

Pharmaceutical Patents in the TRIPS Agreement and the Right to Health - Can These Rights Be Reconciled?

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The World Trade Organization Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) requires pharmaceutical patent protection in all member States. As a result of this patent protection, pharmaceutical patent holders enjoy a strong monopoly position and can control the price of medicines. 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. If patent holders inflate drug prices, this will impact upon the access to medicines. Therefore, pharmaceutical patent protection under the TRIPS Agreement regime is potentially in conflict with the right to health. This article analyses the relationship between the TRIPS Agreement and the right to health by using the public international law tools of treaty interpretation. It explores how the TRIPS regime, and ultimately the whole WTO regime, relates to the right to health. Further, it examines the specific relevant provisions of the TRIPS Agreement to determine how far the TRIPS regime relates to the right to health.

INTRODUCTION

Serious epidemic disease, such as HIV AIDS is a global health threat.¹ But with

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1 According to UNAIDS, “by the end of 2007, the estimated number of people living with HIV worldwide in 2007 was 33.2 million (30.6-36.1 million).” The report shows that, in 2007, 2.5 million people are newly infected with AIDS, and 2.1 million people died of 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.” See 2007 UNAIDS Annual Report (March 2008), available at: http://data.unaids.org/pub/Report/2008/jc1535_annual_report07_en.pdf (accessed on 9 May 2012). According to UNAIDS, in 2008 there are 33.4 million people living with HIV and the estimated HIV related death was two million in 2008. Every day, 1200 children are infected with AIDS, 2500 young people (15-24) are infected with AIDS and 3700 adults (25+) are infected with AIDS. See UNAIDS Annual Report 2009 http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/report/2010/2009_annual_report_en.pdf (accessed on 9 May 2012).

access to affordable medicines, these kinds of diseases are controllable.² The right to health is a basic human right,³ and it enjoys wide international recognition and national implementation.⁴ The right to health entails access to essential drugs as a major concern of the realisation of the right to health.⁵

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. Article 27.1 of TRIPS requires that inventions may not be excluded from the ambit of the patent system, inter alia because of their field of technology. Thus pharmaceutical inventions are prima facie eligible for patent protection in accordance with this non-discrimination requirement. 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. However, the monopoly created by a pharmaceutical patent may allow patent holders to prevent the introduction of

2 WHO Secretariat “More Equitable Price for Essential Drugs: What Do We Mean and What Are the Issues?” 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) Executive Summary, available at http://www.wto.org/english/tratop_e/trips_e/hosbjor_execsum_e.htm, (accessed 9 May 2012).

3 The right to health has been incorporated in the Universal Declaration of Human Rights (1948) (hereinafter UDHR) as an important human rights law source. See UNGA, *The Universal Declaration of Human Rights, Resolution 217A (III)* (10 December 1948) UN Doc A/810, art 25. Also, it has been incorporated as a binding treaty norm, see *International Covenant on Economic, Social and Cultural Rights* (hereinafter ICESCR), opened for signature 16 December 1966, 993 UNTS 3; 6 ILM 360, art 12 (entered into force 3 January 1976).

4 For example, the right to health has been accepted as a treaty norm in the International Covenant on Economic, Social and Cultural Rights by 156 members of the United Nations; 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”. 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 International Convention on the Elimination of All Forms of Racial Discrimination (1965) (CERD), the Convention on the Elimination of All Forms of Discrimination Against Women (1979) (CEDAW), 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. International humanitarian law, international environmental law and international labor law have included health concerns. In addition, individual states have provided health right protection in their national constitutions. According to research, 67.5% of the constitutions of all nations have provisions addressing health or health care. See Eleanor D Kinney & 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.

5 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 Session) (27 June 2001) E/CN.4/Sub.2/2001/13 para 42. The UN Commission on Human Rights ceased to exist on 19 June 2006 and its function has been replaced by the Human Rights Council.

competitive generic products during the term of the patent.⁶ 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 the drug's technology.⁷ When the ability of drug companies to control the drug price is combined with the global reach of the TRIPS patent monopoly, high prices will result, meaning that many poor countries will not be able to secure access to essential medicines.⁸ This negative impact of TRIPS on access to medicines has raised concern as to whether the TRIPS regime is in conflict with the right to health.⁹ Resolution 2000/7 of the Sub-Commission on the Promotion and Protection of Human Rights of the UN Commission on Human Rights recognises that "TRIPS could affect the enjoyment of the right to health – in particular through its effect on access to pharmaceuticals".¹⁰ Some argue that the denial of affordable drugs due to the impacts of patent protection for pharmaceuticals under TRIPS constitutes a violation of the right to health.¹¹ In addition, the commercial motivation of intellectual property protection 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.¹² This article addresses the following questions: Can the right to health be introduced

6 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, Cambridge, 2005) 393, 408-410.

7 UN Commission on Human Rights n 5, supra, para 42.

8 Such as drugs for HIV/AIDS. According to UNAIDS, most poor countries from sub-Saharan Africa are suffering from AIDS. See 2007 UNAIDS Annual Report (March 2008), available at: http://data.unaids.org/pub/Report/2008/jc1535_annual_report07_en.pdf (accessed 9 May 2012). Also see Commission on Human Rights, "The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health" (Sixtieth Session) (1 March 2004) E/CN.4/2004/49/Add.1 para 43.

9 In 2001, the Sub-Commission on the Promotion and Protection of Human Rights raised the issue of the promotion and protection of the right to health and the role of the TRIPS Agreement. See 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 para 1 (hereinafter Resolution 2000/7). Also see 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*, above n 6, paras 1-2.

10 See UN Commission on Human Rights n 5, supra, para 2. Also see UN Commission on Human Rights Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property Rights and Human Rights*, supra n.9. Also see Commission on Human Rights "The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health" (Sixtieth Session) (1 March 2004) E/CN.4/2004/49/Add.1 para 43.

11 For this view, see Amit Gupta, 'Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?' (2004) 2 *Buff Intell Prop L J* 127, 151-153; Lissett Ferreira, 'Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations' (2002) 71 *Fordham L Rev* 1133, 1165.

12 UN Commission on Human Rights n 5, supra, para 38. Also see Commission on Human Rights, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, (Sixtieth Session) (1 March 2004) E/CN.4/2004/49/Add.1 para 42.

into TRIPS and into the entire fabric of WTO laws? To what extent can TRIPS introduce such sources external to WTO laws into its own regime? Can all the flexibilities of TRIPS adequately respond to the right to health? How and to what extent can they respond to the right to health?

THE RIGHT TO HEALTH IN INTERNATIONAL LAW

SCOPE AND CONTENT OF THE RIGHT TO HEALTH

Various terms are used to address the right to health as a human right. Usually, the term 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”.¹³ The right to health has been widely recognised as a legal right rather than an aspirational right,¹⁴ having regard to recognition of the right in the Universal Declaration of Human Rights (UDHR) and the ICESCR.¹⁵ Shaw is of the view that the Universal

13 Brigit Toebes, ‘The Right to Health’ in Asbjørn Eide, Catarina Krause and Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers, Dordrecht, London, 2001) 169, 170. For example, Art 12 of ICESCR uses the term of “health”, while Art 25(1) of UDHR uses the term of “medical care”, Art 152(1) of the European Constitution used the term of “human health protection”, although Toebes comments that “its fate is at the present time uncertain”.

14 Recognition in international commitment to treaties can reinforce the status of a customary international norm. 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. Even if there is only a limited number of parties to a particular treaty, according to the author, the intentions of treaty parties to restrict the scope of a treaty to them are irrelevant to the community expectations in international law. 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. Charney also has pointed out a tendency in the acceptance of custom 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. See Anthony D’Amato, *The concept of Custom in International Law* (Cornell University Press, Ithaca, NY, 1971) 90; also see 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, 174-175, quoted in Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, Cambridge, 2003) 105.

15 But see Lisa Forman, ‘Ensuring Reasonable Health: Health Rights, The Judiciary, and South African HIV/AIDS Policy’ (2005) 33 *J L Med & Ethics* 711, 711, 713-714; 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. 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 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 easily 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 BHR 308, paras 18-20 (SA Con Ct) Chaskalson P J.

Declaration of Human Rights (UDHR) has become binding either through custom or general principles of international law or through the interpretation of the UN Charter itself by subsequent practice.¹⁶ Brownlie also argues that some provisions of the UDHR have either become general principles of law or represent elementary considerations of humanity and the indirect legal effect of the UDHR is not to be underestimated.¹⁷ However, the indeterminacy and vagueness of the right to health still accounts for the difficulty in its implementation at a national level.¹⁸ It is, therefore, very important to clarify the content and scope of the right to health.

In recent years, there has been a considerable development of the normative content of the right to health and there is a wide range of literature clarifying the content and scope of this right¹⁹ These clarifications of the normative content will enhance the implementation of the right to health at a national level. The right to health does not mean that everyone has a right to be healthy.²⁰ Under international human rights law, the right to health includes two parts: elements related to healthcare (including curative and preventive health care), and elements related to a number

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- 16 See Malcolm N Shaw, *International Law* (5th ed, Cambridge University Press, Cambridge, 2003) 260-261.
- 17 See Ian Brownlie, *Principles of Public International Law* (7th ed, Oxford University Press, Oxford, 2008) 559-560.
- 18 Lisa Forman, n 15, *supra* at 711. Also see Jennifer Prah Ruger, 'Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements' (2006) 18 *Yale Journal of Law & the Humanities* 273, 312.
- 19 Eg, CESCR, General Comment No. 14: The Right to the Highest Attainable Standard of Health (22nd Session) (4 July 2000) E/C.12/2000 (hereinafter General Comment No. 14); Office of the UN High Commissioner for Human Rights and World Health Organization "Fact Sheet No. 31: The Right to Health" (June 2008), available at: HYPERLINK "<http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>"[HYPERLINK "http://www.ohchr.org/Documents/Publications/Factsheet31.pdf"](http://www.ohchr.org/Documents/Publications/Factsheet31.pdf) HYPERLINK "<http://www.unhcr.org/refworld/docid/48625a742.html>" (last accessed on 5 August 2011); Brigit Toebes, *The Right to Health as a Human Right in International Law* (Intersentia, Antwerp, Netherlands, 1999); Toebes, above n 22, 169, 170; Brigit HYPERLINK "http://muse.jhu.edu/journals/human_rights_quarterly/v021/21.3toebes.html" \l "authbio1#authbio1" Toebes, 'Towards an Improved Understanding of the International Human Right to Health' (1999) 21.3 *Human Rights Quarterly* 661. 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 & J H Hubben (eds), *Health Law, Human Rights and the Biomedicine Convention* (Martinus Nijhoff Publishers, Leiden, 2005) 49, 55; Virginia A Leary, 'Defining the Right to Health Care' in Audrey R Chapman (ed), *Health Care Reform – A Human Rights Approach* (Georgetown University Press, Washington, 1994) 87. Virginia A Leary, 'The Right to Health in International Human Rights Law' (1994) 1 *Health and Human Rights* 24.
- 20 Katarina Tomaševski, 'Health Right' in Asbjørn Eide, Catarina Krause & Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers, Dordrecht, London, 1995) 125, 125; also see CESCR, General Comment No. 14, n.19 *supra* at para 8; Leary, 'Defining the Right to Health Care', above 26, 87, 99.

of ‘underlying preconditions for health’.²¹ This means that the right to health covers not only the right to medicines and disease prevention, but also matters such as the preconditions a state should guarantee for the protection of people’s health. In its curative facet, the right to health requires first the enjoyment of “the highest attainable standard of physical and mental health”.²² The Committee on 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.”²³ 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.²⁴ The “preventive means” 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.²⁵ 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 by requiring 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.²⁶ In this way, it requires that medicines should be made available in urgent situations or disasters.

There are also essential elements that can be identified as “availability”, “accessibility”, “acceptability” and “quality” in the right to health.²⁷ Among these, Accessibility means not only physical accessibility, but includes economic accessibility that requires health facilities, goods and services to be affordable for all.²⁸ This means that the access to medicines involves affordable prices.²⁹

21 Brigit Toebes, ‘The Right to Health’ in Asbjørn Eide, Catarina Krause and Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers, Dordrecht, London, 2001) 169, with “Toebes, n. 13 supra at

22 Art 12.1 of ICESCR.

23 CESCR, *General Comment No. 14*, n 19, supra, para 9.

24 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, 160-161; the author is of the view that the right to life and the right to health determines a right to essential affordable medicines.

25 See Art 12.2(b) of ICESCR; also see CESCR, *General Comment No. 14*, n 19 supra, para 15.

26 CESCR, *General Comment No. 14*, n 19, supra, para 16.

27 *Ibid*, para 12.

28 *Ibid*, para 12(b)

29 *Ibid*, para 12.

Finally, the right to health is understood to be circumscribed within certain limits, and does not encompass everything that involves health. Toebes observes, the right to health does not include the right against torture or inhumane or degrading treatment, regular education at school or general environmental pollution.³⁰

OBLIGATION

The inclusion of the right to health in a wide array of international human rights instruments entails obligations on states to implement the right to health at the national level.³¹ National governments and judiciaries are responsible for guaranteeing the realisation of the human rights norms.³² According to the ICESCR, the realisation of the right to health, among certain other rights, is subject to a progressive process which recognises the limits of available resources.³³ The condition 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.”³⁴ There are constraints on availability of resources in each state. Nevertheless, a consideration of concrete and purposeful steps towards full realisation must be taken.³⁵ There are three levels of obligations on state parties: the negative obligation *to respect*, and the positive obligations *to protect* and *to fulfil*.³⁶

To respect means that a state should not take actions that have adverse effects on people’s health.³⁷ *To protect* includes the obligation of states to legislate or to take other measures to ensure equal access to health care and health-related services provided by third parties.³⁸ *To fulfil* means a state must adopt detailed plans for the

30 Toebes, ‘Towards an Improved Understanding of the International Human Right to Health’, n.21 supra, 676.

31 Lisa Forman, n 18, supra at 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.

32 Hurst Hannum, ‘The Status of the Universal Declaration of Human Rights in National and International Law’ (1995/1996) 25 Ga J Int’l & Comp L 287, 292.

33 Art 2.1 of ICESCR.

34 CESCR, *General Comment No. 14*, e n 19, supra, para 31.

35 Ibid, paras 30-32.

36 Ibid, para 33.

37 Ibid, para 34. *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”. This includes absence of discriminatory practices and gender inequality. *To respect* also requires no prohibition or impediment by a state on “traditional preventive care and healing practices and medicines”, regulations to prohibit the “marketing of unsafe drugs”, and provision of services on a basis of individual autonomy except in cases of mental illness and communicable diseases”.

38 Ibid, para 35. States should ensure the adequate “availability”, “accessibility”, “acceptability” and “quality of health facilities, goods and services” when these are privatized. They should control the marketing of medical equipment and medicines by third parties to ensure the meeting of the standards of professional requirements, and not to limit access to health-related information and services.

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.³⁹ To *fulfil* the right to health, although it is subject to progressive realisation, also means immediate obligations in 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 achieve access to essential medication.⁴⁰

PUBLIC HEALTH AND THE RIGHT TO HEALTH

The preventive health care elements of the right to health link the right to health with public health. The modern concept of health derives from two related but quite different disciplines: medicine and public health.⁴¹ “While medicine generally focuses on the health of an individual, public health emphasises the health of the population” as a whole.⁴² 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. While human rights are intended to be based on the guarantee of individual protection,⁴³ public health targets the protection of population and this contemplates further clarification between the concepts. In international human rights law, public health can also involve 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 in modern society.⁴⁴ 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 is thus compatible with general human rights principles. In the case of epidemics, individual rights of liberty of movement, identity, privacy, dignity, religion, expression and association may be restricted.⁴⁵

39 Ibid, para 36.

40 CESCR, *The Nature of States' Parties Obligations* (5th Session, 1990) para 10, U N Doc E/1991/23, Annex III..

41 Jonathan M Mann, Lawrence Gostin, Sofia Gruskin, Troyen Brennan, Zita Lazzarini & Harvey Fineberg, ‘Health and Human Rights’ in Jonathan M Mann, Sofia Gruskin, Michael A Grodin & George J Annas (eds), *Health and Human Rights: A Reader* (Routledge, New York and London, 1999) 7, 8.

42 Ibid.

43 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 Jonathan M Mann, Sofia Gruskin, Michael A Grodin & George J Annas (eds), *Health and Human Rights: A Reader* (Routledge, New York and London, 1999) 46, 46.

44 Katarina Tomaševski, ‘Health Right’ in Asbjørn Eide, Catarina Krause & Allan Rosas (eds), *Economic, Social and Cultural Rights* (Martinus Nijhoff Publishers, Dordrecht, London, 1995) 125, 137-138.

45 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: HYPERLINK "<http://www.hhrjournal.org/archives-pdf/4065261.pdf.banned.pdf>"<http://www.hhrjournal.org/archives-pdf/4065261.pdf.banned.pdf> (last accessed on 18 August 2011), with reference to G A Res 2200, 21 UN GAOR Supp (No. 16) at 49, UN Doc A/6316, 1966. Articles 12, 18, 19 and 22.

Although the term “public health” is not directly incorporated into the Universal Declaration of Human Rights (UDHR) and ICESCR, “public health” is used as a ground for the limitation of some human rights, especially in the health context.⁴⁶ This is partly determined by the fact that “public health” is a compulsory measure in health law, and “public health” is also part of “public order”.⁴⁷ “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”.⁴⁸ Public health has also been broadly interpreted in other situations, such as the prevention of disease among cattle by the European Commission of Human Rights.⁴⁹

In the Siracusa Principles,⁵⁰ principle 25 allows a state to take measures to deal with a serious threat to the whole population or to individuals in the population.⁵¹ Public health may also justify restrictive measures by international regulations, such as those promulgated by the WHO.⁵² The public health ground often carries

46 CESCR, *General Comment No. 14*, n 19, supra, 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.” Also see WHO, ‘25 Questions & answers on Health & Human Rights’ (2002) Issue No 1 Health & Human Rights Publication Series 18.

47 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.” 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. Public health can therefore be covered under the grounds of “ordre public” or “public order”. 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, New York, 1981) 290, 302

48 Kiss, *Ibid*, at 303; see also Principle 25 of *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, that also alludes to epidemic disease being covered by public health. 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.

49 See *X v Netherlands* (1962) 5 Y B Eur Conv Human Rights 278, quoted in Kiss, n 47, supra at 303..

50 UN Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights* (28 September 1984) E/CN.4/1985/4, available at: <http://www.unhcr.org/refworld/docid/4672bc122.html> (last accessed on 29 July 2011). These principles were developed by a group of international law experts during a high-level international conference sponsored by the following organisations: the International Commission of Jurists, the International Association of Penal Law, the American Association for the International Commission of Jurists, the Urban Morgan Institute of Human Rights and the International Institute of Higher Studies in Criminal Sciences, in Siracusa, Sicily in 1984 to consider the limitation and derogation provisions of the International Covenant on Civil and Political Rights, and the principles were adopted by the UN Commission on Human Rights.

51 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, 6.

52 Alexandre Kiss, ‘Commentary by the Rapporteur on the Limitation Provisions’ (1985) Vol 7 No 1 Human Rights Quarterly 15, 20.

more weight under Article 12 of the ICSECR, since a state is required to prevent epidemic disease under that Article.⁵³ 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 least restrictive as possible.⁵⁴

TRIPS AND HUMAN RIGHTS

The application of the right to health in international law may be in conflict with the pharmaceutical patent protection obligations under TRIPS. The right to health may entail access to affordable medicines and pharmaceutical patent protection can give the patent holder the monopolised power to inflate the drug prices and thus have an impact on the access to medicines.

This apparent conflict between various treaty norms is a product of globalisation. It has been observed⁵⁵ that one of the problems of TRIPS is that the WTO failed to address any conflicts arising under international law when a country has ratified treaties that may contain different obligations to those under the WTO Agreements. In order to resolve the conflict between the right to health and TRIPS, the obligations under the right to health contained in the human rights treaties should be mutually exclusive of the obligations under TRIPS.⁵⁶ 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”.⁵⁷ Abbot 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.⁵⁸

53 See Kiss, n 47, supra at 303.

54 CESCR, *General Comment No. 14*, n 19 supra at para 29.

55 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.

56 According to his analysis on the conflict of norms in public international law, Pauwelyn 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”. 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. See Pauwelyn, n 14, supra at 175-188.

57 Pauwelyn, n 14 supra at 176.

58 Frederick M Abbott, ‘The ‘Rule of Reason’ and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS’ in Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi (eds) *Human Rights and International Trade* (Oxford University Press, New York, 2005) 279, 280..

Treaty interpretation is a means used in international law to avoid possible conflicts among treaties.⁵⁹ Judicial deliberation is also part of a wider and much more complex picture of the international system,⁶⁰ so treaty interpretation may become a useful and positive tool in some instances through incorporation of other rules of international law. French takes the position 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”.⁶¹ 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.⁶²

The establishment of the WTO dispute settlement system provides a judicial style process for WTO members to seek a settlement in trade disputes. The interpretive function of the DSB is one of the important factors that influence the development of TRIPS jurisprudence.⁶³ The DSU requires the interpretation of the WTO Agreement in compliance with the customary rules of public international law,⁶⁴ and the *US-Gasoline case* has reaffirmed such rules of interpretation since the establishment of WTO.⁶⁵

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) is regarded as constituting a codification of such customary rules of public international law.⁶⁶ In *Japan-Taxes*,⁶⁷ the

59 This kind of view can be found in Pauwelyn, n 14 supra at 244-274; also see Gabrielle Marceau, ‘WTO Dispute Settlement and Human Rights’ 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, Ann Arbor, 2006) 181, 196-202.

60 Duncan French, ‘Treaty Interpretation and the Incorporation of Extraneous Legal Rules’ (2006) 55 ICLQ 281, 284.

61 Ibid, 285-286.

62 Pauwelyn, n 14 supra at 461.

63 Ernst-Ulrich Petersmann, *The GATT/WTO Dispute Settlement System: International Law, International Organizations, and Dispute Settlement* (Kluwer Law International, London and Boston, 1997) 17; see also James Cameron & Kevin R Gray, ‘Principles of International Law in the WTO Dispute Settlement Body’ (2001) 50 Int’l Comp L Q 248, 251-252.

64 Article 3.2 of the DSU.

65 See United States – *Standard for Reformulated and Conventional Gasoline* (29 April 1996) WT/DS2/AB/R at page 17.

66 See Sir Ian Sinclair, *The Vienna Convention on the Law of Treaties* (2nd ed, Manchester University Press, Manchester, 1984) 153; and the author expresses the view that, “there is no doubt that Art 31 to 33 of the Convention constitutes a general expression of the principles of customary international law relating to treaty interpretation.”

67 *Japan – Tax on Alcoholic Beverages* (4 October 1996) WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R section D page 10 (AB, WTO).

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*,⁶⁸ 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 of interpretation contained in the VCLT are accepted as customary international law and are therefore binding on all members of WTO.

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.⁶⁹ 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.⁷⁰ Article 32 provides supplementary means for treaty interpretation by using preparatory works.⁷¹ The application of Article 31(3)(c) by WTO is crucial to introduction of human rights norms into the interpretation of WTO laws, and it provides that “any relevant rules of international law applicable in the relations between the parties” can be considered for interpretation of a treaty. The relevant customary international law rules, general principles of international law and related conventional rules can also be applied in the interpretation of a treaty.⁷² These also find their expressions in the WTO dispute settlement cases.

TRIPS AND HUMAN RIGHTS NORMS

The promulgation of TRIPS within the WTO regime is intended to serve the purpose of regulating intellectual property protection for a better and fairer international trade environment.⁷³ The members of the WTO hope that TRIPS will promote the establishment of the international trade framework, and, ultimately, it

68 *United States – Measures Affecting the Cross-Border Supplying of Gambling and Betting Services* (10 November 2004) WT/DS285/R paras 6.9 and 6.10 (Panel Report, WTO).

69 Art 31.1 and art 31.2 of VCLT.

70 Art 31.3 of VCLT.

71 Art 32 of VCLT.

72 In the *EU Biotech Products* case, and it provides, “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).” *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (29 September, 2006) WT/DS291-3/R para 7.67 (Panel Report, WTO).

73 See Daniel Gervais, *The TRIPS Agreement-Drafting History and Analysis* (2nd ed, Sweet & Maxwell, London, 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.

will enhance the international economic order.⁷⁴

This aim can be found to be reflected in the preamble to TRIPS with the use of the expression “to reduce the distortion and impediment to international trade”.⁷⁵ 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”,⁷⁶ this aim may overlap with that of the human rights regime. At about the time that the GATT was created (1947), the United Nations human rights regime was also introduced with the adoption of the UDHR (1948). 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.⁷⁷ 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”.⁷⁸ Robert Howse and Makau Mutua also have argued that the reference to sustainable development in the Preamble of WTO and provisions of TRIPS should be interpreted in light of the treaty commitments of the relevant parties and in light of customary international law.⁷⁹ 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.⁸⁰

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 road map provided in the VCLT to meet the requirements of “customary rules of interpretation of public international law” as required by the WTO law. 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.

74 Thomas Cottier, ‘The Value and Effects of Protecting Intellectual Property Rights within the World Trade Organization’ in Thomas Cottier *Trade and Intellectual Property Protection in WTO Law: Collected Essays* (Cameron May, London, 2005) 81, 82-86.

75 See para 1 of the Preamble of TRIPS.

76 See Preamble of the Marrakesh Agreement Establishing the World Trade Organization.

77 Caroline Dommen, ‘Safeguarding the Legitimacy of the Multilateral Trading System: The Role of Human Rights’ 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, Ann Arbor, 2006) 121, 121-123.

78 *Ibid.*, 121-122.

79 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, January 2000) 20-21, available at: [HYPERLINK "http://www.dd-rd.ca/site/_PDF/publications/globalization/wto/protecting_human_rightsWTO.pdf"](http://www.dd-rd.ca/site/_PDF/publications/globalization/wto/protecting_human_rightsWTO.pdf) http://www.dd-rd.ca/site/_PDF/publications/globalization/wto/protecting_human_rightsWTO.pdf (accessed 9 May 2012).

80 *Ibid.*

Article 31(3)(c) requires a reference to other relevant international law rules aiming at promoting some “coherence” in international law,⁸¹ 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.⁸² French also points out that the reference to “other” legal rules in treaty interpretation can ensure equity in the judicial decision-making process, to encourage coherent legal reasoning and prevent disintegration of legal rules into their various sub-disciplines and to permit a tribunal to ensure that the narrow application of a rule is not allowed to overrule broader notions of justice.⁸³ Therefore, “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.”⁸⁴ 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 exclusively on States but also on individuals as legal subjects”.⁸⁵ It is, therefore, arguable that the interpreters of TRIPS are obliged to give due consideration to the right to health during the interpretation of the provisions of TRIPS when utilising the tool or indicator of Article 31(3)(c) of VCLT.

The TRIPS Agreement provides for minimum standards of protection of intellectual property; 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.⁸⁶

TRIPS adopts open-textured language in its carve-outs to achieve the conceptualised goal and this gives an opportunity to consider the right to health when the related provisions of TRIPS are interpreted. 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*

81 See International Law Commission, *Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law - Report of the Study Group of the International Law Commission* (58th Session and 61st Session, General Assembly, 2006) Supplement No. 10 (A/61/10) para 251 (17) – (21); The Report provides with systematic interpretation of international law, in particular through the operation of the rule of interpretation contained in Article 31(3)(c) of VCLT.

82 Marceau, n 59 *supra* at 202.

83 French, n.60 *supra* at 285-286.

84 Marceau, n 59 *supra* at, 199-200.

85 Ernst-Ulrich Petersmann, ‘Human Rights and International Trade Law: Defining and Connecting the Two Fields’ in Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi (eds) *Human Rights and International Trade* (Oxford University Press, New York, 2005) 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.

86 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, 418-19.

or morality”.⁸⁷ 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.”⁸⁸ The understanding of such open-textured terms as “public health”, “*order 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.⁸⁹

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 dynamic process. This means that the right to health may be included into this process with the evolution of the connotation of the provisions. One example of this relevance of the right to health 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 owners of pharmaceutical related patents may conflict with or constitute 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.⁹⁰ 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 encompass 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. 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

87 See art 8.1 and Art 27.2 of TRIPS.

88 See art 27 of TRIPS.

89 See Campbell McLachlan “the Principle of Systemic Integration and Art 31(3)(c) of the Vienna Convention” (2005) 54 ICLQ 279, 312.

90 See art 8(1) of TRIPS.

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 interests, and the more effective dispute settlement system of GATT/WTO.⁹¹ The author also observes that other regimes also entered into this process to challenge TRIPS; these other regimes included the human rights regime.⁹² 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.⁹³ Helfer points out that human rights norms can help to expand intellectual property protection standards, such as the invocation of an author's right and property rights, and they can also help to impose external limits on intellectual property.⁹⁴ 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 right to health into the interpretation of TRIPS. According to Wai, 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.⁹⁵

At the same time, Helfer also points out that the establishment of TRIPS also creates incentives for other regimes to develop soft law.⁹⁶ In the human rights regime many norms are outlined in a general way. The human rights regime, however, develops soft laws to elucidate the norms, such as by way of General Comments by the competent treaty committees. These soft laws together with the 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.⁹⁷ Although the comment is not binding on state parties of ICESCR,⁹⁸ it proffered more clarity to the meaning of the right to health.⁹⁹ The Comment declares that the core obligations as include "To provide essential drugs, as from time to time defined under the WHO Action Programme

91 Laurence R Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale J Int'l L* 1, 18-23.

92 *Ibid.*, 27-51.

93 *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.

94 Laurence R Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 *U C Davis L Rev* 971, 1015-1018.

95 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.

96 Helfer, n 91 *supra*, 72-75.

97 CESCR "General Comment No. 14", n.19 *supra* at, para 43.

98 Helfer, n.91 *supra* at 73.

99 See David Weissbrodt and HYPERLINK "<http://www.google.com.au/search?tbo=p&tbm=bks&q=inauthor:%22Frank+C.+Newman%22>" Frank Newman, *International Human Rights: Law, Policy, and Process* (3d ed. Anderson Publishing Co, Cincinnati, 2001) 88-93.

on Essential Drugs”.¹⁰⁰ 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.¹⁰¹ 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.¹⁰² 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.

APPLICATION OF THE RIGHT TO HEALTH IN TRIPS

PREAMBLE

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. 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.¹⁰³ This is an interesting and perhaps unexpected development in the field of international trade negotiations, because the position previously adopted under the GATT was that the intellectual property system was an “acceptable obstacle” to free trade.¹⁰⁴ 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.¹⁰⁵ 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. While intellectual property uses the approach of “protectionism”, TRIPS treats patents, copyrights, trademarks and trade secrets as “pro-competitive”.¹⁰⁶ This suggests that overly strong intellectual property

100 CESCR, *General Comment No. 14*, n.19 supra at para 43.

101 Helfer, n 91 supra at 77-78.

102 Ibid, 78.

103 Katharina Gamharter, *Access to Affordable Medicines: Developing Responses under TRIPS and EC Law* (Springer, Wien New York, 2004) 68; also see Gervais, n.73 supra at 37.

104 See Gervais, n.73 supra at, 8; see also Duncan Matthews, *Globalising Intellectual Property Rights- The TRIPS Agreement* (Routledge, London, New York, 2002) 9.

105 See Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (Oxford University Press, Oxford, 2007) 2.

106 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.

protection will not enhance free trade but distort it.¹⁰⁷ 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 shows that the trade goal in TRIPS should not take a predominant role. The Preamble is an essential part of TRIPS, and it will be relied on when unclear wording in TRIPS requires interpretation.¹⁰⁸ 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.¹⁰⁹

In the case of *Canada-Patent Protection of Pharmaceutical Products*,¹¹⁰ the WTO panel introduced the notion of public policy by observing that “both society and the scientist have a ‘legitimate interest’ in using the patent disclosure to support the advance of science and technology”.¹¹¹ However, the public policy considerations at the domestic regime level will vary according to the practical situation of different countries, and paragraph 5 of the preamble recognizes this

107 Frankel, n 86 supra at 390; also see Gamharter, above n 135, 68; also see Gervais, above n 135, 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 137, 3, and the author quoted from J Bhagwat and A Panagariya “Bilateral Trade Treaties Are a Sham” (2003) Financial Times (13 July 2003) available at: [HYPERLINK "http://www.cfr.org/publication/6118/bilateral_trade_treaties_are_a_sham.html"](http://www.cfr.org/publication/6118/bilateral_trade_treaties_are_a_sham.html)["http://www.cfr.org/publication/6118/bilateral_trade_treaties_are_a_sham.html"](http://www.cfr.org/publication/6118/bilateral_trade_treaties_are_a_sham.html) (last accessed on 5 August, 2011). Also, see Keith E Maskus and Mohan Penubartib, ‘How trade-related are intellectual property rights?’ (1995) 39 Journal of International Economics 227, 229. The author argues that there is no clear presumption that stronger IP protection will attract more imports.

108 See Gervais, n.73 supra at 76-82. Also see Gamharter, above n 135, 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 *Canada-Patent Protection of Pharmaceutical Products* (17 March 2000) WT/DS114/R paras 7.23 -7.26 (Panel, WTO), where the Panel did not rely on the Preamble but on arts 7 and 8 to find the meaning of art 30 of TRIPS.

109 Gervais, n.73 supra at, 76-82.

110 *Canada-Patent Protection of Pharmaceutical Products*, above n 142. On 19 December 1997, the EC requested consultations with Canada in respect of the alleged lack of protection of inventions by Canada in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation, in particular the Patent Act. The EC alleged that Canada’s legislation is not compatible with its obligations under the TRIPS Agreement, because it does not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by Articles 27.1, 28 and 33 of the TRIPS Agreement

111 Ibid, para 7.14, and it provides that, “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.”

consideration.¹¹²

ARTICLES 7 AND 8

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. 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 the public at large in securing access to science, technology and culture.¹¹³ 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 made¹¹⁴ and a total exclusion of patentability of pharmaceutical inventions could lead to delays or reductions in research and development efforts by private industry.¹¹⁵ The difficulty in interpreting this open-textured sentence is that it is hard for panels and ABs to find the balancing point of “promotion of technological innovation and to the transfer and dissemination of technology”.¹¹⁶

Article 8 expresses some broad principles to underpin TRIPS.¹¹⁷ Paragraph one 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 two then touches upon the desirability of technology transfer which is generally regarded as advantageous in economic and ultimately

112 See paragraph 5 of TRIPS Preamble, and it provides, “Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.”

113 Gervais, n.73 supra at 116-120; as discussed in the 1st part, the justification of intellectual property protection can be the disclosure for rewarding and a balance needs to be struck at the national level.

114 For example, see Harvey E Bale “Patents and Public Health: a Good or Bad Mix?”, available at: [HYPERLINK "http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm"](http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm) http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm (last accessed on 16 October 2008); also see Harvey E Bale “Pharmaceutical Access and Innovation: Challenges and Issues” (1999) Vol 42 Number 4 Development (Palgrave Macmillan) 84-86.

115 Gervais, n.73 supra at 119.

116 See Frankel, n 86 supra at 392.

117 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.

social development. Such expression suggests that Article 8(1) is not subordinate to other provisions of TRIPS¹¹⁸ and Article 8 has constituted a policy statement to explain the rationale for measures taken under Articles 30, 31 and 40.¹¹⁹

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 Agreement¹²⁰ 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,¹²¹ and they have also been highlighted by the Declaration on TRIPS and Public Health.¹²² In the case of *Canada-Patent Protection of Pharmaceutical Products*,¹²³ the panel emphasised the object and purpose to be found in Article 7 and Article 8 as relevant to the interpretation. 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. According to Yu, 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”¹²⁴ as well as a “shield” to ensure the members’ use of flexibilities in TRIPS.¹²⁵

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 upon the context to clarify the meaning of the text.¹²⁶ It is elementary that, in finding the object and

118 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.

119 Gervais, n.73 supra at 68-69.

120 See Frankel, n 86 supra at 392.

121 Gervais, n.73 supra at 120 and 122; also see WTO Ministerial “Doha WTO Ministerial Declaration” (20 November, 2001) WT/MIN(01)/DEC/1 para19. 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.”

122 WTO Ministerial, *Declaration on the TRIPS Agreement and Public Health* (hereinafter Doha Declaration) (20 November 2001) WT/MIN(01)/DEC/2 parh 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.

123 *Canada-Patent Protection of Pharmaceutical Products*, above n 142, para 7.14.

124 Peter K Yu “The Objectives and Principles of TRIPS” (2009) 46 *Houston Law Review* 979, 1020-1025.

125 *Ibid*, 1025-1031.

126 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.

purpose of a WTO agreement, the object and purpose should be examined by taking the treaty as a whole, and should involve not only examination of any preamble but also other related provisions, such as those in DSU.¹²⁷

SUBSEQUENT DEVELOPMENT OF TRIPS

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, however, can also be enlightened by the subsequent development of TRIPS. In November 2001, the WTO Ministerial meeting adopted the Declaration on the TRIPS Agreement and Public Health that recognises the WTO member's right to protect public health and to promote access to medicines for all.¹²⁸ 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.¹²⁹ This Decision should be understood as a document granting a legitimate waiver of rights and obligations under TRIPS to enable the generic medicine producers to export to the countries without pharmaceutical production capacity, and the waiver will be permanent unless an amendment is made to replace the related provisions.¹³⁰ 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.¹³¹ 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 31bis has been added as a proposed amendment.¹³² This proposal was originally open for acceptance by members until 1 December 2007, but was extended to 31 December 2009¹³³ for the first time, to 31

127 Michael Lennard "Navigating by the Stars: Interpreting the WTO Agreements" (2002) 5 J Int'l Econ L 17, 27-28.

128 See WTO Ministerial, Doha Declaration, n.122 supra eg see paras 4, 5, 6.

129 WTO General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (hereinafter 2003 Decision) (1 September 2003) WT/L/540 and Corr.1 para 1.

130 Ibid, para 11.

131 See WTO TRIPS Council, *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* (6 December 2005) IP/C/41.

132 See WTO General Council, *Amendment of the TRIPS Agreement* (8 December 2005) WT/L/641.

133 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* (21 December 2007) WT/L/711.

December 2011 for the second time, and to 31 December 2013 for the third time¹³⁴.

The Doha Declaration has in fact functioned as an interpretation of TRIPS by the Ministerial Conference, and when it is examined with the draft text of the negotiation basis of the Doha Declaration, the recommendation for such an interpretation is approximately a formal “recommendation” by the TRIPS Council.¹³⁵ In addition, the Doha Declaration should constitute evidence of subsequent practice for the purpose of the interpretation of TRIPS. 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.¹³⁶ 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.¹³⁷ These subsequent developments can further illuminate the members’ intention concerning the promotion of social and economic welfare, and the promotion of the protection on health.

THE RIGHT TO HEALTH

The right to health is reflected in the object and purpose of TRIPS. 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 the Appellate Body to sources outside WTO including human rights norms.¹³⁸ As argued above, the open-textured language used by members may suggest an intention to refer to outside sources, and such reference allows the right to health to be taken into consideration when seeking to interpret TRIPS.¹³⁹ As also guided by Article 31(3)(c) of VCLT, this allows the TRIPS interpreter to refer to the right to health to find the meaning behind the ordinary meaning of the language used in TRIPS.

134 See WTO General Council, *Amendment of the TRIPS Agreement – Second Extensions of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement* (17 December 2009) WT/L/785. And WTO General Council, *Amendment of the TRIPS Agreement – Third Extensions of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement* (5 December 2011) WT/L/829.

135 Gamharter, n.103 supra at 137; but see Gathii, n.136 supra at 314-315, the author argued that the Doha Declaration could constitute soft law with substantial hortatory authority, even if the Doha Declaration is not legally binding.

136 Sir Gerald Fitzmaurice, *The Law and Procedure of the International Court of Justice* (Grotius Publications, Cambridge, 1986) 357.

137 Gathii, n.126 supra at 311-312.

138 See paragraph 5 of Preamble, Art 7 and Art 8 of TRIPS.

139 See III.C.3.

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 enjoyment of social and economic welfare.¹⁴⁰ 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 to TRIPS can be seen to provide another avenue to consider respect for human rights. 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”.¹⁴¹ 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.¹⁴² When issues of public health are matters of concern to the national interest, domestic national policies should be given effect 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.¹⁴³

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 human beings. 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.¹⁴⁴ 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 concern for the right to health should be given due consideration during the interpretation of the specific provisions of TRIPS.

140 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”.

141 See CESCR, *General Comment No. 14*, n.19 supra at para 43.

142 See to right to Health and Public Health.

143 See WTO Ministerial, *Doha Declaration*, n.122 supra, paras 5(b) and 5(c).

144 n.140 supra.

The Doha Health Declaration directly incorporates the expression “access to medicines” in paragraph 4.¹⁴⁵ Because 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.

Paragraph 3 also emphasises the importance of intellectual property protection in developing new medicines and its impacts on prices.¹⁴⁶ This emphasis acknowledges that intellectual property protection can provide incentives for encouragement of the creation of new products, including pharmaceutical products and medicines. However, Abbot makes the point that Paragraph 3 is a controversial juxtaposition, observing that there is emphasis both on the importance of patents and prices but without discussion of explicit recognition of the concern of developing countries to address the diversion of medical research caused by the incentives.¹⁴⁷ Gamharter argues that the reference to “intellectual property protection” suggests a broader coverage instead of a narrow scope focussed only on patents.¹⁴⁸ This juxtaposition in Paragraph 3 recognises the need to find a good balance between patent protection and the promotion of access to medicines.

This understanding of the object and purpose contained in TRIPS can 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.¹⁴⁹

145 See WTO Ministerial, *Doha Declaration*, above n 122 supra, para 4, and 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.”

146 See WTO Ministerial, *Doha Declaration*, n.122 supra at 165

147 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.

148 Gamharter, n.103 supra at 135.

149 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 a balance between public interest and private right, but the balance is a dynamic one that must respond to the ever-changing situation. 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; 717-724, 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-

SPECIFIC PROVISIONS

The TRIPS Agreement contains a number of Articles which contain and express aspects of an inherent balance mechanism underlying the whole Agreement. Interpretation of some Articles which express aspects of this balance mechanism may reveal that the right to health is relevant to an understanding of the balance mechanism. Among these, articles 27, 28, 31 together with Articles 6 and 30, when considered as a whole, have taken the right to health into consideration.

ARTICLE 31

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.¹⁵⁰ In this sense, the interpretation of Article 31 has become a very important key to the illumination of the trail of TRIPS towards a harmonization between the right to health and patent protection.¹⁵¹ Article 31 deals with “other use without authorisation of the right holder”, and it is traditionally regarded as referring to compulsory licensing or non-voluntary licenses.¹⁵² 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.¹⁵³ Where a patent is not being worked in a country compulsory licensing involves the limitation on the patent holder’s right to exclude the party to whom the compulsory licence is granted from exploiting the patented invention in ways allowed by the license. With appropriate compulsory licensing arrangements another party can manufacture and supply life-saving drugs that are affordable.

Article 31 contains a chapeau and 12 paragraphs which prescribe the circumstances, duration, scope, remuneration and other issues for a compulsory license. Some of them contain ambiguous terminology, such as the terms “circumstances” in paragraphs (b) and (g) and “purposes” in paragraph (c), and it is also argued that

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.

150 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*, n.5 supra at para 66.

151 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, 491-497. 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.

152 Gervais, n73 supra at 250.

153 Carlos M Correa, ‘Integrating Public Health Concerns into Patent Legislation in Developing Countries’ (South Centre, Geneva, 2002) 93, available at: [HYPERLINK "http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf"](http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf)<http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf> (accessed 9 May 2012).

the factors contributing to the legitimate need to issue compulsory licenses are not fully developed within the text of Article 31.¹⁵⁴ The open-textured words contained in this article, including “national emergency” and “other circumstances of extreme urgency” allow a 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 practicable¹⁵⁵ 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.¹⁵⁶ Paragraph 5(b) of the Doha Health Declaration confirms the right of each Member to grant compulsory licenses, and emphasises the freedom of each member to establish grounds for compulsory licenses. The explicit expression of “compulsory licenses” contained in this paragraph is a confirmation and clarification of the words “other uses without authorization of right holders” in Article 31.¹⁵⁷ This paragraph 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 a 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 license provided it is based on good faith.¹⁵⁸ The same paragraph explicitly states that 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.¹⁵⁹ 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

154 Sara M Ford, ‘Compulsory Licensing Provisions under TRIPS: Balancing Pills and Patents’ (2000) 15 Am U Int’l L Rev 941, 956-62.

155 But in the case of public non-commercial use, the government or contractor should inform the patent holder promptly.

156 Frederick M Abbott, ‘TRIPS, Access to Medicines and the WTO Doha Ministerial Conference’ (Quaker United Nations Office, Geneva, 8 September 2001) 33, available at HYPERLINK "<http://www.quono.org>"www.quono.org (last accessed on 18 August 2011).

157 Gamharter, n.103 supra at 160.

158 See Ibid.

159 Gamharter, n.103 supra at, 161-162.

should also take the right to health into consideration.

At the same time, the express language contained in the Doha Health 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.¹⁶⁰ In addition, the interpretation of the textured terms “national emergency” and “extreme urgency” should be conducted in an evolutionary manner, since the circumstances which constitute “national emergency” or “extreme urgency” will change with the change of circumstances.

THE RIGHT TO HEALTH

The grounds for the grant of compulsory licensing must give consideration to the need *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 right to health in TRIPS.

Firstly, the interpretation of compulsory licensing can also be crucial for the promotion of the access to medicines at an affordable price. 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”.¹⁶¹ Specifically, a dispute concerning pharmaceutical patent protection must be interpreted by reference 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.

Secondly, 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. 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 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.¹⁶² The fact that a license can be granted on a governmental decision without a requirement of prior request or

160 Correa, n.105 supra at, 316.

161 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.

162 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.

negotiation with a third party or patent holder can expedite the procedures for seeking to respond to the public health needs.¹⁶³ 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.¹⁶⁴

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”,¹⁶⁵ the quick spread of life-threatening diseases can easily be defined by a state to constitute a “national emergency” or “extreme urgency”.

CONCLUSION

This article 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 this right. 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 proper treaty interpretation approach. Following this approach, this article 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. All these flexibilities promote the realisation of the right to health.

The proliferation of international norms creates the potential for conflict between them, but not all the norms are in real conflict. A proper 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.

163 Correa, n.105 supra at, 316-317.

164 Ibid, 317.

165 WTO Ministerial, *Doha Declaration*, n.122 supra, para 5(c).