a more formal term appearing in many international instruments.

#### A. *Wide Recognition*

The atrocities committed during the Third Reich provided a catalyst after World War II for the inclusion of the health right as a human right within the framework of the United Nations. A special Memorandum had declared that "medicine is one of the pillars of peace", and this led to the insertion of a reference to health in Article 55 of the UN Charter.[2] Since then, the right to

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[1] Brigit Toebes, 'The Right to Health' in Asbjørn Eide, Catarina Krause and Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers, 2001) 169, 170. For example, art 12 of ICESCR used the term of "health", while art 25(1) of UDHR used the term of "medical care", art 152(1) of the *European Constitution* used the term of "human health protection", although "its fate is at the present time uncertain".

[2] The Memorandum quoted a statement of Spellman, then Archbishop of New York. See World Health Organization (WHO), *The First Ten Years of the World Health Organization* (Columbia University Press, 1958) 38; and art 55 of the *Charter of the United Nations* ('*UN Charter*') provides: "With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote: a. higher standards of living, full employment, and conditions of economic and

health has been included in various human rights conventions and treaties, and been confirmed as an international law norm.

The right to health has been accepted as a treaty norm in the International Covenant on Economic, Social and Cultural Rights (ICESCR) by 156 members of the United Nations.[3] Article 12 of ICESCR states that

> 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>    (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
>    (b) The improvement of all aspects of environmental and industrial hygiene;
>    (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>    (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The right to health has also been incorporated in the Universal Declaration of Human Rights (UDHR)[4] as an important human rights source. Article 25 of the UDHR states

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

### 1. *International Recognition*

Apart from the right to health being recognised in the UDHR and ICESCR at the United Nations level, the right to health has been recognised as one of fundamental human rights at the regional level, as in the Charter of Funda-

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social progress and development; b. solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and c. universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion."

[3] *International Covenant on Economic, Social and Cultural Rights* ('*ICESCR*'), opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976).

[4] *Universal Declaration of Human Rights*, GA Res 217A (III), UN GAOR, 3rd sess, 183rd ple mtg, UN Doc A/810 (10 December 1948) ('*UDHR*').

mental Rights of the European Union 2000 (EUCFR),[5] the European Social Charter of 1961 as revised in 1996,[6] the African Charter on Human and People's Rights,[7] the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights.[8]

Other international organisations and international instruments have also recognised the right to health as a fundamental right of human beings or have included the right to health in specific areas. The World Health Organization (WHO), whose very establishment indicates the importance that the international community puts on health, in its Constitution sets as its objective the "attainment by all peoples of the highest possible level of health".[9] The Constitution also recognises that, "the enjoyment of highest attainable standard of health is one of the fundamental rights of every human being", and that "governments have a responsibility for the health of their peoples through the provision of adequate health and social measures".[10]

The International Convention on the Elimination of All Forms of Racial Discrimination (1965) (CERD),[11] the Convention on the Elimination of All Forms of Discrimination Against Women (1979) (CEDAW),[12] and the Convention on the Rights of the Child (CRC) all recognise the right to health care of the specific group of people as a fundamental right.[13] Furthermore, other

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[5] *The Charter of Fundamental Rights of the European Union* 2000 [7 December 2000] OJ (C 364) 1, ('*EUCFR*'); it includes some articles to handle the health right of human beings, although the status of the EUCFR is not entirely clear at present.

[6] *European Social Charter*, ETS No. 163 (18 October 1961) art 11.

[7] *African Charter on Human and Peoples' Rights*, 1520 UNTS 217, 21 ILM 58 (27 June 1981) ('*African Charter*') art 16.

[8] *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights*, OAS TS No. 69; 28 ILM 156 (1989) art 10.

[9] Art 1 of WHO Constitution provides: "The objective of the World Health Organization (hereinafter called the Organization) shall be the attainment by all peoples of the highest possible level of health."

[10] The Preamble of WHO Constitution provides: "THE STATES Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:. . . . The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States. . . . Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.…".

[11] *International Convention on the Elimination of All Forms of Racial Discrimination*, 660 UNTS 195 (21 December 1965) ('*CERD*') art 5 (e) (iv).

[12] *Convention on the Elimination of All Forms of Discrimination against Women*, 1249 UNTS 13; 19 ILM 33, (18 December 1979) ('*CEDAW*') arts 11(f) and 12.

[13] *Convention on the Rights of the Child*, 1577 UNTS 3; 28 ILM 1456 (20 November 1989) art 24(1). It recognises child's highest attainable standard of health and right to health care services.

areas of international law, such as international humanitarian law,[14] international environmental law[15] and international labour law,[16] have included health concerns.

This wide recognition of the right to health indicates that there is a common understanding about it in the international community and that it constitutes customary international law norm, a treaty norm, and a soft law. This fact is of importance to the later argument of this book which is the requirement that TRIPS should be interpreted by taking it into account.[17]

### 2. *National Recognition*

In addition, this recognition and establishment of the right to health in international human rights law and other areas of international law has influenced individual states to protect the health right of their peoples by addressing it through various provisions regarding health and health care in national constitutions.[18]

67.5 per cent of the constitutions of all nations have provisions addressing health or health care.[19] This is a high level of national recognition of the fundamental rights nature of human health and efforts to promote the implementation of the international human right to health.[20] In the same research, the author, categorised five types of constitutional provisions that addressed

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[14] David F. Fidler, 'International Law and Global Public Health' (1999) 48 *U Kan L Rev 1*, 32. For example, international humanitarian law also contains detailed rules protecting the health of combatants, prisoners of war, and non-combatants in international and civil armed conflicts; Health values have also been introduced into arms control of international law to ban the use, production and stockpiling of certain classes of weapons to address threats to the health of populations and to address concerns for individual health.

[15] Among these laws, the international legal rules on transboudary air pollution; transboundary water pollution; marine pollution; transboundary shipment of hazardous waste, chemicals and pesticides; nuclear accidents; protection of biodiversity; depletion of the ozone layer; and climate change directly relate to the objective of human health.

[16] For example, the ILO (International Labour Organization) *Convention Concerning Occupational Safety and Health and the Working Environment* (ILO No. 155) requires that each state shall formulate, implement and review a national policy on occupational health and safety. Convention concerning Occupational Safety and Health Convention and the Working Environment (entered into force 11 August 1983) 1331 UNTS 279.

[17] See Part Two. Chapter 6.II.

[18] Virginia A. Leary, 'The Development of the Right to Health' (2005) 11 No. 3 *Human Rights Tribune Des Droits Humains*, available at <http://www.hri.ca/pdfs/HRT%20Volume%2011,%20No.3%20Autumn%202005.pdf>.

[19] Eleanor D. Kinney and Brian Alexander Clark, 'Provisions for Health and Health Care in the constitutions of the Countries of the World' (2004) 37 *Cornell Int'l L J* 285, 287.

[20] Ibid., 287.

health and health care in national constitutions: They are either statements of aspiration, statements of entitlement, statements of duty, programmatic statements or referential statements.[21]

The South African Constitution gives an entitlement to the people and imposes a duty on government to protect the health of its people.[22] The Argentine Constitution has incorporated international treaties which refer to the right to health.[23] In Ecuador, the Constitution provides that it is a duty of

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[21] Ibid., 289–90; for example, Art 22 of Chapter I of the *Netherlands Constitution* is an example of an aspirational statement: "The authorities shall take steps to promote the health of the population." (translated & reprinted in *13 Constitutions of the Countries of the World: The Netherlands 4* (Gisbert H. Flanz ed, Dr Frank Hendrick trans, 2003); Art 94 of pt. II, ch. III of the *Mozambique Constitution* is an example of a statement of entitlement, and provides: "All citizens shall have the right to medical and health care, within the terms of the law, and shall have the duty to promote and preserve health."; translated & reprinted in *12 Constitutions of the Countries of the World: Mozambique 42* (Albert P. Blaustein & Gisbert H. Flanz, eds, Afr Eur Inst Trans, 1992)); Art 44 of the *Uruguay Constitution* (1966 as amended to 1996) provides an example of a statement of duty: "The State shall legislate on all questions connected with public health and hygiene, endeavouring to attain the physical, moral, and social improvement of all inhabitants of the country. It is the duty of all inhabitants to take care of their health as well as to receive treatment in case of illness. The State will provide gratis the means of prevention and treatment to both indigents and those lacking sufficient means." Art 52 of the *Constitution of Bulgaria* (1991 as amended to 2003) is an example of programmatic statement, "(1) citizens have the right to health insurance that guarantees them accessible medical care and to free medical care under conditions and according to the procedure determined by law. (2) The citizens' healthcare is financed from the state budget, by employers, by personal and collective insurance payments, and from other sources under conditions and according to a procedure determined by law. (3) The state protects the health of citizens and encourages the development of sports and tourism. (4) No one may be subjected to forced medical treatment or sanitary measures except in cases provided by law. (5) The state exercises control over all health institutions as well as over the production of pharmaceuticals, biologic[al] substances and medical equipment and over their trade." Art 10 of the *Czech Republic Constitution* provides an example of direct reference to international human rights treaties: "International treaties, to whose ratification Parliament has consented and by which the Czech Republic is obligated, are part of the legal order; if the international treaty shall be used." (translated & printed in *5 Constitution of the Countries of The World, Czech Republic 2* (Gisbert H. Flanz ed., Gisbert H. Flanz & Patricie H. Ward trans, 2003)).

[22] Art 27 of *South African Constitution* (1997 as amended to 2003) provides, "(1) Everyone has the right to have access to – (a) health care services, including reproductive health care; (b) sufficient food and water; and (c) social security, including, if they are unable to support themselves and measures, within its available resources, to achieve the progressive realisation of each of these rights. (3) No one may be refused emergency medical treatment."

[23] Subsection 22 of Art 75 of pt II, tit I, s 1, ch IV of the *Argentine Constitution* provides: "The following [international instruments], under the conditions under which they are in force, stand on the same level as the Constitution, [but] do not repeal any Art in the First Part of this Constitution, and must be understood as complementary of the rights and guarantees

the state to guarantee the right to health.[24] India mentions the right to health and its role in the Article 47 of its Constitution; this Article is in Part IV of the Constitution of India which is headed "The Directive Principles of State Policy".[25] The Netherlands Constitution provides a programmatic example; it mandates health protections with the requirement on the state to take steps to promote the health of the population.[26]

In addition, some countries without explicit national constitution provisions to address the health concern of people have enshrined the right to health in their health policies. Australia ratified the ICESCR in 1975,[27] and has established a national health care funding system called "Medicare" to

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recognized therein: The American Declaration of the Rights and Duties of Man; the Universal Declaration of Human Rights; the American Convention on Human Rights; the International Pact on Economic, Social and Cultural Rights; the International Pact on Civil and Political Rights and its empowering Protocol; the Convention on the Prevention and Punishment of Genocide; the International Convention on the Elimination of all Forms of Racial Discrimination; the Convention on the Elimination of all Forms of Discrimination against Woman; the Convention against Torture and other Cruel, Inhuman or Degrading Treatments or Punishments; the Convention on the Rights of the Child. They may only be denounced, if such is to be the case, by the National Executive Power, after prior approval by two-thirds of the totality of the members of each Chamber." (Translated and reprinted in *1 Constitutions of the Countries of the World: Argentina 14* (Gisbert H. Flanz ed., Jonathan M. Miller & Fang-Lian Liao trans, 1999)).

[24] Art 42 of Title III of Chapter IV of *the Ecuador Constitution* provides: "The State guarantees the right to health, its promotion and protection, through the development of food security, the provision of potable water and basic sanitation, the promotion of a healthy family, work and community environment, and the possibility of permanent and uninterrupted access to health services, in conformity with the principles of equity, universality, solidarity, quality and efficiency." Translated and reprinted in *6 Constitutions of the Countries of the World: Ecuador 13* (Gisbert H. Flanz ed, Reka Koerner trans, 1999).

[25] Art 47 of the *Indian Constitution* provides: "Duty of the State to raise the level of nutrition and the standard of living and to improve public health – The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purpose of intoxicating drinks and of drugs which are injurious to health." This Art is linked to the Directive Principles of State Policy (DPSP) part of the Constitution which in Art 37 states: "The provisions contained in this Part shall not be enforced by any court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws."

[26] Art 22 of Chapter I of the *Netherlands Constitution* is an example of an aspirational statement: "The authorities shall take steps to promote the health of the population." (translated & reprinted in *13 Constitutions of the Countries of the World: The Netherlands 4* (Gisbert H. Flanz ed, Dr Frank Hendrick trans, 2003)).

[27] See the status of signature and ratification of ICESCR, available at <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en>.

provide health care that is both affordable and accessible to all Australians.[28] This kind of system recognises health rights as basic human rights and this perspective was acknowledged and also applied in *De Bruyn v Minister of Justice and Customs*.[29]

Canada is a party to the ICESCR and ratified it in 1976.[30] The Canadian health system is a publicly-funded system, known as Medicare.[31] The Canada Health Act (1984) has always been regarded as containing the right to health care and as guaranteeing Canadians access to health care.[32]

Although New Zealand is a party to ICESCR with ratification in 1978,[33] the right to health is not affirmed in the New Zealand Bill of Rights Act 1990. However, the Human Rights Amendment Act 2001 of New Zealand provoked a public discussion about the right to health,[34] and the right to health was set as a priority by the Human Rights Commission in the development of a national plan of action for the promotion and protection of human rights in New Zealand.[35] This shows not only a concern to have the right of access to health care in legislation,[36] but also and more significantly health rights are adhered to by Government notwithstanding that absence of legislation.

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[28] See Financing and Analysis Branch, Commonwealth Department of Health and Aged Care, 'The Australian Health Care System: An Outline – September 2000'(available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/EBA6536E92A7D2D2CA256F9D007D8066/$File/ozhealth.pdf>.

[29] *De Bruyn v Minister of Justice and Customs* [2004] FCAFC 334. The case of *De Bruyn v Minister of Justice and Customs* offers a more positive example of the inclusion of the health consideration in the decision-making process. The court, in deciding whether it would be unjust, oppressive or incompatible with humanitarian considerations to extradite a detainee to South Africa due to risk of his contracting HIV/AIDS in prison, ruled that the Minister had failed to address the question of humanitarian considerations of putting the detainee in the even worse health conditions where the risk of contracting HIV/AIDS considerably greater.

[30] See the status of signature and ratification of ICESCR, available at <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en>.

[31] See Collen M. Flood, 'Just Medicare: The Role of Canadian Courts in Determining Health Care Rights and Access' (2005) 33 *J L Med & Ethics* 669, 669.

[32] Ibid., 670.

[33] See the status of signature and ratification of ICESCR, available at <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en>.

[34] Joanna Manning and Ron Paterson, '"Prioritization": Rationing Health Care in New Zealand' (2005) 33 *J L Med & Ethics* 681, 682–3.

[35] See New Zealand Action Plan for Human Rights Priorities Action (2005–2010) para. 6.4, available at: <http://www.hrc.co.nz/report/actionplan/6economic.html>; Manning and Paterson, above n. 34, 682–3.

[36] Manning and Paterson, above n. 34, 683.

The United States has signed but not ratified the ICESCR.[37] The United States Constitution does not contain explicit guarantees on, or promotion of, an individual's right to health care, nor does the Bill of Rights include any provisions explicitly recognising an individual right to health care.[38] The Supreme Court of the United States also has not provided an interpretation of the Constitution to offer a positive right to health care.[39] Some states of the United States have recognised health care as a fundamental right either by way of state health care legislation or by way of state constitutional amendment. However those state provisions have not been interpreted to include access to health care to uninsured or underinsured people.[40] Although it lacks constitutional guarantee and court interpretation, the United States still offers health care protection to eligible persons with federal funding. The Social Security Act enacted in 1965 provides, on approval from the Department of Human and Health Services, a needs-based group of people with basic medical services.[41] In addition, the uninsured and underinsured in the United States are guaranteed access to health emergency medical care under the Emergency Medical Treatment and Active Labor Act; by tax incentives to non-profit hospitals for providing charitable care; by financial incentives for physicians and protection from malpractice liability in the provision of health care service in underserved areas; and by federal, state and local funding for safety net providers, including community health centres and public hospitals.[42] Access to health care can be attributed to access to sufficient funds. The per capita expenditure on health care saw an increase of 63% between 1990 and 1998 in the United States.[43] This is a high percentage.

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[37] See the status of signature and ratification of ICESCR, available at <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en>.

[38] William P. Gunnar, 'The Fundamental Law That Shapes The United States Health Care System: Is Universal Health Care Realistic Within The Established Paradigm?' (2006) 15 *Annals Health L* 151, 178–9.

[39] Ibid., 158–60.

[40] Ibid., 179; also see Rory Weiner, 'Universal Health Insurance under State Equal Protection Law' (2002) 23 W New Eng L Rev 327, 333–4; reporting that six states – Alaska, Hawaii, Michigan, North Carolina, New York, and Wyoming – have constitutional provisions requiring the legislature to promote and protect the public health. None of these states has interpreted the provision to mean that the state must expand access to health care for the uninsured or underinsured.

[41] Gunnar, above n. 38, 165–7.

[42] Ibid., 179, also see Robert F. Rich, 'Health Policy, Health Insurance and the Social Contract' (2000) 21 *Comp Lab L & Pol'y J* 397, 397.

[43] Rich, above n. 42, 414.

### 3. *Significance of the Recognition*

Recognition by international commitment to treaties can reinforce the status of a customary international norm.[44] D'Amato, after an analysis of various considerations in treaties and custom, pointed out that the generalised provisions in bilateral and multilateral treaties generated customary rules of law binding upon all states.[45] According to the author even if there is only a limited number of parties to a particular treaty, the intentions of the treaty parties to restrict the scope of a treaty to them are irrelevant to the community expectations in international law.[46] For example, international codification conventions and the United Nations Charter have direct and immediate impact upon international law and the treaty principles may extend to non-parties.[47] Charney has also pointed out a tendency that the acceptance of the existence of custom can be based on treaties adopted by a large majority of states without there being a great amount of state practice.[48]

The recognition and implementation of the right to health at the national level reinforces the international law status of the right to health. National implementation shows that the right to health is not an empty concept.

## B. *Scope and Content of the Right to Health*

The right to health has been widely recognised, but the indeterminacy and vagueness of the right perhaps accounts for the difficulty in the implementation of the right to health at a national level.[49] These characteristics of indeterminacy and vagueness make the right appear aspirational rather than justiciable.[50] It is, therefore, very important to clarify the content and scope of the right to health.

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[44] Anthony D'Amato, *The concept of Custom in International Law* (Cornell University Press, 1971) 90.

[45] Ibid., 104.

[46] Ibid., 151.

[47] Ibid., 137.

[48] Jonathan Charney, 'International Lawmaking – Art 38 of the ICJ Statute Reconsidered' in Jost Delbrück, *New Trends in International Lawmaking – International 'Legislation' in the Public Interest* (Duncker & Humblot, Berlin, 1997) 171, 174–5, cited in Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 105.

[49] Lisa Forman, 'Ensuring Reasonable Health: Health Rights, The Judiciary, and South African HIV/AIDS Policy' (2005) 33 *J L Med & Ethics* 711, 711.

[50] Ibid., 713–4; also see the cases of *Soobramoney v Minister of Health, KwaZulu-Natal (Soobramoney)*, where the court ruled that the right to embrace the ongoing treatment of

1. *Scope*

The right to health does not mean that everyone has a right to be healthy.[51] The right to health cannot guarantee specific individuals' health.

Further, under international human rights law, the right to health includes two parts: elements related to healthcare (including curative and preventive health care), and the other elements which are related to a number of "underlying preconditions for health".[52] It means that the right to health not only covers the right to medicines, but it also covers matters such as the preconditions a state should guarantee for the protection of people's health.

Finally, the right to health is understood to be contained within certain limits, and does not encompass everything that involves health. As a commentator observed[53]

> …with a few minor exceptions, the right to health does not include a prohibition against torture or inhuman and degrading treatment, nor does it include protection against arbitrary killing or medical or scientific experimentation. The right to health also does not include regular education at schools nor a right to adequate housing. It offers protection against environmental pollution only if there are clear health risks, and it is related to the right to work only if it concerns the safeguarding of industrial hygiene and the prevention, treatment, and control of occupational diseases.

Nevertheless, overlap exists between the right to health and other human rights, such as the right to life (infant mortality), prohibition of torture and

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illness for the purpose of prolonging life could not diminish the preventive health care and treatment of curable illness so that the obligations under s 27(1) of the Constitution could not be easier to be fulfilled. This ruling showed some unwillingness of the South African Court in the enforcement of such a positive right, and it implied that this right is aspirational rather than justiciable. *Soobramoney v Minister of Health, KwaZulu-Natal* [1998] 4 BHRC 308, [18]–[20] (SA Con Ct) Chaskalson P. J.

[51] Katarina Tomaševski, 'Health Right' in Asbjørn Eide, Catarina Krause and Allan Rosas (eds), Economic, Social and Cultural Rights (Martinus Nijhoff Publishers, 1995) 125, 125; also see Committee on Economic Social and Cultural Rights ('*CESCR*'), *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 8; also see Virginia A. Leary, 'Defining the Right to Health Care' in Audrey R. Chapman (ed), *Health Care Reform – A Human Rights Approach* (Georgetown University Press, 1994) 87, 99.

[52] Toebes, above n. 1, 174; also see Brigit Toebes, 'Towards an Improved Understanding of the International Human Right to Health' (1999) 21.3 *Human Rights Quarterly* 661, 665–71. The author classifies the right to health issue into four parts: (1) general issues, (2) healthcare, (3) underlying preconditions for health, and (4) vulnerable groups and health-specific subjects; also Rolf de Groot, 'Right to Health Care and Scarcity of Resources' in J. K. M. Gevers, E. H. Hondius and J. H. Hubben (eds), *Health Law, Human Rights and the Biomedicine Convention* (Martinus Nijhoff Publishers, 2005) 49, 55.

[53] Toebes (1999), above n. 52, 676.

inhuman and degrading treatment (the safeguarding of adequate prison conditions, measures to combat "traditional practices"), the right to food (access to healthy foodstuffs),[54] and in particular, with rights contained in Article 11 of the ICESCR concerned with food, housing, and clothing.[55] This overlap makes it more difficult to determine what should be included in the right itself. Toebes rejects the idea that health is a repository for everything that affects health.[56] Another author argues that it is not convincing to bring every aspect of social life into connection with the right to health, and claims that international treaties should make it clear and explicit.[57]

### 2. *Elements in Content*

#### (a) *Curative and Preventive Elements*

The right to health is the right to health care, and this contains both curative and preventive aspects.

In its curative facet, the right to health firstly requires the enjoyment of "the highest attainable standard of physical and mental health".[58] The Committee of Economic, Social and Cultural Rights (CESCR) elucidated the understanding of "the highest attainable standard of health" by stating that "the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."[59] Access to necessary medicines should be understood in light of this explanation. The right to health includes the right to maternal, child and reproductive health.[60] Article 12.2(d) of the ICESCR also requires "the creation of conditions which could assure to all medical service and medical attention in the event of sickness". General Comment No. 14: The Right to Highest Attainable Standard of Health[61] goes further with the inclusion of "the provision of equal and timely access to basic preventive, curative, rehabilitative health services and health

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[54] Ibid., 676.

[55] Ibid., 668.

[56] Brigit Toebes, *The Right to Health as a Human Right in International Law* (Intersentia, 1999) 259–60.

[57] Groot, above n. 52, 55; the author is of the view that art 12(b) of ICESCR is not clear enough.

[58] Art 12.1 of ICESCR.

[59] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 9.

[60] Ibid., para. 14. It provides, "requiring measures to improve child and maternal health, sexual and reproductive health services, including access to family planning, pre- and post-natal care, emergency obstetric services and access to information, as well as to resources necessary to act on that information."

[61] Hereinafter "General Comment No. 14".

education;…; appropriate treatment of prevalent diseases, illness, injuries and disabilities; the provision of essential drugs; and…".[62] In this sense, drugs, as a basic means for the guarantee of people's enjoyment of health should be made available to ensure the realisation of the right to health. It is also implied that the right to health encompasses a minimum and universal right to affordable essential medicines.[63]

The right to health contains "preventive means". It requires "the improvement of all aspects of environmental and industrial hygiene" for the prevention of occupational diseases, and comprises "preventive measures in respect of occupational accidents and diseases" and the prevention of the population's exposure to harmful substances.[64] Article 12.2 (c) of the ICESCR contains a provision to prevent, control and treat epidemic, endemic and occupational diseases. This indicates a public health dimension in the right to health. General Comment No. 14 illustrates the preventive facet. It requires the establishment of prevention and education programmes and promotion of social determinants of good health; the creation of a system of urgent medical care in emergency situations and the provision of disaster relief and joint efforts for the availability of relevant technologies, epidemiological surveillance and data collection and the implementation or enhancement of immunisation programmes.[65] In this way, it requires that medicines should be made available in urgent situations or disasters.

In summary, the right to health requires the availability of medical goods and services for curative and preventive purposes, and that these two are interrelated and interdependent. Medicines that can cure communicable disease can, thus, prevent the prevalence of epidemic diseases. At the same time, prevention of the epidemic diseases can enhance people's health through the reduction of infectious diseases.

(b) *Underlying Preconditions*

The right to health cannot be examined solely through preventive and curative health care. It encompasses topics ranging from economic development and gender equality to political democracy and agricultural sustainability. The right to health, therefore, in its second facet, contains people's right to

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[62] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 17.

[63] Melissa McClellan, '"Tools for Success": The TRIPS Agreement and The Human Rights to Essential Medicine' (2005) 12 *Wash & Lee J Civil Rts & Soc Just* 153, 160–1; the author is of the view that the right to life and the right to health determines a right to essential affordable medicines.

[64] See art 12.2(b) of ICESCR; also see CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 15.

[65] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 16.

the enjoyment of underlying preconditions for the realisation of the right to health.[66]

This includes the improvement of hygiene in areas such as the environment and industry, and the creation of conditions to provide medical services and medical attention for everyone.[67]

General Comment No. 14 further articulates the interrelationship between the right to health and other human rights, including the right to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement.[68] General Comment No. 14 explains that Article 12.2(b) of the ICESCR also suggests adequate housing, safe and hygienic working conditions, and adequate supply of food and proper nutrition.[69] Article 12.2(c) of the ICESCR includes the improvement and furtherance of participation by the population in the provision of preventive and curative health services, including participation in political decisions in relation to the right to health taken at both the community and national levels.[70] The underlying preconditions are reflected in Article 27 of the South African Constitution which requires not only access to health services and goods, but also access to water, food and social security measures in order to realise the health right.[71]

In summary, the realisation of the right to health is determined not only by access to medicines and medical services, but also by other related conditions.

(c) *Essential Elements*

From the above-discussed elements of the right to health, the essential elements of the right to health can be identified as "availability", "accessibility", "acceptability" and "quality".[72]

First is the availability of functioning public health and health-care facilities, of goods and services, and programmes, and of essential drugs.[73] Essential

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[66] See Toebes, above n. 56, 245. Also see Toebes, above n. 1, 174.

[67] See art 12.2(b) and (d) of ICESCR.

[68] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 3.

[69] Ibid., para. 15.

[70] Ibid., para. 17.

[71] Art 27 of the *South African Constitution* (1997 as amended to 2003) provides: "(1) Everyone has the right to have access to – (a) health care services, including reproductive health care; (b) sufficient food and water; and (c) social security, including, if they are unable to support themselves and measures, within its available resources, to achieve the progressive realisation of each of these rights. (3) No one may be refused emergency medical treatment."

[72] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 12.

[73] Ibid., para. 12(a).

drugs as defined by the WHO Action Programme on Essential Drugs have been included as underlying conditions.[74] On this basis, drugs for health problems, especially for the protection of public health, should be made available, and WHO information should be used to ensure the realisation of the right to health.

Second is the accessibility of health facilities, goods and services without discrimination. Accessibility means not only physical accessibility, but includes economic accessibility that requires health facilities, goods and services to be affordable for all.[75] This means that the access to medicines involves questions of price.[76]

Access to medicine as an important part of the right to health has been recognised by some courts. In the South African *TAC* case,[77] the court held that socio-economic rights were justiciable, and the government was required to devise and implement, within its available resources, a comprehensive and co-ordinated programme to progressively realise the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV.[78] This example shows that access to medicine and medical services, when the resources are available, is important for ensuring the realisation of the right to health. In 1999, the Venezuelan Supreme Court, in the case of *Cruz Bermúdez, et al. v Ministerio de Sanidad y Asistencia Social* (*Bermúdez*),[79] ruled that the government's failure to provide people living with HIV/AIDS with access to ARV therapies violated their right to health.

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[74] Ibid., para. 12(a).

[75] Ibid., para. 12(b).

[76] Ibid., para. 12.

[77] *Soobramoney v Minister of Health, KwaZulu-Natal* [1998] 4 BHRC 308, [18] (SA Con Ct) Chaskalson P. J.; also see *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) AIR SC 2426, 2429. The court was required to determine whether the state's failure to provide comprehensive anti-retroviral drugs to prevent mother-child HIV transmission constituted a breach of Art 27(1). The court held that a court will be required to evaluate state policy and to give a judgment on whether or not it was consistent with the constitution in a dispute concerning socio-economic rights.

[78] *Minister of Health and Others v Treatment Action Campaign and Others in South Africa* [2002] 13 BHRC 1, [25] and [135] (SA Con Ct).

[79] Mary Ann Torres, 'The Human Right to Health, National Courts, and Access to HIV/AIDS Treatment: A Case Study from Venezuela' (2002) 3 *Chi J Int'l L* 105, 106; *Cruz Bermúdez, et al. v Ministerio de Sanidad y Asistencia Social, Sala Político Administrativa, Corte Suprema de Justicia, Republica de Venezuela, Expediente Numero*: 15.789 (1999); all references to the *Bermúdez* case are based on the translation of Mary Ann Torres. In this case, the plaintiff raised its claims under the right to life, the right to health and access to scientific advances under Venezuelan law, but the Supreme Court focused its opinion on the right to health.

Third is acceptability, which requires that all health facilities, goods and services should be respectful of medical ethics and be culturally appropriate.[80]

Fourth is quality. This means that the health facilities, goods and services should be of good quality.[81]

### 3. *Obligations of States*

The inclusion of the right to health in a wide array of international human rights instruments entails obligations on states.[82] Nevertheless, the realisation of the right to health is still subject to some difficulties.[83] The first difficulty is the indeterminacy and vagueness of the right to health in the international human rights instruments.[84] Furthermore, historically, there has been a limited role for judicial enforcement of socio-economic rights,[85] and this creates difficulty for the entrenchment of the right to health. The reason for this is that, under the doctrine of separation of powers, the line between the judiciary and executive could easily be blurred by active judicial enforcement.[86] In addition, the categorisation of the right to health as a kind of positive right adds more difficulty for the realisation of the right, since a positive right requires a reallocation of state resources, and requiring a state to take positive measures to enforce the right may delay its realisation.[87]

In view of these difficulties, the right to health requires more authoritative interpretation to clarify the obligations of states and to offer benchmarks and indicators of a more practical kind for states. Especially, in the public health context, the issues conflict between access to medicines and the constraint of available resources and the competition between the right to access to medicines and affordable price require more guidance at the international level. This kind of interpretative guidance can be found in the Limburg Principles and Maastricht Guidelines.[88] They offer general guidance on the interpretation

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[80] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 12.

[81] Ibid., para. 12.

[82] Forman, above n. 49, 711; the author is of the view that the inclusion of the right to health in human rights treaties show that the right to health is a legal right.

[83] Ibid. The author points out the argument by some researches that the right to health is an inappropriate "legal" human right.

[84] Ibid.

[85] Ibid.

[86] Ibid.

[87] Jennifer Prah Ruger, 'Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements' (2006) 18 *Yale J L & Human* 273, 312.

[88] *Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights* and *Maastricht Guidelines on Violations of Economic, Social and*

of the socio-economic rights.[89] In dealing with the right to health, the CESCR issued General Comment No. 14 in 2000 to focus on the normative aspect of Article 12 of the ICESCR and to elucidate the obligations of state parties. These obligations include legal, international and core obligations.

(a) *Legal Obligations*

According to the ICESCR, the realisation of the right to health is subject to a progressive process which recognises the limits of available resources.[90] The expression of the progressive realisation, however, "should not be interpreted as depriving States parties' obligations of all meaningful content," but should mean that "States parties have specific and continuing obligations to move as expeditiously and effectively as possible towards the full realisation of the right to health."[91] There are constraints on availability of resources in each state. Nevertheless, the consideration of concrete and purposeful steps can be taken towards full realisation.[92] There are three levels of obligations on state parties: the negative obligation to respect, and positive obligations *to protect* and *to fulfil*.[93]

(i) To Respect

To *respect* means that a state should not take actions that have adverse effects on people's health. To *respect* includes "refraining from denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum seekers and illegal immigrants, to preventive, curative and palliative health services".[94] This includes an absence of discriminatory practices and gender inequality.[95] To *respect* also contains no prohibition or impediment by a state on "traditional preventive care and healing practices and medicines", to regulate to prohibit the "marketing of unsafe drugs", and to provide services on a basis of individual autonomy except in cases of mental illness and communicable diseases".[96] However, in the case of communicable diseases, a state can provide coercive treatment.

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*Cultural Rights* mainly deal with the principles for the interpretation of such rights for its implementation.

89 Ibid.

90 Art 2.1 of ICESCR.

91 CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 31.

92 Ibid., paras. 30–2.

93 Ibid., para. 33.

94 Ibid., para. 34.

95 Ibid.

96 Ibid.

(ii) To Protect

To *protect* includes the obligation of states to legislate or to take measures to ensure equal access to health care and health-related services provided by third parties.[97] They should ensure the adequate "availability", "accessibility" and "acceptability" and "quality of health facilities, goods and facilities" when these are privatised.[98] They should control the marketing of medical equipment and medicines by third parties to ensure the meeting of the standard of professional requirements, and not limit access to health-related information and services.[99]

The violation of the protection of the right to health includes the failure of a state to take necessary measures to protect persons within their jurisdiction from infringements of the right to health by third parties, and includes omissions such as the failure to regulate the activities of individuals, groups and corporations.[100] Therefore, the marketing of drugs should be regulated, and a state should be obliged to establish a mechanism to regulate the marketing of patented drugs for the purpose of realising the right to health. Usually, brand name drug producers will make use of the monopoly afforded by patent protection to set high prices for drugs. In this situation, a state needs to provide a mechanism to regulate the marketing of the drugs. One option is to develop a competition policy to help generic producers compete with the brand name producers. In developing such a policy, a state should provide anti-competition remedies against patent abusers, especially when drug prices charged by brand name drug producers are too high and greatly exceed the price of generic equivalents.[101] In other words, patent holders who refuse to grant licences to generic producers must be dealt with under the state anti-competition rules. This means that TRIPS, as a multilateral treaty which sets the minimum standard for domestic patent laws, should contain certain provisions, such as compulsory licensing provisions, to deal with this issue. WHO, in addressing the affordability of medications under national pharmaceutical policy, listed the key policy issues as[102]

- adoption of the essential medicines concept to identify priorities for government involvement in the pharmaceutical sector;

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[97] Ibid., para. 35.

[98] Ibid.

[99] Ibid.

[100] Ibid., para. 51.

[101] Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right under International Law' 21 *B U Int'l L J* 325, 355.

[102] World Health Organization, 'How to Develop and Implement a National Drug Policy' in WHO Policy Perspectives on Medicines (January 2003) Issue No. 6, available at <http://www.who.int/medicines/publications/policyperspectives/PPM_No6-6pg-en.pdf>.

- selection of essential medicines in a two-step process: (1) market approval; (2) selection of essential medicines relevant to the national morbidity pattern;
- defining the selection criteria (i.e. sound and adequate evidence, cost-effectiveness, etc.);
- defining the selection process (i.e. appointment of a standing committee, etc.);
- ensuring a selection mechanism for traditional and herbal medicines.
- for single-source products: price negotiations, competition through price information and therapeutic substitution, and TRIPS-compliant measures such as compulsory licensing, "early workings" of patented medicines for generic manufacturers and parallel imports.

(iii) To Fulfil

To *fulfil* means a state must adopt detailed plans for the realisation of the right to health, and these include recognition of the right to health in the national political and legal system, including legislative implementation, and adoption of a national health policy.[103] General Comment No. 14 emphasises the fulfilment of the right to health by imposing obligations on states to take positive measures for the enjoyment of the right to health by individuals and communities. These include fostering recognition of factors which favour positive health results, ensuring that health services are culturally appropriate and that health care staff is trained to recognise and to respond to the specific needs of vulnerable or marginalised groups, and ensuring the dissemination of information.[104] To *fulfil* obliges a state to provide affordable health insurance system (either public or private or mixture of the two), and to ensure provision of public health infrastructures.[105]

The non-fulfilment of the right to health includes the failure to take necessary steps to ensure the realisation of the right to health and insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health.[106] A country which has no national pharmaceutical policy or no national policy for the prevention and treatment of diseases such as epidemics or pandemics, or has insufficient expenditure on medications for these diseases, could be in violation of the obligation to *fulfil*.[107] The Venezuelan Supreme Court, in the case of *Cruz Bermude, et al. v Ministerio de Danidad y Asistencia Social* (*Bermudez*),[108] ordered the Ministry

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[103] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 36.

[104] Ibid., para. 37.

[105] Ibid., para. 36.

[106] Ibid., para. 52.

[107] Yamin, above n. 101, 358.

[108] Torres, above n. 79, 112.

*Mariela Viceconte v Ministry of Health and Social Welfare* [1998] Case No. 31.777/96. In this case, the court was requested to order that the Argentine Government take protective

of Health to request from the President the funds needed for HIV/AIDS prevention and control for the remainder of the fiscal year and an increase in budgetary allocations for future needs, and to provide ARV therapies and associated medicines to infected people in Venezuela.

To *fulfil* the right to health, although it is subject to a progressive realisation, also means immediate obligations for each state to take deliberate steps toward the full realisation of the right and to provide interim solutions such as supporting the purchasing power of indigent persons and groups in order that they might have access to essential medication.[109] In Argentina, in the case of *Mariela Viceconte v Ministry of Health and Social Welfare*,[110] it was held that the Government was legally obliged to intervene to provide health care when individuals and the private sector could not protect their health. A deadline was set for the obligation to be met, after the finding of excessive delays by the government in the fulfilment of its obligation.[111] In Ecuador, in *Mendoza & Ors v Ministry of Public Health*, a case concerning the withdrawal of drug therapy for HIV/AIDS patients, the judgment in the Argentine case was echoed by a ruling that the Ministry of Health had an obligation to protect the right to health and could not suspend a HIV treatment programme.[112]

In South Africa, besides the recognition of the right to health, the Constitutional Court held that it was under a duty to ensure that effective relief was granted to protect and enforce the constitution if there was an infringement of that right.[113] The court ruled that government policy had to meet the constitutional requirement of providing reasonable measures within available resources for the progressive realisation of the rights of HIV infected women and newborn children.[114]

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measures against haemorrhagic fever, which threatened the lives of 3.5 million people due to the lack of access to preventive medical services for most people, to produce the Candid-1 vaccine and to rehabilitate those environments where the disease was breeding.

[109] CESCR, *The Nature of States' Parties Obligations*, 5th Sess, E/1991/23 (14 December 1990) para. 10.

[110] *Mariela Viceconte v Ministry of Health and Social Welfare* [1998] Case No. 31.777/96. In this case, the court was requested to order that the Argentine Government take protective measures against haemorrhagic fever, which threatened the lives of 3.5 million people due to the lack of access to preventive medical services for most people, to produce the Candid-1 vaccine and to rehabilitate those environments where the disease was breeding.

[111] Ibid.

[112] *Mendoza & Ors v Ministry of Public Health* Resn No. 0749-2003-RA (28 Jan 2004) Vol. 1 No. 1 *Housing and ESC Rights Law Quarterly* 6, available at: <http://www.cohre.org/sites/default/files/housing_and_esc_rights_law_quarterly_vol_1_no_1_june_2004.pdf>.

[113] *Minister of Health and Others v Treatment Action Campaign and Others in South Africa* [2002] 13 BHRC 1, [101] (SA Con Ct).

[114] Ibid., [112] and [122].

The Supreme Court of India, in the case of *Paschim Banga Khet Majoor Samity v State of West Bengal*,[115] declared that the right to health was a fundamental right and enforced that right by asking the Government of West Bengal to pay the labourer plaintiff compensation for the loss suffered when he was refused admission to public hospitals and eventually treated in a private hospital.[116] It directed the government to formulate a blueprint for primary health care with particular reference to the treatment of patients in case of urgency.[117]

(b) *International Obligations*

In addition to the general legal obligations of states, states recognise the essential role of international cooperation and that the Alma-Ata Declaration should be referred to achieve equality in the health of the people.[118] States are required to respect the enjoyment of the right to health in other countries, and to prevent third member parties from violating the right in other countries.[119] It means that third party members of TRIPS must allow the compulsory licensing of other members in cases which involve the protection of the right to health. The export and import of medicines under such compulsory licensing should also be allowed. States are required, depending on the availability of resources, to facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required.[120] This means that a developed country or a country with manufacturing capacity should facilitate assistance to a country without manufacturing capacity. States must take the right to health into consideration when concluding other international agreements.[121]

(c) *Core Obligations*

The right to health is subject to progressive realisation.[122] This is because states are constrained by the limited availability of resources, which make it impossible for each government promptly to provide adequate health care for all of the people. Accordingly scholars and activists have attempted to

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[115] *Paschim Banga Khet Majoor Samity v State of West Bengal* (1996) 4 SCC 37.

[116] The petitioner sustained serious injuries after falling off a train. He was refused treatment at six successive State hospitals because the hospitals either had inadequate medical facilities or did not have a vacant bed.

[117] *Paschim Banga Khet Majoor Samity v State of West Benga* (1996) 4 SCC 37.

[118] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 38.

[119] Ibid.

[120] Ibid., para. 39.

[121] Ibid.

[122] Art 2.1 of ICESCR.

delineate core content in the right to health in order to set core obligations on states.[123] The idea of the "core obligation" of states has been introduced to make the right to health irreducible,[124] and this means that, "irrespective of their available resources, states are to provide access to: maternal and child healthcare (including family planning), immunisation against the major infectious diseases, appropriate treatment for common diseases and injuries, essential drugs, and adequate supply of safe water and basic sanitation".[125] Toebes is of the view that "[t]he core content of the right to health . . . consists of a right to number [sic] of basic health services which can be derived from the Primary Health Care strategy of the WHO".[126]

Therefore, access to medicines and the provision of essential drugs is the core obligation and states must guarantee the availability of the drugs within the limit of available resources. Laws of a state which restrict access to medicines because of a failure by a state to use the maximum of its available resources would therefore, constitute a violation of the state's obligations under ICESCR.[127] The 2002 resolution by the U N Commission on Human Rights called on states to prevent the denial or limiting of "equal access for all persons for preventive, curative or palliative pharmaceuticals or medical technologies" used for the treatment of pandemics such as HIV/AIDS.[128] It follows from this reasoning that members of TRIPS should consider the promotion of access to medicines when they seek to make their patent laws TRIPS compliant, because they are bound by the core obligations of the right to health.

### 4. *Summary*

The right to health contains both curative and preventive aspects in order to ensure the enjoyment of this human right. Access to medicines is crucial to the realisation of the right. At the same time, the realisation of the right to health cannot be achieved without the realisation of other related rights, such as the right to water, the right to housing, the right to food. These rights constitute underlying conditions of the right to health. The right to health also imposes obligations on states to ensure the implementation and realisation

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[123] Toebes (1999), above n. 52, 676.

[124] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 43.

[125] Toebes, above n. 56, 347; also Toebes (1999), above n. 52, 675–6.

[126] Toebes, above n. 56, 347.

[127] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 47.

[128] Commission on Human Rights, *Access to Medication in the Context of Pandemics such as HIV/AIDS*, Resolution 2002/32, 49th mtg, E/2002/23- E/CN.4/2002/200 (22 April 2002) para. 3(a).

of the right to health, and this will require states to make health policies and related legislation to *respect*, to *protect*, and to *fulfil* the right.

All of these relate to the patent protection of pharmaceuticals and the protection of people's right of access to medicine, which is the main issue addressed in this book. It follows that a state should make an intellectual property law that contains enough flexibility to respond to or at least not hinder the requirement to provide access to medicines to ensure the enjoyment of the right to health. It also requires states to take this health right into account when entering into international treaties.

This means that it is necessary for TRIPS members to take legal measures to ensure access of essential medicines when making arrangements under TRIPS. The arrangement needs to include enough flexibility to ensure that TRIPS regime does not set restrictions on domestic patent laws that hinder accessibility to and the affordability of medicines.[129]

### C. *Public Health under the Right to Health*

The modern concept of health derives from two related but quite different disciplines: medicine and public health.[130] While medicine generally focuses on the health of an individual, public health emphasises the health of the population.[131] By bringing the concept of health into the human rights field as the right to health, public health is inevitably incorporated into the right to health. Therefore, the understanding of public health and its relationship with the right to health needs clarification, and the following paragraphs will explore these aspects.

#### 1. *The Right to Health Originates from Public Health*

The right to health is strongly linked to public health, and its origin can be traced back to the protection of public health. Since the early eras of recorded human history, health issues have been a major concern for society and authorities have taken measures to improve the health of the population.[132] For example, according to historical records, hygiene measures such as the construction of water supplies and draining systems were taken,

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[129] The flexibility will be discussed later in this book, see Part Two. Chapters 5 and 6.

[130] Jonathan M. Mann et al., 'Health and Human Rights' in Jonathan M. Mann et al. (eds), *Health and Human Rights: A Reader* (Routledge, 1999) 7, 8.

[131] Ibid.

[132] George Rosen, *A History of Public Health* (MD Publications, 1958) 25.

particularly in cities, as far back as 2000BC.[133] The societies of ancient Greece and Rome took steps to respond to disease control, protection of occupational health and the administration of public health.[134] It seems that, even at that time, people began to share a common understanding on improvement of the general health of the public, and such understanding involved an early recognition of the right to health.

Modern understanding of the right to health has various origins and was regarded first as one of the basic economic rights. Some believe that health rights emerged during the economic dislocations of the Industrial Revolution, and that such rights inspired many philosophers, including Karl Marx, to conclude that human beings also had rights to economic security.[135] Some believe that notions of the right to health originated from public health reform proposals during the Sanitary Revolution of the 19th century. At that time, the economic dislocations of the Industrial Revolution and scientific advances, such as the germ theory of disease, empowered them to propose reform.[136] In the Public Health Act of 1848 in England, the right to health was for the first time recognised by the legislature (acknowledging utilitarian ideas are important than egalitarian one).[137] In more recent times, Jonathan M. Mann, a pioneer in both the health and human rights fields, was dedicated to the establishment of the link between health and human rights and the developments in these fields afterwards have drawn attention to the links in these two fields.[138] He proposed that health is a human rights issue and human rights are a health issue, and that there exists a linkage between the two.[139] According to him, public health and medicines are two main disciplines in health,[140] so public health protection promotes the right to health.

### 2. *The Right to Health Realises Public Health*

The history of public health is, to some extent, the history of infectious diseases and the control of such transmissible diseases and the control and the related improvement of the physical environment, and of the provision of

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[133] Ibid., 26.
[134] Ibid., 30–49.
[135] Eleanor D. Kinney, 'The International Human Right to Health: What Does This Mean for Our Nation and World?' (2001) 34 *Ind L Rev* 1457, 1459.
[136] Ibid.
[137] Rosen, above n. 132, 219–21.
[138] Leary, above n. 18.
[139] Mann, above n. 130, 11–8.
[140] Ibid., 8.

water and food of good quality and the provision of medical care.[141] The world has been confronted with infectious diseases over the long history of human civilisation.[142] Since 1851, when an International Sanitary Meeting was held to combat the world's infectious diseases, cooperation on the public health protection has been addressed at an international level, although infectious disease control at that time still lay at the national level.[143]

In the era of globalisation, peoples' right to health has become even more closely tied with public health. Diseases, such as epidemics and endemics, travel across borders, and infectious diseases emerge and re-emerge globally.[144] The last two decades have seen the emergence of many newly recognised pathogens, including HIV/AIDS, Legionnaires' disease, Lyme disease, and in both developing countries and developed countries.[145]

The modern world has become a more connected society with the ever-growing exchange of information, commodities and services, the mobility of people, and the convergence of culture and cooperation in environmental issues.[146] Such globalisation of society also brings the globalisation of infectious diseases through the means of immigration, transportation, trade and commerce and exchange.[147] Some commentators are of the view that the spread of diseases is due to the universalisation of infectious disease and economic privilege that causes unequal access to health resources and abets pathogen transmission.[148] In this situation, public health has also become globalised[149] and poses a challenge for international society and the international human rights law.

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[141] Rosen, above n. 132, 25; also see International Federation of Red Cross and Red Crescent Societies and François-Xavier Bagnoud Center for Health and Human Rights, 'Public Health: An Introduction' in Mann et al. (eds), above n. 130, 29, 29.

[142] See Kenneth F. Kiple, 'Introduction' in Kenneth F. Kiple and Rachael Rockwell Graham (eds), *The Cambridge World History of Human Disease* (Cambridge University Press, 1993) 1, 3.

[143] David P. Fidler, 'The Globalization of Public Health: Emerging Infectious Diseases and International Relations' (1997) 5 *Ind J Global Legal Stud* 11, 24.

[144] Allyn L. Taylor, 'Controlling the Global Spread of Infectious Diseases: Toward A Reinforced Role for the International Health Regulations' (1997) 33 *Hous L R* 1327, 1331–8; also see Benjamin Mason Meier and Larisa M. Mori, 'The Highest Attainable Standard: Advancing a Collective Human Right to Public Health' (2005) 37 *Colum Hum Rts L Rev* 101, 104–12.

[145] Taylor, above n. 144, 1333.

[146] Ibid., 1337.

[147] Ibid.

[148] Meier and Mori, above 144, 105–7.

[149] David P. Fidler, 'Globalization, International Law, and Emerging Infectious Diseases' (1996) 2(2) *Emerging Infectious Diseases* 77, 78; also see Fidler, above n. 143, 30–1.

With this aspect of globalisation, protection of public health will require not only health protection through society-based disease prevention and health promotion efforts that attempt to assure the availability, accessibility and acceptability of health services involving both curative and preventive means,[150] but it will also require a change in societal determinants, including the conditions underpinning human health.[151]

With the inclusion of the control and treatment of epidemic diseases in the right to health,[152] public health is a basic human right. This means that a state must have health laws or policies which ensure the realisation of the right to health. The right to health promotes the protection of public health through the requirements on the provision of health care and the establishment of societal determinants to ensure the health protection. As discussed above, the right to health contains a right to health-care goods and services, and to medicines for the curative and preventive means. The respect of and fulfillment of the right to health can promote the realisation of the goal of public health by the availability of healthcare and the guarantee of the preconditions for individual health. The availability, accessibility and affordability of health services and goods contained in the right to health, as an actual result, help the control and treatment of infectious diseases for the protection of public health. At the same time, the right to health, at the societal level, provides a right to the preconditions for health and the protection for certain vulnerable groups and such protection will greatly enhance the protection of public health. In this fashion, the right to health realises public health. The right to health also provides the basic tools for the realisation of public health by ensuring access to medical knowledge, disease surveillance and treatment options; thus it broadens the concept of the right to health as a collective public good.[153] In addition, the right to health gives special attention to vulnerable or marginalised peoples' rights, and is the expression of a group-based public health concern.[154]

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[150] Kinney, above n. 135, 1458.

[151] Taylor, above n. 144, 1335.

[152] See art 12.2 (c) of ICESCR.

[153] Meier and Mori, above 144, 132.

[154] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) paras 12 and 43. For example, the General Comment No. 14 has the expression on the physical accessibility to give special attention to marginalised and vulnerable people.

### 3. *The Right to Health Depends on Public Health*

The right to health is concerned with promoting and protecting the well-being of individuals by ensuring respect for individual rights and dignity.[155] By comparison, public health can be defined as "ensuring the conditions in which people can be healthy",[156] and this means that public health is concerned with the population and the prevention of disease.

Public health improves health standards for the realisation of the right to health. Although the right to health has been found to deal mainly with the individual's health right by focusing on individual access to health care, it is realised with the help of collective health promotions and disease prevention.[157] Based on the widespread governmental efforts in public health to ensure the satisfaction of the core content of the right to health, public health programmes have provided the most efficient ways for the realisation of the right to health.[158] In the face of the constraint of the resources, various public health programmes enhance the health standards for more people.[159]

Public health is an inalienable part of the realisation of the right to health. General Comment No. 14 requires adopting and implementing a national pubic health strategy to prevent epidemics and to address the health concerns of the whole population; such expression reflects the inclusion of the public health concerns into the right to health.[160] This direct mentioning of population-based health obligation fits within the public health paradigm,[161] and "the adoption and implementation of a national health strategy [under General Comment 14] is to be within a public health or population based framework utilising epidemiological data".[162] It indicates that public health is part of the right to health. A commentator who analysed the relationship between the right to health and public health by examining a continuum of individual health, population health and public health concluded that the

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[155] International Federation of Red Cross and Red Crescent Societies and François-Xavier Bagnoud Center for Health and Human Rights, 'The Public Health – Human Rights Dialogue' in Mann et al. (eds), above n. 130, 46, 46.

[156] Jonathan M. Mann et al., 'Introduction' in Mann et al. (eds), above n. 130, 1, 2–3.

[157] Meier and Mori, above n. 144, 112–8.

[158] Ibid., 122; See Audrey Chapman, 'Core Obligations Related to the Right to Health' in Audrey Chapman & Sage Russell (eds), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia, 2002) 185, 189.

[159] Meier and Mori, above n. 144, 122.

[160] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 43(f).

[161] Lawrence O. Gostin & Lance Gable, 'The Human Rights of Persons with Mental Disabilities' (2004) 63 *Md L Rev* 20, 112.

[162] Chapman, above n. 158, 189–90.

right to health includes a collective right to public health.[163] Thus, without the realisation of public health, the right to health cannot be realised.

### 4. *The Right to Health Limits other Rights under Public Health*

In international human rights law, public health can also mean a limitation on other human rights. The prevention of the spread of disease has become a trend in international health law, and compulsory health measures have become familiar to modern society.[164] With the need to protect society, international human rights law recognises that public health may derogate from individual rights. This derogation can be lawful on the grounds of public health, and thus compatible with general human rights principles. In the case of epidemics, individual rights of liberty of movement, identity, privacy, dignity, freedom of religion, freedom of expression and the right to freedom of association may be restricted.[165]

This suggests that the realisation of the right to health for the sake of public health protection can limit other human rights, provided that it is in compatible with the general principles of human rights. Property rights may also be limited in certain situations when proportionality is taken into consideration. Specific limitations on human rights will be dealt with in the following chapter.

## II. The Right to Life in International Law – Refusal of Access to Life-Saving Facilities

Health is a very broad and subjective concept and is influenced by many factors, such as the right to life, the right to housing, the right to education, the right to water.[166] There is an overlap in these rights. The right to life, in some situations, may be regarded as *jus cogens* in international law,[167] and may support access to life-saving drugs. This invites a discussion of the relationship between the right to life and the right to health, and, especially in the

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[163] Meier and Mori, above n. 144, 129–37.

[164] Tomaševski, above n. 51, 137–8.

[165] Virginia A. Leary, 'The Right to Health in International Human Rights Law' (1994) Vol. 1 Issue 1 *Health and Human Rights: An International Journal*, available at <http://www.hhrjournal.org/archives-pdf/4065261.pdf.bannered.pdf>; citing G A Res 2200, 21 UN GAOR Supp (No. 16) at 49, UN Doc A/6316, 1966. articles 12, 18, 19 and 22.

[166] Toebes, above n. 1, 174.

[167] See Manfred Nowak, *U.N. Covenant on Civil and Political Rights: CCPR Commentary* (Kehl: NP Engel, 1993) 105.

case of the availability of life-saving drugs, whether the refusal of access to life-saving facilities amounts to a breach of the right to life, and so, whether the right to health also achieve the status of *jus cogens* in this situation.

## A. *The Right to Life*

The right to life has been included in some international instruments as a basic human right. Article 3 of the Universal Declaration of Human Rights,[168] and Article 6 of the International Covenant on Civil and Political Rights (ICCPR)[169] recognise the general principle of the right to life.

Some regional conventions, such as Article 2 of European Convention on Human Rights (ECHR)[170] Article 4 of the African Charter on Human and People's Rights,[171] also recognise the right. The right to life has been guaranteed in many national constitutions or laws.[172]

### 1. *Scope of the Right to Life*

Although some scholars argue that the right to life is restricted to protection against intentional or arbitrary deprivation of human life by government agents,[173] others hold the view that a restrictive approach is no longer ade-

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[168] Art 3 of UDHR provides: "Everyone has the right to life, liberty and security of person."

[169] Art 6 of ICCPR.

[170] *European Convention on Human Rights*, opened for signature 4 November 1950, 213 UNTS 222 (entered into force 3 September 1953) art 2.

[171] *African Charter on Human and People's Rights*, opened for signature 27 June 1981, 1520 UNTS 217 (entered into force 21 October 1981) art 4.

[172] For example, art 2.2 of the *German Basic Law* (1949), s 7 of the *Canadian Charter of Rights and Freedoms* (1982), art 40.3.1 of the *Irish Constitution* (1987), s 1 of *Human Rights Act 1988* (UK), s 8 of *Bill of Rights Act of New Zealand* (1990), s 11 of the *South African Constitution* (1996), and the *14th Amendment to the US Constitution.*

[173] This is a traditional concept and has a very restrictive scope. Traditionally, the concept of the right to life focused on protection against intentional or arbitrary deprivation of human life by government agents. Some scholars, such as Dinstein, argue that "the right to life" is the right to be safeguarded against arbitrary killing. In this sense, the protection of the right to life is de facto limited to criminal prohibition of homicide offences. See B. G. Ramcharan, 'The Concept and Dimension of the Right to Life' in B. G. Ramcharan (ed), *The Right to Life in International Law* (Martinus Nijhoff Publishers, 1985) 1, 3–6. Also see Nowak, above n. 167, 106–7. In addition, the right to life can also encompass, in the modern time sense, other areas, such as terrorism, skyjacking, and public transportation. This kind of research can be found at Dorde Dordević, 'Right to Life' in *Final Document of Mt Kopaonik School of Natural Law* (Mt Kopaonik, December 13–17, 2004) 63, 63–5; Miroslav Dordević and Dorde Dordević, 'Right to Life' in *Final Document of Mt Kopaonik School of Natural Law* (Mt Kopaonik, December 13–17, 2002) 41, 42.

quate and is contradicted by the available evidence of practice.[174] According to Ramcharan,[175] the right to life is an imperative norm of international law to inspire and to influence all other human rights. Accordingly, it should encompass various aspects ranging from domestic democratic policy-making for the survival of the individual to international cooperation against mass destruction, from topics of examination of the relationship with other human rights (such as right to peace and right to a safe and healthy environment) to the standard-setting and promotion of other human rights norms.[176] This body of scholarship is based on the premise that the right to life may mean[177]

> to protect every individual life from all possible threats, and seeks to enable each individual to have access to the means of survival, realise full life expectancy, avoid serious environmental risks to life, and to enjoy protection by the State against unwarranted deprivation of life whether by State authorities or by other persons within society.

It would, therefore, be the obligation of a government to be internationally accountable not only for the deliberate deprivation of the right to life, but also for failing to take all possible measures to meet survival requirements in the areas of nutrition and health, or for failing to use all available means at its disposal to reduce infant mortality and to eliminate famine, malnutrition and epidemics.[178] The control of epidemics has caused the public health dimension to enter into the ambit of the right to life, and accordingly the right to health interrelates with the right to life.

This view has also been reflected in comments by the Human Rights Committee. The Human Rights Committee on ICCPR has extended the scope of

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[174] Ramcharan, above n. 173, 3–6.

[175] Ibid., 6–7. The author holds the view that "The right to life firstly is an imperative norm of international law to inspire and to influence all other human rights. Then, the right to life, in its modern sense, encompasses not merely protection against intentional or arbitrary deprivation of life, but also places a duty on the part of each government to pursue policies which are designed to ensure access to the means of survival for every individual within its country. Thirdly, the right to life, as it has been progressively developed by the General Assembly, includes protection against the use of weapons of mass destruction, such as nuclear weapons. Fourthly, the right to life is closely inter-related with rights such as the right to peace, the right to a safe and healthy environment and the right to development. Fifthly, the effective protection of the right to life is closely related to, and affected by, the implementation of human rights standards directed at regulating situations in which threats to life are particularly susceptible. Sixthly, there is a range of issues awaiting the urgent attention of international lawyers, if the right to life to be adequately protected in the future. Seventhly, protection of the right to life is closely related to the promotion and the protection of human rights in general."

[176] Ibid.

[177] Ibid.

[178] Ibid., 8–10.

protection under the right to life to include other threats to human life, such as malnutrition, life-threatening illness, nuclear energy or armed conflict.[179] The Committee considers "it would be desirable for state parties of ICCPR to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics".[180] The public health dimension is mentioned, but the extent to which the right to life can relate to has not been effectively examined. The definition of the broader scope of the right to life therefore remains vague. However, the Committee has made it known that while assuming that the scope of the right to life is broad, it would not necessarily hold Article 6(1) of the ICCPR to be violated when legislation does not achieve a sufficient reduction in the infant mortality rate.[181]

2. *Content of the Right to Life*

Firstly, the right to life relates to "being alive" rather than to "quality of life". Przetacznik is of the view that a distinction should be made between the "right to life" and the "right to living".[182] In *Lawson v Housing New Zealand*[183] it was doubted that the right to life should extend to social and economic factors. It was held that the right to life did not encompass a right not to be charged market rent for accommodation regardless of affordability and impact on a tenant's living standard. This approach means that the right to life must amount to fatality; the right to life does not cover inferior housing, poor quality health systems, or poor criminal law enforcement that leads to vicious but non-fatal attacks.[184]

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[179] Nowak, above n. 167, 107.

[180] See Human Rights Committee, *General Comment 6*, 16th Sess, (1982) HRI/GEN/1/Rev.1 at 6 (1994) para. 5; also Nowak, above n. 167, 107; citing Gen C 6/16 para. 5.

[181] Nowak, above n. 167, 107.

[182] Ramcharan, above n. 173, 3–6.

[183] *Lawson v Housing New Zealand* [1997] 2 NZLR 474, 473–5 (HC).

[184] Andrew Butler and Petra Butler, *The New Zealand Bill of Rights Act: A Commentary* (LexisNexis NZ, 2005) 212. But see Jane Ball and Thomas Knorr-Siedow, 'Housing Rights in Germany: How National Constitutional Law Dominates European Rights Provision', and the authors pointed out that "German housing rights would tend to be dealt with under the principles of right to life, and family support, human dignity and property. This is a product of the national constitution, not simply the European Convention on Human Rights." Available at: <http://www.feantsa.org/files/housing_rights/Jane_preliminary%20German%20report.doc>. Also see Jayna Kothari, 'Right of Housing: Constitutional Perspective on India and South Africa' (June 2001), and the author introduced the leading case of *Olga Tellis v Bombay Municipal Corporation* ((1985) 3 SCC 545), in which the Indian Supreme Court elaborated on the right to adequate housing, shelter and livelihood

Secondly, the right to life means an obligation on states to ensure the right to life. The first sentence of Article 6(1) of ICCPR uses the word "inherent". This has led the Human Rights Committee to conclude that the right to life must not be understood as a negative right directed solely at the state but rather that it calls for positive measures to protect it.[185] The second sentence of Article 6(1) of the ICCPR requires states to protect the right to life by law. This not only requires states to provide protection in the fields of private law and administrative law, but it also authorises states to provide a minimum of prohibitive norms under criminal law.[186]

Thirdly, the right to life requires "due process of law" and "justice" in a deprivation of life. The third sentence of Article 6(1) of the ICCPR uses the terms "arbitrarily" and "deprived". Although "arbitrarily" is vague, it should cover more than cases of intentional killing, and the elements of unlawfulness and injustice, as well as those of capriciousness and unreasonableness may be involved.[187] This means that premature death as a result of an intentional violent act can amount to deprivation of life. It is argued that self-defence, defence of a third person, arrest, prevention of escape, suppression of riot or insurrection by the use of force by State organs do not constitute arbitrary killing.[188] However, this should be interpreted narrowly.[189] In addition, the right to life means limitations on death penalty,[190] and affects euthanasia, abortion and suicide death.[191]

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being part of the all-encompassing Right to Life under Art 21 of the Indian Constitution. Available at: <http://www.escr-net.org/caselaw/caselaw_show.htm?doc_id=401006>.

185 Nowak, above n. 167, 105.

186 Ibid., 106.

187 Ibid., 110–1.

188 Ibid., 111; citing Robertson (1968) 69 *BYBIL* 30 and Dinstein, 'The Right to Life, Physical Integrity and Liberty' in Henkin at 119.

189 Nowak, above n. 167, 112. In terms of police actions, it has also been identified by the Human Rights Committee in *Suárez de Guerrero* case that police actions resulting in death should be used only when necessary for the use of force in connection with self-defence, emergency, arrest or prevention of escape.

190 Art 6 of ICCPR provides these limitations. Art 6(2) of ICCPR provides with death penalty after a fair, public, hearing that pays regard to the prohibition of discrimination, the presumption of innocence and the minimum rights of the accused under a competent, independent and impartial tribunal provided for by law; art 6(4) provides that amnesty, pardon or commutation should be permitted until the conclusion of the relevant procedure; art 6(5) also prohibits the death penalty for persons under age of 18 and for pregnant women. See Human Rights Committee, *General Comment 6*, 16th Sess, (1982) Un Doc HRI/GEN/1/Rev.1 at 6 (1994) para. 7; Nowak, above n. 167, 118 and 121. This article also makes express reference to other provisions of the Covenant, and articles 2, 14, 15 and 26 in particular. See Nowak, above n. 167, 118.

191 Art 6 does not expressly determine the point at which the protection of life begins, and it is difficult to interpret that it covers the unborn child/foetus. However, it does not mean

### B. *Relationship between the Right to Life and the Right to Health*

How the right to life can be applied in the context of the right to health requires clarification. This poses the serious question of whether refusal of access to life-saving equipment could amount to a breach of the right to life.

In Europe, if a person is denied a life-saving medicine due to its high cost, it is possible for the cost to be met by the state. In the case of life essential treatment or medicines, resort may be made to the right to life which is in the Article 2 of the European Convention on Human Rights (ECHR).[192]

In the case of *Nitecki v Poland*,[193] a man who was suffering life-threatening conditions known as amyotrophic lateral sclerosis (ALS), was prescribed a drug that he could not afford. In considering his application under Articles 2, 8 and 14 of the ECHR, the court considered that: "it cannot be excluded that the acts of omissions of the authorities in the field of healthcare policy may in certain circumstances engage their responsibility under Article 2."[194] The court also held that, "an issue may arise under Article 2 where it is shown that the authorities of a Contracting State put an individual's life at risk through the denial of healthcare which they have undertaken to make available to the population generally…"[195] The same wording was used in the case of *Pentiacova v Moldova*,[196] and in *Cyprus v Turkey* [GC].[197]

Therefore, in the ECHR, the right to life, when it is raised in the content of the right to health, is considered along with the situation of availability of

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that the unborn child is not protected whatsoever by Art 6, and the right of the unborn chid should be balanced against other basic rights, especially the right of the mother to life and privacy. However, these dimensions of the content of the right to life do not overlap with the right to health, and not dealt with further in this book. See Nowak, above n. 167, 123–4. The right to life should include the right to death, since there is no criminal liability for an attempted suicide. The euthanasia can arise to active and passive one. See Elizabeth Wicks, *Human Rights and Healthcare* (Hart Publishing, 2007) 259–61; also See Miroslav Dordević and Dorde Dordević, 'Right to Life' in *Final Document of Mt Kopaonik School of Natural Law* (Mt Kopaonik, December 13–17, 2002) 41, 42. If a state legislation limits criminal responsibility after careful weighing of all affected rights and adequate precautions being taken against potential abuse and if this does not go against wishes of the affected, it should not be interpreted as a violation to the right to life under art 6 of ICCPR. See Nowak, above n. 167, 124–5.

[192] André den Exter, 'Access to Health Care in the Netherlands: The Influence of (European) Treaty Law' (2005) 33 *J L Med & Ethics* 698, 700.

[193] *Nitecki v Poland* (judgment of 21 March 2002) Application No. 65653/01.

[194] Ibid.

[195] Ibid.

[196] *Pentiacova v Moldova* (4 January 2005) ECHR Application No. 14462/03.

[197] *Cyprus v Turkey [GC]* (2001-IV) ECHR No. 25781/94 para. 219.

resources. In a word, if resources are available, the right to life will be considered to relate to life-saving drugs.

In New Zealand, the refusal of access to life-saving equipment could amount to a breach of section 8 of the New Zealand Bill of Rights Act 1990 in certain circumstances.[198] In *Shortland v Northland Health Ltd*,[199] the patient suffered from diabetes and needed renal dialysis, but Northland Health refused a transplant and ceased dialysis. The patient suffered from moderate dementia and could not understand or provide the high level of cooperation required for his treatment. The High Court admitted that scare resources and unwillingness to expend them on persons with co-morbidities and lower quality of life may have influenced the decision to deny the patient access to the dialysis programme. However, the Court of Appeal gave a generous interpretation of the right to life as protected by section 8 of the New Zealand Bill of Rights Act 1990. It also drew on Article 6 of the ICCPR in assessing the clinical decision to withdraw dialysis treatment. It expressed the opinion that section 151 of Crimes Act 1961 placed a duty on the local health authority to supply the patient with "the necessaries of life" and a failure to perform that duty "without lawful excuse" could lead to criminal responsibility.[200] In this case, the court noted the relationship between the right to life under section 8 of the New Zealand Bill of Rights, guaranteed by Article 6(1) of the ICCPR and the positive duty of the right to health.[201] However, the court held that there was no deprivation of life under Section 151 of the Crimes Act and section 8 of the New Zealand Bill of Rights Act 1990, since the decision was supported by a clinical judgment with a careful process.[202]

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[198] S 8 of *New Zealand Bill of Right Act 1990* provides: "No one shall be deprived of life except on such grounds as are established by law and are consistent with the principles of fundamental justice".

[199] *Shortland v Northland Health Ltd* [1998] 1 NZLR 433.

[200] Ibid., 445; s 151 of the *Crimes Act 1961* provides with the duty to provide the necessaries of life: "(1) Every one who has charge of any other person unable, by reason of detention, age, sickness, insanity, or any other cause, to withdraw himself from such charge, and unable to provide himself with the necessaries of life, is (whether such charge is undertaken by him under any contract or is imposed upon him by law or by reason of his unlawful act or otherwise howsoever) under a legal duty to supply that person with the necessaries of life, and is criminally responsible for omitting without lawful excuse to perform such duty if the death of that person is caused, or if his life is endangered or his health permanently injured, by such omission. (2) Every one is liable to imprisonment for a term not exceeding 7 years who, without lawful excuse, neglects the duty specified in this section so that the life of the person under his charge is endangered or his health permanently injured by such neglect."

[201] *Shortland v Northland Health Ltd* [1998] 1 NZLR 433, 445.

[202] Ibid., 446.

This shows that the right to life can be used to justify life-saving equipment after careful medical decision, but there needs to be a health resource.

In South Africa, in the case of Soobramone,[203] the right to life entrenched in section 11 of the Constitution was invoked by counsel for the appellant to construe section 27(3) to state that everyone who required life-saving treatment is entitled to have the treatment provided at a state hospital without charge. Section 27(1) requires a state to provide health care, and section 27(2) requires a state to realise the goal progressively based on the availability of resources; section 27(3) entitles an individual not to be refused emergency treatment. However, the court ruled that the right to life should not be inferred from the right to medical treatment since it was directly protected by section 27.[204] In this case, the court, in dealing with the life-prolonging equipment in a case of emergency treatment, placed the right to health in priority to the right to life. Therefore, the right to life is second to the right to health in the case of life-saving medical goods and services due to the constraint of availability of resources.

In India, the Supreme Court has provided some recognition of the right to health as part of the right to life, and it has stated that a worker's right to health is an "integral facet of meaningful right to life."[205] In *Frances Mullen v Union Territory of Delhi*,[206] the Supreme Court of India held that the right to life "includes the right to live with dignity", and found that the right to live with human dignity includes the right to good health. Thus, the court recognised the right to health as an integral part of the right to life. This echoes a similar expression of views in the case of *Parmanand Katara v Union of India*.[207] In the *State of Punjab and Others v Mohinder Singh*, "It is now a

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[203] *Soobramoney v Minister of Health, KwaZulu-Natal* [1998] 4 BHRC 308, [13] (SA Con Ct) Chaskalson P. J.

[204] Ibid., [30]–[34].

[205] *Consumer Education & Research Centre v Union of India* [1995] A I R 992, 26 (Supreme Court of India).

[206] *Frances Mullen v Union Territory of Delhi* (1981) 2 SCR 516, cited in Sheetal Shah, 'Illuminating the Possible in the Developing World: Guaranteeing the Human Right to Health in India' (1999) 32 *Vand J Transnat'l L* 435, 467.

[207] See *Frances Mullen v Union Territory of Delhi*, Ibid.; *Parmanand Katara v Union of India* (1989) 4 SCC 286. In this case, a scooter rider was knocked down by a speeding car. Seeing the profusely bleeding scooter rider, a person who was on the road picked up the injured and took him to the nearest hospital. The doctors refused to attend onto the injured and told the man that he should take the patient to a named different hospital located some 20 kilometres away authorised to handle medico-legal cases. The Samaritan carried the victim, lost no time on the way to the other hospital but before he could reach it, the victim succumbed.

settled law that right to health is integral to right to life. Government has a constitutional obligation to provide health facilities."[208]

The principle was also tested in the case of *Paschim Banag Khet Samity v State of West Bengal*.[209] In this case, the condition of an agricultural labourer who had fallen from a moving train, worsened considerably when as many as seven government hospitals in Calcutta refused to admit him because they did not have beds vacant. The Supreme Court ruled that the right to emergency medical care formed a core component of the right to health, and the right to health was an integral part of the right to life.[210] In India, urgent medical treatment can be supported under the right to life, and maybe the right to health forms part of the right to life.

In the Bangladesh case of *Dr Mohiuddin Farooque v Bangladesh & Ors (No. 1)*,[211] the Bangladesh Supreme Court noted that the right to life is not limited to the protection of life and limb necessary for the full enjoyment of life, but includes, among other things, the protection of health and normal longevity of an ordinary human being. The court could compel the state to remove a threat to life even where the primary Directive Principles of State Policy (DPSP) obligation under Article 18 of the Constitution to raise the level of nutrition and improve public health could not be enforced. This case shows that the right to health is also part of the right to life.

In South America, the Inter-America Commission on Human Rights (IACHR) has also considered the right to life in some health cases. In *Odir Miranda v El Salvador*,[212] the IACHR stated that it would take into account the provisions related to the right to health. The petitioners, who claimed to be under the guarantee of the right to life, were refused triple therapy and other medication to prevent death and improve the quality of life of persons living with HIV/AIDS. The Constitutional Court of Colombia has affirmed the constitutional right to life as a right that permits the pursuit of a life of dignity in a case in relation to the right to treatment in cases of HIV/AIDS.[213] The Court held that denial of costly antiretroviral treatment

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[208] *State of Punjab and Others v Mohinder Singh* (1997) AIR SC 1225. Apart from recognising the fundamental right to health as an integral part of the right to life, there is sufficient case law both from the Supreme and High Court that lays down the obligation of the state to provide medical health services.

[209] *Paschim Banag Khet Samity v State of West Bengal* (1996) 4 SCC 37.

[210] Ibid.

[211] *Dr Mohiuddin Farooque v Bangladesh & Ors (No. 1)* 48 DLR (1996) HCD 438.

[212] *Odir Miranda v El Salvador* (7 March 2001) Inter-Am C H R, Case 12.249, Report No. 29/01, paras. 2, 24, 36; available at <http://www.cidh.oas.org/annualrep/2000eng/ChapterIII/Admissible/ElSalvador12.249.htm>.

[213] Protection Writ, Judgment of Fabio Moron Diaz, Magistrado Ponente, T-328/98 (1998) *Corte Constitucional de Colombia*; cited in Alicia Ely Yamin, above n. 101, 335.

under social security violated the constitutional fundamental right to life. In *Glenda Lopez v Instituto Venezolano de Seguros Sociales*,[214] the Supreme Court of Venezuela found that denial of access to certain medication could constitute a violation of the constitutional right to life. Accordingly, in some South American countries, access to life-saving drugs can be supported under the right to life, and this requires states to consider their health policies.

### C. *Summary*

"The right to life" is "being alive" but not "the right to living" or to "quality of life". The right to life is first a negative right. It means a right not to be deprived of life arbitrarily. The right to life can allude to the other aspects, such as the right to health.

The cases mentioned above indicate the relationship between the right to life and the right to health. On the one hand, it is obvious that the interpretation of the right to life has become wider, and it has coincided with the arguments of some researchers that the right to life should include other aspects of the right, including the right to health. The right to life can be used to support access to emergency medical treatment or life-saving drugs, and the right to health forms part of the right to life in some countries. The right to life complements the right to health in the access to life-saving equipment. On the other hand, in the health cases, it is evident that the right to life is restrictively invoked and the right to emergency medical treatment is subject to strict interpretation. Last but not least, the right to life is cautiously implemented in health cases based on the availability of the resources, and the courts are wary of encroaching on the executive power to allocate the resources.

## III. The Right to Property and the Right to Fruits of Creation[215]

This section will deal with the right to property and the right to fruits of creation. It is intended to discuss whether patents can enjoy human rights protection under the right to property and the right to fruits of creation.

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[214] *Glenda Lopez v Instituto Venezolano de Seguros Sociales*, 487-060401 (Supreme Court of Venezuela, Constitutional Chamber 1997); cited in Alicia Ely Yamin, above n. 101, 335.

[215] The term "right to fruits of creation" has been used to refer to the rights contained in art 15.1 of ICESCR and art 27 of UDHR in many pieces of research, for example, see Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections' in Frederick M. Abbott,

The historical separation of the human rights and intellectual property protection regimes, intellectual property protection remained as a "normative backwater" in the human rights "pantheon" and was neglected by treaty bodies and academics.[216] However the inclusion of the right to property and the right to fruits of creation in human rights agreements like the ICESCR and the UDHR connects the regime of intellectual property protection with the human rights regime.[217]

## A. *The Rights*

### 1. *The Right to Property and Intellectual Property Rights*

The right to property has implications for intellectual property rights in national law. This section will consider the nature of the right to property and the nature of intellectual property rights.

#### (a) *The Right to Property*

Article 17 of the UDHR recognises a general right to property.[218] Article 17.1 states that, "Everyone has the right to own property alone"; Article 17.2 states that, "no one shall be arbitrarily deprived of his property." The implications of this Article are that states should recognise the right to property and that states have a right to regulate the property rights of individuals, subject to the rule of law.[219] All these expressions establish links between the right to property and the protection of intellectual property, and have implications for the protection of intellectual property as a basic human right.[220]

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Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights – Foundations and Conceptual Issues* (The University of Michigan Press, 2006) 145, 148.

[216] Laurence R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5 *Minn Intell Prop Rev* 47, 49–51; also see Peter Drahos, 'Intellectual Property and Human Rights' (1999) 3 *I P Q* 349, 357; the author is also of the view that the historical connections between intellectual property rights and human rights are thin.

[217] For the nexus between right to property and intellectual property rights, it has been preliminarily discussed in Drahos, above n. 216, 358–65.

[218] Art 17 of UDHR provides: "(1) Everyone has the right to own property alone as well as in association with others. (2) No one shall be arbitrarily deprived of his property."; Also see Drahos, above n. 216, 358.

[219] Drahos, above n. 216, 358.

[220] Asbjørn Eide, 'Cultural Rights as Individual Human Rights' in Eide, Krause and Rosas (eds), above n. 51, 229, 232–3; the author is of the view that the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which the beneficiary is the author, is closely related to the right to

The right to property has also been recognised in regional instruments. Article 14 of the African Charter on Human and People's Rights provides a guarantee of the right to property subject to the public need or the general interest of the community.[221] Article 21 of the American Convention on Human Rights guarantees a right to property under the protection of law and requires just compensation for the deprival of property in case of public utility or social interest.[222] The right to property was not incorporated in the European Convention on Human Rights due to controversy during drafting, but Article 1 of the First Protocol of the European Convention on Human Rights provides for the protection of the peaceful enjoyment of possessions subject to public interest and international law conditions.[223] That the right to property was not included in the ICCPR weakens the status of the right to property as customary law.[224]

(b) *Scope*

The status of the right to property in international law raises some complex issues and has some implications for intellectual property protection. The controversy on the inclusion of the right to property in the drafting of the UDHR[225] and the lack of consistent international practice makes it difficult to clarify the scope of the right to property.

Does the recognition of a right of property in international law apply with equal force to all the different types of property that can be identified (such as real, personal, equitable, tangible, intangible, documentary, non-

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property. Also see Drahos, above n. 216, 358; the author is of the view that the right to property contained in art 17 of UDHR complements art 27 of UDHR to protect the moral and material interest resulting from scientific, literary or artistic production of which he is the author.

221 Art 14 of the African Charter.

222 *American Convention on Human Rights* ('*ACHR*'), 1144 UNTS 123 (entered into force 18 July 1978) art 21.

223 For a discussion, see Clare Ovey and Robin C. A. White, *European Convention on Human Rights* (3rd ed, Oxford University Press, 2002) 300–2. *First Protocol of the European Convention on Human Rights*, (18 May 1954) 213 UNTS 262; art 1.

224 Drahos, above n. 216, 360; citing Richard B. Lillich, 'Global Protection of Human Rights' in Theodor Meron (ed), *Human Rights in International Law: Legal and Policy Issues* (Clarendon Press, 1984, 1992 reprint) 115, 157.

225 Johannes Morsink, *The Universal Declaration of Human Rights: Origins, Drafting & Intents* (University of Pennsylvania Press, 1999) 139–56; the author discusses the drafting history of UDHR and the controversy over the words 'private" and "alone"; also Peter K. Yu, 'Anticircumvention and Anti-Anticircumvention' (2006) 84 *Denv U L R* 13, 28; the author claims that the UDHR weakens the protection by omitting the word "private" in the right to property, and the fact that later ICCPR and ICESCR did not explicitly recognise the right supports this weakness.

documentary and so on)?[226] Some argue the property right in the UDHR refers only to the personal property necessary for human dignity.[227] However, according to a study on the origins and drafting history of the UDHR, the UDHR is not limited to personal property, and the property right understood with the wording "alone" in Article 17 means personal, real and other property, and it should be understood with work-related rights to gain property and subject to the limits in Article 12, 29, 23 and 24.[228]

Whether all these different kinds of property rights qualify as fundamental human rights is an important question. It has been pointed out that, without the recognition of such property rights, the whole range of human activities from travelling and diplomacy to investment and international transactions become impossible.[229] One study, after an analysis of the globalisation of business regulation and especially of property and contract, argued that the concept of property rights can also serve humanist values by advancing three historical generalisations: the use of property rules for various purposes, the progressive security and immunity from arbitrary confiscation of property rights, and the certainty of effect of the transfer of property with the evolution of the law of contract.[230] The European Court of Human Rights (ECHR) recognises "concrete proprietary interest[s]" under the right to property of Article 1 of the First Protocol of the European Convention on Human Rights and extends it to current and future proprietary interests, including enforceable debts, lease renewal options, final court judgments and vested rights to social security and pension benefits.[231] This indicates that this notion is not limited to the technical notion of property in national law, and that it has an autonomous meaning under the Convention. As identified in *Gasus Dosier – und Fördertechnik GmbH v The Netherlands*, certain other rights

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[226] Drahos, above n. 216, 359.

[227] Ibid., 359–60; citing Henry G. Schermers, 'The International Protection of the Right of Property' in Franz Matscher and Herbert Petzold (eds), *Protecting Human Rights: The European Dimension* (Carl Heymanns Verlad KG, 1988) 115, 157.

[228] Morsink, above n. 225, 139–46 and 156; art 12 of UDHR provides the privacy right, art 23 of UDHR provides the right to work, art 24 of UDHR provides the right to rest, and art 29 of UDHR provides the limitation.

[229] Drahos, above n. 216, 359.

[230] John Braithwaite and Peter Drahos, *Global Business Regulations* (Cambridge University Press, 2000) 39–87.

[231] Laurence R. Helfer, 'The New Innovation Frontier? Intellectual Property and The European Court of Human Rights' (2008) 49 *Harv I L J* 1, 8–9; and the author referred to the cases: *Kopecky v Slovakia*, App No. 44912/98, (2004) IX Eur Court H R 125, 144 (Grand Chamber); Kopecky, (2004) IX Eur Court H R at 139–40 (enumeration added); citing Ali Riza Coban, 'Protection of Property Rights Within The European Convention on Human Rights' (2004) 152–5.

and interests constituting assets can also be regarded as "property rights", including movable and immovable property, immaterial rights and rights granted under public law.[232]

The scope of the right to property includes movable and immovable property and tangible and intangible interests.[233] Because intellectual property rights can be categorised as intangible property, patent rights will fall under this kind of protection. The European Court of Human Rights (ECHR) and the European Commission of Human Rights have consistently ruled to include copyrights and patents under Article 1 of the First Protocol of the European Convention on Human Rights.[234] In the recent case of *Anheuser-Busch Inc v Portugal*, the ECHR ruled that registered trademarks are protected by the property rights clause of the European Convention's first Protocol.[235] The case of *Dima v Romania* also recognises that the copyright from literary and artistic works can be classified in the right to property, but the ECHR limited its power to review the allegations of legal or factual errors committed by national courts to decide whether a design is registrable or not.[236] In *Smith Kline & French Lab Ltd v Netherlands*, the European Commission of Human Rights specifically indicated that "patent falls within the scope of the term possession".[237] These cases indicate that the protection of intangible interests can fall within the scope of the right to property.[238] The European Union has

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[232] *Gasus Dosier – und Fördertechnik GmbH v the Netherlands* (23 February 1995) 360 *Eur Court H R* (ser A) at 46 para. 53; See Sanja Diajic, 'The Right to Property and the *Vasilescu v Romania Case*' (2000) 27 *Syracuse Journal of International Law and Commerce* 363, 370.

[233] Monica Carss-Frisk, 'The Right to Property: A Guide to the Implementation of Art 1 of Protocol No. 1 to the European Convention on Human Rights' at *Human Rights Handbooks No. 4*, 22, available at <http://www.echr.coe.int/NR/rdonlyres/AFE5CA8A-9F42-4F6F-997B-12E290BA2121/0/DG2ENHRHAND042003.pdf>.

[234] Helfer, above n. 231, 12–3; the author referred to the 3 cases as: *Lenzing AG v United Kingdom*, App. No. 38817/97, 94-A Eur Comm'n H R Dec & Rep 136 (1998) (patent); *Aral v Turkey*, App. No. 24563/94 (1998) (admissibility decision) (copyright); *Smith Kline & French Lab Ltd v Netherlands*, App No. 12633/87, 66 Eur Comm'n H R Dec & Rep 70, 79 (1990) (admissibility decision) (patent).

[235] *Anheuser-Busch, Inc v Portugal* App No. 73049/01 (ECHR Oct 10, 2005) paras 43–9 (available at <http://cmiskp.echr.coe.int/tkp197/view.asp?action=html&documentId=787908&portal=hbkm&source=externalbydocnumber&table=1132746FF1FE2A468ACCBCD1763D4D8149>); also see art 1 of the *Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms*.

[236] *Dima v Romania*, App No. 58472/00, para. 89.

[237] See *Smith Kline & French Lab Ltd v Netherlands*, App No. 12633/87, 66 Eur Comm'n H R Dec & Rep 70, 79 (1990) (admissibility decision) (patent); cited in Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' (2007) 29.2 *Human Rights Quarterly* 403, 410.

[238] But see Cullet, above n. 237, 410; the author deems that it is still lack of in-depth analysis, and the author is of the view that the Commission and Court have simply assumed that

gone further with the adoption of the Charter of Fundamental Rights of the European Union,[239] and this Charter has expressly provided the protection of intellectual property rights under the right to property.[240]

(c) *Content*

The specific content of the right to property suffers from a lack of elaboration and sufficient academic study, but the ECHR has established a "tripartite framework" to test it.[241]

(i) Peaceful Enjoyment

The first test established by ECHR on the right to property requires "peaceful enjoyment" of possessions. In the *Vasilescu v Romania*, the applicant held gold coins, and police searched the applicant's house without a warrant and seized 327 gold coins in 1966. The applicant complained to the European Commission of Human Rights, and the Commission referred the case to the European Court of Human Rights. The European Court of Human Rights held that the applicant was deprived of the use and enjoyment of the gold coins since 1966, and was entitled to peaceful enjoyment under Article 1 of Protocol I of the ECHR.[242]

(ii) Interference with Property

The second test is the interference with the property by government. Article 1 has provided 2 distinct categories of government interference – deprivations of property and controls on its use.[243] Deprivations can include expropriations,

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existing intellectual property rights constitute the property rights over science, technology, and culture (which need to be protected in the context of the Convention) without considering the impacts that this has over the realisation of other human rights.

239 Ibid., 410.

240 Art 17 of the *Charter of Fundamental Rights of the European Union* provides with "right to property" and art 17.2 provides, "Intellectual Property shall be protected." (18 December 2000) O J E C(2000/C 364/01).

241 For the term of "tripartite framework", see Helfer, above n. 231, 11.

242 *Vasilescu v Romania* [22 May 1998] 4BHRC 653, 42–53 (Eur Court H R) Bernhardt, Vilhjálmsson, Baka, Lopes Rocha, Gotchev, Jungwiert, Levits, Dasadevall and Voicu.

243 Helfer, above n. 231, 9; citing *Hellborg v Sweden* App No. 47473/99, (2007) 45 Eur H R Rep 3 [29], 43 (judgment of 28 Feb 2006) (explaining this distinction). 'The ECHR has also recognized a third category – interference with the substance of property. This category is reserved for government intrusions that, as a formal matter, "do[ ] not transfer the property to public authorities, nor…limit or control the use of the property. . . ." . . . In practice, however, the Court has not applied this concept consistently or coherently. Commentators have also noted that the cases decided under this rubric could easily fit under the first two categories. . . .; . . . For these reasons, I do not give separate treatment to "substance of property" claims.'

nationalisation, confiscations and other comprehensive dispossession which is too invasive for the ECHR to avoid finding a deprivation.[244] The control on use was identified by the ECHR as being a very broad concept.[245]

In fact, the ECHR has developed standards for the protection of the right to property in over sixty cases using Article 1 of Protocol I. The court has developed three different violations of property rights, in accordance with a separate analysis of the three sentences in the Article 1 of Protocol I. They are: de facto expropriation; unjustified deprivation of, or unnecessary limitations on, the possession and enjoyment of the property; and de jure expropriation not fulfilling the minimum standards of European law.[246]

(iii) Legality of Interference

After the finding of interference with property, the ECHR applies the lawfulness to test the interference. In the case of *Nerva and Others v United Kingdom*, the applicant complained to the European Court of Human Rights about payment by the applicant's employer at less than the statutory minimum as a violation of Article 1 of Protocol I. The employer made an additional pay to the applicant's pay slip with the tips in cheque and credit card vouchers earned by the applicant, but these resulted in deductions due to more tax and national insurance contributions.[247] The domestic court ruled that the tips included by customers in cheque or credit card payments and intended for the applicants were the property of the employer with the result that the latter was entitled to treat the tips as remuneration.[248] The Human Rights Court held, by majority vote, that there was no breach of the applicants' right under Article 1 of the Protocol I since the decision of domestic courts was not arbitrary or manifestly unreasonable.[249] In this case, the ECHR based its ruling on the lawfulness of the possession.

The assessment of legality is based on a proportional analysis, and it must be "provided by law" and pursue "a legitimate aim" in the public interest. It must achieve "a fair balance…between the demands of the general interest

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[244] Helfer, above n. 231, 9.

[245] Ibid.

[246] Diajic, above n. 232, 371; The case of *Vasilescu v Romania* shows that the court found a de facto confiscation of the property which was incompatible with her right to the peaceful processions, *European Court of Human Rights Vasilescu v Romania* [22 May 1998] 4BHRC 653, 53 (ECtHR) Bernhardt, Vilhjálmsson, Baka, Lopes Rocha, Gotchev, Jungwiert, Levits, Dasadevall and Voicu.

[247] *Nerva and Others v United Kingdom* [24 September 2004] 13 BHRC 246, [1]–[15] (Eur Court H R) Costa, Baka, Bratza, Gaukur Jorundsson, Loucaides, Birsan and Ugrekhelidze.

[248] Ibid., [15]–[18].

[249] Ibid., [34]–[44].

of the community and the requirements of the protection of the individual's fundamental rights."[250] In the case of *Chapman v United Kingdom*, the applicant complained that the refusal by a District Council of her requested planning permission to park caravans on her land within the Metropolitan Green Belt, had violated her right to peaceful enjoyment of her possession of that land under Article 1 of the Protocol I.[251] The ECHR considered that the decision made by the District Council was based on the balance of the competing interests between the applicant and the District Council, and held that there was no violation of the Article 1 of the Protocol I because the interference with the applicant's rights was proportionate to the legitimate public interest aim of preservation of the environment.[252]

The ECHR provides the necessary balance by leaving the interpretation of "public interest" to states. If there is public interest and compensation is made, the state interferes with the enjoyment of possession, or expropriates someone's property, the Court will find there is no violation of the right to property only.[253] The public interest "is a less demanding standard than 'necessary' in a democratic society", and the Convention's organs grant states a wide discretion in devising and implementing social and economic policy.[254] Therefore, a de jure expropriation is very likely to be upheld by the Court, while the de facto expropriations and limitations on property rights are subject to the Court's evaluation of the public interest pursued.[255] Great deference is shown to legitimate state interference. [256]

(d) *The Implication*

(i) Compulsory Licensing Interference

The "tripartite" test shows that a patent right can be expropriated in pursuit of public interest. Although *Anheuser-Busch Inc v Portugal* did not deal with the difficult issue of when governments may regulate or restrict intellectual property in the public interest, the indication is that patents should be subject to restriction in the public interest. Public interest generally refers to the "common well-being" or "general welfare" for a community. This is a

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[250] Helfer, above n. 231, 10; citing *Kirilova v Bulgaria*, App No. 42908/98, ¶ 106 (2005).

[251] *Chapman v United Kingdom* [24 May 2000] 10BHRC 48, [10]–[20] (Eur Court H R) Wildhaber, Costa, Pastor Ridruejo, Bonello, Kuris, Turmen, Tulkens, Straznicka, Lorenzen, Fischach, Butkevych, Casadevall, Breve, Baka, Botoucharova, Ugrekhelidze and Schiemann.

[252] *Chapman v United Kingdom*, Ibid., [117]–[120].

[253] Diajic, above n. 232, 373–4.

[254] Ibid., 374.

[255] Ibid., 395.

[256] Ibid., 375 and 395.

group or community based concept, and it means that an action in the public interest should benefit, at least, some of the population.[257] This means that the realisation of public interest may, sometimes, be at the cost of some individual interest, since minorities' interests may be overridden. On the other hand, everyone is a minority in some capacity, and a protection of minority rights arguably becomes part of the public interest. This will require a good proportional analysis of the public interest. At the same time, the objective of public health is to address the threats to health of a community, and this group based benefit should be understood as a public interest.

Patent protection is based on a balance between the protection of private rights and the public interest, and it should establish a system to meet the public interest challenge. This means that, in the establishment of patent protection, a mechanism needs to be created to guarantee that patent rights can be interfered with in the public interest. Compulsory licensing, which may be regarded as such a mechanism, can be included to meet such demands. As it is open for national law to determine public interest, this should be understood to mean that a restriction on a patent can be allowed in the public interest if the nation declares its public interest. Fair compensation for the licensor must be made available in cases of a restriction on a patent on the grounds of public interest.[258]

(ii) Status of the Norm

Although the right to property enjoys detailed interpretation in European Human Rights Court, and it enjoys wide recognition in other regions, the status of the right to property should not be understood to enjoy international understanding.

Firstly, the right to property may not enjoy much recognition as a human right in the international community due to its controversial nature. It is only recognised in the UDHR, and the soft law nature of UDHR weakens the status of the right to property.[259] Simultaneously, it lacks international implementation, and many implementations in the ECHR are the result of the highly developed human rights practices of European Human Rights Court. In fact, that the right to property is only contained in the Protocol I

[257] Two extreme views are: an action has to benefit every single member of society in order to be in the public interest; any action can be in the public interest as long as it benefits some of the population and harms none.

[258] See Part One.Chapter 2.III.A.1.(c).iii. It discussed the interference with the enjoyment of possession, or expropriation of someone's property. If there is public interest and compensation is made, the ECHR will find that this situation does not violate the right to property only if a state shows such public interest and compensation.

[259] Yu, above n. 225, 28.

of ECHR is further evidence of its weaker status as a fundamental human right. The absence of the word "rights" in Article 1 of the Protocol I shows a disagreement among European governments over the inclusion of a property right in the treaty.[260]

Secondly, the fact that the understanding of the right to property in the UDHR needs to be considered in line with the work right, rest right and privacy right, suggests that the property right refers mainly to the property of a person who owns it through their own work to maintain an adequate living standard.[261] On this interpretation the human rights character of the right to property may only support individual intellectual property owners who live off the copyright and patents they have. In addition, the right to property is subject to restriction on the grounds of public interest. Furthermore, the connection between the right to property and intellectual property protection should be understood together with the understanding of Article 15.1(c) of the ICESCR. The right to fruits of creation should be understood together with the right to property,[262] but, as the right to fruits of creation does not equate to intellectual property protection, the right to property may still not support the interests of a corporation.

### 2. *The Right to Fruits of Creation*[263] *and Patent Rights*

#### (a) *UDHR and ICESCR*

Intellectual property may find implications of its protection in human rights protection in the cultural rights of Article 15 of the ICESCR and Article 27 of the UDHR. This is a starting-point for a human rights analysis of intellectual property protection.

Article 15.1(c) of the ICESCR recognises the right of the creator to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author",[264] and such expression entitles "both individuals or groups or communities to a right to intellectual property protection for his own creation."[265] Article 27 of

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[260] Helfer, above n. 231, 8.

[261] See Part Two.Chapter 3.III.A.1.(b).

[262] CESCR, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (art 15, paragraph 1(c)*, 35th Sess, E/C.12/GC/17 (12 January 2006) ('*General Comment No. 17*') para. 7.

[263] The term "right to fruits of creation", see above n. 215.

[264] Art 15.1(c) of ICESCR.

[265] Audrey R. Chapman, 'Approaching Intellectual Property as a Human Right: Obligations Related to Art 15.1(c)' (2001) Vol. XXXV No. 3 *Copyright Bulletin*, 8 UNESCO Publishing;

the UDHR has a similar expression of an individual's right to "the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he is the author."[266] International human rights law is thus regarded as recognising the rights of inventors and authors and as protecting the moral and material interests of inventors and authors.[267]

In addition, this right has been recognised in regional human rights instruments, such as Article 13.2 of the American Declaration of the Rights and Duties of Man of 1948, Article 14.1(c) of the Additional Protocol of American Convention on Human Right in the Area of Economics, Social and Cultural Rights of 1988 ("Protocol of San Salvador").[268]

(b) *Scope and Content*

The scope and content of the provisions relating to the right to the fruits of creation, such as "the protection of the moral and material interests" in the human rights instruments still, needs clarification. The Sub-Commission on the Promotion and Protection of Human Rights (Sub-Commission) of the Commission of Human Rights and the CESCR have given some comments to try to clarify the scope and content of these Articles, including Resolution 2000/7 of the Sub-Commission, the Substantive Issues Arising in the Implantation of the International Covenant by CESCR in 2001 and General Comment No. 17 by the CESCR in 2006. These comments mainly focus on Article 15(1)(c) of ICESCR.

The scope of the right to "scientific, literary or artistic production" is unclear. Does it include inventors? Does it include patent protection? Some research[269] has showed that it is possible to recognise patent rights within the human rights framework, but it is difficult to identify when the rights of "authors" are recognised as human rights, and when the rights fall outside human rights protection.

Firstly, the word "author" generally refers to creators, and it should include authors and inventors. The drafting of the UDHR and the ICESCR, shows

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the author is of the view that inventor can be a group or a community as well as an individual, which is in contrast with the individualism of intellectual property law.

[266] Art 27 of UDHR.

[267] See David Weissbrodt and Kell Schoff, 'Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7' (2003) 5 *Minn Intel Prop Rev* 1, 3; also see Audrey R. Chapman, 'A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science' in *Intellectual Property and Human Rights* (World Intellectual Property Organization, Geneva, 1999), 127–68.

[268] *American Declaration of the Rights and Duties of Man* (1948) OAS Res XXX, art 13.2.

[269] Hans Morten Haugen, 'Patent Rights and Human Rights: Exploring Their Relationships' (2007) 10 No. 2 *The Journal of World Intellectual Property* 97, 98.

that the drafters decided to recognise the intellectual property claims of authors, creators, and inventors as a human right.[270] Although Article 15.1(c) of the ICESCR and General Comment No. 17 do not explicitly use the word "inventor", it has been pointed out that "author" also refers to creators of scientific productions.[271] Together with the understanding that scientific production includes scientific innovations,[272] it should include inventors of scientific creation.[273] However, according to some, "author" refers to a natural person,[274] and legal entities that are holders of intellectual property rights cannot be protected at the level of human rights.[275]

In the CESCR report on the study of the drafting history of Article 15(1)(c) of the ICESCR in comparison with the Article 15(1)(b), three kinds of views of the drafters were identified.[276] The CESCR cautiously advanced the view that it was the drafters' intention to protect individuals' right, and the creator of a corporation-held patent (an employee of the entity) was not thought about by the drafters.[277] Because most pharmaceutical patents belong to big pharmaceutical companies, the protection of patent rights at human rights level will not be justified by such an understanding of "author" in Article 15.1(c). In addition, because inventors need not necessarily be the applicants for patents,[278] the protection for an individual patent holder, sometimes, is not included in the human rights framework.

Secondly, in the phrase "any scientific, literary or artistic production", "scientific production" "refers to creations of the human mind", including scientific publications and innovations.[279] This shows that an invention should be included under the protection of this Article, and that patent

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[270] Chapman, above n. 265, 10.

[271] CESCR, *General Comment No. 17*, 35th Sess, E/C.12/GC/17 (12 January 2006) para. 7; see Hans Morten Haugen, 'General Comment No. 17 on "Authors Rights"' (2007) 10 No. 1 *The Journal of World Intellectual Property* 53, 57. The author is of the view that inventors cannot be categorically excluded from the scope of this paragraph. However, in the American Declaration of the Rights and Duties of Man of 1948, inventors are explicitly addressed.

[272] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 9.

[273] See Weissbrodt and Schoff, above n. 267, 3; also see Chapman, above n. 267; the author points out that inventor is under the protection of this Art.

[274] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) paras. 7–8.

[275] Ibid., para. 7.

[276] CESCR, *Implementation of The International Covenant on Economic, Social and Cultural Rights: Drafting History of the Art 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights*, 24th Sess, E/C.12/2000/15 (9 October 2000) para. 45.

[277] Ibid.

[278] Jill McKeough, Andrew Stewart and Philip Griffith, *Intellectual Property in Australia* (3 ed, LexisNexis Butterworths, 2004) 375.

[279] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 9.

protection can be included under the framework of human rights in certain circumstances.

Thirdly, the understanding of "benefit from the protection" is important to whether patent enjoys protection under this Article or not. In its resolution 2000/7, the Sub-Commission of the Commission of Human Rights affirmed the human rights status of the right to the protection of moral and material interests resulting from scientific, literary or artistic production under Article 27.2 of UDHR and Article 15.1(c) of ICESCR.[280] According to Comment No. 17, the phrase "benefit from the protection" in Article 15.1(c) "need not necessarily reflect the level and means of protection found in present copyright, patent and other intellectual property regimes, as long as the protection available is suited to secure for authors the moral and material interests resulting from their production".[281] This Article does not prevent states from adopting higher protection standards if the standards do not unjustifiably limit the enjoyment by others of their rights under the Covenant.[282] It seems that the protection of moral and material interest can be achieved through means other than standard intellectual property legislation. However, the Comment does not exclude satisfying the Article 15.1(c) by intellectual property legislation. The Comment also requires affordable administrative and legal remedies for all for a protection of moral and material interests,[283] and adequate compensation for any public interest use.[284] Under this framework, it seems that patent will not be excluded from the benefit of protection under Article 15.1(c).[285] A compulsory licence in patent law can be used to meet the demands of public interest,[286] and it generally requires compensation to the licensor.

Fourthly, Article 15 uses the words "moral interest" and "material interests". "Moral interests" is one of the main concerns of paragraph 2 of the Article 27 of the UDHR, and it is seen to link the creator's personal

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[280] Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property Rights and Human Rights Resolution 2000/7*, 25th mtg (17 August 2000) ('*Resolution 2000/7*') para. 1.

[281] Ibid., para. 10; also CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) para. 6; the Committee commented that the scope of protection of moral and material interests of the author under art 15 of ICESCR does not need to coincide with that in intellectual property rights under national legislation and international agreements.

[282] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 11.

[283] Ibid., para. 18.

[284] Ibid., para. 24.

[285] See Haugen, above n. 271, 59.

[286] See Ibid.

character to their honour and reputation.[287] The phrase "material interests" reflects a close link with the right to property and the right of worker to adequate remuneration, but the protection of material interests under Article 15.1(c) can be in the form of one-time payment or for a limited period of time.[288] Article 15.1(c) also has an economic dimension, but it is closely linked to the right to the opportunity to gain one's living by work (Article 6.1 of the ICESCR) and to adequate remuneration (Article 7(a) of the ICESCR), and to the human right to an adequate standard of living (Article 11.1 of the ICESCR).[289] The realisation of Article 15 is dependent on the other human rights, such as the right to own property alone as well as in association with others, guaranteed in the International Bill of Rights and other international and regional instruments.[290] In this sense, it means that the remuneration resulting from patent should not be unduly high, but the limitation on patent rights should also take the adequate remuneration of the inventors and authors into consideration. At the same time, a patent system can provide protection for a limited period. The Comment points out that the right to the protection of the moral and material interests is subject to limitations and must be balanced with the other rights recognised in the Covenant in accordance with the principle of rule of law.[291]

Finally, the Comment No. 17 lists obligations of state parties, including general, specific and core obligations. The core obligations encompass protection of moral and material interests, equal access to scientific progress, and striking a balance between the protection of moral and material interests and the right to participate in cultural life and to enjoy the benefit of scientific progress and its application as well as other human rights.[292] This has implications for the rationale of patent protection which also requires a good balance between the protection of private and public interests.

(c) *Summary*

From the above, it can be seen that the expression "to benefit from the protection of the moral and material interests resulting from any scientific,

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[287] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) paras. 12–13.

[288] Ibid., paras 15–16; but see Peter K. Yu, 'Reconceptualizing Intellectual Property Interests in a Human Rights Framework' (2007) 40 *U C Davis L R* 1039, 1085–86; the author argued that the material interest contained in art 15(1)(c) should stand alone from property rights.

[289] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 4.

[290] Ibid.

[291] Ibid., para. 22.

[292] Ibid., para. 39.

literary or artistic production of which he is the author" can relate to copyright and patent protection to certain extent, but it does not necessarily equate with it. The "author" in the human rights instruments mainly refers to natural persons, and does not include corporate owners or other legal persons. That "material interests" should be understood together with the right to property mainly aims to ensure the standard of living of authors or inventors. However, a good balance should be struck to ensure the participation in cultural life and sharing of scientific progress, and the protection of moral and material interests.

## B. *Human Rights Approach to Patents*

### 1. *History and Justification of Patent Protection*

Because Article 27 of the UDHR and Article 15.1(c) of the ICESCR deal with the protection of material interests which result from scientific, literary or artistic production and because the general provision of Article 17 of the UDHR deals with the right to property, patent protection may fall within the human rights framework. In order to find the nexus between the patent protection regime and the human rights regime and the implications for the right to health, it is necessary to trace the development of patent protection from a domestic system to an international system and to find the justifications for patent protection.

#### (a) *The Development of Patent Protection*

The development of patent protection can be seen in various stages, of which the final stage is a result of the globalisation of trade.[293] The development of intellectual property can be divided into three main periods: the territorial period, the international period, and the global period.

The origins of intellectual property can be traced back to the ideas of Aristotle on intellectual property protection in the 4th century BC.[294] Some scholars find the origin of the laws dealing with intellectual property in the prerogative grants of royalty.[295] In 1474, the first properly developed patent

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[293] Braithwaite and Drahos, above n. 230, 56–65.

[294] Geoff Tansey, 'Trade, Intellectual Property, Food and Biodiversity: A Discussion Paper' (Quaker Peace and Services, London, 1999) 3.

[295] W. R. Cornish, *Intellectual Property: Patents, Copyrights, Trade marks and Allied Rights* (Sweet & Maxwell, 1996) 6; the author thinks that, in the U K, the patent system had its origins in royal grants under prerogative, which from the *Statute of Monopolies 1624* onwards came to be conditional by legislation.

laws were said to have been established by the Venetians, and that model spread to many other European states in the following 100 years.[296] At that time, trade was mainly restricted to a country's own territory and intellectual property protection was mainly a territorial concept. As territoriality accounted for a basic feature of intellectual property, patent protection was based on national protection and differed significantly in the nature and the stringency of those protections from country to country.

Although there was a proliferation of intellectual property protection in Europe in the 19th century, it was still based on national regimes and was in a chaotic state outside Europe.[297] At that time, free-riding problems were common, and some countries benefited from the "positive externalities": Intellectual property owners had to face free-riding.[298] With the development of trade, countries were more interested in international cooperation on intellectual property by entering into bilateral agreements to deal with the free-riding problems.[299] This started the international period of intellectual property. Bilateralism contributed to the recognition of an international framework for intellectual property, and saw the achievement of the two major multilateral pillars,[300] the Paris Convention[301] and Berne Convention.[302] The Paris Convention deals with the protection of industrial property, of which patent protection is part. During this period, free-riding was still tolerated.[303]

Later, a more globalised world economy was formed and the resultant international trade required more international cooperation in the intellectual property field, including patents. Due to the lack of enforcement mechanisms for intellectual property protection in the two major conventions and serious free-riding problems in international trade, countries with the major intellectual property owners began to try to bring intellectual property

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[296] Chapman, above n. 265, 7; also see Peter Drahos, 'The Universality of Intellectual Property Rights: Origins and Development' in *Intellectual Property Rights and Human Rights* (World Intellectual Property Organization, Geneva, 1999) 15 9 WIPO Publication No. 762(E).

[297] Braithwaite and Drahos, above n. 230, 58.

[298] Ibid.

[299] Sam Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886–1986* (Kluwer, Centre for Commercial Law Studies, Queen Mary College, 1987) 25–38.

[300] Braithwaite and Drahos, above n. 230, 59.

[301] *Paris Convention for the Protection of Industrial Property* (20 March 1883) 828 UNTS 305 ('*Paris Convention*').

[302] *Berne Convention for the Protection of Literary and Artistic Works* (9 September 1886, last revised at Paris on 24 July 1971) 828 UNTS 221 ('*Berne Convention*').

[303] Braithwaite and Drahos, above n. 230, 61.

protection into the GATT talks from the end of the Tokyo round talks.[304] From the Uruguay round of trade talks, intellectual property was included as one of the negotiating issues. Finally, TRIPS was signed as one major law of the WTO package under the pressure of United States and other major states with global corporate actors.[305]

Thus, patent protection entered into a global period. TRIPS sets a minimum standard for the protection of patent rights and requires members to implement those protections, otherwise they will be subject to the dispute settlement mechanism. After entering this global period, there was much national implementation of the TRIPS obligations, and also regional and bilateral arrangements. The convergence of intellectual property protections began with this global era.[306]

This development shows that the globalisation of patent protection is inevitable and states are trying to achieve a common goal in a cooperative international society. The proliferation of international treaties on patent protection is a positive response to globalisation. However, this proliferation complicates the game fought between user and owner groups that transcend national boundaries, and entails treaty members taking obligations such as human rights obligations of the parties under other treaties into consideration. In particular, the public good of the whole of international society needs to be taken into account.

(b) *Justifications*

The justifications for patent protection have gone through several stages and the theories underpinning the different justifications include several different approaches. These approaches include the moral argument, the economic argument and the incentive argument.

The first approach can be categorised as the moral argument approach. The earliest rationale for the moral argument is the natural rights perspective. This perspective can be traced back to John Locke, whose famous proposition and proviso was that a person should have a natural property right in the products of his or her own labour when he or she labours on un-appropriated resources.[307] Furthermore, the proposition relating to the

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[304] See Daniel Gervais, *The TRIPS Agreement-Drafting History and Analysis* (2nd ed, Sweet & Maxwell, 2003) 8; see also Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPS Agreement* (Routledge, 2002) 9.

[305] Matthews, above n. 304, 7–28.

[306] Braithwaite and Drahos, above n. 230, 63–4.

[307] John Locke, *Two Treatises of Government* (1698), Peter Laslett (ed), (Cambridge University Press, 1988) 287–8; it provides: "Though the Earth, and all inferior Creatures be common to all Men, yet every Man has a Property in his own Person. This no Body has any Right to

natural ownership of a creator's own idea which can be useful to society, can be found in the preamble to the French Patent Law adopted by the Constitutional Assembly in 1791.[308] It has been argued that justice demands that an inventor's contribution should be recognised by the grant of a reward.[309] This natural rights perspective indicates the innate nature of the patent rights of creators, and in fact, reflects the human rights nature of patent rights.

The personality perspective echoes the natural rights perspective, and was derived from Kant and Hegel. They emphasised that private property rights are basic to human fundamental needs and policymakers should try to create and allocate entitlements to resources in a way that best enables people to satisfy those needs.[310] Hegel expressed the view that the property was, among other things, the means by which an individual could objectively express a personal, singular will.[311] Thus, inventors are entitled to certain private property rights due to their contribution to human prosperity through their inventions. This theory attaches more importance to the individual's rights and social moral obligations. It emphasises the natural rights of individuals and the moral obligations of the society by reflecting, albeit in a small way, an economic view.[312]

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but himself. The Labour of his Body, and the Work of his Hands, we may say, are properly his. Whatsoever then he removes out of the State that Nature hath provided, and left it in, he hath mixed his Labour with, and joined to it something that is his own, and thereby makes it his Property. It being by him removed from the common State Nature placed it in, it hath by this labour something annexed to it, that excludes the common right of other Men. For this Labour being the unquestionable Property of the Labourer, no Man but he can have a right to what this is once joined to, at least where there is enough, and as good left in common for others." And also see William Fisher, 'Theories of Intellectual Property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press, 2001) 168, 170.

[308] See Edith Tilton Penrose, *the Economics of the International Patent System* (Harwood Academic Publishers, 1951) 21; Penrose quoted as, "…every novel idea whose realization or development can become useful to society belongs primarily to him who conceived it, and it would be a violation of the rights of man in their very essence if an industrial invention were not regarded as the property of its creator." Law of 7 January 1791. Also see Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement* (Sweet & Maxwell, 1996) 151.

[309] Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, 2004) 327.

[310] Fisher, above n. 307, 171.

[311] Anthony D'Amato and Doris Estelle Long, *International Intellectual Property Law* (Kluwer Law International, 1997) 35.

[312] But see Chapman, above n. 265, 8; the author thinks that it gives statutory expression to the moral and economic rights of creators.

The above views may help to explain the moral rights of creators contained in Article 15.1(c) of the ICESCR. However, other approaches place more emphasis on economic features.

One such economic justification is that inventors will not disclose their inventions and will not incur the expense of research and development without intellectual property protection.[313] The public benefit from the disclosure of the invention that occurred on publication of the patent application, which is the justification focused on the role that the patent system played in the generation and circulation of technical information.[314] (This is often referred to as the 'information function' of the patent system.) In particular it is said that patent acts as an incentive to individuals or organisations to disclose information that may have otherwise remained secret.[315] Thus, the public good can be achieved through the reward of patent protection for the disclosure of the invention. This has implications for human rights through benefiting scientific progress.

Another justification for patent protection is that it improves the competitive economic advantage of a country by the use of intellectual property laws.[316] This promotes the transfer of technology from developed countries to developing countries with the encouragement of foreign direct investment under the guarantee of a better intellectual property system.

A further justification attaches even more emphasis to an economics perspective. This theory postulates that intellectual property, especially patents, can be used as an incentive to encourage invention and innovation.[317] This incentive theory is said to date back to 1593 when Galileo asked the Venetian Republic for patent protection "since I am not satisfied that the invention which is my property and was developed by me with great effort and at considerable expense should become the common property of anyone who wishes it"…[318] Through this incentive measure, investors will be more willing to fund research and development,[319] and more creations will be produced with more investment in research and development. Such creations will eventually benefit the public through this dynamic stimulation.

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[313] See Blakeney, above n. 308, 153, citing Arrow, *Economic Welfare and the Allocation of Resources for Invention*; also see Penrose, above n. 308, 31–2.

[314] Bently and Sherman, above n. 309, 327.

[315] Ibid.

[316] Chapman, above n. 265, 8.

[317] The World Intellectual Property Organization (WIPO), *Intellectual Property Reading Material* (WIPO, Geneva, 1995) (WIPO Publication No. 476 (E)) 5.

[318] Blakeney, above n. 308, 152, citing Beier, *The Significance of the Patent System for Technical, Economic and Social Progress* (1980) 571.

[319] Bently and Sherman, above n. 309, 328.

Other theorists examine the national systems to emphasise the function and objective of government in finding the justification for the protection of intellectual property. These include the social planning theory and utilitarian approach proposed by William Landes and Richard Posner. The social planning theory asserts that intellectual property rights can and should be shaped so as to help foster the achievement of a just and attractive culture.[320] This theory is inspired by political and legal theorists like Jefferson, the early Marx, the legal realists and the various proponents (ancient and modern) of classical republicanism.[321] The utilitarian approach suggests that lawmakers should strike a balance between the exclusive rights which stimulate the creation of inventions and curtail the widespread public enjoyment of the creations in order to maximise social welfare.[322] With the examination of the function and objective of government in the devising of such a property system, this theory emphasises the role of a state in the allocation of wealth and resources in order to achieve a more democratic system. This ultimately fulfils the obligations of a state under the human rights instruments, including Article 15 of the ICESCR.

The justifications shown above reflect the protection of patent rights in two ways. On the one hand, it is beneficial to have a patent system to guarantee moral rights and to promote access to public good through disclosure of creations and promotion of trade and foreign direct investment in the diffusion of science and technology. This discloses the public good side of patent system. On the other hand, commercial activities and international trade and investment may hinder the sharing of scientific progress and technological creations through high pricing and research blocking by the use of the monopoly position of big private entities. This is the private right side of intellectual property. In the allocation of property rights in creativity, it is necessary to strike a balance. If the protection is not strong enough, it will not result in more creations; whereas, if the protection is too strong, it will block public access to useful matter or just become corporate profit.[323]

The beginning of the global period of patent protection with the marriage of intellectual property protection and world trade complicated the justification for patent protection. The justification for domestic patent protection in the encouragement of creative and innovative works is not necessarily the same as that for world trade.[324] To bring patent protection into the world

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[320] Fisher, above n. 307, 172.

[321] Ibid., 172.

[322] Ibid., 169.

[323] McKeough, Stewart and Griffith, above n. 278, 25–6.

[324] Susy Frankel, "The WTO's Application of 'the Customary Rules of Interpretation of Public International Law' to Intellectual Property" (2005) 46 *Va J Int'l L* 365, 371–5. The author

trade arena serves to stop free riding in order to reduce distortion of international trade.[325] Protection of intellectual property is important for international trade and for the "welfare" that trade brings.[326] While intellectual property uses the approach of "protectionism", TRIPS treats patents, copyrights and trade secrets as "pro-competitive".[327] This suggests that too strong intellectual property protection will not enhance free trade but distort it. TRIPS tries to combine the various interests in the same agreement and sets a "low-level" of harmonisation in order to achieve the awkward goal of both protection and promotion of free trade. This justification may differ from the traditional idea of domestic intellectual property protection. Therefore, it is necessary for TRIPS to incorporate more flexibility to deal with the quite divergent interests at a global level in order to meet the requirements not only in the intellectual property regime, but also in the trade regime and in the human rights regime.

### 2. *Connections between Human Rights and Patent*

#### (a) *Views*

Human rights and patent rights are viewed by some as in two different regimes.[328] It has been pointed out that "human rights are fundamental, inalienable and universal entitlements belonging to individuals and inherent to human persons with timeless expression," while intellectual property protection is of temporary nature, so intellectual property need not be equated with the human right recognised in Article 15.1(c).[329] The Committee was of the

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is of the view that the WTO system is linked intimately with the international intellectual property structure and with trade and the policies and ideologies behind free trade, and over-protecting intellectual property does not achieve the barrier-lowering objective of international trade but in fact inhibits it.

[325] See para. 1 of Preamble of TRIPS Agreement.

[326] Frankel, above n. 324, 373.

[327] Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, 'Two Achievements of Uruguay Round: Putting TRIPS and Dispute Settlement Together' (1997) 37 *Va J Int'l L* 275, 280.

[328] See Haugen, above n. 271, 58, citing Intellectual Property Watch (2005), the Committee's Vice president, who was responsible for the draft, highlighted the difference between human rights and intellectual property rights by referring to the "changeable IP regimes".

[329] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) paras 1–3; also see CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) para. 6. The report suggests that human rights should be distinguished from the legal rights recognised in intellectual property systems. The intellectual property system is instrumental and of a temporary nature and can be arranged in many ways, while human rights are fundamental, inalienable and universal.

opinion that "human rights enjoy universality, indivisibility and interdependence to be human-centred, fundamental, timeless and human welfare and well-being promoting", while intellectual property systems are "legal-rights based, instrumental, temporary and business interest promoting".[330] However, this statement does not elaborate on the exact difference of the two regimes. In fact, a commentator questioned it by asking for the justified reasons for making these distinctions.[331]

In the understanding of human rights protection of benefit from moral and material interests of creators, it has been asserted that a balance between the protection of public and private interest in knowledge contained in Article 15.1(a) and (b) and Article 15.1(c) should be struck, and that states must bear in mind the need to strike a balance between those provisions when adopting and reviewing intellectual property systems.[332] This has also been pointed out by the Sub-Commission on the Promotion and Protection of Human Rights:[333] States are bound, according to Article 15 of ICESCR, to establish intellectual property systems that "strike a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of authors and inventors in such knowledge". On this point, the balance requirements in the human rights instruments are in line with the balanced nature of patent protection systems. The justification for patent shows that patent protection carries certain weight in benefiting public good, and that a patent system is established on a good balance between the private interest and public interest. This is important in understanding the connections between the two regimes.

(b) *Relationships between the Two Regimes*

(i) Right to the Benefits of Scientific Progress and Patent

Article 27 of the UDHR provides for a right of free participation in cultural life and a right to enjoy the arts and to share in scientific advancement.[334] Article 15 of the ICESCR also provides the right of individuals to the

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[330] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) paras. 5–6.

[331] Haugen, above n. 271, 58.

[332] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) para. 17.

[333] Sub-Commission on the Promotion and Protection of Human Right, *The Impact of TRIPS Agreement*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) para. 10.

[334] Art 27.1 of UDHR.

benefits of scientific progress.[335] An understanding on these Articles is important for the understanding of a human rights approach to patent protection. The right of everyone to enjoy the benefits of scientific progress has been conceptualised as[336]

> A right of access to beneficial scientific and technological developments;
> A right of choice in determining priorities and making decisions about major scientific and technological development;
> A right to be protected from possible harmful effects of scientific and technological development, on both individual and collective levels.

This conceptualisation has implications for our perspective upon patent protection. From the human rights view of the right to benefit from scientific progress it has been argued that the standard is different from "the current tendency to favour the interests of large corporations or to promote the abstract principle of scientific competitiveness".[337] Instead, in terms of access, the right to benefit from scientific advancement means that disadvantaged people should benefit from it under the non-discrimination principle in human rights lens.[338] However, the justification for patent protection shows that protection will promote the disclosure of scientific innovation and stimulate the dissemination of technology through business investment.[339] The problem here is in deciding what level of patent protection can promote scientific innovation dissemination and how a country's policy can ensure both the promotion of patent protection and the enjoyment of scientific progress. Patent protection can have positive effects in the long run at a short term cost.[340] The global approach to patent protection shows that dissemination of technology can be promoted in developing countries in the long run when patent protection can be achieved at a global level.[341] Another important aspect of this human rights view of the benefit of scientific progress, is that it should promote scientific research and prevent the harmful impact of scientific innovation. This implies a system that should seek to ensure the flexibility of scientific research and the public order including the possibility of public morality exclusion in patent protection.

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[335] See art 15.1 (a) and (b) of ICESCR: "The States Parties to the present Covenant recognize the right of everyone: (a) To take part in cultural life; (b) To enjoy the benefits of scientific progress and its applications".

[336] Chapman, above n. 267.

[337] Ibid.

[338] Ibid.

[339] See Part One.Chapter 2. III.B.1.(b).

[340] Haugen, above n. 269, 100.

[341] See Part One.Chapter 2. III.B.1.

These balance requirements have been reflected in the comment by the CESCR Committee on the interpretation of Article 15 of the ICESCR. States need to strike a balance when adopting and reviewing intellectual property systems and private interests should not be unduly advantaged and the public interest in enjoying broad access to new knowledge should be considered.[342] Patent protection needs to meet the following considerations in order to be consistent with human rights norms when intellectual property rights are analysed from a human rights perspective[343]

> Intellectual property rights must be consistent with the understanding of human dignity in the various international human rights instruments and the norms defined therein;
> Intellectual property rights related to science must promote scientific progress and access to its benefits;
> Intellectual property regimes must respect the freedom indispensable for scientific research and creative activity;
> Intellectual property regimes must encourage the development of international contacts and cooperation in the scientific and cultural fields.

Therefore, intellectual property protection should serve the objective of human well-being as a social product.[344]

Article 15.2 of the ICESCR requires states to take steps to realise the right in Article 15.1, including the conservation, the development and diffusion of science and culture.[345] Meeting this requirement entails the balance between private interest and public interest. Article 15.3 provides that the States Parties need to take steps to promote respect for the freedom of scientific research and creativity activity.[346] This reflects the idea that the necessary exceptions or fair use should be made available in the intellectual property systems for research purposes and creation activities to achieve a balance in the devising of an intellectual property system.

(ii) Balance with Other Human Rights

In addition to the balance requirements of the public and private interest, each human right needs to be balanced with the other human rights. Human

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[342] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) para. 17.

[343] Chapman, above n. 267.

[344] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) para. 4.

[345] Art 15.2 of ICESCR.

[346] Art 15.3 of ICESCR.

rights should always be the first responsibility of governments and the balance should not be detrimental to any of the other rights in the ICESCR.[347] In its 2001 Statement, the CESCR analysed the universality, indivisibility and interdependence of human rights, and was of the view that the entire range of civil, cultural, economic, political and social rights, as well as the right to development, are relevant to the intellectual property system.[348] In addition, intellectual property rights must promote and protect all human rights, including the full range of rights guaranteed in the ICESCR.[349]

It has also been pointed out that an adequate balance should be struck between the effective protection of the moral and material interest of creators and states' obligations in relation to the rights to food, health and education and as well as the rights to take part in cultural life and to enjoy the benefits of scientific progress and its applications or any other right recognised in ICESCR.[350] The limitations on the "right to fruits of creation" contained in paragraphs 22, 23, and 24 of General Comment No. 17 show that the right to food, the right to health and the right to education and other rights listed can be achieved subject to certain conditions.[351] In elaborating the core obligations, the Committee also requires states, in relation to the compliance with Article 15.1(c) and "[i]n conformity with other human rights instruments…which are of immediate effect…"[352]

> To strike an adequate balance between the effective protection of the moral and material interests of authors and States parties' obligations in relation to the rights to food, health and education, as well as the rights to take part in cultural life and to enjoy the benefits of scientific progress and its applications.

The Comment requires states to strike a balance between their obligations under Article 15.1(c) and under the other provisions of the Covenant and requires that the private interests should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration. States should not implement protection for moral and material interests resulting from creation to the extent that to do so would impede their ability to comply with their core obligations in relation to the rights to food, health and education,….[353]

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[347] Sub-Commission on the Promotion and Protection of Human Right, *The Impact of TRIPS Agreement*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) para. 13.

[348] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) para. 5.

[349] Ibid.

[350] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 39.

[351] Ibid., paras. 23, 23 and 24.

[352] Ibid., para. 39.

[353] Ibid., para. 35.

# Chapter 3

## Conflict or Coexistence between Human Rights Norms and TRIPS

The right to health is a human right that finds expression in binding human rights treaties and in soft laws. Similarly, the right to fruits of creation contained in the various treaties has the status of a binding treaty norm, and the right to property contained in the UDHR has the status of soft law. The realisation of all the human rights norms unavoidably comes into competition in certain situations. Access to medicines and protection of the material interests of inventors complicate the implementation of the human rights regime. The human rights regime, nevertheless, has to find a way to balance the competing interests and rights.

There is overlap between the human rights regime and the TRIPS regime for the protection of patent. These two regimes can relate to the same subject-matter at certain points. Although the justification for patent protection can vary historically and economically when considered within the intellectual property protection regime, a different justification may be grounded in the human rights regime.

The apparent conflict between the right to health contained in the human rights regime and the pharmaceutical patent protection provided by the TRIPS regime, however, raises concerns for human rights bodies and trade activists. There are two levels of questions: How can a conflict exist between the two regimes? And, if there is a conflict, how can that conflict be resolved or avoided?

### I. TRIPS and the Right to Health

The human rights regime encompasses the protection of the right to health, and the right to fruits of creation and the right to the benefit of scientific progress. The conclusion of the TRIPS Agreement establishes a global level of patent protection within the patent system. However, the implementation

of TRIPS was primarily focussed upon issues of trade and did not reflect the fundamental nature of all human rights, including the right to enjoy the benefit of scientific progress and the right to health.[1] Different levels of development in different countries may result in various needs for intellectual property protection. Intellectual property regimes should facilitate and promote development cooperation, technology transfer and scientific and cultural collaboration, and accordingly the international rules concerning intellectual property protection should not necessarily be uniform in order to address the development goals.[2] The Sub-Commission also called for international cooperation according to Articles 2.1, 11.2 and 15.4 of the ICESCR.[3] The TRIPS Agreement provides for minimum but high standards of intellectual property protection. Pharmaceutical patent protection is included under this protection. On the one hand, the conclusion of TRIPS was a piece of international law making, which required the parties to take the whole of international law into consideration. On the other hand, patent protection can promote innovation and technology transfer. This requires the treaty makers to include the protection goal and development goal as well as the international obligations of member states in the same treaty.

### A. *The History of TRIPS*

The TRIPS Agreement was concluded during the Uruguay round negotiations to integrate intellectual property protection into the international trade arena and is one of the WTO pillar agreements. The conclusion of TRIPS was more a product of the collaboration and effort of corporate actors from the developed countries rather than a product of the consent of each member of WTO. Developing countries may in fact have been reluctant to create such a system,[4] and so the completion of the Agreement can be seen as a victory by the developed country members exerting pressure on the developing

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[1] Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property Rights and Human Rights Resolution 2000/7*, 25th mtg (17 August 2000) ('*Resolution 2000/7*') para. 2.

[2] Committee on Economic Social and Cultural Rights (CESCR), *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess, E/C.12/2001/15 (14 December 2001) ('*Substantive Issues Arising in ICESCR*') para. 15.

[3] Sub-Commission on the Promotion and Protection of Human Rights, *Resolution 2000/7*, 25th mtg (17 August 2000) para. 7.

[4] See Duncan Matthews, *Globalising Intellectual Property Rights- The TRIPS Agreement* (Routledge, 2002) 29–45.

members to reach a compromise on the political and economic interests of the different members.

The adoption of TRIPS into the WTO package and the inclusion of intellectual property matters within the world trade negotiations can be traced back to the Tokyo round negotiations on the GATT. From the genesis of the GATT until the end of the Tokyo round negotiation, which lasted for 6 years from 1973 to 1979, it had always been held that the intellectual property issue was an "acceptable obstacle" to free trade.[5] At the beginning of GATT, only a few Articles contained protection of marks of origin (Article IX), patents, trademarks and copyrights and prevention of deceptive practices (Article XX(d))[6]. Articles XXII and XXIII dealt with consultations and dispute settlements.

During the Tokyo round negotiation, and especially at the end of the negotiation of that round, intellectual property protection began to gain attention from the contracting parties in the negotiation on the counterfeits and intellectual piracy. However, no agreement was reached, and efforts continued toward an intent to bring intellectual property protection into the agreement. Prior to the GATT, there were several international conventions to regulate international intellectual property issues, namely the Paris Convention and the Berne Convention. However, there were two major areas of controversy in the Paris and Berne treaties: (a) they lacked detailed rules on the enforcement of rights before national judicial administrative authorities, and (b) the absence of a binding and effective dispute settlement mechanism.[7] Therefore, the negotiations on the protection of intellectual property rights against counterfeits and piracies was adopted into the Uruguay Round of GATT, and new standards for intellectual property in the GATT framework were proposed by the contracting parties at the Ministerial Conference held at Punta de Este (Uruguay) in September 1986 to protect trade-related intellectual property rights.

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[5] See Daniel Gervais, *The TRIPS Agreement-Drafting History and Analysis* (2nd ed., Sweet & Maxwell, 2003) 8; see also Matthews, above n. 4, 9.

[6] See GATT analytic text, Art XX(d) provides: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Art II and Art XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices."

[7] Gervais, above n. 5, 8; see also Matthews, above n. 4, 10.

During this round of negotiations, divergences between the major developed countries and developing countries on the protection of intellectual property emerged and appeared to be insoluble. Early in 1988, the developing countries began to express serious concern about the possible overprotection of intellectual property rights, which could impede transfer of technology and increase the cost of agricultural and pharmaceutical products. Not until the Brussels Ministerial meeting was some progress made on the negotiation, but still four major issues remained irreconcilable. They were the protection of pharmaceutical products by patents, dispute settlement, the nature and duration of transitional arrangements for developing nations, and the protection of geographic indications. Finally, in 1992, the negotiations resumed and both the United States and India submitted changes for the draft of TRIPS. The 1992 text became the basis for TRIPS which was adopted at Marrakesh in 1994 with no extensive modification.[8]

The history of TRIPS shows a struggle and a compromise of political and economic interests between the developed countries and the developing countries. In order to accommodate the various interests of the multilateral treaty members, TRIPS may use many "treaty language" which can be ambiguous for the conclusion of the treaty.

## B. *Patent Protection in TRIPS and the Right to Health*

### 1. *Intellectual Property Protection in TRIPS*

The conclusion of TRIPS marks the beginning of the global era of intellectual property protection.[9] Such global protection is the result of bringing the intellectual property regimes into the WTO regime.[10]

The global level of protection established by the TRIPS Agreement has important implications. Firstly, the minimum standard requirements at the global level, on the one hand, promotes convergence of intellectual property amongst member nations and have, for some countries, facilitated international trade. On the other hand, the utilisation of minimum standards protection of intellectual property rights has been criticised as not taking the divergent development levels of members into consideration and for

[8] See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (3rd ed., Sweet & Maxwell, 2008) 26–7.

[9] John Braithwaite and Peter Drahos, *Global Business Regulations* (Cambridge University Press, 2000) 58–63.

[10] See Ibid., 63–4.

having a deleterious effect on the public welfare of some members.[11] Secondly, TRIPS makes the enforcement of intellectual property protection at a global level possible through its imposition of the WTO dispute settlement mechanism. This gives strength to TRIPS since such mechanism allows cessations and nullifications of obligations in the enforcement of agreements.

### 2. *Pharmaceutical Patent Protection and the Right to Health*

As a very important part of intellectual property protection, the section for patent protection in TRIPS runs from Article 27 to Article 34. These Articles brought some major changes in patent protection. Significant changes include the requirements that there be no discrimination as to provision of product or process patents, that patents should be available in all fields of technology, the definition of the exclusive rights conferred by the product and process patents, the 20-year protection term counted from the filing date, and the burden of proof in the process patent.[12] Some of these changes, together with other provisions of TRIPS, have important implications for pharmaceutical patent protection and thus may be relevant to the issue of access to medicines.

#### (a) *Article 27 (1) – Non-discrimination*

Article 27(1) deals with patentable subject-matter, and is a clause which requires that patent protection for inventions should be available in all fields of technology without discrimination.[13] According to this, there ought to be no distinction between a process patent and a product patent, nor between industries, if the inventions meet the three criteria for patentability. The three criteria for patentability are novelty (no prior disclosure), inventive step (creativity, non-obviousness), and industrial application (manner of new manufacture).[14] TRIPS also uses a footnote to clarify the terms "non-obvious" and "useful", which correspond to the latter two criteria.[15] With the inclusion of this clause in TRIPS, it is reasonable to infer that "a general

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[11] See eg Susan K. Sell, *Private Power, Public Law – The Globalization of Intellectual Property* (Cambridge University Press, 2003) 13.

[12] Art 27 deals with the patentable subject matter, art 28 deals with the rights conferred, art 33 deals with the term of protection, and art 34 deals with the burden of proof in process patent.

[13] Art 27(1) of TRIPS.

[14] Art 28.1 of TRIPS.

[15] Footnote 5 of TRIPS.

principle of eligibility" of patentability is established.[16] Inventions in pharmaceuticals for first use, no matter whether for a process or a product can easily meet the three requirements and should be patentable. Holders of a pharmaceutical patent may be able to control the price of drugs by taking advantage of their monopoly interest. If the patent holders make the price of drugs too high this can impact on access to medicines and so be relevant to consideration of the right to health.

(b) *Article 27(2) – The Exclusion and Its Proviso*

Article 27(2) of TRIPS deals with the exclusion of patentable subject-matter. This provision contains a serious restriction on the eligibility of inventions to be patented. Inventions may be excluded from patentability based on a risk that their commercial exploitation within the territory could offend the *ordre public* or morality within that territory.[17] Given the wording of the Article it appears that the concept of *ordre public* particularly includes the protection of human, animal or plant life or health and the avoidance of serious prejudice to the environment. It seems that member countries can exclude the patentability of pharmaceuticals under the justification that such an exclusion advances or is necessary for protection of human health. However, the Article is also subject to the restrictive proviso that such exclusions are legitimate only so long as they are not made simply because the exploitation of the technology in question is prohibited by the domestic law of the member. With this proviso, it seems that the exclusion of patentability of pharmaceuticals is subject to a restrictive interpretation.

The key to understanding this Article is an understanding of the protection under *ordre public*. Are there necessary connections between *ordre public* and human health? Can the protection of public health give rise to the *ordre public* exception? If so, to what extent can the protection of public health justify the protection of *ordre public*? If there is connection between the right to health and public health,[18] should the right to health be considered when the public health dimension is referred to?

(c) *Article 8(1) – The Principles and The "Limitation"*

Article 8 deals with the main principles of TRIPS, and under Article 8 members may "adopt measures necessary to protect public health and nutrition

[16] Gervais, above n. 5, 220. The author is of the view that the exclusion from patentability would be looked upon as an exception to the rule, and should be interpreted in a restrictive fashion.

[17] Art 27(2) of TRIPS.

[18] See Part One.Chapter 2.I.C.

and to promote the public interest in sectors of vital importance to their socio-economic and technological development,…".[19] Such measures are limited in the sense that they have to be consistent with TRIPS. This will mean that, in the adoption of its health policy by a country, access to medicine will be an important issue. One issue is that due to the requirement that there shall be no discrimination against a field of technology under TRIPS obligations, protection of the pharmaceutical patent should be maintained. Therefore, any special measures to exclude the patentability of pharmaceutical inventions taken by a country may be inconsistent with the other Articles, such as the non-discrimination Article. Another issue is that it is likely that there will be a conflict between the need to provide access to medicines and the right of patent owners to charge high prices, supported by the monopoly position provided by patent protection. Pharmaceutical patent protection in TRIPS has impacted on access to medicines, and understanding this Article is crucial to finding out whether there is a conflict between the right to health and pharmaceutical patent protection in TRIPS.

## II. Limitation and Derogation in the Regimes – an Internal Mechanism

### A. *Limitation and Derogation in Human Rights*

The interplay between the right to health and the right to fruits of creation or the right to property in human rights regime emerges as an issue in the implementation of such norms. Although all the rights are recognised in the human rights regime, few are absolute and all are subject to limitation in the public interest at any time and are subject to derogation in time of public emergency. These mechanisms of limitation and derogation balance the competing interests of the various human rights in the human rights regime.

The limitation mechanism is often invoked to limit other fundamental human rights in various countries based on the grounds of "national security", "public safety" "public order" (sometimes supplemented by *ordre public*, in parentheses), "public health" and "public morals".[20] The derogation

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[19] Art 8(1) of TRIPS.

[20] See *Universal Declaration of Human Rights*, GA Res 217A (III), UN GAOR, 3rd sess, 183rd ple mtg, UN Doc A/810 (10 December 1948) ('*UDHR*') art 29 and *International Covenant on Economic, Social and Cultural Rights* ('*ICESCR*'), opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) art 4 of ICESCR; also CESCR, *General Comment*

mechanism is often invoked to derogate from other fundamental human rights based on the ground of "public emergency".[21] The distinction between limitation and derogation, however, needs to be addressed in order to be used properly. Derogation distinguishes itself from limitation in scope and character, in the methods by which it may be effected, and in the circumstances in which it may be imposed.[22] According to one commentator, derogation is invoked in time of public emergency and is of a temporary character, but limitation is invoked in the public interest at any time and can be permanent.[23] Limitation requires the guarantee of the principle of legality, but derogation entails no such requirement.[24]

1. *Limitation*

(a) *Clauses*

The UDHR focuses its limitation on rights and freedoms in one provision with the expression "for the purpose of securing due recognition and respect for the rights and freedoms of others and meeting the requirements of morality, public order and the general welfare in a democratic society".[25] This kind of general expression of the limitation principle may show the general character of the UDHR and may be considered to be sufficient for the limitation on the rights contained in the UDHR.[26] The ICESCR provides a general limitation with only one exception in Article 8.[27] It prescribes more elements in the general limitation though the rights contained in the ICESCR are still of a vague and broad character. Article 4 of ICESCR provides a general limitation

> The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant,

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*No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 28; the CESCR points out that "Issues of public health are sometimes used by States as grounds for limiting the exercise of other fundamental rights."

[21] Art 4.1 of ICCPR.

[22] Alexandre Charles Kiss, 'Permissible Limitations on Rights' in Louis Henkin (ed.), The International Bill of Rights – The Covenant on Civil and Political Rights (Columbia University Press, 1981) 290, 290.

[23] Ibid.

[24] Ibid.

[25] See art 29(2) of UDHR.

[26] Kiss, above n. 22, 291.

[27] Art 8(1)(a) and (c) of ICESCR provides with limitation on the specific grounds of "national security" and "public order", and is generally thought that such limitation should be narrowly prescribed under the right to form trade unions, which compares the general limitations under the other rights in ICESCR.

> the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.

The ICESCR does not, like its counterpart the ICCPR, include particular formulae to tailor limitations to the extent strictly necessary so as to ensure maximum protection to the individual.[28] In the ICCPR, "national security", "public safety" "public order (sometimes supplemented by *ordre public*, in parentheses)", "public health" and "public morals" are used in specific provisions as grounds for limitation.[29]

In addition to the limitation clauses contained in the UDHR, ICESCR and ICCPR, limitation should be understood together with non-derogation. Article 29 of the UDHR needs to be understood in line with Article 30 of the UDHR to deal with the non-derogation of the rights,[30] and Article 4 of the limitation clause of the ICESCR should be understood together with non-derogation clause of Article 5 of the ICESCR, which provides

> (1) Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights or freedoms recognized herein, or at their limitation to a greater extent than is provided for in the present Covenant.
> (2) No restriction upon or derogation from any of the fundamental human rights recognized or existing in any country in virtue of law, conventions, regulations or custom shall be admitted on the pretext that the present Covenant does not recognize such rights or that it recognizes them to a lesser extent.

This reflects the principle of proportionality, and it means that, in the implementation of any limitation, due consideration always needs to be given to the other rights recognised in the Covenant.

In summary, the invocation of limitation in the human rights regime involves a general test concerning the "nature of these rights", "determined

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[28] Kiss, above n. 22, 291. Such specific limitations are not used in ICESCR is the result of the large and ill-determined scope of most provisions in ICESCR and the rights are difficult to define precisely. The only exception in ICESCR is art 8, since it contains a specific limitation clause which is due to its specific and narrow character in the right.

[29] *International Covenant on Civil and Political Rights* ('*ICCPR*'), opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976). In ICCPR, "National Security" is used in articles 12(3), 14(1), 19(3), 21, and 22(2); "Public Safety" is used in articles 18(3), 21, 22(2); "Public Order" is used in articles 12(3), 14(1), 18(3), 21, 22(2); "Public Health" is used in articles 12(3), 18(3), 19(3), 21, 22(2); and "Public Morals" is used in articles 12(3), 14(1), 18(3), 19(3), 21, 22(2).

[30] Art 30 of UDHR.

by law", "general welfare in a democratic society" and proportionality, and the specific grounds' tests of "public order" (sometimes supplemented by *ordre public*, in parentheses)", "morality" (public morals), "national security", "public safety", or "public health".

(b) *Elements*

(i) Principle of Legality

The wording "determined by law", "prescribed by law", "in accordance with law", "provided by law" are generally used in limitation clauses, and both the ICESCR and UDHR use the first phrase to indicate that the limitation should be in accordance with the rule of law. It might suggest that action must be authorised by specific legal provisions, which is different from the expressions "in accordance with the law" or "in pursuance to the law".[31] This requirement that all restrictions have a basis in national law embodies the principle of legality.[32] Use of the phrase "determined by law" in the limitation in Article 29(2) of the UDHR, was intended to protect the individual against arbitrary measures if public authorities interfered with an individual's rights through administrative channels.[33] The Siracusa Principles adopted by a group of human rights experts also examined the term "prescribed by law" in the ICCPR. Principle No. 15 requires that limitations on the exercise of human rights shall be made according to national law and such law should be consistent with the Covenant (ICCPR), and should be in force at the time the limitation is applied. Principle No. 16 requires that a limitation not be arbitrary or unreasonable, and Principle No. 17 provides the clear and accessible requirements of such a limitation.[34] This means that a limitation should be applied generally and, as noted by Kiss, "the aim of this condition

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[31] See Kiss, above n. 22, 304. The author discussed the expressions "prescribed by law" and "in accordance with law" and suggested that "in accordance with law" might be satisfied with reference to general legal principles, common law, or accepted government authority.

[32] Bert B. Lockwood Jr, Janet Finn and Grace Jubinsky, 'Working Paper for the Committee of Experts on Limitation Provisions' (1985) Vol. 7 No. 1 *Human Rights Quarterly* 35, 45, citing Erica-Irene A. Daes, 'Restrictions and Limitations on Human Rights' in R. Cassin Amicorum Discipulorumque Liber III (1971) 79, 82.

[33] Erica-Irene A. Daes, A Study on the Individuals' Duties to the Community and the Limitations on Human Rights and Freedom under Art 29 of the Universal Declaration of Human Rights, Centre for Human Rights, UN Human Rights Study Series (United Nations Publication, 1983) 69–75.

[34] UN Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, U.N. Doc. E/CN.4/1985/4, Annex para. 30, reprinted in (1985) Vol. 7 No. 1 *Human Rights Quarterly* 3, 5.

is to exclude the possibilities of restricting the scope of recognised rights by measures taken by the executive authority."[35] Kiss also commented that "prescribed by law" means that adequate information should be available to citizens, and that the content and aptness of the laws themselves should be subject to discussion so that no arbitrary limitations are imposed.[36] After an analysis of several cases, Badar concluded that the principle of legality means that a legal regime governing the interference in question should be ascertainable and conduct to be regulated by rules should be clear and foreseeable and the limit should be defined in a reasonably clear manner in domestic law.[37] Moreover, "determined by law" should be understood with Article 29(3) of the UDHR and the expression "compatible with the nature of the rights" in the ICESCR. Article 29(3) of the UDHR states that the limitation should be exercised without being contrary to the purposes and principles of the United Nations.[38] The inclusion of this expression is generally thought to prevent states from unjustly imposing limitations on rights.

The wording "purposes and principles of United Nations" shows that the law must be in accordance with the principles in the UN Charter and the UDHR.[39] Since the expression "the nature of the rights" lacks elaboration by the Human Rights body and by scholarship, it is difficult to establish the meaning of the expression. However, according to the rules of interpretation contained in Article 31 of the Vienna Convention on the Law of Treaties, the interpretation should be "in good faith" and should be put in "context".[40] If the meaning of a treaty Article still cannot be identified, reference can be made to the preparatory works. Using this guidance, "the nature of the rights" should be understood in line with the Preamble of the ICESCR. The principles of the UN Charter and the UDHR are consecrated in the Preamble of the ICESCR and the "ideal of free human beings enjoying freedom from fear and want" are included for the enjoyment of economic, social and cultural rights.[41] Therefore, the purpose of the expression "determined by law" in the UDHR and ICESCR can be deduced to have as its goal preventing

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[35] Alexandre Kiss, 'Commentary by the Rapporteur on the Limitation Provisions' (1985) Vol. 7 No. 1 *Human Rights Quarterly* 15, 18.

[36] Ibid., 18–9.

[37] Mohamed Elewa Badar, 'Basic Principles Governing Limitations on Individual Rights and Freedoms in Human Rights Instruments' (2003) Vol. 7 No. 4 *The International Journal of Human Rights* 63, 68–70.

[38] Art 29(3) of UDHR.

[39] Kiss, above n. 22, 305; also see Lockwood, Finn and Jubinsky, above n. 32, 46.

[40] See Kiss, above n. 22, 291–2.

[41] Preamble of ICESCR.

arbitrary interference with an individual's right, and the limitation should be made not only in accordance with domestic law, but in accordance with a domestic law that is itself in accordance with the principles of the UN Charter and the UDHR.

(ii) General Welfare in Democratic Society

Given that both the UDHR and ICESCR deal with rights connected with economic and social welfare it is understandable that there should be requirement to consider "general welfare". Economic and social welfare may be a proper motivation for limiting individual rights.[42] The crucial element in this expression is the concept of "democratic society". Since democracy can have different meanings in different countries, defining the various parameters of this notion might avoid abuse that could occur in the absence of clarification.[43]

The wording "in a democratic society" was tested in the Siracusa Principles, and Principle No. 20 states that a state should demonstrate that it will not impair the democratic functioning of the society by imposing limitations. Principle No. 21 reiterates the idea that there is no single model of democratic society but recognises that the respect for the human rights set forth in the UN Charter and the UDHR can qualify a state as meeting the definition of "democratic society".[44] The intention of this term is to guarantee against the risks of arbitrary treatment, and, as Kiss commented, a State imposing limitations should demonstrate that it has fulfilled the conditions for the real functioning of democracy in the state.[45] Kiss was also of the view that "democratic society" implies the recognition of political freedom and individual rights to reduce or moderate the authority of the state and the existence of appropriate supervisory institutions to monitor respect for human rights.[46] The conclusion is the acceptable view that, in the UDHR and the ICESCR, the notion of "democratic society" can mean that a law of a state which respects human rights under the UN Charter and UDHR, can be recognised, if the limitation on the right is for the general welfare.

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[42] Kiss, above n. 22, 292.

[43] See Badar, above n. 37, 76.

[44] UN Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, U.N. Doc. E/CN.4/1985/4, reprinted in (1985) Vol. 7 No. 1 *Human Rights Quarterly* 3, 5; also see Lockwood, Finn and Jubinsky, above n. 32, 51.

[45] Kiss, above n. 35, 19.

[46] Kiss, above n. 22, 307–8.

(c) *Grounds*

(i) Public Order and *Ordre Public*[47]

"Public order" is often used to limit rights by national law, including health rights where, for example, the state fails to provide immunisation against major infectious disease in the community or the state incarcerates, or restricts the movement of, persons with transmissible diseases.[48] In most cases, "public order" is often used parenthetically with the words "*ordre public*".[49] The Siracusa Principles do not give much elaboration of it, except to reiterate in Principle No. 22 respect for human rights as part of public order (*ordre public*). Principle No. 22 also stresses the definition of the "public order" as the sum of the rules which ensure the functioning of society, and No. 23 gives guidance on its interpretation in the context of the purpose of the particular human right which is limited.[50] An understanding of public order needs to note that this is borrowed from national legal systems and is used differently in different legal systems.[51]

*Ordre Public* is a French term, and its meaning differs in private law, private international law and public law.[52] According to Kiss, the term *ordre public* in French private law refers to a legal concept applicable as the basis for restricting or negating private contractual rights, and in private international law, as a basis to avoid applying foreign law. This is similar to the concept of "public policy" employed in Common Law countries.[53] *Ordre public* in French public law is more relevant to public order, and it refers to the sum of principles on which society is founded to approximately equate to the "police power" to maintain the accepted level of public welfare, social organisation, and security.[54] Kiss further observed the object of *ordre public* is to maintain good order, safety, public health with expansion on the concept to the ideas of "esthetic elements" (protection of monuments), "moral elements" (regulation of prostitution or pornography, special protection for the morals of children), an "*ordre public* economic" (consumer protection,

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[47] The discussion of the meaning of "public order" and "ordre public" can be used to compare the language of "ordre public" used in the TRIPS Agreement, and it will be discussed in Part One.Chapter 3.II.B.

[48] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 28.

[49] Kiss, above n. 35, 19.

[50] UN Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, U.N. Doc. E/CN.4/1985/4, reprinted in (1985) Vol. 7 No. 1 *Human Rights Quarterly* 3, 5.

[51] Kiss, above n. 22, 300; also see Lockwood, Finn and Jubinsky, above n. 32, 58.

[52] Kiss, above n. 22, 300.

[53] Ibid.; also see Lockwood, Finn and Jubinsky, above n. 32, 58–9.

[54] Lockwood, Finn and Jubinsky, above n. 32, 59; also see Kiss, above n. 22, 300.

speculation control), and an "*ordre public politique*" (respect for the constitutional political system).[55] Therefore, the convergence of *ordre public* in private and public law can permit limitations on particular human rights necessary for the accepted level of public welfare and social organisation.[56] Analogously, the socio-economic rights in the ICESCR and UDHR should enjoy a status similar to public law and should be interpreted as a broad police power. As Kiss observed, the notion of public order can be understood "as a basis for restricting some specified rights and freedoms in the interest of the adequate functioning of the public institutions necessary to the collectivity when other conditions are met."[57] The examples that can be deemed to be appropriate in invoking *ordre public* are given as the prescription for peace and good order, safety, public health, ethical and moral considerations and economic order.[58] Public health can therefore be covered under the grounds of "*ordre public*" or "public order".

(ii) Morality and Public Morals

"Morality" is used in the UDHR and, sometimes, it is referred to as "public morals". For example, the omission of "public" in Article 14(1) of the ICCPR, according to a commentator, indicates that the limitation clause is concerned with the protection of private morality,[59] and the reason for "morality" being used in the UDHR might be attributed to the general character of the UDHR. According to Kiss, the concept of "morality" implies unenforceable principles in general situations but principles accepted by a great majority of the citizens as general guidelines for their individual or collective behaviour.[60] However, public morals should not be used as a reason to impose restrictions upon the conduct of individuals alone, in private, or between consenting adults, and such a limitation should be construed narrowly: a majority absolute right cannot impose standards of sexual morality on all.[61]

(iii) Public Health

Although the term "public health" is not directly incorporated into the UDHR and ICESCR, "public health" is used as a ground for the limitation of some

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[55] Kiss, above n. 22, 300–1.
[56] Ibid.
[57] Ibid., 302.
[58] Ibid.
[59] Lockwood, Finn and Jubinsky, above n. 32, 66.
[60] Kiss, above n. 22, 304.
[61] Lockwood, Finn and Jubinsky, above n. 32, 66; citing Paul Sieghart, *The International Law of Human Rights* (Oxford University, 1984) 96.

human rights, especially in the health context.[62] This is partly determined by the fact that "public health" is a compulsory measure in health law,[63] and "public health" is also part of "public order".[64] "Public health" is generally related to the prevention of epidemics, although it is sometimes also used to refer to other issues, such as the control of prostitution, which, as Kiss observed, should come under "public morals".[65] Public health has also been broadly interpreted in other situations, such as the prevention of disease among cattle by European Commission of Human Rights.[66] In the Siracusa Principles, principle 25 allows a state to take measures to deal with a serious threat to the whole population or individuals of the population.[67] Public health may also justify restrictive measures by international regulations, such as those promulgated by the World Health Organization.[68] The public health ground often carries more weight under the Article 12 of ICSECR, since a state is required to prevent epidemic disease under that Article.[69]

However, the implementation of the limitation under the ground of "public health" should be understood to protect individual rights and be in alignment with the proportionality contained in the Article 5 of the ICESCR. General Comment No. 14 pointed out that Article 4 of the ICESCR is intended for the protection of individual rights instead of imposing limitations, and the limitation on grounds of public health should also take the general elements identified in Article 4 of the ICESCR into consideration in justifying the limitation.[70] The same Comment also stated that the principle of proportionality in the exercise of such limitation was in line with Article 5.1

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[62] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 28. The CESCR points out that, "Issues of public health are sometimes used by States as grounds for limiting the exercise of other fundamental rights."

[63] See Part One.Chapter 2.I.C.

[64] See Part One.Chapter 3. II.A.1.(c).

[65] Kiss, above n. 22, 303; see also Principle 25 of *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, it also alludes to epidemic disease being covered by public health.

[66] See *X v Netherlands* (1962) 5 *Y B Eur Conv Human Rights* 278, cited in Kiss, above n. 22, 303.

[67] Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, para. 30, reprinted in (1985) Vol. 7 No. 1 *Human Rights Quarterly* 3, 6.

[68] Kiss, above n. 35, 20.

[69] Also see Kiss, above n. 22, 303.

[70] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 28. It points out that "a State party which, for example, restricts the movement of, or incarcerates, persons with transmissible diseases such as HIV/AIDS, refuses to allow doctors to treat persons believed to be opposed to a government, or fails to provide immunization against the community's major infectious disease, on grounds such as national security or the

of the ICESCR to basically permit limitation on the grounds of protection of public health for a limited period and subject to review.[71] It seems that public health is a ground for limitation, but the restriction on other human rights on the ground of public health should also be as little restrictive as possible.

2. *Derogation – Public Emergency*

The recognition of a "public emergency" may always be used to justify derogation from some of the fundamental human rights. Article 4 of the ICCPR provides for derogation in case of "public emergency" in circumstances threatening the life of the nation.[72] Principle 39 of the Siracusa Principles provides guidance on the phrase "public emergency which threatens the life of the nation", and it elaborated "the threatening of the life of the nation" as something affecting the whole of the population, and either the whole or part of the territory of the State, and threatening "the physical integrity of the population, the political independence or the territorial integrity of the State or the existence or basic functioning of institutions indispensable to ensure and project the rights recognized in the Covenant".[73] Principles 40 and 41 state that internal conflict and unrest, and economic difficulties cannot justify derogation measures.[74]

3. *Application*

In the application of the limitation on socio-economic rights in accordance with the clauses in the UDHR and ICESCR, the limitation clauses contained in the ICESCR should be considered instead of that in the UDHR. Firstly, the UDHR is a declaration and as soft law is not binding. Therefore, the limitation clause contained in UDHR has less effect. Secondly, the UDHR sets a general principle for the protection of human rights at a global level,

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preservation of public order, has the burden of justifying such serious measures in relation to each of the elements identified in Art 4."

[71] Ibid., para. 29; also art 5.1 of ICESCR.

[72] Art 4.1 of ICCPR.

[73] Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, reprinted in (1985) Vol. 7 No. 1 *Human Rights Quarterly* 3, 7–8.

[74] Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, reprinted in (1985) Vol. 7 No. 1 *Human Rights Quarterly* 3, 7–8.

and that general nature determines the inclusion of the general limitation clause. As Kiss observed.[75]

> The Universal Declaration of Human Rights is the only international instrument aimed at the global protection of human rights which concentrates limitations upon rights and freedoms in a single provision. In the Covenant on Civil and Political Rights, as in all other human rights conventions, the limitations are scattered, with specific provisions – generally identical, but with some variations – applicable to particular freedoms or rights. The change from a single, general clause to several particular formulas reflected a desire to tailor limitations to the extent strictly necessary so as to assure maximum protection to the individual.

Thirdly, circumstances have changed to make the limitation clauses in the UDHR out-dated. In discussing the general limitation in UDHR, the Commission on Human Rights working group expressed the view in the "General *Provisions" of the draft* UN Declaration on the Rights of Indigenous Peoples that the limitation principle contained in the UDHR is an out-dated standard in relation to individual rights since the UDHR was adopted in 1948 and a very different approach has been taken by the international community since then.[76]

The right to property and the right to the fruits of creation may justifiably be limited when there is an invocation of the principle that such a limitation is to safeguard "public health" in order to prevent epidemics. Firstly, because the protection of public health is a compulsory measure in health law, the principle of legality can be used to justify limits on the right to property and the right to fruits of creation. Secondly, health is a welfare issue, and the limitation under "public health" can be categorised as being for the protection of the general welfare of the society. Thirdly, epidemic disease can cause refugee problems and other chaos in a nation,[77] and this public health issue can provide the grounds of "public order" or "public emergency" to limit other human rights, including the right to property and the right to fruits of creation. Finally, proportionality has to be taken into consideration when the prevention of epidemics and the limitation on individual's right to property

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[75] Kiss, above n. 22, 291.

[76] Commission on Human Rights, *General Provisions' of the Draft UN Declaration on the Rights of Indigenous Peoples*, 62nd Sess, E/CN.4/2005/WG.15/CRP.2 (24 November 2005) paras. 11–12.

[77] See Wesley A. Cann Jr, 'On the relationship between Intellectual Property Rights and the Need of Less-developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism' (2004) 25 *U Pa J Int'l Econ L* 755,770–3.

or fruits of creation are contemplated. This can also have implications for the limitation or derogation of patent protection, since patent protection can overlap with the right to fruits of creation.

### B. *Use of Limitation and Derogation Language in TRIPS*

#### 1. *Terms used in TRIPS and in WTO Jurisprudence*

##### (a) *Terms used in TRIPS*

The TRIPS Agreement contains similar wordings to those used for limitation or derogation in human rights regime, but the word "limitation" is not directly included in TRIPS. The relevant wordings in TRIPS are open-textured, and used as carve-outs or as policy considerations.

Article 8 of TRIPS provides

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

This Article uses the words "necessary", "public health" and "public interest in sectors of vital importance to their socio-economic and technological development".

Article 27.2 of TRIPS provides

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *Ordre Public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

This Article uses "*ordre public*" and "morality". In addition, Article 31 uses the phrase "national emergency".[78] The question arises whether all these terms should have the same meaning as in the human rights regime. What is the relationship between the two regimes when considering the meaning of these words?

[78] See art 31 of TRIPS.

Understanding the implications of the terms "*ordre public*" and "morality" is crucial to a comprehension of the exclusion of patentability of certain inventions. The scope of this exception needs to be clarified. The language used in the TRIPS regime has also been mirrored by similar language in other patent systems. Examples can be found in the European Patent Convention 1973 (EPC)[79] and the European Union's Directive on Legal Protection of Biotechnological Inventions (Biotechnology Directive).[80] Article 53(a) of the EPC provides for exceptions to patentability under "*ordre public*" or morality.[81] The Onco-mouse case[82] provides discussion and testing of the meaning of these terms.

In this case, the Technical Board of Appeal was of the opinion that "a general principle of patentability such that EPC provisions restricting patentable subject matter should be interpreted narrowly",[83] and the Examining Division in the case balanced the factors by cautiously confining the patent to the *Onco-mouse* application.[84] Later, in a case concerning an application to patent a transgenic plant, Article 53(a) and the terms morality and "*ordre public*" were interpreted by the Board of Appeals.[85] The Board held that *ordre public* can bar patentability in cases "likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment."[86] When considering the term morality, the Board focused on the test of "destructive use" and held that "it would undoubtedly

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[79] *Convention on the Grant of European Patents* ('*EPC*'), (5 October 1973) 1065 UNTS 199; 13 ILM 270.

[80] *Council Directive 98/44 on Legal Protection of Biotechnological Inventions* [1998] OJ L 213, 13. Member states should be in compliance with the Directive by July 20, 2000. However, it should also be noted that the Biotechnology Directive is presently subject to legal challenge by several member countries. Case C-377/78, *Netherlands v Parliament* 1988 O J 9C 378, 13; A. Scott, 'The Dutch Challenge to the Biopatenting Directive' (1999) 4 *Eur Intell Prop Rev* 212; P. Farrant & V. Salmon, 'Netherlands Seeks End to EU Biotech Directive' (July/August 1999) *IP Worldwide* 3.

[81] Art 53 of *EPC*.

[82] This is a patent application filed by Harvard University concerning transgenic mammals, and the inventors had already been granted a United States patent in 1988.

[83] *Onco-mouse III* (1991) EPOR 527, cited in Cynthia M. Ho, 'Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men' (2000) 2 *Wash U J L & Pol'y* 247, 259–60.

[84] See Ho, above n. 83, 260–1.

[85] In this case, the Greenpeace raised opposition, and argued that the grant of a patent for plant life forms and the exploitation of such a patent runs per se contrary to morality and or *ordre public. Greenpeace UK v Plant Genetic Systems N V* (Opposition Div EPO 1992), reported in (1993)24 *Int'l Rev Indus Prop & Copyright L* 618, cited in Ho, above n. 83, 261–2.

[86] PGS 1995 O J EPO at 562, 557, cited in Ho, above n. 83, 267.

be against "*Ordre Public*" or morality to propose a misuse or a destructive use of technology".[87] The decisions in these cases reflected the controversial nature of the interpretation of the grounds to exclude patentability. As Ho commented, the morality issue is "inherently controversial" and it will be very difficult to satisfy every party when a thorough evaluation is to be taken.[88]

This controversial language has also been adopted within the TRIPS Agreement. The use of *ordre public* in TRIPS was originally drafted as "public order" by the TRIPS negotiators. The Brussels Draft provided

> 2. PARTIES may exclude from patentability inventions, the prevention within their territory of the publication or any exploitation of which is necessary; to protect public morality or order, including to secure compliance with laws or regulations which are not inconsistent with the provisions of the Agreement; or to protect human, animal or plant life or health.

The 1990 Draft shows

> 4.1 Inventions, [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values].

The change from the English term "public order" to the French civil law concept of *ordre public*, whose meaning is closer to "public policy" in Common Law,[89] indicates that there are nuances to be considered in the understanding of this term.[90]

Interpretation of this term within TRIPS may be assisted by reference to the understanding on the term in other WTO covered agreements. Article XX(b) of GATT is of relevance to the understanding of the term in TRIPS.[91] The similar language used in TRIPS and GATT can contribute to the understanding of the term *ordre public* in each. The WTO jurisprudence shows that when similar language is used in various covered agreements it is permissible to refer to the other for the understanding of the relevant terms.[92] As part of WTO law, the Dispute Settlement Body needs to follow a consistent understanding and approach to interpretation. In the case of intan-

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[87] PGS 1995 O J EPO at 562, 563–4, cited in Ho, above n. 83, 266.

[88] Ho, above n. 83, 283–4.

[89] See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell, 1998) 149.

[90] The interpretation of this term will be dealt with in Part Two.Chapter 5.III.A.5.

[91] See Gervais, above n. 89, 149.

[92] The *US – Gambling* case indicates that the interpretation of "public order" in GATS also refers to the interpretation of "public order" in GATT. Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Service*s, WTO Doc WT/DS285/R (10 November 2004) [3.278].

gible intellectual property rights embodied in tangible goods for import and export, the GATT is inevitably relevant for the understanding of this aspect of the implications of TRIPS. The understanding of the term used in GATT is relevant to the understanding of the term in TRIPS.

(b) *WTO Jurisprudence*

"Public order" can find similar expression in the French notion of *ordre public* or Common Law concept of public policy.[93] TRIPS does not offer cases on the understanding of these terms, but the words "*ordre public*" and "public morals" have been tested in WTO jurisprudence. "Public order" and "morality" are not directly incorporated into the preamble and general provision of TRIPS, but appear in specific Articles, such as in the exclusion of subject-matter from patentability.[94] "Public health" is directly incorporated into the socio-economic clause of TRIPS, and a necessity requirement is included with the adoption of related measures in safeguarding public health and nutrition.[95]

"Public order" and "public morals" have been tested in WTO GATS jurisprudence.[96] The ordinary meaning of "public", according to the panel in the *US-Gambling* case, is[97]

> Of or pertaining to the people as a whole; belonging to, affecting, or concerning the community or nation.

Therefore, for the WTO panel the word "public" refers to the whole community or people.[98] The word "moral" is defined as[99]

> […] habits of life with regard to right and wrong conduct.

It is, therefore, the definition of the right or wrong conduct of the whole community. The word "order" is defined as[100]

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[93] See Part One. Chapter 3.II.A.1.(c).(i); also see *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, Ibid., [3.278].

[94] Art 27(2) of TRIPS.

[95] See art 8 of TRIPS.

[96] Art XIV of GATS.

[97] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.463]. In the panel report, the panel quoted the definition from *The Shorter Oxford English Dictionary* (2002).

[98] Ibid., [6.463].

[99] Ibid., [6.464], the panel quoted the definition from *The Shorter Oxford English Dictionary* (2002).

[100] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.466]; the panel quoted the definition from *The Shorter Oxford English Dictionary* (2002).

> A condition in which the laws regulating the public conduct of members of a community are maintained and observed; the rule of law or constituted authority; absence of violence or violent crimes.

The panel was of the view that "public order" and "public moral" are two distinct concepts under Article XIV(a) of GATS, but that there is overlap between the two.[101] The case also invoked supplementary means for the interpretation of "public order" and "public moral", and the views of Lauterpacht (the elder) were referred to:[102]

> "public order" as the "fundamental national conceptions of law, decency and morality." He further stated that "the protection of the interest of minors … falls naturally within the notion of *ordre public*.

As the original text provides "necessary to protect public morals or to maintain public order", the meaning of "public order" and "public moral" is still subject to the necessity test. The parameters for the necessary test were discussed in the *Korean Beef* case, which put it closer to "indispensable" than to simply "making a contribution to".[103] These parameters were set with detailed guiding principles in *US-Gambling*[104] by referring to *Korean Beef* and *EC – Asbestos*,[105] including: "the importance of interests or values that the challenged measure is intended to protect",[106] "the extent to which the challenged measure contributes to the realization of the end pursued by that measure",[107] and "the trade impact of the challenged measure".[108]

Finally, *US – Gambling* applied the two-tiered test adopted by WTO jurisprudence in respect of Article XX of GATT 1994 as shown in *US – Gasoline*,[109]

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[101] Ibid., [6.468].

[102] Ibid., [6.471]; with quotation of *Case Concerning the Application of the Convention of 1902 Governing the Guardianship of Infants (Netherlands v Sweden)* [1958] ICJ 55, 90 (Judgment of 28 November) (sep op of J. Lauterpacht).

[103] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [161].

[104] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.488].

[105] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [178]; Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WTO Doc WT/DS135/AB/R (18 September 2000) [172].

[106] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [162].

[107] Ibid., [163].

[108] Ibid., [163] and [166].

[109] See Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (29 April 1996) p. 22.

*US – Shrimp*[110] and *Korea – Various Measures on Beef*.[111] The chapeau of the Article XIV of GATS is to be applied to test the "public order" and "public morals".

2. *Two-tiered Test under GATT Article XX*

(a) *The Test*

Article XX of GATT adopts open-textured language with a "chapeau" and 10 specific provisions,[112] and during the interpretation of this article the WTO panels and Appellate Body (AB) developed a specific test of interpretation. This two-tiered test is used to interpret the open–textured language contained in the Article XX in the WTO dispute settlement cases. In *US-Gasolin*e,[113] the Appellate Body presented the test as: "first, provisional justification by reason of characterisation of the measure under the specific provisions of Article XX; second, further appraisal of the same measure under introductory clause of Article XX, which is known as the chapeau clause."

The second of the tiers emphasises the "chapeau" of Article XX of GATT, which provides

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

Two conditions are contained in this chapeau. The first is the "arbitrary or unjustifiable discrimination between countries where the same conditions prevail" and the second is the "disguised restriction on international trade". The main purpose of the first condition of "arbitrary or unjustifiable discrimination" serves to restrict attempts to legitimise discrimination against certain countries. In *US-Shrimp*,[114] the three constitutive elements of the concept were reviewed as (i) needing to have the actual consequence of discrimination, (ii) to be of the character of "arbitrary or unjustifiable" and (iii) to occur between countries with same conditions. The concept of discrimination under

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[110] See Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (12 October 1998), paras 115–119.

[111] See Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [156].

[112] For specific provisions, see art XX of GATT.

[113] Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS4 (10 April 1995) [22].

[114] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [23]-[24] and [150].

the chapeau differs from other GATT provisions which were already found to be inconsistent with one of the substantive obligations of GATT.[115] The "disguised restriction" can be read side-by-side with "arbitrary and unjustifiable discrimination", and "concealed" or "unannounced" restriction or discrimination in international trade does not exhaust the meaning of "disguised restriction".[116] The main purpose this served was to avoid abuse or illegitimate use of the exceptions to substantive rules available in Article XX.[117] The interpretation of the panels and ABs focused on the publication of the measures, but this publication-emphasis method is criticised by many commentators as being manifestly absurd because it allows certain of these barriers on the mere basis of their being publicly announced.[118] The main object and purpose for GATT is the reduction of barriers to international trade and the publication emphasis may be unwarranted.[119]

The nature and scope of Article XX as described in *US-Shrimp*,[120] is to strike a balance between rights and duties, but the line of equilibrium is not fixed and unchanging and moves with the variation of the measures and the difference of the facts of specific cases. However, the main purpose of the carve-outs contained in the Article XX of the GATT is to protect vital state interests to allow the autonomy of the members to take measures, but this autonomy in taking measures should respect the requirements of the General Agreement and other covered Agreements. In *US-Gasoline*,[121] the AB emphasised the function of Article XX as

> It is of some importance that the Appellate Body point out what this does not mean. It does not mean, or imply, that the ability of any WTO Member to take measures to control air pollution or, more generally, to protect the environment, is at issue. That would be to ignore the fact that Article XX of the General Agreement contains provisions designed to permit important state interests – including the protection of human health, as well as the conservation of exhaustible natural resources – to find expression. The provisions of Article XX were not changed as a result of the Uruguay Round of Multilateral

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[115] Ibid., [150].

[116] See Analytical Text of GATT, para. 538.

[117] Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS4 (10 April 1995) [25].

[118] See Jan Klabbers, 'Jurisprudence in International Trade Law: Art XX of GATT' (1992) 26 *J World Trade* 63, 91.

[119] Salman Bal, 'International Free Trade Agreements and Human Rights: Reinterpreting Art XX of the GATT' (2001) 10 *Minn J Global Trade* 62, 74.

[120] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [156] and [159].

[121] Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS4 (10 April 1995) [30]–[31].

> Trade Negotiations. Indeed, in the preamble to the WTO Agreement and in the Decision on Trade and Environment,(footnote omitted) there is specific acknowledgement to be found about the importance of coordinating policies on trade and the environment. WTO Members have a large measure of autonomy to determine their own policies on the environment (including its relationship with trade), their environmental objectives and the environmental legislation they enact and implement. So far as concerns the WTO, that autonomy is circumscribed only by the need to respect the requirements of the General Agreement and the other covered agreements.

The second tier of the test is subject to the specific provisions contained in Article XX of GATT: Article XX(b) is related to the protection of public health, and emphasises the protection with human, animal or plant life or health. The panel in *US-Gasoline* presented a three-tier test[122]

(1) that the *policy* in respect of the measures for which the provision was invoked fell within the range of policies designed to protect human, animal or plant life or health;
(2) that the inconsistent measures for which the exception was being invoked were *necessary* to fulfil the policy objective; and
(3) that the measures were applied in conformity with the requirements of the *introductory clause* of Article XX.

In deciding the value of the evidence, the panel enjoys some discretion to determine the weight to be given to certain elements.[123] In the case of *EC-Asbestos*,[124] the Appellate Body, in the evaluation of the "necessity" requirement under GATT Article XX, stressed the value pursued in the measure taken to prevent human life and health from the risk posed by asbestos fibres was both vital and important in the highest degree, and thus upheld the measure since it was "necessary" to protect human health. However, in the *Korea-Beef* case,[125] the Appellate Body did not judge the measure to be "necessary" under GATT Article XX(d). The two cases show that the superior status of vital interests is based on the judge's discretion and is case specific.

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[122] Panel Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS4 (29 January 1996) [6.20].

[123] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WTO Doc WT/DS135/AB/R (18 September 2000) [161].

[124] Ibid., [172]; quoting Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [162].

[125] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [161]–[162] and [164].

(b) *TRIPS and the Article XX Two-tiered Test*

TRIPS has similar language to the language used in Article XX of GATT, including some of the provisions such as "to protect human, animal or plant life or health". These are the same expression as in Article 27 of TRIPS and similar to the expression for protecting public health in Article 8 of TRIPS.[126]

The test under GATT Article XX can be used in the other covered agreements of WTO regime such as TRIPS. In the *US – Gambling* case, the panel had to find the meaning of "public order" and "public morals" under GATS Article XIV, but there was no prior case on this Article in GATS. The panel then referred to GATT jurisprudence. In the *EC – Bananas III*, the Appellate Body confirmed that, if there were analogous provisions to GATT contained in the GATS, the jurisprudence under the GATT could be relevant the interpretation.[127] The panel then applied the GATT/WTO jurisprudence for the interpretation of the Article XIV of GATS in view of the textual similarity of the two Articles.[128]

Based on the similarity of the language used in TRIPS to that used in GATT and GATS, the issue arises whether the two-tiered test under Article XX of GATT should be used for TRIPS. One commentator's view is that the two-tiered test interpretive approach adopted in GATT jurisprudence should not be directly applied to TRIPS.[129] This mainly relates to the various goal achieved between the GATT and TRIPS regime. It is generally argued that the interpretation of Article XX of GATT reflects a trade goal, and it will not have the same weight in the interpretation of TRIPS, since TRIPS is to strike a balance between trade and protection.[130] The goal of balance between intellectual property protection and trade promotion in TRIPS is different from the trade goal of tariff reduction and elimination in GATT.[131] In *Section 211 Omnibus Appropriations Act*,[132] the Appellate Body concluded that no new exception based on the GATT would be allowed if it violated a substantive TRIPS obligation. This should not be understood to exclude the trade

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[126] See art XX.(b) of GATT and art 27.2 of TRIPS.

[127] Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas* (EC – Bananas III), WT/DS27/AB/R (9 September 1997) [231].

[128] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.448].

[129] Susy Frankel, 'The WTO's Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property' (2005) 46 *Va J Int'l L* 365, 424–5.

[130] Ibid., 389.

[131] Ibid.

[132] Appellate Body Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, WTO Doc WT/DS176/AB/R (2 January 2002) [275]–[280].

goal absolutely, and the chapeau test should be applied in the specific case of TRIPS when the trade goal is the main concern of the specific TRIPS provision.

### C. *Relationship of the Concepts in the Two Regimes*

The relationship between human rights and patent protection may connect the TRIPS regime to the human rights regime. The use of "public order" and "public morals" and "public health" and "public emergency" satisfy the human rights regime to limit or derogate some of the human rights. However, if there is some overlap between the patent protection and human rights protection, should the use of the language in human rights regime be applied to the understanding of the TRIPS regime? If so, how far can the understanding on these in the human right regime be used to understand the TRIPS regime? Or, even if there is no overlap between patent protection and human rights regime, can the understanding on these terms in the human rights area be used to understand TRIPS? The challenge is to understand these two regimes in order to understand human rights concerns in TRIPS. This is complicated by the issue whether TRIPS should understand these terms by referring to its own regime or should TRIPS understand these terms by following the terms in human rights regime.

## III. Human Rights in TRIPS – Is an External Mechanism Needed

Both human rights and intellectual property protection have contributed to the development of international law. There is a separation between human rights protection and intellectual property protection. This separation may result from the historical isolation of these two areas, and such separation also leads to jurisprudential separation.[133] The synergies between the intellectual property protection and the human rights protections have not led to much progress except the recent clarification of Article 15.1(c) of the ICESCR. Patent protection for pharmaceuticals is mandatory for WTO members under TRIPS emerged as a potential obstacle for the access to medicines. This has fuelled the debate by bringing trade regulation into the debate between the right to health and patent legislation. TRIPS must meet the challenge of

[133] Laurence R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5 *Minn Intell Prop Rev* 47, 49–50.

the human rights claims when the system is under examination by WTO panels.

As discussed above, the right to fruits of creation may be limited in the public health context only if it meets the requirements of the limitation clauses.[134] However, TRIPS, which is not equal to the human right to fruits of creation, should also meet the challenge of the right to health.

There are many different views as to whether TRIPS has taken the human rights norm of the right to health into consideration. From a human rights approach Walker is of the view that TRIPS has not taken a consistent approach to human rights.[135] The reasons for this view are that "human rights are only included as exceptions in the TRIPS Agreement"; "the responsibilities of intellectual property rights holders have not been set out clearly"; "the intellectual property protection in the TRIPS Agreement is not necessarily useful for knowledge rich but economically poor people"; and "the minimum standard approach to intellectual property protection is not appropriate for countries with different levels of technological development".[136] This is a positivist approach, and the author uses the human rights approach to set up intellectual property rights holders' responsibility. However, TRIPS, as a multilateral agreement to deal with intellectual property protection in the international trade context, does not deal with human rights as its subject matter. Therefore, the existence of human rights considerations in TRIPS should not be regarded as exceptional, and thus, further clarification of these human rights consideration is needed.

Petersmann views the human rights issue in WTO from the angle of constitutionalism, and calls for a stronger process of "transnational constitutionalisation" to meet the multi-level governance to change the international system from a "state-centred UN system" to a "citizen-centred and human rights based system" to guarantee the coexistence of market freedoms and human rights.[137] This approach is prospective. However, the realisation of "transnational constitutionalisaiton" is aspirational rather than realistic.

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[134] See Part One.Chapter 3.II.A.3.

[135] Simon Walker, 'A Human Rights Approach to the WTO's TRIPS Agreement' in Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights – Foundations and Conceptual Issues* (The University of Michigan Press, 2006) 171, 173–4.

[136] Ibid.

[137] Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi, 'Linking Trade Regulation on Human Rights in International Law: An Overview' in Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press, 2005) 1, 4.

Abbott observes the realisation of the right to health from the competition principles in TRIPS and is of the view that the introduction of human rights is not constrained by TRIPS and existing WTO rules.[138] This is a pragmatic approach, but it uses competition policy to analyse the issue and does not consider the goal of TRIPS under the whole WTO context. The TRIPS Agreement in the WTO context should promote international trade and grant intellectual property protection.

Victor Mosoti approaches the issue from the standpoint of institutional cooperation between the norm-creating international organisations, to try to find the synergies of the various international organisations through "mutual observership", or through "formal agreements" or through "memoranda of understanding".[139] This is also a prospective approach but with a different orientation from Petersmann's. There has been some cooperation between the various international organisations; these include cooperation between the WTO and WIPO, and mainly cover technical assistance.[140] In addition, the WTO Secretariat also cooperates with a range of other international organisations, including the WHO and the Office of UN High Commissioner for Human Rights.[141] The problem is that the various organisations need to clarify the understanding of the various norms in their own regime first instead of reaching agreement or memorandum with others. Or the agreement or memorandum will become a more political statement.

On the one hand, international organisations should strengthen their cooperative roles in the whole international community. The proliferation in international law and the creation of more and more norms in various international regimes will be fragmented without such cooperation. On the other hand, it is necessary for the various international regimes to clarify their own regimes in order to facilitate such cooperation. This will require a further understanding on their own regimes and the norms created in that regime.

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[138] Frederick M. Abbott, 'The "Rule of Reason" and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in Cottier, Pauwelyn and Bürgi (eds), above n. 137, 279, 300.

[139] Victor Mosoti, 'Institutional Cooperation and Norm Creation in International Organizations' in Cottier, Pauwelyn and Bürgi (eds), above n. 137, 165, 165–79.

[140] The cooperation between the WTO and WIPO covers notifications of countries' laws, technical assistance, and implementing the TRIPS obligations that stem from art 6*ter* of the Paris Convention for the Protection of Industrial Property, which is one of WIPO's treaties. See WTO <http://www.wto.org/english/thewto_e/coher_e/wto_wipo_e.htm>.

[141] See WTO <http://www.wto.org/english/thewto_e/coher_e/wto_wipo_e.htm>. These include participating in these organisations' meetings as an observer, working together on technical assistance (particularly with the WHO on matters related to TRIPS and public health) and other help that staff in the organizations give to each other.

### A. *Integration or Fragmentation*

The human rights norms are not just more political rather than legal rights,[142] and they can be applied in national law through treaty-making or applied as customary international law or as *jus cogens*. The right to health can be applied in international law but perhaps with conflict between it and the pharmaceutical patent protection in TRIPS.

This raises the question of "conflict" in international law. Wilfred Jenks was of the view, similar to that of Kelsen, Klein, Wilting, and Wolfram Karl, that a strict definition of "conflict" only covers mutually exclusive obligations to mean that two (or more) treaty instruments contain obligations which cannot be complied with simultaneously.[143] However, Joost Pauwelyn, in his analysis on the conflict of norms in public international law, adopts a wider definition of "conflict" to refer to four situations, including "conflicting commands that are merely different or mutually exclusive", "conflict between a command and prohibition", "conflict between a command and an exemption", and "conflict between a prohibition and a permission".[144] Only the mutually exclusive conflict can be referred to as necessary conflict, and this kind of conflict, in the WTO context, has not been identified by Pauwelyn.[145]

TRIPS requires a certain level of intellectual property protection. These requirements include the protection of the subject-matter where, in domestic law, there is no difference in patent protection on the basis of the field of technology or place of invention or process or product patent. The term of protection requires that members of TRIPS make their laws comply with TRIPS and grant the same periods of protection.[146] These protection requirements can constitute commanding norms in WTO law. However, the right to health also imposes positive obligations on states to provide affirmative protections for individuals, and these include commanding obligations on

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[142] Some argue that human rights norms are not legal, because they can not be enforced. See Lisa Forman, 'Ensuring Reasonable Health: Health Rights, The Judiciary, and South African HIV/AIDS Policy' (2005) 33 *J L Med & Ethics* 711, 711. The author points out that, due to the reluctance of judicial recognition and enforcement of the "positive" obligations pertaining to social welfare, the right to health has often fallen largely into the political rather than legal sphere.

[143] Wolfram Karl, 'Conflict Between Treaties' in R. Bernhardt (ed.), *Encyclopaedia of Public International Law* vol. 7 (1984) 468, 468; cited in Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' in Abbott, Breining-Kaufmann and Cottier (eds), above n. 135, 181, 207–8.

[144] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 175–88.

[145] Ibid., 183.

[146] But TRIPS offers a moratorium for some developing countries and least developed countries to protect certain patent.

the state. Whether there is a necessary conflict between the TRIPS regime and the right to health lies in the demonstration that compliance with TRIPS necessitates violation of a human right to health.

As discussed above, the right to health may entail access to affordable medicines and pharmaceutical patent protection may give the patent holder the monopolised power to inflate the drug prices and thus have an impact on the access to medicines. It seems that conflict does arise between the two.

This apparent conflict between various treaty norms is a product of the ever-growing globalisation which makes the world a more interrelated one instead of an isolated one.[147] This will raise the question, in TRIPS and human rights laws, whether there is integration or fragmentation in the international law system. A commentator has observed[148] that one of the problems of TRIPS is that, after its incorporation into the WTO laws, the WTO failed to address any conflicts arising under international law when a country has ratified treaties that may differ from its obligations under the WTO. As the ICESCR has been ratified by 160 states and the WTO has 153 members, the WTO needs to take potential conflicts into consideration when completing the agreements. The conflict may cause the emergence of a new hierarchy of values in international law, and it may show a tendency towards "relative normativity".[149] TRIPS is a multilateral agreement to try to set a minimum standard of global protection, so the patent protection imposes commanding obligations. However, as the intellectual property system is a system which is established on a fine balance, in the application of the rules in the treaties, the norms may conflict with each other. Under such circumstances, TRIPS will have to carve out to strike a balance. The norms in both human rights regime and TRIPS, if they deal with the same subject-matter and when the norms in TRIPS can be carved out to the extent to give effect to exception, may accumulate instead of conflict.[150]

TRIPS contains various carve-outs and such carve-outs may allow pharmaceutical patent protection to relate to the human rights regime consistently.[151]

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[147] See Pauwelyn, above n. 144, 19–20.

[148] David Weissbrodt and Kell Schoff, 'Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7' (2003) 5 *Minn Intel Prop Rev* 1, 13.

[149] Pauwelyn, above n. 144, 21.

[150] See Ibid., 162–3, the author discusses how norms interact to find the accumulation of norms in a situation that norms can also accumulate in case of carve-out to give effect to another norm.

[151] These include: Art 27.1 is a non-discrimination clause and has flexibilities in the application of conditions of patentability and the permitting of differentiation. Art 27.2 permits exclusion for *ordre public* or morality with a proviso that such exclusion is not made merely because the exploitation is prohibited by law. Art 27.3(a) permits exclusion for diagnostic, therapeutic and surgical methods; art 27.3(b) permits exclusion for plants,

Many of the carve-outs contained in the balance mechanism are said to offer flexibilities in the field of patent protection to cope with the public health issue.[152]

In addition to these carve-outs, TRIPS contains provisions that are open-textured, and the understanding of such provisions may offer to the possibility of reference to the human right to health to harmonise with the seeming conflict between the pharmaceutical patent protection and the right to health.

The preamble sets a tone for TRIPS by addressing the reduction of distortions and impediments to international trade, recognition of public policy objectives of national laws and maximum flexibility for least developed country.[153] Article 7 deals with the objective of TRIPS, and it states that the protection and enforcement of intellectual protection should contribute to the dissemination of technology, advantages to users and social welfare.[154] Article 8 states the principles of TRIPS.[155] In November 2001, the WTO Ministerial meeting adopted the Declaration on the TRIPS Agreement and Public Health,[156] and this Declaration recognises the WTO member's right to protect public health and to promote access to medicines for all. In December 2005, the WTO Ministerial Conference was held in Hong Kong and the General Council proposed an Amendment to Article 31 of TRIPS for clarification of "importing countries" and "exporting countries" and measures to prevent diversion of public health related pharmaceuticals.

In addition, as the TRIPS is part of the whole WTO laws, the test of the consideration of the right to health in TRIPS may also need to be subject to that test in other related WTO laws when consistency in the WTO laws may

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animals and essentially biological processes, other than non-biological and microbiological processes. Art 30 provides exceptions to patent rights after a three-step test. Art 31 authorises the granting of compulsory licenses, but art 31(f) requires that such use shall predominantly for the supply of the domestic market of the Member authorizing such use. Art 73 allows security exceptions to maintain international peace and security.

[152] For a full range of flexibilities TRIPS offered, see Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections' in Abbott, Breining-Kaufmann and Cottier (eds), above n. 135, 145, 151

[153] See Preamble of TRIPS.

[154] Art 7 of TRIPS.

[155] Art 8.1 deals with the adoption of measures to protect public health and nutrition, vital areas of socio-economic and technological development on condition that these measures are consistent with the provisions of this Agreement and Art 8.2 deals with the prevention of anticompetitive practices.

[156] This declaration is referred to as the Doha Declaration, see *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) ('*Doha Declaration*').

require that. Access to medicine relies on the import and export of medicines to the needy countries to meet public health concerns, and right to health may also entail a test of GATT to find the existence of such accumulation between the human rights norms and the GATT.

### B. *Resolution of the Conflict*

TRIPS may be able to accommodate the human rights norms by carving out some parts in it, and by the flexibilities of its open-textured provisions. These flexibilities give a balance between the public and private interest while intellectual property protection and trade promotion are considered in TRIPS, and the protection of public health, as one of public goods concern, might be dealt with in striking the balance. The issue is whether these carve-outs and flexibilities are adequate to give effect to the right to health in TRIPS. In order to find out whether there is the necessary conflict between the right to health and TRIPS, it is necessary to find out when TRIPS unavoidably violates the right to health. As stated above, in order to establish a necessary conflict between the right to health and TRIPS, the obligations under the human rights norm of the right to health contained in the ICESCR should be mutually exclusive of the obligations under TRIPS. When the WTO panel examines TRIPS, it will have to interpret TRIPS and its flexibilities, and the "objective" question will need to be determined by normal rules of treaty interpretation.[157] As Pauwelyn suggested, the approach of equating conflict to breach should move the debate on "what is conflict" from the abstract relationship between two norms of international law to the more concrete and common question of "when is there a breach of a given norm". The author also suggested that another advantage of approaching conflict in terms of breach is that conflict thereby becomes an "objective" question, based on "the rights and obligations set out in the norms in question, to be determined by normal rules of, for example, treaty interpretation".[158] Another author is of the similar view that such conflict would need to be resolved by customary rules of treaty interpretation, including use of the principle of consistent interpretation.[159]

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[157] Pauwelyn, above n. 144, 176; Also see Abbott, above n. 138, 280.

[158] Pauwelyn, above n. 144, 176.

[159] Abbott, above n. 138, 280.

Treaty interpretation is a means used in international law to avoid possible conflicts among treaties,[160] and extraneous legal rules can be incorporated through treaty interpretation. As judicial deliberation in one jurisdiction is also part of a wider and much more complex picture of the international system,[161] so treaty interpretation may become a useful and positive tool in some instances through incorporation of other rules of international law. French viewed treaty interpretation through "other" legal rules from the angle of the competent tribunals of certain treaties, and was of the view that tribunals needed to seek justice by "incorporating recent developments as an integrated part of pre-existing text", including "new rules of law", "evolving values and technical standards", to encourage a more coherent approach to legal reasoning and prevent disintegration of legal rules into their various sub-disciplines and "to ensure broader notion of justice".[162] Through this kind of treaty interpretation with the incorporation of other legal rules, a possible conflict may be identified or be avoided. In the WTO tribunal, it is crucial to interpret the WTO laws with a consideration of the right to health to avoid possible contradictions in judicial decisions.[163]

TRIPS may conflict with the norms in other agreements. Most provisions of TRIPS set command norms for the members to take measures, but the human rights instruments also set command norms for parties. These two regimes deal with different subject-matters, and the conflict only appears when the right to health requires that access to medicines obliges states to provide drugs while the pharmaceutical patent protection may impact such access. Seemingly, there is some conflict, but TRIPS also deals with health concerns in several provisions through its carve-outs and open-textured provisions and conceptual ideas. These flexibilities and conceptual ideas may enable TRIPS to avoid the potential conflict between the right to health and the pharmaceutical patent protection. This becomes a kind of "objective question", which requires an interpretation of TRIPS.

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[160] This kind of view can be found in Pauwelyn, above n. 144, 244–74; also see Marceau, above n. 143, 196–202.

[161] Duncan French, 'Treaty Interpretation and the Incorporation of Extraneous Legal Rules' (2006) 55 *ICLQ* 281, 284.

[162] Ibid., 285–6.

[163] Pauwelyn, above n. 144, 461.

# Part Two

## Interpretation of TRIPS

The interpretation of a treaty is the process used to find the intention of the treaty parties, to clarify the meaning of the text and to ascertain the object and purpose of a treaty in order to give effect to that treaty.[1] The interpretation of a treaty is, therefore, a basic step for the observance of a treaty in good faith.[2] The process of treaty interpretation can also contribute to the integration of a treaty or treaties within the legal system in which the text is situated.[3] Interpretation can be advantageous, when, in some contexts, it favours one disputant over another; it is also a limited tool, since it only offers an auxiliary way toward the clarification of the obligations of the parties.[4] Treaty interpretation norms have evolved from the various national systems of jurisprudence regarding the interpretation of statutes and contracts. There is a long history and many rules of Roman Law were applied to treaty interpretation by Grotius and later authorities.[5] The law of the interpretation of treaties has developed its own doctrines and principles and has been widely applied in international custom and practice.

The Vienna Convention on the Law of Treaties (VCLT) is a codification of those various doctrines and principles, and the rules and principles contained in the VCLT have been given broad application.[6]

The TRIPS Agreement is a multilateral treaty and is a part of the WTO package.[7] There was an extensive program of negotiation and compromise that led to the formulation of a text for a multilateral agreement on TRIPS. In that process negotiators and drafters of the various drafts and final text had recourse to language and drafting techniques commonly used in international treaties in an attempt to find wordings that could be agreed to by the various interests.[8] In such a process language may contain ambiguities, and indeed it has been observed that in some cases the ambiguity of the

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[1] Sir Ian Sinclair, *The Vienna Convention on the Law of Treaties* (Manchester University Press, 2nd ed., 1984) 114–5.

[2] Sir Robert Jennings QC & Sir Arthur Watts QC (eds), *Oppenheim's International Law I* (Longman, 9th ed., 1992) 1267.

[3] Campbell McLachlan, 'the Principle of Systemic Integration and Art 31(3)(c) of the Vienna Convention' (2005) 54 *ICLQ* 279, 286–7.

[4] Susy Frankel, 'The WTO's Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property' (2005) 46 *Va J Int'l L* 365, 368.

[5] Jennings & Watts, above n. 2, 1269–70.

[6] *Vienna Convention on the Law of Treaties*, opened for signature on 23 May 1969, 1155 UNTS 331, 8 ILM 679 (entered into force on 27 January 1980 ) ('*VCLT*').

[7] The WTO covered agreement include: GATT, GATS, TRIPS, SPS, TBT and others.

[8] See generally, Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPS Agreement* (Routledge, 2002) 7–28 According to the author, TRIPS was a victory for some developed countries using the "carrot" and "stick" approach to reach a compromise between the interests of developed countries and developing countries.

language was a deliberate negotiating tactic. In order to achieve both social and economic goals, TRIPS negotiators and drafters used language in the drafts and final text to accommodate the divergent or even conflicting intentions of treaty parties.[9]

The intellectual property protection system is based on a fine balance between the protection of private interests and the public interest. TRIPS, in comparison with the intellectual property protection prescribed in the preceding conventions such as the Paris Convention and the Berne Convention, introduced many changes ranging from the level of intellectual property protection to the scope of the protection, especially in the fields of patents.[10] Such changes have impacted on the protection of intellectual property rights and public goods in new ways. Public health policy is one of the major "global public goods" with significant political and legal dimensions attracting widespread attention from Governments, NGO's public and private organisations and individuals. The standards applicable to patent protection under the provisions of TRIPS and their impact upon patents for pharmaceutical products and methods has been said to have seriously affected access to affordable medicines. This may cause potential conflict between the implementation of TRIPS and the realisation of the right to health.[11]

In resolution 2000/7 of the UN Human Rights Commission the Sub-Commission notes

> Noting further that actual or potential conflicts exist between the implementation of TRIPS and the realization of economic, social and cultural rights in relation to, inter alia, impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food of plant variety rights and the patenting genetically modified organism, "bio-piracy" and the reduction of communities' (especially indigenous communities') control over their own genetic and natural resources and cultural values, and restrictions on

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[9] See eg TRIPS Preamble, art. 7, and art. 8. Also see Gregory Shaffer, 'Recognizing Public goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005) 884, 891.

[10] For a discussion of the main changes introduced by TRIPS in the field of patent, see Katharina Gamharter, *Access to Affordable Medicines: Developing Responses under TRIPS and EC Law* (Springer, 2004) 19–56; the author gives a range of protection changes in TRIPS patent protection, including the terms of protection, the dispute settlement process and the moratorium of the intellectual property protection enforcement.

[11] Sub-Commission on the Promotion and Protection of Human Right, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) ('*The Impact of TRIPS Agreement*') para. 2.

> access to patented pharmaceuticals and the implications for the enjoyment of the right to health.

Public health is one dimension of the right to health, and it promotes the realisation of the right to health as well as relies on the right to health for its realisation.[12] As the public health is also a public good concern, intellectual property protection will have to balance the protection of the private right with the protection of public health. This gives rise to an inquiry as to whether TRIPS has indeed been in conflict with the attainment of public health and the respect and protection of the right to health. Further, this will relate to the issue of whether TRIPS has taken the right to health into consideration or not. It may be that the public interest in the right to health requires that the purely private property conceptions of intellectual property protection in TRIPS should be overridden or modified or interpreted to give effect to the public good. However, as discussed above, the right to property and the right to fruits of creation can also have some implications for the protection of intellectual property.[13] Therefore, in order to understand the relationship between the right to health and pharmaceutical patent protection in TRIPS, the interpretation of TRIPS, and eventually, the interpretation of the whole WTO laws that are related to the interpretation of TRIPS, is necessary.[14]

The WTO Panels or Appellate Body established under Dispute Settlement Body (DSB) shall, in the course of deciding disputes adopt interpretations and make decisions that promote safeguarding the "security" and "predictability" of the WTO system, and shall serve "to preserve the rights and obligations of Members under the covered agreement" and "to clarify the existing provisions of those agreements".[15] In the course of hearing and deciding disputes the Panel and Appellate Body may provide clarification of TRIPS provisions and in doing so shed light on the way that TRIPS provisions respond to the right to health. Issues relevant to the interaction between the provisions of TRIPS and the right to health are likely to arise when Panels are charged with resolving disputes regarding patents on medicines in the presence of the ambiguous and conflicting texts in TRIPS.[16] The Panel and Appellate Body will have to decide whether human rights norms or the right to health,

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[12] See Part One.Chapter 2.I.C.

[13] See Part One.Chapter 2.III.A and B.

[14] As explained in Part One.Chapter 3.III.B, the resolution of the seeming conflict relies on a treaty interpretation.

[15] *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 2 ('*Understanding on Rules and Procedures Governing the Settlement of Disputes*') ('*DSU*'), art. 3.2.

[16] See Shaffer, above n. 9, 884, 884–5.

the right to property and the right to fruits of creation can all be taken into account when interpreting TRIPS.

Article 3.2 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) requires the interpretation of WTO laws in accordance with the customary rules of interpretation of public international law.[17] It provides

> The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

As one of the three pillars of WTO laws,[18] TRIPS is undoubtedly required to be interpreted in the same vein. This has been reaffirmed in the Doha Declaration.[19] In the *United States–Gasoline*[20] case, the WTO Appellate Body determined that the interpretation of WTO law should be in compliance with the customary rules of public international law as laid down in the Vienna Convention on the Law of Treaties (VCLT). Since then, the WTO Panel and Appellate Body have constantly repeated that Articles 31 and 32 of the VCLT are codified customary international law and thus form part of the binding principles for the interpretation of WTO law, including in the TRIPS disputes. Articles 31 and 32 are binding on every WTO member regardless of whether they have ratified the VCLT or not,[21] because the reference to the customary international laws of interpretation in the Dispute Settlement Understanding facilitated the application of the codified customary international law of VCLT to all WTO members.[22] In the *Japan-Tax* case,[23] the Appellate Body also clearly articulated that the VCLT represented a codification of customary international law and should be binding on all

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[17] Art 3.2 of DUS.

[18] GATT, GATS and TRIPS are the three pillars of WTO.

[19] *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) ('*Doha Declaration*') para. 5(a).

[20] See Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (29 April 1996) section B pp. 17–18; and it provides that the WTO Agreement could not be read in 'clinical isolation from public international law'.

[21] Matthias Oesch, *Standards of Review in WTO Dispute Resolution* (Oxford University Press, 2003) 42–3.

[22] Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5 *J Int'l Econ L* 17, 43.

[23] Appellate Body Report, *Japan – Tax on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) section D pages 12–14.

states.[24] It is, therefore, a valuable perspective for a legalistic interpretation of TRIPS to offer to assess TRIPS in relation to the right to health. At the same time, it is also important, through the interpretation of TRIPS, to clarify the lines between the WTO laws and a range of sources outside the WTO regime, when the sources from various regimes come to pose challenge to WTO laws. Otherwise, the multilateral trading system is under threat to be overloaded with different sources to be applied when interpreting WTO laws.

This part, through discussing the application of VCLT rules of treaty interpretation in the past WTO dispute settlement cases, will introduce the various doctrines and principles of customary rules of interpretation of public international law contained in VCLT in order to find the approach that will be used by the WTO Dispute Settlement Body to interpret TRIPS. It will also analyse the interpretation relationship between TRIPS and WTO covered agreements and the incorporated agreements of TRIPS for the purpose of the interpretation of TRIPS with reference to the WTO covered agreements and TRIPS incorporated agreements. Then, it will discuss the introduction and application of human rights norms to TRIPS and related WTO covered agreements with a discussion of the right to health, and the implications of the right to health, to explore how human rights norms can be applied to the interpretation of TRIPS. Finally, it will provide an analysis on the object and purpose of TRIPS and a full interpretation of the specific TRIPS flexibilities by applying the above-discussed interpretations rules to see to what extent TRIPS can respond to the right to health.

[24] See James Cameron & Kevin R Gray, 'Principles of International Law in the WTO Dispute Settlement Body' (2001) 50 *Int'l Comp L Q* 248, 254.

# Chapter 4

## Rules of Interpretation of Public International Law

TRIPS has provoked controversy and opposition for its apparent lack of consideration of human rights and specifically of the right to health, especially in the face of national and global public health problems including the AIDS pandemic, and the impacts of malaria, tuberculosis and other endemic diseases. It is, therefore, important and necessary, in order to have a better understanding of TRIPS, to have an overview of the basic principles of treaty interpretation and the application of the principles of VCLT to the interpretation by the WTO Dispute Settlement Body.

The WTO laws are a unity, which means that each covered agreement should be interpreted in a consistent manner with the other covered agreements. The analysis reveals the interpretation relationship between TRIPS and the related covered agreements of the WTO for the purposes of the interpretation of TRIPS. In addition, the incorporated conventions of TRIPS constitute a necessary element and their interpretation relationship with TRIPS should be clarified for better understanding and interpretation of TRIPS.

### I. Application of VCLT by the WTO

The establishment of the WTO dispute settlement system provides a judicial style process for WTO members to seek a settlement in trade disputes, and has vested the WTO Dispute Settlement Body (DSB) with many characteristics that have paved the way for the development of GATT jurisprudence.[25] Amongst other characteristics, the interpretive function of the DSB is one of the important factors that influence the jurisprudence concerning GATT

[25] Ibid., 249.

and enhances the security and consistency of WTO law in the WTO legal system.[26]

The correct principles and processes of interpretation of the treaty is often a fundamental issue for the DSB because parties have conflicting understandings of certain provisions. As mentioned above, the DSU requires the interpretation of the WTO Agreement in compliance with the customary rules of public international law, and the *US-Gasoline case* has reaffirmed such rules of interpretation since the establishment of WTO.[27]

Thus, the customary rules of interpretation of public international law should prevail in the interpretation of WTO agreements. In this regard, the Vienna Convention on the Law of Treaties (VCLT) shall constitute a codification of such customary rules of public international law.[28] In *Japan-Taxes*,[29] the Appellate Body implicitly applied the VCLT rules to the non-parties by taking VCLT as a codification of customary international law to bind all states. Then, in *US-Gambling*,[30] the customary rules of interpretation of public international law were introduced and Articles 31, 32, and 33 of VCLT were expressly quoted as applicable and necessary for the interpretation of the covered agreement. It, therefore, does not matter that many WTO members (including the United States) are not parties to the VCLT. The rules contained in VCLT are applicable to the WTO members in terms of treaty interpretation.

## A. *Article 31(1) of VCLT and Its Application*

### 1. *Ordinary Meaning – Article 31(1)*

Article 31(1) deals with the principles of the rules of good faith interpretation by giving the terms of the treaty their ordinary meaning.

Article 31(1) provides

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[26] Ernst-Ulrich Petersmann, *The GATT/WTO Dispute Settlement System: International Law, International Organizations, and Dispute Settlement* (Kluwer Law International, 1997) 17; see also Cameron & Gray, above n. 24, 251–2.

[27] See Appellate Body Report, *United States – Standard for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (29 April 1996) p17.

[28] See Sinclair, above n. 1, 153; and the author expresses the view that, "there is no doubt that arts 31 to 33 of the Convention constitutes a general expression of the principles of customary international law relating to treaty interpretation."

[29] Appellate Body Report, *Japan – Tax on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) section D p10.

[30] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.9] and [6.10].

> A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

This apparently simple and straightforward provision has a number of parts which will be discussed sequentially.

The requirement of interpretation in good faith follows in the same suit of that contained in the Article 26 of the VCLT for the performance in good faith of a treaty in force,[31] and indicates that "good faith" is important for the interpretation and observance of international treaties. The plain meaning doctrine of treaty interpretation is a principle of interpretation expounded nearly two hundred years ago by Vattel,[32] and is "the pivot of the traditional doctrine of interpretation".[33]

Article 31(1), at the same time, requires that the test of the ordinary meaning of the terms of a treaty should be consistent with the spirit, purpose and context of the clause or instrument containing the words. If applying the ordinary meaning of terms produces a result that is clearly inconsistent or at odds with the spirit, purpose and context of the instrument the ordinary meaning rule should not be applied. In addition, the ordinary meaning interpretation does not mean that only a pure grammatical analysis should be employed. There should be consideration of all the consequences that flow from the text normally and reasonably.[34]

The expression "in light of its object and purpose" shows a teleological approach to interpretation. This "teleological" approach can be compared with the "subjective" approach and is generally viewed as leading to more flexible interpretations over time than the "subjective approach".[35] However, the risk of undue emphasis on the "object and purpose" of a treaty is that it will encourage teleological methods of interpretation to deny the relevance of the intentions of the parties.[36] What is required is a clarification of the relationship between "textual interpretation" and "teleological interpretation". Sir Ian Sinclair discussing this question has argued that "ordinary meaning" should be given the primary role and that consideration of object and purpose should serve as an ancillary and secondary process in the application

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[31] Art 26 of VCLT provides, "Every treaty in force is binding upon the parties to it and must be performed by them in good faith."

[32] Hersch Lauterpacht, systematically arranged and edited by E Lauterpacht, *International Law, Being the Collected Papers of Hersch Lauterpacht* (Volume 4, Cambridge University Press, 1978) 394.

[33] Ibid., 393.

[34] Sinclair, above n. 1, 121.

[35] Lennard, above n. 22, 21.

[36] Sinclair, above n. 1, 131.

of the rule.[37] The VCLT artfully combines the "textual approach" with this "teleological approach" to best suit the situation to ensure stability and flexibility by giving primacy to text first.[38] This approach also reflects an evolutionary attitude towards interpretation by including more flexibility in the process instead of adopting or maintaining a more static attitude often found in subjective interpretation.

2. *Application*

The treaty interpretation rule codified in the VCLT of finding the ordinary meaning of words in their context in the light of the treaty's object and purpose has been utilised in WTO dispute settlement cases by the Panels and the Appellate Body. This principle had been applied even before the GATT 1994.[39] It has been argued that there may have been a tacit acceptance in the GATT 1947 regime to apply the rules contained in VCLT, since these rules were frequently referred to by the Panels with reference to the drafting history of the agreement.[40] For example in the *EEC-Regulations on Imports and Components* case,[41] Article XX(d) was interpreted in the light of the object and purpose. In the *United States – Restrictions on Imported Sugar* case,[42] some basic rules of treaty interpretation, such as the "ordinary meaning" principle mirrored in Article 31 of VCLT, was referred to and applied. In other cases, such as *European Economic Community – Restrictions on Imports of Dessert Apples – Complaint by Chile*[43] and *Canada – Measures Affecting Exports of Unprocessed Herring and Salmon*,[44] the Panels also used the principles of looking at the "plain meaning" and "contextual understanding" of the GATT 1947. All of these examples suggest that the VCLT had already been applied widely in the process of dispute settlement in cases concerning GATT well before the WTO was established.

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[37] Ibid., 130.

[38] Lennard, above n. 22, 21–2.

[39] The predecessor of WTO, GATT has already started to apply the VCLT rules although there is no express language to show the application of such rules in the GATT before WTO.

[40] Cameron & Gray, above n. 24, 253.

[41] GATT Panel Report, *EEC-Regulations on Imports and Components*, L/6657–37S/132 (16 May 1990) [5.12]–[5.18].

[42] GATT Panel Report, *United States – Restrictions on Imported Sugar*, L/6514–36S/331 (22 June 1989) [5.2].

[43] GATT Panel Report, *European Economic Community – Restrictions on Imports of Dessert Apples – Complaint by Chile*, L/6491–36S/93 (22 June 1989) [12.13].

[44] GATT Panel Report, *Canada – Measures Affecting Exports of Unprocessed Herring and Salmon*, L/6268–35S/98 (22 March 1988) [4.5] and [4.6].

Since the establishment of the WTO this rule has been widely applied. In *Canada-Certain Measures Concerning Periodicals*,[45] the Appellate body used the "ordinary meaning" approach to analyse the texts of GATT 1994, GATS and Article II of the WTO agreement to find that obligations under GATT 1994 and GATS can co-exist and that one does not override the other. In *EC Bananas*,[46] the Appellate Body also applied the "ordinary meaning" principle to interpret the term "affecting" and also referred to the conclusions of previous panels for confirmation of the "ordinary meaning" of the word "affecting" in GATS. The panel in the *US-Gambling* case employed the interpretation method as the application of "ordinary meaning" of words in good faith under Article 31 of VCLT and the doctrine of "effective interpretation".[47] These examples show that application of the "ordinary meaning" interpretation rule is a first step in WTO jurisprudence to interpret WTO covered agreements. Interpretation of TRIPS should follow this route to explore the meaning of related terms.

The "object and purpose" interpretation method has been emphasised in WTO jurisprudence. It was confirmed in the *Japan-Alcohol* case that the object and purpose principle should be used to determine the meaning of the "terms of the treaty" and not as an independent basis for interpretation.[48] It should be considered together with the terms intended to be interpreted. The examination of the object and purpose requires not only consideration of the preamble of a treaty but also other related provisions.[49] In addition, the object and purpose of a particular provision may also be taken into account, as long as it reflects one of the objects and purposes of the relevant WTO Agreement as a whole.[50] In *US-Shrimp*, the Appellate Body adopted an approach to analyse the text of a provision first in its context to reveal "object

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[45] Appellate Body Report, *Canada – Certain Measures Concerning Periodicals*, WTO Doc WT/DS31/AB/R (30 June 1997) Section IV p 19.

[46] Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WTO Doc WT/DS27/AB/R (9 September 1997) [c.1.220].

[47] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.46] and [6.47].

[48] Appellate Body Report, *Japan – Tax on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) Section D.

[49] Lennard, above n. 22, 27–8, the author gave the example of the AB's Report in *EC–Computer Equipment* to propose that other related provisions, such as those in the Dispute Settlement Understanding, should also be considered to examine the object and purpose. In para. 82 of the Report, "we agree with the Panel that the security and predictability of 'the reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade' is an object and purpose of the WTO Agreement, generally, as well as of the GATT 1994".

[50] Lennard, above n. 22, 28.

and purpose" of the analysed provision, and then to reveal the objects and purposes of the wider agreement through it.[51] According to a commentator, this can overcome difficulties in interpretation when a wider object and purpose of the treaty as a whole is too broadly expressed to cover that of the provision directly.[52] Therefore, when seeking the ordinary meaning of a term of a treaty to be interpreted, the object and purpose of a treaty should be considered and the examination of the object and purpose of the treaty should be expanded to a wider context: not only the preamble but also the related provisions of a treaty; not only the object and purpose of specific provisions but also the general object and purpose of the whole agreement.

The interpretation of TRIPS should be conducted in the light of the object and purpose of the Agreement. Such an approach to interpretation of all the provisions of TRIPS has been affirmed by the Doha Declaration.[53] Paragraph 5(a) of the Doha Declaration provides, "In applying the customary rules of interpretation of public international law, each provision of TRIPS shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." The expression of "in particular, in its objectives and principles" explicitly indicates that a wider context of examination of the object and purpose of TRIPS should be applied, and these should include not only the Preamble of TRIPS but also Article 7 and Article 8 of TRIPS. The expression "in particular"[54] also requires that Articles 7 and 8 should be given more emphasis.[55]

### B. *Contextual Material – Article 31(2) of VCLT*

Article 31(1) provides the ordinary meaning rules applied in interpretation, but also requires consideration of the context and object and purpose of a treaty. Article 31(2) gives further elaboration of the relevance and permissible uses of contextual material, and it provides

> The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

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[51] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp*, WTO Doc WT/DS58/AB/R (12 October 1998) [116]–[117]; also see Lennard, above n. 22, 28.

[52] Lennard, above n. 22, 28.

[53] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 5(a).

[54] Ibid.

[55] Art 7 deals with the object and purpose of the TRIPS Agreement and art. 8 deals with the principles of the TRIPS Agreement. The principles have been introduced at Part One. Chapter 3.I.B.2.(c). These two articles will be discussed in detail in Part Two.Chapter 5.II.

(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;
(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

The Article 31(2) is a statutory clarification of the contextual materials for the interpretation of a treaty. It permits consideration of any agreement relating to the treaty in question that was made between all the parties in connection with the conclusion of the treaty. It equally recognises the relevance of, and permits consideration of, any instrument made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty as an aid to the interpretation of plain meaning. The passing of time and the conclusion of additional agreements between the parties might bring about a change in the relevant context of a treaty. Accordingly the Article provides for this circumstance by the use of the phrase "in connection with the conclusion of the treaty" to distinguish from "at the time of the conclusion of the treaty".[56]

## C. *Article 31(3) of VCLT and Its Application*

### 1. *Non-contextual Materials – Article 31(3)*

Article 31(3) requires consideration of other factors in addition to a contextual reading, and it provides

> There shall be taken into account, together with the context:
> (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
> (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
> (c) any relevant rules of international law applicable in the relations between the parties.

In order to facilitate the construction of a treaty in good faith by giving the ordinary and plain meaning of a term of a treaty, the VCLT allows for reference to factors extrinsic to the treaty itself. In this sub-paragraph, the VCLT offers the elaboration that any subsequent agreement, any subsequent practice and any relevant rules of international law applicable between the parties shall be taken into consideration, and all these can be used to provide assistance to the interpretation of a treaty.

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[56] Jennings & Watts (eds), above n. 2, 1273–4.

(a) *Subsequent Agreement – Article 31(3)(a)*

A Subsequent agreement between the parties regarding the interpretation of treaty or the application of its provisions can be considered in the process of interpretation. The International Law Commission commentary on this provision also stated that[57]

> an agreement as to the interpretation of a provision reached after the conclusion of the treaty represents an authentic interpretation by the parties which must be read into the treaty for purpose of its interpretation.

It is important to distinguish an agreement in relation to the interpretation of a provision of a treaty and agreement dealing with the same subject matter but not for the purpose of agreeing on an interpretation of the earlier treaty.

The Doha Declaration re-emphasised the interpretation of the original TRIPS Agreement in the light of its object and purpose and provided further elaboration of the context and relevance of the health issue to the interpretation of TRIPS provisions.[58] This declaration is a subsequent agreement reached among the members.[59] This means that it has authoritative relevance for an authentic interpretation of TRIPS text and related provisions.

(b) *Subsequent Practice – Article 31(3)(b)*

The term "subsequent practice" in paragraph 31(3)(b) of the VCLT refers to a specific form of subsequent practice common to all the parties to the treaty rather than to subsequent practices in general.[60] The International Law Commission regarded certain subsequent practice as constituting "an objective evidence of the understanding of the parties as to the meaning of the treaty".[61] The approach has also been characterised as a "striking innovation" by some.[62] The International Law Commission states[63]

> The [original text of Article 31(3)(b)] spoke of a practice which 'establishes the understanding of all the parties'. By omitting the word 'all', the Commission did not intend to change the rule. It considered that the phrase 'the understanding

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[57] International Law Commission, 'Commentary on the draft Vienna Convention' (1966) Vol II *Yearbook of the International Law Commission*, 221 ('*ILC Commentary*').

[58] See *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 5(a).

[59] See Part Two.Chapter 5.II.B discussion on the status of Doha Declaration.

[60] Sinclair, above n. 1, 138.

[61] International Law Commission, above n. 57, 221 para. 15.

[62] Francis G Jacobs, 'Varieties of Approach to Treaty Interpretation: With Special Reference to the Draft Convention on the Law of Treaties before the Vienna Diplomatic Conference' (1969) 18 *ICLQ* 318, 327–9.

[63] International Law Commission, above n. 57, 222 para. 15.

> of the parties' necessarily means the 'parties as a whole'. It omitted the word 'all' merely to avoid any possible misconception that every party must individually have engaged in the practice where it suffices that it should have accepted the practice.

This indicates that the intention or understanding of the parties instead of the specific engagement of every party is more important in the understanding of the subsequent practice. The common understanding by TRIPS members can constitute subsequent practice in the interpretation of the TRIPS provisions.

Panels and Appellate Body have applied the rule of Article 31(3)(b) in dispute settlement cases and it can be regarded as an accepted part of WTO jurisprudence. In *Japan – Alcoholic Beverages II*[64] the Appellate Body stated that subsequent practice within the meaning of Article 31(3)(b) could be established by a "concordant, common and consistent" sequence of acts or pronouncements sufficient to establish a discernible pattern. This was reaffirmed in the *US-Gambling* case as[65]

> …(i) there must be a common, consistent, discernible pattern of acts or pronouncements; *and* (ii) those acts or pronouncements must imply *agreement* on the interpretation of the relevant provision. (original emphasis)

This means that it is not necessary for every member of WTO to act or carry out a practice in the same way, but that consistent practice among some members is enough to establish a relevant subsequent practice for the purposes of the rule contained in the Article. In the *EC-Chicken Cuts*,[66] it was clearly explained by the Panel that subsequent practice is sufficiently established when the practice shows that parties have accepted the rules instead of specific engagements in a particular practice by all signatories. However,

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[64] Appellate Body Report, *Japan – Tax on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) (Japan – Alcoholic Beverages II) p. 13 (DSR 1996: I, 97 at 106). The Panel also notes that Ian Sinclair has stated that "[i]t should of course be stressed that paragraph 3(b) of Art 31 of the Convention does not cover subsequent practice in general, but only a specific form of subsequent practice – that is to say, concordant subsequent practice common to all the parties": Sir Ian Sinclair, above n. 1, 138. In addition, Anthony Aust has stated that "[h]owever precise a text appears to be, the way in which it is actually applied by the parties is usually a good indication of what they understand it to mean, provided the practice is consistent, and is common to, or accepted by all the parties": Anthony Aust, *Modern Treaty Law and Practice* (Cambridge University Press, 2000) 194.

[65] Appellate Body Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/AB/R (10 November 2004) [192].

[66] Panel Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WTO Doc WT/DS269/R (30 May 2005) [7.253].

in the *EC – Chicken Cuts*[67] the Appellate Body emphasised that the practice must be adopted by some instead of one or few parties' in order for the practice to recognised as sufficient to fall within the rule within WTO jurisprudence. It is noteworthy that "the purpose of treaty interpretation is to establish the *common* intention of the parties to the treaty".[68] The practice of only one party is of more limited value than the practice of all parties.[69]

A question arises where parties do not engage in a subsequent practice whether some inference can be drawn about their understanding or acceptance of the implications of that practice. In *EC – Chicken Cuts*[70] a Panel took the view that a lack of reaction to a particular practice and reaction of a party can be used to deduce that party's intention.[71] The Appellate Body took a different view. The Appellate Body affirmed the view adopted in *Japan – Alcoholic Beverages II*[72]

> *in Japan – Alcoholic Beverages II*, cautioned that relying on "subsequent practice" for purposes of interpretation must not lead to interference with the "exclusive authority" of the Ministerial Conference and the General Council to adopt interpretations of WTO agreements that are binding on all Members.[73]

This attitude shows that, when the inference from the practice diverges from the interpretation by the WTO Ministerial Conference or the General Council, the interpretation of the Ministerial Conference and the General Council of WTO prevails.

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[67] Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WTO Doc WT/DS269/AB/R and WT/DS286/AB/R (12 September 2005) [259].

[68] Appellate Body Report, *European Communities – Customs Classification of Certain Computer Equipment*, WTO Doc WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R (5 June 1998) [93].

[69] Ibid., [93].

[70] Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts,* WTO Doc WT/DS269/AB/R and WT/DS286/AB/R (12 September 2005) [272]–[273].

[71] Mustafa Yasseen states that: "…acceptance by a party may be 'deduced from that party's reaction or lack of reaction to the practice at issue'." Mustafa Yasseen, 'L'interprétation des Traités d'après la Convention de Vienne sur le Droit des Traités' in *Recueil des Cours de l'Académie de Droit International* (1974) Vol III page 49 para. 18. This has been accepted by the WTO DSB, see Panel Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WTO Doc WT/DS269/R (30 May 2005) [7.253].

[72] Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts,* WTO Doc WT/DS269/AB/R and WT/DS286/AB/R (12 September 2005) [273].

[73] The fact that such "exclusive authority" to adopt interpretations of the treaty "has been established so specifically in the *WTO Agreement*" was one of the reasons for the AB to conclude, in *Japan – Alcoholic Beverages II*, that "such authority does not exist by implication or by inadvertence elsewhere". Appellate Body Report, *Japan – Tax on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) p. 12.

Based on the above, an inference can be drawn that various countries' practices in providing compulsory licensing on pharmaceutical patents based on Article 31 of TRIPS may constitute a subsequent practice of the members in protecting the health rights of the members. This is arguable if this practice can be proved to be a "concordant, common and consistent" practice of WTO members. If this practice is not interfering with the "exclusive authority" of the Ministerial Conference and the General Council that interpretation can be adopted.[74]

(c) *Relevant Rules of International Law – Article 31(3)(c)*

Article 31(3)(c) deals with the doctrine in treaty interpretation with reference to other sources of international law, but this has long been marginalised and ignored.[75] Relevant rules of international law, according to Sir Robert Jennings and Sir Arthur Watts, not only include the rules of international law as the background necessary to view the treaty provisions, but also include rules indicating parties' intentions provided that these are not inconsistent with generally recognised principles of international law or with previous treaty obligations towards third states.[76] However, the relevant rules of international law, under certain circumstances, can become complex. On the one hand, lack of consideration of relevant rules of international law, may cause conflicts in the integration of the international law system. On the other hand, too liberal application of the relevant rules of international law will also endanger the applicable laws of WTO jurisprudence and result in unpredictability in the dispute settlement process.

(i) Scope

Article 31(3)(c) of VCLT raises several issues to be discussed. Firstly, there is a question of the scope of phrase "the relevant rules of international law." Which rules of international law should be considered and under what situations can such outside sources be referred to? In other words, the question can be whether the reference of "rules of international law" in this subparagraph can include all of the sources of international law, including the general principles of international law, customary international law, or other relevant conventional international law or not. If it is not permitted to refer to the entire corpus of sources of international laws which sources do fall within the ambit of the paragraph?

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[74] Detailed discussion, see Part Two.Chapter 5.II.B.

[75] Duncan French, 'Treaty Interpretation and the Incorporation of Extraneous Legal Rules' (2006) 55 *ICLQ* 281, 300.

[76] Jennings & Watts (eds), above n. 2, 1275.

Secondly it is unclear whether the wording "applicable in relations between the parties" refers to all parties to the treaty in question or just those parties in dispute.

According to Michael Lennard the relevant rules of international law should be very restrictively used in the interpretation of WTO laws. The author is of the view that the customary international law can be applied, and the general principles of public international law are usually referred in fields of evidence, procedure and jurisdiction.[77] However, McLachlan holds another view that customary international law and general principles of international law should be considered, especially in one of the following three situations[78]

> (a) The treaty rule is unclear and the ambiguity is resolved by reference to a developed body of international law (…);
> (b) The terms used in the treaty have a well-recognised meaning in customary international law, to which the parties can therefore be taken to have intended to refer.…
> (c) The terms of the treaty are by their nature open-textured and reference to other sources of international law will assist in giving content to the rule.…

This view is supported by the study by the International Law Commission (ILC) in its identification of the status of customary international law and general principle of international law. The ILC also identified the same three aspects as McLachlan.[79]

McLachlan is also of the view that reference to broader principles of customary international law can become necessary when the treaty to be interpreted belongs to a particular part of international law or when the international tribunal has to look beyond the particular sub-system to rules developed in another part of customary international law.[80]

Such an approach has important implications for the question of the relevance of the right to health in the interpretation in relevant provisions of TRIPS. The right to health is a rule in the human rights regime and it is a

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[77] Lennard, above n. 22, 42–4.

[78] McLachlan, above n. 3, 312. Also see French, above 75, 303–4; French is of the view that the art. 31(3)(c) may be referred to by tribunal in case of ambiguity in treaty rule, already existence of well-recognised meaning in customary international law and open-textured nature of treaty itself.

[79] The ILC focused on three situations, and they are: unclear and ambiguous treaty rule needs the reference to a developed body of international law, a well-recognised meaning in customary international law to refer to the terms to be interpreted and open-textured treaty with reference to other sources of international law.

[80] McLachlan, above n. 3, 312.

well-established rule of international law both as a treaty norm and as customary international law.[81] If, during the interpretation of TRIPS, a term relating to health requires interpretation and is ambiguous or is open-textured, the right to health may be resorted to clarify the meaning of the intended term.

(ii) Parties

The second issue is, whether in the context of conventional international law, it is necessary for all the parties to the treaty being interpreted to also be parties to the treaty which is to be relied upon as a source of international law for the purpose of interpretation.[82] In other words, if in the process of interpreting a provision of TRIPS which is related to health and it is proposed to have recourse to the concepts of the right to health found in the ICESCR, is it necessary for the member of TRIPS also be members of the ICESCR before this is permissible?

There are four possible solutions.[83]

The first is that "all parties of the treaty to be interpreted must also be parties to the treaty to be referred to". In other words that all members of TRIPS should be members of the ICESCR before it can be invoked as an interpretation aid. This may provide some clarity and certainty but is a very narrow approach.

The second possibility is that only the disputing parties need to be parties of the other treaty to be used as an interpretation source. This broadens the range of available treaties but risks potential inconsistency in interpretation decisions.

The third possibility is the treatment of the rule to be applied as a rule of customary international law. The right to health can also be applied as customary international law to any country no matter is a member of the ICESCR or not.

The fourth and final possibility is the establishment of "an intermediate test" which requires the identification of implicit acceptance or tolerance "by all parties to the treaty" being interpreted.

There is no decisive answer to this range of possibilities, and it will be the most defensible understanding by referring all parties to the principal treaty and by requiring all parties to the secondary treaty.[84]

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[81] See Part One.Chapter 2.I.A.3.

[82] McLachlan, above n. 3, 314.

[83] The four suggested solutions and their respective merits are discussed by McLachlan; ibid., 314–5.

[84] Ibid., 315.

Another view held by a commentator is that Article 31(3)(c) will only require applicability between the parties to a particular dispute.[85] The commentator points out that, viewing from pragmatic level and theoretical level together with the analysis on the provision Article 31(3)(c) itself and its negotiating history, the limiting applicability of the parties in the interpretation is not totally correct.[86] Furthermore, under certain circumstances, as pointed out by McLachlan, Article 31(3)(c) may not require such membership involved in a specific dispute if the terms involved are subject to a common understanding of the parties and enlightened by the object and purpose of the treaty to be interpreted.[87] This will be especially true when open-textured language is used to call for a programmatic interpretation.[88] In the recent *EU Biotech Products* case, while dealing with the issue on whether it requires all parties to be parties of a treaty referred to, the Panel is also of the view that "the mere fact that one or more disputing parties are not parties to a convention does not necessarily mean that a convention cannot shed light on the meaning and scope of a treaty term to be interpreted."[89]

Such an approach means that the norm of the right to health may be referred to in the interpretation of TRIPS and the treaty which establishes the right to health may be used to assist interpretation. This would be permissible when the object and purpose of TRIPS enlightens that the right to health is a common understanding of all the WTO members or some provisions of TRIPS in relation to the right to health are open-textured, even though not all members of the WTO belong to the same human rights treaty that contains the right to health.

(iii) Inter-temporality

In dealing with the Article 31(3)(c), there is also an important issue of inter-temporality. The second source being referred to may be subject to change with lapse of time. The concept of Inter-temporal law means that a treaty shall be interpreted in the light of the general rules of international law in force at the time of its conclusion. A treaty's terms are normally interpreted on the basis of their meaning at the time the treaty was concluded and in the light of circumstances then prevailing. There is always the possibility that a treaty will now conflict with some newly emerged rules of *jus cogens* although it was not in conflict with any rule of *jus cogens* when it was concluded.

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[85] French, above 75, 306–7.

[86] Ibid.

[87] McLachlan, above n. 3, 315.

[88] Ibid.

[89] Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* WTO Doc WT/DS291–3/R (29 September, 2006) [7.94].

A treaty should be interpreted in an evolutionary manner since it will not always stay static.[90] Under this circumstance, the law in force at the time of the conclusion of the treaty to be interpreted can become a starting point for such interpretation.

Paragraph 3(c) of Article 31 of the VCLT was originally designed to deal with the inter-temporality of interpretation. On the one hand, a treaty provision should be read not only in its own context, but in a wider context of general international law, whether conventional or customary; on the other hand, it should also be read in the light of the evolution and development of international law, which has become evidenced in deciding a meaning to be given to expressions incorporated in a treaty, especially if these expressions themselves denote relative or evolving notions such as "public policy" or "the protection of morals".[91] It is, therefore, important to interpret a treaty in a way that is consistent with the development of the relative wider context of international law. There are differing opinions about this evolutionary approach.

Pauwelyn finds that, basically, a treaty should be interpreted in light of the laws contemporary with it when the treaty was concluded, since Article 31(3)(c) originally referred to "rules of international law in force at the time of conclusion of the treaty" when it was drafted.[92] This kind of interpretation reflects the "contemporaneity" approach in interpretation. Nonetheless, in the same discussion Pauwelyn is also of the view that an "evolutionary" approach should also be adopted under certain situations in WTO laws based on the intentions of the parties. An example is the use of "broad and unspecified terms".[93] The author points out that such a treaty is of "living" or "continuing" character, and should be interpreted in an evolutionary manner. Under this approach, WTO law can be interpreted in an evolutionary manner instead of in a static manner.

The Panel in *EC-Chicken Cuts* used an evolutionary approach to interpret the WTO treaty by referring to HS since the GN and TBN, which were concluded in 1937 and 1959 respectively, are out of fashion.[94] It is the opinion of

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[90] Jennings & Watts (eds), above n. 2, 1281–2.

[91] Sinclair, above n. 1, 139.

[92] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 264–5.

[93] Ibid., 265.

[94] HS is *Harmonized Commodity Description and Coding System*, and it was concluded in 1983. HS is an internationally standardised system of names and numbers for classifying traded products developed and maintained by the WTO. GN is *Geneva Nomenclature*, and it was concluded in 1937. BTN is *Brussels Tariff Nomenclature*, and it was concluded in 1959. On 11 October 2002, Brazil requested consultations with the European Communities

the Panel that "the timing of their conclusion suggests to us that they might be of limited relevance for the headings contained in the HS given changes in trade patterns and technology since their conclusion".[95] However, it is important to remember that evolutionary interpretation is used to clarify the ordinary meaning of the words used in the treaty, and, if it does not achieve this goal and offer clarity, a meaning supplied by an evolutionary approach should not be adopted.[96]

These principles of inter-temporality in interpretation have implications for the interpretation of TRIPS in relation to the right to health. It not only means that it is possible to have reference to the sources of conventional international law, but that when the terms used in TRIPS provisions are evolving or are "broad and unspecified terms" they can be interpreted in an evolutionary manner.[97]

(d) *Application Relationship*

The application of the three non-contextual material for the purpose of interpretation, which are the subsequent agreement, subsequent practice and relevant rules of international law respectively, is not ranked in any particular order during the interpretation, and all the three additional factors form a mandatory part of the interpretation process.[98]

2. *Application of Article 31(3)(c) in WTO*

The application of Article 31(3)(c) by WTO is crucial to introduction of human rights norms into the interpretation of WTO laws. As discussed above, the relevant customary international law rules, general principles of international law and related conventional rules can also be applied in the

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concerning EC Commission Regulation No. 1223/2002 ("Regulation No. 1223/2002"), of 8 July 2002, which provides a new description of frozen boneless chicken cuts under the EC Combined Nomenclature ("CN") code 0207.14.10. According to Brazil, this new description includes a salt content to the product that did not exist before and subjects the imports of these products to a higher tariff than that applicable to salted meat (CN code 0210) in the EC's Schedules under the GATT 1994. Panel Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WTO Doc WT/DS269/R (30 May 2005) [7.197]–[7.205].

[95] Panel Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WTO Doc WT/DS269/R (30 May 2005) [7.198].

[96] Ibid., [7.205].

[97] For example, the TRIPS Agreement uses some terms such as "public order", "morality" and "public health" in art. 8, art. 27 etc. These terms can be broad and unspecified.

[98] McLachlan, above n. 3, 290.

interpretation of a treaty. These also find their expressions in the WTO dispute settlement cases.

A milestone in the application of the Article 31(3)(c) in WTO laws is the *Shrimp – Turtle* case. In that case, the Appellate Body had to determine the meaning of the terms "exhaustible" and "natural resources" contained in Article XX(g) of GATT.[99] The AB found that such open-textured terms were "by definition, evolutionary" instead of "static".[100] The Appellate Body referred to international environmental law texts contained in Article 56 of the United Nations Convention on Law of Sea (UNCLOS) to support a finding that "natural resources" could include both living and non-living resources.[101] This kind of reference is a direct reference to an outside WTO source for the interpretation of WTO laws. Similarly this kind of reference to non WTO sources can also be found in the *EC-Asbestos* Case,[102] in which the Convention Concerning Safety in the Use of Asbestos was referred to for the finding of health objectives.

Furthermore, the WTO Panel also referred to Article 31(3)(c) in the *EU Biotech Products* case[103]

> Article 31(3)(c) directly speaks to the issue of the relevance of other rules of international law to the interpretation of a treaty. In considering the provisions of Article 31(3)(c), we note, initially, that it refers to "rules of international law". Textually, this reference seems sufficiently broad to encompass all generally accepted sources of public international law, that is to say, (i) international conventions (treaties), (ii) international custom (customary international law), and (iii) the recognized general principles of law. In our view, there can be no doubt that treaties and customary rules of international law are "rules of international law" within the meaning of Article 31(3)(c).

With this clear statement by the Panel, Article 31(3)(c) has been applied by the WTO dispute settlement body to resort to other relevant resources outside WTO laws in a more clear-cut way.

Article 31(3)(c) is not the only basis for arguing that other relevant sources of international law can be applied to the WTO dispute settlement process.

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[99] Art XX(g) of GATT.

[100] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp*, WTO Doc WT/DS58/AB/R (12 October 1998) [130]; citing *Namibia (Legal Consequences) Advisory Opinion* (1971) ICJ Rep 31.

[101] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [130]–[134].

[102] Panel Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WTO Doc WT/DS135/R (12 March 2001) [8.210], [8.295], and [8.298].

[103] Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc WT/DS291–3/R (29 September, 2006) [7.67].

Some scholars argue that the text of the WTO itself implicitly permits reference to sources outside WTO laws in order to interpret WTO covered agreements. Palmeter and Marvroidis, by relying on Article 7 of DSU,[104] are of the view that customs, international agreements and general principles of law can be referred to resolve WTO disputes.[105] Schoenbaum, after an examination of Article 11 of the DSU,[106] argues that, through the grant of authority to the panels and the Appellate Body, the WTO implies that WTO jurists have power to decide all international legal issues involved in a dispute properly before them.[107] This has reinforced the application of extraneous WTO sources into the interpretation of WTO covered agreements, and underpins the possibility of the introduction of human rights norms during the interpretation of WTO laws.

### D. *Supplementary Means – Article 32 and Its Application*

#### 1. *Article 32*

In case the utilisation of the rules so far discussed still does not produce a reasonable result, the VCLT also provides supplementary rules for interpretation. Article 32 of VCLT provides

> Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31:
> (a) leaves the meaning ambiguous or obscure; or
> (b) leads to a result which is manifestly absurd or unreasonable.

Article 32 is often resorted to when a clear and reasonable meaning still cannot be established by applying the basic rule of interpretation laid down in Article 31. The supplementary means of interpretation, therefore, is not considered as a rigid and utterly unyielding hierarchical rule followed by the general rules of interpretation, but it should also be included by the would-be interpreter when such materials can be assistance to the meaning attributed

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[104] Art 7 of the DSU.

[105] David Palmeter & Petros C Mavroidis, 'The WTO Legal System: Sources of Law' (1998) 92 *Am J Int'l L* 398–9 and 413. The authors explained the role of ICJ Art 38(1) by comparing it to Articles 3(2) and 7 of the DSU.

[106] Art 11 of DSU.

[107] Thomas J Schoenbaum, 'WTO Dispute Settlement: Praise and Suggestions for Reform' (1998) 47 *Int'l & Comp L Q* 647, 653.

to the text. The relationship between the general rules of interpretation and supplementary rules of interpretation is very subtle.[108] This is because they play a systemic or constitutional function in describing the operation of the international legal order.[109]

2. *Application*

The recourse to the supplementary means of interpretation can be relevant to the interpretation of TRIPS when seeking to interpret concerns like public health implications or social or economic impacts. This is due to the fact that, the negotiating history of TRIPS shows that various members tried to "massage" the divergent interests into this multilateral agreement and the TRIPS itself also incorporated other treaties into itself. These factors may arise to the reference to the negotiating history of TRIPS or the incorporated agreement in order to confirm the meaning of treaty term to be interpreted.

The supplementary means to assist interpretation have been resorted to in WTO jurisprudence.[110] However, this technique of reference to supplementary means of interpretation is a second order approach to interpretation, and can only be used for the confirmation of the meaning based on the interpretation rules prescribed in Article 31 of VCLT.[111] In the *US-gambling* case,[112] the panel referred to the use of supplementary means, including the negotiating history of the treaty, to confirm the meanings applied under Article 31 of VCLT. In *US-Shrimp*, the negotiating history was referred to in order to confirm the interpretation of the Chapeau of Article XX of GATT.[113] In case that meaning of a relevant term of TRIPS itself found needs to be confirmed, the negotiation history of both TRIPS and the incorporated treaties should be able to be referred to.

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[108] Sinclair, above n. 1, 117.

[109] McLachlan, above n. 3, 313.

[110] For example, in case of *Canada-Certain Measures Concerning Periodicals,* the *travaux preparatories* were referred to by the AB. Also, in the *European Communities – Measures Affecting Importation of Certain Poultry Products*, the AB, pursuant to art. 32 of VCLT, referred to the circumstances of conclusion of the agreement to recognise the Oilseed Agreement as a supplementary means of interpretation of Schedule LXXX. See Appellate Body Report, *European Communities – Measures Affecting Importation of Certain Poultry Products*, WTO Doc WT/DS69/AB/R (13 July 1998) Section IV [83].

[111] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.48].

[112] Ibid., [6.47] and [6.48].

[113] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Product*, WTO Doc WT/DS58/AB/R (12 October 1998) Section VI [157].

### E. *Summary*

The above mentioned principles contained in the VCLT shows that the "textual" approach is fundamental in treaty interpretation, and the text serves as a basic lens to objectively discern the "intention" of negotiators.[114] This kind of approach has been considered to be the best balance between the requirement for providing stability and coherence to ensure international relations and the necessity and requirement for offering flexibility in adopting extrinsic materials in limited circumstances.[115] The arrangement of Article 31 also shows the requirement to ensure the primary role of "text" and to give regard to the context and object and purpose of a treaty intended to be interpreted.

The application of VCLT rules in general WTO jurisprudence, therefore, arguably shows that the application of VCLT has become a binding principle in the WTO dispute settlement system and should be employed by panels and the Appellate Body when reasoning to a decision in disputes before them. Where a dispute involves provisions of the TRIPS agreement, TRIPS, as one of WTO covered agreements, should also be interpreted in compliance with the principles laid down in the VCLT.

## II. Consistent Interpretation of TRIPS and WTO Laws

### A. *TRIPS and Other Covered Agreements*

Bringing intellectual property rights standards within the purview of the WTO and establishing harmonised minimum standards through TRIPS was intended to facilitate international trade for market access for the trade of products.[116] The TRIPS Agreement has no specific provision to provide itself with an internal mechanism for interpretation, so the interpretation of the Agreement will need to resort to the mechanisms found within WTO practice and jurisprudence. The WTO has provided guidance on the rules

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[114] Lennard, above n. 22, 21.

[115] Ibid., 22.

[116] See for example Thomas Cottier, 'The Agreement on Trade-related Aspects of Intellectual Property Rights' in Thomas Cottier, *Trade and Intellectual Property Protection in WTO Law: Collected Essays* (Cameron May, 2005) 117, 117. The author mentioned that the deficiencies in international IP system has resulted in the decision of the GATT Contracting Parties to vest regulatory leadership in the WTO, and it was initially was conceived as an agreement relating to border enforcement against counterfeiting and piracy, emerged in the Uruguay Round as the third pillar of the multilateral trading system.

principles and practices of interpretation and established a "coherent body" of procedural and substantive law,[117] although the decisions made by panels and AB are not binding on future panels and AB. This coherent body of law should mean that interpretation of covered agreements by panels and AB should be conducted in a consistent manner with the interpretation of specific part of the covered agreement conducted by taking the whole WTO system into consideration. It was noted by the Panel in *US-Combed Cotton Safeguards*,[118] where the Panel considered the Agreement on Textiles and Clothing (ATC) that a particular agreement under consideration is an integral part of the WTO system

> The treaty in question here is the WTO Agreement, of which the ATC is an integral part. Thus, it is the WTO Agreement in its entirety, including GATT Article III, that provides the context of Article 6 of ATC. As the International Law Commission explained in its commentary to the final set of draft Articles on the law of treaties, with regard to what became Article 31(1) of the Vienna Convention:…

It is evident that in WTO all of the covered agreements are integral parts, and the interpretation of any one of the agreements should be consistent with the interpretation of the other agreements. The TRIPS Agreement forms part of the WTO "coherent body" of law, and the interpretation of TRIPS should also be accomplished by considering the whole of the WTO laws.

1. *Historical Link*

Historically, TRIPS is related to GATT. Before the creation of TRIPS, some intellectual property issues had been under discussion and included within the covering of GATT. Some intellectual property issues were included into the GATT 1947. Intellectual property is mentioned in one form or another in a number of GATT Articles.[119] Another example is Article XX(d) of GATT which suggests adoption of enforcement measures for intellectual property protection to be allowable under the GATT framework.[120] In the 1989 case

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[117] Donald McRae, 'What Is the Future of WTO Dispute Settlement?' (2004) 7 *J Int'l Econ L* 3, 5.

[118] Panel Report, *United States – Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan*, WTO Doc WT/DS192/R (5 November 2001) [7.46].

[119] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell, 1998) 5–9.

[120] Art XX (d) of GATT 1947 allows some intellectual property protection exceptions, "including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Art II and Art XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices."

of *United States – Section 337 of the Tariff Act of 1930*,[121] the panel also made it clear that the substantive patent law of a contracting party could probably not be challenged under GATT in light of Article XX(d). Article XII(3)(c)(iii) and XVIII(10) are also said to apply to trademark situations where a trademark owner needs to use the mark for the maintenance of his or her right.[122]

This historical link shows that the establishment of TRIPS can give implications to GATT. GATT is an agreement that deals with the reduction of tariffs for the furtherance of liberalising trade. The evolution of TRIPS from some Articles in GATT implies the idea that TRIPS has a role in liberalising international trade. Especially, the change from "tolerable free riding" to reinforcing the intellectual property protection[123] reflects the idea that the liberalisation of trade needs to be accompanied with normal trade. This trade goal may be reflected in TRIPS. An interpretation of certain provisions of TRIPS, especially in finding the object and purpose of the Agreement, may need to take this link between GATT and TRIPS into consideration.

### 2. *Textual Link*

The WTO Agreements form an integrated system. The legal texts of WTO laws suggest that WTO laws are an integrated system and each part is to be read consistently with the other parts and the whole. The Preamble of the Marrakesh Agreement Establishing the World Trade Organization states that the parties to the Agreement "Resolved to develop an integrated, more viable and durable multilateral trading system encompassing the General Agreement on Tariffs and Trade, the results of past trade liberalization efforts, and all of the results of the Uruguay Round of Multilateral Trade Negotiations". Article II.2 of this Agreement also reiterates the integrated nature of the agreements and associated legal instruments included in Annexes 1, 2, and 3 and their binding force.[124] The integrated nature of all of the related agreements suggests an intention of the parties that there should be consistency in the observance and performance of the agreements as well as consistency in

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[121] GATT Panel Report, *United States – Section 337 of the Tariff Act of 1930*, L/6439–36S/345 (7 November 1989) [5.35].

[122] David Hartridge and Arvind Subramanian, 'Intellectual Property Rights: The Issue in GATT' (1989) 22 *Vanderbilt Journal of Transnational Law* 897, 901.

[123] Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet & Maxwell, 1996) 31–5; the author gave the history of GATT, WTO and TRIPS to show that IP protection is the topic initiated in the Tokyo Round talk.

[124] Art II.2 of the *Marrakesh Agreement*.

their interpretation. This element of consistency implies that because TRIPS is part of the result of the "Multilateral Trade Negotiation" the interpretation of TRIPS will need to consider the purposes of the trade negotiators within this framework.

The preamble to TRIPS makes reference to the relevance of GATT principles in its preamble,[125] it is arguably reasonable that the interpretation of TRIPS shall be in compliance with the GATT principles. A number of GATT principles are relevant to and can be applied to the field of intellectual property. An example is the national treatment principle contained in Article III of GATT[126] which traditionally applies to products instead of persons in GATT.[127] Any compulsory licensing scheme for pharmaceutical products will be subject to this principle, since the scheme will affect "internal sale, offering for sale, purchase, transportation, distribution or use of products".[128] The interpretation of the compulsory licensing flexibility contained in TRIPS, accordingly, will need to follow the logic link between GATT and TRIPS. In addition, TRIPS adopts similar language used in the other covered agreements of WTO, and understanding on these languages used in TRIPS needs to refer to the understanding under other covered agreements. An example is the use of the phrases "necessary to protect human, animal or plant life or health" in GATT and "necessary to protect public health and nutrition" in TRIPS, and this suggests that it will be relevant and possibly useful to consult the related language in the other covered agreements for interpretation of the meaning.[129] This manner of consultation has been affirmed in the *US-Gambling* case.[130] When the Panel found that it was necessary to investigate the meaning of the terms "public order" and "public policy" under GATS, the similar expressions contained in GATT were consulted.[131] The Panel noted

> Although these Appellate Body statements were made in the context of Article XX of the GATT 1994, it is our view that such statements are also valid with respect to the protection of public morals and public order under Article XVI of the GATS.

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[125] The preamble of TRIPS provides, "*Recognizing*, to this end, the need for new rules and disciplines concerning: (a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions."

[126] Art III.1 of GATT.

[127] Daniel Gervais, *The TRIPS Agreement-Drafting History and Analysis* (2nd ed., Sweet & Maxwell, 2003) 7.

[128] Ibid., 7.

[129] See art. XX (b) of GATT and art. 8.2 of TRIPS.

[130] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.460]–[6.461].

[131] Ibid., [6.461].

### B. *TRIPS and Incorporated Conventions*

One of the characteristics of TRIPS is the explicit incorporation of other conventions to establish some basic standards for intellectual property protection.[132] These conventions are under the administration of other organisations including the World Intellectual Property Organisation which is a specialised agency of the United Nations. Membership of the other treaties differs from the membership of TRIPS although there may be considerable overlap or commonality. The interpretation of TRIPS is, no doubt, subject to consideration of such incorporation according to the contextual and supplementary interpretation principles codified in VCLT.

The two major concerns for such interpretation are the scope of the incorporated conventions in the process of interpretation of TRIPS and the intertemporality issue concerning the incorporated conventions.[133]

The first question is what is the extent to which the incorporated conventions can be utilised in the interpretation of TRIPS itself. Can the negotiation history of the incorporated conventions be referred to while interpreting TRIPS? In the *Canada – Patent Protection of Pharmaceutical Products* case,[134] the relationship between TRIPS and Berne Convention became an important part of the interpretation exercise, since Article 30 of TRIPS originated from Article 9.2 of the Berne Convention, and the Panels referred to the Berne Convention as a kind of contextual interpretation of Article 30 of TRIPS. The Panel also opined that, as a context of TRIPS during the interpretation of the related provisions, the reference could go beyond the negotiating history of TRIPS to refer to that of the incorporated conventions as a result of the Article 32 of VCLT.[135] However, a commentator has also cautiously pointed out that this kind of reference may involve a leap to assume the attention of all the parties in the negotiating history behind the Paris and Berne Conventions, since the incorporation of such Conventions into TRIPS was done "without much attention on the details of their negotiating history" and it would result

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[132] Art 2 of TRIPS deals with the compliance with the articles 1 through 12 and art. 19 of the *Paris Convention* (1967) and the non derogation of existing obligations of the Members under the *Paris Convention*, the *Berne Convention*, the *Rome Convention* and the *Treaty on Intellectual Property in Respect of Integrated Circuits*.

[133] For a discussion of the two issues, see Frankel, above n. 4, 401–8.

[134] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.14]; in the Panel report, it noted that, "… Thus, as the Panel will have occasion to elaborate further below, Art 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (1971) (hereinafter referred to as the Berne Convention) is an important contextual element for the interpretation of Art 30 of TRIPS."

[135] Ibid., [7.15].

in putting more weight on the incorporated conventions instead of on TRIPS itself.[136] Nevertheless, the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits should constitute part of TRIPS for the purpose of interpretation.

Another question raised in the interpretation of TRIPS is the inter-temporality of the incorporated conventions. As the VCLT does provide a solution to this issue, the International Court of Justice permits this process by resorting to the intention of the parties of a treaty with an evolutionary approach to the nature or terms of a treaty.[137] Pauwelyn has argued that, "the incorporation of the WIPO treaties would only be dynamic if that were the intentions of the parties."[138] It would follow from this position that if TRIPS uses no international norms and no open-textured terms, the incorporated conventions could only be used to assist in the interpretation of TRIPS with their meanings limited to those understood or established at the time they were incorporated. The TRIPS Agreement, however, uses provisions which are not merely open-textured but open-ended,[139] and such open-textured or open-ended language used in the provisions reflects an intention of the parties to apply a dynamic interpretation to the treaties incorporated into it.[140] Therefore, if it is the intention of the parties, or an international term or open-textured language is used, a dynamic reference to the incorporated conventions can be used.

## III. Evolutionary Interpretation

The rule of evolution is an important doctrine of treaty interpretation in public international law and requires that a treaty shall be interpreted in the light of the general rules of international law in force at the time of its conclusion.[141] The VCLT does not directly provide a manner of evolutionary

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[136] Frankel, above n. 4, 404.

[137] McLachlan, above n. 3, 317–8; also see *Namibia (Legal Consequences) Advisory Opinion* (1971) ICJ Rep 31; *Aegean Sea Continental Shelf Case* (*Greece v Turkey*) (1978) ICJ Rep 3.

[138] Pauwelyn, above n. 92, 265; but see Frankel, above n. 4, 408; the author is of the view that international law is a developing rather than static phenomenon, and this approach cannot be used to legislate the missing parts of TRIPS outside of the negotiation process.

[139] The concept "open-textured" can not be confined to a definite meaning because it is applicable for different contexts and times, but "open-ended" can be understood as a term set within a broad area, but with no definite meaning determined for different situations.

[140] Frankel, above n. 4, 407–8.

[141] See Part Two.Chapter 4.I.C.1.(c).iii, it discussed the inter-temporality issue with preliminary discussion on the evolution manner of interpretation. This section will discuss in details why TRIPS can be interpreted in an evolutionary manner.

interpretation of treaties and Article 31(3)(c) of VCLT omits any key to the problem of inter-temporality.[142] However, the International Court of Justice accepted the evolutionary approach in its decisions in several cases provided that there are evolutionary terms or an evolutionary nature contained or shown in the treaty.[143] This intentional examination also finds favour among some scholars and commentators.[144]

There are three kinds of situations when it is permissible to interpret a treaty in an evolutionary manner. They are[145]

(i) when the terms used have or are acquiring an evolving meaning in general international law,
(ii) when language used in expressing the object and purpose of a treaty to show a recognition or intention for the treaty to be able to have a progressive development, and
(iii) when the description of obligations is expressed in broad terms.

Following such principles it is argued that the interpretation of TRIPS Agreement requires an evolutionary approach.

The TRIPS Agreement contains many terms which require evolutionary interpretation. Pauwelyn suggests that if a treaty uses broad or unspecified terms this is an indication that the parties intended them to be interpreted in an evolutionary manner.[146] The broad terms may play a decisive role in the interpretation of a treaty by considering their evolutionary notions. As Sinclair stated[147]

> there is some evidence that the evolution and development of international law may exercise a decisive influence on the meaning to be given to expressions incorporated in a treaty, particularly if these expressions themselves denote relative or evolving notions such as 'public policy' or 'the protection of morals'.

TRIPS, which involves a compromise of the interests of the developed and developing countries to ensure the protection of intellectual property rights

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[142] McLachlan, above n. 3, 316.

[143] See *Namibia (Legal Consequences) Advisory Opinion* (1971) ICJ Rep 31; *Aegean Sea Continental Shelf Case* (*Greece v Turkey*) (1978) ICJ Rep 3.

[144] See Rosalyn Higgins, 'Some Observations on the Inter-Temporal Rule in International Law' in Jerzey Makarcyk (ed), *Theory of International Law, Essays in Honour of K. Skubiszewski* (Kluwer, 1999) 173; cited in Pauwelyn, above n. 92, 267.

[145] McLachlan, above n. 3, 317–8; also see Pauwelyn, above n. 92, 265–8.

[146] Pauwelyn, above n. 92, 267; the author points out that the use of 'exhaustible natural resources', 'public morals' or 'essential security interests' in GATT Arts. XX and XXI is an indication that the drafters intended these terms to be interpreted in an 'evolutionary' manner.

[147] Sinclair, above n. 1, 139.

to promote social and technological development,[148] uses many open-textured terms to reach its goal. This open-textured nature of TRIPS indicates that TRIPS should be interpreted in an evolutionary manner. For example, Article 8 of TRIPS contains the expressions "public health" and "public interest in sectors of vital importance to their socio-economic and technological development", and inserting such expressions can be considered to indicate the intention of the parties of the Agreement to interpret these terms in an evolutionary way.[149] The expression of "national emergency" and "extreme urgency" and the expression of "in a manner conducive to social and economic welfare and to a balance of rights and obligations" in Article 31 are open-textured to invite an evolutionary manner of interpretation of TRIPS.[150] Even more, the provisions of TRIPS are not only open-textured but open-ended.[151] This kind of open-endedness, according to a commentator, calls for a dynamic process of interpretation of the Agreement since new subject can be introduced into the Agreement without further negotiation among the members of TRIPS.[152] Article 27 of TRIPS requires the provision of patent protection in all fields of technology without discrimination, and this kind of open-endedness indicates that an evolutionary interpretation of TRIPS is required in order to cope with the dynamic development of technology.

In addition, TRIPS is an Agreement intending to require harmonised minimum standards of intellectual property rights in order to reduce the barriers to legitimate trade, and it tries to meet the underlying public policy objectives of national systems in development and technology transfer for the protection of intellectual property rights.[153] It also needs to take the needs of the least-developed countries into consideration to ensure the maximum flexibility in implementation.[154] The establishment of intellectual

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[148] See the analysis in the object and purpose of TRIPS at Part Two.Chapter 5.II. Also see Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections' in Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights – Foundations and Conceptual Issues* (The University of Michigan Press, 2006) 145, 145. The author pointed out IPRs reflected a balancing of general public interests and private stakeholders interests, and thus IPRs take into account social welfare concerns as well as those of individual inventors and artists. TRIPS struck such a balance, and it is capable of flexible interpretation.

[149] Art 8.1 of TRIPS.

[150] For example, art. 31(b) provides: "…This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.…"

[151] Frankel, above n. 4, 408.

[152] Ibid.

[153] See paragraph 1 and 5 of the Preamble of TRIPS.

[154] See paragraph 6 of the Preamble of TRIPS.

property rights is based on a dynamic balance, and such a dynamic balance requires the implementation and achievement of intellectual property protection in a progressive manner responding to the pace of the development of technology. In this fashion, TRIPS reveals in its preamble an implied intention that the interpretation of the Agreement should be conducted in an evolutionary manner.

# Chapter 5

## Examination of TRIPS in Light of the Interpretive Analyses

### I. Coverage and Flexibilities Offered by TRIPS

The roadmap for the interpretation of TRIPS is given, so the examination of TRIPS needs to follow this roadmap.

The TRIPS Agreement contains a number of Articles which have and express aspects of an inherent balance mechanism underlying the whole Agreement. This balance mechanism which has potential impact on many questions pertaining to the Treaty may also be able to offer flexibilities in the interpretation of TRIPS as a whole and of those aspects of the Agreement pertaining to the field of patent protection.[1] Interpretation of some Articles which express aspects of this balance mechanism may reveal that human rights norms are relevant to the understanding of the balance mechanism. References to public health concerns in a number of Articles suggest that the human rights norm of the right to health may find its expression in the balance mechanism and be relevant to the process of interpretation of TRIPS.

The TRIPS Agreement commences with a Preamble and follows with the main body. Altogether TRIPS contains seven Parts. Part One of the main body of the Agreement sets out general provisions and basic principles. Article 1 refers to the nature and scope of obligations under the Agreement, Article 2 sets out the relevance of norms found in some other international conventions concerning intellectual property, Articles 3 and 4 incorporate the familiar non-discrimination principles of national treatment and most favoured nation treatment within the agreement, Article 5 refers to

[1] For a full range of flexibilities TRIPS offered, see Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections' in Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights – Foundations and Conceptual Issues* (The University of Michigan Press, 2006) 145, 151.

multilateral Agreements and Article 6 to exhaustion of rights. Article 7 and 8 however express the Objectives and Principles of the entire Agreement.

The first "flexibility" relevant to the right to health can be found in the Preamble and in Articles 7 and 8 of TRIPS.

The preamble sets a context and tone for TRIPS by addressing the desire for a reduction of distortions and impediments to international trade, recognition of the public policy objectives of national laws and the need to allow maximum flexibility for least developed countries.[2] The Preamble is an essential part of TRIPS, and it will be heavily relied on when unclear wording in TRIPS requires interpretation.[3] When compared with WIPO treaties, the Preamble shows that TRIPS has adopted a more economic and welfare-based approach, and such an approach may require a more balanced reading during interpretation.[4]

Article 7 deals with the objective of TRIPS, and it states that the protection and enforcement of intellectual property protection should contribute to the dissemination of technology in a way that promotes advantages to both users and producers in a context of social and economic welfare and a balance of rights and obligations. The value of intellectual property protection and enforcement is located within a general context of social welfare.

Article 8 expresses some broad principles to underpin TRIPS. Paragraph 1 explicitly refers to the relevance of issues of public health and nutrition and vital areas of socio-economic and technological development when members make laws for the implementation of the Agreement. Paragraph two refers to the possible need to make provisions that seek to prevent owners abusing intellectual property in ways that might adversely affect trade or the international transfer of technology. Paragraph 2 then touches upon the desirability of technology transfer which is generally regarded as advantageous in economic and ultimately social development.

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[2] See Preamble of TRIPS.

[3] See Daniel Gervais, *The TRIPS Agreement-Drafting History and Analysis* (2nd ed., Sweet & Maxwell, 2003) 76–82. Also see Katharina Gamharter, *Access to Affordable Medicines: Developing Responses under TRIPS and EC Law* (Springer, 2004) 68–70; the author is of the view that the Preamble of TRIPS provides a basis for the assessment of flexibilities and of the other provisions related to access to affordable medicines. But see Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.23]–[7.26]; Canada called attention to the text of the first recital in the Preamble to the TRIPS and to part of the text of art 1.1, and suggested the invocation of arts 7 and 8 of TRIPS. The Panel was of the view that "both the goals and the limitations stated in arts 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes". It indicates that the Panel did not rely on the Preamble but on arts 7 and 8 to find the meaning of Art 30 of TRIPS.

[4] Gervais, above n. 3, 76–82.

These two Articles were specifically referred to in the Doha negotiation when the TRIPS Council was sought to provide an explanation of how members could read and implement TRIPS when seeking to provide a proper and due balance.[5] Therefore, it seems that both the Preamble and the Articles 7 and 8 are of great importance to understanding TRIPS obligations and should be considered together for the identification of the object and purpose of TRIPS and for the interpretation of the TRIPS balance mechanism. Both Article 7 and Article 8 should enjoy higher legal status during the interpretation of TRIPS.

Part II of the Agreement sets out the minimum standards concerning the availability, scope and use of intellectual property rights to be implemented by members. This part contains Articles Article 27 to Article 34 which set standards for patent protection for inventions. The standards required by these Articles are highly relevant to the question of patentability of inventions concerning pharmaceutical products and processes. Patents concerning such inventions may indirectly relate to important issues relevant to the right to health. It can be seen that these Articles concerning obligations in relation to patents include a number of flexibilities.

Article 27.1 sets out a basic requirement that patents shall be available for products and processes in all fields of technology provided they meet three threshold characteristics of novelty inventiveness and industrial applicability. It is essentially a non-discrimination clause prohibiting members from denying patent protection to certain kinds of inventions. Nonetheless it has flexibilities in application of conditions of patentability and the permitting of differentiation. Article 27.2 permits members to legislate for exclusion of the patentability of inventions. It is expressed widely as a public interest provision. Inventions may be excluded from patentability where it is necessary to protect public order, morality, human, animal, plant life and health, and the environment. Article 27.3(a) permits exclusion for diagnostic, therapeutic and surgical methods. Article 27.3(b) provides in a relatively more specific way for the possibility of exclusion of patents for inventions which are for methods of medical treatment of humans or, animals or where the inventions are plants, animals and essentially biological processes, other than non-biological and microbiological processes. Article 30 provides exceptions to patent rights. Article 31 authorises in certain situations the grant

[5] Gervais, above n. 3, 115–20; Also *Doha WTO Ministerial Declaration*, WTO Doc WT/MIN(01)/DEC/1 (20 November, 2001) para. 19; Paragraph 19 of the Doha Ministerial Declaration provides, "In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of TRIPS and shall take fully into account the development dimension."

of compulsory licences which derogate from normal patent rights. All these flexibilities can be seen to relate to the right to health under a proper interpretation of TRIPS.

The other parts of TRIPS include: Part III which deals with the enforcement of intellectual property rights; Part IV which is related to the maintenance and acquisition of intellectual property rights; Part V which is related to dispute settlement; Part VI which deals with transitional arrangement; and Part VII which is about institutional arrangements. Some of these can also have interpretive value for the relation of TRIPS to the right to health.

This chapter will give a detailed analysis of the related provisions of TRIPS by applying the interpretation method and interpretive analysis introduced above to explore the extent to which the TRIPS regime recognises and relates to the right to health.[6]

## II. Object and Purpose of TRIPS

### A. *Ordinary Language Used in TRIPS*

Article 31(1) of the VCLT provides that the interpretation of TRIPS shall be conducted in the light of the object and purpose of the Agreement and such a way of reading the provisions of TRIPS has been affirmed by the Doha Declaration.[7] Following this approach, the Preamble, Article 7 and Article 8 of TRIPS should be given consideration during interpretation of the provisions of the Agreement. The object and purpose of TRIPS is, of course, not to be approached in isolation from the terms of the treaty but intrinsic to and dependent on the context to clarify the meaning of the text.[8] Therefore, bearing in mind that interpretation of the object and purpose of TRIPS is essential to assist the interpreter in the understanding of the treaty, it is necessary to have a full analysis on the object and purpose of TRIPS.

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[6] For example, see Amit Gupta, 'Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?' (2004) 2 *Buff Intell Prop L J* 127, 131–2; the author deems that many provisions in the TRIPS Agreement, especially the Preamble and Articles 1, 7, 8, 27, 30 and 31, can be interpreted to allow member countries flexibility in balancing right to patent protection and right to health.

[7] *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) ('*Doha Declaration*') para. 5(a).

[8] James Thuo Gathii, 'The Legal Status of The Doha Declaration on TRIPS and Public Health under The Vienna Convention on the Law of Treaties' (2002)15 *Harvard Journal of Law & Technology* 291, 305.

One commentator is also of the view that, in finding the object and purpose of a WTO agreement, the object and purpose should be examined by taking the treaty as a whole, and should not only involve the examination of any preamble but also involve other related provisions, such as those in DSU.[9]

1. *Preamble*

The Preamble of TRIPS provides an introductory statement of the purpose of the Agreement, and the first paragraph provides,

> *Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Textually in its ordinary meaning the first paragraph places the issue of the need to establish adequate protection for intellectual property rights within a desire to promote a more efficient and undistorted international trade regime.[10] This is an interesting and perhaps unexpected development because in the field of international trade negotiations since the genesis of the GATT and before the end of Tokyo round negotiations, the position had been adopted that the intellectual property system was an "acceptable obstacle" to free trade.[11] The intellectual property protection system was regarded as involving trade restrictions rather than useful mechanisms for trade promotion. Intellectual property protection was considered to contradict the notion contained in Article XX(d) of GATT, which permitted GATT contracting parties to justify trade restrictions imposed by intellectual property protections.[12] However the Preamble makes it clear that it is a specific goal of TRIPS to transform the "acceptable obstacle" from an impediment to trade to being a beneficial regime embedded and incorporated in the international trade system.

The second phrase of the paragraph requires adequate and effective protection of intellectual property, and as a scholar pointed out, this terminology while understandable at a general level creates difficulty in close interpretation since it will be difficult to equate the object and purpose of "effective

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[9] Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5 *J Int'l Econ L* 17, 27–8.

[10] Gamharter, above n. 3, 68; also see Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell, 1998) 37.

[11] See Gervais, above n. 3, 8; see also Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPS Agreement* (Routledge, 2002) 9.

[12] See Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (Oxford University Press, 2007) 2.

and adequate" intellectual property laws to "desiring to reduce distortion and impediments to international trade".[13] The author is of the view that standards for protection and enforcement of intellectual property rights that are overly strong would become a trade barrier in themselves and would distort international trade instead of promoting trade.[14] Therefore, the understanding of the third phrase of the first paragraph, which provides for a balancing effect between the protection of intellectual property and the liberalisation of trade, becomes important. This "mitigating effect" created by the third phrase, according to one commentator, shows that the trade goal in TRIPS should not take a predominant role.[15] This signals or reflects an objective that is different from that of GATT.[16] It can be inferred that it is possible that normal trade can also be achieved to a certain extent without strong intellectual property protection. This implies a perspective for the interpretation of TRIPS in which the trade goal does not need to take a predominant position in the interpretation of the provisions. Other concerns can and should also be taken into consideration.

The establishment of intellectual property system is based on a fine balance struck between public and private interests, including the balance between the protection of public goods and private interest. This justification which had generally been applied in relation to domestic intellectual property policy can be used to justify the setting of standards of intellectual property protection in the international context.[17]

In the case of *Canada-Patent Protection of Pharmaceutical Products*, the panel also introduced the notion of public policy by observing that[18]

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[13] Susy Frankel, 'The WTO's Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property' (2005) 46 *Va J Int'l L* 365, 390.

[14] Ibid.; also see Gamharter, above n. 3, 68; also see Gervais, above n. 10, 37; these authors are of the view that the first paragraph also indicates that excessive protection may equally constitute barriers to legitimate trade. Some also argue that TRIPS negotiations was not about free trading but about changing domestic regulatory and legal regimes, and TRIPS should not be placed in the multilateral trade system; For this view, see Correa, above n. 12, 3; and the author cited J. Bhagwat and A. Panagariya, 'Bilateral Tgrade Treaties Are a Sham' (13 July 2003, Financial Times) available at: <http://www.cfr.org/publication/6118/bilateral_trade_treaties_are_a_sham.html>.

[15] Frankel, above n. 13, 390.

[16] Ibid. In fact, the TRIPS Agreement is sometimes used to be other tool to make it shift in terms of economic consideration and is considered as an exchange in order to obtain better market access in other sectors.

[17] See Frankel, above n. 13, 390; the author is of the view that the TRIPS should not be construed as having abandoned more traditional justifications for intellectual property law, because the treaty reflects the need to balance the rights of both creators and users of intellectual property across international borders.

[18] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.69].

> It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a "legitimate interest" in using the patent disclosure to support the advance of science and technology.

However, the public policy considerations at the domestic regime level will vary according to the practical situation of different countries. Therefore, paragraph 5 of the preamble provides:

> *Recognizing* the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

The TRIPS strategy is to recognise the national systems and seek to move toward multilateral international trade objectives through mechanisms to harmonise aspects of the previously different national systems to some common minimum standards. At a domestic level a system of intellectual property rights that grants exclusive rights to owners and so excludes unauthorised parties may appear to be restricting competition from rivals, but at the international level TRIPS is generally regarded as pro-competitive through a systemic promotion of competition within a globalised intellectual property protection system.[19] While the international perspective may suggest a pro-competitive role for intellectual property protection the system is still based upon the grant and enforcement of exclusive rights that starts from an exclusion of free riders, and it is a matter for domestic government policy to determine the local balance between protecting private rights and public interest exceptions. However, the introduction of a public goods perspective into the perception of intellectual property protection still requires a non-rivalry in consumption and non-excludability in use to let the free riders to use the intellectual property rights, and this leaves the domestic government to decide on the provision of the "optimal levels of various goods, desired goods and the best jurisdictional level".[20]

The public goods dimension has also been taken into account and is reflected in the treaty language of "developmental and technological objectives". This

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[19] Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, 'Two Achievements of Uruguay Round: Putting TRIPS and Dispute Settlement Together' (1997) 37 *Va J Int'l L* 275, 280.

[20] Keith E. Maskus & Jerome H. Reichman, 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005) 393, 3, 8–9.

means that, during interpretation of TRIPS, the trade goal can be ameliorated or complemented by a balance between the desire to promote both public goods and private interests.[21] Dreyfuss and Lowenfeld have argued that provided that national intellectual property laws are in compliance with the minimum standards set in TRIPS, deference to national policies should be given.[22] In such an approach due consideration should be given to national interest and the choices in implementation in domestic policies.[23] The right to health, as a social and economic concern, encompasses concerns about the prevention of epidemic diseases and serves as a vehicle to inform the public interest when the public health issue is taken into consideration.[24] When issues of public health are matters of concern to the national interest, domestic national policies should be given effect to during the interpretation of TRIPS in light of the object and purpose of the Agreement. The Doha Declaration further clarifies this by emphasising each member's right to take steps to respond to its own perceptions of the right to health through recognition of what circumstances constitute a national health or other extreme emergency, to formulate its laws making fullest use of the flexibilities found in Articles 7 and 8, to grant compulsory licences and determine the grounds for such licences.[25]

### 2. *Articles 7 and 8*

The Articles entitled "objectives" and "principles" of TRIPS shed more light on the interpretation of TRIPS.

Article 7 – is entitled Objectives and provides:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users

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[21] But see Correa, above n. 12, 12–3. The author is of the view that the recognition is made in a somewhat restrictive manner, as the stated 'underlying public policy objectives' can be read to relate only to 'the national systems for the protection of intellectual property' and not to more general national policies. The author argues that this paragraph could be of little value for those seeking an interpretation of the provision of the TRIPS Agreement favourable to balancing its protectionist goals against the pro-competitive goals of GATT and to consider the critical role of public goods in the so called 'information economy'. The author opines that the Preamble does not contain any reference to issues of particular concern to developing countries, such as the transfer of technology.

[22] See Dreyfuss & Lowenfeld, above n. 19, 304–7.

[23] See Frankel, above n. 13, 375.

[24] See Part One.Chapter 2.I.C, for the discussion on the right to health and public health.

[25] See *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) paras. 5(b) and 5(c).

> of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 is entitled Principles and provides:

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The open-textured language used in these Articles and the lack of guidance on the balance of the competing objectives may appear to suggest that it is difficult to use them to interpret the Agreement.[26] However the very lack of a limiting specificity and precision may make them very useful to those arguing for a more expansive and dynamic interpretation. These two Articles could enjoy higher legal status in the interpretation of TRIPS because they have been specifically referred to in the Doha Ministerial Declaration as relevant to interpretation of aspects of the Agreement,[27] and they have also been highlighted by the Declaration on TRIPS and Public Health.[28]

In the case of *Canada-Patent Protection of Pharmaceutical Products*,[29] the panel emphasised the object and purpose to be found in Article 7 and Article 8 during the interpretation as:

> …The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of TRIPS which indicate its object and purposes.

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[26] See Frankel, above n. 13, 392.

[27] Gervais, above n. 3, 120 and 122; also see *Doha WTO Ministerial Declaration*, WTO Doc WT/MIN(01)/DEC/1 (20 November, 2001) para. 19. It provides, "In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of TRIPS and shall take fully into account the development dimension."

[28] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 5(a). It provides, "In applying the customary rules of interpretation of public international law, each provision of TRIPS shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." It seems that the objectives and principles of TRIPS have been given emphasis.

[29] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000).

Article 7 tries to strike a balance between the interests of right holders and the interests of users, based on an equilibrium between rewarding creators and inventors for innovation and promoting the interests of business and public at large in securing access to science, technology and culture.[30] This is especially important in the pharmaceutical area, since the risk of failure in creation is quite high, or to put it another way the chances of successful outcomes from expensive research programs are quite low. It is claimed that in this high risk industry the patent system has a strong incentive effect in encouraging investment that otherwise would not be made[31] and a total exclusion of patentability of pharmaceutical inventions could lead to delays or reductions in research and development efforts by private industry.[32] This provision was originally proposed by developing countries, and it may be used frequently in dispute settlement procedures to limit an obligation to protect or enforce a given intellectual property right in order to protect some arguably wider public goods interest.[33] The reference of social and economic welfare can also be used to justify the exceptions to exclusive rights when the right holder fails to participate in those activities which are expected to contribute to social and economic development.[34] This suggests that pharmaceutical products and process can be patented but certain exceptions are allowed in order to achieve or facilitate behaviour thought conducive to promotion of social and economic welfare. The interpretation primarily guided by the plain language meaning of the provisions should take into account considerations of the intended promotion of social and economic goals.

The difficulty in interpreting this open-textured sentence is that it is hard for panels and ABs to find the point of "promotion of technological innovation and to the transfer and dissemination of technology".[35] According to a commentator assessment of the appropriate point is a policy choice to be made by the national domestic law and policy mechanism provided of course that the member country is TRIPS compliant.[36] The right to health implies a legal obligation on states to promote the social and economic welfare of the society, and a state is obliged to respect, protect and fulfil it through its

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[30] Gervais, above n. 3, 116–20; as discussed in the Part One, the justification of intellectual property protection can be the disclosure for rewarding and a balance needs to be struck at the national level.

[31] For example see Harvey E. Bale, 'Pharmaceutical Access and Innovation: Challenges and Issues' (1999) *Vol. 42 Number 4 Development* (Palgrave Macmillan) 84–6.

[32] Gervais, above n. 3, 119.

[33] Ibid., 116.

[34] Ibid.

[35] See Frankel, above n. 13, 392.

[36] Ibid.

own legislation arrangement.[37] Since various states may adopt various health policies and design domestic laws to promote these general welfare goals, the interpretation of the point in relation to the dissemination of patented pharmaceutical technology and the protection of innovation can depend upon specific states' own domestic arrangements, only if their patent protection can meet the requirements under TRIPS. At the same time, because protection of the right to health is intended to promote general economic and social welfare, this may require that the interpretation of certain exceptions available within TRIPS should be read to take the requirements of the right to health into consideration in certain situations. Taking the policy that there should be the deference to national health policies and law arrangements the carve-outs specifically provided for in TRIPS and reading them together in the light of the object and purpose of general welfare promotion contained in Article 7, it is possible to envisage an interpretation of TRIPS that has taken the right to health into consideration.

Article 8 deals with specific actions that members can take, such as protecting public health or adopting measures against abuse of intellectual property rights, which is an amplification of the objectives of TRIPS enunciated in the Preamble.[38] Article 8(1) mandates that the formulation or amendment of laws and regulations and adoption of measures should be "consistent with the provisions of this Agreement". Such expression suggests that Article 8(1) is not subordinate to other provisions of TRIPS[39] and Article 8 has constituted a policy statement to explain the rationale for measures taken under Articles 30, 31 and 40.[40]

It seems that both the Preamble and the Articles 7 and 8 are of great importance to understanding TRIPS obligations and should be considered together for the identification of the object and purpose of TRIPS and for the interpretation of the TRIPS balance mechanism. According to a commentator, the objectives and principles of TRIPS can be used as "guiding light" for the interpretation of TRIPS to ensure "a compromise struck between the developed and the less-developed countries"[41] as well as a "shield" to ensure the members' use of flexibility in TRIPS.[42]

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[37] See Part One.Chapter 2.I.B.3.

[38] Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet & Maxwell, 1996) 43.

[39] Daya Shanker, 'The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration on TRIPS' (2002) 36 *Journal of World Trade* 721, 741.

[40] Gervais, above n. 10, 68–9.

[41] Peter K. Yu, 'The Objectives and Principles of TRIPS' (2009) 46 *Houston Law Review* 979, 1020–25.

[42] Ibid., 1025–31.

### 3. *Summary*

The reading of the Preamble and Articles 7 and 8 of TRIPS shows the object and purpose of TRIPS as protection on intellectual property rights and promotion for free trade. This dual objective distinguishes TRIPS from that of the other pillar of WTO, the GATT, which is free trade promotion oriented. A proper balance needs to be achieved through the protection of intellectual property and free trade through the implementation of TRIPS. In addition, TRIPS tries to achieve social and economic goals to balance the public and private interest, including specific social and economic goals of protection of health and nutrition. The main problem is that the minimum-standard protection on intellectual property reinforces pharmaceutical patent protection for pharmaceutical product and process inventions. Stronger patent protection standards vigorously enforced may have an adverse impact on affordability and access to medicines. The situation made more problematic because there is a lack of guidance on implementation of the balance between the public and private interests to achieve social and economic goals. This situation leads to diversifying interpretations of TRIPS among members and discourages members' utilisation of the principles of TRIPS.

## B. *Subsequent Agreement and Practice*

The understanding on a balance between the public and private interests contained in the object and purpose of TRIPS, especially the specific social and economic interest on health, can also be enlightened by the subsequent development of TRIPS. The contextual interpretation permitted by the VCLT sheds light on the interpretation to clarify the object and purpose of TRIPS.

### 1. *Doha Declaration*

With the lapse of the general transitional period for developing countries and changing situations, cases involving the TRIPS obligations of South Africa and Brazil emerged as a kind of trigger for some clarification of TRIPS.[43] The 4th WTO Ministerial Conference was held at Doha in November 2001 to focus on access to patented medicines in developing and least-developed countries. On 14 November 2001, the Doha Ministerial meeting had the Declaration on TRIPS Agreement and Public Health (Doha Declaration).

[43] Gathii, above n. 8, 294–7.

The Doha Declaration is titled as "Declaration on TRIPS and Public Health", and this title amplified the scope of health consideration. It is significant that the title was not confined by specific reference to medicines or pharmaceutical products or processes but referred to public health. The concept of public health encompasses a far wider range of conditions and issues.[44]

The whole Declaration comprises 7 paragraphs. Paragraphs 1 to 3 outlines the problems to be addressed and also acknowledges the incentive function of intellectual property rights for the development of new drugs and the issue of price concerns due to intellectual property protection.[45]

Paragraph 4 states that the interpretation and implementation of TRIPS should be "in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all".[46] This paragraph is a very controversial part of the Declaration. One consideration is that a formal interpretation of TRIPS depends on the a formal "recommendation" by the TRIPS Council according to Article IX(2) of WTO Agreement.[47] However the apparent strictness of this rule may be ameliorated by the use of the term "we agree" to begin paragraph 4. This expression shows that the Declaration is made in the form of an agreement and the function of the Declaration has already suggested its interpretive status. Furthermore the factual result achieved by the Declaration also manifests its approximate interpretation status.[48] This paragraph, therefore, has clarified the intentions of members of TRIPS to implement TRIPS in a manner supportive to public health.

Paragraph 5 of the Declaration recognises the various flexibilities offered by TRIPS, including an interpretation of TRIPS in light of its object and purpose by applying customary rules of interpretation of public international law and a clarification of compulsory licensing and exhaustion of rights.[49]

Paragraph 6 emphasises the serious situation of the members without sufficient manufacturing capacities and urges the TRIPS Council to find the solutions to this problem.[50]

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[44] See Frederick M. Abbott, 'The Doha Declaration on TRIPS and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469, 490; See also Gamharter, above n. 3, 133.

[45] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) paras. 1–3.

[46] Ibid., para. 4.

[47] Art IX(2) of the *Marrakesh Agreement* requires that the Ministerial Conference and the General Council, in an interpretation of a Multilateral Trade Agreement in Annex 1, shall exercise their authority based on a recommendation by the Council overseeing the functioning of that Agreement.

[48] Abbott, above n. 44, 491.

[49] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 5.

[50] Ibid., para. 6.

Paragraph 7 addresses the issues of extending transitional periods by addressing another concern of developed countries' providing incentives to their enterprises and institutions to promote and encourage transfer of technology at first.[51]

In summary, the Doha Declaration has in fact functioned as an interpretation of TRIPS by the Ministerial Conference and the recommendation for such an interpretation is approximately a formal "recommendation" by the TRIPS Council, examined with the draft text of the negotiation basis of the Doha Declaration.[52]

In addition, the Doha Declaration should constitute evidence of subsequent practices for the purpose of the interpretation of TRIPS.[53] Sir Gerald Fitzmaurice has argued that actual conduct among the treaty parties in relation to a treaty can provide legitimate evidence as to its correct interpretation and usually form a more reliable guide to intention and purpose than anything to be found in the preparatory work for instance.[54] Gathii argued that the different flexibilities allowed by the Doha Declaration and used by many WTO members was a manifestation of such subsequent practice, and decisions and policies adopted by WTO members also constituted subsequent practice.[55] Many state practices and following agreements have arguably become evidence for the interpretation of Doha Declaration compliance conduct.

The most noticeable cases are the Brazil case and the South African case. In the Brazil patent protection case, the United States raised a complaint against Brazil for the Government's decision to grant compulsory licences against the US patentees for failure to work patents granted in Brazil.[56] The case ended with a withdrawal by the United States filed under the WTO's Dispute Settlement Understanding against Brazil in 2000 and a mutually agreed solution was reached in 2001.[57] The South African case saw a similar result. South African parliament threatened to pass laws concerning pharmaceuticals and generics that affect US pharmaceutical interests in South

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[51] Ibid., para. 7.

[52] Gamharter, above n. 3, 137; but see Gathii, above n. 8, 314–5, the author argued that the Doha Declaration could constitute soft law with substantial hortatory authority, even if the Doha Declaration is not legally binding.

[53] For the discussion on the subsequent practice, see Part Two.Chapter 4.I.C.1.(b).

[54] Sir Gerald Fitzmaurice, *The Law and Procedure of the International Court of Justice* (Grotius Publications, 1986) 357.

[55] Gathii, above n. 8, 311–2.

[56] *Brazil – Measures Affecting Patent Protection*, WTO Doc WT/DS199/1 (30 May 2000) (Request for consultation by the United States).

[57] *Brazil – Measures Affecting Patent Protection*, WTO Doc WT/DS199/4 (19 July 2001) (WTO Notification of Mutually Agreed Solution).

Africa, and then it was charged by thirty-nine pharmaceutical companies to challenge the law as being inconsistent with South Africa's obligations under TRIPS. Consequently, the United States eventually withdrew South Africa from the watch list, but noted that the withdrawal was not recognition of the legitimacy of the South African approach to compulsory licensing.[58]

### 2. *The 2003 Decision*

On 30 August 2003, the General Council, in a Decision of the General Council, made "the Implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health" (2003 Decision) to clarify aspects of the Doha declaration on Public Health particularly the recognition of the "eligible importing members" and "eligible exporting members" and to clarify the measures to prevent the diversions of medicines.[59] In the Preamble of the 2003 Decision, it was pointed out that this Decision is based on paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization,[60] and it functions in accordance with paragraph 2 of Article IV of the WTO Agreement, which should be regarded as the conduct of the Ministerial Conference.[61] This Decision should be understood as a document granting a legitimate waiver of rights and obligations under TRIPS. Paragraph 11 of the 2003 Decision further provides,[62]

> This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

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[58] For the South African Case news report, 'WTO mulls drug patent issues' (June 21, 2001) available at: <http://edition.cnn.com/BUSINESS/programs/yourbusiness/stories2001/wto.drugs/>.

[59] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr.1 (1 September 2003).

[60] Paragraph 1, 3 and 4 of Art IX of the *Marrakesh Agreement Establishing the World Trade Organization* provides with the function of the General Council to make Decisions in terms of waiver of obligations. *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) ('*Marrakesh Agreement*').

[61] Art 4.2 of *Marrakesh Agreement* provides that, "…In the intervals between meetings of the Ministerial Conference, its function shall be conducted by the General Council…"

[62] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 11.

This indicates that the waiver will be permanent unless an amendment is made to replace the related provisions. This will have several interpreting values. The first is that any interpretation needs to take the waiver of the rights and obligations into consideration. The second is that the waiver can be effective until a formal amendment is made.

This decision can further illuminate the members' intention concerning the promotion of social and economic welfare, and the promotion of the protection on health. The Preamble of the 2003 Decision states that[63]

> Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002.

This shows that this 2003 Decision is dedicated to paragraph 6 of Doha Declaration, and it should be regarded as a continuation of the Doha Declaration. In addition, in the Preamble, it also states that[64]

> Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products.

This further shows that this Decision is targeted to deal with Article 31(f) and (h) in the pharmaceutical products sector. Based on these statements, it can be found that the object and purpose of TRIPS contains a public health supportive goal, which is one of the public interest concerns.

### 3. *2005 Decision – Proposed Amendment of Article 31bis*

On 6 December 2005, during the Hong Kong Ministerial meeting, the Council for the TRIPS Agreement submitted a proposal for an amendment to the TRIPS Agreement.[65] This proposed amendment proposal was a further clarification entitled "Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of

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[63] Ibid., Preamble.

[64] Ibid., para. 6.

[65] See *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of the Paragraph 6 of the Doha Declaration on TRIPS and Public Health: Proposal for a Decision on an Amendment to TRIPS*, WTO Doc IP/C/41 (6 December 2005) ('*Implementation of Paragraph 11 of the 2003 Decision*').

the Doha Declaration on TRIPS and Public Health". This proposal consisted of three parts: Amendment of TRIPS, Attachment, Annex to the Protocol Amending TRIPS, Annex to TRIPS. The General Council has made the Decision on the Amendment of TRIPS (2005 Decision) to amend TRIPS, and Article 31*bis* has been added as a proposed amendment.[66] This proposal is open for acceptance by members until 1 December 2007, and has been extended to 31 December 2009[67] for the first time and to 31 December 2011[68] for the second time.

This is a Decision made by the General Council based on the proposal made by the Council for TRIPS,[69] and it has adopted all the paragraphs contained in the 2003 Decision, except for the express reference to the waiver of rights and obligations contained in Article 31(f) and (h) in regards to the pharmaceutical products sector of the Preamble of the 2003 Decision. It forms a formal amendment proposal. This proposal further shows the intention of the members to protect health rights of people. It helps to clarify the intent of the members to address certain significant difficulties posed by the effect of the exclusive right of patent owners to control export and import of their patented invention which had consequent impact upon access to medicines. The decision shows an intention to allow the export of the pharmaceuticals to the countries without sufficient manufacturing capacity to address the problem by the grant of compulsory licences to manufacturers within their own jurisdictions. The 2005 Hong Kong Ministerial Declaration reaffirmed the importance of the 2003 Decision and the 2005 Decision. This is a further indication that the object and purpose of TRIPS includes an intention to support the right to health.[70]

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[66] See *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641(8 December 2005).

[67] See *Amendment of the TRIPS Agreement – Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WTO Doc WT/L/711 (21 December 2007).

[68] See *Amendment of the TRIPS Agreement – Second Extensions of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WTO WT/L/785 (17 December 2009).

[69] Art 10.1 of *Marrakesh Agreement* provides with the procedure for submission of amendment proposal.

[70] See *Hong Kong WTO Ministerial Declaration*, WTO Doc WT/MIN(05)/DEC (22 December 2005) para. 40.

## III. Interpreting Specific Provisions

### A. *Article 27 – Non-discrimination and Exclusion of Protection*

Article 27 deals with the patentability of subject matter, and the definition and application of patenting requirements is of crucial importance. An overly broad patent regime with wide patentability criteria for innovations could lead to distortions in competition that would have a potential to inflate drug prices and so have a negative impact on access to medicines.[71]

Paragraph one of Article 27 provides as

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [Footnote omitted] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

#### 1. *Patentability*

The first paragraph prescribes the eligibility requirements for an invention to be patented although it is limited by the exclusions laid down in paragraphs 2 and 3. The most important significance of this paragraph lies in the fact that it is the first time that a general principle of the eligibility threshold requirements for patentability has been established.[72] According to this principle, any exclusion from patentability is regarded as an exception, and it means that a restrictive manner of interpretation should be adopted in interpreting the languages contained in the first paragraph.[73] This requires that patent protection is to be available for any inventions whether product invention or process invention in any field of technology provided that they meet the criteria of patentability. Establishing this wide principle is regarded by industrialised developed members as fulfilling a major expectation of the harmonisation agenda while from the perspective of developing countries it can be seen as possibly the greatest concession made by developing countries during negotiations.[74]

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[71] Carlos M. Correa, 'Integrating Public Health Concerns into Patent Legislation in Developing Countries' (South Centre, Geneva, 2002) 37, available at: <http://www.southcentre.org/index.php?option=com_content&task=view&id=69&Itemid=67>.

[72] Gervais, above n. 3, 220; also Gamharter, above n. 3, 21.

[73] Gervais, above n. 3, 220.

[74] Gamharter, above n. 3, 21.

(a) *Three Criteria*

The first threshold requirement of patentability is that an invention is "new" or "novel". This generally means that the invention must not be publicly described or disclosed before the filing of the patent application. The TRIPS does not provide a definition of the term "novelty" and in practice the definition differs among states".[75] The Paris Convention also does not offer a definition of "novelty".[76] The term has not acquired a generally accepted meaning in the international law. This lack of definition means that the concept of novelty provides one of the "flexibilities" of the Agreement and that member states may choose how to set the novelty criteria within their own jurisdiction.

The second requirement of patentability is that the invention must include an "inventive step", and this is further explained with a footnote that this term contemplates the same concept as "non-obviousness". The further explanation of the footnote of this Article is to accommodate the various concepts of "inventive step" used by different legal systems.[77] It aims at restricting the strong protection granted by a patent to inventions which constitute a veritable advance in the art and to keep trivial developments in the public domain.[78] TRIPS does not provide a specific definition of what constitutes an "inventive step" or the tests that should be used to determine if the criteria are met and as with the term novelty this concept is open for interpretation. In practice different states have different variations, concepts and tests for the inventive step requirement. In the chemical and pharmaceutical field, there is often close structural relationship between a compound which is claimed to be new and inventive, and known compounds, such as salts of acids, bases, isomers, and homologues.[79] Although there is strong structural relationship between the two, former chemicals and pharmaceuticals invention can still be subject to patent protection for their new and inventive step.

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[75] For example, the United States, disclosure that has taken place outside the United States is only destructive of novelty when made in a written form, and this may permit the patenting in that country of knowledge, including knowledge of indigenous communities that has been used perhaps for centuries but not published in written form outside United States; see Correa, above n. 71, 41; The *European Patent Convention* refers to a "state of art" requirement, and "state of art" comprises everything made available to the public by means of a written or oral description, by use or in any other way, before the date of filing or the priority date of the European patent application, whichever is the earliest; see Gamharter, above n. 3, 23.

[76] Art 2 of TRIPS provides with the compliance with existing obligations under the Paris Convention.

[77] Gamharter, above n. 3, 24.

[78] Ibid.

[79] Correa, above n. 71, 46.

Another requirement is that the invention must be capable of "industrial application", and, according to the footnote, "useful" carries the same meaning in this context. The concepts of "industrial applicability" and "useful" can differ greatly in practice in various legal systems,[80] and TRIPS tries to accommodate the various approaches to harmonise them in one agreement. In terms of the requirement for the industrial applicability/usefulness for pharmaceutical patent protection, it can find the analogy to the recent development in chemistry, genetics and bio-technology field that there is a tendency to require an industrial applicability/usefulness.[81] Similarly with the terms novelty and inventive step requirement of "industrial application" is still open for interpretation and can be regarded as flexibility where individual states may set their own concept, definition, scope and tests.

(b) *Interpretation*

TRIPS has established a general principle regarding the standard required for patentability by prescribing three criteria and so moving toward harmonisation. However, TRIPS leaves the three criteria open meaning that there is room, not only for individual members but also for a Panel or the Appellate Body to interpret just what will satisfy the obligation so described. Firstly, all of them are open-textured, and this requires a further clarification of the terms of "novelty", "inventive step" and "industrial application". This open-textured nature may require a Panel or Appellate Body to refer to other areas to find the meaning. The incorporated Paris Convention does not establish the content of the thresholds of patentability either, so the clarification of the three criteria is left to the law of national states.[82] This kind of open-textured language allows the States much flexibility to define the concepts, and this self-definition can enhance the protection of health in pharmaceutical area.[83] For example, because "there is no universal rule for novelty" the "novelty" requirement may be adjusted to a standard considered appropriate for developing countries.[84] As Correa observed, "WTO members still have the option, with certain limits, of defining the scope of patentability in quite a broad way, depending on each country's strengths and weakness in different areas, and on the impact that patentability may have on the access to or

[80] For example, "utility" used in the US can be broader and an invention may be considered "useful" even if it does not yet have a feasible specific use.

[81] Gamharter, above n. 3, 25.

[82] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: TRIPS and Policy Option* (Zed Books, 2000) 57–61.

[83] This will be discussed below in the Second Use Patent.

[84] Gervais, above n. 3, 221.

development of technology."[85] Under this kind of situation, the interpreter may need to defer to national states' laws to find the specific requirements of the three criteria.

2. *Non-discrimination*

Another important aspect of Article 27.1 is that for the first time it has set up a non-discrimination standard for members to protect intellectual property rights. "Discrimination refers to unfair or unjustifiably adverse treatment."[86] The interpretation of discrimination, according to Abbot, should be considered together with important public interests and in light of the Doha Declaration.[87] Considering the object and purpose of TRIPS and viewing the Doha Declaration is a subsequent development of TRIPS relevant to proper interpretation of obligations, it is possible to argue that specific rules applicable to pharmaceutical or public health patents which may prima facie raise look as if they are discriminatory do not constitute "discrimination" when these rules are necessary to address important public interests.[88]

(a) *Place, Product and Process, and Field of Technology*

The TRIPS Agreement obligation that there should be no discrimination against the patentability of an invention based upon the "place of invention" may have particular relevance to the United States, because the United States adopts a first-to-invent system, which is different from the more commonly used file-to-file system.[89] With the entrenchment of non-discrimination of place of invention, the first-to-file and first-to-invent system can be harmonised in TRIPS by giving effect to patent protection in both situations.

Another important characteristic of Article 27.1 lies in the requirement that there should be non-discrimination of the field of technology. Before TRIPS, patent laws of many developing countries excluded the patentability of pharmaceuticals.[90] The inclusion of non-discrimination of the field of technology has been regarded as one of the greatest achievement of the entire TRIPS Agreement.[91] This means that the members must now provide that

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[85] Correa, above n. 82, 50.

[86] Frederick M. Abbott, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health' (Quaker United Nations Office, Geneva, February 2002) 49 <www.quno.org>.

[87] Ibid., 50.

[88] See Ibid.

[89] Gervais, above n. 3, 221.

[90] Gamharter, above n. 3, 26.

[91] J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, 2001) 109.

patents are available for pharmaceutical inventions. Watal is of the view that the requirement of non-discrimination in the field of technology has prevented the establishment of special compulsory licensing requirements for some fields of technology such as pharmaceuticals.[92]

The last is the non-discrimination requirement that patents must be available regardless of whether the products are to be imported or locally made. With the inclusion of this non-discrimination principle, the access to medicines can be impacted under certain situations. For example, certain life-saving generic drugs in a country cannot be made available through import to another country where the medicines still enjoy patent, while the local place has no manufacturing capacity. With this non-discrimination, the "local working requirements" required in some patent systems can be frustrated.[93] Before TRIPS Article 5A of the Paris Convention leaves contracting states free to impose compulsory licensing of a patent for failure to work.[94] One consequence of this non-discrimination principle is that it may reduce the circumstances in which the grant of compulsory licences for failure to work are required or justified. This may reduce the scope of the flexibility of compulsory licensing and have a restrictive effect upon access to medicines.

(b) *Canada – Pharmaceutical Patents*

In the *Canada – pharmaceutical patents* case, these non-discrimination elements were tested. The panel first admitted that the ordinary meaning of "discrimination" is potentially broader than the specific definitions of "national treatment" and "most favoured nation treatment". The Panel suggested interpreting the term "discrimination" with caution and care without adding more precision, since this is a normative term which is the result of different treatment to cause "*de jure* discrimination" or "*de facto* discrimination".[95] Therefore, the panel decided to defer attempting to define the term at the outset and sought to restrict itself to a reading only to the extent necessary to resolve those issues.[96] In terms of *de facto* discrimination, the Panel found that there should be both a *de facto* discriminatory effect and a discriminatory objective in the measures to justify a finding of *de facto* discrimination.[97] Finally, based on the interpretation of "discrimination" the Panel found no discrimination in Section 55.2(1) of Canadian Patent Act

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[92] Ibid., 109–10.

[93] Gervais, above n. 3, 222.

[94] Ibid.

[95] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.94].

[96] Ibid., [7.98].

[97] Ibid., [7.101].

based upon the "field of technology".[98] This case established the test of "discrimination" by *de facto* discrimination both in effect and by purpose, and *de jure* discrimination.

(c) *Open-endedness*

The language used in the above non-discrimination clauses is not only open-textured but also open-ended, and this open-ended nature requires an evolutionary interpretation.[99] The ordinary meaning approach to interpretation is insufficient to supply the interpretation of the terms, and there should be reference to other sources to explore the meaning. The open-endedness of the language used means that any new technology should not be excluded from the patent system. The open-endedness in TRIPS permitting the patentability of inventions in any field of technology certainly can include any form of pharmaceutical inventions.

3. *Interpreting Open-ended Language*

The open-textured language used in the requirements concerning patentability and the open-ended language used in the non-discrimination provisions leaves much room for a manner of interpretation that proceeds by referring to other sources. In addition, Article 27.1 also includes the clauses "any inventions" and "in all fields of technology", and these open-textured and open-ended terminologies together with the open-textured language used in the requirements on patentability and non-discrimination may give rise to more flexibility in frustrating what are called second use patents for pharmaceuticals.

The TRIPS does not establish a definition of "invention", and this lack of definition is not a loophole of TRIPS but a reflection of the fact that there is no unique concept of "invention".[100] Because DSU provides that the rulings of the DSB cannot add or diminish the rights and obligations provided in the covered agreement.[101] Interpretation of the term or concept of "invention" by the interpreter should not operate in such a way as to fill in the gaps or cure the ambiguities of TRIPS, but should aim to "clarify the existing provisions" through the interpretation. The Panel and AB should not "decide, through

[98] Ibid., [7.105].

[99] Frankel, above n. 13, 407–8.

[100] Correa, above n. 82, 51.

[101] Carlos M. Correa, 'TRIPS Dispute: Implications for the Pharmaceutical Sector' (Quaker United Nations Office, Geneva, 2001) <www.quno.org>.

adjudication, a normative policy issue that is still obviously a matter of unresolved political debate."[102]

The term of "invention" has no established single meaning, although it has been defined on the basis of its subjective elements or has been considered by the characteristics of the results obtained.[103] Most countries laws just limit the definition of invention by applying the three criteria for patentability to frustrate inventions.[104]

According to Correa, one of the main areas where the lack of a uniform definition of invention is relevant relates to the distinction between "invention" and "discovery".[105] Especially, in the pharmaceutical area, it is difficult to distinguish between "invention" and "discovery", because different legal systems differ from each. The distinction, or distinctions, between the two categories has substantially changed over time.[106] There are a variety of definitions and approaches in various countries.[107] In general it can be said that the importance of the distinction between the two ideas is that discovery is not patentable but that an invention is potentially patentable in patent laws of many countries if it meets the other threshold criteria.[108]

The open-textured or even open-ended language used in this Article gives rise to an issue for interpretation to be approached by referring to other sources to find the definition. While "discovery" is often explained as the mere recognition of what already objectively exists in nature, "invention" is sometimes said to require a solution to a problem by the application of technical means.[109] Since the dividing line between the two concepts for the purposes of the requirement of patentability can not be found in other sources of international law, including the incorporated Paris Convention, Correa suggests deferring to the laws of national states for the interpretation of the term to leave a certain degree of flexibility in a changing scientific

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[102] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.28].

[103] Correa, above n. 82, 51. For example, it has been defined by those relating to the inventor or the activity he/she performs, or has been defined by the existence of "unexpected" or "surprising" effects.

[104] Correa, above n. 82, 51.

[105] Ibid.

[106] Ibid., 52.

[107] For example, under US law, a micro-organism whose function has been identified is patentable, that is, it may be treated as an "invention". This concept, however, is not shared by other countries. The legislation of Brazil only allows for the patenting of a genetically modified micro-organism.

[108] Correa, above n. 82, 51.

[109] Ibid., 52.

and technological context.[110] Under this kind of situation, Correa suggests it is possible to find more flexibility in interpreting "invention". Developing countries which lack local research or innovation capabilities may seek to limit the patentability of substances existing in nature or to limit the patentability of biological materials provided that the law meets the requirements under Article 27.3.b of TRIPS to protect patentability of micro-organism and non-biological and microbiological inventions for the production of plants and animals.[111] This manner of interpretation should follow the VCLT rules to refer it in the context of TRIPS in the light of the object and purpose of TRIPS. As discussed above, the object and purpose of TRIPS serves a dichotic goal in trade and protection, and a fine balance should be struck in the protection.[112] The limitation on the patentability of substances existing in nature and some micro-organism innovations may belong to national policy arrangements, and deference should be given to national laws.

In this sense, TRIPS offers some flexibility for the consideration of health issues. As the international human rights law inserts a legal obligation on the states, and requires states to respect, to protect and to fulfil the right to health, it leaves the states some freedom to have their own arrangements to develop health policy to satisfy this requirement.[113] This national deference on the free limitation on the patentability of the substances of nature and certain micro-organisms is a reflection upon this requirement and should be interpreted as promoting and complying with the right to health.

4. *Second Use Patent*

(a) *Ordinary Meaning*

The major patents in the pharmaceutical area do not relate to new chemical entities, but to manufacturing processes, formulations, and particularly, to new uses of previously known products.[114] However, the dominant pattern in patent law is to require the novelty of inventions.[115] Because the concept of novelty is not precisely defined, the novelty requirements may frustrate the second and subsequent use patents. Second and subsequent use patents refers to the protection of new uses for substances, active principle, molecules, or compounds that have been previously patented or are already in the public

[110] Ibid., 51; also Correa, above n. 101.
[111] Correa, above n. 71, 16–7.
[112] See Part Two. Chapter 5.II.
[113] See Part One. Chapter 2.I.B.3(a), it discussed the state legal obligations.
[114] Correa, above n. 71, 20.
[115] Correa, above n. 82, 57.

domain.[116] It creates a patent for a new use of a pharmaceutical by allowing use of the pharmaceutical for the "old" known use without infringing the patent claim.[117] Another variant is called the Swiss style claim a name derived from the practice of the Swiss Federal Intellectual Property Office to permit a claim for a patent framed as "The use of substance X in the manufacture of a medicament for a new therapeutic use". Jacob J explained in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc*[118]

> [T]he claim is trying to steer clear of two obstacles to patentability, namely the requirement of novelty and the ban on methods of treatment of the human body by therapy…Such claims are unnecessary when X is new for then X can be patented by itself…But when X is old the Swiss form of the claim is said to confer novelty and yet not to be a method of treatment…So the manufacture of an old pill for use in a new treatment was considered…novel. The justification for novelty was the new therapeutic use. And since the claim was to a manufacture of a pill it was not a claim to a method of treatment.

In the *Swiss claims*,[119] it was ruled that the inventor may claim patent protection for such an innovation. However, Blakeney is of the view that this case amplified the approach found in *Re GEC's Application* that a process patent was patentable if it led to the production, improvement or preservation of a "vendible product".[120]

Article 27 of TRIPS, however, uses a broad description of "invention" as simply a product or process, and this vagueness requires further clarification during interpretation. Some hold the view that members of TRIPS may exclude second and subsequent medical uses from the definition of "invention"[121] Correa is also of the view that WTO members have the discretion to exclude from patentability due to the non-fulfilment of basic

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[116] See O. Mitnovetski & D. Nicol, 'Are Patents for Methods of Medical Treatment Contrary to the *ordre Public* and Morality or "generally Inconvenient"?' (2004) 30 *J Med Ethics* 470, 472, available at <http://jme.bmjjournals.com/cgi/reprint/30/5/470.pdf>.

[117] Susy Frankel and Geoff McLay, *Intellectual Property in New Zealand* (LexisNexis Butterworths, 2002) 339.

[118] *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 271–2.

[119] *Pharmaceutical Management Agency v Commissioner of Patents* [2000] 2 NZLR 529, para. 17 (CA).

[120] Blakeney, above n. 38, 81–83.

[121] Edson Beas Rodrigues Jr and Bryan Murphy, 'Brazil's Prior Consent Law: A Dialogue between Brazil and the United States over Where TRIPS Currently Sets the Balance between the Protection of Pharmaceutical Patent and Access to Medicines' (2006) 16 *Alb L J Sci & Tech* 423, 430; in this Article, the author gives example of the Andean Court of Justice's interpretation on art 27 of TRIPS to opine that TRIPS does not mandate protection of second use patents since patent protections required under art 27 of TRIPS are only for inventions related to products, compounds or processes.

patentability conditions, innovations which are just mere discovery, or of non-industrial application, or that are the equivalent of patenting a therapeutic method and lack of novelty.[122] The author is of the view that second use patents present novelty only in the application of the pharmaceutical compound and applications for this kind of invention are worded like medical instructions on how to use a given compound to treat a certain illness.[123]

(b) *Contextual Interpretation*

The interpretation of the requirement of invention may need to refer to subsequent agreement and practice and even the preparatory work of TRIPS. Whether a "second use patent" falls within the interpretation of invention may also require a further reference to the object and purpose of TRIPS and to paragraphs 2 and 3 of Article 27. The open-endedness of Article 27 may require the expansion of patent protection commensurate with the development of technology in any field, and this may include any development of pharmaceutical technology. The development of pharmaceutical technology should be conducive to the social and economic welfare. The reading of the Doha Declaration shows that TRIPS should be interpreted in a way that is compliant with public health objectives, and the subsequent development of TRIPS. Such an interpretation may allow some flexibility in TRIPS by frustrating second use patentability. This limitation of the reach of the patent system may exclude the expansion of patents in the field in a way that facilitates more restrictions to access to medicines by granting patent owners more control of the possible market. However, such a restriction may also tend to diminish the incentives for pharmaceutical innovators in researching and developing of new and useful second uses for known pharmaceuticals and this might be said to have a negative effect on access to medicines.

5. *Exclusion of Patentability*

Paragraph 2 of Article 27 provides

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *Ordre Public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Paragraph 3 of Article 27 provides

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[122] Correa, above n. 71, 23–4.

[123] Ibid., 23.

> Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Correa is of the view that developing countries can take advantage of the flexibility offered in these exclusions, and suggests that the ethical, economic and legal implications of allowing the patenting of plants and animals, even if genetically altered, strongly indicate that these should be subject to a clear exclusion from patentability.[124] However, the interpretation of this paragraph requires more contemplation.

### (a) Ordre Public *or Morality*

#### (i) Contextual Interpretation

TRIPS allows exclusion of patentability under justification of protection of *ordre public* or morality if the invention is commercially exploited within a territory. The interpretation of the exclusion should be focused on *ordre public* and morality.

It is generally regarded that the exclusion of patentability can apply to certain inventions on a case-by-case basis instead of categories of inventions.[125] However, the interpretation of the open-textured language needs to be understood in its context and in the light of the sources outside TRIPS. Firstly, the interpretation of this language should be placed in the context of this Article and the treaty itself. In this Article, "the commercial exploitation" has been used to limit the exclusion grounds, and it means that the risk must come not from the invention but from its commercial exploitation.[126] However, it has been argued that TRIPS

> does not require an actual ban on the commercialization as a condition for exclusions; only the necessity of such a ban is required. In order to justify an exclusion under Article 27.2, a member state would therefore have to demonstrate that it is necessary to prevent- by whatever means – the commercial exploitation of the invention. Yet, the member state would not have to prove

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[124] Correa, above n. 82, 230.
[125] Gervais, above n. 3, 222.
[126] Ibid.

> that under its national laws the commercialization of the invention was or is actually prohibited.[127]

Another factor is that the consideration of the impact of commercial exploitation is based in a territory of the country concerned. It suggests that the impact assessment is country specific and exclusion should be conducted within territory. This implies that interpretation should defer to national law and this leaves flexibility for countries to deal with public interest issues.

The proviso in this Article shows that the mere fact that a national law prohibits the exploitation of an invention is not sufficient to exclude the possibility of patentability if other threshold criteria are met. Gervais finds that the change made to the final version of TRIPS compared with the earlier Brussels draft reinforces this view.[128] The proviso restricts the mere invocation of domestic laws and it echoes the restrictions and limitations resulting from domestic law in terms of the grant of patent in the Article 4*quater* of Paris Convention.[129] The interpretation of this exclusion, therefore, is focused on the interpretation of the open-textured language of "*ordre public*" and "morality", and the specific grounds set forth in the Article – "to protect human, animal or plant life or health or to avoid serious prejudice to the environment".[130]

TRIPS itself does not offer a definition of *ordre public* and morality, and there is no generally accepted concept of *ordre public*.[131] This is open for TRIPS to define, and such open-textured language suggests a reference to other sources, including the sources in the human rights law. The reference to *ordre public* is always associated with its parenthetical use of "public order". The deliberation on the use of the French words "*ordre public*" instead of "public order", however, shows the intention of TRIPS members to refer to the civil law origin of *ordre public*.[132] As discussed in Chapter 3.II.A, *ordre public* in French private law and private international law is similar to "public policy".[133] French private law refers to it as a basis for

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[127] Correa, above n. 82, 63; citing Dan Leskien and Michael Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a *sui generis* system' (1997) *IPGRI, Issues in Genetic Resources No. 6*, Rome, 15.

[128] Gervais, above n. 3, 223; in the Brussels Draft, it reads as "including to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement."

[129] Correa, above n. 82, 63–4; art 4*quater* of Paris Convention.

[130] See Correa, above n. 82, 63.

[131] Ibid., 62.

[132] See Gervais, above n. 3, 223.

[133] See also Gervais, above n. 3, 222, the author thinks that the *ordre public* here refers to public policy.

restricting or negating private contractual rights and French private international law refers to it to avoid applying foreign law.[134] In French public law, *ordre public* is related to "public order", which refers to "police power" to maintain security, social organisation and public welfare.[135] Generally, the object of *ordre public* is to maintain good order, safety, and public health for a security reason or reasons. In addition, the concept of *ordre public* is vague and evolutionary,[136] and it will require interpreters to take an evolutionary approach to interpret the term.

Morality mainly refers to unenforceable principles in general situations but accepted by a great majority of the citizens as general guidelines for individual or collective behaviour.[137] It depends upon the prevailing values of different cultures and countries and changes over time.[138]

However WTO jurisprudence offers an interpretation of *ordre public* and public morality.[139] As shown in the *US-Gambling* case, the "public order" and "public morality" are two distinct concepts but can have a certain overlap.[140] The findings of the Panel in that case show that both *ordre public* and public morality are related to the "people as a whole"[141] and concerned with protecting fundamental interests relating to "standards of law, security and morality".[142]

The grounds for exclusion of patentability in Article 27.2 give specific reference to "including protecting human, animal or panting life or health". The word "including" incorporates the protection of human, animal or plant life as a sub-species of *ordre public* and morality. According to one opinion,

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[134] See Part One.Chapter 3.II.A.1.(c).(i); also see Bert B Lockwood Jr, Janet Finn and Grace Jubinsky, 'Working Paper for the Committee of Experts on Limitation Provisions (1985) Vol. 7 No. 1 *Human Rights Quarterly* 35, 58–9.

[135] See Part One.Chapter 3.II.A. 1.(c).(i); also see Lockwood Jr, Finn and Jubinsky, above n. 134, 59.

[136] Correa, above n. 82, 62, citing Frédéric Pollaud-dulian, 'La Brevetabilité des inventions. Etude Comparative de jurisprudence, France-OEB' (1997) *Le Droit des Affaires* No. 16, Paris, 166.

[137] See Part One.Chapter 3.II.A.1.(c).(ii); also see Alexandre Charles Kiss, 'Permissible Limitations on Rights"' in Louis Henkin (ed.), *The International Bill of Rights – The Covenant on Civil and Political Rights* (Columbia University Press, 1981) 290, 304.

[138] See Gervais, above n. 3, 223; also see Correa, above n. 82, 62–3.

[139] See Part One.Chapter 3.II.B.

[140] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.468].

[141] Ibid., [6.463].

[142] Ibid., [6.467]. The Guidelines for Examination of the European Patent Office provides that '*ordre public*' is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour. See Correa, above n. 12, 287–8.

however, protection of life and health is so important that "it will not require any additional considerations relating to *ordre public* or morality".[143] According to this perspective on interpretation members need not prove the existence of *ordre public* or morality if it is necessary to protect life or health interests.[144] This opinion also refers to paragraph 4 of the Doha Declaration as a mechanism to safeguard the use of the flexibility found in Article 27.2 of "to the full".[145] This kind of opinion, however, requires more deliberation.

Firstly, the word "including" should be interpreted by reference to the textual meaning of the term which is equal to "inclusive of (syntactically it agrees with sometimes with the word for the group previously or afterwards mentioned)".[146] In other words, it can be to make something part of something else. Therefore, the protection of life and health should be understood to be part of the *ordre public* and morality. Secondly, the concept of *ordre public* can contain health protection in a certain sense.[147] As *ordre public* concerns the security of the whole people, it may mean that only when the need for protection of health can be seen to be necessary to protect the security of the whole people that the exclusion of patentability can be invoked. Thirdly, it seems to be difficult to pass the necessity test by directly applying the protection of health.[148] The *US-Gambling* requires specific guidelines in the necessity test,[149] and they are: "the importance of interests or values that the challenged measure is intended to protect",[150] "the extent to which the challenged measure contributes to the realization of the end pursued by that measure",[151] and "the trade impact of the challenged measure".[152] Among the three criteria, the third one of "the trade impact" should be less emphasised during the examination of the exclusion grounds in TRIPS context. TRIPS is a balance between trade and intellectual property protection, and this purpose is different from that of GATT, which is used to reduce trade barrier for promotion of trade.[153] Health is an important interest and one of the highest

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143 Correa, above n. 12, 289.

144 Ibid.

145 Ibid., 290.

146 See *Shorter Oxford English Dictionary* Volume 1, 980.

147 See discussion in Part One.Chapter 3.II.A.1(c).(i), it offers that, in certain situation, the "public health" can be covered under the grounds of *ordre public* or "public order".

148 For the discussion on the test, see Part One.Chapter 3.II.B.1.(b).

149 Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.488].

150 Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [162].

151 Ibid., [163].

152 Ibid., [163] and [166].

153 See Part Two.Chapter 6.II.B.

values.[154] However promoting the protection of health without establishing the policy of intellectual property protection will be hard to pass the test on the "extent", considering the justification of patent protection and national intellectual property protection policy in the promotion of trade to create welfare. Therefore, the interpretation of the words of "including protecting human, animal or plant life or health" needs to be in line with the interpretation of *ordre public* and morality.

(ii) Relationship with GATT Article XX(b)

The understanding on the grounds of exclusion may cause some confusion. Does the term *ordre public* only refer to "public policy" or also refer to police power or "public order" in TRIPS? One view is that it refers to public policy.[155] The other view takes a narrow interpretation and refers the term to security issues such as riots or public disorder.[156] The discussion of what is to be understood by these terms needs to refer to the context of TRIPS as provided by VCLT.

Firstly, the context of the whole paragraph gives an implication of the understanding of this term. Article 27.2 also gives specific examples of proper grounds for exclusion in order "to protect human, animal or plant life or health or to avoid serous prejudice to the environment", and these examples can allude to the public order exclusion. The understanding on the *ordre public* should be understood as allowing protection of safety or public health for security reasons.

Secondly, the understanding of the specific exclusions should also be understood together with Article XX(b) of GATT which is one of the WTO covered agreements. Article XX(b) of GATT also uses a similar expression when referring to permitted exclusions that are "necessary to protect human, animal or plant life or health" and this has led to a suggestion that Article 27 of TRIPS should be interpreted by referring to GATT Article XX(b).[157] Article XX(b) has been interpreted and applied rather narrowly in GATT/WTO case law, and it seems to be hard to apply this to the TRIPS context.[158] The exception under Article XX of GATT is subject to a two tiered test that requires that the exception adopted by a member should pass the test under

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[154] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WTO Doc WT/DS135/AB/R (18 September 2000) [172].

[155] See Gervais, above n. 3, 222–3.

[156] See Correa, above n. 82, 62.

[157] Gervais, above n. 3, 223; this can be verified by detailed exclusions contained in art 27.3, which specifically excludes certain inventions from patentability.

[158] Correa, above n. 71, 14.

the chapeau and specific provisions of Article XX.[159] An exclusion of the patentability of all pharmaceutical inventions, even the inventions of essential medicines, is unlikely to pass the two-tiered test of GATT. Nevertheless, because GATT has different goals to TRIPS the exception under the GATT should be viewed differently.[160]

Thirdly then, it is necessary for the interpretation of such open-textured language to refer to the object and purpose of TRIPS found in Articles 7 and 8 of TRIPS.[161] The object and purpose of TRIPS may differ from GATT in the sense that, apart from the trade goal, a protection goal is reflected in TRIPS contrasting with the trade goal of GATT.[162] When contemplating the protection goal, a balance between public interest and private interest should be struck, and public policy should be considered. The protection of intellectual property should be conducive to social and economic welfare. The enjoyment of the right to health is one of the social and economic rights intended to promote the social and economic welfare of human beings. In this sense, the protection of human health may reach the level of a public policy issue when pharmaceutical patent protection totally blocks access to medicines. However, bearing in mind the justification of intellectual property protection, the human rights characteristic of intellectual property protection together with the economic incentive and rewarding theory of intellectual property protection can be considered to play a conducive role for the promotion of the social and economic welfare of society.[163] This suggests the need for the striking of a balance in the establishment of national policies for health and intellectual property. When considering this balance, the concept of *ordre public* should not be understood as a private law concept but as a public law concept. Such a perspective allows that a serious ground such as the maintenance of security could be used to justify the exclusion of patentability of pharmaceutical inventions. The ground of "public health" is mainly related to measures to control epidemic disease. The concept of public health can be included in the scope of matters relevant to *ordre public*. If public health is not maintained and there is an outbreak of infectious disease this circumstance could cause public disorder of sufficient seriousness to impact upon the security of a nation. This kind of interpretation, suggests that medicines inventions can not be excluded from patentability.

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[159] See Part Two.Chapter 6.II.B.

[160] See Part Two.Chapter 6.II.B.

[161] See Correa, above n. 71, 15.

[162] See Part Two.Chapter 5.II.

[163] See Part One.Chapter 2.III.B.1.(b). The justification of intellectual property protection has been discussed as: natural rights, reward for disclosure, incentive and others.

In addition, an exclusion based upon the ground of "public order" can be permanent,[164] and this means that the patentability will be excluded under such ground. However, a situation that can be regarded as an *ordre public* consideration can happen after the grant of a patent.[165] When this occurs, whether the patent should be invalidated or should continue to be in force will become a difficult issue. This could cause difficulty and unpredictability in the patent system. In this sense, the temporary nature of the ground of "public emergency" used to control communication of epidemic disease can take its place for the limitation of patent right.

(iii) Summary

The concept of the *ordre public* should be interpreted to include consideration of the right to health. The Doha Declaration requires the interpretation of TRIPS with consideration of the right to protect public health. The interpretation of this Article shows that the concepts of *ordre public* or morality can overlap, and that the concept of *ordre public* can include the concept of public health in some contexts. Public health is a dimension of the right to health and determines the realisation of the right to health. In view of the above interpretation, it can be found that the protection of public health can be a ground for the exclusion of patentability of certain individual pharmaceutical inventions,[166] when the public health issue can give rise to threats to security such as causing or exacerbating riots or other civil disturbance.[167] However, given the rarity of such a situation, Article 27.2 should not be operated to justify a general exclusion of patentability of pharmaceutical inventions.

Although the exclusion of pharmaceutical inventions from patentability would not provide a general solution to problems restricting the access to medicines, it still means that the invocation of *ordre public* can be used to

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[164] See Kiss, above n. 137, 290.

[165] Correa, above n. 71, 15.

[166] See Wesley A. Cann Jr, 'On the relationship between Intellectual Property Rights and the Need of Less-developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism' (2004) 25 *U Pa J Int'l Econ L* 755, 810–2. The author expressed the view that Art 27.2 can exclude the patentability of one or two medicines. Also see Frederick M. Abbott, 'TRIPS, Access to Medicines and the WTO Doha Ministerial Conference' (Quaker United Nations Office, Geneva, 8 September 2001) 25, available at www.quno.org (last accessed on 14 August 2011).

[167] See Cann, above n. 166, 827–8; the author expressed the view that a consuming nation that is experiencing a high incidence of HIV/AIDS infection could argue that a variety of factors are either constituting an external threat or are giving rise to a potential external threat, and HIV/AIDS epidemic can pose a threat to both global stability and international security.

exclude certain patents on the grounds of protection of security. It may mean that, when the patenting of certain pharmaceutical inventions creates a problem serious enough to cause the whole country to lose the capacity to control certain epidemic disease and cause a general security problem, a country can exclude the patentability of certain medicines under this extreme situation.

(b) *Diagnostic, Therapeutic and Surgical Methods*

Sub-paragraph a of Paragraph 3 of the Article 27 allows a member to choose to exclude the patentability of diagnostic, therapeutic and surgical methods, and most member countries have chosen to enact such an exclusion.[168] The permitted exclusion contained in this subparagraph is narrower than that in the second paragraph. This exclusion helps to avoid monopolisation to affect human and animal health. However, with the development of genes therapies, it may have to face the challenge of this exclusion to see the protection of health. Pat Loughlan has argued that allowing patenting of methods of therapeutic treatment has harmful impacts on the medical profession and health policy, and this general argument was taken up in Australia in the Federal Court by Shepperd J. in the Rescare appeal.[169] Since then the majority judges in Bristol Myers have argued that such exclusion makes no sense that if you can patent a pharmaceutical and administration of that pharmaceutical is the only method of treating an illness it makes no sense to generally ban methods of treatment.[170] Japan has also decided to promote medical treatment diagnostic patents in order to stimulate innovation in a country that has a very high demand for health services but an aging and demising pool of available doctors.[171]

(c) *Plants and Animals*

The exclusion of plants and animals permitted to members in sub-paragraph b of Article 27.3 emphasises the protection of plants and animals. The Doha Ministerial Declaration provides for a review of the relationship between the

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[168] See Correa, above n. 82, 67; also see Gamharter, above n. 3, 82.

[169] See Pat Loughlan, 'Of patents and patients: New Monopolies in Medical Methods' (1995) 6 *AIPJ* 5, 5; and *Anaesthetic Supplies Pty ltd v Rescare Australia Ltd* (1994) 28 IPR 383, 418 Sheppard J.

[170] *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 (22 March 2000) paras. 129–139 Black J., Lehane and Finkelstein J. J.

[171] For example, see JPO, 'Application of Methods related to Medical Activity to the Patent Law, available at <http://www.jpo.go.jp/shiryou_e/toushin_e/shingikai_e/pdf/iryou-wg_re.pdf>; also the Draft Report sent by JIPA regarding *Concerning Protection of Patents of Medical-related Acts* (2005) Vol. 5 No. 1 *Journal of JIPA* 52–3, available at <http://www.jipa.or.jp/content/english/journal/vol5_01/2005_1_52.pdf>.

TRIPS and Convention on Biological Diversity and the protection of traditional knowledge.[172] This means that TRIPS needs to consider the right of the traditional knowledge owners. The study on the properties of plants and animals can inspire medical inventions, and the protection of traditional knowledge owners should help the traditional knowledge owners gain more right to access to the medicines resulting from the traditional knowledge.

Article 27.3 while permitting members to exclude certain plant and animal inventions requires the protection of micro-organisms. In some jurisdictions, the concept of "micro-organism" has been extensively interpreted so as to embrace any cell and sub-cellular elements.[173] However, scientific research suggests that only bacteria, fungi, algae, protozoa or viruses should unequivocally identified as "micro-organism".[174] This open concept of micro-organism should be interpreted by referring to national law.

Plant varieties should also be protected according to Article 27.3(b), or should be protected by *sui generis* system. This gives rise to the consideration of the Convention for Biological Diversity and UPOV. According to Pauwelyn, if the different regimes deal with same subject matter, the commanding obligation on the state to protect should accumulate if they do not necessarily conflict.[175] This gives a broad freedom to develop a *sui generis* regime, and national law can be established to meet these requirements.

### B. *Article 28 – Rights Conferred*

The interpretation of Article 27 gives a new perspective in the assessment of patentable subject matter and it shows certain degrees of flexibility in the compliance with the right to health. The Article 28 of TRIPS deals with the specific rights in a patent, and the specific definition of the exclusive rights conferred by product and process patents of this Article can be regarded as a significant achievement of TRIPS.[176]

> A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or

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[172] *Doha WTO Ministerial Declaration*, WTO Doc WT/MIN(01)/DEC/1 (20 November, 2001) para. 19.

[173] Correa, above n. 82, 68.

[174] Ibid.

[175] See Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 161–2.

[176] Gamharter, above n. 3, 34.

importing[177] for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

1. *Product and Process Patents*

The first paragraph requires that members confer upon the patent right owner the exclusive rights of making, using, offering for sale, sale and import. The interpretation of the Article may require resort to the background of the conclusion of this Article. The first paragraph of Article 28 was inspired by Article 19 of the draft Patent Law Treaty.[178]

(a) *Product Patents*

Article 28(1)(a) of TRIPS requires the protection of the exclusive rights of a product patent, including the protection of product patents from the acts of making, using, offering for sale, selling or importing by third parties without the prior consent of the patent owner. These specific requirements for product patents provide for very comprehensive protection to prevent infringement by a wide range of activities. This Article does not specifically require the protection against the stocking of a patented product, although such an exclusive right has been included in many national patent systems.[179] However, the *Canada-patent* case shows that the activity of stockpiling is in violation of the obligations under TRIPS.

In the *Canada-patent*, the stockpiling provision of the Canadian Patent Act was examined by the panel. The panel was of the view that the stockpiling was in violation of the obligations under TRIPS, since the making and constructing and using of the patented product during the term of the patent, without the patent owner's permission, would be a violation of Article 28.1 if not excused under Article 30 of the Agreement.[180] This shows that the activity of stockpiling, although not stipulated in Article 28 specifically, it is still subject to the exclusive rights, and each right should be considered independently and equally by having separate meaning and scope of protection.[181]

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[177] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of art 6 (footnote in original).

[178] Gervais, above n. 10, 153.

[179] Gervais, above n. 3, 236.

[180] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.18] and [7.38].

[181] Gamharter, above n. 3, 35.

However, the panel examined this matter by considering the economic curtailment, and this seems to emphasise the commercial purpose of the goods instead of mere activity of storage.[182]

There is no hierarchy in the rights of making, using, offering for sale, and selling and importing. As shown in the *Canada-patent* case in view of the argument made by Canada claiming that the stockpiling of the patented pharmaceuticals was a "limited exception" if it preserved the exclusive right to sell to the consumer during the patent term, the panel did not support creating a hierarchy of patent rights within the TRIPS to imply that "making" and "using" of the patented product is secondary to the right to exclusive selling.[183]

The right to import a patented product raises the issue of parallel importation, and this is further explained with a footnote in this Article. The footnote provides, "This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6".

The other distribution of goods contained in the footnote may still comprise "exporting sampling and warehousing or stockpiling", and this echoes the protection of stockpiling right in the *Canada-patent* case.[184] The reference to Article 6 raises the question of interpretation of parallel import, which has become a hot issue in intellectual property protection.

(b) *Process Patents*

Article 28(1)(b) also requires the protection of process patents, and it requires protection through the prevention of "acts of using the process" or acts of "using, offering for sale, selling or importing" "the product obtained directly by that process". With the introduction of this requirement TRIPS strengthens patent protection by extending the protection to the product directly obtained from the patented process.[185] The specific rights conferred on the process patent have extended the rights conferred by Article 5$^{quater}$ of the

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[182] Australian and UK law provides for 'keep' as an exclusive right of the patent owner and seems to determine this based on keeping for a commercial purpose for the goods, not the mere activity of storage.

[183] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.33].

[184] See Gamharter, above n. 3, 35.

[185] See Watal, above n. 91, 111; also See Carlos M. Correa, 'Patent Rights' in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: TRIPS* (Kluwer Law International, 1998) 189, 205. Although many patent courts had already reached this position, see something like the saccaharin importation doctrine (1900) 17 RPC 30 and even indirect products like Beecham in [1978] RPC 153.

Paris Convention.[186] The entrenchment of the process patent is significant, since the transitional periods established by Articles 65 and 66 will be countered by the claimed processes and the exclusive marketing rights justified under Article 70.9 can serve the purpose of product patent.[187]

Another implication of the extension of the scope of the exclusive rights provided by grant of a process patent is that it blurs the line between the exclusion of patentability of plant or animal per se inventions contained in Article 27.3(b) and the protection of plant or animal inventions obtained from a non-biological or microbiological process allowed under Article 27.3(b).[188] A research shows that the actual scope of the rights conferred is defined by the patent claims set out in the patent application.[189] The interpretation of claims is still open, and one view is to leave it to national legislation to determine,[190] but it should not unduly extend the claimed scope of a patent and restrict the activity of competitors.[191]

### 2. *Exhaustion in Article 6*

Article 28 makes a reference to Article 6 of TRIPS in regard to protection of product patent rights, and this reference connects interpretation of the Article 28 to the interpretation of the Article 6 of TRIPS. This will require an interpretation of the Article 6 for the understanding of the Article 28.

As will be analysed, the Article 6 is left open for interpretation, and it is free to establish exhaustion of rights.[192] The free establishment of the exhaustion issue can easily lead to controversy when the wording of Article 6 is so minimal and the implications of that wording so unclear. "Some commentators have argued that it will cause conflict with the exclusive rights conferred under Article 28(1)(a) and the requirement of non-discrimination on "whether products are imported or locally produced" under Article 27(1).[193] It will also conflict with the principle of territoriality and undermine the independence of patent rights established by the Paris Convention.[194]

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[186] Art 5*quater* of *Paris Convention*.

[187] See Watal, above n. 91, 111; art 65 provides the transitional arrangement of a moratorium of 4 years for developing countries, and art 66 provides a moratorium of 10 years for least-developed countries; art 70.9 of TRIPS provides exclusive marketing rights.

[188] See Gamharter, above n. 3, 44.

[189] See Carlos M. Correa, above n. 185, 205; also see Gamharter, above n. 3, 44–5.

[190] See Carlos M. Correa, above n. 185, 205.

[191] See Gamharter, above n. 3, 44–5.

[192] See Part Two.Chapter 5.III.C.

[193] See Correa, above n. 71, 76.

[194] See Ibid.

The interpretation, however, should be considered in the context of the Article. Generally, this is regarded as relating to distribution of goods, and this can be verified by the deliberation on the footnoting of Article 6 in Article 28.[195] It means that the rights for use, sale or importation or offer for sale of the patented goods should be exhausted rather than other intellectual property rights. This uncertainty surrounding Article 6 has the potential to cause a problem for the access to medicine in some countries without manufacturing capacity with the silence of exhaustion of rights, since Article 28 seemingly forecloses the idea of international exhaustion. However, with the clarification in the Doha Declaration, especially with interpretation of TRIPS in a public health supportive manner specified in the Doha Declaration, Article 6 can be seen to provide freedom for members to define the nature and scope of exhaustion. This shows that Article 28 should not form an obstacle for the parallel import of products in a way that will assist access to affordable medicines.

## C. *Article 6 – Exhaustion of Rights*

### 1. *The Article*

Article 6 of TRIPS deals with exhaustion of rights and it provides

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

The express language used in this Article means that it is left open for interpretation.

#### (a) *Parallel Import and Exhaustion*

##### (i) Exhaustion of Rights

The exhaustion of rights in relation to an intellectual property rights refers to the loss of the proprietary exclusive right enjoyed by the rights holder to control the resale of the protected product after first sale in the relevant market by or with the consent of the rights holder without restriction.[196] There are three views about the scope of the concept of exhaustion of rights, and the views are that exhaustion of rights can be divided into national exhaustion, international exhaustion and regional exhaustion. Supporters of the view

[195] Gervais, above n. 3, 115.

[196] In US, it is generally referred to as first-sale doctrine.

that the Article refers to a concept of national exhaustion rely on the territorial nature of intellectual protection, and require that the resale of intellectual property protected goods cannot be exhausted by sales outside the territory. Those who consider that Article 6 refers to international exhaustion argue that there will be a loss of intellectual property exclusive rights after first sale of the goods in any market, and the resale of the goods or the import of those marketed patent protected good will not infringe the patent right anymore. The concept of regional exhaustion extends the idea of national exhaustion to a group of two or more countries based on a multilateral agreement of the participating countries. In this form of exhaustion the resale of the goods that have been placed on the market in any country that is a member of the regional grouping will not be an infringement of the rights of sale of the intellectual property right holders or its licensees.

The various opinions on exhaustion of rights are mainly divided between the developed countries and developing countries with the former arguing for the territorial exhaustion which greatly restricts the impact of the concept and the latter arguing for the recognition of an international exhaustion doctrine with far wider implications.[197] Typically the United States of America maintains that the proper scope of the concept is one of national exhaustion, but most developing countries support the international exhaustion. The European Community (EC) recognises and applies a doctrine of regional exhaustion.

An additionally complicating factor is that some countries maintain that parallel importation based upon exhaustion of rights should be permitted in relation to some intellectual property rights and not others. For example German law, recognises international exhaustion of trademark rights but not of patent or copyright rights.[198]

During the TRIPS negotiations, some developed countries, including the United States and Switzerland, tried to support the principle of national exhaustion, but some other countries or members, including Australia, Brazil, Hong Kong, India and New Zealand, defended the principle of "international exhaustion" or preferred to let the members to decide on their own.[199] These divergent views on the doctrine of exhaustion of rights reflect the

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[197] Abdulqawi A. Yusuf, 'TRIPs: Background, Principles and General Provisions' in Correa and Yusuf, above n. 185, 3, 18.

[198] Contrast: *Cinzo* (trademark); *Tylosin* BGH 3 June 1976 [1976] GRUR 519, 8 IIC 64 (1977) (patent); German Copyright Act section 17 noted in Friedrich-Karl Beier, 'Industrial Property and the Free Movement of Goods in the Internal European Market', 21 IIC 131, at 158, Note 74 (1990); See Warwick A. Rothnie, *Parallel Imports* (Sweet & Maxwell, 1993) 5.

[199] Gervais, above n. 3, 112.

various concerns of the various countries or members in their negotiation of TRIPS.

(ii) Parallel Import

The exhaustion of intellectual property rights is related to what is referred to as parallel import. Parallel importation arises when legitimate non-counterfeited goods are put on a foreign market by the rights holder in that market and are then imported into a domestic market without the permission or authorisation of the rights holder in the domestic market.[200] The concept of international exhaustion would then allow parallel import from any country. Regional exhaustion allows parallel import from a country member of a regional agreement. A purely national exhaustion doctrine would mean that the rights are exhausted domestically and commercialisation in foreign countries is not considered to have exhausted the patentee's (the domestic intellectual property rights holders) right.[201]

Warwick A. Rothnie, after examination of patent cases in the United States and Anglo-Commonwealth jurisdictions concluded that both jurisdictions decided the permission or ban of parallel imports upon the key issue of whether the person who made the first sale in the foreign market also had authority to sell in the domestic market. There were differences in approach principally being that in the United States the doctrine was based upon a previous notice under the contractual right while in the Anglo Commonwealth jurisdictions the doctrinal basis was an aspect of patent law operation.[202]

The concept of parallel import is most controversial in relation to the pharmaceutical industry. On one side, the research-based pharmaceutical industries argue against parallel import because they would like to seek to discriminate in price between different markets. They also argue that where parallel importation would operate to bring about a reduction of profits it will have an adverse effect on the process of innovation and the development of new drugs. As Rothnie observed, after examination of the pharmaceutical industry in the EC, the permission of parallel import in the EC will potentially reduce the ability of some firms to continue investing in increasingly expensive and risky R&D (research and development) in relation to potential new drugs and scare away desirable sources of investment by "exporting" the "low-priced" drugs of some Member States to others which have not wholly accepted the objects of such parallel import.[203] It is also difficult for

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[200] See Correa, above n. 12, 78.

[201] See Ibid., 79.

[202] See Rothnie, above n. 198, 183–4.

[203] See Ibid., 508–10; also see Correa, above n. 71, 73.

health authorities in various countries to sustain differential price controls and regulatory regimes for health and safety of pharmaceuticals.[204]

On the other side, it is emphasised by health authorities and some human rights bodies together with some scholars that parallel import is a useful mechanism to facilitate opportunities to purchase the cheapest medicines which has the effect of increasing the affordability of medicines and promotes access to medicines.[205]

Accordingly it is argued that parallel import is also important for the realisation of the right to health, specifically for the access to affordable medicines. The recognition of the import right in relation to goods protected by a patent means that parallel import may not be allowed under the national jurisdiction. When a country has no manufacturing capacity for pharmaceuticals, and the access to medicines in such country relies on the import of such medicines from a third country. However, because of the import right accorded to TRIPS Agreement, and if a country also adopts national exhaustion, the patent holds back the import of the medicines from a third country which can manufacture the needed medicine which belongs to generics and to be much cheaper. As a result, the access to medicines may become difficult. Especially, some developing countries or least-developed countries, they are in need of the medicines but they are lack of local manufacturing capacity. It is necessary for them to adopt some parallel import.

(b) *Open Interpretation*

The fact that TRIPS does refer to the concept of exhaustion of rights but does not provide any clear specific explanation of the scope of the doctrine being referred to and then specifies that nothing in the Agreement itself shall be used to address the issue can be attributed to the lack of consensus among the members.[206] The silence on the exhaustion of rights may have led to diverging interpretations.[207] This deliberation has reflected the various interests on intellectual property protection and constitutes a major gap in the harmonisation of the parallel import. However, the interpretation of this Article is crucial to the issue of access to medicines in the health context.

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[204] See Gamharter, above n. 3, 37.

[205] See Sub-Commission on the Promotion and Protection of Human Right, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) ('*The Impact of TRIPS Agreement*') para. 66; also see Frederick M. Abbott, 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005) 393, 416–8; also see Correa, above n. 71, 73.

[206] Yusuf, above n. 197, 18.

[207] Gervais, above n. 3, 112.

A purely textual analysis of Article 6 is not likely to provide a clear meaning when the silence on this issue is worded. The open-ended nature of Article 6 may be construed as referring to a system of international exhaustion in order to help some countries which are in need of cheap medicines but which lack manufacturing capacity to justify import from a foreign country producing generics instead of brand name medicines. The apparently broad leeway left by Article 6 may give members of TRIPS opportunity to implement parallel import policies. However the doctrine of international exhaustion still remains controversial.[208] While such an approach has been regarded by developing countries as a key to solve the public health problem,[209] it was also raised by some pharmaceutical companies as inconsistent with the South African legislation intended to allow the Ministry of Health to authorise the parallel importation of medicines.[210]

However, the interpretation of the "exhaustion of rights" can also be informed by the subsequent development of TRIPS. Paragraph 5(d) of the Doha Declaration provides that

> Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
> (d) The effect of the provision in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

This Declaration is not to be regarded as a substantive addition to TRIPS, but as a further clarification of the existing Agreement to show the intention of the parties to allow members the freedom to establish the international exhaustion of intellectual property rights. This will give more flexibility in adopting mechanisms that will increase or facilitate access to medicines.

### 2. *Relationship with GATT and Incorporated Conventions*

#### (a) *Relationship with Paris Convention*

The territorial nature of intellectual property rights is an important principle in Paris and Berne Conventions, and it can be argued that it stands in opposition to a doctrine of international exhaustion. Article 4*bis*(1) of the Paris Convention requires the members of the Union to treat patents obtained

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[208] See Correa, above n. 71, 76.

[209] Correa, above n. 12, 80.

[210] See eg Susan K. Sell, *Private Power, Public Law – The Globalization of Intellectual Property* (Cambridge University Press, 2003) 151–3.

in any country of the Union as "independent of patents obtained for the same invention in other countries".[211] Article 4*bis*(2) of the Paris Convention reinforces the protection by understanding this Article in an "unrestricted sense".[212] Therefore, some argue that parallel import should be banned for Members that are parties to the Paris Convention.[213] The interpretation of TRIPS also needs to take into consideration the incorporated law contained in the Paris Treaty. However, it can also be argued that the interpretation of this principle does not need to take the territorial nature of patent protection under Paris Convention into consideration. This is firstly because the rights in the importing countries are subject to domestic law and will not affect the territorial nature of patent in one country. Secondly because the Paris Convention can only cover Part II, III and IV of TRIPS and Article 6 belongs to Part I of TRIPS which is out of the coverage of Paris Convention.[214] It is, therefore, legitimate for each Member to establish international exhaustion to allow for parallel import.

(b) *Relationship with GATT*

(i) Relationship

Although the concept and scope of exhaustion of rights is open for interpretation, as one view observed, the existing GATT law is still valid to govern other aspects of exhaustion and parallel importation.[215] The exemption of exhaustion of rights from WTO dispute settlement may have implications for exhaustions which derive from other covered WTO Agreements. The national exhaustion or regional exhaustion of rights may be considered as import and export restrictions under the Article XI(1) of GATT, and similar obligations against restrictions on parallel imports can be found in Article XVI of GATS.[216] As the interpretation of TRIPS should be consistent with the interpretation of covered agreement(s)of WTO laws,[217] it gives rise to

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[211] See Art 4*bis*(1) of Paris Convention (1967 version), it provides, "Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not."

[212] See Art 4*bis*(2) of Paris Convention (1967 version).

[213] N. Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2002) 105.

[214] Correa, above n. 12, 81.

[215] Thomas Cottier, 'The Prospect for Intellectual Property in GATT' in Thomas Cottier, *Trade and Intellectual Property Protection in WTO Law: Collected Essays* (Cameron May, 2005) 11, 25.

[216] Art XI(1) of GATT.

[217] See Part Two.Chapter 4.II.

the question whether the free establishment of exhaustion of rights will be in conflict with GATT or GATS obligations or not.

In addition, Article XX of GATT also provides a general exception, and paragraph (d) provides:

> necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices.

According to this Article, it seems that an exception can be allowed to restrict the availability of parallel import based on certain types of national legislation. That then raises the question whether it means that the concepts of national exhaustion or regional exhaustion can only exist as exceptions? If so, can national exhaustion and regional exhaustion pass the test of Article XX of GATT? If a country adopts national exhaustion instead of international exhaustion to ban the parallel import will it cause discrimination against contracting parties? Will this become a disguised restriction on international trade? The parallel import of drugs will allow the country which has no manufacturing capacity to get the drugs at a cheaper price from a generics producer. Sometimes, some companies will adopt tiered pricing to export certain medicines at a lower price to some countries than that will be charged at domestic market. When parallel import is adopted, the worries for those companies are that patented drugs continue to be exported to third countries or even come back to the home market. Because the pharmaceutical companies are mainly from industrialised countries, this has become a main concern of those industrialised countries.

(ii) Interpretation of Relationship

As discussed above, the GATT is fundamentally predicated upon a trade goal but TRIPS contains a protection goal as well as a trade goal.[218] This difference in the goals can support different interpretations of the Articles contained in GATT and TRIPS. This difference gives rise to the *sui generis* status of Article 6 as well as an integral part of WTO at the same time.[219] This is related to the distribution of goods, and the protection goal of GATT is to promote trade. The trade goal is not to create trade barriers, but to eliminate trade barriers. In this sense to promote a trade goal parallel import should be allowed.

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[218] See Part Two.Chapter 5.II.

[219] Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* WTO Doc WT/DS50/R (5 September 1997) [7.19].

However the exhaustion of rights issue in the patent area is still not resolved and remains as a controversial area.

It has been pointed out that the interpretation of Article 6 should not be given too much effect in order to pass the circumvention of the carve-out of dispute settlement.[220] This will help to pre-empt the field of intellectual property rights exhaustion from any application of GATT or GATS principles.[221] In this sense, it seems that there is a certain overlap between the GATT and the TRIPS. The interpretation of the Article 6 of the exhaustion of rights should be left open for national jurisdictions to establish, based on their concepts of national treatment and MFN treatment.

The interpretation of Article 6 may also require resort to the interpretation method of Article XX of GATT. The GATT XX interpretation method adopts a two-tiered test being first the Chapeau test and then the specific provision test.[222] It can be argued that the free adoption of national exhaustion or international exhaustion should pass the test under this Article.

Firstly, adoption of a national exhaustion standard should not constitute a contradiction to the chapeau of GATT XX. The three constitutive elements analysed in the *US-Shrimp*[223] will not contradict the adoption of national exhaustion, since the principle is based on Articles 3 and 4 of TRIPS to offer national treatment and MFN. As a result of these treatments, it will not cause actual discrimination and it will not become "arbitrary or unjustifiable" between countries with same conditions. Secondly, as discussed above the trade goal informing GATT should not be applied to TRIPS with the same weight,[224] and this will give more freedom to adopt international exhaustion or national exhaustion, and suffice to pass the "necessity" test for domestic patent measures.

The necessity test contained in the specific provision of Article XX(d) of GATT has been tested in the *Korea – Various Measures on Beef* [225]

> Article XX(d) is susceptible of application in respect of a wide variety of "laws and regulations" to be enforced. It seems to us that a treaty interpreter

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[220] Gamharter, above n. 3, 41.

[221] Ibid.

[222] See Part One.Chapter 3.II.B.2.

[223] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [23]–[24] and [150]. The concept was reviewed as to have actual consequence of discrimination, to be of the character of "arbitrary or unjustifiable" and to occur between countries with same conditions.

[224] See Part One. Chapter 3.II.B.2.(b).

[225] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [161]–[162] and [164].

> assessing a measure claimed to be necessary to secure compliance of a WTO-consistent law or regulation may, in appropriate cases, take into account the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect. The more vital or important those common interests or values are, the easier it would be to accept as "necessary" a measure designed as an enforcement instrument.

At a first sight this suggests that a member that adopts national exhaustion instead of international exhaustion may not cause to consider common interests or values. The consideration for national exhaustion or international exhaustion may be related to economic considerations.[226] Pharmaceutical products patent holders find that parallel import is particularly and especially inconvenient for them because their business strategies involve seeking to discriminate in price between different markets. They have made strenuous efforts to resist systems of parallel importation. Warwick A Rothnie, after his examination on the pharmaceutical industry in EC, cautiously concluded that the system of parallel import permitted within the EC has the potential to reduce the ability of some firms to continue making the financial investments necessary for the increasingly expensive and risky R&D required to identify and develop new drugs. The result could be to scare away desirable sources of investment by "exporting" the "low-priced" drugs of some Member States to others which have not wholly accepted the objects of such parallel import.[227] Therefore those countries, that wish to adopt policies to promote research and development of technology may consider that it is in their interest to ban parallel import.

In fact, free adoption of a doctrine of national exhaustion helps to stop the re-importation of the drugs, because industrialised countries mostly operate under a doctrine of national exhaustion in patent law.[228] Even if they do not operate under this doctrine, then can also adopt measures under GATT Article XX(d) which allow them, in the present context, to ban the re-importation of these specifically labelled products which were destined for another market.[229]

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[226] But Warwick A. Rothnie after his examination on the patent cases in U.S. and Anglo-Commonwealth jurisdictions, concluded that both jurisdictions decided the permission or ban of parallel imports upon the key issue of whether the person who made the first sale in the foreign market also had authority to sell in domestic market. However there are different doctrinal underpinnings in that the permission of parallel import is based on a previous notice under the contractual right and the ban of parallel import is based on the operation of patent law. See Rothnie, above n. 198, 183–4.

[227] See Rothnie, above n. 198, 508–10.

[228] Thomas Cottier, 'TRIPS, The Doha Declaration and Public Health' in Cottier, above n. 215, 309, 312.

[229] Ibid. According to the 2003 Decision, members can allow parallel import of needed drugs with specific labels on the drugs. See *Implementation of paragraph 6 of the Doha*

### D. *Article 31 – Compulsory Licensing*

Article 31 deals with "other use without authorization of the right holder", and it is traditionally regarded as referring to compulsory licensing or non-voluntary licences.[230] Compulsory licensing is important in health-sensitive patent law, and it may become an important tool to promote competition and increase the affordability of drugs.[231] The understanding on the Article 31 of TRIPS, therefore, is very significant for the understanding on the access to medicines under TRIPS.

Compulsory licences are theoretically made available to address a lack or insufficiency of working of the patent to remedy anti-competitive practices or to promote some other public interest.[232] Compulsory licensing, involves the limitation on the patent holders right to exclude the party to whom the compulsory licence is granted from exploiting the patented invention in ways allowed by the licensee. Compulsory licences should be limited in and should provide for reasonable remuneration to the patent holder. The mechanism of compulsory licensing can be used as a tool to facilitate the conditions for manufacture of cheap health related generics medicines to deal with pervasive health problems where patents restrict either the supply or the affordability of medicines.[233] With appropriate compulsory licensing arrangements another party can manufacture and supply life-saving drugs that are affordable.

However before there was a further clarification of the provision, the compulsory licence mechanism had not been used by many developing countries as a tool to address their public health issues.[234] There are several reasons why countries were unable or unwilling to use the compulsory licensing mechanism.[235] Political pressure from developed countries discouraged developing countries issuing compulsory licences.[236] The negative impact on foreign direct investment and the lack of necessary administrative, financial and technical preconditions ensuring effective granting procedures might also contribute to the reluctance to issue compulsory licence.[237] In some developing countries there was no patent protection or a patent for a given product had not

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*Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) ('*2003 Decision*').

230 Gervais, above n. 3, 250.

231 Correa, above n. 71, 93.

232 Ibid., 94.

233 Correa, above n. 12, 312.

234 Abbott, above n. 86, 25.

235 This can be found at Abbott, Ibid.

236 Gamharter, above n. 3, 162.

237 Abbott, above n. 86, 25.

been applied for and so there was no basis for compulsory licences.[238] In fact, these kinds of countries which do not offer pharmaceutical patent protection generally do not have any manufacturing capacity. Another main reason was the transitional period of 10 years for developing countries to implement pharmaceutical patent protection under TRIPS, that allowed some developing countries to avail themselves of this transitional period until 1 January 2005.[239] The various political, economic and institutional reasons can account for the reluctance of developing and least developed countries to issue compulsory licences, but it is precisely the developing and least developed countries that need more affordable medicines to promote access to medicines.

In fact, human rights bodies have observed that Article 31 is of significant importance for the promotion of the right to health by facilitating access to affordable essential drugs.[240] In this sense, the interpretation of the Article 31 has become a very important key to the illumination of the trail of TRIPS towards a human rights framework to intellectual property protection.[241]

Article 31 contains a chapeau and 12 paragraphs, and interpretation of each paragraph should be conducted according to the interpretation method prescribed in the VCLT. These paragraphs provide for the circumstances, duration, scope, remuneration and other issues for a compulsory licence. Some of them, according to certain scholarship, contain ambiguous terminology, such as the terms "circumstances" in paragraphs (b) and (g) and "purposes" in paragraph (c), and it is also argued that the factors contributing to the legitimate need to issue compulsory licences are not fully developed within the text of Article 31.[242] It is, therefore, important to find a clarification and a detailed interpretation on the Article to determine the legitimate conditions and scope of the mechanism of compulsory licensing to facilitate access to medicines.

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[238] Gamharter, above n. 3, 162.

[239] Art 66 of TRIPS provides with a 10-year transitional period for least-developed country member.

[240] Sub-Commission on the Promotion and Protection of Human Right, *The Impact of TRIPS Agreement*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) para. 66.

[241] For example, see Patrick L. Wojahn, 'A Conflict of Rights: Intellectual Property under TRIPS, the Right to Health, and AIDS Drugs' (2001–2002) 6 *UCLA J Int'l L & Foreign Aff* 463, 491–7. The author is of the view that the right to health should prevail in the interpretation of the TRIPS Agreement, and points out that the TRIPS Agreement itself requires to be interpreted to allow for state parties to consider their public health needs and the transfer of health-related technology in implementing its provision by applying the text of the treaty to interpret.

[242] Sara M. Ford, 'Compulsory Licensing Provisions under TRIPS: Balancing Pills and Patents' (2000) 15 *Am U Int'l L Rev* 941, 956–62.

### 1. *The Title and Chapeau*

Article 31 is entitled "other use without authorization of the right holder", and the chapeau of the Article provides

> Where the law of a Member allows for other use[243] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

In the chapeau the term "other use" has been footnoted with an explanation to define the scope of "other use" as "use other than that allowed under Article 30".[244] This shows that the relationship between Article 31 and Article 30 is that Article 31 deals with exceptions that Article 30 does not deal. In the *Canada – Pharmaceutical Patents* case, the panel disagreed with Canada's argument concerning the distinction of mandatory and permissive character of the Article 30 and the Article 31.[245] The panel was of the view that both provisions permit exceptions under certain mandatory conditions.[246] It seems that Article 31 can allow some exceptions based on certain circumstances in which Article 30 will not apply. It seems that the interpretation of Article 31 should be conducted with consideration of Article 30.

In addition Article 31 should be understood together with the non-discrimination requirements of Article 27. It is generally argued that Article 30 and Article 31 are specific propositions and Article 27.1 is a general proposition.[247] However it has been otherwise argued that Article 30 is not an exception to Article 27 but deals with different subject matter because the non-discrimination clause only guarantees non-discrimination and does not dictate what exclusive rights a patent confers.[248] Therefore, Article 30 can not limit non-discrimination, since Article 27 sets a non-discrimination standard instead of exclusive rights and Article 30 only permits the providing of exceptions to exclusive rights.[249] This is only exceptions to the exclusive

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[243] "Other use" refers to use other than that allowed under art 30 (footnote in original).

[244] Footnote 7 of TRIPS provides that, "'Other use' refers to use other than that allowed under art 30."

[245] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.90].

[246] Ibid., para. 7.90 (Panel Report, WTO).

[247] See Paul Champ & Amir Attaran, 'Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S. – Brazil Patents Dispute' (2002) 27 *Yale J Int'l L* 365, 368–90; cited in Kevin J. Nowak, 'Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Art 27, (2005) 26 *Mich J Int'l L* 899, 935.

[248] See Nowak, above n. 247, 935–6.

[249] See Ibid., 940–1.

rights conferred under Article 28. In the same vein, Article 31 expressly contains the language of "other use without authorization of the right holder", and this kind of explicit expression shows that they are exceptions of the exclusive rights of the right holder conferred under Article 28.[250]

The title and chapeau of Article 31 suggests that the Article is an exception that must be exercised in compliance with the non-discrimination requirements of Article 27.1 but can justify the creation of exceptions to the exclusive rights of the Article 28. This also suggests that the exceptions permitted by Article 31 should be different from those permitted by Article 30 and based upon different circumstances.[251] This requires a clarification of the various circumstances that would justify the issuing compulsory licensing and which are different from those exceptions permitted in Article 30.

### 2. *Individual Merits*

Paragraph (a) emphasises the authorisation of exceptions created under Article 31 requires individual consideration, which means that a system for the grant of compulsory licensing must provide that it be conducted as a case-by-case specific issue.[252] This individual merits consideration precludes a system of automatic licensing. In some national systems an automatic licensing system applies to certain categories of inventions and this practice cannot continue once a country must comply with the provisions of TRIPS. One possible approach to reducing the control of patent holders in relation to pharmaceutical inventions was to provide for forms of automatic licensing if certain conditions were met.[253] Given the requirements of Article 31(a), it seems that this door to seek to assist the availability of pharmaceuticals through automatic licence is closed.[254]

### 3. *Circumstances*

As discussed above the non-discrimination requirements of Article 27.1 still apply to compulsory licensing under Article 31, but Article 31 is an exception

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[250] Art 28 provides with "A patent shall confer on its owner the following exclusive rights".

[251] But both of them do not differ from characters they have and both should be of mandatory nature to have exceptions.

[252] Art 31(a) of TRIPS provides, "authorization of such use shall be considered on its individual merits."

[253] However, the concern of the negative impact in the use of compulsory licensing has been raised, such as the consequences of the possibility of discouraging foreign investment, transfer of technology, and research, including research into local disease. See Correa, above n. 71, 100.

[254] Watal, above n. 91, 322; also see Gervais, above n. 3, 250.

to the exclusive rights conferred under Article 28. It is necessary for Article 31 to set the grounds for issuing compulsory licences, and Paragraph (b) provides

> such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

(a) *Prior Negotiation*

The interpretation of this paragraph will be crucial for the health context, and it includes several conditions for an interpreter to contemplate. The first condition in this paragraph is that the law relating to grant of compulsory licence must require that the applicant for a licence must first seek to obtain authorisation from the right holder upon reasonable commercial terms within a reasonable period of time. Reasonableness is not defined here and it remains open for interpretation and assessment. Given the requirements of paragraph (a) presumably "reasonableness" will be assessed depending upon the circumstances of the individual case. The nature of the technology will be relevant to the consideration of reasonableness.[255] When national practice has not established, what can be considered the "reasonable" commercial terms for the field of technology, the practices in relevant neighbouring countries or at a global scale should be taken into account.[256]

In the health context, it seems that this requirement for prior negotiation is highly likely to slow down the process for the grant of a compulsory licence for prompt access to medicines. Where the issuing country decides that it needs to use a compulsory licence to assist it to respond to a health crisis or emergency the requirement of prior negotiations could seem to be "procedurally cumbersome".[257]

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[255] Gervais, above n. 3, 250–1.

[256] Ibid., 251.

[257] Abbott, above n. 86, 28.

(b) *National Emergency and Extreme Urgency*

However the paragraph goes on to provide for the waiver of the requirement for prior negotiation in exceptional circumstances to justify a system for grant compulsory licence and this clause has important implications for implementing policies to facilitate access to medicines through compulsory licensing. The open-textured words contained in this paragraph, including "national emergency" and "other circumstances of extreme urgency" in this exceptional requirement allow a more flexible approach to using compulsory licensing to facilitate the access to medicine. The TRIPS Agreement does not define "national emergency" and "other circumstances of extreme urgency and the only requirement within the text is that the invoking party should notify the patent holder of such use as soon as reasonably practicable.[258] When an interpreter tries to interpret the open-textured circumstances of "national emergency" and "other circumstances of extreme urgency", according to the VCLT reference to the sources outside TRIPS ambit will be needed to clarify this term. Evidence of subsequent development of the Treaty may be resorted to for clarification of such open-textured terms, and the Ministerial Declaration and the Doha Declaration should be referred to as supplementary means of interpretation of this Agreement.[259]

The recourse to the Doha Declaration will find that this option has been addressed and clarified. Paragraph 5 of the Doha Declaration provides that

> 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in TRIPS, we recognize that these flexibilities include:
>
> […]
>
> (b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted;
>
> (c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

Paragraph 5(b) confirms the right of each member to grant compulsory licences, and emphasises the freedom of each member to establish grounds for compulsory licences. The explicit expression of "compulsory licences" contained in this paragraph is a confirmation and clarification on the words referred as "other uses without authorization of right holders" in Article 31.[260] This confirmation suggests the operational ambit of Article 31. This para-

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[258] But in the case of public non-commercial use, the government or contractor should inform the patent holder promptly.

[259] Abbott, above n. 166, 33.

[260] Gamharter, above n. 3, 160.

graph also confirms that each member has the freedom to determine the grounds for issuing compulsory licensing, and this freedom will give much more leeway and make implementation of policies to facilitate the access to medicine through compulsory licensing less procedurally cumbersome.

Paragraph 5(c) makes it clear that the member has the right to determine what constitutes national emergency or other circumstances of extreme urgency, and this suggests that a member can invoke public health as a ground for the issuing of compulsory licence provided it is based on good faith.[261] This shows the exclusion of the argument that prevention of abuse, as stipulated in Article 5(A)(2) Paris Convention, is a fundamental requirement for the grant of compulsory licences of any kind.[262] The same paragraph explicitly expresses those epidemics such as HIV/AIDS, malaria and tuberculosis constitute public health crises and that they are representative of national emergency or other circumstances of extreme urgency. This illustrative list of examples indicates that the criterion of national emergency is not necessarily limited to sudden and unforeseen events, but can also encompass a continuous crisis situation.[263] This helps to establish the link between compulsory licensing and the promotion of access to medicines. The freedom to establish what constitutes a national emergency will enable the interpreter to find that Article 31 should also take the human right to health into consideration. As discussed above, under the national emergency and public health grounds, certain human rights should be limited or derogated. The free establishment of what is meant by national emergency will allow the member to rank the public health issue as at the forefront to meet the challenge of the other human rights.

At the same time, the express language contained in the Doha Declaration that allows members' free establishment of what is a "national emergency" and "extreme urgency" contrasts with the more stringent "necessity test" under Article XX(b) of GATT and it imposes a burden to the complaining party to prove the non-existence of the invoked urgent situation.[264] In this sense, TRIPS is friendlier to a public health perspective than GATT and it meets the different goals of GATT and TRIPS.

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[261] See Ibid.

[262] But see Ibid.; citing J. Straus, 'Implications of the TRIPS Agreement in the Field of Patent Law' in F.-K. Beier and G. Schricker (eds), *From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property and Copyright Law* (Vol. 18, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich, 1996) 204.

[263] Gamharter, above n. 3, 161–2.

[264] Correa, above n. 12, 316.

In addition, the interpretation of the terms "national emergency" and "extreme urgency" should be conducted in an evolutionary manner. Since the terms "national emergency" and "extreme urgency" are open-textured reference to other sources should be resorted to. This open-textured character suggests a reference to other sources and will bring the human rights regime into the TRIPS regime. Concurrently, the interpretation of the terms shall follow an evolutionary manner since the circumstances which constitute "national emergency" or "extreme urgency" will change with the change of circumstances.[265] The protection of public health should be construed by following up the changing circumstances of the term.

(c) *Public Non-commercial Use*

Article 31(b) also includes "public non-commercial use" as one of the grounds justifying the issue of a compulsory licence with the waiver of prior negotiation with the right holder but it does require that the right holder shall be promptly informed. However the concept of "public non-commercial use" as a ground to issue a compulsory licence needs further clarification.

The interpretation of "public non-commercial use" is controversial. Some commentators have argued that this should be limited to a use by government in defence or space programmes but not for purposes to do with the supply of medicines.[266] Others argue that this can be used by both governments and private entities for non-trade purposes, and can be used for purposes concerning access to or supply of patented medicines.[267]

Firstly, following the plain language of the Article, the term of "public non-commercial use" requires no prior negotiation except a prompt notification to right holder. This is consistent with similar provisions concerning compulsory licences granted under the under the justification of "national emergency" or "extreme urgency". Because a licence can be issued without, prior negotiation it is a "sensitive" issue for patent holders and indeed for those s countries which have adopted or promote strict patent systems.[268] The meaning of this term is not defined by TRIPS and WTO jurisprudence and so interpretation may need to resort to other sources, including the contextual material or even the *travaux préparatoires*.

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[265] See Part Two.Chapter 4.III. It discusses evolutionary interpretation of TRIPS.

[266] See Daya Shanker, 'Korea, Pharmaceutical Industry and Non-commercial Use of Compulsory Licenses' <SSRN: http://ssrn.com/abstract=438880>, the author introduced that Gorlin had this opinion.

[267] See Ibid.

[268] See Ibid.

The meaning of "public" can refer to "pertaining to the people of a country or locality" or "the well-being of the community".[269] The dictionary meaning of "commercial" is "of or relating to commerce or trade" or "viewed as a matter of profit and loss".[270] In other words, it describes a product that can be bought by or is intended to be bought by the general public or it can be made, done or operated primarily for profit. In this sense, the plain meaning of the "public non-commercial use" could be the use of the patent for a non-profitable purpose or the use by government without an intention to sell to the people in general for profit. However, the use is only limited to government or can be applied to other institutions are still not clear. The plain meaning may not lead to a proper understanding on this term, and it needs to consider the contextual material.

The object and purpose of the Agreement should be considered. As discussed above, the object and purpose of the TRIPS is to strike a balance between trade and intellectual property protection, and between the protection of private rights and the public interest.[271] In the light of the object and purpose of TRIPS the public interest should be given due consideration for the interpretation of "public non-commercial use". The further reference to the Doha Declaration shows that paragraph 5(b) gives freedom to members to determine the grounds to issue compulsory licences, and "should not prevent members from taking measures to protect public health".[272] Public health is a major public interest concern, and the interpretation of the term "public non-commercial use" can refer to the use for public interest purposes, including the public interest in health. Despite the apparent width of this provision there is a question whether it only refers to epidemic disease or to non-epidemic disease concerns.

Subsequent practice may be referred to as an aid to the interpretation. From November 2006 through February 2007, Thailand has unilaterally declared compulsory licences on the grounds of "public non-commercial use" in relation to three patented drugs.[273] These include two anti-retroviral drugs and one drug for the treatment of coronary disease: "(i) Stocrin, a first-line anti-retroviral used in treating HIV/AIDS; (ii) Kaletra, a second-line anti-retroviral also used to treat HIV/AIDS; and (iii) Plavix, a platelet

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[269] *The Shorter Oxford Dictionary* Volume II, 1613–4.

[270] *The Shorter Oxford Dictionary* Volume I, 349.

[271] See Part Two.Chapter 5.II.

[272] See *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) paragraph 4 and 5(b).

[273] See Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 *J Int'l Econ L* 921, 952–3.

anti-aggregate that reduces the risk of clot formation."[274] While the third was not used directly to ameliorate an epidemic, the Thai authority stressed that all three licences were granted to be used for public health sector purposes instead of uses within the "private" commercial pharmaceuticals market being sold at patentee's prices.[275] This shows that the "public non-commercial use" can not only be used to respond to an epidemic disease but it can be used for non-epidemic disease, provided that the purpose is for public health needs, which is a purpose of public interest. In other words, the "public non-commercial use" can be invoked for a public interest purpose, and this is different from the grounds of "national emergency" or "extreme urgency" which usually arise from disastrous situations such as epidemic diseases.

The compulsory licences were issued to the Ministry of Health of Thailand and are clearly used by government instead of private institutions. Abbot Laboratory criticised Thai government practice in issuing these licences on the basis that there was a lack of prior negotiation and was short of adequate remuneration. In fact, Thailand had tried to negotiate with the right holder for 2 years to reach an agreement.[276] However, it has been argued that, based on Doha Declaration, this issuance did not require a prior negotiation and was not limited to an emergency situation.[277] It is further argued that the low remuneration could be appealed under Thai law and that the practice was procedurally lawful.[278] This case shows that the "public non-commercial use" justification can be used for many purposes, provided that it is for public interest, and that it requires no prior negotiation, and that the amount of reasonable remuneration is left open for each country to decide.

A submission by the Advisory Council on Intellectual Property of the Australia Government proposed that the "'public non-commercial use' can

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[274] On November 29, 2006, Thailand government issued compulsory license on three AIDS related drugs, and it aroused reactions from pharmaceutical companies. For this information, it is available at <http://spicyipindia.blogspot.com/2007/04/patents-and-public-interest-musings.html>. This can be found at the Ministry of Public Health and National Health Security Office, Thailand, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, February 2007, ISBN 978-974-94591-5-7.

[275] This can be found at the Ministry of Public Health and National Health Security Office, Thailand, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, February 2007, ISBN 978-974-94591-5-7.

[276] Available at <http://www.ip-watch.org/weblog/index.php?p=538>.

[277] See Robert Weissman, 'Clarifications on Thai Compulsory Licensing' available at <http://www.essentialaction.org/access/index.php?/archives/56-Clarifications-on-Thai-Compulsory-Licensing.html>.

[278] See Sean Flynn, 'Thai Law on Compulsory Licenses' available at <http://lists.essential.org/pipermail/ip-health/2006-December/010326.html>.

only be available for crown entities operating solely in the public interest and should not be available to hybrid public/private organisations that predominantly operate for profit."[279] However, the author is of the opinion that this limitation is based on the express language contained in Australia and United States Free Trade Agreement rather than on TRIPS.[280] In general, it seems that the "use" is limited to governmental use, and it should not include private parties.[281] Considering the language of "In the case of public non-commercial use, where the government or contractor" used in Article 31(b) it is argued that this means that the "use" can be conducted by "the government authorizing a government department to exploit by itself or through a contractor".[282]

These various understandings concerning the limits of "public non-commercial use" suggests some ambiguity in the treaty language, but interpretation shows that the permitted use of the patent is use by government for public interest purposes and for non-profitable purposes. Although one single country's practice can not constitute national practice, this practice, at least, indicates an attitude towards public non-commercial use.

The preparatory works should also be referred to. The Brussels Draft for the first time introduced the term of "public non-commercial use" and it provides[283]

> Notwithstanding the provision of subparagraphs (a)-(k) above, where such use is made for public non-commercial purposes by the government or by any third party authorized by the government, PARTIES are not obliged to apply the conditions set forth in sub-paragraphs […] above in such cases…

Before this, the Draft of July 23, 1990 did not adopt similar texts.[284] The specific limitation to "government" in the Brussels Draft has become one of the

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[279] ACIP, 'Review of Crown Use of Provisions for Patents and Designs' (November 2005) available at <http://www.acip.gov.au/library/review_of_Crown_Use_provisions.pdf>.

[280] *United States-Australia Free Trade Agreement* (18 May 2004) 43 ILM 1248, art 17.9.7.

[281] But see Shanker, above n. 266. The author argues that private parties should be included under the "public non-commercial use".

[282] Correa, above n. 12, 316. The WTO website offers explanatory notes relating to Compulsory Licensing for Pharmaceutical and TRIPS, which point out that, "…this is where the confusion about emergencies arises. For "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try first for a voluntary licence…" It uses "government use" to explain "public non-commercial use", and it seems to be a general understanding. Available at: <http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm>.

[283] See *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, GATT Doc MTN.TNC/W/35/Rev.1 (3 December 1990).

[284] *Communication from Peru*, GATT Doc MTN.TNC/W/76 (7 May 1991). It provides "1.A2.2.c Where the exploitation of the patented invention is required by reason of an

bases for arguments by a commentator to confine the definition of this term to the limited scope of "government".[285] However a critical response argues the view or views of one or two countries or companies during the negotiation can not constitute *travaux préparatoires*.[286]

In summary, the interpretation of "public non-commercial use" shows that such permitted use is not for profitable purposes and should be for public interest purposes, including for the purposes of treatment of epidemic disease or other diseases causing a health crisis. This seems to be only used by government, and the remuneration of the patentee is left open for each member to decide. Public interest is left open for each country to define and because public health can be a public interest concern, the use of a pharmaceutical patent for non-commercial use by government should be regarded as a "public non-commercial use".

### 4. *Scope and Duration*

Paragraph (c) requires a limitation on the scope and duration of a compulsory licence to the extent necessary to meet the purpose for which it was authorised. This shows the temporary nature and proportionality requirements of a compulsory licence system.[287] Article 31 (c) specifically refers to a limit upon duration of compulsory licensing in relation to semi-conductor technology. In this field of technology a compulsory licence can only be granted for public non-commercial use or to remedy an anti-competitive practice after due process. It seems that a compulsory licence cannot be so readily or flexibly granted in relation to semi-conductor technology as may be justified in the case of pharmaceutical technology, and this shows a constraints on "any" area of compulsory licence.[288] On the other hand, as analysed above, it also indicates that "public non-commercial use" can be used to cover a broader area than the grounds of "national emergency" or "extreme urgency".

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overriding public interest, the possibility of exploitation of the patented invention by the government, or by third persons authorized by it."

[285] See Shanker, above n. 266; the author refers to Gorlin's view.

[286] See Ibid.

[287] Gervais, above n. 3, 251, and Art 31.(c) of TRIPS provides, "the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive."

[288] Gervais, above n. 3, 251.

(a) *Duration – Temporary*

Because a compulsory licence should be limited to a duration necessary to respond to the purpose for which it was authorised it is necessary to consider the purposes that may justify a grant of compulsory licence and the scope of that purpose or purposes. Patent protection is based on a balance between public interest and private right, but the balance is a dynamic one that must respond to the ever-changing situation.[289] The issuance of a compulsory licence is a tool to meet the purposes prescribed in Article 31, and as result of the compulsory licence, a dynamic balance between the protection of public interest and private rights should be struck. This suggests that, once the purpose can be fulfilled, the balance should be tipped to ensure a new balance in it. It is, therefore, necessary to refer to other paragraphs of Article 31 to clarify the meaning of the duration constraints. Paragraph (g) is relevant and provides that when the circumstances that led to the grant of a compulsory licence cease and are unlikely to recur, the authorisation to use should come to an end while providing protection for the licensee. According to the duration requirement, a compulsory licence for "national emergency" or "extreme urgency" shall be terminated when the invoked situation has ceased to exist and ceased to be a threat.[290]

Where the "national emergency" or "extreme urgency" lasts only for certain period of time, the temporal limits on a compulsory licence may well be sufficient to meet the temporary nature of the situation. At the same time, paragraph (g) provides protection for the legitimate interests of the compulsory licensee, particularly recognising the legitimate interests that flow from reasonable investment and recognising the right to dispose of excess products.[291] Paragraph (g) also includes a mechanism of administrative review to ensure a reasonable assessment of whether the circumstances that justify the grant of a compulsory licence still continue to exist. The provision of the protection of legitimate interests and the review mechanism ensures the legality and proportionality of the compulsory licensing mechanism.

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[289] See Kelley A. Friedgen, 'Rethinking the Struggle between Health & Intellectual Property: A Proposed Framework for Dynamic, rather than Absolute, Patent Protection of Essential Medicines' (2002) 16 *Emory Int'l L Rev* 689; 717–24, and 736. The author discussed a framework to balance national and international interests in health and property, and concluded that not all public health challenges were the same and not everyone would benefit from the same treatment, and at the same time, also provided the potential to reflect on long-range as well as short-term goals and illustrated situations where patent recognition could be leveraged towards public-health minded aims, such as the promotion of research and development regarding endemic diseases.

[290] See para. (g) of art 31 of TRIPS.

[291] Gervais, above n. 3, 251.

(b) *Scope – Proportional*

The scope of compulsory licensing requires a consideration of the purpose of the compulsory licence. This may indicate that only certain claims of a patent can be available under compulsory licensing.[292] The proportional requirements set a limitation on the compulsory licence. However, members are free to establish the grounds required to grant compulsory licences, and this freedom can enable the achievement of the desired aim of compulsory licensing.[293]

5. *Domestic Supply and the Paragraph 6 Problem*[294]

Paragraph (f) of the Article 31 provides

> any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(a) *The Problem*

Paragraph (f) provides that the supply of the products under a compulsory licence should be mainly used for domestic market of the granting country. Export of goods produced under a compulsory licence is permitted only on the condition that the non-predominant part is exported.[295] The textual interpretation of this provision will mean that a country which manufactures patented product under compulsory licence can only mainly supply the manufactured products within the granting country itself. This provision becomes problematic when the meaning of domestic supply is not clear and it may become a major obstacle to providing access to medicines.[296] Therefore, the meaning of this provision has also become a pivotal point in the understanding of the promotion of the right to health under TRIPS.

The provision of access to medicines requires that medicines are available and affordable. A compulsory licence is a tool used to promote access to affordable medicines in those countries that are in the need of the medicines for justified grounds. However some countries have no manufacturing

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[292] Gervais, above n. 3, 251.

[293] Watal, above n. 91, 324.

[294] Paragraph 6 refers to "paragraph 6" of the Doha Declaration. It provides: "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002".

[295] Gervais, above n. 3, 252.

[296] For example, see Jonathan Michael Berger, 'Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity' (2002) 17 *Conn J Int'l L* 157, 207–11.

capacity to produce the medicine in any event. In such cases the grant of a compulsory licence to manufacture a patented medicine to supply the market, will not be of any use. Such a situation presents a major problem in providing access to medicines.[297] One solution is through import from a country in which the desired medicines are manufactured under a compulsory licence but paragraph (f) requires that the compulsory licence must be used to predominantly supply the domestic and not the export market. It is not clear whether the word "predominantly" refers to a requirement that the major part of the production should be intended for supply of the domestic market or whether it refers to a situation where a granting member takes the greatest share of supply as among those Members receiving supplies.[298] According to Abbott this stipulation of predominant supply of the domestic market imposes two inter-linked problems. The first is that it limits countries without manufacturing capacity with a restriction on the availability of export drugs. The second is that it limits the flexibility of countries to authorise compulsory licensing with restrictions on the predominant part of their production to the domestic market to exploit economies of scale.[299] With these restrictions it seems that the mechanism of compulsory licensing will not provide a solution to remedy the inadequate supply of affordable medicine in countries which lack manufacturing capacity.

Recognising this problem, the Doha Ministerial Conference addressed this matter, in the Doha Declaration in paragraph 6

> We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

With the entrenchment of this concern the Doha Declaration initiated a process to address the problem of countries that lack manufacturing capacity, and this clarification will assist interpretation of TRIPS provisions in a manner that is supportive of the right to health. In 2003, the TRIPS Council made a Decision to handle such issue.[300] In 2005 during the Ministerial meeting

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[297] For example, see Abbott, above n. 86, 25.

[298] Ibid., 26. The author points out two situations: One is that more than 50% of the production by a compulsory licensee should be intended for supply of the domestic market of the Member granting the license; the other one is that the granting Member only receives a major part of the supply (40%), but other three Members each may receive 20% of the supply.

[299] Abbott, above n. 86, 26.

[300] *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003).

in Hong Kong, a Ministerial Declaration was made for the amendment of Article 31[301]

> We reaffirm the importance we attach to the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and to an amendment to the TRIPS Agreement replacing its provisions. In this regard, we welcome the work that has taken place in the Council for TRIPS and the Decision of the General Council of 6 December 2005 on an Amendment of the TRIPS Agreement.

It follows with the introduction of Article 31*bis* in the 2005 Decision, although such Decision was extended for acceptance by members until the end of 2009.[302] However, any solution to this problem will raise legal issues, economic concerns and practical issues.

(i) Legal Issues

The requirement of predominant supply to the local market (see above) impacts upon the flexibility to use compulsory licences to permit export to assist access to medicines and this issue attracted discussion among the members of WTO. The first step in seeking to identify this issue and to work toward a solution to this problem is to find a legal basis for the solution. With the guidance of the Doha Declaration, the TRIPS Council was required to find a solution to report to the General Council at the end of 2002. There was a process of discussion of possible solutions to this problem among the developing countries group and the developed countries group, including discussions of an Article 30 based solution and an Article 31 based solution.[303] This involved discussions on a requirement of an authoritative interpretation of Article 30 and an amendment to Article 31(f). In addition, an analysis of the relationship between Article 30 and Article 31 is needed, since footnote 7 to Article 31 explicitly states that "other use" refers to use other than that allowed under Article 30. As discussed above, the legal basis for the invocation of Article 31 to use the patent without the authorisation of patent holder also needs to be examined to determine whether such a use is allowable under Article 30.[304] Paragraph 6 of the Doha Declaration indicated a need for a solution to this problem and also set a timeline for resolution.

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[301] *Hong Kong WTO Ministerial Declaration*, WTO Doc WT/MIN(05)/DEC (22 December 2005) para. 40.

[302] See *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005); also see *Amendment of the TRIPS Agreement – Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/711 (21 December 2007).

[303] For an introduction of all the discussions on the solution, see Gamharter, above n. 3, 171–80.

[304] Ibid., 176.

Apart from this legal basis for an analysis of TRIPS provisions to be public health supportive a legal mechanism is required in the interpretation or implementation of Article 31. According to Article IX(2) of the WTO Agreement, an authoritative interpretation of TRIPS provisions can only be achieved through the Ministerial Conference or the General Council.[305] Article IX(1) (3) and (4) of the WTO Agreement prescribes the waiver situation decided by the Ministerial Conference, and Article IV(2) of WTO Agreement establishes the function of the General Council during the intervals between meetings of the Ministerial Conference.[306] If there is to be a waiver under Article 31(f), it must be subject to the administrative procedure of the WTO.

(ii) Economic Scale Concern

During the discussion the issue on how to enhance the economies of scale was also raised. The African group made a proposal with regard to the meaning of "domestic market" as used in Article 31(f).[307] The submission suggested that "domestic market" should be understood to mean, under certain circumstances, the combined markets of Members that had formed or were in the process of forming a customs union or a free trade area.[308] This would support the supply of the needed product in a situation where, if the market of an importing country is very small so as to make the manufacturing of the product uneconomic, the supply to the whole customs union or free trade area can help to achieve economically viable production to facilitate the access to medicines within the whole region. It was argued that the members under a regional arrangement should be able to benefit under one compulsory licence.[309] According to Article XXIV of GATT 1994, the members of WTO are free to enter into regional and bilateral agreements.[310] This implies that a free trade region or customs union should be treated as one domestic market, and this depends upon a further clarification on the concept of "domestic market".

(iii) Practical Issues

Importing country – The importing country, or the beneficiary country, can face some problematic issues in the actual implementation of Article 31(f).

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[305] See art IX(2) of *Marrakesh Agreement*.

[306] See art IX(1) (3) (4) and art IV(2) of *Marrakesh Agreement*.

[307] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Joint Communication from the African Group in the WTO*, WTO Doc IP/C/W/351 (Geneva, 24 June 2002) para. 6(d).

[308] Ibid.

[309] Ibid.

[310] See art XXIV of GATT 1994.

This will arouse a discussion about whether the importing countries should focus on the solution for developing countries and least developed countries,[311] or should encompass any country which is in the need of the product,[312] or should include countries that require a case-by-case examination.[313] The scope of the importing country requires further clarification.

Exporting country – The exporting country, or the supplying country, should be confined to be eligible country. It still raises the argument whether it should be limited only to developing countries or least-developed countries[314] or should also include developed countries.[315] This requires a further clarification.

Scope of disease – Article 31(f) deals with the conditions for the grant of a valid compulsory licence, but paragraph 6 of Doha Declaration specifically tries to find a solution to the public health issue. In this sense, the solution is targeted to health related products, so the scope of diseases to be covered under this provision needs clarification. The developing countries adopt a more extensive view using differing bases for arguing for the scope of exceptions. They suggest differing considerations ranging from referring to the disease in case a country has sufficient manufacturing capacity or a lack of manufacturing capacity[316] to those diseases which are "public health" relevant

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[311] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Joint Communication from the African Group in the WTO*, WTO Doc IP/C/W/351 (Geneva, 24 June 2002) para. 6(a); *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Communication from the United Arab Emirates*, WTO Doc IP/C/W/354 (Geneva, 24 June 2002) paras. 10–1; *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc IP/C/W/355 (Geneva, 24 June 2002) para. 4.

[312] See *Communication from the United Arab Emirates*, WTO Doc IP/C/W/399 (Geneva, 4 March 2003) footnote 3; the EC pointed out that "any country may find itself in the position of being unable to manufacture a particular treatment and having to seek supplies abroad" and cited the prior anthrax crisis in North America as a case in point; but it was sharply rejected by the US.

[313] See *Minutes of Meeting*, WTO Doc IP/C/M/36 (Geneva, 25–27 June 2002) para. 102; and *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002) para. 14.

[314] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Second Communication from the United States*, WTO Doc IP/C/W/358 (Geneva, 9 July 2002) para. 15; also see statement of the US, *Minutes of Meeting*, WTO Doc IP/C/M/36 (Geneva, 25–27 June 2002) para. 137.

[315] See statement of Brazil, *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002) para. 10; statement of Norway WTO TRIPS Council, *Minutes of Meeting*, WTO Doc IP/C/M/36 (Geneva, 25–27 June 2002) para. 35 and para. 173.

[316] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Joint Communication from the African Group in the WTO*, WTO Doc IP/C/W/351 (Geneva, 24 June 2002).

in light of the entire Doha Declaration.[317] However, the developed countries adopted a more restrictive view ranging from a support of paragraph 1 of the Doha Declaration[318] to an argument that the provision should be restricted to the three diseases, HIV/AIDS, malaria and tuberculosis, explicitly mentioned in the Doha Declaration.[319]

Scope of products – The scope of products discussion involves the question of whether the exceptions provided by the Declaration and the Decision includes medicines, related processes,[320] active ingredients,[321] diagnostic kits,[322] and related technical equipment[323] or whether they are only confined to patented pharmaceuticals.[324]

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[317] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Communication from the United Arab Emirates*, WTO Doc IP/C/W/354 (Geneva, 24 June 2002) para. 6; *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc IP/C/W/355 (Geneva, 24 June 2002) para. 2.

[318] See *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health Communication from the European Communities and their Member States*, WTO Doc IP/C/W/352 (Geneva, 20 June 2002) para. 11; *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002); statement of Canada; para. 32 statement of Korea; para. 42 statement of New Zealand.

[319] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Communication from the United States*, WTO Doc IP/C/W/340 (Geneva, 14 March 2002); and *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Second Communication from the United States*, WTO Doc IP/C/W/358 (Geneva, 9 July 2002) para. 11.

[320] See statement of Hungary, *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002) para. 37; statement of Indonesia, *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002) para. 39 and WTO TRIPS Council *Elements of a Paragraph 6 Solution Communication from Kenya, the Coordinator of the African Group* (IP/C/W/389, Geneva, 14 November 2002) para. 5.

[321] See *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002) para. 32 statement of Korea; para. 3 statement of Hungary; para. 49 statement of Philippines; and *Elements of a Paragraph 6 Solution Communication from Kenya, the Coordinator of the African Group*, WTO Doc IP/C/W/389 (14 November 2002) para. 5.

[322] See *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002), statement of Egypt para. 28; statement of Korea para. 32; statement of Hungary para. 37; statement of Hong Kong, China para. 41; statement of Philippines para. 49 and *Elements of a Paragraph 6 Solution Communication from Kenya, the Coordinator of the African Group*, WTO Doc IP/C/W/389 (14 November 2002) para. 5.

[323] See statement of Egypt, *Minutes of Meeting*, WTO Doc IP/C/M/37 (Geneva, 11 October 2002) para. 28.

[324] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Second Communication from the United States*, WTO Doc IP/C/W/358 (Geneva, 9 July 2002) para. 16.

Diversion – The diversion issue was discussed and safeguard measures were required in the solution to the problem. On one side there was the concern of some developed countries that the export of such product under compulsory licence will be diverted for one reason or another to other markets instead of the targeted market and cause a detrimental effect on brand name products.[325] On the other side developing countries were cautioned with the further burdens imposed upon them.[326] At the same time, developed countries and the developing and least-developed countries disagreed about who had the burden of responsibility for enforcement of safeguards to prevent product diversion with former emphasising the responsibility of all members[327] and the latter proposing the responsibility of interested parties.[328]

In addition to the above mentioned problems, the issue of manufacturing capacity was also discussed.

(b) *Subsequent Agreement*

Paragraph 6 of Doha Declaration recognises and seeks to address a concern regarding the problem of those countries with insufficient or no manufacturing capacity, and, with the timeline set in the Doha Declaration, the Council for TRIPS was instructed "to find an expeditious solution to this problem."[329] It was not until after the timeline that a decision was made under the name of the General Council on 30 August, 2003. The title of the decision is "Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health" (the 2003 Decision) followed by the 2005 Decision on the Amendment of the TRIPS Agreement (the 2005 Decision).

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[325] See *Communication from the United Arab Emirates*, WTO Doc IP/C/W/399 (Geneva, 4 March 2003) para. 19; *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Communication from the United States*, WTO Doc IP/C/W/340 (Geneva, 14 March 2002) paras. 3–4.

[326] See statement of Zimbabwe, *Minutes of Meeting*, WTO Doc IP/C/M/35 (Geneva, 22 March 2002) para. 88; Also see statement of Hungary WTO TRIPS Council, *Minutes of Meeting*, WTO Doc IP/C/M/36 (Geneva, 25–27 June 2002) para. 67.

[327] See *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Joint Communication from the African Group in the WTO*, WTO Doc IP/C/W/351 (Geneva, 24 June 2002) para. 14; *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Second Communication from the United States*, WTO Doc IP/C/W/358 (Geneva, 9 July 2002) para. 28.

[328] See *Review of Legislation Responses from Barbados to questions posed by Canada*, WTO Doc IP/C/W/325 (Geneva, 21 November 2001) para. 14.

[329] See *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 6.

(i) Legal Value and Objective of the 2003 Decision and 2005 Decision

The preamble of the 2003 Decision provides

> Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");
> Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement provide for waiver decision-making procedures made by the Ministerial Conference[330] and paragraph 2 of Article IV of WTO Agreement provides the General Council with the power of in the process of decision-making.[331] When made under the name of the General Council, the Decision takes effect as a waiver to deal with the problem presented in the paragraph 6 of the Doha Declaration. Such a decision should constitute another subsequent agreement of the members on the issue, and the interpretation of the TRIPS needs to refer to the Decision in the consideration of the problems presented.

However, it has been argued that the waiver decision made by the General Council is of only a temporary nature in order to respond to exceptional circumstances and so it can not overcome the difficulties in lack of manufacturing capacity entirely.[332] The language used in the preamble may not be strong or explicit enough to support a full solution to the problems in TRIPS, but the language used in the paragraph 7 may better serve this purpose by enhancing the desirability of promoting the transfer of technology and capacity building in all sectors including the pharmaceutical sector.[333] This enhancing language illuminates the purpose of the TRIPS and counters the weakness of language in relation to waiver.

Furthermore, this waiver mechanism, although it is of a temporary nature, is, de facto, permanent effective when considered with the explicit language in paragraph 11 of the Decision. Paragraph 11 has negated the "temporary" problem by extending the effectiveness of the Decision to an amendment made by the members. The WTO Agreement does not provide for such a "waiver leading to an amendment" mechanism expressly, but it still remains consistent with the WTO arrangement because the WTO also does not prevent members from using a combination of expressly prescribed legal

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[330] Art IX(3) of *Marrakesh Agreement*.

[331] Paragraph 2 of Art IV of *Marrakesh Agreement*.

[332] See P. Vandoren and J. C. Van Eeckhaute, 'The WTO Decision on Paragraph 6 of the Doha Declaration on TRIPS and Public Health: Making it Work' (2003) Vol. 6 No. 6 *Journal of World Intellectual Property* 779, 782–3.

[333] *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 7.

mechanisms to achieve their objectives.[334] The express language should also reveal the intentions of the members to deal with the problems, and the interpretation of the provision needs to take this objective into consideration.

In addition, this waiver mechanism is further safeguarded with an express exclusion, contained in the paragraph 10 of the 2003 Decision, of the challenges under Article XXIII.1(b) and (c) of GATT.[335] This mechanism arrangement, Article XXIII of GATT, which deals with non-violation issues, has been excluded from invocation in case of any conflict with TRIPS provisions and subsequent development and the WTO covered agreement.[336] This clarification, on one side, promotes the consistency of the WTO covered agreement during the interpretation of TRIPS provision. On the other side, this clarification further elucidates the intention of members and the objective of the Decision in the promotion of the access to medicines, and provides guidance on the interpretation of TRIPS provisions.

On 6 December 2005, the WTO General Council approved changes to TRIPS to make permanent decisions on this issue originating from the 2003 Decision. This forms the basis of the first Amendment of one of the core agreements of WTO covered agreements.[337] The proposed amendment is made up of 5 main parts, and they are: Decision of Amendment of TRIPS Agreement made by the General Council, Protocol Amending TRIPS, Annex to the Protocol Amending TRIPS, Annex to TRIPS and Appendix to the Annex to TRIPS. Article 31*bis* has 5 paragraphs, and it has mainly adopted the content from the 2003 Decision.[338] The first paragraph legalises the status of an exporting member under compulsory licensing to state that the production of pharmaceutical products and its export to an eligible importing members in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.[339] Paragraph 2 further clarifies the remuneration issue to allow the exporting country to get a waiver for paying remuneration when the remuneration for the same product has been paid in the importing country.[340] Paragraph 3 adopts the same language as paragraph 6(i) of the 2003

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[334] Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and The Protection of Public Health' (2005) 99 *Am J Int'l L* 317, 347.

[335] *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 10.

[336] Art XXIII.1 of GATT.

[337] See *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005); And see WTO 2005 press release, 'Members Ok Amendment to make Health Flexibility Permanent' (6 December 2005) Press/426.

[338] Paragraph 40 of the *Hong Kong Ministerial Declaration* reaffirmed the importance of the 2003 Decision and the proposed amendment in 2005. *Hong Kong WTO Ministerial Declaration*, WTO Doc WT/MIN(05)/DEC (22 December 2005).

[339] Art 31*bis*.1.

[340] Art 31*bis*.2.

Decision, and gives special attention to the least developed countries. Paragraph 4 is the same as paragraph 10 of the 2003 Decision.[341] Paragraph 5 is the same as paragraph 9 of the 2003 Decision,[342] and it shows that Article 31(f) and (h) need to be understood in accordance with the Decision. Then there is an Annex to clarify such issues as "pharmaceutical product" (1(a) of 2003 Decision), "eligible importing members" (1(b) of 2003 Decision), "exporting member" (1(c) of 2003 Decision) and the labelling process. There is an Appendix to the Annex to give further guidance on the "Assessment of Manufacturing Capacities in the Pharmaceutical Sector".

The 2005 Decision of the proposed amendment has adopted the paragraphs provided in the 2003 Decision and this adoption shows the intention of the members to address the health situation.[343] The 2005 Decision made by the General Council also noted the Doha Declaration and the issues of paragraph 6 and reiterated recognition of the problem of seeking supply of affordable medicines for the eligible importing members.[344] This statement indicates the object and purpose of the 2005 Decision.

The amendment is open for acceptance by members until 1 December 2007 and shall enter into force until acceptance by two thirds of members.[345] It has still been extended for acceptance by members until the end of 2009[346]

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[341] Art 31*bis*.4.

[342] Art 31*bis*.5.

[343] See *Implementation of Paragraph 11 of 2003 Decision*, WTO Doc IP/C/41 (6 December 2005).

[344] *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005) preamble.

[345] To date of writing, the following members have accepted the amendment: United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Rep. of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007), Israel (10 August 2007), Japan (31 August 2007), Australia (12 September 2007), Singapore (28 September 2007), Hong Kong, China (27 November 2007), China (28 November 2007), European Union (30 November 2007), Mauritius (16 April 2008), Egypt (18 April 2008), Mexico (23 May 2008), Jordan (6 August 2008), Brazil (13 November 2008), Morocco (2 December 2008), Albania (28 January 2009), Macau, China (16 June 2009), Canada (16 June 2009), Bahrain (4 August 2009), Colombia (7 August 2009), Zambia (10 August 2009), Nicaragua (25 January 2010), Pakistan (8 February 2010), Former Yugoslav Republic of Macedonia (16 March 2010), Uganda (12 July 2010), Mongolia (17 September 2010), Croatia (6 December 2010), Senegal (18 January 2011), Bangladesh (15 March 2011) <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm>.

[346] See *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005); also see *Amendment of the TRIPS Agreement – Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/711 (21 December 2007); "The period for acceptances by Members of the Protocol Amending the TRIPS Agreement referred to in paragraph 2 of the Decision and paragraph 3 of the Protocol shall be

for the first time and to 31 December 2011[347] for the second time. The final acceptance of the proposed amendment is still pending, but the amendment procedure has disclosed the intention of the members, which can enlighten the interpretation of the provisions.

(ii) Clarification of Practical Issues

Both the 2003 Decision and the 2005 Decision have elucidated the objective of the Doha Declaration, and the paragraph 6 problem contained in the Doha Declaration has been clarified in the 2003 Decision and has been reaffirmed in the 2005 Decision.

Scope of products and diseases – Paragraph 1 provides an understanding on the scope of products and diseases for the purpose of the Decision. Paragraph 1(a) of the Decision expressly defines "pharmaceutical product" as any patented product, product manufactured through a patented process, active ingredients and diagnostic kits.[348] One argument is made that vaccines and related technical equipment can be regarded as a form of "pharmaceutical product" and so they can be implicitly included.[349] Considering the object and purpose of the Decision and the balance sought to be struck in TRIPS and the open-ended language of "pharmaceutical product", these should be included as eligible product if they assist the solution of the health problem.

In addition, paragraph 1(a) of the Decision refers to directly to paragraph 1 of the Doha Declaration,[350] and this reference has clarified the scope of diseases. Paragraph 1 of the Doha Declaration refers to "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". This reference taken from the Doha Declaration is non-exhaustive with a focus on the 3 mentioned epidemics. Furthermore, because paragraph 1(a) of the Decision serves the purpose of the Decision,[351] the interpretation of the

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extended until 31 December 2009 or such later date as may be decided by the Ministerial Conference."

[347] See *Amendment of the TRIPS Agreement – Second Extensions of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/785 (17 December 2009).

[348] *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 1(a).

[349] See Vandoren and Eeckhaute, above n. 332, 784.

[350] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 1. It provides: "We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

[351] Paragraph 1(a) of the Decision.

compulsory licensing provisions should be understood as dealing with any disease which brings a public health problem.[352] However, with the emphasis on the problem of developing and least-developed countries in paragraph 1 of the Doha Declaration whether the scope is sufficiently wide to also deal with the problem in developed countries or not will require further consideration during the interpretation. However, referring to paragraph 4 of the Doha Declaration, the interpreter can find that the TRIPS should be interpreted in a manner to support all WTO members' right to protect public health and to promote the access to medicines for all.[353] Given this perspective, the scope should cover the diseases within developed countries.

Eligible importing countries – Paragraph 1(b) provides 2 footnotes to give a further clarification of what is included within the eligible importing countries.[354] This paragraph first affirms the automatic eligibility of least-developed countries, and also confirms that other countries are eligible upon giving notification to the TRIPS Council. The footnote further clarifies that such a notification does not require an approval by a WTO body.[355] This clarification can expedite the process of the issuance of a compulsory licence and counters the concerns that the notification to lead to other WTO members seeking a rebuttal.[356] At the same time, this paragraph confirms that the use of the system "in whole or in a limited way" by any country is not only limited to "emergencies or circumstances of extreme urgency".[357] This freedom in the use of the system can promote the facilitation of access to medicines.

Interestingly, 22 developed countries voluntarily chose not to use the system and some other countries chose only to use the system under situations of "national emergency or other circumstances of extreme urgency".[358] This

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[352] See Gamharter, above n. 3, 210–1.

[353] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 4. It provides: "We agree that TRIPS does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to TRIPS, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

[354] *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 1(b).

[355] Footnote 2 provides, "It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision."

[356] Gamharter, above n. 3, 213.

[357] See *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 1(b).

[358] Footnote 3 provides the countries that voluntarily chose not to use the system, "Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America."

voluntary choice not to use the system will not hamper the interpretation of the provision in a public health supportive manner, since the free contracting out of the members will not cause any conflict with obligations under TRIPS and its subsequent development.

Eligible exporting countries – In order to overcome the predominant supply difficulty paragraph 1(c) makes clear that any WTO member can act as an exporter under the system.[359] This means that not only developing and least-developed countries, but also developed countries are eligible to export, if they have manufacturing capacity.

Paragraph 2 explicitly provides a waiver of the obligation of an exporting member under Article 31(f) of TRIPS regarding predominant domestic supply.[360] The same paragraph requires a purpose consideration to exporting under the compulsory licensing system, and these purpose requirements indicate that this Decision can meet the purpose of health problems.[361] During the interpretation of this provision, the health purpose should be given due consideration when a waiver of exporting countries is given.

Diversion – The problem of the possibility that pharmaceuticals manufactured and exported to assist the needs of an eligible importing country being diverted onto the market of a country which is not an eligible importing country to the detriment of the economic interests of the patent owner is dealt with in the Decision with a list of measures, including a notification measure and a marking measure. According to the Decision both the eligible importing countries and eligible exporting countries are obliged to meet certain conditions in use of this flexibility. The eligible member is obliged to give a notification to specify the names and expected quantities of the products.[362] This information also needs to be made publicly as shown in footnote 5.[363] The eligible exporting country is obliged to identify the products with specific labelling or marking and to publicise the information.[364] These are safeguard measures, and intended to limit the availability of the products to the extent necessary to meet the purpose. The interpretation of the provision should follow this clarification, but still needs to give due consideration of the limiting purpose in case of expansive interpretation.

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[359] *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) para. 1(c).
[360] Ibid., para. 2.
[361] Ibid., preamble.
[362] Ibid., para. 2(a)(i).
[363] Ibid., footnote 5. It provides: "The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision."
[364] Ibid., para. 2(b).

Economic scale – Paragraph 6 of the 2003 Decision provides:

> 6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:
>
> (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of TRIPS shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;
>
> (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of TRIPS, including in conjunction with other relevant intergovernmental organizations.

This paragraph of the Decision establishes that a developing country or least-developed country which is a party to a regional trade agreement can be the subject of a waiver from the obligation under Article 31(f) to enable a pharmaceutical product produced or imported under a compulsory licence in the member country to be exported to the markets of other developing countries. Coupled with the "enabling clause" of Article XXIV of GATT this provision facilitates a regional member to obtain access to medicines more easily. Nonetheless if there is patent for the pharmaceutical the subject of the waiver in the importing country the importing country still has to grant a compulsory licence in order to respond to the territoriality requirement of patent protection.

(c) *Subsequent Practice*

The subsequent practice should also be referred to. Compulsory licences concerning health-related patents have been granted in many countries, ranging from high income countries to middle-income and low-income countries.[365] The high income countries include Canada, the United States, Germany, Italy and Israel. The middle income countries include Malaysia, Indonesia, Korea, South Africa, Brazil and Thailand. The low-income countries include

[365] See <http://www.cptech.org/ip/health/cl/recent-examples.html>.

Cameroon, Ghana, Eritrea, Zambia, Zimbabwe and Mozambique. This is evidence that compulsory licensing has been widely exercised in the international community. These countries used various justifications to issue compulsory licences including an invocation of the "public interest" by Brazil.

The least-developed countries are provided with an exemption from the general requirement to give notice to the TRIPS Council before they import the products under compulsory licence. This can be verified by many examples. Cameroon used the system in January 2005 to import, manufacture or sell HIV/AIDS treatment medicines: Nevirapine, Lamivudine. Ghana used the system on October 26 of 2005 to import generic HIV/AIDS medicines. Eritrea, in June 5 2005, used the system to import generic HIV/AIDS medicines. Zambia used the system in September 21 of 2004 to manufacture lamivudine, stavudine and nevirapine with royalty. Zimbabwe declared an emergency for 6 months to use a compulsory licence to make, use or import generic HIV/AIDS medicines. Rwanda, as a least-developed country, became the first country to inform the WTO of an intention to use the "paragraph 6" system to import generics on 19 July 2007, although it did not have to provide such a notification prior to use.[366]

On 4 October 2007, Canada has become the first exporting country to notify the WTO that it would export generic medicines which to Rwanda under this system.[367]

(d) *Interpretation*

(i) Contextual Interpretation

A purely textual interpretation of Article 31(f) does not provide a sufficiently wide meaning to facilitate enough access to medicines. In order to clarify the meaning of Article 31(f), it is necessary to refer to contextual material, subsequent developments and practices and also the object and purpose of TRIPS.

The Doha Declaration, the 2003 Decision and the 2005 Decision should all be referred to for interpretation of the compulsory licence flexibility contained in Article 31(f). As analysed above, the Doha Declaration is health supportive, and the 2003 Decision and 2005 Decision are specifically intended to deal with Article 31(f) and (h) of TRIPS in the pharmaceutical products

[366] See WTO, available at <http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm>.

[367] See WTO News (4 October 2007), this includes the triple combination AIDS therapy drug, TriAvir available at <http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm>.

sector.[368] Consideration of these documents will help to find the meaning of Article 31(f). The flexibility provided in this Article together with the subsequent development in the Decision and the proposed amendment can meet the object and purpose of TRIPS. The measures taken in the subsequent development adopt a public health supportive perspective to facilitate access to medicines. This meets the object and purpose of the goal in the intellectual property protection to strike a good balance in the protection of the public interest. At the same time other measures which prevent misappropriation of product also meet the object and purpose in the promotion of international trade. In the light of the goal of protection intellectual property, and in the light of the promotion of international trade goal in TRIPS compulsory licensing should be interpreted to promote access to medicines under the justified situations.

Paragraph 9 of 2003 Decision and paragraph 5 of Article 31*bis* show that the interpretation of Article 31(f) needs to be understood "without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31".[369] Therefore, the Article 31(f) should be interpreted with reference to the clarification in the subsequent development. The meaning contained in Article 31(f) should be subject to the change of the definition in accordance with the Decisions, and these Decisions show that they should be health supportive.

The meaning of the phrase "predominantly for the supply of domestic market" should be understood differently after reference to the subsequent development. Where a country lacks manufacturing capacity a supply of the licenced pharmaceuticals should be able to be imported from other countries which can produce generics. The exporting countries should produce the pharmaceuticals for the purposes of public health.

The understanding of "domestic market" can be regarded as having varied from the paragraph 3 of the Article 31*bis*, and now should be understood as a market belonging to the same regional arrangement where "those other developing or least developed country parties to the regional trade agreement that share the health problem in question".[370] This clarification is limited to developing and least developed countries, which are in consistency

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[368] See Part Two.Chapter 5.II.B.

[369] See *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003) preamble and paragraph 9; the Preamble provides: "in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Art 31 of the TRIPS Agreement with respect to pharmaceutical products"; *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005) para. 5 of Art 31*bis*.

[370] *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005), Art 31*bis*; and *2003 Decision*, WTO Doc WT/L/540 and Corr.1 (1 September 2003). para. 6(i).

with the arrangement of the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903).

The definition of the scope of disease and products and the effort in the enhancement of economy scale all disclose the intention of members to facilitate access to medicines in cases of public health problems. At the same time, TRIPS, viewed from the perspective of these subsequent developments, adopts a cautious approach in the adoption of such flexibility in order to protect the normal international trade. The anti diversion measures, including the marking and the notification requirements, also shows that TRIPS tries to protect normal international trade in pharmaceutical products, which is also consistent with the objective to enhance the protection of intellectual property rights during this process.

(ii) Article 6 in the Interpretation

With the clarification of the "eligible importing country", "eligible exporting countries" and "domestic market", Article 31(f) should be understood by reference to the subsequent development. This evolutionary understanding will promote the access to medicines in the countries which lack manufacturing capacity. However, the interpretation of paragraph (f) needs to be understood in line with the interpretation of Article 6 of TRIPS.

The interpretation of Article 6 shows that members of TRIPS are free to determine the nature and meaning of the exhaustion of rights.[371] Paragraph 5(d) of Doha Declaration reiterated specifically that members are free to establish the exhaustion of rights.[372] This interpretation indicates that the specific arrangement under the Article 31(f) will not impair the members' right under TRIPS to allow parallel import. This interpretation of Article 31(f) and its subsequent development together with the understanding of Article 6 of TRIPS, means that the availability of medicines can be achieved in those countries which lack manufacturing capacity.

(iii) WTO Covered Agreement

The interpretation of the Article can also be argued to be consistent with the requirements of GATT. The waiver in the Decision justifies compulsory licensing without violation of Article XXIII of GATT. The enhancement of economy scale issue has also been justified with the express inclusion of the waiver based on Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity

[371] See the interpretation of the art 6, Part Two.Chapter 5.III.C.

[372] See the discussion of this paragraph in Part Two.Chapter 5.III.C.

and Fuller Participation of Developing Countries (L/4903). The GATT approach that would otherwise cause discrimination to the other market can be overcome by special arrangement.

### 6. *Adequate Remuneration*

There is a question whether the requirement for remuneration contained in Article 31 amounted to a breach of human rights requirements, given that the human rights protection for moral and material interest is only applied to individuals as a natural person. Since the human rights instruments do not forbid remuneration to be paid to corporate entities, there is a further question whether these two norms can accumulate in the circumstances where the payment of remuneration will not prevent access to medicines and the patent owner is a corporation.

Article 31(h) provides for adequate remuneration to be paid to the right holder in fair and equitable way by taking the "economic value of the authorization" into account.[373] Both the terms "adequate" and "the economic value of authorization" are open to be interpreted. Generally under this kind of situation, the granting country would be left to decide the payment.[374] When a country needs to import the product from another country and the circumstances do require that remuneration be provided it gives rise to the question of whether the eligible export country should pay or the eligible import country should pay. If the economic situation in the importing country is different from that of the export country the relative economic strength of the two countries should be considered.

Paragraph 3 of the 2003 Decision clarifies this with express language

> Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of TRIPS shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

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[373] Art 31(h) of TRIPS provides, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."

[374] For example, in the Thailand compulsory licensing case, it was claimed that the royalty is too low. But the Thailand government decided the royalty.

Paragraph 2 of Article 31*bis* of the 2005 Decision adopts the same language. In addition, paragraph 9 of 2003 Decision and Paragraph 5 of 2005 Decision provides that the remuneration should be paid only by one country and not by both importing and exporting countries. This is based on the idea that the amount of compensation should be determined in the country of consumption where the patent is effectively exploited and the importing country will usually lack sufficient resources to enable it to make payment.[375] Through this arrangement, a double payment has been avoided.

## E. *Article 30 – Limited Exceptions*

### 1. *Relationship with Articles 27.1, 28 and 31*

To fully understand this Article requires a comparison of the relationship between Article 27.1 and Article 28 of TRIPS. Article 27(1) deals with the non-discrimination requirements of patentable subject matter,[376] and Article 28 deals with the specific rights conferred.[377] Textually, Article 30 deals with exceptions "to the exclusive rights conferred by a patent", so the reading of the "exclusive rights" should align with the reading of Article 27 and Article 28, which would suggest that this Article can not eliminate the availability of patents. In other words, Article 30 can only limit the patent rights which should be or have been granted.[378] From the reading of Article 31, the footnote 7 clarifies the "other use" as referring to "use other than that allowed under Article 30", and such an expression suggests that the exceptions justified under Article 30 should not include the cases of use by governments or by third parties authorised by governments.[379] Thus, it is reasonable to deduce that the exceptions justified under Article 30 should constitute general exceptions in contrast with the special exceptions justified under Article 31.[380] However, footnote 7 does not exclude an exception under Article 30 if a compulsory licence may not be issued within Article 31 rules and procedure.[381]

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[375] See Vandoren and Eeckhaute, above n. 332, 784.
[376] Art 27.1 of TRIPS.
[377] Art 28 of TRIPS.
[378] See also Nowak, above n. 247, 940–2.
[379] See also Abbott, above n. 86.
[380] But see Gamharter, above n. 3, 86–7; the author deems that art 31 is a specific exception to art 30.
[381] Abbott, above n. 86.

Similarly, the Panel, in the case of *Canada-Patent Protection of Pharmaceutical Products*, also discussed the relationship between Article 30 and Article 27.1 and Article 31. The Panel was of the view that Article 30 exceptions are explicitly described as "exceptions to the exclusive rights conferred by a patent" and contain no indication that any exemption from non-discrimination rules is intended, and Article 27.1 applies to exceptions of the kind authorised by Article 30.[382] The Panel also quoted the footnote 7 to illustrate the relationship between Article 30 and Article 31 to state that the scope defined in Article 31 in terms of exceptions is not covered by Article 30, and was of the view that both provisions permit exceptions to patent rights subject to certain mandatory conditions.[383]

2. *Article 30 – Exceptions to Rights Conferred*

Article 30 is one of the flexibilities offered by TRIPS to deal with the limited exceptions, and it is also one of the provisions discussed by the WTO Members intending to introduce to solve the public health problems.[384] Article 30 provides,

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

This Article is composed of three main important conditions, which have constituted the "three-step" test of the validity of alleged limited exceptions to the minimum standards required by TRIPS. The *Canada – Patent Protection of Pharmaceutical Products* Case provides an interesting illustration of factors to consider in relation to the three-step test of this Article.

In the *Canada – Patent Protection of Pharmaceutical Products* Case, both the stockpiling exception and the regulatory review exception were examined by the Panel to clarify the "three-step test". On 19 December 1997, the European Communities (hereinafter referred to as EC) and their member States requested Canada to hold consultations regarding the protection of inventions in the area of pharmaceuticals under the relevant provisions of the

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[382] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.91] and [7.93].

[383] Ibid., para. 7.91 (Panel Report, WTO).

[384] For a compilation of the views expressed by Members prior to the June 2002 TRIPS Council meeting, see *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*, IP/C/W/363 16 *et seqq* (Geneva, 11 July 2002).

Canadian implementing legislation. In this case, Canada claimed that the disputed sections of the *Patent Act* were exceptions under Article 30 of TRIPS. Sections 55.2(1) and 55.2(2) of the Canadian Patent Act create exceptions to the exclusive rights of patent owners. Section 55.2(1) is known as the "regulatory review exception", and allows third parties to obtain government marketing approval during the term of the patent, which without such an exception might otherwise be delayed until after the expiry of the patent term.[385] Section 55.2(2) is referred to as "the stockpiling exception", and permits competitors to manufacture and stockpile patented goods during a certain period before the patent expires without selling them until after the expiry of the patent.[386]

The Panel first reiterated the principles of interpretation referring to the rules of Article 31(1) of VCLT concerning interpretation in good faith in the light of object and purpose and the rules of Article 31(2)(b) concerning any subsequent practice and the rules of Article 32 concerning supplementary means of interpretation including the preparatory work and the circumstances of its conclusion.[387] The Panel also pointed out that Article 9(2) of the Berne Convention was an important contextual element for the interpretation of Article 30 of TRIPS and that consideration of incorporated international instruments on intellectual property may be needed to interpret the provisions as a consequence of the extended context.[388] During the examination, the Panel also established that the three criteria must be in order for examination and that although separate from each other and required to be satisfied independently they were cumulative, and that any failure of compliance of these criteria would result in disallowance of an alleged Article 30 exception.[389]

(a) *Exceptions to be Limited*

Article 30 of TRIPS allows Members to provide "limited exceptions to the exclusive rights conferred by a patent", and the words "limited" and

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[385] Section 55.2(1) of *Canada Patent Act* provides as, "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any Product."

[386] Section 55.2(2) of *Canada Patent Act* provides as, "It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires."

[387] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.13].

[388] Ibid., [7.14] and [7.15].

[389] Ibid., [7.20].

"exception" constitute the first condition. The ordinary meaning of "limited" refers to "restricted in scope, extent, amount, etc.", or in other words, it means small in amount or number or being kept within a certain boundary like size, time or range.[390] The ordinary meaning of "exception" refers to something not included in a rule or principle.[391] In the instant case, Canada asserted an interpretation of "limited" according to the conventional dictionary definition, but the EC interpreted the word "limited" to connote a narrow exception to be described by words such as "narrow, small, minor, insignificant or restricted."[392] The ordinary meaning shown in the dictionary did not support such a potentially restrictive interpretation. It was argued that the term should be read in the context of relevant treaty languages. In order to define the terms contained in this Article, the Panel consulted the antecedents of Article 30, which is Article 9(2) of the Berne Convention, and the negotiating records of TRIPS. The panel, however, found both that the words in Article 9(2)[393] of Berne Convention were different from those in Article 30 of TRIPS and the term "limited exception" was adopted before the modelled text of Berne Article 9(2).[394] The Panel, therefore, agreed with the EC that the word "limited" has a narrower connotation and is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed. The Panel concluded that a literal textual reading could justify the limited exception, focusing on the extent to which legal rights have been curtailed rather than the size or extent of the economic impact.[395] Therefore, the Panel finally concluded that the stockpiling exception was a violation of TRIPS due to a substantial curtailment of the exclusive rights that TRIPS required to be granted to patent owners. The proposed exception did not to satisfy the first step of "limited exception" by applying a narrow exception.[396]

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[390] See *Shorter Oxford English Dictionary* 1598; also see Abbott, above n. 86.

[391] See Abbott, above n. 86; also see *Shorter Oxford English Dictionary* 880, and it provides: "the action of excepting someone or something from a group, the scope of a proposition, etc., the state or fact of being so excepted; a person who or thing which is excepted *esp* a particular case or individual that does not follow some general rule or to which a generalization is not applicable".

[392] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.27] and [7.28].

[393] Art 9(2) of *Berne Convention* provides, "It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author."

[394] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.29].

[395] Ibid., [7.29]–[7.31].

[396] Ibid., [7.36].

The Panel did not apply the other two conditions because of the cumulative test of the "three-step" test. Once a proposed exception fails one limb of the test it is not a valid exception.

In the examination of the regulatory review exception, however, the Panel concluded that Canada's regulatory review was legitimate.[397] In contrast, the Panel first examined the criterion of "limited exception" to find that the Canada's regulatory review exception is a "limited exception" within the meaning of Article 30 because of the narrow scope of its curtailment of Article 28.1 rights.[398]

This manner of interpretation by the Panel, however, does not follow the VCLT in full because it does not take full consideration of the context and object and purpose of TRIPS, and this leaves the decision of the panel open to criticism and raises doubts about the final result.[399] Some commentators also criticised the approach of making a presumption that the exception had to be read narrowly and that the consideration of the expression "limited" solely from the perspective of the rights holder, without regard to the policy goals or purposes of the exception, did not adequately consider Article 30 in the light of its object and purpose.[400] In fact, the report of the decision shows that, the Panel did give some consideration to the object and purpose of TRIPS and it offers as the following[401]

> The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of TRIPS which indicate its object and purposes.

The Panel, however, did not apply the object and purpose of TRIPS in the interpretation of the word in full before it referred to the negotiating history of the word. One commentator points out that the Panel "conspicuously disregarded" Article 7 and Article 8 and effectively subordinated them to Article 30 of TRIPS.[402]

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397 Ibid., [7.84].

398 Ibid., [7.45].

399 See Frankel, above n. 13, 394–9.

400 Robert Howse, 'The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times' 3 *Journal of World Intellectual Property* 493, 496; citing the Appellate Body report, *EC Measures Concerning Meat and Meat Products* (Hormones), WTO Doc WT/DS26/AB/R, WT/DS48/AB [9]; see also Frederick Abbott, 'WTO Dispute Settlement Practice Relating to the Agreement on Trade-Related Intellectual Property Rights' in Federico Ortino and Ernst-Ulrich Petersmann (eds), *The WTO Dispute Settlement System 1995–2003* (Kluwer Law International, 2004) 421, 430.

401 Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.26].

402 Shanker, above n. 39, 742.

(b) *Unreasonable Conflict with Normal Exploitation of Patent*

The second condition requires that the exception should not unreasonably conflict with normal exploitation of a patent, and the interpretation of the terms "unreasonably", "conflict", "normal" and "exploitation" becomes crucial in the understanding of the second limb of this Article.

In the *Canada – Patent Protection of Pharmaceutical Products* Case, the Panel analysed the second condition by focusing more on an assessment of the extent of economic impact of the exception and took a similar approach to the third condition that will be dealt with successively. This economic impact assessment can be compared with the greater focus on the curtailment of rights used in the assessment of the first condition.[403]

During examination of the second condition requiring that the exception must "not unreasonably conflict with a normal exploitation", the Panel focused on the interpretation of "normal exploitation" to find that "exploitation" referred to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The Panel considered that the meaning of "normal" could be both an empirical conclusion about what is common within a relevant community or a normative standard of entitlement.[404] The Panel, therefore, was of the view that the normal practice of exploitation by patent owners was to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity.[405] Then, the Panel accepted Canada's argument that an additional period of *de facto* market exclusivity created by using patent rights to preclude submissions for regulatory authorisation should not be considered as "normal".[406] Finally, the Panel concluded that the regulatory review did not conflict with a normal exploitation of patents, within the meaning of the second condition of Article 30 of TRIPS.[407]

Some commentators have made the criticism that the Panel interpreted the term "normal" only with regard to the expectations of right holders and did not take into account the interests that might dictate a limit on the period of protection required by TRIPS to a maximum of twenty years.[408]

(c) *Unreasonable Prejudice to Legitimate Interests*

The third condition was also examined by the Panel by focusing on the meaning of "legitimate interests". The Panel examined whether patent owners could

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[403] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.49].

[404] Ibid., [7.54].

[405] Ibid., [7.55].

[406] Ibid., [7.57].

[407] Ibid., [7.59].

[408] Howse, above n. 400, 499.

claim a "legitimate interest" in the economic benefits that could be derived from the additional period of *de facto* market exclusivity, and, if so, whether the regulatory review exception "unreasonably prejudiced" that interest.[409] The Panel, after rejecting EC's argument of equating legitimate interest to legal interest, defined the "legitimate interests" in the way that it is often used in legal discourse – " as a normative claim calling for protection of interest that are 'justifiable' in the sense that they are supported by relevant public choices or other social norms."[410] The Panel also consulted TRIPS negotiating history to find the list approach on the "limited exceptions", but this approach was eventually abandoned in favour of a more general authorisation following the outlines of the present Article 30.[411] Therefore, the negotiation records cannot give an explanation of the reason for this decision.

In making an assessment of the "legitimate interests", the Panel referred to Article 9(2) of the Berne Convention and the negotiating history. The Panel examined the drafting committee report to find that the concepts of "normal exploitation" and "legitimate interests" underlying the three examples used by the drafting committee were consistent with the Panels' definitions of these concepts and of the differences between them.[412] Thus, the panel then found that it could not accept the EC's interpretation of "legitimate interests" as referring to legal interests pursuant to Article 28.1.[413]

The Panel then considered the EC's argument of the entitlement to impose the same type of delay to competing products entering the market due to suffering from such loss of market exclusivity. The Panel scrutinised relevant action taken by Member governments to find that some governments had enacted *de jure* patent term extension to compensate the *de facto* diminution of the normal period of market exclusivity due to delays in obtaining marketing approval and others had adopted regulatory review exceptions similar to the one in question.[414] The Panel concluded that the claims on behalf of patent owners for reduction of market exclusivity due to delay in marketing approval was neither compelling nor so widely recognised as a "legitimate interest" within the meaning of Article 30 of TRIPS and the concerns about

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[409] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.61].

[410] Ibid., [7.69].

[411] See document MTN.GNG/NG11/W/76 of 23 July 1990 – *Status of Work in the Negotiating Group: Chairman's Report to the Group of Negotiations on Goods*, Part III, Section 5, para. 2.2.

[412] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.72].

[413] Ibid., [7.73].

[414] Ibid., [7.74]–[7.81].

regulatory review exceptions in general were apparently not clear enough or compelling enough to make their way explicitly into the recorded agenda of the TRIPS negotiations, so the Panel concluded that Canada did not prejudice the "legitimate interest" of affected patent owners within the meaning of Article 30.[415]

In referring to "legitimate interest of third parties", the Panel did not find further explanation in the records of the TRIPS negotiations.[416] Thus, the Panel was not able to attach substantive meaning to the phrase, but the Panel decided that the term "legitimate interest" should be construed to be broader than "legal interests".[417]

This manner of interpretation that still does not give full consideration to the object and purpose of the Agreement may leave a lack of full application of VCLT rules. In fact, Canada argued in the case that third party interests were those of users and payers of health care products,[418] and a scholar noted that the Panel did not take public health into account of as one of the interests that can be advanced consistently with TRIPS in accordance with Article 8(1) of TRIPS.[419]

3. *Interpretation*

(a) *Health Related Exceptions*

The relationship between Article 30 and Article 27.1 and Article 28 reveals that Article 30 can only justify exceptions to the exclusive rights established by Article 28 but not to the availability of patents established by the non-discrimination clause of Article 27. It is only a limited exception to Article 28 inside the ambit of Article 27.1 and Article 30 mainly deals with exceptions after the grant of patent. In other words, the exclusion of patentability of certain inventions justified under Article 27 will start from the beginning of the invention, when the grant would contravene considerations necessary to preserve the *ordre public*. This can happen after the grant of a patent in certain cases when the situation changes to give rise to potential threats to the *ordre public*. The exception allowed under Article 30 is an exception after the grant of a patent for certain inventions.

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[415] Ibid., [7.82]–[7.83].
[416] Ibid., [7.71].
[417] Ibid.
[418] Ibid., [4.14].
[419] Howse, above n. 400, 504.

Can some health related patent exceptions be justified under this Article 30? As a commentator observed, Article 30 should be sufficient to guarantee the exceptions below as being legitimate exceptions.[420]

i) importation of a product that has been put in the market elsewhere by the patentee, with his consent or by an otherwise authorized person;
ii) acts done privately and on a non-commercial scale for a non-commercial purpose;
iii) using the invention for research and experimentation and for teaching purposes;
iv) seeking regulatory approval for marketing of a product before the expiry of the patent;
v) preparation of medicines for individual cases according to a prescription;
vi) use of the invention by a third party who started – or undertook *bona fide* preparatory acts – before the application for the patent (or of its publication).

The issue might be whether the use of patented pharmaceutical inventions for afore-mentioned purposes in a specific country will be justified as a "limited exception", "not unreasonably in conflict with normal exploitation of the patent" and "not in prejudice against legitimate interest of the patent holder when taking account of the legitimate interest of third parties" when considering a public health concern.

The findings of the Panel in the case of *Canada-Patent Protection of Pharmaceutical Products* provided guidance on the three-step test required by this Article, and the statement of the Panel concerning the relationship of the three conditions also guides the interpretation of Article 30. The Panel's manner of interpretation, however, does not follow the VCLT in full because it fails to give full consideration to the context and the object and purpose of TRIPS and because of its emphasis on the patent holder's right and economic impact upon the owners' expectations. These criticisms of the interpretation raise doubts about the final result. One commentator concludes that the findings of the Panel in this case are ambiguous with regard to the balance expressed in both the general provisions such as Article 7 and Article 8 and the wording of Article 30 itself.[421] When following the VCLT roadmap and the three-step test pattern, the interpretation of the three step test provision needs to be done in light of the object and purpose of the Agreement by giving ordinary meaning of the term in its context.

[420] Correa, above n. 12, 303.
[421] Gamharter, above n. 3, 95.

(b) *Ordinary Meaning*

The starting point of the interpretation may be exploration of the meaning of the three criteria. In the first condition, the word "limited", as explained in the *Canada- Patent Protection of Pharmaceutical Products* case, means "narrow, small, minor, insignificant or restricted"[422] instead of the meaning argued by Canada as "confined within definite limits" or "restricted in scope, extent, amount."[423] The measurement of "limited" is not made by "simply counting the number of legal rights impaired by an exception" but by "the extent to which the patent owner's rights have been curtailed".[424] In addition, "limited" exception also means that a single right such as selling has been preserved but all other rights such as making, using, offering for sale and importing are curtailed can not justify as limited. All other rights such as making, using, offering for sale and importing are of the same importance to constitute the exclusive rights of a patent holder.[425] The afore-mentioned exceptions, including experimental use and the regulatory review of the patent, should all meet the criteria of being "limited", since these exceptions are restricted in specific kind, amount and country.[426]

The second condition contains the words "unreasonably", "conflict" "normal" and "exploitation". The meaning of the word "unreasonably" was not explained in the Panel's report, and its ordinary meaning is that something "does not appeal to logic or is inequitable".[427] The word "conflict" means "to stand in opposition".[428] The meaning of the words "normal exploitation" was given by the Panel to be that "exploitation" referred to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent and that "normal" can be both an "empirical conclusion" about what is common within a relevant community or a "normative standard" of entitlement.[429]

Thus, the phrase of the second limb means that the action permitted by the exception should not operate inequitably or is unfairly in opposition to the commercial activity ordinarily used by the patent holder. The panel in *Canada-Patent Protection of Pharmaceutical Products* case goes even further

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[422] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.28].

[423] Ibid., [7.27].

[424] Ibid., [7.32].

[425] Ibid., [7.33].

[426] See Nowak, above n. 247, 937–8.

[427] See Abbott, above n. 86.

[428] See Ibid.

[429] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.54].

to consider all forms of competition resulting in curtailment of economic value as abnormal exploitation.[430] This view has been criticised on the basis that the use of patented subject matter by third parties is a "legal power established by law" to promote competition instead of exploitation of the patent.[431] It has also been pointed out that the economic assessment on "normal exploitation" lacks sufficient guidance, since the economic return coming from one exclusive right can not be at the same level as that from the other exclusive rights under the patent.[432] This textual ordinary literal interpretation is insufficient, and it is necessary to resort to the contextual reading under the object and purpose of TRIPS.

The terms contained in the third condition include "unreasonably prejudice", "legitimate interest" and "third parties". The Panel referred to the words "legitimate interest" as not being an equivalent to the term "legal interest", but "as a normative claim calling for protection of an interest that is 'justifiable' in the sense that they are supported by relevant public choices or other social norms."[433] The phrase "unreasonably prejudice" means to act adversely in an inequitable way.[434] The meaning of the term "third parties" is that a relationship exists between two primary entities and there is another entity which is somehow affected or excluded, and it can identify those persons or enterprises that are not directly part of the referenced relation.[435] In the context of health the primary party is likely to be the patent holder and the other person or country which produce or import such health related pharmaceuticals and "third parties" would refer to the other persons or countries which do not produce or import such health related pharmaceuticals. This limb poses four main questions when seeking to locate a balance required by the test[436]

(1) what are "legitimate interests of a patent holder";
(2) does the exception unreasonably prejudice those legitimate interest;
(3) what are the legitimate interest of third parties, and
(4) considering the third party's legitimate interests, does the exception unreasonably prejudice the legitimate interest of patent owners.

Another question is whether such an exception will influence a third country under the most favoured nation treatment of Article 4 of TRIPS. The relationship between Article 30 and Article 27.1 and Article 28 shows that Article 30 can only justify exceptions to the exclusive rights established by Article 28

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[430] Ibid., [7.55].
[431] Correa, above n. 12, 308.
[432] Ibid.
[433] Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [7.69].
[434] See Abbott, above n. 86.
[435] See Ibid.
[436] Nowak, above n. 247, 926.

but not to the availability of patents established by the non-discrimination clause. It is, therefore, not discrimination to a third party in terms of patent availability and not derogation to a third party in terms of most favoured treatment. However, to pass the test under this limb requires reference to contextual material for the afore-mentioned activities.

(c) *Contextual Interpretation*

To find the ordinary meaning of terms is just the starting point. The VCLT also entails a contextual reading of the terms in the light of the object and purpose of a treaty to an interpretation. As discussed above, the main object and purpose of TRIPS is to give a balanced reading of the provisions of TRIPS to find an appropriate balance between protection and free trade.[437] According to the treaty language contained in the Preamble, Article 7 and Article 8 TRIPS is made for the protection of intellectual property rights, for the promotion of technological innovation, and to facilitate the transfer and dissemination of technology. At the same time, the protection of public health and nutrition and the promotion of the public interest in sectors of vital importance to a member's socio-economic and technological development are adopted as purposes of TRIPS.[438] In summary, TRIPS needs to address international trade policy as well as intellectual property protection policy. Specifically, putting the intellectual property policy into the present context the patent system should be addressed by TRIPS. It is possible to claim that at one level the patent system is used to "serve the public interest and not to benefit individual inventors."[439]

Furthermore paragraph 5 of the Doha Declaration requires interpretation in the light of the object and purpose of TRIPS. At the same time, although the Panel in the *Canada – Pharmaceutical* case made an interpretation of this Article, the WTO Agreement has made it clear that the Ministerial Conference and the General Council is entitled to make a formal interpretation instead of being bound by a panel report, and effect should be given to the decisions made in the Doha Declaration during such formal interpretation.[440] In addition, as a matter of customary international law, a decision made by the DSB involving states parties does not bind states not party to the dispute,[441] so the interpretation of TRIPS in a public health concern by a DSB if charged with such dispute should be done in a manner not bound by the previous decisions.

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[437] See Part Two.Chapter 5.II.

[438] See art 7 and art 8 of TRIPS.

[439] P. Welfens, J. Addison, D. Audretsch, T. Gries, and H. Grupp, *Globalization, Economic Growth and Innovation Dynamics* (Springer, 1999) 138.

[440] Abbott, above n. 44, 492–3.

[441] Ibid., 469, footnote 83.

The interpretation of the three-step may require resort to consideration of the object and purpose of TRIPS. The negotiations during the Uruguay round of GATT on the protection of intellectual property rights was adopted to combat impediments to free trade, and counterfeit and "pirate" products were regarded as part of such impediments.[442] The very limited use of health related pharmaceutical inventions in a certain country, however, cannot be said to cause impediments on free trade. However, an exception which permits such a policy can be seen to be meeting socio-economic development goals contained in Articles 7 and 8 "in a manner conducive to social and economic welfare."

In the same vein, this object and purpose approach can also be applied to enlighten the interpretation of the second and third conditions. Both the experimental use and regulatory review should be interpreted in the light of the object and purpose.

The concept of "legitimate interests" calls for an interpretation with consideration of public policy analysis. Viewed from the stated object and purpose of TRIPS it can be considered that the patent system is instituted to serve international trade policy and intellectual property protection policy. However, the experimental use of inventions serves the policy to promote more innovation of pharmaceuticals, and successively serves one of the policy goals of intellectual property protection.

Furthermore most of the countries in the world are members of ICESCR, and they have established health provisions in their constitutions or have adopted various health policies.[443] The right to health, thus, becomes a kind of public choice or social norm in such countries. The use of a certain pharmaceutical patents to meet a public health concern should also be a "legitimate interest" not only of the health-inflicted people but also of the patent holder, and the production or importation of such product may not inequitably prejudice the interest of the patent holder when viewed from this normative perspective. The legitimate interest of the patent holder, therefore, may not be prejudiced, if the establishment of system of healthcare in a country makes the availability of medicines subject to a public health concern.

(d) *Supplementary Means*

In view of the above analysis, Article 30 can be used to justify exceptions when considering them through a health context. The only question is whether, when there is large scale production or importation, equitable remuneration should be paid to the patent holder. The incorporated conventions of TRIPS

[442] Gervais, above n. 10, 10–2.

[443] Eleanor D. Kinney and Brian Alexander Clark, 'Provisions for Health and Health Care in the constitutions of the Countries of the World' (2004) 37 *Cornell Int'l L J* 285, 294.

can offer some understanding upon this Article. The predecessor of Article 30 can be found in Article 9(2) of the Berne Convention,[444] and Article 30 may also borrow some of understanding in this Article. As discussed, the "contemporaneous" approach informs the understanding of this Article,[445] and the material relating to the Berne Convention 1971 text can be referred to.[446]

> If it is considered that reproduction conflicts with the normal exploitation of the work, reproduction is not permitted at all. If it is considered that reproduction does not conflict with the normal exploitation of the work, the next step would be to consider whether it does not unreasonably prejudice the legitimate interests of the author. Only if such is not the case would it be possible in certain special cases to introduce a compulsory licence, or to provide for use without payment. A practical example may be photocopying for various purposes. If it consists of producing a very large number of copies, it may not be permitted, as it conflicts with a normal exploitation of the work. If it implies a rather large number of copies for use in industrial undertakings, it may not unreasonably prejudice the legitimate interests of the author, provided that, according to national legislation, an equitable remuneration is paid. If a small number of copies is made, photocopying may be permitted without payment, particularly for individual or scientific use.[447]

This draft contemplates the compensation of the right holder. Therefore, it is reasonable to consider whether, in case of a health based exception, the invocation of Article 30 also needs to consider reasonable remuneration to the patent holder.

### F. *Article 73 – Security Exception*

Article 73 deals with security exceptions, and it offers another flexibility to allow a members to take action "which it considers necessary for the protection of its essential security interests…taken in time of war or other emergency in international relations" and maintenance of national peace and

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[444] Gervais, above n. 10, 159. Also see Correa, above n. 12, 307. Art 9.(2) of *Berne Convention* provides, "It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author."

[445] See Part Two.Chapter 4.I.C.1.(d).

[446] Art 2 of TRIPS requires the non-derogation from the *Berne Convention*, and footnote 2 of TRIPS defines the *Berne Convention* to be the Paris Act of this Convention of 24 July 1971.

[447] World Intellectual Property Organization (WIPO), 'Report on the Work of Main Committee I' (Substantive Provisions of the Berne Convention: Articles 1 to 20) paragraph 85" in 'Records of the Intellectual Property Conference of Stockholm' (June 11–July 14, 1967, Geneva, 1971) Vol. II, 1145–46.

order.[448] However, this flexibility is somewhat ignored.[449] This Article can be read in alignment with Article XXI of GATT and Article XIV*bis* of GATS.[450] Due to the "universal nature" of these exceptions, this Article serves to relieve a party from all of its substantive obligations under TRIPS.[451]

The ground for protection of essential security interests is generally related to trade measures unilaterally imposed for non-economic reasons and the measures have often, according to one commentator, reflected a power-based approach to international relations with a blurring line between a nation's essential security interests and foreign/domestic policy agenda.[452] The open-textured language contained in this security exception provision, together with the uncertainty of the distinction between national security interest and national foreign/domestic policy, will require a clarification of the coverage of the essential security interests and the extent of essential securities that it can cover.

1. *Coverage of the Exception*

The breadth of the exception seems to include any of the grounds that a member claims to invoke. The reference to the invocation of Article XXI of GATT can be used to find the scope of the essential securities. Sweden invoked the Article XXI of GATT to protect the footwear industry, since it deemed that maintenance of such a vital industry was indispensable "in case of war or other emergency in international relations."[453] The European Community has invoked Article XXI to respond to "risks of political instability" in a region[454] and Article XXI has been invoked by nations to take measures to support foreign polices of another nation.[455] From these cases, it

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[448] Art 73 of TRIPS.

[449] Cann, above n. 166, 762.

[450] Art XXI of GATT provides security exceptions. See Correa, above n. 12, 520.

[451] Cann, above n. 166, 822.

[452] Cann, above n. 166, 823; also see Wesley A. Cann Jr, 'Creating Standards and Accountability for the use of the WTO Security Exception: Reducing the Role of Power-Based Relations and Establishing a New Balance Between Sovereignty and Multilateralism' (2001) 26 *Yale J Int'l L* 413, 414.

[453] GATT Panel Report, *Sweden – Import Restrictions on Certain Footwear*, L/4250 (17 November 1975) para. 4.

[454] GATT Panel Report, *Trade Measure Taken by the European Community Against the Socialist Federal Republic of Yugoslavia*, L/6948 (2 December 1991).

[455] For a discussion of this, see Cann Jr (2001), above n. 452, 424–5. Eg, *Trade Restrictions Affecting Argentina Applied for Non-economic Reasons* (18 May 1982) L/5319/Rev.1 (GATT) (stating that the European Community, Australia and Canada, in light of the invasion of the Falkland Islands, have taken certain measures against Argentina on the basis of "inherent rights" in art XXI).

can be argued that "essential security interests" covers wide range of issues but that they should be related to external relations of a member or a nation and should serve for non-economic reasons. According to Cann, "potential" threats to essential interests should also be included.[456] This point, however, may deserve further discussion, especially in the health context. The interpretation of this Article can not be too liberal to cover the potential external threats, since an overly liberal interpretation has the potential for abuse that could damage the stability of TRIPS and the whole WTO law.

Can the health situation be considered to be an essential security interests so that the security exception can be based on? According to a commentator, the HIV/AIDS epidemic is destroying the social, economic and political structure of many nations, because the family unit is being torn apart, farming and industrial productivity is being curtailed, the medical and educational communities are being attacked, and refugee populations are being created.[457] Each of these impacts can threaten economic growth and development, life expectancy, food security, military defence capabilities, government revenues and resources and the provision of essential services.[458] In such a situation, the entire nation, as well as entire regions, may collapse. This indicates that the health situation, if it is serious enough to arise to threaten the entire nation or region, can be covered with this "essential security" exception. According to Correa, "a health crisis or a natural disaster may justify the invocation of such an exception."[459]

### 2. *Limit of the Exception*

The TRIPS Agreement left it open for members to define for themselves what constitutes "essential security interests" and "emergency" and so interpretation of the open-textured security exception will require clarification of the extent of the exception. It is argued that the distinction between the expression of "it considers necessary" contained in the Article 73.b and the expression of "necessary" contained in Article XX of GATT shows that the security exception is subjective in nature and within the total discretion of the nation exercising the exception.[460] As discussed above, the exception under Article XX is also subject to the two-tiered test and should prohibit arbitrary and unjustifiable discrimination and disguised restrictions on trade, which implies an objective, measurable and reviewable standard that should

[456] Cann, above n. 166, 825.
[457] Ibid., 827–8.
[458] Ibid.
[459] Correa, above n. 12, 520.
[460] Cann, above n. 166, 826.

be applied in the invocation of the measure.[461] In the same fashion, this distinction in expression should also support the distinction of the expression of "necessary" contained in the Article 8 of TRIPS and this Article. Therefore, the definition of "essential security interests" should be left open to be self-defining. However, the self-defining nature of the exception does not mean that a member can invoke this Article in the health situation without consideration of the context. This Article is dealing with essential security interests, and it is only when the health situation has become serious enough to arise to threaten world or regional peace or order that this exception can be invoked.

In addition, an "emergency" situation should be differentiated from the concept of "national emergency or other circumstances of extreme urgency" that is contained in Article 31, although the Doha Declaration has provided a discretion for members to have the "right to determine what constitutes a national emergency or other circumstances of extreme urgency" with a special recognition of public health crises.[462] The self-defining nature of "emergency" in the Article 73 does not mean that an emergency established under public health can be the same as the one established under the security exception. Firstly, the "national emergency or other circumstances of extreme urgency" under Article 31 is providing for a response that is of a temporary nature and can only limit the normative TRIPS Agreement minimum standards for intellectual property subject matters during a limited period of time and under particular circumstances, but the essential security interest emergency can result in a permanent limitation. Furthermore, the object and purpose of TRIPS should always be born in mind to give effective interpretation of the provisions. A too liberal interpretation will only encroach upon the protection goal and trade goal of TRIPS by giving too much leeway to the social-economic goal. Therefore, the security exception is applicable only to a very serious situation that presents a threat to or poses a risk of regional or world disorder, and only the extent that is necessary to respond to such a threat.

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[461] See Part One.Chapter 3.II.B.2; also Cann, above n. 166, 826.

[462] But see Cann, above n. 166, 827–8, the author is of the view that the "national emergency or other circumstances of extreme urgency" constitute the "emergency" contained in the art 73, since the security exception is ambiguous to result in the use of a boundless of potpourri of actual and potential external threats to find that the HIV/AIDS epidemic can pose a threat to both global stability and international security.

# Chapter 6

## Application of Human Rights Norms

### I. TRIPS and Human Rights Norms

#### A. *TRIPS is Not Self-contained*

The TRIPS is part of WTO laws, and the WTO laws are a whole unit to be interpreted in consistency with each other. An examination of how TRIPS responds to other international law norms is also an examination of how the unified vehicle of WTO laws responds to other international norms. The introduction of human rights norms into the TRIPS regime, therefore, also becomes part of the introduction of human rights norms into WTO laws.

##### 1. *WTO is Not a "Closed Legal Circuit"*[1]

As part of the wider corpus of public international law, WTO law itself is not a closed system, and should be a sub-system of international law.[2] As a sub-system of international law there is no doubt that WTO law is subject to the general international law and is influenced by other sub-systems of international law. Pauwelyn points out that States automatically and necessarily contract with one another within the system of international law, and the fact that the WTO may exclude some general international law rules does not mean that the "entire field" of general international law and other "sub-systems of international law" such as human rights laws can not be applied to it.[3] The WTO is a system which encompasses the established international trade norms and extends its ambit beyond international trade to many areas.

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[1] For the term "closed legal circuit", it is referred to by Pauwelyn. See Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 35.

[2] Ibid., 37–9.

[3] Ibid.

(a) *WTO Law is Broader than GATT*

WTO laws are wider than the predecessor laws found within the now superseded GATT. WTO laws not only cover the topics of trade in goods, but also cover the topics of trade in services and trade-related intellectual property rights and others. As a multilateral treaty in the international trade system, the WTO laws not only deal with topics of trade, but also deal with many other issues such as environmental concerns, health concerns, social concerns, security concerns and others. These issues are often dealt with or require exceptions to general WTO obligations, which link WTO laws with other systems of law and policy.[4] The wide coverage of the topics required to be addressed in an international trade treaty suggests the width of the WTO laws and, through such extensive scope, extends the links between WTO laws and other related international norms.

Article XX of GATT provides general exceptions to the application of GATT, and such exceptions are followed by a "chapeau" to emphasise a balance of rights and duties applicable to a Member during its invocation as an exception.[5] There are also several subparagraphs contained in Article XX. Paragraph (a) provides an exception for public morals justification, paragraph (b) provides an exception for human, animal or plant life or health justification and paragraph (d) provides an exception for necessary compliance with laws or regulations which are not GATT inconsistent and paragraph (e) provides an exception relating to the products of prison labour. These exceptions show that the WTO laws have taken some broader issues into consideration, and they also underpin WTO's link with other areas of international law. Salman Bal, after an analysis of Article XX, especially of paragraphs (a), (b), (d) and (e), argued that Article XX of the GATT should be reinterpreted for trade related human rights compliance, and the purpose of Article XX (a) (b) (d) should be invoked to safeguard a human rights application in the GATT.[6] As the author noted:[7]

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[4] Jiaxiang Hu, 'The Role of International Law in the Development of WTO Law' (2004) 7 *J Int'l Econ L* 143, 144–5.

[5] WTO Analytic Text, and the introductory clause provides, "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures."

[6] For a full discussion of invocation of Art XX to respond to the human rights issues, see Salman Bal, 'International Free Trade Agreements and Human Rights: Reinterpreting Art XX of the GATT' (2001) 10 *Minn J Global Trade* 62, 87–97 and 104–7.

[7] Ibid., 87–97 and 108.

> It is true that GATT is meant to deal primarily with free trade concerns. The general exceptions clause in Article XX is meant to override these concerns and to prevail over any provision of the GATT… Under the provisions of Article XX the balance must be in favour of non-trade issue, such as human rights.

Article XIV of the GATS also provides general exceptions.[8] In the *US-Gambling*[9] case, the exceptions "necessary to protect public morals or to maintain public order", "public order" and "public morals" were tested with the guidance offered in GATT jurisprudence, including the Appellate Body's opinions in *US-Gasoline*,[10] *US-Shrimp*[11] and *Korea-Various Measures on Beef*[12] cases. The interpretation of this exception was not confined to GATS itself, but also refers to sources immediately outside GATS. Following the same fashion, the meaning of TRIPS Agreement carve-outs should not be understood as confined to an internal ambit, but as being informed by reference to other sources outside its immediate ambit.

(b) *The Text of WTO DSU*

Article 3.2 of the WTO DSU requires the interpretation of WTO laws in accordance with the customary rules of public international law laid down in VCLT, and such requirements recognise the necessary invocation of laws and sources outside WTO laws. As discussed above, Article 31(3)(c) of VCLT provides for the interpretation of a treaty by taking into account any relevant rules of international law applicable in the relations between the parties. Following the method prescribed by the VCLT, there is a possibility that WTO laws include human rights norms and other relevant international law rules brought into it through interpretation rules. Article 32 of the VCLT also allows the Panels and Appellate Body of WTO to consider outside legal materials as supplementary means to interpret WTO laws in

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[8] Art XIV of GATS provides, "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measure: (a) necessary to protect public morals or to maintain public order; (b) necessary to protect human, animal or plant life or health…"

[9] Panel Report, *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services*, WTO Doc WT/DS285/R (10 November 2004) [6.447]–[6.449].

[10] See Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS4 (10 April 1995) P 22.

[11] See Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [115]–[119].

[12] See Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [156].

the WTO dispute settlement system and jurisprudence.[13] The interpretation method contained in the legal texts of WTO laws shows that WTO laws are not intended to be a closed system but rather as a part of the whole international law system.

Article 7 of the DSU requires the panel to examine the matters "in light of relevant provisions" and "address the relevant provisions in any covered agreement or agreements cited by the parties to the dispute."[14] Such a justification, according to Pauwelyn, suggests that WTO panels may apply other non-WTO rules in particular circumstances.[15] It is also argued by Pauwelyn that Article 11 of the DSU, which contains the expression "a panel should make an objective assessment of…the applicability of…relevant covered agreement" and "make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreement", are the Articles to mandate WTO panels to refer to other rules of international law.[16] This kind of reference indicates the status of the WTO law as part of public international law and not a closed legal circuit. Further Marceau is of the view that Articles 1, 4, 7, 11 and 19 of DSU identify the status of WTO as a subsystem of international law with specific rights and obligations, specific causes of action, specific remedies and specific countermeasures.[17]

(c) *Evolutionary Manner of Interpretation of WTO Laws*

The WTO laws adopt an evolutionary manner to interpret the covered agreements in the WTO dispute settlement cases and the legal texts.[18] The Preamble of the WTO Agreement commits the optimal use of the world's resources in accordance with the objective of sustainable development, and the objectivity of sustainable development can only be understood in light of contemporary law and policy that defines and supports this goal.[19] Such

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[13] Hu, above n. 4, 147.

[14] See art 7 of DSU.

[15] Joost Pauwelyn, 'Human Rights in WTO Dispute Settlement' in Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press, 2005) 205, 212–3.

[16] Ibid., 216.

[17] Gabrielle Marceau, 'WTO Dispute Settlement and Human Right' in Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights – Foundations and Conceptual Issues* (The University of Michigan Press, 2006) 181, 189–90.

[18] See Part Two.Chapter 4.III. It discussed the evolutionary interpretation of TRIPS, and as part of WTO, it suggests that WTO should adopt an evolutionary manner to interpret its covered agreements.

[19] Hu, above n. 4, 148.

an expression in the legal text of WTO shows that the interpretation of the WTO laws should be understood with the evolution of the contemporary law and such an understanding enables the WTO laws to include other relevant international law rules.

At the same time, the DSB adopted an evolutionary manner to interpret WTO laws in its dispute settlement cases, and this evolutionary manner of interpretation in the WTO jurisprudence also shows that WTO laws are not a closed circuit. As noted in *Japan-Alcohol*[20] case, the Appellate Body ruled that:

> WTO rules are reliable, comprehensible and enforceable. WTO rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world. They will serve the multilateral trading system best if they are interpreted with that in mind. In that way, we will achieve the 'security and predictability' sought for the multilateral trading system by the Members of the WTO through the establishment of the dispute settlement system.

The facts in every case will change, and the rules in WTO laws are capable of adapting to respond to the changing facts of different cases. Accordingly the AB adopted a flexible interpretation of WTO laws, and the understanding of such laws requires reference to the "ever-changing ebb" in the laws and extends the WTO laws to be open to the greater flexibility of the whole international law system.

In the *US-Shrimp* case,[21] the Appellate Body, in determining the meaning of the phrase "exhaustible natural resources" in Article XX(g) of GATT, "noted that the generic term 'natural resources' in Article XX(g) is not 'static' in its content or reference but is rather 'by definition, evolutionary'." Therefore, the AB referred to the United Nations Convention on the Law of the Sea (UNCLOS) to determine the meaning of "exhaustible resources".[22] The discussion of the interpretation of the term "exhaustible natural resources" in the *Shrimp-Turtle* case followed an evolutionary approach to adjust the application of the treaty according to the changing situations that developed over time.[23] With such an evolutionary manner of interpretation the WTO laws are expanding to respond to a large area of the whole international law system.

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[20] Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (1 November 1996) Section H(2)(c).

[21] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [130].

[22] Ibid., [130]–[131].

[23] Ibid.

(d) *Extraneous Sources in WTO Jurisprudence*

When the meaning of some provisions of the covered agreements are ambiguous the panel or Appellate Body in some WTO dispute settlement cases have found justifications to refer to extraneous sources. This process of dispute settlement suggests that WTO laws are not closed. In the *EC Bananas* case,[24] the Appellate Body found that the Panel's ruling concerning the Lomé Waiver was inconsistent with GATT Article XIII:1 by considering the difficult reconciliation with the limited GATT practice in the interpretation of waivers. One scholar[25] argues that this deliberation by the Appellate Body implied that the DSB should seek outside sources when related provisions are obscure and ambiguous. Furthermore, the scholar is of the opinion that the DSB can seek to find a rule from already existing rules or practices or even from the general principles of law that guide this legal system.[26] In the *US-Shrimp* case, as discussed above, the Appellate Body invoked the 1982 United Nations Convention on the Law of the Sea (UNCLOS) to note the meaning of exhaustible natural resources, which is further evidence of the WTO DSB's resorting to laws and regulations outside WTO laws.[27] In the *EU Biotech Products* case,[28] the Panel affirmed the reference to the laws outside WTO laws to interpret the covered agreements. The explicit affirmation is an indication that WTO laws are part of the whole framework of the international law system.

2. *TRIPS should not be Isolated from Human Rights Norms*

The inclusion of the intellectual property protection system into the trade area is further evidence that WTO laws are not a self-contained closed system. The inclusion of intellectual property protection into the WTO was considered valuable and desirable because it created an opportunity to enhance intellectual property protection by using a new forum to regulate technology imports within the whole "constitutionalization of international economic relations".[29] The understanding of the regulation of the international

[24] Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas,* WTO Doc WT/DS27/AB/R (9 September 1997) [184]–[188].

[25] Hu, above n. 4, 145–7.

[26] Ibid., 147.

[27] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products,* WTO Doc WT/DS58/AB/R (12 October 1998) [130].

[28] Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products,* WTO Doc WT/DS291–3/R (9 September 1997) [7.67].

[29] Thomas Cottier, 'The Value and Effects of Protecting Intellectual Property Rights within the Wold Trade Organization' in Thomas Cottier, *Trade and Intellectual Property Protection in WTO Law: Collected Essays* (Cameron May, 2005) 81, 82–6.

economic relations can not be isolated from the other related international law norms, including human rights norms. It is, therefore, an effect of the inclusion of intellectual property protection within the wider framework that other relevant international law norms will be relevant to the interpretation of the intellectual property regime expressed in the language of TRIPS.

The requirements of consistent interpretation between TRIPS and other covered agreements of the WTO and the openness of WTO laws indicate that all the covered agreements of WTO will be treated as relevant sources to respond to other areas of international law.[30] Because TRIPS itself is not a closed system and exists as a sub-system of international law it will be subject to other systems of international law. As a consequence TRIPS should not be insulated from related human rights norms.[31]

### B. *TRIPS Invites the Use of Human Rights Norms*[32]

#### 1. *The Aim of TRIPS*

The TRIPS Agreement firstly sets outs the aims and objectives of the treaty and establishes some familiar WTO concepts as mechanisms to pursue those aims. Establishment of familiar international law mechanisms refers to the wider body of international law and one implication of this is that it is possible to argue that this allows human rights considerations to be introduced at a framework level.

The inclusion of intellectual property protection into the WTO regime and the establishment of TRIPS are intended to serve the purpose of regulating intellectual property protection for a better and fairer international trade environment.[33] Some research argues that linking intellectual property protection to GATT has made it possible to narrow the gap between fundamentally different perceptions of trade and thereby to achieve justice,

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[30] For the analysis of interpretation relationship between TRIPS and other covered agreements of WTO, see Part Two.Chapter 4.II.

[31] Just as in Nicaragua case, the ICJ made another reference to human rights laws for their own enforcement mechanism, based on the idea of open system of the intended mechanism. See *Military and Parliamentary Activities in and against Nicaragua (Nicaragua v United States of America) (Merits, Judgement)* [1986] ICJ Rep 14, [267]–[268].

[32] For the expression "invites", see Susy Frankel, 'The WTO's Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property' (2005) 46 *Va J Int'l L* 365, 418.

[33] See Daniel Gervais, *The TRIPS Agreement-Drafting History and Analysis* (2nd ed., Sweet & Maxwell, 2003) 3–26; it discussed that the drafting of TRIPS showed the intent of the governments to set up a binding obligation to eliminate trade in counterfeit and pirated goods.

fairness and equity in overall trade negotiation.[34] Through this, the members of the WTO hope that it will promote the establishment of the international trade framework, and, ultimately, it will enhance the international economic order.[35] Therefore, on the whole and at least theoretically, the aim of TRIPS is to serve the aim of the WTO and its predecessor the GATT.

This aim can be found to be reflected in the preamble of TRIPS with the use of the expression "to reduce the distortion and impediment to international trade".[36] Given that the WTO sets the aim of "raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand",[37] this aim may overlap with that of the human rights regime. At the time that the GATT was created, the United Nations human rights regime was also brought into existence with the creation of the UDHR, ICCPR and ICESCR. Dommen, after an analysis of the objectives of international trade and human rights regime, gives the opinion that the Preamble of GATT and WTO share the same aim as that of human rights regime.[38] The two regimes share much the same aim: "to set up a multilateral, institutional framework within which States could cooperate to ensure protection of human rights", and "to promote the expansion of trade in order to raise standards of living, ensure full employment and increase incomes around the world".[39] Robert Howse and Makau Mutua also have argued that the reference to sustainable development in the Preamble of WTO and the provisions of TRIPS should be interpreted in the light of the treaty commitments of the relevant parties and in light of customary international law.[40] Following their argument that the same aim set in the two regimes, the commentators are of the view that human rights violations are also violations of WTO rules.[41]

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[34] Thomas Cottier, 'The Prospect for Intellectual Property in GATT' in Cottier, above n. 29, 11, 12–3.

[35] Thomas Cottier, 'The Value and Effects of Protecting Intellectual Property Rights within the World Trade Organization' in Cottier, above n. 29, 81, 82–86.

[36] See para. 1 of the Preamble of TRIPS.

[37] See Preamble of the Marrakesh Agreement Establishing the World Trade Organization.

[38] Caroline Dommen, 'Safeguarding the Legitimacy of the Multilateral Trading System: The Role of Human Rights' in Abbott, Breining-Kaufmann and Cottier (eds), above n. 17, 121, 121–3.

[39] Ibid., 121–2.

[40] Robert Howse and Makau Mutua, 'Protecting Human Rights in a Global Economy – Challenges for the World Trade Organization' (International Center for Human Rights and Democratic Development, Policy Paper, 2000) 10–17 and 20–2.

[41] Ibid.

### 2. *Article 31(3)(c) of VCLT*

The TRIPS Agreement lacks an internal interpretation mechanism, so the interpretation of its provision needs to resort to the roadmap provided in VCLT to meet the requirements of "customary rules of interpretation of public international law" as required by the WTO law.[42] As discussed, Article 31(3)(c) has been invoked by WTO panels and the Appellate Body in WTO cases to justify to reference to other sources outside WTO laws. This offers an opportunity for TRIPS to be found to open to wider international law sources, and as a result of this process, human rights norms may join this pool of resources to play a role in the interpretation of the related provisions of TRIPS.

Article 31(3)(c) requires a reference to other relevant international law rules aiming at promoting some "coherence" in international law, and accordingly the human rights norms, provided that they are TRIPS provision-related, should be taken into account in the interpretation of TRIPS so as to avoid conflicts with other treaties.[43] French also points out that the reference to "other" legal rules in treaty interpretation can ensure equity in the judicial decision-making process, encourage coherent legal reasoning, prevent disintegration of legal rules into their various sub-disciplines, and permit a tribunal to ensure that the narrow application of a rule is not allowed to overrule broader notions of justice.[44] Therefore, "the Article 31(3)(c) can be viewed as an obligation on the interpreter to be 'aware of' – and to take into account – what is otherwise international law between the WTO disputing parties."[45] Human rights norms enjoy universal recognition, and according to some research, the "human rights treaties have become part of an objective 'constitutional order' based no longer on exclusively States but also on individuals as legal subjects".[46] It is, therefore, arguable that the interpreters of TRIPS are obliged to give due consideration to related human rights norms during the interpretation of the provisions of TRIPS when utilising the tool or indicator of Article 31(3)(c) of VCLT.

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[42] Frankel, above n. 32, 419.

[43] Marceau, above n. 17, 202.

[44] Duncan French, 'Treaty Interpretation and the Incorporation of Extraneous Legal Rules' (2006) 55 *ICLQ* 281, 285–286.

[45] Gabrielle Marceau, above n. 17, 199–200.

[46] Ernst-Ulrich Petersmann, 'Human Rights and International Trade Law: Defining and Connecting the Two Fields' in Cottier, Pauwelyn and Bürgi (eds), above n. 15, 29, 35; the author opines that interpretation of trade rules should give due regard to human rights obligations as a result of human rights being a 'constitutional order' in state practices.

### 3. *The Language used in TRIPS*

The TRIPS Agreement provides for minimum standards of protection of intellectual property, and such a minimum standard multilateral treaty must inevitably try to strike a balance between the interests of intellectual property owners and the interests of users. TRIPS reflects this in various ways. It firstly utilises some "conceptual ideas" outside the "immediate ambit" of intellectual property law to meet the requirements of balance.[47]

TRIPS adopts open-textured languages in its carve-outs to achieve the conceptualised goal and this gives an opportunity to consider human rights norms when the related provisions of TRIPS are interpreted. This can be found in the expressions used to frame some exceptions intended to provide recognition of public health and environmental concerns. The Agreement adopts language such as "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development", and "necessary to protect *ordre public* or morality".[48] Members can also exclude the patentability of some inventions where the prevention of commercial exploitation of the invention is necessary "to protect human, animal or plant life or health or to avoid serious prejudice to the environment."[49] The understanding of such open-textured terms as "public health", "*ordre public* or morality" and "public interest" may require an interpretation of the language with reference to other relevant rules of international law, and human rights norms may be referred to in this process of interpretation. It has been argued by some researchers and commentators that open-textured language contained in a treaty suggests the intention of the treaty parties to refer to other extraneous rules in the process of interpretation of the treaty language in question.[50]

The TRIPS Agreement not only includes open-textured language but also language which can be described as open-ended language. While this enables the Agreement considerable capacity to be dynamic in its response to changing conditions it also requires dynamic interpretation.[51] The open-endedness of language in the Agreement requires that the interpretation of such language can only be conducted in an evolutionary manner to cope with the

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[47] Frankel, above n. 32, 418–9.

[48] See art 8.1 and art 27.2 of TRIPS.

[49] See art 27 of TRIPS.

[50] See Campbell McLachlan, 'The Principle of Systemic Integration and Art 31(3)(c) of the Vienna Convention' (2005) 54 *ICLQ* 279, 312.

[51] Frankel, above n. 32, 408.

dynamic process. This means that human rights norms may be included into this process with the evolution of the connotation of the provisions.

The understanding of the health concern is a result of a dynamic process in the international law context. One example of this relevance of human rights concerns to the subject matter of TRIPS concerns pharmaceutical compositions for human therapeutic use. Pharmaceutical compositions are an essential element in treating illness and disease and so intimately connected to issues of public health responses and to the human rights norms of the right to health. However novel inventive industrially applicable pharmaceutical compositions and or methods for their composition are likely to be patented either as product inventions or as process inventions.

In some circumstances the minimum standards of protection for owner of pharmaceutical related patents may conflict with or operate to be an obstacle to securing access to drugs to treat major public health crises. One possible mechanism for responding to this apparent conflict of interests is found in an open-ended reference in Article 8(1) of TRIPS Agreement to "measures necessary…to promote the public interest in sectors of vital importance to [members'] socio-economic…development." This language requires a dynamic understanding.[52] Does it apply to patent systems that provide protection for the invention of life-saving drugs?

The international health context has evolved through a long process into a public health context by crossing the borders of the exchange of information, trade and others. During this dynamic process, the understanding of what is a public health concern and what is required to respond to a health concern may not be the understandings that pertained at the time when the treaty was made. The right to health has also evolved from an initial vagueness to more specificity that encompasses more specific content and scope. Interpreters will be obliged to refer to other rules of international law to consider the dimensions and implications of such an important concept.

The TRIPS Agreement also offers a kind of internal limitation on the scope of some of its carve-outs.[53] For example, a three-step test is to establish the validity of limited exceptions. The interpretation of related provisions of TRIPS may also require consideration of these internal limitations. This limitation will help to underpin the understanding of the relevance of human rights norms in the interpretation of TRIPS, and the need to examine those norms in related situations.

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[52] See art 8(1) of TRIPS.

[53] Frankel, above n. 32, 418–9.

## 4. *The Regime Shift in Intellectual Property Protection*

Viewed as a political and normative process, the regimes of international intellectual property protection shift during this dynamic process.[54] Helfer observes that the regime shift of intellectual property protection from WIPO to GATT and to TRIPS is a result of political choice and is based on the features of GATT/WTO such as significant negotiating leverage in the GATT/WTO enjoyed by some developed countries, the expansion of the area of agreement among states with widely divergent interest, and the more effective dispute settlement system of GATT/WTO.[55] The author also observes that other regimes also entered into this process to challenge TRIPS and these other regimes included the human rights regime.[56] In such a dynamic process, the human rights regime can give incentives for TRIPS and WTO to integrate new hard and soft laws into its regime.[57] Helfer points out that human rights norms can help to expand intellectual property protection standards, such as the invocation of author's right and property rights, and they can also help to impose external limits on intellectual property.[58] This dynamic process in the regime shift of international intellectual property protection into the whole international law context opens a wider door for integration of the human rights norms into the interpretation of TRIPS. According to a commentator, the countering use of human rights norms will result in the consideration of international human rights law such as the UDHR and the ICESCR in the course of WTO treaty interpretation and application.[59]

At the same time, Helfer also points out that the establishment of TRIPS also creates incentives for other regimes to develop soft law. In the human rights regime many norms are outlined in a vague way. The human rights

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[54] Laurence R. Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale J Int'l L* 1, 13–8.

[55] Ibid., 18–23.

[56] Ibid., 27–51.

[57] Ibid., 58–61. The author used the term counterregime to express the idea of incentives creating for international intellectual property regime to integrate the laws created in other areas of international law.

[58] Laurence R. Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 *U C Davis L Rev* 971, 1015–18.

[59] Robert Wai, 'Countering, Branding, Dealing: Using Economic and Social Rights in and around the International Trade Regime' (2003) 14 *Eur J Int'l L* 35, 57–60; the author is of the view that social and economic rights can be an effective tool, and may be appropriately deployed, in a 'countering' strategy and this countering involves the use of international social and economic rights as part of a corrective or countervailing strategy in the interpretation and application of existing international trade agreements.

regime, however, develops soft laws to elucidate the norms. These soft laws together with the hard human rights treaty norms have become counter-regimes to TRIPS.

The ICESCR Committee adopted a general comment on the right to health in May 2000 based on Article 12 of ICESCR of the right to health.[60] Although the Comment is not binding on state parties of ICESCR,[61] it proffered more clarity to the meaning of the right to health.[62] The Comment provides that the core obligations as include "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs".[63] The introduction of such counter-regime norms offers an opportunity for TRIPS interpreters to use these soft laws developed under the counter-regimes, such as the human right regime especially when seeking to interpret some "evolutionary" terms.[64] As pointed out by Helfer, the *Shrimp-Turtle* case is likely to indicate that the WTO invites competing arguments as to how WTO panels should (or should not) take soft laws generated outside the trade regime into account.[65] This suggests that TRIPS may invite some soft laws created in the related human rights regime into the interpretation process, and this introduction should be understood to be conducted in an evolutionary way.

## II. Rights to Health, Property and Fruits of Creation in TRIPS

### A. *Application*

#### 1. *Hierarchical Status of Various Human Rights Norms*

##### (a) *Human Rights Sources and UN Human Rights Bodies*

The human rights regime developed in the United Nations has also addressed intellectual property issues in the last decade.[66] The United Nations human rights regime mainly consists of two different types of human rights bodies. One type is a charter-based body and the other is a treaty-based body.

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[60] Committee on Economic Social and Cultural Rights ('*CESCR*'), *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 43.

[61] Helfer, above n. 54, 73.

[62] See David Weissbrodt and Frank Newman, *International Human Rights: Law, Policy, and Process* (Anderson Publishing Co, 3rd ed., 2001) 88–93.

[63] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 43.

[64] Helfer, above n. 54, 77–8.

[65] Ibid., 78.

[66] Ibid., 45.

The charter-based bodies are derived from provisions contained in the Charter of the United Nations and "hold broad human rights mandates, address an unlimited audience and take action based on majority voting."[67] There are several human rights fora addressing the intellectual property issues in this body, including the Commission on Human Rights (replaced by the Human Rights Council in 2006) and the Subcommission on the Promotion and Protection of Human Rights (superseded by the Human Rights Advisory Committee in 2007).

The treaty-based bodies derive their "existence from provisions contained in a specific legal instrument, hold narrower mandates, address a limited audience and base their decision-making on consensus."[68] The Committee on Economic, Social and Cultural Rights (CESCR) is one of the fora in this body, and the ICESCR is under the supervision of the treaty-based forum. In addition, the High Commissioner for Human Rights is also an important human rights forum under the United Nations human rights system.

All of these bodies have also adopted non-binding declarations, resolutions, recommendations, and reports concerning the human rights recognised in ICESCR or other internationally recognised rights as they address intellectual property issues.[69] The various official documents issued by such bodies constitute an important part of the soft law sources in human rights regimes, and also may offer more leeway to a TRIPS interpreter to refer to the human rights regime when the related provision is under consideration.

(b) *The Status of the Human Rights Norms*

Human rights norms are based on international treaties, customary international law and general international law. Customary international law sources are often marked by features of continuing uncertainty and human rights norms share this characteristic.[70] Many human rights norms are vague in content and scope and this contributes to uncertainty in the whole

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[67] See United Nations, available at <http://www.un.org/Depts/dhl/resguide/specthr.htm #subcom>.

[68] See Ibid.

[69] These can be shown in the Part One, such as *Substantive Issues Arising in the Implementation of the ICESCR* issued by CESCR; *General Comment No. 17*; *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights* by Sub-Commission on the Promotion and Protection of Human Rights.

[70] See Karol Wolfke, *Custom in Present International Law* (Martinus Nijhoff Publishers, 2nd rev ed., 1993) xiii. The author gave the view that the difficulty of customary international law has ambiguity of the terms involved, and contributes to the greatest number of doubts and controversies. Also see Karel Vasak, 'Human Rights: As a Legal Reality' in Karel Vasak (general editor, revised and edited for the English edition by Philip Alston), *The International Dimensions of Human Rights* (Greenwood Press, 1982) 3, 3. The author pointed out

international law. Basically, the relevant human rights norms and the human rights regimes relating to the intellectual property protection and TRIPS exist as customary international law, treaty law and soft law.

(i) Customary International Law

Some human rights norms have achieved the status of customary international law.[71] Customary human rights laws "are based on principles of concern to all States and protect interests which are not limited to a particular State or group of States."[72] The customary international law, as observed by Palmeter and Mavroidis, also plays a specific role in WTO dispute settlement.[73] In *EC-Bananas*,[74] the Appellate Body looked to "customary international law and prevailing practice of international tribunals" in the ruling on the issue of representation of delegations. In *EC-Hormones*,[75] the disputing party invoked the "precautionary principle" as one part of customary international law, and the Appellate Body also assumed that principles of substantive customary international law may play a significant role in determining what the WTO Agreement rights and obligations mean in a particular case. This kind of expression has also been echoed in the opinion given by the Appellate Body in the *US-Shrimp* case.[76] The problem is in determining to what extent the WTO can apply customary international law in its dispute settlement cases. In *Korea-Government Procurement*,[77] the WTO panel put the application of customary rules of international law as

> However, the relationship of the WTO Agreements to customary international law is broader than this. Customary international law applies generally to the economic relations between the WTO Members. Such international law applies to the extent that the WTO treaty agreements do not "contract out" from it. To put it another way, to the extent there is no conflict or inconsistency, or an expression in a covered WTO agreement that implies differently, we are of the

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human rights was relegated to the uncertain area zone due to the political connotations in it, and these political shadows eclipsed the light of pure law.

[71] See Part One.Chapter 2.I.A.3.

[72] Oscar Schachter, *International Law in Theory and Practice* (Springer, 1991) 343.

[73] David Palmeter & Petros C Mavroidis, 'The WTO Legal System: Sources of Law' (1998) 92 *Am J Int'l L* 398, 406–7.

[74] Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WTO Doc WT/DS27/AB/R (9 September 1997) [10].

[75] Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products*, WTO Doc WT/DS26/AB/R and WT/DS48/AB/R (13 February 1998) [123].

[76] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [110].

[77] Panel Report, *Korea-Measures Affecting Government Procurement*, WTO Doc WT/DS163/R (1 May 2000) [7.96].

> view that the customary rules of international law apply to the WTO treaties and to the process of treaty formation under the WTO.

The right to health is a customary international law norm,[78] and so, following the treaty interpretation roadmap of the VCLT, it may be referred to in the interpretation of WTO laws under certain circumstances. McLachlan has pointed out that the two situations where it is necessary to refer to broader principles of customary international law, are that reference within a particular part of international law and reference looking beyond the particular sub-system to rules developed in another part of customary international law.[79] The TRIPS Agreement, as part of the world trade law system, is not necessarily related to the human rights law area, but it is not insulated from human rights norms. The open-textured language used in TRIPS, including the protection of "public health" in Article 8 and the "health" concern in the Article 27 may require a reference of a particular part of international law. A reading of the textual language of such provisions suggests that the treaty parties did not intend to contract out of this health area, but on the contrary intended to contract out of the intellectual property area in order to respond to health concerns. The crucial point is developing a proper understanding of such treaty language and TRIPS interpreters need to consult other areas of international law in order to do so. The right to health, as discussed in the first part, has been developed with its meaning established in the customary international law area as well as in the treaty law area.[80]

The application of the customary international law norm of the right to health, however, may pose some difficulties due to the vague nature of customary international law and further clarification may still be required.

(ii) Treaty Law

Most human rights norms are also treaty norms, and because of the binding nature of treaty norms, they are hard laws and State parties to related human rights treaties have obligations under these treaties. The right to health, the right to property and the right to fruits of creation are also human rights treaty norms contained in the widely accepted multi-lateral treaty of ICESCR, and the interpretation of TRIPS and WTO laws may need to refer to these treaty norms.

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[78] See Part One.Chapter 2.I.A.3. Also for a discussion of the status of the right to health as customary international law, see Patrick L Wojahn, 'A Conflict of Rights: Intellectual Property under TRIPS, the Right to Health, and AIDS Drugs' (2001–2002) 6 *UCLA J Int'l L & Foreign Aff* 463, 493–6.

[79] McLachlan, above n. 50, 312.

[80] See Part One.Chapter 2.I.A.

The WTO law cases have also referred to other relevant multi-lateral treaties during the interpretation of its covered agreements. On one hand, some international conventions have already been incorporated into the WTO law and TRIPS, and it requires a reference to the relevant conventions. On the other hand, other international multi-lateral treaties can also be referred to in WTO cases. The *US-Tuna* case[81] in GATT was the first to reference to another multi-lateral agreement, the Convention on International Trade in Endangered Species (CITES), although the panel ruled that the cited treaty was not relevant due to the lack of uniform membership in GATT. However, this kind of view that the treaty relied on should be accepted by all GATT parties is criticised by Palmeter and Mavroidis as being inconsistent with Article 31(3)(c) of VCLT.[82] Later on, the *US-Shrimp* case[83] introduced a significant change into WTO jurisprudence, and the Appellate Body referred to an international environmental law, the 1982 United Nations Convention on the Law of the Sea (UNCLOS), to investigate the meaning of exhaustible natural resources.

121 of the members of the ICESCR are also WTO members,[84] and such a large duality membership creates a stronger possibility for the TRIPS interpreter to refer to ICESCR relevant norms during the interpretation of TRIPS Agreement. The right to health and the right to fruits of creation, as treaty norms, should be binding on the disputants in a TRIPS-related dispute settlement case if they are parties to the ICESCR. During the interpretation of TRIPS, when the related provisions of TRIPS dealing with health exclusion are examined, these norms can be referred to following the guidance of Article 31(3)(c) of VCLT.[85] However, it may be more difficult to refer to these ICESCR treaty norms when disputants are not parties to ICESCR. Nonetheless, the open-textured language contained in TRIPS with such expressions as "public health" and "to protect life and health" will call for a programmatic

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[81] GATT Panel Report, *United States – Restrictions on Imported Sugar*, GATT Doc L/6514–36S/331 (22 June 1989) [5.1]–[5.9].

[82] Palmeter & Mavroidis, above n. 73, 411.

[83] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [130].

[84] By 2003, there were 116 members of ICESCR are also members of WTO. See International Centre for Human Rights and Democratic Development, 'Human Rights: The WTO's Missing Development Agenda' <http://www.dd-rd.ca/site/_PDF/publications/globalization/pamphlet.pdf>. By the date of writing, there are 153 members in WTO and among them 121 are also ICESCR members. See the membership status of WTO at <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>; and see the membership status of ICESCR at <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en>.

[85] For example, art 8.1 and art 27 of TRIPS.

interpretation.[86] This can justify reference to the right to health to elaboration of such terms with the examination of the object and purpose of TRIPS.

Treaty norms can overlap with customary international law at certain points, and in practice, a treaty normally prevails over custom.[87] Therefore, in practice, although the right to health is regarded as customary international law, the panel and Appellate Body of the WTO should take a treaty norm into consideration first if the disputants are also parties to the ICESCR.[88] In addition, because the content of certain norms of customary international law can be more uncertain and vague than that of treaty norms, a reference to treaty norms can help to clarify the meaning of such norms.

With the reference to the right to health and the right to fruits of creation contained in the ICESCR, the treaty itself does not offer many indications of the various norms and benchmarks for proper application. Accordingly there is a greater need to make reference to more soft laws to clarify the content and benchmarks of the various norms during the interpretation.

(iii) Soft Law

Soft law refers to the non-enforceable legal instruments which are not directly enforced in courts and tribunals but they, nonetheless, have an impact on international relations, and ultimately, upon international law.[89] Soft law is often contrasted with hard law that has binding force usually through the conclusion of treaties in international law,[90] and soft laws are not covered by the VCLT to refer to the international law defined by the Article 38 of the Statute of International Court of Justice.[91] However, Hillgenberg argues that, after an analysis of Article 2(1) of the VCLT requirements, these soft laws are still sources of law unless they obviously violate *jus cogens*.[92]

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[86] See McLachlan, above n. 50, 315.

[87] Pauwelyn, above n. 1, 133.

[88] The customary international law norm of the right to health should not make much difference from the codified treaty norm of the right to health, although the customary international law norm tends to be vaguer.

[89] See Pierre-Marie Dupuy, 'Soft Law and the International Law of the Environment' (1991) 12 *Mich J Int'l L* 420, 422–5, and 428–31.

[90] See Damilola Sunday Olawuyi, 'The Emergence of International Environmental Law on Chemicals – An Appraisal of the Role of Soft Law' (20 June 2007) <SSRN: http://ssrn.com/abstract=996430>.

[91] Art 38 of the Statute of International Court of Justice defines the sources of international law as: international conventions, international custom and the general principles of law recognised by civilized nations.

[92] See Hartmut Hillgenberg, 'A Fresh Look at Soft Law' (1999) 10 *EJIL* 499, 502–3; the author offers the view that the art 2(1) of the Vienna Convention is intended to distinguish

Generally, soft law includes a great variety of instruments. Professor Kiss has classified soft law into two categories as normative recommendations and programs of action and declarations of principles.[93] Kiss includes resolutions from institutions in the first category, while documents that proclaim general guidelines which states should follow are included in the second category.[94] Chinkin, in examining the role of soft law in international economic law, suggests a classification that lists soft law as "legal soft law",[95] "non-legal soft law" such as non-binding or voluntary resolutions and codes of conduct formulated and accepted by international and regional organisations, and statements prepared by individuals in a non-governmental capacity, but purported to lay down international principles.[96]

Human rights norms, such as the right to health, the right to property and the right to fruits of creation, have also developed a large amount of soft law in the human rights regimes, and this requires consideration of them during the introduction of human rights norms into the interpretation of the WTO laws. This soft law regime mainly consists of the various Comments by the treaty based human rights body of the Committee on Economic, Social and Cultural Rights (CESCR),[97] the "legal soft law" of the UDHR and the related resolutions and other legal documents by the charter based human rights body of the Commission on Human Rights and the Sub-Commission on the Promotion and Protection of Human Right of the United Nations.[98]

Reliance on soft law sometimes causes controversy due to the refusal by some international practitioners to accept its existence and some confusion as to its status in the realm of law when regarded by others. When it is argued that the "soft" human rights mechanism should be invoked to the trade area, there are some commentators who are sceptical of the ability of

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between treaties under international law and those under domestic law, and the provisions of the Vienna Convention does not apply to the exclusion of non-treaty agreements.

[93] Alexandre Kiss, *Introduction to International Environmental Law* (UNITAR, 2nd ed., 2005) 52.

[94] See Ibid., 52–4.

[95] Usually, a treaty with vague or weak requirements and characterise this is referred to as "legal soft law".

[96] C. M. Chinkin, 'The Challenge of Soft Law: Development and Change in International Law' (1989) 38 *ICLQ* 850, 851.

[97] The CESCR is a body of independent experts established under ECOSOC Resolution 1985/17 of 28 May 1985 to monitor the implementation of ICESCR, which was assigned to the United Nations Economic and Social Council (ECOSOC) in Part IV of the Covenant; See Office of the United Nations High Commissioner for Human Rights, <http://www2.ohchr.org/english/bodies/cescr/index.htm>.

[98] See Part One.Chapter 2.I.B.3 for the various soft law sources.

the "soft" mechanisms of the human rights regime.[99] In the author's opinion despite the controversy and scepticism, human rights soft law, should be referred to in the process of interpretation of TRIPS and WTO laws.

Firstly, the related soft law in the special human rights regime can serve as a foundation upon which binding obligations can later be built with the introduction of human rights norms into the interpretation of TRIPS. Although many human rights norms exist in treaties, they still remain "soft" since hard treaty law requires to be precisely worded with specific and exact obligations undertaken or rights granted.[100] As observed by Chinkin, a treaty that provides only for the gradual acquiring of standards or for general goals and programmed action is itself "soft".[101] Article 2.1 of the ICESCR requires a progressive realisation of the economic and social rights contained in this treaty,[102] and the realisation of the right to health also depends on many factors to be progressively established.[103] Furthermore, there is a lack of specific content and benchmarks concerning the right to health and the right to fruits of creation in the ICESCR. This lack of specificity weakens the binding nature of the ICESCR treaty norms. One solution is for the ICESCR to open its door to other soft laws to compensate for its lack of specific content and benchmarks during implementation. Such soft law should also be taken into the interpretation of TRIPS and WTO laws as a bundle of the sources together with established treaty norms sources.

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[99] See Andrew T. F. Lang, 'Rethinking Trade and Human Rights' (2007) 15(2) *Tulane Journal of International and Comparative Law* 335, 399. The author presented some of the criticism on the effectiveness of the framework, including the criticism from Sol Picciotto, 'The WTO as a Node of Global Governance: Economic Regulation and Human Rights Discourses' (unpublished manuscript presented at the Conference on Human Rights and Global Justice at the University of Warwick, 29–13 March 2006, available at: <http://eprints.lancs.ac.uk/152/>). In reaction to TRIPS and public health campaign, for example, Picciotto suggests that: [a]lthough the political impact of the campaign has been very important, especially due to the global awareness of the AIDS issue, it is doubtful that the invocation of human rights discourses has had more than a marginal effect. The same can be said of the global campaign that resulted in the compromise in the Doha Ministerial Declaration on TRIPS and Public Health and its subsequent implementation by WTO Council Decisions.

[100] Chinkin, above n. 96, 851.

[101] Ibid.

[102] Art 2.1 of ICESCR provides, "Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."

[103] See Part One.Chapter 2.I.B.2.(b).

Secondly, the evolving nature of human rights norms requires that soft laws should be included into the interpretation of TRIPS. The growth of the human rights regime has been the growth from vague enlightenment to the establishment of more specific rights and obligations. For example, the right to health, as a treaty norm contained in the ICESCR is required to cope with the changing nature of the health context and such specific issues as the access to medical goods and services needs to be clarified with the development in the later area in order to implement such a norm. The cultural rights contained in Article 15(1)(c) of the ICESCR also evolves with the changes in the international context. So for example the "soft law" Comment by CESCR has provided clarification that "the author" refers to natural person instead of corporate.[104]

Thirdly, the evolutionary manner of interpretation of TRIPS indicates that soft law can be introduced into the interpretation of TRIPS. As noted earlier, international law is not composed only of rules, it is a continuing process. The growth of the "economic corollary" is itself an "offshoot" of the human rights movement.[105] TRIPS, included as corollary of the WTO in the economic field, will need to respond to the development of the human rights norms and concepts. The evolutionary manner of interpretation of TRIPS gives leeway for the soft law of the human rights regime to play a role in this dynamic process. In interpreting the "evolutionary" term of "public health" and "health", the TRIPS interpreter may need to first consult treaties and soft law developed in other international regimes to ascertain the contemporary concerns of the parties. Howse proposes that, in interpreting the patent exceptions of Article 30 of TRIPS, the panel should refer to the principles in the protection of public health contained in the Article 8(1).[106] Howse also suggests that the interpretation will need to have recourse to international health law,[107] and that there should then be reference to the human right of the right to health as part of such health concern and also to its related "soft law" sources.[108] According to Helfer, the *Shrimp-Turtle* case is likely to invite

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[104] See CESCR, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art 15, paragraph 1(c)*, 35th Sess E/C.12/GC/17 (12 January 2006) paras. 7–8 ('*General Comment No. 17*').

[105] Chinkin, above n. 96, 853.

[106] Robert Howse, 'The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times' (2000) 3 *Journal of World Intellectual Property* 493, 504; also see art 30 and art 8(1) of TRIPS.

[107] Howse, above n. 106, 504.

[108] See Ibid. The author is of the view to take into the body of health law, including "soft law" developed as resolutions or other forms of authoritative reports during the interpretation.

competing arguments as to how WTO panels should (or should not) take soft law generated outside the trade regime into account.[109] In the *United States – Section 110(5)* case,[110] the panel viewed the not-yet-in-force WIPO Copyright Treaty as an important part of the "overall framework for multilateral copyright protection" and this is evidence of an openness of WTO jurisprudence to soft law in the interpretation of TRIPS.

Based upon all of the above arguments, the soft law developed under the right to health, the right to property and the right to fruits of creation should also be referred to and these human rights norms introduced into the interpretation of TRIPS.[111]

(iv) Vital Interest Protection

In WTO cases, what are called "vital interests" have also been considered as carrying more weight than other concerns.[112] So, for a relevant instance, it is possible that the norm of the right to health could be regarded to be a vital interest and so enjoy a higher hierarchical status in the WTO adjudication process notwithstanding that this is largely a judge-made process. In the *EC-Asbestos* case, the Appellate Body interpreted the value in the preservation of human life and health pursued through the elimination, or reduction, of the well-known, and life-threatening health risk posed by asbestos fibres as being of the highest degree importance, and ruled that the measures taken to protect human health were justified under GATT Article XX.[113]

> '[t]he more vital or important [the] common interest or values' pursued, the easier it would be to accept as 'necessary' measures designed to achieve those ends. In this case, the objective pursued by the measure is the preservation of human life and health through the elimination, or reduction, of the well-known

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[109] Helfer, above n. 54, 78.

[110] Panel Report, *United States – Section 110(5) of the U.S. Copyright Act*, (June 15, 2000) WTO Doc WT/DS160/R [6.70].

[111] For example, the human rights regime has also produced many soft laws. The right to property contained in the UDHR is soft law and the content of the right to health and the right to fruits of creation also exist in soft law forms with Comment No. 14 and Comment No. 17 by CESCR. In addition, the intellectual property protection issues are also matters of concern to the human rights bodies, such as the Human Right Commission and its Sub-Commission together with CESCR.

[112] See Pauwelyn, above n. 1, 108–9.

[113] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* WTO Doc WT/DS135/AB/R (18 September 2000) [para. 172], citing *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [162].

> and life-threatening, health risk posed by asbestos fibres. The value pursued is both vital and important in the highest degree.

In contrast in *Korea-Beef*,[114] the Appellate Body found that the measures taken were not necessary under GATT Article XX(d) given the interest at stake, i.e. to avoid consumers confusing imported with domestic beef. These two cases gave guidance on the invocation of the "vital interest" in WTO case analysis between a risk assessment and SPS measure. If a case involves a life-threatening risk or constitutes a clear and immediate threat to public health or safety, the "vital interest" may be invoked under such situation.[115] The WTO panel and Appellate Body also gave a far stricter and more limited interpretation of the protection of animal or plant health and took a more expansive approach considering that protection of human beings was a matter of "vital interest".[116]

Because epidemic disease knows no border, the prevention and treatment of such disease is for the good of public health. The right to health ensures the protection of the public health, so the right to health serves the basic needs and interests as well as the fundamental values of the international community. If pharmaceutical patent protection has a propensity to obstruct access to medicine in a way that could have a negative or life threatening threat of impact upon the public health of mankind, this may give rise to the recognition that this is a matter of "vital interest" and may be a matter for consideration by Panels and the Appellate Body in the interpretation of TRIPS related cases.

### 2. *The Impact of Reference to Human Rights*

The open-textured language used in Article 8 of TRIPS requires the consideration of "public health" and similarly open textured language contained in the Article 27 excludes the patent on the grounds of "health" concern. Such language "invites" reference to the whole health context in international law. Because the right to health is part of this wider health context in the whole international law TRIPS interpreters should to refer to the right to health contained in the human rights regime. Furthermore, the evolutionary

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[114] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R and WT/DS169/AB/R (10 January 2001) [166].

[115] Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products*, WTO Doc WT/DS26/AB/R and WT/DS48/AB/R (13 February 1998) [194].

[116] See Panel Report, *Australia – Measures Affecting Importation of Salmon*, WTO Doc WT/DS18/R (12 June 1998) [8.34]-[8.37]. Also see Panel Report, *Japan – Measures Affecting Agricultural Products*, WTO Doc WT/DS76/R (27 October 1998) [8.29] and [9.1].

manner of interpretation of TRIPS will also enable interpreters to follow up with consideration of the subsequent development of TRIPS itself and the on going development of the wider health context, and the development of the health rights in the human rights regime. In the same fashion, the development of the right to the fruits of creation and the right to property in the human rights regime will also need to be taken into consideration.[117]

(a) *Human Rights Limit Patent Protection*

The human rights norms and the related hard law and soft laws can challenge the TRIPS regime in many aspects and inform expand or limit the interpretation and application of TRIPS.

Firstly, the human rights regime evolves through the development of its soft laws and can create counter-regime influences through its hard law and soft law to challenge the TRIPS regime. It did not take a long time for the system of intellectual property protection to attract the attention of human rights bodies.[118]

The CESCR is a treaty based human rights body designed to interpret and supervise the implementation of the ICESCR.[119] The first concern expressed by the CESCR is found in the statement entitled Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: Statement of the United Nations Committee on Economic, Social and Cultural Rights to the Third Ministerial Conference of the World Trade Organization in 1999. The Committee expressed the concern of the UNDP about potential negative consequences of TRIPS upon the enjoyment of human rights, including the access to health care, and urged WTO members to make human rights obligations a matter of priority in their negotiations.[120]

Other human rights bodies have also expressed their concerns about the potential relationship between intellectual property protection and human rights. The first challenge by a human rights body to the implications of TRIPS is found in a document issued by the Sub-commission on the Promotion and

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[117] The following three ideas of human rights impact on intellectual property protection are inspired by the paper from Helfer, above n. 58.

[118] See Ibid., 988.

[119] See ECOSOC Resolution 1985/17 (22nd Plenary Meeting) (28 May 1985).

[120] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: Statement of the United Nations Committee on Economic, Social and Cultural Rights to the Third Ministerial Conference of the World Trade Organization*, 21st Sess E/C.12/1999/9 (26 November 1999) paras. 4 and 8.

Protection of Human Rights in 2001.[121] In this document, focus of attention of this human rights body is upon the human right to health. The document reaffirmed the obligation to respect, protect and fulfil the right to health contained in Article 12 of the ICESCR.[122] Then, it analysed the operational aspects of intellectual property systems and their effects on medical research to point out that the economic incentive created by intellectual property rights for the innovation of new technologies, including pharmaceuticals, has the potential to promote the enjoyment of the right to health and to justify intellectual property rights promotion of the respect for the right to health.[123] However the document proceeded to point out that patents can also create limitations upon medical research and undermine promotion of the respect for human rights by directing medical research toward more profitable diseases, curtailing the development of potentially effective but unpatentable drugs and negatively affecting the use of traditional medicines.[124] Then, the document discusses the impact of the intellectual property system on access to drugs and the affordability of drugs, although it acknowledged that these negative effects were also impacted by other factors such as the level of import duties, taxes, and local market approval costs.[125]

In 2001, the CESCR issued another statement on Human Rights and Intellectual Property. The Statement points out the universality, indivisibility and interdependence of human rights and contrasts these characteristics with the instrumental, temporary and business-oriented character of intellectual property protection.[126] Pursuing this process of differentiation the Statement offers the opinion that the scope of protection of the human rights norm concerning moral and material interests of the author contained in the Article 15 of the ICESCR does not necessarily coincide with perspectives underpinning intellectual property rights protections for authors, inventors or creators under national legislation or international agreements.[127]

This analysis takes the perspective that the international patent protection system reformed and reinforced by TRIPS had a mainly negative impact on

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[121] See Sub-Commission on the Promotion and Protection of Human Right, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) ('*The Impact of TRIPS Agreement*').

[122] Ibid., paras. 29–36.

[123] Ibid., para. 37.

[124] Ibid., paras. 38 and 41.

[125] Ibid., para. 43.

[126] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess E/C.12/2001/15 (14 December 2001) paras. 5–6.

[127] Ibid.

the affordability of drugs and encouraged some negative directions upon the research leading to the development of useful drugs. It also emphasised that the human rights aspect of the protection of moral and material interest flowing from the process of successful invention has a very different perspective and underlying value system from that contained in TRIPS. If the interpretation of TRIPS needs to take the human rights perspectives upon the right to health into consideration it is likely to be found that the right to the fruits of creation may not justify the scope of patent protection of new inventive industrially applicable pharmaceutical innovations.

Article 50(1) of the 2001 Draft Articles on State Responsibility provides a prohibition against taking countermeasures in respect of "obligations for the protection of fundamental human rights".[128] This means that human rights norms still need to be applied in relation to TRIPS provisions and measures. Where TRIPS provision can be seen to be a counter measure it will be challenged by the human rights regime and this must influence the interpretation of TRIPS.

Secondly, human rights law can also create limitations on intellectual property protection and so have a limiting effect upon the intellectual property standards required by TRIPS. This limitation will also influence the interpretation of TRIPS. Firstly, the treaty norm of the right to health contained in the ICESCR and the later Comment No. 14 on the right to health ensures that access to medicines is an essential element in the right to health.[129] The Comment also mandates the core obligations of state parties to provide essential drugs defined under the WHO Action Programme on Essential Drugs,[130] and this obligation will also insert further limitations on TRIPS standards to ensure that they do not operate to block the access to essential drugs. In the statement issued by CESCR on the Human Rights and Intellectual Property, the Committee also reaffirmed the core obligations of state parties, and pointed out that any difficulty in the compliance with the core obligations relating to the right to health made by any intellectual property regime will be regarded as being inconsistent.[131] In addition, in General Comment No. 17, the CESCR also points out the social product nature of medicine production covered by the intellectual property system

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[128] Art 50(1) of the *2001 Draft Articles on State Responsibility* provides, 'Obligations not Affected by Countermeasures: 1. Countermeasures shall not affect: (a)…(b) Obligations for the protection of fundamental human rights; (c)…; (d)…; (e)…'

[129] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 12.

[130] Ibid., para. 43.

[131] CESCR, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess E/C.12/2001/15 (14 December 2001) para. 12.

and reaffirms the duty of State parties to prevent unreasonably high costs for access to essential medicines from undermining the right to health of large segments of the population.[132] This clarification sets a limitation on the intellectual property protection contained in TRIPS when the corresponding intellectual property protection has become an obstacle to access to essential medicines. Accordingly an interpreter of TRIPS needs to bear this limitation in mind during an interpretation of related TRIPS provisions that involve a health context.

Bearing this limitation in mind the open-textured language used in Article 8 and Article 27 of TRIPS may need further contemplation. Furthermore, the elucidation of Article 15(1)(c) of the ICESCR with the statement that the material interest arising from invention can only be enjoyed by a natural person and the requirement to respect and protect the material interest of inventors is intended to enable them to enjoy an adequate standard of living,[133] together with an urging of the private business sector, private research institutions and other non-State actors to respect the rights recognised in Article 15(1)(c),[134] also inserts further limitations on the protection scope and standard provided by TRIPS. Excluding the enjoyment of the right to a legal person means that human rights justifications of the protection of intellectual property can not be invoked to protect the intellectual property rights of big pharmaceutical companies.[135] This will cause a difficulty for the TRIPS interpreter, when the TRIPS related dispute arises, to distinguish the between corporate interests and natural person's interests during the process of the WTO dispute settlement mechanism seeking to solve a dispute among members.

Furthermore, when interpreting claims to property rights, an international trade panellist should be sensitive to limited social resources that inform the international obligations on social and economic rights.[136] For example, a panellist should consider the limited public resources of some states when considering whether a government has done what is necessary to get voluntary agreement before compulsory licensing or provide "adequate remuneration" under Article 31 of the TRIPS.[137] The right to property can also impose external limits on intellectual property resulting from the lack of availability of resources.

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[132] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 35.

[133] Ibid., paras. 7 and 39.

[134] Ibid., para. 55.

[135] But see art 1.3 of TRIPS, it requires the protection for both natural and legal persons.

[136] CESCR, *General Comment 3: The Nature of States' Parties Obligations*, 5th Sess, E/1991/23 (1990) paras. 8–11.

[137] Wai, above n. 59, 66–7.

(b) *Human Rights Reinforce Patent Protection*

The human rights regime can also influence the interpretation of TRIPS in ways that will expand and reinforce the intellectual property protection contained in TRIPS. Firstly, the author's right contained in the ICESCR and UDHR taken together with the establishment of "core obligations" of state parties to respect and protect an author's right and the "violation of author's right" in the General Comment No. 17 will enhance the protection of intellectual property rights.[138] As observed by Helfer, industries and industrial groups that rely on intellectual property for their economic well-being can invoke the author's rights in the human rights regime to further augment existing standards of protection, and the expansion of intellectual property protection standards will be reinforced at the expense of other human rights and the interests of licensees, users, and consumers.[139]

Does this mean that, during the interpretation of TRIPS, the author's right found in the human rights regime can be referred to and indeed should be referred to in order to promote the coherence of international law? This author's right contained in the UDHR and ICESCR has a close relationship with natural rights,[140] and also coincides with the natural right justification of intellectual property protection.[141] Using this kind of fundamental human rights perspective may further reinforce the justification of intellectual property protection and this approach has also been applied by several courts to enhance this protection.[142]

In addition, the right to property contained in the UDHR and other human rights regimes will also enhance the protection of intellectual property protection. The European Human Rights Court ruled in the *Anheuser-Busch Inc v Portugal* case that registered trademarks are justified by the property rights clause of the European Convention's first Protocol.[143] The TRIPS interpreter will also need to consider the fundamental right underlying and supporting

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[138] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) paras. 39–46.

[139] Helfer, above n. 58, 1015.

[140] See Alan Strowel, 'Droit D'auteur et Copyright: Divergences et Convergences' (1993) 290–321, cited in Helfer, above n. 58, 1015.

[141] See Part One.Chapter 2.III.B.1.(b), it introduced the justification.

[142] See Christophe Geiger, 'Constitutionalising Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union' (2006) 37 *Int'l Rev Intell Prop & Comp L* 371, 382–5.

[143] *Anheuser-Busch Inc v Portugal* (Oct 10, 2005) Eur Court HR App No. 73049/01 [43]–[49], available at <http://cmiskp.echr.coe.int/tkp197/view.asp?action=html&documentId=787908&portal=hbkm&source=externalbydocnumber&table=1132746FF1FE2A468ACCBCD1763D4D8149>; also see art 1 of the *Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms*. For these cases, see Part One.Chapter 2.III.A.1.

this intellectual property protection when the property rights contained in the human rights regime is invoked.

(c) *Human Rights Realisation through Interpretation of TRIPS*

The interpretation of TRIPS needs to take the seeming paradox of both the limitation and promotion of intellectual property protection in the human rights treaties into consideration and this will not be a straightforward or easy task. On one hand, the protection of author's right and the protection of property rights in human rights regime reflect the protection of intellectual property as a fundamental human right.[144] The intellectual property protection, The High Commissioner's report on The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, recognised that intellectual property protection acts as an economic incentive for innovation in the pharmaceutical industry and thus has the potential to promote the enjoyment of the right to health.[145] On the other hand, the intellectual property protection can also decrease the affordability of drugs and negatively impact upon the access to essential drugs contemplated in the right to health.[146] This seeming paradox will require an understanding of the protection of intellectual property that is balanced between the enjoyment of the property right and right to fruits of creation and the right to health.

Article 27 of the UDHR and Article 15 of the ICESCR, however, also require a participation in cultural life to enable enjoyment of scientific progress, and this is a first step towards a balanced understanding on this seeming paradox.[147] A further understanding on this issue can be found in the related obligations of the General Comment 17, and it requires State parties to strike an adequate balance between their obligations under Article15(1)(c) and under the other provisions of the Covenant.[148] In striking this balance, the CESCR is of the view that the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration, and further requires that any kind of protection of the moral and material interest resulting from one's scientific, literary or

[144] Although the scope is not exactly the same in the two regimes, the human rights protection on the right to property and the right to fruits of creation still reflect the protection of intellectual property. See Part One.Chapter 1.III on the analysis on the human rights regime and patent protection.

[145] Sub-Commission on the Promotion and Protection of Human Right, *The Impact of TRIPS Agreement*, 52nd Sess E/CN.4/Sub.2/2001/13 (27 June 2001) para. 37.

[146] Ibid., para. 42.

[147] See art 27.1 of UDHR and art 15.1(a)(b) and art 15.2 of ICESCR.

[148] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) para. 35.

artistic productions should not become impediments to its core obligations.[149] The core obligations require an adequate balance between the effective protection of the moral and material interests of authors and States parties' obligations in relation to the rights to food, health and education.[150] The core obligations also require a balanced understanding between the protection of moral and material interest and the rights to take part in cultural life and to enjoy the benefits of scientific progress.[151] This requirement of balance reflects a goal for the encouragement of the creation of public goods. This perspective can be seen at work within one of the justifications of the patent system, the reward for disclosure justification where the inventor obtains a property grant as a reward for full disclosure of the nature and method of achieving a new invention. This system helps to promote public access to a vast systemised database of scientific and technological information.[152] In such a system private rights are secured by individuals and a public good is created through the disclosure. It is, therefore, crucial for TRIPS interpreters to keep this balanced reading of all these human rights norms in mind when TRIPS is interpreted. This balanced reading also promotes a coherent and harmonious understanding of the intellectual property protection during the interpretation of TRIPS.

The human rights treaties themselves contain an internal limitation mechanism which also serves as a balance for the achievement of the human rights through the interpretation of TRIPS. The limitation relating to the right to health and the right to fruits of creation within the UDHR should be given less weight than that in the ICESCR.[153] However, according to the ICESCR, after an analysis on the application of the various limitation on the right to health, the right to property and the right to the fruits of creation, the limitation should be proportionate and lawful, and the limitation under the justification of public health, public order or national emergency can be inserted but should be temporary and as least restrictive as appropriate.[154] This kind of limitation reflects a certain degree of compatibility between the human rights regime and the TRIPS regime by operating to maximise the flexibilities offered by TRIPS.

This kind of balanced reading in the human rights regime and the internal limitation, however, offers a good foundation for the achievement of human rights through interpretation of TRIPS. The interpretation of TRIPS,

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[149] Ibid.
[150] Ibid., para. 39.
[151] Ibid.
[152] See Part One.Chapter 2.III.B.1.(b).
[153] See Part One.Chapter 3.II.A.3.
[154] See Part One.Chapter 3.II.A.

as suggested by Pauwelyn, can avoid seeming conflicts in norms in international law, and it is necessary for TRIPS to be interpreted in such a harmonious way to promote coherence in international law.[155] It is also noted by the International Law Commission (ILC) that where several norms bear on a single issue they should be interpreted in a harmonised way to give rise to a single set of compatible obligations.[156]

Firstly, interpretation of TRIPS drawing upon reference to sources outside WTO law and adopting an evolutionary manner enables the consideration of the human rights regime in the process of interpretation and helps to realise human rights. An important part of TRIPS interpretation is the need to take other relevant rules of international law into consideration, and this is partly because the making of a treaty is regarded as a dynamic process instead of being merely an exercise in the setting of static international law rules. During this dynamic process, familiar to international law, the regimes for intellectual property protection may have to be interpreted so as to respond to outside sources to seek clarification. As a multi-lateral treaty and one part of the WTO package deal, TRIPS contains many open-textured languages. This was a deliberate strategy of the proponent negotiators to assist the conclusion of a text of a treaty among members with divergent views opinions and interests.[157] The adoption of such open-texture language implies an intention of treaty members to refer to other sources during the interpretation of these provisions.[158] McLachlan pointed out, in justifying the reference to other treaties in WTO dispute settlement decisions, that[159]

> The open-textured language of exclusions in the Covered Agreements themselves calls for a programmatic interpretation which may properly take account of other material sources of international law. In doing so, the tribunal is using other treaties not so much as sources of binding law, but as a rather elaborate law dictionary.

The adoption of the open-textured language concerning health related issues in TRIPS may imply that the members have bound themselves to refer to the health context in the whole international law, including the human rights regime, during the interpretation of TRIPS. Human rights perspectives will

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[155] See Pauwelyn, above n. 1, 244–74.

[156] International Law Commission, 'Report of Its Work on the 58th Session', 61st Sess Supplement No. 10(A/61/10) (1 May–9 June and 3 July–11 August, 2006) [251].

[157] For example, art 8 of TRIPS uses the terms of "public health" and "public interest", art 27 of TRIPS uses the terms of "*ordre public*", "morality" and "to protect human, animal or plant life or health", art 31 of TRIPS uses the terms of "national emergency" and "extreme urgency".

[158] See Pauwelyn, above n. 1, 267.

[159] McLachlan, above n. 50, 315.

be enhanced by adoption of a method of interpretation consistent with the guidance of Article 31(3)(c) of VCLT that reference should be made to "any relevant rules of international law applicable in the relations between the parties".

Secondly, TRIPS, as is essential in any intellectual property system, also includes a balance mechanism that provides a possibility of realisation of human rights through interpretation. As discussed, theoretical models and even national systems of intellectual property law can be said to be based upon a fine balance between public and private interests,[160] and although TRIPS adopts a minimum standard compliance approach the negotiators have nonetheless sought to strike and preserve a good balance between the private and public interest that is serviceable in an international context. In order to maximise the flexibility necessarily required in a multi-lateral treaty that will impact upon members with a range of differences in economic development and national priorities and interests, TRIPS mainly adopts carve-outs and moratorium and uses many instances of open-textured language.[161] These flexibilities are one of the means through which the balancing of interests can be calibrated. The establishment of a balancing mechanism enables an interpretation that may promote coherence between the human rights regime and the TRIPS regime to help the realisation of human rights.

In addition to the balancing mechanism contained in TRIPS, the Doha Declaration, made in the form of Ministerial Declaration to make it binding on the members of WTO, together with the following decision made on the August 30th of 2003, have confirmed that the interpretation and implementation of TRIPS should be "in a manner supportive of WTO member's right to protect public health".[162] The Declaration and Decision give guidance to a TRIPS Agreement interpreter to interpret the flexibilities contained in TRIPS to help the realisation of human rights. Furthermore, the WTO members have proposed an amendment to TRIPS during the meeting of 6 December 2005 in Hong Kong to adopt the Doha Declaration and the following

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[160] See Part One.Chapter 2.III.B.1. Also see Jill McKeough, Andrew Stewart and Philip Griffith, *Intellectual Property in Australia* (LexisNexis Butterworths, 3 ed., 2004) 25–6.

[161] For the balancing mechanism, see Katharina Gamharter, *Access to Affordable Medicines: Developing Responses under TRIPS and EC Law* (Springer, 2004) 67–106; also see Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections' in Abbott, Breining-Kaufmann and Cottier (eds), above n. 17, 145, 150–2.

[162] *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) ('*Doha Declaration*') para. 4. For a detailed discussion on the Doha Declaration and the Decision, please refer to Part Two.Chapter 5.II.B.

Decision into a proposed amendment[163] that has now been extended for the acceptance by members.[164] This proposed programme further clarifies the TRIPS members' intention and furthers the interpretation of TRIPS to promote the realisation of the right to health.

On 19th July 2007, Rwanda notified the TRIPS Council of an intention to make use of the Decision made on August 30th of 2003 to import cheaper generics made under a compulsory license granted in a third country since Rwanda was unable to manufacture the medicines themselves.[165] This evidenced a good example of the invocation of the TRIPS flexibility in order to realise the right to health.

Thirdly, the limitation mechanism contained in the human rights regime itself enables TRIPS interpreters to harmonise the seeming conflict during interpretation and this promotes the realisation of the human rights. As discussed in the first Part, the realisation of the human rights is subject to an internal limitation mechanism under the principle of legality, proportionality and promotion of general welfare.[166] Taking these principles into consideration the limitation under "public health", "national security" or "public order" needs to be least restrictive, of limited duration and subject to review.[167]

The limitation to the protection of the moral and material interest resulting from a creator's scientific and artistic productions also requires a balance with the other rights recognised in the ICESCR and also should be proportionate and, under certain circumstances, require compensatory measures, such as payment of adequate compensation.[168] This reflects the fact that any

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[163] *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of the Paragraph 6 of the Doha Declaration on TRIPS and Public Health: Proposal for a Decision on an Amendment to TRIPS*, WTO Doc IP/C/41 (6 December 2005) ('*Implementation of Paragraph 11 of the 2003 Decision*'). For a detailed discussion on the Proposal, please refer to Part Two.Chapter 5.II.B.

[164] This proposal was originally open for acceptance by members until 1 December 2007, but was extended to 31 December 2009 for the first time and to 31 December 2011 for the second time. See WTO General Council, *Amendment of the TRIPS Agreement – Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/711 (21 December 2007). See *Amendment of the TRIPS Agreement – Second Extensions of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/785 (17 December 2009).

[165] See WTO, 'Patents and Health: WTO Receives First Notification under "Paragraph 6" System' (20 July 2007), available at: <http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm>.

[166] See Part Two.Chapter 3.II.A.

[167] CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) paras. 28–29.

[168] CESCR, *General Comment No. 17*, 35th Sess E/C.12/GC/17 (12 January 2006) paras. 22–4.

limitation under terms such as "public health", "morality" "national security" or "national emergency" should be temporary with limited duration. Similarly the reading of the limitation on the rights to material and moral interests resulting from scientific and artistic productions also shows that the limitation needs to be proportionate and can require compensation under certain circumstances. This echoes the compulsory licensing mechanism contained in TRIPS, and gives much more leeway for the interpretation of the TRIPS flexibilities. During the interpretation of TRIPS, this internal limitation mechanism should also be considered, and it gives rise to the invocation of TRIPS flexibility to achieve the realisation of human rights.

In summary, the human rights regime challenges and limits the patent protection system and also expands and reinforces patent protection. The balanced understanding gives rise to a coherent and harmonised interpretation of TRIPS. Likewise, the interpretation of TRIPS can promote a harmonised and coherent relationship between TRIPS and the human rights regime, and the realisation of human rights can also be achieved with such a balanced interpretation of the intellectual property protection under TRIPS.

### B. *Applying GATT Interpretation Methods to TRIPS*

As part of the whole package deal of the WTO laws, the covered agreements should be interpreted in a harmonised way and consistent with each other. TRIPS can and should also invite the rules contained in the covered agreement into the interpretation of itself. The procedure of GATT should also be referred to by the TRIPS disputes settlement mechanism and be used as a general principle.[169] The right to health has an impact on the access to medicines, and the introduction of the right to health, the right to property and the right to fruits of creation into the interpretation of TRIPS will also be subject to a GATT interpretation method since the drugs which are subject to patent rights are used for trade as goods in the WTO context for the access to medicines.

#### 1. *Links between Human Rights and GATT*

The regulation of free trade is the main purpose of GATT and the whole WTO. Human rights issues may not play a major role in this agreement, and the in the past GATT and the international trading system instruments have

[169] Frankel, above n. 32, 424.

been criticised for lack of attention to and consideration of human rights.[170] However human rights issues have been considered by the WTO in GATT.

Firstly, some GATT legal texts show the links between human rights considerations and GATT. Article XXIII.2 provides that, when GATT investigates and makes recommendations with respect to claims of nullification and impairment, they may consult with the Economic and Social Council of the UN and with appropriate intergovernmental organisations.[171] This has been suggested to show some links between the social and economic human rights and GATT.[172] Article XXIX.1 of the GATT also provides observation of the principles of various provisions of the Havana Charter.[173] Article 7 of the Havana Charter attempted to establish a legal rights framework for trade issues with devotion to fair labour standards.[174] This has also been regarded as recognising some links with the preservation of human rights when dealing with some products in respect of prison labour.[175]

Secondly, some mechanisms adopted by GATT are also regarded as having taken some human rights concern into consideration. Robert Wai is of the opinion that some human rights considerations, especially concerning the social and economic rights, can be achieved through some mechanisms adopted by WTO-GATT. Examples of such mechanisms are anti-dumping or countervailing measures, or some of the principles adopted by GATT such as Most Favoured Nations and National Treatment and the carve-outs contained in Article XX of GATT.[176]

Thirdly, the open-textured language contained in Article XX of GATT has also been argued to encompass some human rights concerns. It has also been argued that the international social and economic right might help to articulate the purposes listed in exceptions such as Article XX(a) "public

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[170] See Bal, above n. 6, 75; also see Howse and Mutua, above n. 40, 17.

[171] GATT art XXIII:2.

[172] Wai, above n. 59, 59.

[173] See Virginia Leary, 'Workers' Rights and International Trade: The Social Clause (GATT, ILO, NAFTA, U S Laws)' in J. Bhagwati and R. Hudec (eds), *Fair Trade and Harmonization: Prerequisites for Free Trade?* (1996) cited in Wai, above n. 59, 59.

[174] See UN ESCOR Conf on Trade & EMP, *Havana Charter*, (1950) UN Doc E/Conf.2/78., art 7.

[175] Wai, above n. 59, 59.

[176] Ibid., 60–2; also see Howse and Mutua, above n. 40. The author states that the GATT non-Discriminatory treatment and some provisions reflect the protection and promotion of human rights.

morals"[177] or Article XX(b) "human, animal or plant life or health".[178] Robert Howse is also of the view that the establishment of WTO should give Article XX new opportunities to be re-interpreted in light of international human rights despite the fact that the general human interests were reflected in the agreement at the outset of GATT when human rights were still at "infancy" but have been neglected in GATT jurisprudence for long time.[179] Because the WTO requires the interpretation of WTO laws in accordance with customary rules of interpretation of public international law,[180] the VCLT has been referred to in order to guide the whole interpretation process. Article 31(3)(c) of the VCLT can also be used to invite other rules of international law rules into the interpretation of the GATT rules, especially in the interpretation of the open-textured language of Article XX of GATT. The exceptions contained in the Article XX of GATT are considered to overlap with concerns of international human rights law.[181]

2. *Application of GATT Interpretation Method*

The GATT adopts its own two-tiered system of interpretation, and this two-tiered test can be applied to the interpretation of TRIPS with different emphasis on the Chapeau of Article XX of GATT.[182] The TRIPS Agreement provides some similar wordings to those used in the GATT such as "to protect human, animal or plant life or health",[183] and "to protect public health" in its principles.[184] This suggests that the interpretation method used by GATT through Article XX can also be applied to the interpretation of TRIPS. The interpretation of the TRIPS carve-outs, however is a different challenge and cannot be approached in the same manner as used in the GATT. It has been argued that in the GATT the trade goal dominates all other interests. However the different approach taken in TRIPS where there is a balance between a protection and a trade goal requires less assertion of trade dominance and more consideration of other interests in the interpretation of the

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[177] Feddersen, 'Focusing on Substantive Law in International Economic Relations: The Public Morals of GATT Art XX(a) and "Conventional" Rules of Interpretation' (1998) 7 *Minnesota J Global Trade* 75; cited in Wai, above n. 59, 61.

[178] See GATT Panel Report, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, DS10/R (adopted on 7 November 1990) [73]; it refers to the WHO.

[179] Howse and Mutua, above n. 40.

[180] See art 3.2 of DSU.

[181] Legal articles include: Wai, above n. 59, 61; Bal, above n. 6, 66–9.

[182] See Part One.Chapter 3.II.B.2.

[183] See art 27.2 of TRIPS and art XX(b) of GATT.

[184] Art 8.1 of TRIPS.

TRIPS carve-outs.[185] In this kind of situation, the invitation of the GATT interpretation method should not be given the same amount of weight as that in the TRIPS.

The protection of health can become a vital interest encompassed in TRIPS, and it should easily pass the specific provision test.[186] The right to health imposes obligations on states to *respect*, to *protect* and to *fulfil*[187] the right and this requires *inter alia* access to medicines that are affordable within available resources. The first tier of the test requires that the measure taken by a state to ensure the access to medicines as part of its obligation toward fulfilment of the right to health must be a "necessary" measure to protect the "vital interest" in health.[188] A state law in the protection of health right for public health concern will pass this tier of test, as public health protection is necessary for the trade restrictions at certain point. The second tier of the test prohibits any "arbitrary or unjustifiable discrimination" or "a disguised restriction on international trade". A limitation on patent protection in order to protect public health should not constitute an "arbitrary or unjustifiable discrimination", and the protection of public health will promote the realisation of the right to health.[189] The prohibition of "a disguised restriction on international trade" reflects the dominance of the trade goal in GATT, and this tier of the test should not be applied in view of the difference between the application the method of interpretation of GATT Article XX and method of interpretation of TRIPS flowing from the different balance of goals.[190] With this introduction of human rights norms, the carve-outs such as "to protect human, animal or plant life or health" and "to protect public health" in TRIPS for health concern should pass the test under the interpretation method of the Article XX of GATT.

## III. The Right to Health in TRIPS

### A. *Object and Purpose*

The object and purpose of TRIPS gives reference to human rights, and the right to health is reflected in the TRIPS.

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[185] See the interpretation at Part Two.Chapter 5.

[186] See Part One.Chapter 3.II.B.2(a), and it provides the test requirements on justifying health.

[187] See Part One.Chapter 2.I.B.3.

[188] See the analysis on this tier of test at Part One.Chapter 3.II.B.2(b).

[189] See Part One.Chapter 2.I.C.

[190] See Part One.Chapter 3.II.B.2(b), and it suggests that less trade emphasis should be put on interpretation of TRIPS provisions.

Firstly, the open-textured language used in the Preamble, Articles 7 and 8, such as the use of phrases like "public policy", "conducive to social and economic welfare" and "public health" and the lack of any internal explanation of the meaning of such phrases invite and require reference by panels and Appellate Body to sources outside WTO including human rights norms.[191] As argued above, the open-textured language used by members may suggest an intention to refer to outsides sources, and such reference allows the right to health to be taken into consideration when seeking to interpret TRIPS.[192] As also guided by Article 31(3)(c) of VCLT, this allows the TRIPS interpreter to refer to the human rights norms to find the meaning behind the ordinary meaning of the language used in TRIPS.

Such terms as "public policy" and "conducive to social and economic welfare" suggest that the interpretation of TRIPS should be conducted in the light of the human rights concerns because human rights are aimed at respect for human dignity and promotion of the larger freedom of human beings to enhance a better enjoyment of social and economic welfare.[193] Without respect for fundamental human rights enjoyment of social and economic welfare can not be widely achieved.

The reference to "public policy objectives of national systems" contained in the Preamble of TRIPS can be seen to provide another avenue to consider respect for human rights. The public policy perspectives concerning intellectual property protection at the national level should be interpreted as including national obligations under international treaties. The right to health includes obligations for states to *respect, protect and fulfil* and core obligations "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs".[194] In this sense, the right to health, as part of it, enjoys the respect from TRIPS.

The specific language used in Article 8 further elucidates the object and purpose of TRIPS. The adoption of measures in the protection of "public health" suggests a general view of TRIPS for the protection of health of

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[191] See paragraph 5 of Preamble, art 7 and art 8 of TRIPS.

[192] See Part Two.Chapter 6.I.B.3.

[193] This can be found at the Preamble of UDHR as 'Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom'; and in ICESCR as 'Recognizing that, in accordance with the Universal Declaration of Human Rights, the ideal of free human beings enjoying freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his economic, social and cultural rights, as well as his civil and political rights'.

[194] See Part One.Chapter 2.I.B.3.

human beings. "[P]ublic health" is related to the control of epidemic disease to ensure people's right to health which is an aspect of the preventive aspect of the right to health.[195] The "public health" consideration can be used as a justification for the protection of the right to health to limit other human rights for a limited duration. That TRIPS singled out the protection of "public health" shows an intention of members of TRIPS to give a higher status to the protection of the health, and an intention that the concern on the right to health should be given due consideration during the interpretation of the specific provisions of TRIPS.

The Doha Declaration directly incorporates the expression of "access to medicines" in paragraph 4 as

> We agree that TRIPS does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to TRIPS, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Because the access to medicines is a very important part of the right to health, the specific words used to promote "access to medicines" are a reflection of the intention of the members of TRIPS to take the right to health into consideration. The interpretation of TRIPS will be enlightened by this object and purpose, and the understanding of the objectives and principles of TRIPS should be understood in the light of the issue of access to medicines contained in the human rights regime.

Paragraph 3 also emphasises that:

> We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

This emphasis acknowledges that intellectual property protection can provide incentives for encouragement of the creation of new products, including pharmaceutical products and medicines. It is part of the general justification of the intellectual property system that it can have positive benefits.[196] However the paragraph also refers to the possibility that intellectual property systems can have strong effects upon the prices that rights holders may seek to charge given their protected position on the market for such medicines. Abbot makes the point that Paragraph 3 is a controversial juxtaposition. He observes that there is emphasis both on the importance of patents and prices but without discussion of explicit recognition of the concern of developing

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[195] See Part One.Chapter 2.I.C.

[196] See Part One.Chapter 2.III.B.1.(b).

countries to address the diversion of medical research caused by the incentives. The author is of the view that it is a modest concession to pharmaceutical companies by developing countries.[197] Another commentator argues that the reference to "intellectual property protection" suggests a broader coverage instead of a narrow scope focussed only on patents.[198]

This juxtaposition in Paragraph 3 recognises the need to find a good balance between patent protection and the promotion of access to medicines, and this reflects the balanced reading contained in the human rights approach to the intellectual property protection. As discussed, the human rights regime can also reinforce the intellectual property protection regime.[199] The reiteration of the importance of intellectual property protection can constitute a form of recognition of the place of intellectual property protection contained in the human rights regime.

The two paragraphs cause difficulty in the implementation of the balance between the goals of protection of intellectual property and promotion of access to medicines. On one side, the public health supportive manner to promote access to medicines gives rise to the consideration of the right to health. On the other side, the protection of intellectual property can be seen as consistent with and expression of the implementation of the human rights recognition of the right to property and the cultural rights, but at the same time it has the potential to inflate the prices of medicines which appears in conflict with the right to health to the extent that it negatively impacts upon access to medicines by artificially inflating prices. This understanding of the object and purpose contained in TRIPS can also be understood with certain limitations contained in the human rights regime when there is reference to human rights norms. The temporary limitation under "public health" may help to justify the limitation on pharmaceutical patent protection, and this can shed light upon the understanding on the compulsory licensing contained in the Article 31 of TRIPS.[200]

In addition, the open-textured term of "public health" may also be understood in an evolutionary manner. It is possible that the evolution and development of diseases will require adjustments and changes to the law related to the disease. Access to medicines requires the provision of essential drugs to cope with epidemics and other medical emergencies and this gives grounds to certain limitations to the private property economic interests of intellectual

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[197] Frederick M. Abbott, 'The Doha Declaration on TRIPS and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469, 491.

[198] Gamharter, above n. 161, 135.

[199] See Part Two.Chapter 6.II.A.2.(b).

[200] For detailed discussion, see Part Two.Chapter 5.III.D, the art 31 has been analysed.

property holders under patent in order to respond to the obligation to preserve and safeguard "public health" in various situations. It shows that the interpretation of TRIPS can be conducted in an evolutionary manner with the inclusion of a "public health" perspective into TRIPS and this evolutionary interpretation on "public health" should also provide a perspective to the interpretation of the scope and implications of the exceptions of TRIPS.

### B. *Specific Provisions*

The right to health has been referred to during the interpretation of the specific provisions of TRIPS. Especially, Articles 27, 28, 31 together with Articles 6 and 30, when considered as a whole, have taken the right to health into consideration, and the right to health has been intensively referred to.

#### 1. *Article 27*

Article 27 has taken the right to health into consideration. Although the non-discrimination requirement makes it impossible to exclude the patentability of pharmaceutical inventions, Article 27(2) still provides for the exclusion on the justified grounds.

The interpretation of the open-textured language of this Article implies an intention of TRIPS members to refer to sources outside TRIPS to determine the meaning of the language.[201] The human rights regime may be an appropriate and relevant outside source. The right to health and the human rights context can be a useful reference when seeking to define the meaning of *ordre public* or morality, and the limitations in the human rights regime can contribute to the understanding of the terms used in this Article. Furthermore, Paragraph 4 of the Doha Declaration provides an interpretation of TRIPS "in a manner supportive of WTO members' right to protect public health",[202] and this gives an express link to the human rights context as a source to be referred to in the interpretation. The public health concern is related to control of epidemic disease, and is one dimension of the right to health.[203] In fact, the right to health also depends upon the realisation of public health.[204]

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[201] The language used such as "*ordre public*" and "public health" etc does not have specified definition in TRIPS, and such language used implies the intent of negotiators of TRIPS to refer to the sources outside TRIPS.

[202] See *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 4.

[203] See Part One.Chapter 2.I.C.

[204] See Part One.Chapter 2.I.C.3.

The specific exclusion grounds of "to protect human, animal or plant life or health" may refer to the human right to health. The interpretation of the term of *ordre public* or morality, therefore, can also refer to the right to health.

The right to health imposes upon a state an obligation to establish its health legislation and health policy to ensure adequate access to medicines.[205] When a state has a supply of life saving drugs they should be made available to combat disease.[206] On the other side, other human rights like the human right to property and human right to enjoy the fruits of creation can reinforce the validity or value of intellectual property protection.[207] The balance of these competing rights has also been echoed in this Article during the process of interpretation.

Some human rights can be limited upon grounds, including public order or morality grounds, when several factors of general social welfare and the rule of law and the rule of proportionality are considered.[208] The limitations justifiable to protect the *ordre public* can be used to permanently limit other human rights for security reasons, and public health concerns can be included into justifiability of exclusions based upon the need to protect or promote the *ordre public*.[209] This means that the right to "the fruits of creation" and the right to property may be limited where required to protect the *ordre public*. This kind of limitation has been echoed by the permitted exclusion provided by TRIPS.

Patent protection can have an adverse effect upon access to medicines, but the problems that impact upon access to medicines cannot be totally solved by manipulation or adjustment of patents upon medicines. There will still be outstanding issues about access to medicines even if patents over medicines did not exist. The exclusion contained in Article 27.2 with specific reference, by way of particular example to the protection of human health, therefore, can be interpreted as a mechanism that facilitates human rights obligations in this sense by limiting the patent covering certain medicines when serious security grounds arise. However, the interpretation shows that this form of limitation can only be invoked when a public health crisis is of sufficient severity that it either has caused, or has the potential to cause, riots or some other forms of security problem.[210] This can be seen to be a reflection of

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[205] See Part One.Chapter 2.I.B.3.

[206] See Part One.Chapter 2.II.B and C.

[207] See Part One.Chapter 2.III.A and Chapter 6.II.A.2.(b).

[208] See Part One.Chapter 3.II.A.

[209] See discussion in Part One.Chapter 3.II.A.1(c).(i), it offers that, in certain situation, the "public health" can be covered under the grounds of *ordre public* or "public order".

[210] See Part One.Chapter 3.II.A.3, the extent of public health to security has been discussed.

the rule of proportionality in the operation of the limitation as discussed above.[211]

2. *Article 28*

The access to medicines requires the availability of the medicines at affordable prices. The problem is that many countries which are in the need of the medicine lack manufacturing capacity and so need to source a supply of medicine through importation. If cheap medicines are made available through parallel import from another country, patent protection which allows the owner of patent rights the exclusive right to control importation of the product can then give rise to a problem. It seems that the full-fledged protection within conferred by both product patent and process patents over the use, selling and offer for sale and import rights has restricted the cheaper sources of access to medicines, although some cheaper sources can be made available through the price difference in different markets.

However, the exclusive rights conferred under Article 28 should be subject to Article 6 exhaustion of rights. As discussed above the meaning and scope of Article 6 should be left free for the national jurisdiction to establish, and this provides an option to permit parallel import.[212] The object and purpose of this Article is to deal with the distribution of goods, and for the sake of the public health context it can be argued that parallel importation of patented medicines, should be allowed. However, the object and purpose of TRIPS, as analysed, should be understood to encompass both protection and promotion goals, and a balance between public good and private interest should be struck. The parallel import of cheap sources of medicines may meet the goal to satisfy the public good in relation to public health issues. This understanding can be reinforced with the subsequent development contained in paragraph 5 of the Doha Declaration, and it makes clear that, in the public health context, the nature and scope of exhaustion of rights should be left to each jurisdiction to establish. This assists the interpretation in this Article, and the access to cheaper sources of medicines through parallel import should be allowed under national practice, subject to the requirements of national treatment and MFN being met.

According to this understanding, the Article 28 does not set up an obstacle for the availability of cheap sources of pharmaceuticals if parallel importation is permitted under Article 28. Then, the understanding on Article 28 shows the respect and protection of the right to health, since it does not

[211] See Part One.Chapter 3.IIA.1 and Chapter 3.II.A.3.
[212] See Part Two.Chapter 5.III.C.

necessarily refrain the right to health by "denying or limiting the equal access to all persons" of the cheap sources, which are contained in the legal obligations under the right to health.[213]

### 3. *Article 31*

The interpretation of Article 31 finds the expression of the right to health, including *to respect, to protect* and *to fulfil*. In addition, it meets the international obligation under the right to health.

#### (a) *Grounds*

The grounds for the grant of compulsory licensing can give consideration *to respect, to protect* and *to fulfil* the right to health. The interpretation of this open-textured provision is crucial in the understanding of the human rights consideration in TRIPS.

Firstly, the interpretation of compulsory licensing can also be crucial for the promotion of the access to medicines at an affordable price, as it has been carved out of the exclusive rights contained in the Article 28 and forms an exception to the non-discrimination requirements contained in the Article 27.1.[214] The application of this carve-out and exception will be determined by the object and purpose of TRIPS and this Article. After an examination of Article 27, Article 30 and Article 31, it has been pointed out that the non-discrimination requirements "must not allow countries to have exceptions for purely economic protectionist reasons".[215] The carve-outs of this Article should be only justified by other considerations. The object and purpose of TRIPS shows that public interest concerns and objectives should be taken into account in order to strike a good balance in the protection of private rights and the protection of public interests. The carve-outs contained here should be understood in accordance with this object and purpose of a balancing mechanism in protection. Specifically, if a dispute concerning pharmaceutical patent protection has been lodged with the WTO, the interpreter needs to refer to the object and purpose of TRIPS. An interpretation that recognises the need to provide promotion of access to medicine, therefore, should be adopted when interpreting this compulsory licensing mechanism. As discussed, the right to health is understood to promote the

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[213] See Part One.Chapter 2.I.B.3.(a).

[214] As for the relationship between articles 27.1, 28 and 31, please refer to Part Two.Chapter 5.III.E.1.

[215] See Kevin J. Nowak, 'Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Art 27' (2005) 26 *Mich J Int'l L* 899, 939.

access to medicines and medical services and this is an essential core element in the right to health.[216] A public interest supportive manner of interpretive approach capable of facilitating the access to medicines is just a reflection of the consideration of the right to health.

Secondly, the human rights regime has an interface with the compulsory licensing exception contained in TRIPS.[217] The patent protection system seems to involve a dilemma between the encouragement of inventions with enjoyment of a certain degree of human rights protection, *viz* of the right to fruits of creation and the right to property and human right to health to ensure the access to medicines. It is an important principle in the human rights regime that human rights can be limited or derogated under the principle of legality, proportionality and other principles.[218] The concept of "public emergency" is an important principle for the derogation of human rights, and "public emergency" can be invoked for limitation and derogation when epidemic disease is rampant and poses a threat to a large segment of the population, or even to the life of the whole nation.[219] This derogation can overlap with the ground of "national emergency" justifying a compulsory license in the health context, and this indicates a human rights consideration underpinning TRIPS finding one expression in the promotion of access to medicines. "Other circumstances of extreme urgency" can also be given a similar understanding to promote the access to medicines. From this perspective the interpretation of "national emergency" and "other circumstances of extreme urgency" together with the understanding on the "public non-commercial use" should not be regarded only as grounds that limit the private rights in TRIPS, but also as a tool to limit the human rights perspectives of the right to property and the right to the fruits of creation. This form of interpretation can promote general welfare by facilitating dissemination of pharmaceutical technology, and the implementation of the right to health can be advanced.

Thirdly, the provision that members are free to establish the constituents of the grounds of "national emergency", "extreme urgency" and "public non-commercial use" will enable a state to seek to fulfil the obligation upon states to *respect* and to *protect* the right to health.[220] The fact that a health crisis actually exists can constitute a national emergency and extreme urgency together with public non-commercial use will help to solve the problem of access to affordable medicines when the patent is not available for public

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[216] See Part One.Chapter 2.I.B.3.

[217] See Part One.Chapter 2.III.A.1.(d).(i).

[218] See Part One.Chapter 3.II.A.1.

[219] See Part One.Chapter 3.II.A.2, and it has been discussed that the right to fruits of creation should be derogated in a public health context.

[220] See Part One.Chapter 2.I.B.3.

interest purposes. The public non-commercial use justification can not only be used for compulsory licensing to deal with epidemic disease but it can be used to handle other diseases which impact upon the public interest domain.[221] The access to medicines is further facilitated through this kind of interpretation. The fact that a license can be granted on a governmental decision without a requirement of prior request or negotiation with a third party or patent holder can expedite the procedures for seeking to respond to the public health needs.[222] Similarly the fact that there is no need to specify the quantity and value of the product to be produced or imported allows flexibility that could make the access to medicines easier and faster.[223] This assists the realisation of the right to health in terms of the state legal obligation of "*to respect*" "*to protect*" and "*to fulfil*".

Finally, given that members are free to establish the grounds that will justify the grant of compulsory licensing and the clarification that "it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency",[224] the quick spread of life-threatening diseases can easily be defined by a state to constitute a "national emergency" or "extreme urgency". In this circumstance, the promotion of the access to the use of patented drugs to respond to these life-threatening diseases will meet the requirements under the right to life, while the right to life can be used to support access to emergency medical treatment or life-saving drugs.[225]

(b) *Duration*

The requirement of limited duration of the compulsory license shows the temporary nature in this mechanism which calibrates TRIPS to the human rights protection. As discussed, human rights have a permanent nature and are inalienable and fundamental to individuals.[226] Patent protection includes a certain degree of human rights protection, although the scope of the

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[221] This is likely to vary with the wealth and expectation of a country. In some countries a certain level of health care may be demanded by the population who have a high expectation while in another country there is no expectation or experience of such a level of care. It seems that a line between them is open for different country to decide.

[222] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (Oxford University Press, 2007) 316–7.

[223] Ibid., 317.

[224] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) para. 5(c).

[225] See Part One.Chapter 2.II for the analysis of the relationship between the right to health and the right to life.

[226] See Part One.Chapter 2.III.B.2(a).

protection does not necessarily overlap.[227] However a human rights approach to patent protection requires a good balance between the patent protection and the benefit of scientific progress, and between the patent protection and other human rights protections, such as the right to health.[228] Therefore human rights protection, on one hand, reinforces patent protection,[229] but on the other hand, it also limits patent protection.[230] The interpretation of the duration of the compulsory licensing meets the dynamic requirement in patent protection, and this interpretation can be used to achieve the limitation and reinforcement posed by the right to health.[231]

The grant of a compulsory licence may provide a useful response to a situation that poses a severe threat to the right to health, but that response may be required to be dynamic to meet the changing circumstances of the emergency or the impact of the benefits provided by the compulsory licence. The requirement that the compulsory licence should not be permanent, but should be limited in time is a recognition that circumstances may change in such a dynamic situation. TRIPS is based on a dynamic balance, and this dynamic balance may require a temporary balance between private personal property rights and public interests when the existing situation justifies such a response. The grant of a compulsory licence could be regarded as a flexible exception to its normative dynamic balance provided by the minimum standards set out for patents in TRIPS. Through this kind of dynamic temporary exception TRIPS provides a mechanism that can seek to respond to the public interest goal and the private protection goal in an attempt to meet the ever-changing situation. Because human rights are permanent in nature but TRIPS strikes a dynamic balance, the purpose of temporary exception in patent protection is to provide a means of adjustment to meet the immediate or current needs of the permanent requirement of human rights. This means that, when the general standards set out in TRIPS are not sufficient to meet the requirements of human rights in the ever-changing situation, resort may be had to this flexibility mechanism to calibrate the operation of the patent standards to meet the human rights imperative purpose until an appropriate dynamic balance has been achieved. At the same time, bearing in mind the human rights perspective on intellectual property protection, the right to property and the right to fruits of creation need to be considered within the calibration of this balance, and these reinforcing forces in intellectual

[227] See Part One.Chapter 2.III.B.2(a).
[228] See Part One.Chapter 2.III.B.2.(b).
[229] See Part Two.Chapter 6.II.A.2.(b).
[230] See Part Two.Chapter 6.II.A.2.(a).
[231] See Part Two.Chapter 6.II.A.2.(c).

property protection will put more weight on the dynamic balance to counter the right to health.[232] In this kind of situation the changing temporary nature of compulsory license in TRIPS, can be operated so as not to divert itself from human rights requirement, but to adjust itself with its flexible dynamics to meet the human rights requirements when circumstances so demand.

In addition, the human rights regime offers an internal mechanism to solve a seeming conflict. It does this with limitations and derogations to balance the requirement under various human rights. The derogation under the rubric of "national emergency" or "public health" is frequently used to respond to the various human rights requirements, but derogations under such grounds are of temporary nature.[233] The issues of duration and the proportionality should be considered in any derogation of the rights.[234] This temporary requirement on the derogation of human rights shows that the grounds of "national emergency" or "extreme urgency" for compulsory license, although they should be conducted temporarily, can respond to the challenge of human rights requirements.

(c) *Scope*

Finally, the proportional requirements on the scope for compulsory licensing will enable the balance between the patent protection and the right to health.[235] There may be a danger that proportional requirement concerning the scope of compulsory licensing will impact the realisation of the right to health. This danger can be averted if the member makes appropriate or skilful use of the flexibility provided by the open textured nature of the language that permits or justifies the grant of compulsory licenses. The proportionality arrangement concerning the scope can be read to be a consideration of human rights requirements.

Human rights considerations impact upon and may restrict the private personal right of intellectual property protection through the necessity to respond to the obligation to secure the right to health, but human rights concerns also reinforce intellectual property protection through the requirement to secure the right to property and the right to fruits of creation.[236] Within the human rights regime internal mechanism, the grounds of "national

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[232] See Part Two.Chapter 6.II.A.2.(b).

[233] See Part One.Chapter 3.II.A. According to Kiss, limitation is of permanent nature, and derogation is of temporary nature. The "national emergency" and "public health" are grounds used to derogate some of the human rights.

[234] For example, see CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) paras. 28–29.

[235] See Part Two.Chapter 5.III.D.4.(b).

[236] See Part Two.Chapter 6.II.A.2 for interpretation of scope.

emergency" or "public health" can be used to limit the human rights, but also require proportionality.[237] This proportionality ensures that there should be the minimum limitation or derogation of human rights, and this requires a balance of various human rights to establish or find the parameters of the limitation. The proportionality on the scope of compulsory licensing reflects this idea in that it treats compulsory licensing as a case-by-case issue to ensure the protection of property rights and the protection of health rights. Then, the access to medicine can be facilitated through an appropriate use of the flexibility to determine the situations which justify issuance of a compulsory license to respond to the perceived and recognised situation.

(d) *Supply and Parallel Importation*

The domestic supply problem has been clarified by the subsequent development, and the interpretation of this paragraph reveals the consideration of the right to health. Reference to subsequent agreements and subsequent practices can help to find the intentions of the members in the promotion of the access to medicines. The relationship between the right to health and patent protection can be found in this flexibility after the clarification of the interpretation of this Article, although direct reference to the right to health will not be resorted to.

Firstly interpretation of this provision shows that an effort has been made in the TRIPS environment to facilitate access to affordable medicines; and the special consideration relating to developing countries and least-developed countries reveals the intentions of members. Secondly, an evolutionary attitude towards interpretation requires that a later law should be followed in identifying the meaning of a treaty language. A subsequent development should be regarded as a later law, and the arrangements made in the subsequent development of the Declaration and the Decisions show that access to medicine can be achieved through the utilisation of an exception. In this way, a harmonisation between the human rights regime and TRIPS can be achieved with carve-outs to the necessary extent.

The arrangement of a system to facilitate a supply of pharmaceuticals to a country that lacks capacity to manufacture can be seen to be a response to the international obligation concerning the right to health.[238] The international obligation under the right to health requires international cooperation, respect for the enjoyment of the right to health in other countries, and

[237] See Part One.Chapter 3.II.A.3.

[238] See Part One.Chapter 2.I.B.3.(b), it requires international cooperation, the respect for the enjoyment of the right to health in other countries, and prevention of third parties from violating the right in other countries.

prevention of a third country from violations of the right to health. For a developed country member of TRIPS to allow another country to produce pharmaceutical products to export to a third country to solve the health problem in that third country is a manifestation of respect for the enjoyment of the right to health within the other country, and it is also a reflection of international cooperation.

In addition, the requirement "*to respect, to protect and to fulfil*" can be satisfied through this kind of arrangement. The non-interference with the patent right holder through permission to allow export of pharmaceuticals to a third country and those developing and least developed countries that are enjoined in the same regional agreement shows respect for the access to medicine. Providing a solution to the problem of a country which lacks manufacturing capacity by a system that enables lawful export from a country with generics manufacturing capacity shows affirmative action in the protection and fulfilment of the right to health in the promotion of the access to medicines. The special health purpose limitation in such an arrangement is a reflection of proportionality of the respect for the right to health.

Finally, the permission of parallel importation found within the interpretation of Article 6 indicates a respect of the right to health, and this interpretation facilitates access to medicines under Article 31. The interpretation of the Article 6 needs to consider the relationship with GATT XX(d),[239] but the interpretation of GATT XX will need to be conducted in the light of human rights.[240] Therefore, when adoption of patent measures is subject to the two-tiered test, the right to health should be considered. In fact, the analysis of GATT XX(d) shows that an open interpretation of exhaustion of rights will pass the test, and leaves it open for domestic law to make appropriate arrangements for parallel import systems and access to medicines. However, it has to be pointed out that, when the law of national exhaustion becomes an obstacle for the access to medicines elimination of a ban on parallel import is necessary. This interpretation will promote access to affordable pharmaceutical goods under the arrangements provided in Article 31 and its subsequent development.

(e) *Remuneration*

The requirement of adequate remuneration indicates respect concerning the work right and the right to property. At the same time, the provisions refer to an adequate amount and this terminology allows more flexibility in

[239] See Part Two.Chapter 5.III.C.2.(b) for a discussion of the relationship between art 6 and GATT.

[240] See Part Two.Chapter 6.II.B.

the interpretation.[241] As explained during the discussion of the limitation in Article 15.1(c) of ICESCR, the limitation and derogation should take the material interest of the creator into consideration.[242] The consideration of reasonable payment means that the material interests of creators have also been protected.

(f) *Summary*

In summary, the system of compulsory licensing provided under Article 31 and its subsequent development in TRIPS is policy development and a mechanism that shows consideration of human rights concerns within TRIPS.

The compulsory licensing mechanism shows respect to the right to health. A basic obligation under the right to health is the requirement *to respect* the right to health and this requires access to health services for all persons.[243] With the free establishment of compulsory licensing in TRIPS, a state can utilise this mechanism to facilitate access to cheaper or affordable generic drugs to be used for health services, and this shows that TRIPS encompasses mechanisms that recognise the need for mechanisms that respond to the right to health. The interpretation of the Article 6 shows that it leaves open for members of TRIPS to interpret the exhaustion of rights, and it means that the Article 6 will not ban the parallel importation. This will promote the access to medicines and will reinforce the respect of the right to health.

The provision of compulsory licensing reflects the obligation *to protect* under the right to health.[244] Indeed lack of a compulsory license system to facilitate access to drugs can be seen to be a violation of the obligation *to protect* under the right to health.[245]

The actual affirmative actions shown in the subsequent development of TRIPS expressed in the Doha Declaration, the 2003 Decision and the intended Amendment are responses to the obligation to *fulfil* the right to health.[246] The detailed arrangements provided for under Article 31 are enabling mechanisms to facilitate affirmative action in the promotion of the access to medicines.

Under Article 31 and its subsequent development, the compulsory licensing mechanism will permit the export of generics to meet the needs of a country that lacks sufficient manufacturing capacity to produce necessary drugs. The permission of parallel importation and the permission to allow

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[241] See the interpretation at Part Two.Chapter 5.III.D.6.
[242] See Part One.Chapter 2.III.A.1.
[243] See Part One.Chapter 2.I.B.3.(a).(i).
[244] See Part One.Chapter 2.I.B.3.(a).(ii).
[245] See Part One.Chapter 2.I.B.3.(a).(ii).
[246] See Part One.Chapter 2.I.B.3.(a).(iii).

third country suppliers to export under compulsory licence, subject to the actual arrangements under the 2003 Decision and the intended amendment are the reflections of responses to international obligations under the right to health.[247]

The compulsory licensing mechanism provides a balance between the protection of the right to property and the protection of the right to health, and a balance between the right to fruits of creation and the enjoyment of scientific progress. The right to property will require limitation when this is necessary to safeguard the public interest, and this means that the compulsory licensing can be seen to be a form of interface between the right to property and human rights concerns. The requirement that the licence be of a temporary nature plus the requirement that the licences be proportional arrangements recognises the need for a balanced consideration between the protection of the right to property and the right to health.

4. *Article 30*

These exceptions are significant when considering TRIPS in the light of the human rights regime.

Firstly, the public health policy can be considered in the interpretation. This is a reflection of *respect* for the right to health under the legal obligation.[248]

Secondly, the regulatory review exception can be significant to the right to health. The regulatory review exception can have economic impact on pharmaceutical patents, since it can assist introduction of generics to produce medicines earlier and help lower price of medicines and assist affordability. This is to *fulfil* and try to meet the core obligations of the right to health.[249]

Thirdly, the funding of health research is part of the right to health, and, through the exception permitting experimental use, a state *fulfils* the right to health, and promotes the realisation of the right to health.[250] The research exception can stimulate research in the pharmaceutical field, and promote more innovation in that field to address the ever evolving problems presented by diseases. Ultimately, this can help to realise the right to health.

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[247] See Part One.Chapter 2.I.B.3.(b).

[248] See Part One.Chapter 2.I.B.3.

[249] See Part One.Chapter 2.I.B.3.

[250] See CESCR, *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 37. It provides: "…The obligation to fulfil (promote) the right to health requires States to undertake actions that create, maintain and restore the health of the population. Such obligations include: (i) fostering recognition of factors favouring positive health results, e.g. research and provision of information; (ii)…(iii)…(iv) …"

Finally, the curtailment on economic interest is considered in this Article, and it shows a degree of protection for the property rights of the right holder.[251]

5. *Article 73*

The protection of the right to health balanced with the consideration of the property right and the right to fruits of creation can also be relevant to consideration of the security exception. The human rights regime recognises the validity of a limitation based upon the need to preserve "public order". Such a limitation may be a permanent where that is necessary for the maintenance of the political order and national security.[252] The mechanisms that could be invoked under the security exception could be utilised, if the health situation is serious enough to negatively impact upon national, regional or world peace and order. This kind of interface is a reflection of the balanced view adopted within the TRIPS intellectual property protection system towards the human rights frameworks.

[251] See Part One.Chapter 2.III.A.1.
[252] See Part One.Chapter 3.II.A.1.

# Part Three

## Impacts of Interpretation

Regional or bilateral free trade agreements (FTAs) have been used by many countries to adopt TRIPS-plus measures[1] to provide heightened levels of intellectual property protection. As a result access to medicines may be restricted and public health affected.[2] Thus, it will impact on the right to health.

The establishment of FTAs can be accomplished under three sets of provisions within the WTO legal system, namely Article XXIV of GATT, Article V of GATS, and the Enabling Clause.[3] To be recognised within the WTO system FTAs must comply with requirements concerning substance and procedure.[4] The adoption of TRIPS-plus in FTAs will be subject to this process and thus the relationship between the FTAs and TRIPS may be examined when considering the interpretation and implementation of TRIPS-plus provisions.

The establishment of the WTO dispute settlement system provides a judicial style process for WTO members to seek a settlement in trade disputes,[5] and Article 3.2 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) requires the interpretation of WTO laws in accordance with the customary rules of interpretation of public international law.[6] The examination of TRIPS provisions by following the interpretive approach contained in WTO law promotes access to medicines in TRIPS, and, ultimately, promotes the realisation of the right to health.

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[1] Generally speaking, TRIPS-plus refers to a higher level of intellectual property protection above that required by the TRIPS Agreement. It can imply the inclusion of a new area of intellectual property rights, implementation of more extensive standards, or elimination of an option for Members under TRIPS. See David Vivas-Eugui, 'Regional and Bilateral Agreements and a TRIPS-Plus World: The Free Trade of the Americas (FTAA)' 4, WTO <http://www.wto.org/english/tratop_e/region_e/sem_nov03_e/vivas_eugui_paper_e.pdf>.

[2] For e.g., see Jakkrit Kuanpoth, 'TRIPS-Plus Rules under Free Trade Agreements: An Asian Perspective' in Christopher Heath & Anselm Kamperman Sanders (eds), *Intellectual Property & Free Trade Agreements* (Hart Publishing, 2007) 27, 30–38.

[3] These three sets of rules are alternative in that art XXIV is applicable to agreements on trade in goods, the Enabling Clause covers trade in goods integration agreements concluded between developing countries, and art V of GATS deals with agreements providing for liberalisation in trade in services.

[4] Paragraph 8 of art XXIV obliges WTO members entering an FTA to abolish or diminish approximately to zero customs duties and other regulations of commerce with respect to barriers in all trade originating from one of their regional partners (namely, the 'internal requirement'), while the second, in paragraph 5, requires the Contracting Parties to an FTA not to increase duties or increase severity of the regulations of commerce with respect to third states (the "external requirements").

[5] James Cameron & Kevin R. Gray, 'Principles of International Law in the WTO Dispute Settlement Body' (2001) 50 *Int'l Comp L Q* 248, 249.

[6] *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 2, *Understanding on Rules and Procedures Governing the Settlement of Disputes* ('*DSU*'), art 3.2.

Many FTAs also have dispute settlement chapters or provisions to establish their own mechanism to settle disputes under the FTAs.[7] This can lead to the interpretation of the FTAs provisions by the relevant tribunals established under the FTAs. Consequently, the interpretation approach established by some FTAs will impact on issues concerning access to medicines and the right to health.

However, the establishment of TRIPS-plus and the interpretation approach adopted in FTAs will, no doubt, be impacted by TRIPS and WTO and the interpretation of TRIPS in WTO regime through the relationship established between FTAs and WTO law. As a result, consideration of issues concerning the protection of public health and the right to health in the FTAs can be impacted through the interpretation approach.

The interpretation of TRIPS with consideration of subsequent developments concerning the health issue has led TRIPS to be interpreted in a manner supportive of public health.[8] This poses the question whether the interpretation of FTAs should be consistent with TRIPS and the WTO or not. Will an interpretation of patent protection provisions in FTAs promote harmonisation between FTAs and TRIPS in the health context when the heightened patent protections in FTAs impose more restrictions on access to medicines?[9]

This part through discussion of the approach to interpretation of TRIPS considers the possibilities of the relationship between TRIPS and the TRIPS-plus provisions in the intellectual property chapters of FTAs regime to affect the interpretation of the patent provisions in FTAs. This part intends to analyse the TRIPS-plus regimes by examining patent provisions in FTAs to discern how the approach adopted by FTAs has affected their interpretation and to investigate the impact of different interpretation approaches on public health and the right to health. It is proposed that a harmonisation between TRIPS and TRIPS-plus can be achieved in the context of protection of the right to health through this kind of interpretation.

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[7] For example, Chapter 21 of the *US-Australia Free Trade Agreement* ('*US-Australia FTA*') (18 May 2004) 43 ILM 1248 (also known in Australia as '*AUSFTA*'); Chapter 19 of *US-Bahrain FTA*; Chapter 20 of *CAFTA-DR*; Chapter 22 of *US-Chile FTA*; Chapter 21 of *US-Colombia FTA*; art 17 of *US-Jordan FTA*; Chapter 20 of *US-Morocco FTA*, 44 ILM 544(15 June 2004); Chapter 20 of *US-Oman FTA*; Chapter 20 of *US-Panama Trade Promotion Agreement* ('*TPA*'), or sometimes it is called free trade agreement.; Chapter 21 of *US-Peru TPA*; and Chapter 20 of US-Singapore FTA.

[8] See *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) ('*Doha Declaration*') para. 4.

[9] For discussion of restriction on access to medicines, see Kuanpoth, above n. 2, 32–8. Also see Bryan Christopher Mercurio, 'TRIPS-Plus Provisions in FTAs: Recent Trend' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (Oxford University Press, 2006) 215, 224–34.

# Chapter 7

# Impacts on TRIPS-Plus in FTAs

## I. Interpretive Relationship Between TRIPS and FTAs

### A. *Relationship in the Interpretation*

#### 1. *Choice of Forum and Interpretation Rules in FTAs*

Some FTAs allow a choice of forum in dispute settlement. They allow the choice of either a WTO forum or a forum under the FTA.[10] In the US-Australia FTA, Art 21.4 provides for choice of forum in that the parties can choose either a forum under the FTA or other forum as both parties are party to, including the WTO forum.[11] Similar choice of forum articles can be found in most of the other US FTAs.[12]

The WTO DSB has left open whether a FTA dispute is exclusively subject to FTA jurisdiction.[13] If members of an FTA choose a WTO panel, it seems

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[10] There are three ways for FTAs to regulate choice of forum: "(1) leave the choice of forum up to the complainant", such as the art 21.4 of the US-Australia and most other US FTAs. Also see art 21.2 of the *Australia-Chile FTA*; (2) "oblige the complainant to submit the dispute to the WTO"; (3) "oblige the complainant to submit the dispute under the FTA". See Joost Pauwelyn, 'Legal Avenues to "Multilateralizing Regionalism": Beyond Article XXIV' (paper presented at the Conference on Multilateralising Regionalism, Geneva, Switzerland, 10–12 September 2007).

[11] Art 21.4.1 of the US-Australia FTA.

[12] Such as art 19.4 the *US-Bahrain FTA*; art 20.4.1 of *US-Morocco FTA*; art 21.3.1 of *US-Peru TPA*. In NAFTA, article 2005.1 provides for choice of forum for any dispute arising under both NAFTA and GATT. Available at: Office of the United States Trade Representative <www.ustr.gov> (last accessed on 16 February 2010).

[13] Appellate Body Report, *Mexico – Tax on Soft Drinks and Other Beverages*, WT/DS308/AB/R (6 March 2006) [54].

that the WTO panel will accept such jurisdiction.[14] In the *Mexico – Soft Drinks*[15] and the *Argentina – Poultry*[16] cases, the panel exercised its jurisdiction over the disputes arising from NAFTA and MERCOSUR respectively.

With this kind of choice of forum, after acceptance of jurisdiction over the disputes, either the WTO panel or the FTA panel will have to interpret the relevant provisions within its own ambit. Can the WTO interpret FTA provisions on the same subject matter that has been dealt with by both the WTO and the FTAs? Can the FTA panels also interpret the WTO provisions on the same subject matter? What are the rules for the interpretation of the provisions?

Firstly, a distinction should be made between the "jurisdiction" and the "interpretation". Although there is a choice of forum, a WTO panel can only have authority to rule on the claims arising from WTO covered agreements.[17] This means that the claims that a WTO panel can decide can only be relevant to WTO violation while the same is true for a FTA panel which can only decide on claims relevant to a FTA violation. In *Mexico – Soft Drinks*, the WTO Panel noted that it only had authority to rule on claims of breaches of WTO law, which means that "resolution of the present WTO case cannot be linked to the NAFTA dispute".[18] This, however, does not mean that the "applicable law" or "relevant law" should be restricted to WTO law or

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[14] In *Mexico – Tax on Soft Drinks and Other Beverages*, the AB, after examining Articles 3.2, 7.1, 7.2, 11, 19.2, and 23 of DSU, held that a WTO Panel was obliged to make objective assessment of the matter before it and it had "no discretion to decline to exercise its jurisdiction". Otherwise, "a decision by a panel to decline to exercise validly established jurisdiction would seem to 'diminish' the right of a complaining Member to 'seek the redress of a violation of obligations'"; Ibid., [46]–[57]. But see Caroline Henckels, 'Overcoming Jurisdictional Isolationism at the WTO-FTA Nexus: A Potential Approach for the WTO' (2008) 19 *EJIL* 571, 571–599, arguing overlap of jurisdiction between the WTO and the FTAs, will cause fragmentation of international law. The author argues that the WTO's judicial organ should use its inherent power of comity to decline to exercise jurisdiction so that the dispute can be resolved by an FTA tribunal where a dispute is inextricably connected with a dispute under an FTA and that exercising jurisdiction would not be reasonable in the circumstances.

[15] Panel Report, *Mexico – Tax Measures on Soft Drinks and Other Beverages*, (7 October 2005) WTO Doc WT/DS308/R [7.18]; and Appellate Body Report, *Mexico – Tax on Soft Drinks and Other Beverages*, WTO Doc WT/DS308/AB/R (6 March 2006) [54].

[16] Panel Report, *Argentina – Definitive Anti-Dumping Duties on Poultry from Brazil*, WTO Doc WT/DS241/R (22 April 2003) [7.38].

[17] DSU, art 1.

[18] Panel Report, *Mexico – Tax Measures on Soft Drinks and Other Beverages*, WT/DS308/R (7 October 2005) [7.11] and [7.15].

FTA law respectively.[19] At the same time, it is different between interpreting the law in issue with reference to another law and applying the law in issue together with another law.[20]

When interpreting the law, the full application of customary rules of treaty interpretation will be followed by WTO panels.[21] Articles 31–33 of the Vienna Convention on the Law of Treaties (VCLT) are codified customary international law rules for the treaty interpretation purposes by the WTO panel.[22]

The FTAs also have their own interpretation rules. In the US-Australia FTA, Article 21.9.2 provides for the interpretation of the treaty in accordance with VCLT rules,[23] even though the United States has not ratified VCLT.

> The panel shall consider this Agreement in accordance with applicable rules of interpretation under international law as reflected in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (1969).

Similar language is also used in the Korea-US FTA.[24] However, most other FTAs do not expressly incorporate VCLT rules of interpretation. Some FTAs require their interpretation to be in accordance with customary rules of public international law[25] and most others refer to applicable rules of international

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[19] See Pauwelyn, above n. 10. The authors pointed out that the distinction should be made between "jurisdiction" and "applicable law" or "relevant law" in deciding WTO violation claims.

[20] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 204–5. The author argues that the distinction should be made between "interpreting a norm with reference to another norm' and the 'applying a norm together with another norm".

[21] See Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (29 April 1996) section B page 17–18, and it provides that the WTO Agreement could not be read in "clinical isolation from public international law".

[22] See Sir Ian Sinclair, *The Vienna Convention on the Law of Treaties* (Manchester University Press, 1984) 153. Article 31 of VCLT has 4 sections to provide good faith textual interpretation, reference to the object and purpose interpretation and contextual interpretation and the reference to other international law interpretation. Article 32 deals with supplementary means of interpretation, and art 33 deals with the authenticity of two or more languages of a treaty. Also see Cameron & Gray, above n. 5, 254. In the *Japan-Tax* case, the Appellate Body also clearly stated that the VCLT represented a codification of customary international law and should be binding on all states. Appellate Body Report, *Japan – Tax on Alcoholic Beverages*, WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) section D page 12–14.

[23] *US-Australia FTA*, art 21.9.2.

[24] *Korea-US FTA*, art 22.11.2.

[25] Such as *Australia-Singapore FTA*, art 16.5 and *ASEAN-Australia-New Zealand Free Trade Agreement*, art 17.4.

law for the interpretation and application of the FTAs.[26] In this kind of situation the VCLT rules, being the codified customary international law rules, should be followed as interpretation rules for the panels to deal with state to state disputes.[27]

Article 31 of VCLT requires the interpretation of a treaty to follow good faith interpretation by referring to the object and purpose of the treaty.[28] It also requires reference to the subsequent agreement and subsequent practice or the "relevant rules of international law applicable" for the interpretation purpose in case any ambiguity arises.[29] Article 32 provides supplementary means for treaty interpretation by using preparatory works.[30] The reference to sources outside the immediate ambit of the treaty being interpreted is an important role in VCLT, which means that, in FTA dispute settlement cases, FTA panellists may be able to refer to TRIPS for the interpretation of FTAs.

### 2. *Impacts on Interpretation*

The choice of forum used under various FTAs will impact on the interpretation of TRIPS and the WTO law in several ways. The proliferation of FTAs may overlap with WTO law and may cause conflict between the decisions of WTO law and FTAs when each regime interacts with each other.[31] Finding ways to overcome this kind of potential conflict between the different regimes will be a central issue in international law. It is suggested that treaty interpretation is an effective way to give maximum effect to each treaty to avoid the seeming conflict.[32]

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[26] This can be found in most FTAs, eg. art 102.2 of *NAFTA*, art 1.2.2 of the *US-Chile FTA*, and art 17.6.1 (b) of *New Zealand-Thailand Closer Economic Partnership Agreement*.

[27] *Vienna Convention on the Law of Treaties*, opened for signature on 23 May 1969, 1155 UNTS 331(entered into force on 27 January 1980) ('*VCLT*'). The VCLT has been ratified by 111 states as of October 2010, see <http://treaties.un.org/Pages/ViewDetailsIII.aspx?&src=TREATY&mtdsg_no=XXIII~1&chapter=23&Temp=mtdsg3&lang=en>. This was confirmed in the *Canada – Agricultural Products*, in which the NAFTA panel ruled that the applicable rules of international law should include arts 31 and 32 of the VCLT. See Panel Report, *Tariffs Applied by Canada to Certain U.S. Origin Agricultural Products* (2 December 1996) NAFTA Doc CDA-95-2008-01 [118]–[119].

[28] VCLT, art 31.1 and art 31.2.

[29] VCLT, art 31.3.

[30] VCLT, art 32.

[31] See Pauwelyn, above n. 10, 5. The author notes that there may be an overlap of substantive rules in a dispute settlement procedure which may lead to conflict.

[32] This kind of view can be found in Pauwelyn, above n. 20, 244–74; also see Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' in Frederick M. Abbott, Christine

More importantly, an FTA panel may have reason to interpret a WTO provision to determine the meaning of an FTA provision. As in *Canada – Agricultural Products*, the NAFTA panel accepted Canada's submission that Article 4.2 of the WTO Agreement on Agriculture should be referred to for the interpretation of Article 710 of the FTA.[33] Further, the panel also referred to the VCLT to note that the object and purpose and the *travaux préparatoires* of the WTO Agreement on Agriculture should also be analysed for the interpretation of Article 4.2 of WTO Agreement.[34] This approach that an FTA panel can interpret a WTO provision can have significant impact on the interpretation of the TRIPS-plus provisions in the FTAs. As pointed out by a commentator, such an interpretation can "filter into the international realm" by way of establishment of FTA dispute settlement system or by way of citations from FTA dispute decisions.[35]

In the health context, TRIPS contains a flexibility mechanism to ensure the access to medicines, which includes carve-outs, open textured language and the compulsory licensing mechanism, etc.[36] The object and purpose of TRIPS requires the protection of intellectual property and the facilitation of international trade, but requires a balance between the protection goal and the trade goal as well as the balance between right holder and user.[37] Should an FTA panel take this into consideration when it interprets TRIPS-plus provisions? The subsequent development on the public health protection in the TRIPS and WTO regime has led to an interpretation of TRIPS, when taking consideration of subsequent developments, that can be characterised as health supportive.[38] Should the FTA panel take the subsequent development in TRIPS and the public health regime into consideration to interpret relevant TRIPS-plus provisions? Especially, when an FTA panel interprets

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Breining-Kaufmann, and Thomas Cottier (eds), *International Trade and Human Rights: Foundations and Conceptual Issues* (University of Michigan Press, 2006) 181, 196–202.

[33] Panel Report, *Tariffs Applied by Canada to Certain U.S. Origin Agricultural Products* (2 December 1996) NAFTA Doc CDA-95-2008-01 [170]–[172]. The FTA panel referred to art 4.2 of WTO Agreement on Agriculture for the interpretation of art 710 of the FTA.

[34] Ibid., [172]–[173].

[35] Susy Frankel, 'The Legitimacy and Purpose of Intellectual Property Chapters in FTAs' in Ross Buckley, Vai Io Lo and Laurence Boulle (eds), *Challenges to Multilateral Trade: The Impact of Bilateral, Preferential and Regional Agreement* (Kluwer Law International, 2008) 185, 198.

[36] Such as arts 30 and 31 of TRIPS.

[37] Preamble of TRIPS and Susy Frankel 'The WTO's Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property' (2005) 46 *Va J Int'l L* 365, 390. For the object and purpose of TRIPS, see the analysis in Part Two. Chapter 5.II.

[38] *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) ('*Doha Declaration*') para. 4.

TRIPS provisions, to what extent should the panel interpret it to ensure its consistency with the WTO interpretation when the WTO panel has established its jurisprudence?

### B. *Relationship with TRIPS*

The heightened patent protection in FTAs means that the interpretation of TRIPS-plus provisions in FTAs will be different from that in TRIPS, but the interpretation relationship between the TRIPS-plus provisions and TRIPS shows that the interpretation of the TRIPS-plus provisions will be impacted by this relationship. The heightened patent protections in FTAs impose more restrictions on access to medicines,[39] and this means that a proper interpretation of TRIPS-plus provisions is needed to promote harmonisation between FTAs and the TRIPS regime for the protection of the right to health.

While it is suggested that there must be a rational level in TRIPS-plus,[40] consideration of the rational limit of intellectual property protection, should refer to the object and purpose of intellectual property protection.[41] TRIPS is the international instrument which provides a coherent statement of the object and purpose of intellectual protection and therefore should be referred to provide a basis for rationalising the height of the boundary under this trade-related intellectual property protection framework.[42] TRIPS tries to set a minimum standard for members to adjust their laws to the same level of protection, and it strikes a balance in its ambit with its object and purpose and its flexibility, but most favoured nation treatment (MFN) should not be used as a lever to increase the minimum level of protection[43] and should not be used to circumvent the balance in the preamble of TRIPS.[44] Therefore, the flexibility contained in TRIPS and object and purpose of TRIPS should be given consideration in rationalising the boundary of the patent protection level in FTAs.[45] Thus, while interpreting the TRIPS-plus provisions, an FTA panel needs to consider the object and purpose of TRIPS.

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[39] For discussion of restriction on access to medicines, see Kuanpoth, above n. 2, 32–38. Also see Mercurio, above n. 9, 224–234.

[40] See analysis in Part Three.Chapter 7.II.C.

[41] See Frankel, above n. 35, 192–3.

[42] Ibid.

[43] In fact, the benefit for one country from the greater level of protection does not necessarily mean the benefit for trade overall. See Frankel, above n. 37, 192. For the analysis on the impact of MFN, see Part Three.Chapter 7.II.B.C.

[44] Frankel, above n. 37, 417.

[45] Peter K. Yu, 'The Objectives and Principles of TRIPS' (2009) 46 *Houston Law Review* 979, 1025–30. The author argues that the objectives and principles of TRIPS should be used

Moreover, this interpretation approach used in FTAs will extend the application of TRIPS in an evolutionary manner, which will lead to the inclusion of the application of the subsequent development of TRIPS. Post-TRIPS FTAs have shown the influence of TRIPS and its subsequent development. In the US-Peru TPA, the direct reference in the FTAs to the Doha Declaration[46] and the 2003 Decision[47] should influence the interpretation of FTAs.[48] Many other FTA members adopted side letters or Memoranda of Understanding (MOU) to clarify their intentions to adhere to the TRIPS flexibilities.[49]

The US and the Morocco have exchanged side letters concerning public health,[50] and similar side letters on public health can be found in the US-Bahrain FTA[51] and in the US-Oman FTA.[52] The US and the Canada have also made "memorandums of understanding" concerning the protection of health after the Doha Declaration and the 2003 Decision to promote the availability of generics to countries where there is health crisis.[53] In the US-CAFTA-DR, there is an Understanding Regarding Certain Public Health Measures to recognise the Doha Declaration and parties' obligation not to affect party's ability to take the necessary measures to protect public health and to promote access to medicines.[54] In addition, in the US-Colombia FTA, there is direct reference to the Doha Declaration and the 2003 Decision to deal with the patent protection and public health measures in the FTA.[55] The US-Panama TPA[56] and the US-Peru TPA[57] also include direct reference to the Doha Declaration and the subsequent amendment of TRIPS.

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as a "shield" to protect against aggressive demands for increased intellectual property protection.

[46] *US-Peru TPA*, art 16.13.2.(b).

[47] *US-Peru TPA*, art 16.13.2.(b). *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr.1 (1 September 2003). ('*2003 Decision*').

[48] E.g. art 16.10.2.(e) of *US-Peru TPA* provides for express reference to the Doha Declaration.

[49] For example the *US-Canada MOU*, for the news of the MOU, see Office of the United States Trade Representative, <http://www.ustr.gov/about-us/press-office/press-releases/archives/2004/july/us-and-canada-agree-assist-poor-countries-ac>; also see the US-Morocco FTA.

[50] *Side Letter on Public Health between the US and Morocco* (15 June, 2004).

[51] *Side Letter on Public Health between the US and Bahrain* (14 September, 2004).

[52] *Side Letter on Public Health between the US and Oman* (19 January 2006).

[53] See the *MOU between the US and Canada*, above n. 49.

[54] See the *Understanding Regarding Certain Public Health Measures between the US and CAFTA-DR* (August 5, 2004).

[55] *US-Colombia FTA*, art 16.13.

[56] *US-Panama TPA*, art 15.10.2(e).

[57] *US-Peru TPA*, art 16.10.2(e).

Interestingly, in the US-Chile FTA, there is one sentence to recognise the principles set out in the Doha Declaration in the preamble of the intellectual property rights chapter,[58] but there are no other provisions in this Chapter to deal with the specific implementation of the object and purpose. The US-Chile FTA also contains express language for non-derogation from TRIPS and an obligation to be bound by TRIPS obligations, stating in Chapter 17 Article 17.1.5

> Nothing in this Chapter concerning intellectual property rights shall derogate from the obligations and rights of one Party with respect to the other by virtue of TRIPS or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO).

An express statement of non-derogation from TRIPS may show an intention by FTA members to try to align FTAs with the flexibilities offered under TRIPS and the Doha Declaration, even though heightened intellectual property protection is provided in the FTAs.[59] This non-derogation language in the FTAs indicates that the parties have been influenced by TRIPS.

## II. Heightened Patent Protection in FTAs

### A. *Heightened Patent Protection in FTAs*

TRIPS requires minimum standards concerning intellectual property subject matters and this means that patent standards required in FTAs should be at least compliant with the TRIPS minimum.[60] However, because there is no clause in TRIPS relating to Free Trade Agreements there is more freedom in FTAs for differing standards and levels of intellectual property protection.

According to a commentator three main levels of intellectual property protection can be found among the various FTAs: "TRIPS equivalent and a little extra", "TRIPS–plus" and "TRIPS-super-plus".[61]

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[58] See Preamble of the Chapter 17 of *US-Chile FTA*.

[59] Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreement' (Occasional Paper 14, Quaker United Nations Office, 2004) 4. However, the author refers to the draft CAFTA-DR non-derogation text to opine that various other provisions in the Chapter constrain the rights a WTO member has under TRIPS and thus, those obligations imposed will exclude the exercise of the flexibility of TRIPS.

[60] Frankel, above n. 35, 187–8.

[61] For a definition of the three levels of intellectual property protection, see ibid., 195–6.

FTAs are used to liberalise trade, and intellectual property protection can be pro-competitive to facilitate trade.[62] There has been an increasing number of FTAs established to provide more opportunities for trade between the parties, and all these FTAs include an intellectual property rights chapter.[63] The patent protection provisions in FTAs typically require a higher level of protection.[64]

The establishment of an FTA can be influenced by political negotiations, and intellectual property protection chapters are always used as tools of negotiation leverage during FTA negotiations.[65] Some countries, in order to gain market access, have agreed to heighten intellectual property protection under pressure from other developed countries.[66] There is also a likelihood that an

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[62] At a domestic level a system of intellectual property rights that grants exclusive rights to owners and so excludes unauthorised parties may appear to be restricting competition from rivals, but at the international level TRIPS is generally regarded as pro-competitive through a systemic promotion of competition within a globalised intellectual property protection system. See Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, 'Two Achievements of Uruguay Round: Putting TRIPS and Dispute Settlement Together' (1997) 37 *Va J Int'l L* 275, 280.

[63] For example, the United States has negotiated a series of FTAs with developing and developed countries, including Israel, Jordan, Chile, Australia, Singapore, Morocco, Central America (including Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic) (CAFTADR), Bahrain, Peru, and Oman (pending implementation), and has signed, but has been waiting for ratification, of the agreements with Panama, Colombia and South Korea. In addition, the US is also member of the North America Free Trade Agreement (NAFTA). The United States is negotiating with Malaysia, Thailand, the Southern African Customs Union (SACU) (The five member countries of the Southern African Customs Union (SACU): Botswana, Lesotho, Namibia, South Africa and Swaziland) and the United Arab Emirates (UAE) to reach free trade agreement. Full texts of these agreements are available at: Office of the United States Trade Representative <www.ustr.gov>. In addition, other FTAs in other countries have also been reached with intellectual property chapters being included. For example, United States-Australia Free Trade Agreement (US-Australia FTA) (18 May 2004) 43 ILM 1248, New Zealand and Thailand Closer Economic Partnership Agreement, Trans-Pacific Strategic Economic Partnership (Trans-Pacific SEP) Agreement, Thailand and Australia Free Trade Agreement (TAFTA), and Free Trade Agreement between the Government of the People's Republic of China and the Government of New Zealand (China-New Zealand FTA).

[64] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' (2007) 10 *J Int'l Econ L* 921, 963.

[65] Abbott, above n. 59, 3.

[66] Roger Kampf, 'TRIPS and FTAs: A World of Preferential or Detrimental Relations?' in Heath & Sanders (eds), above n. 2, 87, 102–4. The author gave several reasons to include 'TRIPS plus' in the FTAs, including trade-offs, securing investment and technology transfer, higher level of IP protection and lack of results at multilateral level, interpretation of TRIPS provisions and domestic policy considerations.

industrialised country will seek intellectual property laws that respond to technological and commercial developments that have taken place since the negotiation of TRIPS. As a result of the requirement of a minimum level of intellectual property protection in TRIPS and the process of leverage in FTA negotiation and a desire for modernisation, there will usually be a heightened level of patent protection in FTAs.

FTAs do not have a standard or consistent model of agreement. FTAs have been negotiated between developed economies, between developed and developing countries and between developing counties. In broad terms there are two kinds of FTAs: one requiring normal TRIPS compliance or little bit extra and the other requiring TRIPS-plus standards.[67] The majority include TRIPS-plus provisions. The United States has concluded a series of FTAs. In these FTAs, there are usually TRIPS-plus provisions. This is even true of the provisions in the US-Australia FTA, which is an FTA reached between two developed countries.[68] More typically FTAs have been negotiated between the US and a number of developing countries, such as Morocco[69] and Peru.[70] However, the China-New Zealand FTA requires only TRIPS compliance for intellectual property rights protection and not much more is mentioned about intellectual property protection.[71] A similar arrangement can be found in the FTA between New Zealand and Thailand.[72] The Australia and Thailand Free Trade Agreements also requires TRIPS compliance or little bit extra instead of heightened patent protections.[73]

Various patent and pharmaceutical regulatory terms appearing in the different FTAs serve similar purposes to heighten the level of pharmaceutical patent protection in regards to the scope or term of patent protection, regulatory review procedures or limits of grounds for exceptional uses.[74]

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[67] But see footnote 61.

[68] See *US-Australia FTA*, art 17.9.6 (also known in Australia as AUSFTA). Parallel importation arises when legitimate non-counterfeited goods are put on a foreign market by the rights holder in that market and are then imported into a domestic market without the permission or authorization of the rights holder in the domestic market. See Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (Oxford University Press, Oxford, 2007) 78.

[69] See *US-Morocco FTA*, such as art 15.9.2 and art 15.9.4 of US-Morocco FTA.

[70] See *US-Peru TPA* (12 April 2006), art 16.9.2 and art 16.9.5.

[71] See Chapter 12 of *China-New Zealand FTA*, art 159 defines the scope of intellectual property protection to be within TRIPS regime, except that art 165 gives special attention to the protection of traditional knowledge protection.

[72] Art 12.3 of *New Zealand-Thailand Closer Economic Partnership Agreement* provides with requirements on TRIPS-compliance.

[73] Art 1302 of *Thailand-Australia Free Trade Agreement* provides with requirements on TRIPS compliance.

[74] Abbott and Reichman, above n. 64, 963.

The US-Australia FTA uses express terms to provide for second-use patents,[75] and to ban parallel imports.[76] The US-Morocco FTA provides for second-use patents[77] and bans parallel imports.[78] The US-Peru TPA highlights protection for plants and animals to expand the scope of patent protection[79] and sets more stringent requirements on applications for marketing approval.[80] In the US-Peru and US-Morocco FTAs, pharmaceutical patent protection was highlighted in intense negotiations. The US-Peru TPA requires a patent term extension with express language to offset regulatory review delay,[81] and Article 16.10.2 has special provisions on pharmaceutical products, including the protection of disclosure of data information. The US-Morocco FTA has similar restrictions setting patent term extensions for regulatory delay[82] and requiring prior consent of patent holders for granting market approval to a third person.[83] The US-Australia FTA requires compensation for delay in granting a patent, and limits the ground for compulsory licensing.[84]

Although FTA negotiation is a market-access opportunity for export-oriented industries, only a few developing countries are in a position to expand export opportunities in the pharmaceutical sector, or are in a position to protect a substantial domestic pharmaceutical sector.[85] It has also been argued that strong intellectual property protection can encourage technology transfer from developed countries to developing countries.[86] However, in a 2005 report, the World Bank argued that "stronger IPR embedded in

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[75] See art 17.9.1 of the *US-Australia FTA*. Second and subsequent use patents refers to the protection of new uses for substances, active principle, molecules, or compounds that have been previously patented or are already in the public domain. See O. Mitnovetski & D. Nicol, '*Are Patents for Methods of Medical Treatment Contrary to the Ordre Public and Morality Or "Generally Inconvenient"*' (2004) 30 *J Med Ethics* 470, 472.

[76] See *US-Australia FTA*, art 17.9.6. Parallel importation arises when legitimate non counterfeited goods are put on a foreign market by the rights holder in that market and are then imported into a domestic market without the permission or authorisation of the rights holder in the domestic market. See Correa, above n. 68, 78.

[77] See *United States-Morocco FTA* (15 June 2004) 44 ILM 544, art 15.9.2.

[78] See *US-Morocco FTA*, art 15.9.4.

[79] See art 16.9.2 of *US-Peru TPA* (12 April 2006).

[80] See art 16.9.5 of *US-Peru TPA*.

[81] See art 16.9.5 and 6 of *US-Peru TPA*.

[82] Art 15.10.3 of *US-Morocco FTA*.

[83] Art 15.10.2 of *US-Morocco FTA*.

[84] See art 17.9.7 and art 17.9. 8 of *US-Australia FTA*.

[85] Abbott, above n. 59, 3.

[86] See Bernard M. Hoekman, Keith E. Maskus and Kamal Saggi, 'Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options' (2005) 33(10) *World Development* 1587, 1592. The author argues that an increase in patent rights can promote the flow of international trade in middle-income countries and large developing countries, but not poor countries.

the TRIPS-plus agreements have not been shown to accelerate technological flows to low-income countries – though it may do so for middle-income countries".[87] Developing or least developed countries may all too easily accept the provisions that restrict access to medicines in FTAs, because the provisions are usually highly complex with respect to patent and regulatory approval and are usually not subject to close examination by suitably expert public health officials.[88] It is presumed by some developing countries that making concessions in relation to patents and pharmaceuticals will obtain reciprocal concessions from the United States in other industries such as agriculture.[89] The resultant heightened level of pharmaceutical patent protection has potential to impose more restrictions upon practices that facilitate access to medicine,[90] and where this is so there will be a negative impact on public health.[91]

These restrictive provisions strengthen the protection of originator-patent holder pharmaceutical enterprises on national markets, and thereby set up barriers to the introduction of generic pharmaceutical products.[92] In particular, the flexibility of compulsory licensing offered by TRIPS can be precluded because there is no language that expressly avoids this result.[93] Typically in FTAs, no provision is made for the registration of generic medicines produced under compulsory licenses but consent of the patent holder for marketing approval is required. It seems that the trend in the negotiation of FTAs has run against public health protection.[94] For example, an Australian

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[87] World Bank Report 2005, 2.

[88] Abbott, above n. 59, 3.

[89] Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 *Am J Int'l L* 317, 353. Abbott argues that the US has a leading voice at the IMF and the World Bank, and in economic and financial matters more broadly, which gives it considerable leverage in trade negotiations and that this implicit leverage operates in WTO negotiations as well as in bilateral negotiations; also see Abbott, above n. 59, 3, the author considers that developing countries can accept obligations in the public health sector in exchange for concessions on the export of agricultural products.

[90] See for example Mercurio, above n. 9. 224–34. The author discussed the restriction through "linking 'market approval' to the patent status of a drug", "data exclusivity periods", "patent term extensions", "limits on compulsory licences", "limits on parallel import".

[91] For example, see Robert Galantucci, 'Data Protection in a US-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers' (2007) 17 *FDMIPMELJ* 1083, 1099–103. The author argues that the FTA's strict intellectual property provisions may make it more difficult for Malaysians to acquire affordable medications.

[92] Abbott and Reichman, above n. 64, 963.

[93] Ibid.

[94] Abbott, above n. 59, 4.

commentator expressed concern about the effect on public health of the protection of test data contained in the Article 17.10 of US-Australia FTA.[95]

The built-in flexibilities within TRIPS are intended to strike a balance between the interests of intellectual property holders and of users.[96] Due to the heightened pharmaceutical patent protection in FTAs, there is a concern that there has been a shifting of the balance and this raises the possibility of conflict between this new level of patent protection in these TRIPS-plus provisions and the previously balanced support for public health found in TRIPS.

### B. *Justification for Heightened Patent Protection in FTAs*

The exemptions[97] and restrictions[98] in the WTO regime allow the parties to enter into FTAs. Generally speaking, parties to FTAs are free to offer a

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[95] See David Richardson, 'Intellectual Property Rights and the Australia – US Free Trade Agreement' (31 May 2004) <http://www.aph.gov.au/Library/pubs/RP/2003–04/04rp14.htm#health>.

[96] Daniel Gervais, 'TRIPS and Development' in Daniel J. Gervais (ed), *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford University Press, 2007) 3, 47–52.

[97] The justification for the establishment of bilateral or regional agreements under the WTO framework is contained in the art XXIV of GATT, art V of GATS and the Enabling Clause. Art XXIV of GATT provides exemptions for FTAs from the obligations under GATT. Art V paragraph 1 of GATS provides similar exemptions. It only requires that the agreement intended to be made "has substantial coverage and provides for the absence or elimination of substantially all discrimination". With these exemptions, FTAs can be established with autonomy among the FTA members. Although the establishment of FTAs is under the framework of WTO, unlike GATT or GATS, TRIPS has no specific clause for the establishment of intellectual property protection in FTAs. This means that inclusion of intellectual property protection in an FTA is neither permitted nor prohibited. Many FTAs have an intellectual property rights chapter. This may reflect an intention of the parties to include intellectual property protection into FTAs under TRIPS.

[98] Although there is an exemption in WTO law to allow FTA members autonomy in the adoption of measures which are inconsistent with GATT, according to paragraph 12 of the art XXIV of GATT, WTO law requires the observance of the agreement by the contracting parties to the FTAs. When inconsistent measures are adopted by WTO members, they should meet certain requirements. The requirements for adoption of measures that are inconsistent with GATT are generally regarded as being set out in paragraph 5 and paragraph 8 of art XXIV under the GATT framework. If these requirements are met, these inconsistent measures still can be regarded as WTO compliant. In *Turkey Textiles*, the two conditions are: First, the party claiming the benefit of this defense must demonstrate that the measure at issue is introduced upon the formation of the customs union that fully meets the requirements of sub-paragraph 8(a) and 5(a) of art XXIV. (timing issue) Second, that party must demonstrate that the formation of the Custom Union would be prevented if it were not allowed to introduce the measure at issue. (necessity issue). See Appellate Body Report, *Turkey – Restrictions on Imports of Textile and Clothing Product*, WTO Doc WT/DS34/AB/R (22 October 1999) [58].

heightened level of patent protection in order to enhance and facilitate the liberalisation of trade.

Firstly, heightened protection is still WTO compliant. The restriction requirements show that heightened intellectual property protection is unlikely to be inconsistent with TRIPS and WTO, but lower level protection for a FTA will not pass the necessity test if it is inconsistent with TRIPS.[99] Thus, it is usually accepted that FTAs can adopt a heightened level of intellectual property protection.

Secondly, TRIPS itself has an express statement that members may give more extensive protection.[100] This means that members may increase the protection level bilaterally, given that TRIPS is a minimum standard setting agreement. At the same time, lacking a consensus on the optimum level of intellectual property protection in the world, other mechanisms are sought to heighten intellectual property protection[101] and an FTA can be used as such a tool.

Thirdly, the lawful exception to the MFN requirement will not be applied to post-TRIPS FTAs.[102] Under MFN where one member grants any "advantage, favor, privilege or immunity by a Member to the nationals of any other country" it must be "accorded immediately and unconditionally to the nationals of all other Members".[103] The MFN exception is guaranteed by general provisions within WTO Agreements, which are the Article XXIV in GATT and the Article V in GATS respectively. TRIPS lacks such a general exemption provision. This lack of a general provision in TRIPS suggests the absence of a system to justify MFN exemption. As a result, a heightened

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[99] The lower level of intellectual property protection may not pass the necessity test, but the higher level of intellectual property protection can pass the test, since it will justify more protection of intellectual property rights. However, the protection of the public health may require carve-outs and flexibility from FTAs as well as from TRIPS.

[100] See art 1.1 of TRIPS. However, this article includes a proviso that the protection should not "contravene the provisions of this Agreement". Frankel opines that "the provisions of this Agreement" should be "primarily directed to the non-discrimination principles, national treatment and most-favored nation treatment". See Susy Frankel, 'Challenging TRIPS-Plus Agreement: The Potential Utility of Non-violation Clauses' (2010) 12 *J Int'l Econ L* 1023, 1033.

[101] See Frankel, above n. 35, 190.

[102] See Kampf, above n. 66, 93. The author expressed the view that, although Article 24.1 TRIPS could be read as an explicit invitation to enter into bilateral (or multilateral) negotiations aimed at increasing the level of protection of geographical indications for wines and spirits, it does, for example, not incorporate a specific derogation from the principle of MFN treatment.

[103] See art 4 of TRIPS.

level of patent protection becomes possible[104] through an FTA.[105] However, the status of FTAs under the TRIPS arrangement will require an application of MFN into the FTAs to ensure the equal treatment of foreigners when the protection level enjoyed by the parties to the FTA is above the TRIPS minimum level of protection.[106] Otherwise, a national of a member of TRIPS who is not a national of a member of an FTA will not be treated equally in a member country of an FTA.[107]

### C. *Implication of the Justification*

The justification of heightened patent protection in the FTAs, and the lack of MFN exemption in TRIPS, means that heightened patent protection can be applied to a national of a third party WTO member.[108] This general WTO mechanism is subject in differing WTO treaties to certain exceptions. A bilateral agreement to extend heightened patent protection amounts to an "advantage favour or privilege" and so should be extended to the nationals of all other members, but operation of an applicable exemption would allow the parties to justify the heightened patent protection between them to a third member while excluding the nationals of that third party from the advantages offered by the FTA.

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[104] But see Frankel, above n. 35, 187. The author is of the view that the impact of increased standards of intellectual property is far reaching, and the reason for such absence of MFN exemption in TRIPS needs more examination.

[105] See Peter Drahos, 'Expanding Intellectual Property's Empire: The Role of FTAs' (GRAIN, 30 November 2003) <http://www.grain.org/article/entries/3614-expanding-intellectual-property-s-empire-the-role-of-ftas>.

[106] See Frankel, above n. 35, 190.

[107] See Mecurio, above n. 9, 223. In Abbott and Reichman, above n. 64, 963–4, the author argues that EU's pharmaceutical originator enterprises are beneficiaries of the terms concluded in US FTA, based on art 4 of the TRIPS to extend MFN treatment to all WTO Members. Also see Rafael Pastor, 'The Impact of Free Trade Agreements on Intellectual Property Standards in a Post-TRIPS World' <www.bilaterals.org/IMG/doc/FTAs_and_IPS.doc>. The author also expresses the opinion that the MFN clause has a wide impact when it comes to signing FTAs, which include TRIPS-plus provisions. In this sense, if a country is willing to grant a higher IPR standard to another country in order to enhance its trade balance, this literally means that all the advantages, favours, privileges or immunities could be automatically demanded for all nationals of another WTO member which is not subscribing to the particular FTA. Pastor argues that this clause is an acute tactical mechanism to ensure the objectives of the global intellectual property ratchet, which aims at gradually imposing the highest level of intellectual property protection to the whole world.

[108] See Mercurio, above n. 9, 223.

This, however, requires further contemplation. From a trade perspective, the object and purpose of intellectual property protection is to reduce the "distortions and impediments to international trade" as well as to offer protection of intellectual property rights.[109] At the same time, the enforcement of intellectual property rights should not become "barriers to legitimate trade".[110] On the one hand, the protection of intellectual property rights will facilitate international trade by encouraging technology transfer and by reducing free riders.[111] On the other hand, this object and purpose can be distorted with overly strong intellectual property protection.[112] It follows that if FTAs are established to further liberalise international trade and accordingly they can be justified under WTO jurisprudence and the MFN exception, FTAs should be subject to the object and purpose of TRIPS.[113]

Further, the lack of an MFN exception mechanism in TRIPS should not be used as a tool to ratchet up patent protection levels in a way that impedes the access to medicines. Although FTAs can offer heightened patent protection, it is argued that there should be a rational ceiling for this high level.[114] Unlike the FTAs under GATT and GATS, for the reduction and elimination of tariff and other trade barriers, the level for patent protection should be rationalised both for the protection goal and for the trade goal reflected in TRIPS and WTO laws. This rational limit of patent protection should be reflected in the interpretation of the TRIPS-plus provisions in FTAs.

In 2009 the academics Ruse Kahn and Kur argued that TRIPS-plus bilateral agreements could suggest the possibility of ever escalating levels of intellectual property rights and that there was a need for recognition of certain ceiling rules.[115] The idea that intellectual property rights might have no limit could be seen as an implication concomitant to the fact that TRIPS is expressed as requiring observance of minimum standards of protection[116] and as permitting members to provide greater protections without explicitly defining upper limits. In addition, as argued above, the lack of MFN

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[109] See the first paragraph of the Preamble of TRIPS.

[110] See the first paragraph of the Preamble of TRIPS.

[111] See M. Scott Taylor, 'TRIPS, Trade, and Growth' (1994) 35 *International Economic Review* 361, 361.

[112] See Part Two.Chapter 5, footnote 14.

[113] Frankel, above n. 100, 1030.

[114] Ibid., 1024. The author used the word "ceiling". Also see Annette Kur & Henning Grosse Ruse-Khan, 'Enough is Enough – The Notion of Binding Ceilings in International Intellectual Property Protection' <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1326429>.

[115] Kur and Ruse-Khan, above n. 114.

[116] Frankel, above n. 35, 187–8.

exemption in the TRIPS Agreement, has paved a way for heightened intellectual property protection in TRIPS-plus.[117]

However once higher levels of protection are established in a bilateral agreement the "freeze-plus" approach to TRIPS-plus will possibly impede any return to levels of protection reflecting the policy bargain found in the TRIPS Agreement itself.[118] In other words the treaty process may make it possible to increase levels of protection above TRIPS minimum requirements but make it extremely difficult to reduce heightened levels of protection back to lower but TRIPS compliant levels.

A heightened level of intellectual property protection could impact on some of the flexibilities and policies provided by TRIPS. Accordingly it has then been proposed that a "ceiling rule" should be recognised or introduced in order to avoid the possibility of detrimental effects for individual countries due to the high level of intellectual property protection in TRIPS-plus.[119]

It is generally recognised that the international intellectual property regime includes existing ceilings or limitation principles on intellectual property rights.[120] It has been argued that some ceilings stemming from other international sources outside the immediate ambit of TRIPS and TRIPS-plus and even the intellectual property treaties could function as ceilings for the implementation of the international agreement of intellectual property rights.[121]

Similarly recognition of the value of public goods and societal interests can become another parameter when considering international intellectual property settings, and the value of effective regulation or safeguarding of public goods or societal interest should become another factor in establishing a ceiling to intellectual property protection in TRIPS and in TRIPS-plus provisions that provide heightened levels of protection.[122]

The protection of public health involves recognition of, and compliance with, the human right to health and gives rise to the protection of public goods, and the "flexibilities" in TRIPS have been specifically recognised to respond to issues concerning public health.[123] Thus, the protection of public health is an important consideration when interpreting levels of patent protection under the TRIPS regime, and so seen through the prism of "ceiling

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[117] See Drahos, above n. 105.

[118] Kur and Ruse-Khan, above n. 114, see part II.1.b).(ii) of their paper.

[119] Ibid.

[120] This has been identified as direct limitations including subject matter, duration and scope, and indirect limitations including other IP rights such as GI. See ibid.

[121] This has been identified as some non-IP rights such as the right to health in human rights regime and traditional knowledge holders' rights. Ibid.

[122] Ibid.

[123] E.g., *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) [4] and [5].

rights" theory, it can also be seen as relevant to interpreting a ceiling for patent rights in the TRIPS-plus regime.

## III. Interpretation and Human Rights

It has been argued by some that the TRIPS-plus provisions adopted in FTAs by many countries requiring a higher level of intellectual property protection involve an erosion of the flexibilities offered by TRIPS.[124] The heightened patent protection in FTAs will impact on the access to medicines and then impact on the realisation of the right to health. It seems that, compared with the TRIPS regime, TRIPS-plus provisions are less friendly towards the right to health. However, it may be possible to interpret the TRIPS-Plus provisions in the light of the TRIPS regime in a way that maintains the level of support for the right to health.

### A. *Flexibility in FTAs*

One way for the TRIPS-plus regime to adopt flexibilities is to use open-textured language. Most FTAs adopt language similar to that used in TRIPS. The language used in Article 27 of TRIPS can be found in many FTAs.[125] The language used to exclude the patentability of subject-matter in order to protect "*Ordre Public* or morality", "to protect human, animal or plant life or health" and exclusion on the protection of "diagnostic, therapeutic and surgical methods for the treatment of human and animals" is frequently used.[126] This open-textured language will require further interpretation where similar issues are involved. If these are to be interpreted in accordance with the interpretation rules followed for TRIPS, some flexibility should be presumed in the FTAs.

Most FTAs also adopt the flexibility of limited exception and compulsory licensing that is similar to TRIPS. A general limited exception clause is always contained in such agreements,[127] and these usually adapt the language which subjects the carve-out to the three step test. As an important flexibility, com-

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[124] See Carlos Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 5 *Bulletin of the World Health Organization* 399, 400.

[125] Such as art 15.9.1 of the *US-Morocco FTA*.

[126] Such phrases can be found in art 17.9.2 of *US-Australia FTA*, art 15.9.1 of the *US-Morocco FTA*, and art 1709.2 of NAFTA.

[127] Such as art 17.9.3 of *US-Australia FTA*, art 15.9.3 of the *US-Morocco FTA*, and art 1709.6 of NAFTA.

pulsory licensing has also been incorporated in some FTAs.[128] The grounds for issuing compulsory licensing, such as "national emergency", "other circumstances of extreme urgency" or "public non-commercial use" are also included.[129] The compulsory licensing clause is different in various FTAs. The US-Morocco FTA lacks such a provision, and the NAFTA includes the expression of "predominantly for the supply of the Party's domestic market."[130] These new varieties will pose challenges for the protection of public health.

Another important feature of an FTA is that some provisions expressly provide for the inclusion of any decision in relation to the protection of public health made after TRIPS, such as the Doha Declaration and its subsequent development.[131] This kind of express inclusion of TRIPS and the related Declaration and amendment will clarify the interpretation of related provisions.[132] The US-Peru TPA, in fact, was signed in 2006 and was ratified by the US in 2007. The signing of this agreement followed the Doha Declaration and the 2003 Decision, so the express inclusion of the protection of public health provision, in fact, shows the influence of TRIPS and the related WTO laws.

The "side letters on public health" are also used as auxiliary means for the incorporation of flexibilities in some FTAs.[133] The TRIPS-plus provisions in patent protection have limited access to medicines in many ways.[134] This high level of intellectual property protection is adverse to the protection of health rights, especially in a developing country with few medicines of its own.[135] Against this background, some governments have exchanged understandings between each other through side letters on public health. For example, in the side letter between the US and Morocco, the parties, drawing on the Doha Declaration, recognised that the intellectual property chapter should not prevent the "effective utilization of the TRIPS/health solutions" and the side letter should "constitute an agreement between the two parties".[136] The United States confirmed that this constitutes an agreement between the two

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[128] Such as art 17.9.7 of *US-Australia FTA*; art 1709.10 of NAFTA.

[129] Art 17.9.7.(b) of *US-Australia FTA*.

[130] Art 1709.10.f of NAFTA.

[131] Such as art 16.10.2(e) of the *US-Peru TPA*.

[132] See Abbott and Reichman, above n. 64, 964; the author is of the view that this introduces an explicit exception from marketing exclusivity with respect to the grant of compulsory licenses.

[133] Such as *Side Letter on Public Health between the US and Morocco*; *Side Letter on Public Health between the US and Bahrain; Side Letter on Public Health between the US and Oman*.

[134] For example, in the *US-Morocco FTA*, second use patent is permitted, parallel import is banned, and compulsory licensing is not mentioned.

[135] Kuanpoth, above n. 2, 30.

[136] *Side Letter on Public Health between the US and Morocco* (15 June 2004).

governments.[137] In this side letter, the language used includes "do not affect", "does not prevent" and "shall constitute", and these indicate an intention of both parties to be bound by this statement.[138] The side letter should constitute a subsequent agreement between the two parties, and this can have value for interpretive purposes.[139]

In addition to the side letters, some understandings are reached by adopting similar language used in some side letters.[140] In NAFTA, the intellectual property protection follows the pattern of TRIPS, and the language "predominantly for the supply of the Party's domestic market", contained in Article 1709.10(f), is in contravention with the 2003 Decision and can impede export of the generics of the major generic producer, Canada. Similarly, the United States and Canada, the two developed members of NAFTA, reached a Memorandum of Understanding (MOU) on July 16th 2004 to ensure that NAFTA will not impede their efforts to assist poor countries to gain reasonable access to generic versions of patented drugs from Canada in response to health crises.[141] The MOU refers to the 2003 Decision to give effect to compulsory licensing in public health context.[142] This MOU should be regarded as a subsequent agreement between the parties, and this will help Canadian generic producers to export medicines to developing countries to promote the access to medicines.[143]

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[137] Ibid.

[138] But see Correa, above n. 124, 402. The author considered that that the content of the side letter or public health must have been incorporated in the text of the Agreement to ensure a binding understanding; also see 3D, 'Trade-related Intellectual Property Rights, Access to Medicines and Human Rights – Morocco' (3D, Geneva, 2006); Comments on the Intellectual Property Chapter of the US-Morocco Free Trade Agreement and the Impact on Access to Medicines, available at:<www.essentialaction.org>; Health Gap, 'Response to USTR Fact Sheet on CAFTA and Access to Medicines' (Press Release, 16 March 2005).

[139] But see Abbott and Reichman, above n. 64, 963. The author pointed out that the "side letters" showed the intention of US to give the appearance of addressing the health problem, but USTR refused to acknowledge that these attachments resulted in any exception to the express terms of the agreements. But also see Andrew D Mitchell and Tania Voon, 'Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law' (2009) 43 *Journal of World Trade* 571, 594. The author argues that the side letters are of little legal significance in interpreting FTAs and the enforceability of these side letters is questionable.

[140] E.g., an *Understanding Regarding Central America Health Measures* has been reached among the CAFTA members on 5 August 2004, and similar language to that in the US-Morocco side letter has been used. Available at: <www.ustr.gov>.

[141] See <http://www.ustr.gov/about-us/press-office/press-releases/archives/2004/july/us-and-canada-agree-assist-poor-countries-ac>.

[142] Ibid.

[143] Ibid.

In summary, FTAs use several mechanisms to maintain certain levels of flexibility, including the use of open-textured language, the use of carve-outs, the use of auxiliary means such as side letters and subsequent understandings. The FTA panellists will have to interpret the flexibilities contained in the various FTAs, and the interpretation of the TRIPS-plus provisions will refer to TRIPS, including its object and purpose and its subsequent developments.

## B. *Interpretation*

### 1. *Compulsory Licensing*

Compulsory licensing is an important flexibility contained in Article 31 of TRIPS to enable generic producers to use a patent to produce medicines at a lower cost and this mechanism is regarded as a means to address the issue of the access to medicines and public health in members of WTO, especially in the less developed countries.[144] In order that the generic producers can export the generics to the less developed countries without production capacity, the 2003 Decision and the proposed Amendment of Article 31*bis* have made a waiver of the obligations under the Article 31(f) of TRIPS that deals with the supply of the generics predominantly for domestic market.[145] Many FTAs still have this flexibility, but it has been restricted with many circumstances. Some pointed out that this flexibility has been "diminished" in FTAs.[146]

Some FTAs follow TRIPS and use language such as "circumstances of extreme urgency" or "national emergency" or "public non-commercial" use as conditions that will permit recourse to compulsory licensing.[147] While interpreting these terms, a FTA panel will have to refer to TRIPS or interpret TRIPS provisions. Thus, the object and purpose of TRIPS and the subsequent development of TRIPS will fall into the scope of the interpretation.[148] The open-textured words contained in articles of this kind, including "national emergency" and "other circumstances of extreme urgency" in this exceptional requirement allow a more flexible approach to using compulsory licensing to facilitate the access to medicine. TRIPS itself does not define

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[144] Keith E. Marskus, 'Ensuring Access to Essential Medicines: Some Economic Considerations' (2001–2002) 20 *Wis Int'l L J* 563, 571.

[145] 2003 Decision, WTO Doc WT/L/540 and Corr.1 (1 September 2003).

[146] See Mitchell and Voon, above n. 139, 593–594.

[147] See art 17.9.7 of *US-Australia FTA*; art 20 of *US-Jordan FTA*; art 16.7.6 of *US-Singapore FTA*.

[148] See analysis in Part Two.Chapter 5.II.

"national emergency" and "other circumstances of extreme urgency and the only requirement within the text is that the invoking party should notify the patent holder of such use as soon as reasonably practicable.[149] When an interpreter tries to interpret the open-textured circumstances of "national emergency" and "other circumstances of extreme urgency", according to the VCLT, reference to sources outside the TRIPS ambit will be needed to clarify this term.[150] Evidence of subsequent development of the Treaty may be resorted to for clarification of such open-textured terms, and the Ministerial Declaration and the Doha Declaration should be referred to as supplementary means of interpretation of this Agreement.[151] TRIPS members have "the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises,…, can represent a national emergency or other circumstances of extreme urgency."[152] Under these circumstances a public health crisis, as defined by the member, can be a ground to justify derogations from other obligations.[153] Public health, therefore, can be used to issue compulsory licensing for generics production. At the same time, the express language contained in the Doha Declaration that allows members freedom to determine for themselves what is a "national emergency" and "extreme urgency" contrasts with the more stringent "necessity test" under Article XX(b) of GATT and it imposes a burden upon the complaining Party to prove the non-existence of the invoked urgent situation.[154]

In TRIPS, the interpretation of "public non-commercial use" is controversial. Some commentators have argued that this should be limited to a use by government in defence or space programs but not for purposes to do with the supply of medicines.[155] Others argue that this can be used by both governments and private entities for non-trade purposes, and can be used

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[149] But in the case of public non-commercial use, the government or contractor should inform the patent holder promptly.

[150] Art 31.3(c) of VCLT allows the reference to any relevant rules of international law.

[151] Frederick M. Abbott, 'TRIPS, Access to Medicines and the WTO Doha Ministerial Conference' (Quaker United Nations Office, 8 September 2001).

[152] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001), para. 5(c).

[153] Ibid., para. 5(b) and (c). Also see Committee on Economic Social and Cultural Rights ('*CESCR*'), *General Comment No. 14*, 22nd Sess, E/C.12/2000/4 (4 July 2000) para. 28, the CESCR points out that, "Issues of public health are sometimes used by States as grounds for limiting the exercise of other fundamental rights."

[154] Correa, above n. 68, 316.

[155] See Daya Shanker, 'Korea, Pharmaceutical Industry and Non-commercial Use of Compulsory Licenses' on <SSRN: http://ssrn.com/abstract=438880>, the author introduced that Gorlin had this opinion.

for purposes concerning access to or supply of patented medicines.[156] In the FTAs, the express language of "by the government or third parties authorized by the government" has implied that this should be used by government or with the authorisation of government to clarify the ambiguity.[157]

Other FTAs lack provisions on compulsory licensing, but they directly incorporate the Doha Declaration and the 2003 Decision and require follow-up of any amendment of TRIPS.[158] This direct incorporation as explicit exception to the pharmaceutical products patent protection is persuasive in confirming the grant of compulsory licenses to cope with public health matters.[159] This explicit exception will also inform the interpretation of TRIPS and its subsequent development. The reference and interpretation of TRIPS will, thus, achieve a harmonisation between TRIPS-plus and TRIPS through this kind of interpretation.

Moreover, the rules of *lexi specialis* and *lexi posterior* need to be considered in interpreting the compulsory licensing flexibility. As a general rule of international law, the *lex posterior* should prevail over the previous law and *lex Specialis* should prevail over general international law where the successive treaty deals with the same subject-matter.[160] Following this rule, if a bilateral or regional FTA is reached after the WTO, the FTA provisions usually prevail over WTO law. Therefore, the compulsory licensing clauses in the FTAs will prevail over the compulsory licensing clauses in TRIPS. However, Pauwelyn pointed out that a treaty with a "continuing" or "living" nature should continue to exist and should be referred to continuously.[161] Under this circumstance, the panel should adopt an evolutionary interpretation approach even though the FTAs are reached later than the TRIPS.[162] The expression of "national emergency" and "extreme urgency" and the expression of "public non-commercial use" in Article 31 are open-textured to invite an evolutionary manner of interpretation of TRIPS.[163]

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[156] Ibid.

[157] E.g., art 17.9.7(b) of *US-Australia FTA*.

[158] Such as art 16.10.2(e) of *US-Peru TPA*; art 16.10.2(e) of *US-Colombia FTA*; art 18.9.3 of *US-Korea FTA*; and art 15.10.2(e) of *US-Panama FTA*, although, up to the date of writing, the FTA has not entered into force.

[159] Abbott and Reichman, above n. 64, 964; and the author pointed out that the explicit expression in US-Peru FTA was a clear exception from marketing exclusivity with respect to the grant of compulsory licenses.

[160] Pauwelyn, above n. 20, 361–2.

[161] Ibid., 378.

[162] For analysis on evolutionary interpretation, see Part Two.Chapter 4.III.

[163] For example, art 31(b) of TRIPS provides: "…This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.…"

At the same time, *Lexi specialis* can offer little help in the interpretation of the FTA provisions.[164] *Lexis specialis* can be determined either by its subject matter or its membership,[165] and the carve-outs of compulsory licensing in TRIPS and FTAs may give rise to the status of *lexi specialis* for each regime. Therefore, the carve-out must be given effect in order to avoid the seeming conflict.[166] The interpretation of the carve-outs of the patent provisions in the FTAs should be considered to prevail over the general provisions of FTAs in order to delimit the scope of the application of the TRIPS-plus provisions in the FTAs. More importantly, subsequent developments in TRIPS have clarified that the concept of public health crises includes "those relating to HIV/AIDS, tuberculosis, malaria and other epidemics",[167] which are the specific narration of the grounds for issuing compulsory licensing. This specificity needs to be treated as *lex specialis*, and the interpretation of the compulsory licensing carve-outs in the FTAs will need to refer to the specific language used in TRIPS in order to be given effect in the interpretation of the TRIPS-plus provisions. Through this kind of reference, the seeming conflict between TRIPS and TRIPS-plus can be avoided.

### 2. *Side Letters*

Some other FTAs lack compulsory licensing mechanisms, but contain side letters to address the public health issue.[168] When uncertainties and ambiguities arise, the interpretation of the TRIPS-plus provisions will be necessary to clarify the intention of the parties of a FTA.[169] As an example, in the US-Morocco FTA as a subsequent development of the FTA itself,[170] a side letter recognised that an FTA should not affect the party's ability to take measures to protect public health, "in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of

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[164] Pauwelyn, above n. 20, 414, the author puts that *lexi specialis* offers little help in giving meaning to terms in a treaty pursuant to arts 31 and 32 of the VCLT.

[165] Ibid., 389–91.

[166] Ibid., 414.

[167] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001), para. 5(c).

[168] Such as *Side Letter on Public Health between the US and Morocco* (15 June, 2004). *Side Letter on Public Health between the US and Bahrain* (14 September, 2004). *Side Letter on Public Health between the US and Oman* (19 January 2006). *Understanding Regarding Certain Public Health Measures in the US-CAFTA-DR FTA* (5 August 2005).

[169] Treaty interpretation is a process to clarify the intentions of the parties. See Sir Sinclair, above n. 22, 114–5.

[170] But see Mitchell and Voon, above n. 139, 594. The author is of the view that the legal effect of the side letters is of little certainty.

extreme urgency or national emergency."[171] Side letters should have relevant value in the interpretation of TRIPS-plus provisions, so that the TRIPS-plus provisions should not affect the ability of parties of an FTA to take measures to protect public health. At the same time, the open-textured words of "circumstances of extreme urgency or national emergency" should be the interpreted in accordance with the approach to interpretation of TRIPS and its subsequent development.[172] The side letters also recognised the commitment provided in the Doha Declaration and 2003 Decision and the utilisation of TRIPS/health solution.[173] Recognition of the TRIPS subsequent development and of the effective utilisation of TRIPS/health solution means that FTA panellists should refer to TRIPS to interpret TRIPS-plus provisions. This approach also implies that references to compulsory licensing contained in TRIPS and its subsequent development should be recognised by FTA panellists in such a way that this compulsory licensing flexibility should be considered to be built in the FTAs to meet public health protection needs. This approach to interpretation will promote harmonisation between TRIPS and TRIPS-plus.

3. *Non-derogation Provisions*

The non-derogation provisions in FTAs refer to the obligations and rights of TRIPS, and this reference can bring the interpretation of TRIPS into the interpretation of the non-derogation provisions and relevant TRIPS-plus provisions.[174] When considering what specific obligations and rights of TRIPS should prevail in FTAs there will need to be interpretation to clarify the intention of the treaty parties.[175] The understanding on this non-derogation provision should first be considered with the non-discrimination clauses in

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[171] E.g., the Preamble of the *US-Morocco Side Letter on Public Health* (15 June, 2004).

[172] But see Abbott and Reichman, above n. 64, 963. The author pointed out that the "side letters" showed the intention of US to give the appearance of addressing the health problem, but USTR refused to acknowledge that these attachments resulted in any exception to the express terms of the agreements. But also see Abbott, above n. 89, 352–3; the author gave the opinion that the phrase "in particular" is language of limitation, and it refers to "cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics". The scope of disease is limited. In addition, the author also pointed out that the circumstances of "national emergency" or "extreme urgency" are also qualified by "in particular", so it eliminated the prospect for compulsory licensing in ordinary circumstances or for "public non-commercial use".

[173] See e.g., the *US-Morocco Side Letter on Public Health* (15 June, 2004).

[174] E.g., art 17.1.5 of *US-Chile FTA*.

[175] The specific rights and obligations are not self-explanatory, and it needs more interpretation in order to avoid ambiguity in the language.

TRIPS. The lack of an MFN exception in TRIPS implies that treaty members may have contemplated the possibility that some parties might wish to heighten the patent protection level through other mechanisms, including FTAs, and so to effect benefits not only to the members of the FTA but also to other third members of TRIPS.[176] This should imply that the interpretation of non-derogation provisions will need to consider the justification of TRIPS-plus. Although TRIPS allows for heightened intellectual property protection, there should be a rational limit in the FTAs.[177] This needs to be interpreted with an understanding of the built-in flexibility of TRIPS in the TRIPS-plus.

Moreover, while interpreting TRIPS, as a commentator observed, the condition in the Article 1 of TRIPS could be seen to imply that there was a possibility that TRIPS might be contravened by unduly heightened patent protection that did not sufficiently reflect the objects and purpose of TRIPS.[178] In this approach the heightened patent protection in the TRIPS-plus provisions needs to be considered in the light of the non-discrimination provisions in TRIPS.[179] In this approach the heightened patent protection in the TRIPS-plus provisions needs to be considered with the non-discrimination provisions in TRIPS. It is, therefore, necessary for panellists of an FTA to consider the justification of TRIPS-plus even though TRIPS lacks an MFN exception. This gives rise to the consideration of the built in flexibilities of TRIPS.

Further, the interpretation of the non-derogation provisions with reference to the rights and obligations of TRIPS should also contemplate the object and purpose of TRIPS. The object and purpose of intellectual property law should be used to test the limits of intellectual property protection in a FTA.[180] The object and purpose of TRIPS is used to balance the competing goals and aspirations, such as protection of private rights and the attainment of public interest, and this should be regarded as a reflection of the goal of intellectual property law.[181] This goal should be considered during the reference to related FTAs, no matter whether it is one between developed and developed countries or one between developed and developing countries, given the diverging economic development levels of the various FTA countries.

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[176] See the analysis in Part Three.Chapter 7.II.B.
[177] Frankel, above n. 35, 192.
[178] Frankel, above n. 100, 1033.
[179] Ibid.
[180] Frankel, above n. 35, 194.
[181] See analysis in Part Two.Chapter 5.II.

### C. *Human Rights*

The right to health ensures access to medicines as an essential element of this right, but the right to property and the right to fruits of creation reinforce intellectual property protection. The balance established between the protection of the public interest and private rights guarantees intellectual property protection in competing interests. The intellectual property chapters in FTAs, on one hand, heighten intellectual property protection and restrict access to medicines with strong patent protection. On the other hand, these chapters also try to facilitate some human rights considerations.

#### 1. *TRIPS Language*

The intellectual property provisions of an FTA may adopt the language used in TRIPS directly,[182] and the interpretation of the TRIPS provisions, thereby, can provide reference to the interpretation of the FTAs. Especially, when a choice is made to use the WTO forum, the Dispute Settlement Body may refer to TRIPS for the interpretation of the FTA intellectual property provisions.

As the interpretation of TRIPS provisions shows that human rights can be achieved,[183] this implies that the human rights considerations in TRIPS can, to certain extent, be absorbed into the FTAs through the reference to TRIPS. The same use of the flexibility through open-textured language, carve-outs or exceptions in FTAs as that in TRIPS needs to be interpreted to include human rights consideration. TRIPS should be interpreted in a health supportive manner; therefore, the interpretation of the related provisions in FTAs may also need to be health supportive in order to promote access to medicines.

#### 2. *Non-derogation Provisions*

The non-derogation provision in FTAs shows that the obligations under TRIPS must be contained in FTAs. This will not only require that the minimum standard protection concerning patent rights found in TRIPS be provided in FTAs, but it should also be understood to bring the human rights concerns contained in TRIPS into consideration. The problem here is that how far the human rights concern contained in TRIPS can be brought into FTAs.

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[182] For example, the language used in Art 17.9 of *US-Australia FTA* and Art 27 of TRIPS.
[183] See Part Two.Chapter 5 and Chapter 6.III.

TRIPS is a treaty that tries to strike a good balance between protecting public interest and private rights, and in the promotion of technology transfer and maintaining social and economic concerns. The object and purpose of TRIPS shows that TRIPS needs to take all these into consideration. Therefore, the right to health can find its expression in certain ways in TRIPS provisions as a result of the interpretation of TRIPS.

The exemptions in WTO shows that members are free to establish FTAs only if they meet the requirements contained in Article XXIV of GATT. Any inconsistent measure adopted by FTAs should pass the timing and necessity test. In accordance with this, if any provision in an FTA adopts a measure that is in violation of the right to health, this can be regarded as inconsistent with TRIPS. Consequently, it will become an issue for consideration whether the necessity test can justify such inconsistency. The interpretation of the object and purpose of TRIPS shows that a good balance should be kept and the right to health should be considered, therefore it is arguable that the FTAs cannot pass the necessity test in respect of that measure. A heightened patent protection in FTAs does not mean that a good balance behind the intellectual property protection and between trade and protection should be undermined. Through this measure of non-derogation, human rights considerations contained in TRIPS penetrate into the FTAs.

3. *Reference to TRIPS*

Another manner of human rights consideration in FTAs is through the soft influence of the TRIPS regime by direct or indirect reference to TRIPS in the FTAs. Analysis shows that the Doha Declaration and the 2003 Decision are health supportive, and can assist the interpretation of TRIPS. The direct incorporation of these documents into the FTAs, or indirect reference to them by exchange of side letters, can promote access to medicines under the FTAs. Some provisions, such as US-Peru FTA have directly incorporated the perspectives and obligations of TRIPS and its subsequent development, such as the Doha Declaration. This is an example of the direct influence of reference to TRIPS. This manner of reference to the development of FTAs reflects the evolutionary nature of treaty making and it assists to clarify the interpretation of the provisions.

4. *Counter-regime of Human Rights*

Finally, the human rights regime counters the FTA and helps the FTAs to adopt measures to meet the human rights obligations.[184] Lang is of the view

[184] See Part Two.Chapter 6.I.B.4.

that the softer processes of "awareness-raising", "persuasion and normative socialisation" play a role in policy change in trade agreement arrangements.[185] The right to health is creating a counter regime for FTAs, when FTAs are not using a health supportive approach to interpret the intellectual property provisions. Therefore, the interpretation of FTAs needs to be conducted in a manner that finds a health supportive balance between the human rights regime and the intellectual property protection regime.

## IV. Summary

The examination shows that the justification of TRIPS-plus necessitates the interpretation of the TRIPS-plus provisions with reference to TRIPS. Consideration of the justification logically suggests that, although heightened patent protection can be included in the intellectual property chapters of FTAs, there should be a "ceiling" upon the level of heightened patent protection that is consistent with the facilitation of trade and does not act as an impediment to trade.[186] This means that the interpretation of TRIPS-plus provisions not only needs to consider the ambit of TRIPS-plus itself, but also needs to take the ambit of TRIPS into consideration.

The choice of forum provisions and the interpretation rules in FTAs have paved the way for an FTA panellist to interpret TRIPS for the purpose of informing the interpretation of the FTA. The adoption of VCLT interpretation approach by FTAs has significant impacts on the interpretation of TRIPS-plus provisions. The interpretation of TRIPS-plus provisions demonstrates that the interpretation will not only need to refer to TRIPS and its object and purpose, but also need to refer to the subsequent development of TRIPS. Through this kind of interpretation, the flexibility on the right to health protection contained in TRIPS can still inform the interpretation of TRIPS-plus provisions. It is, therefore, through this interpretation approach that a harmonisation between TRIPS and TRIPS-plus in FTAs can be achieved.

The interpretation approach used in FTAs is potentially of far reaching effect. It can enhance the possibility of avoiding the seeming conflict between TRIPS and FTAs. With the development of trade, the proliferation of FTAs

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[185] See Andrew T. F. Lang, 'Rethinking Trade and Human Rights' (2007) 15(2) *Tulane Journal of International and Comparative Law* 335, 398. Also see Andrew T. F. Lang, 'The Role of the Human Rights Movement in Trade Policy-Making: Human Rights as a Trigger for Policy Learning' (2007) 5 *NZ J Pub & Int'l L* 77, 89–91.

[186] Frankel, above n. 100, 1034–36.

will create more and more new rules after the establishment of the WTO. The justification between TRIPS and TRIPS-plus and the interpretation of the justification and TRIPS by FTAs will improve the establishment of TRIPS-plus as well as promote the untangling of the evermore complicated "spaghetti bowl"[187] of TRIPS-plus.

[187] See Pauwelyn, above n. 10, 3.

# Chapter 8

## Conclusion

This book has examined how the TRIPS regime relates to the right to health from the perspective of the Dispute Settlement Body of the WTO. This has been done by discussing principles and approaches to treaty interpretation and applying them to the relevant provisions of TRIPS. The process of treaty interpretation follows the rules provided in the VCLT.

The right to health is derived from health law and human rights law. Health law includes the law related to medicine and the law related to public health law, and the two laws merge in the human rights regime. The right to health evolved from the development of the concept in the health area, and is continually evolving concept in the human rights regime.

At the international level the right to health, encompasses not only the curative and preventive elements, but also includes underlying conditions. It not only entails legal and international obligations, but it also imposes core obligations on states under treaties. The right to health requires affordable access to necessary drugs as its essential element. In addition, the individual based right to health is closely tied to the collective based public health concept and establishes a relationship between the two. Public health and the right to health are inter-related and inter-dependent. Public health is related to control of epidemic disease, and is one dimension of the right to health. The realisation of the right to health relies on the attainment of the public health. Public health can also be used to limit or derogate from other human rights.

The right to health interfaces with the right to life, and it will be subjected to complex influences from the right to life in urgent circumstances. The right to life complements the right to health in the access to life-saving equipment and drugs. In health cases, it is evident that the right to life is restrictively invoked and the right to emergency medical treatment is subject to strict interpretation and is cautiously implemented in health cases conditioned as it is on the availability of the resources. The courts are wary of encroaching on the executive power to allocate the resources.

The human rights regime also gives expression to intellectual property protection through the right to property and the right to fruits of creation. The right to property is mainly related to the property owned through labourers' work to maintain a standard of living, and it is subject to limitations in the public interest. The human rights approach to patent protection shows that the protection of patents can fall within the protection of human rights, but that its scope is not necessarily the same. The human rights approach towards patent protection requires a good balance between the promotion of sharing scientific progress and the protection of the material and moral interests of inventors, and a balance between the protection of the moral and material interest of the inventor as a human right and the protection of other human rights.

The seeming conflict between the right to health and the TRIPS regime is seen on examination, to be able to be harmonised with an interpretation of the TRIPS regime.

The object and purpose of TRIPS has been highlighted in the Doha Declaration. Examination of the Preamble and Articles 7 and 8 of TRIPS shows that TRIPS has a goal to promote normal international trade to reduce counterfeits and free riding, and to protect intellectual property rights. This is different from the goal of GATT, the predecessor of WTO. However, TRIPS offers a mechanism for achieving a good balance between the protection of private right and public interest. The public interest includes the protection of public health. At the same time, the concept of "public health" in TRIPS is unspecified and is evolving.

The interpretation of Article 27(2) demonstrates that it deals with the carve-out from non-discrimination contained in Article 27(1), and that *ordre public* is a concept mainly related to reasons of security. Issues of public health can fall into this category when the situation poses a threat to national security or the risk of riots. In addition, the open-textured language used for the second use patent promotes access to medicines.

Article 30 of TRIPS relates to experimental use and regulatory review. This flexibility supports state members fulfilling their obligations to develop health research policy under the right to health.

Article 31 is a mechanism which gives flexibility other than that offered in Article 30. The open-textured language allows members freedom to define "national emergency" or "extreme urgency" and, taken together with the subsequent clarification, shows that members are free to use the compulsory licensing of pharmaceutical related patents to promote access to affordable medicines. The development in Article 31*bis* indicates a solution to some of the practical issues of promoting access to medicines for a country which lacks manufacturing capacity.

The issue of exhaustion of rights is addressed in TRIPS in Article 6 but interpretation of this Article is left open so that it does not create an obstacle to the parallel importation of patented pharmaceuticals. This allows generics produced under compulsory licensing to be exported to the countries which are in need of the drugs.

Article 73 offers further flexibility in time of health crises.

The TRIPS-plus in FTAs are more restrictive on access to medicines, although an understanding of the right to health is still included. The extent of that understanding is insufficient to extend the influence of the right to health to the FTAs regime, but it nevertheless offers the possibility of reference to the right to health through some open-textured language, non-derogation provisions, express language with direct reference to the protection of health, and the creation of a counter-regime of human rights.

This book shows that, although patent protection requirements in TRIPS can impact upon the availability of affordable medicines and so threaten a possible violation of the right to health, TRIPS has enough flexibility to meet the obligations under the right to health. A treaty interpretation approach needs to be adopted to interpret the TRIPS provisions for the understanding of TRIPS flexibility, and the customary rules of interpretation of public international law codified in the VCLT should be followed as the approach to treaty interpretation. Following this approach, this book has demonstrated that the TRIPS provisions meet the right to health in the sense that they offer a flexible mechanism through the open-textured language adopted, the expression of objects and purposes and its subsequent development, to offer compulsory licensing, to offer second use patents and to offer research exceptions. All these flexibilities promote the realisation of the right to health.

This book also shows that the interpretation of TRIPS impacts on the FTAs when their intellectual property chapters provide for TRIPS compliance or TRIPS-plus standards. The FTAs may adopt higher level intellectual property standards that have the potential to further restrict access to affordable medicines and so negatively impact upon the realisation of the right to health; however, the relationship between WTO and FTAs together with the interpretation method and dispute settlement mechanism adopted in the FTAs enable the treaty interpretation approach of TRIPS to influence the interpretation of FTAs. This influence includes consideration of and compliance with the object and purpose of TRIPS in terms of the understanding of the intellectual property protection, and reference to TRIPS and its subsequent development.

This book reveals that the WTO Dispute Settlement Body, in resolving TRIPS dispute settlement cases, needs to apply the customary rules of treaty interpretation of public international law in full to interpret TRIPS so that

the potential conflict between the TRIPS regime and the human rights regime can be avoided, and more positively, so that the regimes work in harmony.

The competing goals of intellectual property protection and realisation of human rights require the international community to recognise that such competition has real and significant policy and operational implications, and it poses the challenge of how these various international law norms can go hand in hand or be brought into some form of positive working alignment. The balanced nature of intellectual property protection and its adoption in the trade arena requires more delicate and nuanced reading and interpretation to facilitate the relationship between human rights compliance and intellectual property protection.

The interpretation of TRIPS is not only a process designed to provide clarification of the meaning of the TRIPS provisions and to identify the intentions of the treaty parties, but it is also a process that must necessarily find ways to harmonise the competing goals. The whole interpretation process shows that, while the right to health restricts the ambit of intellectual property protection, and the right to property and the right to fruits of creation reinforce intellectual property protection. TRIPS encompasses various flexibilities that can meet the challenges from the human rights regime to achieve a harmonisation.

In order to achieve such harmonisation, the principles and rules in international treaty interpretation should be fully applied. The object and purpose of a treaty should always be highlighted, and the contextual materials should be referred to. Last but not least Article 31(3)(c) of VCLT enables reference to sources outside of the treaty being interpreted, and the dynamic application of this Article needs to be emphasised in the interpretation process.

The proliferation of international norms creates the potential for conflict between them, but not all the norms are in real conflict. A treaty interpretation helps by possibly eliminating reducing or providing mechanisms to resolve seeming conflict between them. The interpretation of the TRIPS provisions in relation to the right to health is a reflection of this kind of solution.

The interpretation of the TRIPS provisions requires people to take stock of the legal basis of TRIPS and of the whole WTO law. In doing so, it is found that TRIPS and the whole WTO law is not a self-contained regime, but it is open to many other areas of international law, including non-trade areas.

The way that human rights norms can be introduced in TRIPS and the extent to which they may be introduced have a far-reaching impact on the WTO law. An evolutionary manner of interpretation will help the WTO DSB to meet the challenges of the emerging norms and extend WTO law to have a broader ambit with its mechanisms. Within the WTO dispute settlement system the law applicable may be subject to expansion with international

human rights norms and other sources outside WTO law may be included in its dispute settlements.

This interpretation of TRIPS not only impacts upon the manner of the interpretation of the whole WTO law, but it also reaches beyond the WTO law to have implications for FTAs which stay under the WTO framework. The penetrative effect of such interpretation will assist the examination of TRIPS and WTO law and will also assist examination of FTAs. The effect of such an interpretation method may well be far-reaching.

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