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Revisiting public health emergency in international law:
A precautionary approach

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Certificate

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I certify that this thesis has been composed by me and is my own work.

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30 May 2011

Dedication

To undertake a PhD was never something that was on my 'to do' list until an emergency occurred in my life.

On 31 March 2003, when I was in the third trimester expecting the birth of my second child, my two-year-old fell into a deep coma after an unknown disease attacked her brain cells. It was an unwritten history during the notorious SARS and Birdflu pandemics in East Asia. The doctors failed to spot the culprit as it could have been any possible evolving flu virus strain during a seasonal change. Abbie was then in a persistent vegetative state for ten months before passing away the following winter.

At this time I experienced surreal confusion at the interface of busy birth and muted goodbyes. Therefore, doing a four year project abroad appeared to offer a perfect sanctuary. This work has proven to be an effective therapy as I have been able to relate to the stories that lie behind the ethical debates over pharmaceutical patents, especially in a public health emergency.

This work is thus dedicated to my sweet little angel in heaven and all those who have been captive by disease in speechless suffering, humbly expecting a dim light to break through the endless tunnel of heartbreaks. This work is also dedicated to my family, who have never ceased in their love and support while passing through the valley of death with me, and now are celebrating a new life from the completion of this work.

Acknowledgements

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Summary of Contents

Abstract

This work develops a means to encourage states to take advantage of the flexibilities of compulsory licensing in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which promotes access to medicines in a public health emergency.

In pursuing this solution, the precautionary approach (PA) and the structure of risk analysis have been adopted as a means to build a workable reading of TRIPS and to help states embody the flexibilities of intellectual property (IP). This work argues for a PA reading of TRIPS and that states have the precautionary entitlements to determine an appropriate level of health protection from the perspective of "State responsibility" in international law. A philosophical review is conducted followed by the examination of existing international legal instruments including the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the WHO International Health Regulations, the Codex Alimentarius, and the Cartagena Protocol on Biosafety. The PA has been found to have a pervasive influence on risk regulation in international law, yet the application is fraught with fragmentations in different legal regimes. In order to reach a harmonious interpretation and application of the PA in the WTO, the legal status of PAs of different WTO instruments have been analysed. Further, a comparative study on PAs in terms of legal status in the exemptions of the WTO and TRIPS obligations has been proposed. The political and moral basis for compulsory licencing in a public health emergency has been bolstered through the interpretation and the creation of legal status of the PA in WTO/TRIPS law.

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Part 1: Introductions: Setting the scene

I. Introduction

I.1 Overview

The focus of this work is to suggest a *precautionary approach* (PA) taken in the intellectual property (IP) regime in order to enhance access to medicines in a public health emergency. This work also seeks to finetune the complementary roles of the World Health Organization (WHO) and the World Trade Organization (WTO), and to promote the harmonisation of the PA in the IP and health worlds.

I.2 The need for this thesis

The next section will explore the need for these arguments and the reasons for the approach taken.

I.2.1 A pragmatic approach – The precautionary approach in the health and trade worlds

This work proposes the PA as ethical grounds to legitimate differential treatment of pharmaceutical technologies in compulsory licensing in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[1] The PA has been widely adopted in international environmental protection[2] as well as in the public health sector.[3] Yet its application has been sporadic and fragmented in the WTO regime due to

[1] Compulsory licensing is a mechanism of limitation on patent right after it is issued, Article 31 Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization Annex 1C (TRIPS). See **section 1.3.2**

[2] See **section 2.2**.

[3] See **chapter 3**.

the ambiguity in definition[4] and legal status.[5]

There is also existing literature on the PA incorporated into domestic patent law prior to the issue of a patent (pre-grant), explicitly through exclusions to patentable subject matter based on five criteria: morality, public policy (or public order), legality, public health and environmental harm.[6] Yet little has been addressed on the PA adopted on issues after a patent is issued (post-grant), specifically related to compulsory licensing. In November 2005, Taiwan issued the first precautionary grant of compulsory licensing for a preparedness plan of a pending birdflu pandemic, following the WHO's recommendation of stockpiling sufficient antivirals for at least 10% of its population.[7] Abbott and Reichman noted that this grant appeared to trigger announcements by other countries of plans to issue compulsory licences.[8] The legitimacy of a precautionary compulsory licence then attracted international debates.[9] Legally speaking, if compulsory licensing could not be given a PA reading, governments will not be able to legitimately consider this measure until the actual outbreak of a pandemic, after a certain number of deaths have been reported. As stockpiling of medicines for pandemic preparedness usually takes around six months to one year,[10] by then it could be too late

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4 See **section 2.1.1**.

5 See **sections 2.1.3.1 and 5.1.1.2**.

6 For example, see: Kolitch, S (2006) "The Environmental and Public Health Impacts of U.S. Patent Law: Making the Case for Incorporating a Precautionary Principle" 36(1) *Environmental Law* 221-256 (Kolitch PP); Murphy, K.A. (2009) "The Precautionary Principle in Patent Law: A View from Canada" 12(6) *The Journal of World Intellectual Property* 649-689. See **section 4.3.2.1**

7 Hille, K, "Taiwan Employs Compulsory Licensing for Tamiflu" FT.com, 25 November 2005, available at: http://www.ft.com/cms/s/0/cebeb882-5dcb-11da-be9c-0000779e2340.html

8 Abbott, F.M. and Reichman, J.H. (2007) "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions" 10 *Journal of International Economic Law* 921 (Abbott/Reichman) fn122

9 For example, the patent holder of Tamiflu, Roche expressed that the compulsory licensing was unnecessary. See: "Tamiflu Compulsory License not Necessary, Roche Tells Three Asian Nations" Thepharmaletter, 5 December 2005. Available at: http://www.thepharmaletter.com/file/37733/tamiflu-compulsory-license-not-necessary-roche-tells-three-asian-nations.html

10 In order to building a global monitor network, the WHO has also recommended that countries should stockpile appropriate antiviral medication sufficient for 10 percent of the population or more to contain the virus spread from phase 3 of Pandemic alert period. The stockpiling of antivirus medication often

to contain the disease. Is the loss of human life the only trigger for compulsory licensing? Or could compulsory licensing serve as a trigger to prevent death? It was under these circumstances that the legitimacy of a precautionary compulsory licence started to attract my interest in deliberating the optimal application of PA as a tool to temper IP and health in post-grant situations.[11] Further, the PA has been an important underpinning in risk regulation, it is anticipated that the PA would also have a role to play in the limitations of IP.

Hence, I will propose to redefine the compulsory licensing scheme through the lens of precaution[12] and also create the legal status of the PA in compulsory licensing.[13] It is argued in this work that the PA can serve as a tool to reconcile the discrepancies in the WHO and the WTO agendas,[14] and to harmonise the domestic policy making of legal preparedness in a public health emergency.

I.2.2 Issue based approach: Conflicts between international health and international trade

The rise of non-state actors and their increasing impact on the global public health system demonstrate the need for global governance. In some situations, non-state

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requires 6 months to one year, therefore governments need to prepare for sufficient dosage of drugs before the virus outbreak. See: "WHO Global Influenza Preparedness Plan: the Role of WHO and Recommendations for National Measures before and during Pandemics" (WHO Influenza Preparedness), WHO/CDS/CSR/GIP/2005.5, p23. Available at: http://www.who.int/crs/disease/avian_influenza/en/index.html.

11 This is discussed in **section 4.3.2.3.2**. See also: Hung, P (2010) "The Precautionary Approach under the Right to Health Dilemma" 24(1) *International Review of Law, Computers & Technology* 71-80; Hung, P (2008) "The Mechanism of National Emergency in the TRIPS Agreement – the Compulsory Licensing on Tamiflu in Taiwan" (in Chinese) 4(1) *Taiwan International Law Quarterly* 159-207; Hung, P (2006) "The Validity and Necessity of Compulsory Licensing of Tamiflu – Taiwan Experience" in the *16th World Conference of Medical Law Proceeding* 877-883; Hung, P (2006) "Examining the 'National Emergency' Mechanism in the TRIPS Agreement under the WTO Framework – The Compulsory Licensing of Tamiflu" (in Chinese) masters dissertation, National Tsinghua University, Taiwan

12 See **sections 5.1.2 and 5.2**.

13 See **section 5.2.1.1**.

14 See **section 5.3**.

actors are directly involved in formulating rules that affect public health nationally and globally.[15] In an era of globalisation, states can survive in a public health emergency only through global collaboration.[16] We will focus our discussion on the linkage of the WHO and the WTO which demonstrates the typical tension between international trade and international health in a public health emergency of international concern.

Clash of the WTO and the WHO

The protection of human health and safety is regarded as the first priority in the WHO regime.[17] The goal of the WHO is to ensure the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (the right to health).[18] Yet the principles of the WTO are free trade and non-discrimination[19] which stress the value of free movement of goods and IP protection. On the one hand, the promotion of free trade in order to promote public health is currently stressed by India and Brazil in their

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15 Fidler, D.P. (2002) "A Globalized Theory of Public Health Law"30 *Journal of Law, Medicine and Ethics* 150 (Fidler Globalized Theory).

16 Sell defines "global governance" in IP and public health as "devising, implementing, and enforcing policies in a way that accommodates a broad range of stakeholders and policies". She also identifies the WHO, the WTO, the International Monetary Fund (IMF), and World Bank, and the World Intellectual Property Organization (WIPO) as institutions that involve the "intersection between public health, trade, and intellectual property, governance in public health". Sell, S.K. (2004) "The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions" 77 *Temple Law Review* 363 (Sell Governance). See also: Helfer, L.R. (2004) "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" 29 *Yale Journal of International Law* 1 (Helfer TRIPS); Fidler, D.P. (2002) "A Globalized Theory of Public Health Law" 30 *Journal of Law, Medicine & Ethics* 150-161. (Fidler Globalized Theory) There are still other non-state actors such as the World Medical Association and Medecins Sans Frontieres (MSF) have helped to shape public health policies in global governance. Medecins Sans Frontieres, available at: http://www.msf.org; World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, rev. ed. Edinburgh, 52 World Medical Association General Assembly, October 2000, available at: http://www.wma.net/e/policy/17-c_e.html.

17 Tigerstrom, B. (2005) "The Revised International Health Regulations and Restrict of National Health Measures" 13 *Health Law Journal* 35-76, at 46.

18 The Member States of WHO adopted important principles in regard to public health that are enshrined in the preamble to its Constitution. Hence, the Constitution establishes as a fundamental international principle that enjoyment of the highest attainable standard of health is not only a state or condition of the individual, but "… one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition…"

19 See **sections 1.2.1.1 and 1.2.1.1.1** for the discussion of the principle of non-discrimination in WTO law.

recent complaints against the EU and the Netherlands where the complainants argue that the seizure of generic medicines in transit creates unnecessary barriers to free trade.[20] On the other hand, the rule-based character of the WTO, in certain circumstances, would nevertheless, create institutional conflict with the role of the WHO as the world leader for promoting health.[21] For example, Lin lamented the marginalised role of the WHO in trade responses to the recent H1N1 Influenza outbreak in 2009.[22] It is observed that the role of the WHO is overshadowed by the WTO's more effective dispute settlement mechanism.[23] Member States of these two institutions would prefer the WTO procedure in order to resolve health-related disputes. However, Bloche and Jungman expressed the concern that the dependence on the WTO dispute settlement procedure in resolving health disputes would significantly limit national regulatory authority in health policy-making.[24] Moreover, the WTO DSS is not obliged to use guidance or advice from the WHO as the basis in determining health-related disputes. The WHO's influence on resolving health disputes in international fora therefore remains relatively weak.

The tension between the IP and access to medicines is typically demonstrated in the compulsory licensing mechanism in the TRIPS Agreement.[25] Specifically, the WHO suggest that states should stockpile sufficient medications for an upcoming pandemic

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[20] *European Union and a Member State – Seizure of Generic Drugs in Transit*, Request for Consultations by India and Brazil, WT/DS408/1; WT/DS409/1, 19 May 2010.

[21] See **section 1.3.3**.

[22] Lin, T-Y, (2010) "The Forgotten Role of WHO/IHR in Trade Responses to 2009 A/H1N1 Influenza Outbreak" 44(3) *Journal of World Trade* 515-543

[23] See **section 1.2.1.1.2** . The WTO's prevailing influence over other regimes is also observed by Kelly, C.R. (2006) "Power, Linkage and Accommodation: the WTO as an International Actor and its Influence on Other Actors and Regimes" 24 *Berkeley Journal of International Law* 79.

[24] Bloche, G and Jungman, E (2003) Symposium: Emerging Issues in Population Health: National and Global Perspective: A Tribute to Gene W. Matthews, Part II: International Trade and Health, 31 *Journal of Law, Medicine and Ethics* 529

[25] Compulsory licensing, see **section 1.3.2**.

from pandemic phase 3 onwards,[26] yet is it legitimate to resort to compulsory licensing to secure medication stockpiling for pandemic preparedness prior to the actual outbreak of the pandemic? Further, the trigger for compulsory licensing depends on the identification of a "public health emergency", yet this phrase appears to be self-defining: even after the interpretation of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in 2001,[27] developing countries are still deterred from using thes flexibilities in TRIPS.[28]

It is fair to say that the Doha Declaration has reaffirmed the rights[29] of states' to compulsory licensing;[30] however, empirical studies show that developing countries still hesitate to use this instrument to relieve their disease burden for fear that developed countries would resort to trade retaliation.[31] Regrettably, this instrument has been mainly used as a threatening tool to negotiate drug price reduction instead of being a fair mechanism to redress the imbalance of health and IP.[32] It would be even more controversial to grant a compulsory licence of a patented drug in the preparation for a pending pandemic which has not yet taken place. Is it legitimate for states to take the official information and suggestions from the WHO as "scientific evidence or other relevant information" to grant a compulsory licence on the grounds of a public health emergency in the TRIPS Agreement?

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[26] The WHO has advised states to "promote vaccination" and "review vaccine use strategies" from phase 3 of "Pandemic alert period" onwards. However, phase 3 of the Pandemic alert period is only the preparatory period of a public health emergency; it would be difficult to legitimate the grant of a compulsory licence on the grounds of "national emergency or other circumstances of extreme urgency" during such time. See: WHO Preparedness Plan, **n10** .

[27] *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), adopted by the fourth Ministerial Conference of the World Trade Organization in Doha, Qatar, on 14 November 2001. WT/MIN(01)/DEC/2 of 20 November 2001. See **section 4.3.2.2.1**.

[28] See **section 1.3.3**, **n1**.

[29] Para 4 Doha Declaration.

[30] See **section 4.3.2.2.1**.

[31] See **sections 1.3.2.2.1, 1.3.2.3.2, and 1.3.2.3.3**.

[32] See **sections 1.3.2.2.1, 1.3.2.3.2, and 1.3.2.3.3**.

The compulsory licensing mechanism is supposed to be a tool for redressing the imbalance of IP and health; however, due to international political reasons,[33] it has been serving rather as a threatening tool for drug price reduction than as a systematic and objective mechanism for delineating the boundary of rightholders' rights and obligations and therefore tempering the tension between public and private interests..[34] As a WHO report points out: "In many cases, the most significant barrier to the use of compulsory licensing is the absence of simple, straightforward legislative and administrative procedures, which establishes clear decision-making process and responsibilities".[35] A workable and practical interpretation to trigger the process of compulsory licensing is thus desired to facilitate states' institution of a precautionary measure in a public health emergency.

Accordingly, through the lens of precaution, it is worth examining whether the rationale of risk management[36] for a public health emergency can be harmonised in the context of WHO and WTO law. This work therefore aims to bring harmonisation to the legal infrastructures of risk management in the two regimes and seeks to promote access to essential medicines. Furthermore, a PA analysis would bolster the political and moral basis for compulsory licensing,[37] which will aim to bring congruence of risk management in WTO law.

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[33] See **section 1.3.3.1** for the discussion of the power imbalance of compulsory licensing in an international setting.

[34] See **section 1.3.3**.

[35] *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH Report) Study 4C, August 2005.

[36] "Risk management" is defined in the *Codex Alimentarius* Procedural Manual as: "The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriated prevention and control options". *Codex Alimentarius* Commission 18th Procedural Manual (Codex Manual), "Definitions for the Purposes of the Codex Alimentarius", at 42, available at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_18e.pdf .
See **section 3.1.3**.

[37] See **section 5.3**.

I.3 Parameters, structure and contribution

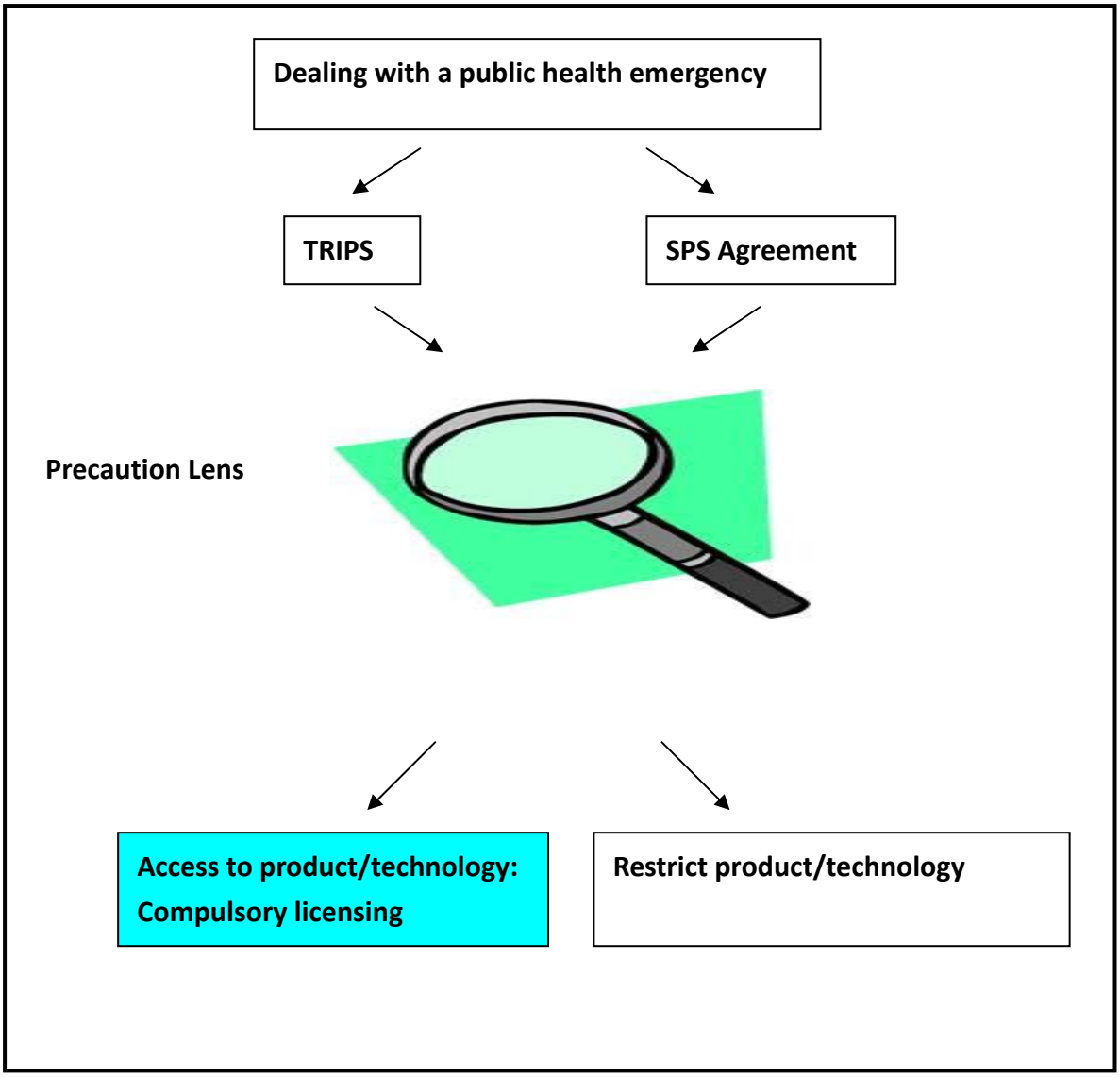
Based on the existing human-rights arguments to enhance access to medicines,[38] this work examines the PA in the context of international trade and international health, particularly in the WTO TRIPS and Sanitary and Phytosanitary (SPS) regimes,[39] and suggests that a safety factor based on the PA can be accommodated into the TRIPS Agreement, particular in the compulsory licensing provision, to promote access to health technologies and redress the access to medicines dilemma in a public health emergency.[40] (See Figure I Research parameter: Precaution lens) On the one hand, this work aim to promote access to products or technologies which are associatd with the reduction or elimination of risks to human health; on the other hand, this work could also arguably serves as grounds to restrict products or technologies which cause risks to human health and safety. Due to the limitation of this work, I will focus on the first scenario and set the scene on the promotion of access to medicines in a public health emergency.

[38] The human-rights dimension is not specifically included in this work; however, it serves as a foundation for this work while it argues for a broader use of the compulsory licensing provision to enhance access to medicines. See **section 1.1.2.2.1** for relevant discussions on a human-rights approach in access to medicines.

[39] Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Marrakesh Agreement Establishing the World Trade Organization, Annex 1A: Multilateral Agreements on Trade in Goods.

[40] See **section 5.3**.

Figure I. Research parameter: Precaution lens



It is argued that the pharmaceutical technology associated with the reduction and elimination of significant risks to human life or health should receive a differential treatment by adopting the PA in the compulsory licensing[41] clause in TRIPS.[42] A differential treatment in order to promote access to medicines could be justified by the harmonisation of the rationale of PAs in WTO law.

[41] Article 31 TRIPS. See **sections 1.3.1 and 1.3.2**.
[42] TRIPS, see **n1**.

Accordingly, in order to legitimise the differential treatment of health technologies in IP,[43] chapter 1 will discuss the current legal and political background for granting a compulsory licence. Chapter 2 will draw into discussion the current application of the PA and the structure of risk analysis from international environmental law. A template for the PA in the international health framework will consequently be developed by means of the philosophical and legal review of the literature on the approach and the examination of relevant international instruments. Chapter 3 will conduct a comprehensive study on the PA applied in the existing international legal instruments in the context of health and environment, specifically the Codex Alimentarius,[44] the International Health Regulations (IHRs),[45] and the Cartagena Protocol on Biosafety (CPB).[46] It is concluded that the implementation of the PA in international law is pervasive, but somehow fragmented and is desperately in need of a clear redefinition in the international public health law regime. In addition to the research of the PA in the health sector, chapter 4 will scrutinise its current application in the international trade world, namely the WTO framework. By means of comparative studies on the PA applied in the exception provisions in the General Agreement on Tariffs and Trade (GATT)[47] and the excluding provisions[48] in the SPS Agreement,[49] this work finds that the current implementation of the PA in the IP regime has been seriously restricted by international political setting. We will also examine the legal status of the compulsory licensing provision in the WTO framework, and reaffirm states' precautionary

[43] See **section 5.2.1.2**.
[44] Codex Alimentarius, see **section 3.1.3**.
[45] See **section 3.1.2**. International Health Regulations (IHRs), Revision of the International Health Regulations, WHA Res. 58.3, World Health Assembly, 58th Assembly, 23 May 2005, available at http://www.who.int/csr/IHR/WHA58_3-en.pdf
[46] Cartagena Protocol on Biosafety (CPB), see **section 3.2**.
[47] General Agreement on Tariffs and Trade (GATT). This work will discuss the precautionary approach used in the health and security exception provisions in Article XX and Article XXI GATT. See **section 4.1**.
[48] The distinction between "exception provisions" and "excluding provisions" in the WTO regime will be discussed in **section 1.2.1.2**.
[49] SPS Agreement, see **section 4.2 n39**.

entitlements[50] to grant a compulsory licence in a public health emergency.[51] Based on the above analysis, chapter 5 will suggest that the PA developed in this thesis be accommodated into the IP regime to promote access to essential medicines. It is further suggested that the flexibilities in the compulsory licensing clause can be embodied by means of adopting a margin of safety to provide protection in the situation of scientific uncertainty. This leads to a suggestion for the introduction of an expedient track to trigger compulsory licensing on pharmaceutical technologies that are strongly associated with the reduction/elimination of risks to human life or health. We will then employ the precautionary template developed in chapter 2 to redefine the compulsory licensing mechanism, and also to assess whether this differentiation of pharmaceutical technologies in compulsory licensing will be incompliance with WTO Members' (Members') obligations in WTO law.[52]

In summary, the contribution of this work would be able to develop a procedure that would boost states' confidence in adopting the PA in compulsory licensing, and to safeguard access to medicines in a public health emergency.[53]

We will firstly introduce the background of international health and international trade for compulsory licensing in chapter 1.

[50] See **sections 2.3, 3.1.2.3, 4.3.2.2, and 5.2.1.1**.
[51] See **section 5.2.1.1**.
[52] See **section 5.2.1.2**.
[53] See **section 6.2.1**.

1 Worlds Collide under a Public Health Emergency

A new generation of risks arising from viruses, persistent chemicals, pollution, nuclear disarmament, ocean fisheries, biotechnology, and climate change has posed health threats to human life and health in the era of globalisation.[54] Particularly, from the late twentieth century onwards, several global virus transmissions have challenged the values and rights of states' in the international legal framework. The emergence of these newly-discovered infectious diseases exposes the lack of a mature legal framework in international public health to provide prompt, concrete and specific guidance during a large-scale emergency.[55]

For example, the rise of the Acquired Immunodeficiency Syndrome (HIV/AIDS) brought the issue of access to essential drugs to the international forum in the late twentieth century.[56] Moreover, the SARS outbreak in 2002 severely damaged society in Canada and Asian countries due to the features of the virus that was too hasty to be prevented within current medical and social infrastructure.[57] More recently, states'

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[54] De Sadeleer, N. (2008) *Environmental Principles: From Political Slogans to Legal Rules*, Oxford University, New York, US, (De Sandeleer) pp150-155.

[55] See **section 1.1.2.1**.

[56] AIDS was first diagnosed just more than two decades ago in the affluent western world, but within a few years it turned to have the severest impacts in African and other resource-poor places such as Thailand. Notably, the HIV therapy initiated international debate on "access to medicines". The cocktail therapy, also known as highly active antiretroviral therapy (HAART) has been developed to manage the condition of AIDS patients, but the therapy requires huge costs which are far beyond those that resource-poor countries can afford due to drug patent protection policy. A global outcry for equitable access to essential medicines for the treatment of HIV/AIDS has resulted in the controversies on the legitimacy of pharmaceutical patent protection in the TRIPS Agreement. (See the Brazil case and the Thailand case in **sections 1.3.2.3.2 and 1.3.2.3.3**)

[57] For more details information about SARS, see Kimball, A.M. (2006) *Risky Trade: Infectious Disease in the Era of Global Trade*, Ashgate Publishing, England, pp44-49. The spread of SARS virus was identified as "on board transmission" on the airplane, and the crisis developed quickly in a matter of weeks to reach two continents including Asia and North America. Other significant features of SARS are its novelty and lack of effective treatment. It was not until SARS broke out did the researchers set out to identify it. The SARS virus evolved and adapted globally before humans' steps to recognise it. Even though the pathogen, a coronavirus was identified after the collaboration of scientists in one month, there was still no arsenal of medical treatments for this new coronavirus.

preparation of sufficient medicines and vaccines for containing the highly virulent strain of avian influenza H5N1 (popularly known as "Bird Flu") and H1N1 (known as "Swine Flu") also triggers contentions of the conflicts between the "right to health" and the protection of intellectual property (IP) rights.[58]

In view of these conflicts, this work draws the structure of risk analysis and the rationale of the precautionary approach (PA) as a safety valve into contemporary IP regime to argue for the adoption of a safety factor as a margin of appreciation in contemporary patent protection.[59] This chapter will start the discussion of the tension between international health and international trade in a public health emergency, and examine the role of IP in the current legal framework. We will then use the mechanism of compulsory licensing as an instrument to explore the possible applications of the PA and the relevant structure of risk analysis in the IP regime. The development of the PA will be addressed in Chapter 2, and the structure of risk analysis will be elaborated in Chapter 3 when we discuss the legal mechanism in the Codex Alimentarius.[60]

Attention will now be turned to the discussion of a public health emergency from the lens of international public health.

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[58] From the first H5N1 outbreak in 2003 till now, the WHO is coordinating the global response to human cases of avian influenza and monitoring the corresponding threat of an influenza pandemic. The World Bank has suggested that millions of people would die and the global economy would shrink by some $800 billion per year should avian influenza become pandemic in humans. The next bird flu outbreak has increasingly become the world's primary focus in infectious disease surveillance systems in many international institutions such as the WHO and the World Bank. World Bank, "Evaluating the Economic Consequences of Avian Influenza", available at: http://siteresources.worldbank.org/INTTOPAVIFLU/Resources/EvaluatingAIeconomics.pdf. WHO, http://www.who.int/csr/disease/avian_influenza/en/index.html; The World Bank: http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTTOPAVIFLU/0,,menuPK:1793605~pagePK:64168427~piPK:64168435~theSitePK:1793593,00.html

[59] See **section 3.1.3.1** for the structure of risk analysis and **chapter 2**.

[60] The Codex Alimentarius Commission was created by the Food and Agriculture Organization of the United Nations (FAO) and WHO to develop food standards, guidelines and related texts under the joint FAO/WHO Food Standards Programme. See FAO website: http://www.fao.org; Codex Alimentarius Commission website: http://www.codexalimentarius.net/web/index_en.jsp **n36**

1.1 International health

From a retrospective view, the main focus of public health in the past was the prevention of the spread of disease by improving national environmental conditions and personal hygiene. All these public health measures and regulations focused on the prevention of infectious diseases domestically.[61] However, traditional approaches for long-term prevention in public health facilities are no longer sufficient for coping with the imminent threat that emerging and re-emerging infectious diseases pose in a highly globalised era. Thus the rethinking of our legal system is required in order to cope with the fundamental change of infectious diseases under globalisation.[62]

As Fidler states,

> The processes that characterize globalization -- trade, investment, capital movements, travel, and technological advances -- render borders more permeable and increase the volume, nature, scope, and complexity of problems governments face within their territorial boundaries. Globalization represents, therefore, a challenge to the traditional notions of politics, economics, law, and culture as defined by geographical borders.[63]

Accordingly, public health law must be re-examined from a global perspective to meet increasing needs. Particularly, globalisation has rendered substantial change in the

[61] Baggott, R. (2000) *Public Health: Policy and Politics*, MACMILLAN Press, UK, pp15-36.
[62] The concepts of "globalisation" and "economic globalisation" in particular, have been commonly used to describe the feature of the post-Cold War era. Joseph Stiglitz, former Chief Economist of the World Bank and winner of the Nobel Prize for Economics in 2001, described the concept of globalisation as: The closer integration of the countries and peoples of the world which has been brought about by the enormous reduction of costs of transportation and communication, and the breaking down of artificial barriers to the flow of goods, services, capital, knowledge, and (to a lesser extent) people across borders. Stiglitz, J. (2002) *Globalisation and Its Discontents*, Penguin, p9.
[63] Fidler, D.P. (2002) "A Globalized Theory of Public Health Law" 30 *Journal of Law, Medicine and Ethics* 150. **n15**

prevalence of infectious disease: viruses evolve swiftly to adapt to the new world of global traffic and trade, and diseases often spread across borders before being identified. The surveillance of infectious diseases requires a sound legal mechanism to meet the needs for prompt preparedness in a public health emergency.

1.1.1 Public health emergency of international concern

The response to a public health emergency was traditionally the subject of concern for a national territory,[64] yet public health emergency has shifted from the domestic to an international plane in the era of globalisation. Traditional response to a public health emergency is no longer fit for the purpose of combating international spread of emerging or reemerging diseases under globalisation. Hence the WHO revised the International Health Regulations (IHRs) in 2005 to meet the swift evolution of virus spread without borders.[65] The term "public health emergency of international concern" (PHEIC) is highlighted in the new IHRs to demonstrate that public health emergencies have broken national boundaries under globalisation.[66]

We will first address how globalisation accelerates the spread of infectious disease, and then discuss the nexus between globalisation and a public health emergency caused by infectious disease.

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[64] For example, the UK Civil Contingencies Act defines "emergency" as "(a) an event or situation which threatens serious damage to human welfare in the United Kingdom or in a Part or region, (b) an event or situation which threatens serious damage to the environment of the United Kingdom or of a part or region, or (c) war, or terrorism, which threatens serious damage to the security of the United Kingdom". Article 1 &19 UK Civil Contingencies Act 2004 (Chapter 36). "Human welfare" involves loss of human life; human illness or injury; homelessness; damage to property; disruption of a supply of money, food, water, energy, fuel, communication, transport, and services relating to health.

[65] International Health Regulations (IHRs), see **n45**.

[66] Article 1 IHRs **n4545**. See **section 3.1.2.1**.

1.1.1.1 The nexus between globalisation and infectious disease

Globalisation accelerates the movement of people and goods, and thus creates new pathways of transmission. According to Weinberg, globalisation of trade and travel may be the main reason of infection transmission, he notes that:

> The increased mobility of populations both in scale and geographical reach is believed to be increasing the likelihood that an infectious disease outbreak may involve more than one country. … The conditions created by this large-scale movement of people, other life forms, and traded goods around the globe, are also conducive to the movement of organisms and vectors (often insects) of disease.[67]

The movement of vectors of disease is attributed to the large scale of movement of people and traded goods.[68] The free movement of people and commercial goods is a global trend of "trade liberalism". When the trade barriers are diminished, the risk to human health is inevitably increased. Health risks caused by globalisation penetrate deeply in our daily lives. Economic and technological globalisation advances free trade in a world market, yet free movement of people and commodity also increases the prevalence of virus transmission.[69] However, in the trade regime, given the importance

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[67] Weinberg, J. (2005) "The Impact of Globalisation on Emerging Infectious Disease" in Lee, K. and Collin, J. (eds) *Global Change and Health*, London School of Hygiene & Tropical Medicines, Open University Press, pp56-59 (Weinberg Globalisation).

[68] From the late twentieth century, several significant infectious diseases outbreaks have occurred globally. Various types of infectious diseases have emerged and spread without borders since the outbreak of Spanish Flu in early twentieth century. The transmission of Spanish Flu was facilitated by the ending of World War I when soldiers on the European Continent discharged to their home towns. The Spanish Flu resulted in three waves of disease, and is estimated to have infected one billion people in the world which brought a death toll of 228000 in the UK. Agence France-Presse, "Mystery of the Spanish Flu Solved" *COSMOS*, 18 January 2007, Available at: http://www.cosmosmagazine.com/node/978; "1918 Killer Flu Secrets Revealed", *BBC News*, 5 February 2004.

[69] Fidler, D.P. (2000) *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence*,

of free trade, it appears that the WTO is willing to take acceptable risks to human health in order to pursue maximum economic benefit. We will have further discussion on this in Chapter 4 when we address the legal status and the application of the health exception provision in the GATT.[70]

Globalisation is like a double-ended sword to public health. On the one hand, globalisation brings about the promise of quality public health infrastructure; on the other hand, economic globalisation brings about the deterioration of environment, such as pollution and global warming, which are all relevant to the flourishing of infectious diseases and severely increase the risks to public health. When states compete to gain a comparative advantageous share in the global market, costs of long term impact on the environment would inevitably be compromised under the pursuit of maximum economic interests. This is particularly common in developing countries which are striving to economically keep up with developed countries.[71] For example, Kimball describes the deterioration of the environment in Asia as rendering it the origin of the majority of newly reported human infections worldwide.[72] It is suggested that the recent economic developement via globalisation comes at the price of an increasing risk of pandemic outbreaks. Hence, risk management of a public health emergency has become a priority topic in international law. It must, therefore, be a concern for both

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Transnational Publishers Inc. p220.

[70] See **sections 4.1.1 and 4.1.1.3**.

[71] Kwok-yuan Yuan observes that the economic growth of many developing countries including China and Mexico, known as the world factories, face the problem of inadequate improvement in biosecurity and regulatory measures in public health protection. Therefore people experience bird flu, SARS, and many food borne infections, antibiotic resistant bacteria and swine flu in the shadow of globalisation. See: Yuan, K.Y. (2009) "The Public Health and Clinical Perspective of Emerging Infectious Diseases: from Avian to Swine Flu" 41st Asia-Pacific Academic Consortium for Public Health (APACPH) Conference, 3 December 2009, Taipei, Taiwan.

[72] In addition to the SARS virus, the H5N1 outbreak in 1997 in Hong Kong also originated from the Guangdong province. The southeast part of China has been one of the most developed areas in China's economy, but it has also been identified as the origin of most emerging diseases in recent years. It shows that the nexus between economic development and environmental degradation has positive relevance, and that environment degradation directly results in the flourishing and evolution of viruses. See: Kimball, A.M. (2006) *Risky Trade: Infectious Disease in the Era of Global Trade*, Ashgate Publishing, England (Kimball).

international public health regimes and international trade regimes.

We will now turn our discussion to the role of the WHO as the primary non-state actor in promoting global health.

1.1.2 The WHO

The WHO stands as the primary international organisation for the global governance in the threat of infectious disease. The WHO Constitution and the United Nations Charter vest the WHO to adopt treaties and regulations to which Member States subscribe.[73] The International Health Regulations (IHRs) were revised in 2005 to protect public health by providing a structure for global disease reporting and by enumerating the rights and duties of individual states in controlling the global spread of disease.[74] State Parties follow the IHRs to adjust their domestic legislation to be consistent with the new Regulations.[75]

[73] Forrest, M. (2000) "Using the Power of the World Health Organization: The International Health Regulations and the Future of International Health Law" 33 *Columbia Journal of Law and Social Problems*153.

[74] See **section 3.1.2**. Revision of the International Health Regulations, WHA Res. 58.3, World Health Assembly, 58th Assembly, 23 May 2005, available at http://www.who.int/csr/IHR/WHA58_3-en.pdf

[75] For instance, the Scottish Executive working with the UK government aims to establish the public health legislative changes required to comply with the new Regulations in due process. The Scottish Public Health Review Group sets out proposals to strengthen the public health response in Scotland and strides to make legislation consistent with current practice. Public Health Legislation in Scotland: A Consultation, Scottish Executive, October 2006. http://www.scotland.gov.uk/Resource/Doc/152453/0040999.pdf

1.1.2.1 International Health Regulations

The IHRs 1969 have not been significantly changed since they were first issued in 1951.[76] The scope of the old IHRs only applied to cholera, plague, and yellow fever, and is unable to cope with modern health threats such as HIV/AIDS, SARS, and bioterrorism, which is severely limiting its effectiveness.[77] After the outbreaks of cholera in Peru, plague in India, and Ebola hemorrhagic fever in Zaire, the 1995 World Health Assembly (WHA) adopted a resolution on *Global health security: epidemic alert and response* and to revise the IHRs.[78] Its aim is to equip the WHO with an effective mechanism to respond to current public health threats including new diseases and naturally occurring, accidental release or deliberate use of chemical and biological agents or radionuclear materials that affect human health.[79]

In addition to the revision of the IHRs in strengthening the global virus surveillance network, the WHO also sets out relevant public health programmes to address the "access to medicines" issue under a public health emergency.

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[76] The origins of the IHRs date back to the first International Sanitary Conference, held in Paris in 1851 to address the European cholera epidemics. In the latter half of the nineteenth century and twentieth century, some sanitary conferences and conventions were negotiated, and the international community established regional and international institutions to enforce these conventions. After two World Wars, the WHO was established by the UN to protect global health. Under the WHO Constitution, WHO State Parties adopted the International Sanitary Regulations (ISRs) in 1951, which was later renamed the International Health Regulations (IHRs) in 1969. Gostin, L.O. (2005) "World Health Law: Toward A New Conception of Global Health Governance for the 21th Century" 5 *Yale Journal of Health Policy, Law & Ethics*413. The International Sanitary Convention dealing with cholera was adopted in Venice in 1892, followed by another Convention dealing with plague in 1897. In 1903, the International Sanitary Convention replaced the conventions of 1892 and 1897. American states set up the International Sanitary Bureau (ISB) in 1902, which became the Pan American Sanitary Bureau (PASB). European States developed their own multilateral institution in 1907, L'Office International D'Hygiene Publique (OIHP).

[77] Gostin, L.O. (2004) "International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations" 291(21) *JAMA* 2623.

[78] Fifty-fourth World Health Assembly, World Health Organization, 21 May 2001. Global health security: epidemic alert and response. Available at : http://www.who.int/inf-pr-2001/en/pr2001WHA-6.html.

[79] See **section 3.1.2**.

1.1.2.2Access to medicines

As mentioned above, health hazards can move rapidly without borders in the age of global travel and commerce. A WHO report has pointed out the importance of international cooperation in response to a pandemic threat,[80] yet the asymmetries of resources and capacity of surveillance in developed and developing countries undermine the global surveillance collaboration. Developing nations often shoulder much of the world's surveillance burden, but do not have adequate resources and capacity to prevent its spread.[81] Meanwhile, developed countries keep on furthering their economic interests in global markets through the creation and protection of IP for pharmaceutical companies, making lifesaving vaccines and drugs more inaccessible in developing countries.[82]

In view of this, a human-rights approach to address this "access to medicines" issue has been adopted in the WHO framework. Access to essential medicines is regarded as part of the progressive fulfillment of the fundamental right to health in the WHO's medicine policy.[83] The WHO has created the "Model List of Essential Medicines" to promote access of essential drugs and ensure the non-profit use of life-saving drugs for common diseases since 1977.[84]

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[80] "Ethical Considerations in Developing a Public Health Response to Pandemic Influenza", WHO, WHO/CDS/EPR/GIP/2007.2, p17. (WHO Influenza Considerations)

[81] "Too Little, Too Late" 13(3) Nature Medicine, March 2007. http://www.nature.com/nm/journal/v13/n3/full/nm0307-225.html.

[82] Cornia, G.A. "Globalisation and Health: Results and Options" 79 Bull. 834-841 World Health Organization, 2001.

[83] "Access to Essential Medicines: a Global Necessity" 32 *Essential Drugs Monitor*, 2003, WHO.

[84] WHO Medicines Strategy 2008-2013, Draft 8, 13 June 2008, http://www.who.int/medicines/publications/Medicines_Strategy_draft08-13.pdf, p3. For example, ARV drugs have been included in the WHO's model Essential Drugs List (EDL) since April 2002. The model Essential Drugs List provides a template for countries seeking to establish their own national lists of priority medicines. In the past 30 years of Medicines Strategy, over 150 countries have their lists of essential medicines. In order to improve health by ensuring the quality, efficacy, safety and rational use of medicines, WHO has also created Essential Medicines and Pharmaceutical Policies Department (the EMP Department); a programme of "Essential Medicines and Pharmaceutical Policies (EMP)" has been

1.1.2.2.1 A human-rights perspective

International legal instruments have recognised the appeal of access to medicines as a fundamental human right. "The right of everyone to the enjoyment of the highest attainable standard of physical and mental health" is recognised by State Parties of the International Covenant on Economic, Social, and Cultural Rights (ICESCR)[85]. It also obliges State Parties to achieve the full realisation of this right, which includes appropriate treatment of prevalent diseases, and the provision of essential drugs.[86]

In 2000, the UN Committee on Economic, Social and Cultural Rights (CESCR), the legal body charged in the ICESCR drafted the official interpretations of and monitoring of States Parties compliance with the ICESCR. General Comment No. 14 is surrounding the issue of the right to health, and it acknowledges a collective right to public health through its modernisation of state obligations under Article 12 of the ICESCR.[87] It states that the core obligations of State Parties should include "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs" and "to adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process…"[88]

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established to enhance its policy objectives.

85 Article 12.1 The International Covenant on Economic, Social, and Cultural Rights (ICRSCR)

86 Article 12.2. "Access to Essential Medicines as a Human Right" 33 *Essential Drugs Monitor*, 2003, WHO.

87 Meier, B.M. "Employing Health Rights for Global Justice: the Promise of Public Health in Response to the Insalubrious Ramifications of Globalization", 39 *Cornell International Law Journal* 711.

88 UN document E/C. 12/2000/4, 11 August 2000, para 43.

As the WHO views "the enjoyment of the highest attainable standard of health …[as] one of the fundamental rights of every human being";[89] it also establishes the "Health and Human Rights Team" to integrate a human rights-based approach to health and to advance the right to health.[90] Further, the department of "Ethics, Trade, Human Rights and Health Law" (ETH) has also been created from 2003 to cooperate with relevant international organsiations. Its focus is to redress the issue that the increasing global economic integration and the advancements of health technologies pose new challenges and opportunities for promoting the highest attainable level of health for all.[91]

In addition, the programme of "Globalization, Trade and Health" is also developed to address the issues relating to trade and health under globalisation. It aims at "seeking a common ground for trade and health", and "making trade and trade agreements work for health".[92] It attempts to express the view of international public health from the health sector regarding the growing trend of globalisation.[93] It is therefore noteworthy that the interface of globalisation, health and human rights has been acknowledged as a

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89 WHO Constitution.

90 WHO "Health and Human Rights" website, http://www.who.int/hhr/en/ .

91 See more discussions on human rights and public health: Gostin, L.O. (2001) "Public Health, Ethics, and Human Rights: A Tribute to the Late Jonathan Mann" 29 *Journal of Law, Medicine and Ethics* 121; Meier, B.M. (2007) "Advancing Health Rights in a Globalized World: Responding to Globalization through a Collective Human Right to Public Health" 35 *Journal of Law, Medicine and Ethics* 545; Meier, B.M. and Mori. L.M. (2005) "The Highest Attainable Standard: Advancing A Collective Human Right to Public Health" 37 *Columbia Human Rights Law Review* 101; Meier, B. M. (2006) "Employing Health Rights for Global Justice: The Promise of Public Health in Response to the Insalubrious Ramifications of Globalization" 39 *Cornell International Law Journal* 711; Aginam, O. (2006) "Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents" 31 *North Carolina Journal of International Law and Commercial Regulations* 901; Fidler, D.P. (2004) "Constitutional Outlines of Public Health's 'New World Order'" 77 *Temple Law Review* 247; Fidler, D.P. (2004) "Fighting the Axis of Illness: HIV/AIDS, Human Rights, and U.S. Foreign Policy" 17 *Harvard Human Rights Journal* 99; Gruskin, S. (2004) "Is There A Government in the Cockpit: A Passenger's Perspective on Global Public Health: The Role of Human Rights" 77 *Temple Law Review* 313; Walker, E.M. (2007) "The HIV/AIDS Pandemic and Human Rights: A Continuum Approach" 19 *Florida Journal of International Law* 335.

92 WHO Website, Trade, Foreign Policy, Diplomacy and Health, http://www.who.int/trade/en/index.html .

93 For example, the WHO has published *International Trade in Health Services and the GATS: Current Issues and Debates*; *Trade and Health: Seeking Common Ground*; *Draft Legal Review of the General Agreement on Trade in Services (GATS) from a Health Policy Perspective*; *GATS and Health Related Service; WTO Agreements and Public Health*, and *Global Public Goods for Health*. See http://www.who.int/trade/en/index.html .

new challenge by the WHO, and a harmonised legal framework is called for to balance these conflicting interests.

1.1.2.2.2 Public health and intellectual property

The WTO TRIPS Agreement is the first international agreement that provides minimum standard protection to pharmaceutical patents. Members to the WTO are obliged to comply with these standards by modifying their domestic legislation. After the TRIPS Agreement came into force, the UN Commissions on Human Rights Resolution called upon states to refrain from taking measures which would deny or limit equal access for all persons to pharmaceutical products used to treat pandemics such as HIV/AIDS, tuberculosis, malaria or other common infections.[94] Moreover, the Resolution also urges states to safeguard access to pharmaceutical products by adapting national legislation in order to make full use of the flexibilities in the TRIPS Agreement.[95]

When the emergence of the HIV/AIDS pandemic in the 1980s, and the discovery of effective treatments in the mid-1990s occurred, the future of patients' treatment appears to be dominated by the pricing and IP protection of drugs. Hence the WHO proposed the use of TRIPS safeguards to ensure access to essential drugs.[96] The WHO also issued

[94] Commission on Human Rights Resolution 2004/26: Access to Medication in the Context of Pandemics: Such as HIV/AIDS, Tuberculosis, and Malaria (2004), article 7.

[95] Commission on Human Rights Resolution 2004/26: Access to Medication in the Context of Pandemics: Such as HIV/AIDS, Tuberculosis, and Malaria (2004), article 11.

[96] For example, in regard to the possible impending avain flu pandemic, the WHO also calls on countries to work out plans to balance the availability of patented pharmaceuticals and ensure adequate protection of populations. In the access to medicines campaign, the WHO's role is to provide advice and technical assistance to countries to help them implement the full flexibilities in the TRIPS Agreement to address the "health implications of trade and intellectual property devices". It aims at "promoting the development and incorporation of TRIPS safeguards within the national policy and legal framework". See: "Access to Essential Medicines: a Global Necessity"32 *Essential Drugs Monitor*, 2003, WHO; "Access to Medicines, Intellectual Property Protection: Impact on Public Health", WHO Drug Information Vol 19, No 3, 2005. At the same time, WHO also explored the flexibilities within the TRIPS framework by publishing the CIPIH Report **n35**. See also: Tsang, KWT. (2005) "H5N1 Influenza Pandemic: Contingency Plans" 366

the "Globalization and Access to Drugs" report to address the repercussions in the pharmaceutical field from the impact of globalisation on access to drugs and the TRIPS Agreement.[97] It was argued that "Public health concerns should be highly considered when implementing the TRIPS Agreement", and that it also identified how much freedom was left for Member States to enact legislation that complied with TRIPS and was consistent with domestic health policy.

In order to address the need, the World Health Assembly (WHA) adopted a resolution on ensuring accessibility of essential medicines in 2002 which called upon the WHO "to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicines, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them".[98] Several resolutions passed by WHO Member States have stressed the importance of using the flexibilities in the TRIPS Agreement. For example, a resolution of the World Health Assembly urges Members "to encourage that bilateral trade agreement take into account the flexibilities contained in the WTO TRIPS Agreement and recognised by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health" (Doha Declaration).[99] The Doha Declaration was adopted by WTO trade ministers to interpret TRIPS to support public health and to promote access to medicines in 2001. We will introduce the Doha Declaration in more details in Chapter 4.[100]

Lancet 553-554.

[97] WHO, *Globalization and Access to Drugs* (2nd edition) January 1999.

[98] Resolution WHA 55.14. Ensuring accessibility of essential medicines, in: Fifty-fifth World Health Assembly, Geneva, 18 May 2002. Ninth plenary meeting, Geneva, World Health Organization, 2002 (A55/VR/9).

[99] *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), adopted by the fourth Ministerial Conference of the World Trade Organization in Doha, Qatar, on 14 November 2001. WT/MIN(01)/DEC/2 of 20 November 2001 **n27**; Resolution WHA 57.14. Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS. In: *Fifty-seventh World Health Assembly*, Geneva, 22 May 2004. *Eighth plenary meeting*, Geneva, World Health Organization, 2004.

[100] See **section 4.3.2.2.1**.

Further to several WHA resolutions,[101] the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) later issued a report of "Public Health, Innovation and Intellectual Property Rights" (CIPIH report) to address the needs of a growing burden of diseases that disproportionately affect developing countries.[102] It examines the role of IP in developing new vaccines, diagnostics and pharmaceuticals in developed, developing and under-developed countries. It recognises that IP rights are an important incentive for the development of new health-care products, however, this incentive alone fails to meet the need for the development of new products where the potential paying market is small. Therefore it encourages trade agreements to take into account the flexibilities, such as compulsory licensing[103] and parallel imports[104] contained in TRIPS recognised by the Doha Declaration.[105]

In summary, the WHO has been working from a human-rights approach to realise the right to health in a public health emergency. The CIPIH report demonstrates that IP should be interpreted and understood through the lens of global health. It reflects the malfunction of IP in resource-poor countries, and urges states to take full advantage of

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101 WHA52.19, WHA53.14, WHA54.10, and WHA57.14.

102 For more discussions, see: *Elements of a Global Strategy and Plan of Action: Progress to Date in the Intergovernmental Working Group*, Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, Agenda item 2.3, A/PHI/IGWG/1/5, 8 December 2006; Sell, S.K.(2004) "The Quest for Global Governance in Intellectual Property and Public Health: Structure, Discursive, and Institutional Dimensions", 77 *Temple Law Review* 363; Sell S.K. (2002) "Post-TRIPS Developments: The Tension between Commercial and Social Agendas in the Context of Intellectual Property" 14 *Florida Journal of International Law* 193 (Sell Post-TRIPS); Nanda, N. and Lodha, R. (2002) "Making Essential Medicines Affordable to the Poor" 20 *Wisconsin International Law Journal* 581; Mercurio, B. (2006) "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" 5 *Northwestern University Journal of International Human Rights* 1; Love, J. (2007) "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D" 40 *U.C. Davis Law Review* 679; Opderbeck, D. W. (2005) "Patent, Essential Medicines, and the Innovation Game" 58 *Vanderbilt Law Review* 501; Love, J. and Hubbard, T. (2007) "The Big Idea: Prizes to Stimulate R & D for New Medicines" 82 Chicago-Kent Law Review 1519.

103 CIPIH Report, **n35**, pp117-121.

104 CIPIH Report, **n35**, pp123-124.

105 Fifty-ninth World Health Assembly, *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: towards a Global Strategy and Plan of Action*, WHA59.24, 27 May 2006.

the flexibilities in TRIPS.

However, back to the WTO regime, while "free trade" is regarded as principle, and health is deemed as exemption to trade/IP, conflicts often arise between contending values of international trade and international health. The pursuit of free trade inevitably increases the probability of virus transmission across borders. The collision of these two worlds also magnifies the significant role of the WTO in public health concerns.

We now turn our discussion to the principles and exemptions of the WTO.

1.2 International trade

The WTO is the most effective institution in international law which introduces minimum standards for patent protection on pharmaceuticals in its TRIPS Agreement. With its effective dispute settlement system (DSS) in international law,[106] the WTO could also work to promote Members' compliance with health measures between the WTO and the IHRs in the WHO.[107] Public health has increasingly become a trade concern. Therefore it is necessary to understand international public health from the WTO perspective.

[106] WTO Dispute Settlement System (DSS) or Dispute Settlement Body (DSB), see **section 1.2.1.1.5**.
[107] Tigerstrom, B. (2005) "The Revised International Health Regulations and Restraint of National Health Measures" 13 *Health Law Journal* 35 (Tigerstrom IHRs).

1.2.1 WTO

"Free Trade" is the primary goal of economic globalisation within the development of the General Agreement on Tariffs and Trade (GATT) from 1948 to 1994. The WTO is currently the principal advocate of a globalised market-based economic system after its foundation in 1995. The foundation of the WTO aims at the utilisation of world resources and promoting the economic fulfillment of human kind. The purpose of the GATT/WTO is in raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, developing the full use of the resources of the world and expanding the production and exchanging of goods.[108] Thus, trade liberalism, global market access and the elimination of tariffs as barriers and non-tariff barriers to global trade are the primary concerns of the WTO.

1.2.1.1 Principles

The basic rules of the WTO are the principle of non-discrimination: most-favoured-nation treatment and national treatment for promoting free trade. It is also equipped with a number of key institutional and procedural rules relating to decision-making and dispute settlement.[109]

1.2.1.1.1 Non-discrimination

Non-discrimination is a key concept in WTO law and policy. There are two main principles of non-discrimination in WTO law: the most-favoured-nation (MFN)

[108] Preamble of the General Agreement on Tariffs and Trade (GATT) **n47**, para 2.
[109] Bossche, P. (2008) *The Law and Policy of the World Trade Organization – Text, Cases and Materials* (2nd edition) Cambridge University Press, New York, US, pp75-316 (Bossche). See **section 1.2.1.1.2** for the WTO Dispute Settlement Body (DSB).

treatment obligation and the national treatment (NT) obligation. The MFN treatment obligation requires Members to treat all other Members in a non-discriminatory way to the same "most-favoured' standard when dealing with the sale of "like products",[110] and the NT obligation requires Members to treat imported "like products" from other Members with the same criteria as is applied in its domestic market.

In other words, if two products are classified as "like products", then they should enjoy the same treatment in tariffs and in market access. In brief, the Dispute Settlement Body will consider "the characteristics of the products"; "their end use"; "consumers' tastes and habits" and "tariff regimes of other Members" in examining whether the various products are "like products".[111]

1.2.1.1.1.1 Most-Favoured-Nation Treatment

The obligation of Most-Favoured-Nation Treatment prohibits discrimination between like products originating in or destined for different countries.[112] "The essence of the non-discrimination obligations is that like products should be treated equally, irrespective of their origin".[113] Any differentiation in tariff or non-tariff barriers between imported

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[110] The classification of "like product" is addressed in the *Spain – Unroasted Coffee* case and the *Asbestos* case. See Bossche, P. (2008) *The Law and Policy of the World Trade Organization: Text, Cases, and Materials*, (2nd edition) Cambridge University Press, New York, US, pp329-331 (Bossche WTO); Bernasconi-Osterwalder, N. *et al.* (2006) (eds) *Environment and Trade: A Guild to WTO Jurisprudence*, Earthscan, London UK, pp7-17 (Bernasconi-Osterwalder WTO); GATT Panel Report, *Spain – Tariff Treatment of Unroasted Coffee* (*Spain Unroasted Coffee*) L/5135, adopted 11 June 1981, BISD 28S/102; WTO Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* (*EC – Asbestos*), WT/DS135/AB/R, paras130 and 145.

[111] GATT Panel Report, *Spain – Tariff Treatment of Unroasted Coffee* L/5135, adopted 11 June 1981, BISD 28S/102; *EC – Asbestos*, **n110**, paras130 and 145.

[112] GATT I:1 **n47**.

[113] In *European Communities – Report for the Importation, Sale and Distribution of Bananas* (*EC – Bananas III*), the issue was whether the EC treated bananas imported from Latin America with a standard less favourable than bananas from EC countries. WT/DS27/AB/R, adopted 25 September 1997. Under the requirement of MFN treatment, imported products should be treated with the same commercial criteria with domestic like products. For example, in *Spain – Unroasted Coffee*, the Panel considered: the characteristics of the

and domestic like products will be regarded as inconsistent with the obligation of MFN treatment.

1.2.1.1.1.2 National Treatment

The obligation of National Treatment is to avoid protectionism in international trade.[114] Its aim is to ensure that internal measures "not be applied to imported or domestic products so as to afford protection to domestic products".[115] Members are obliged to offer equal competitive conditions with imported and domestic like products. It prohibits Members from treating imported products less favourably than like domestic products once the imported product has entered the domestic market.

1.2.1.1.2 Dispute Settlement Body

The most distinctive feature of WTO law is its enforcement mechanism. In other words, WTO law is binding and enforceable. The WTO is equipped with the Dispute Settlement Body (DSB) to settle disputes among Members. A WTO Member can file a complaint to the DSB when he considers one or more fellow Members to be incompliant with the obligations of the WTO agreements. Commentators often describe the mechanism of DSB as the "teeth" of the WTO. It grants Members the right to retaliate if another party is found inconsistent with his obligations in the WTO Agreements. Hence, the WTO appears to be the most effective international trade organisation.

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products; their end-use; and the tariff regimes of other Members to determine whether the various types of unroasted coffee were "like products". Appellate Body Report, *EC – Bananas III*, para 190; GATT Panel Report, *Spain – Unroasted Coffee*, **n110**.

[114] See GATT III **n47**.

[115] Appellate Body Report, *Japan – Taxes on Alcoholic Beverages* (*Japan – Alcoholic Beverages II*), WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, para 109.

The principles of the WTO create a rigid framework to enforce free trade; however, Members' autonomy to protect public health has been substantially restrained under the scrutiny of these principles. Especially under the shadow of "trade retaliations", developing countries could easily be restrained from asserting their autonomy in domestic public health affairs and exercising their legitimate discretion in the flexibilities of TRIPS.[116]

When trade barriers are eliminated, health risks inevitably spread without borders, and the consequences of free trade bring about more unknown risks to human society. Therefore risk regulation has arisen to be one of the primary tasks in WTO law.

1.2.1.2Exemptions to WTO rules

Apart from the basic rules and principles, the WTO also provides a number of rules that address the conflicts between trade liberalisation and other economic and non-economic societal values. The non-economic values and interests include the protection of the environment, public health, public morals, national treasures and national security.[117]

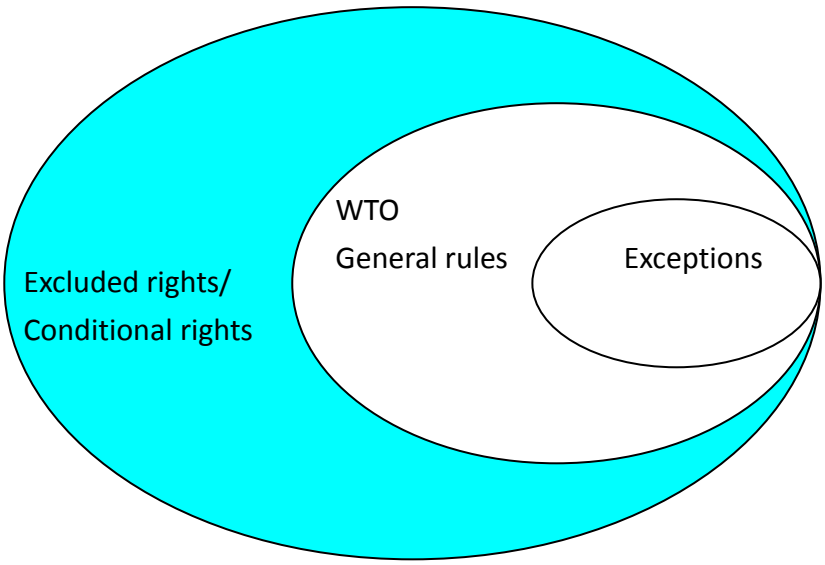
These exemptions from the WTO obligations have been placed into two categories: (1) provisions that establish an exception to a rule which can be referred to as "exception provision", and (2) provisions that exclude the application of other provisions which can

[116] As Sell notes that "Developing countries sought official confirmation that measures to protect public health would not make them subject to dispute settlement procedures in the WTO". "Sell Post-TRIPS" **n102**.

[117] The most common exception rules in relation to health and security in WTO include general exception in GATT XX, and national security exception in GATT XXI **n47**. Yet the exception rules applied are strictly limited in empirical cases. See **sections 4.1.1 and 4.1.2**.

be regarded as "excluding provision", which is also understood as "conditional rights"[118] that are only valid under certain circumstances (See Diagram 1.2.1.2).[119]

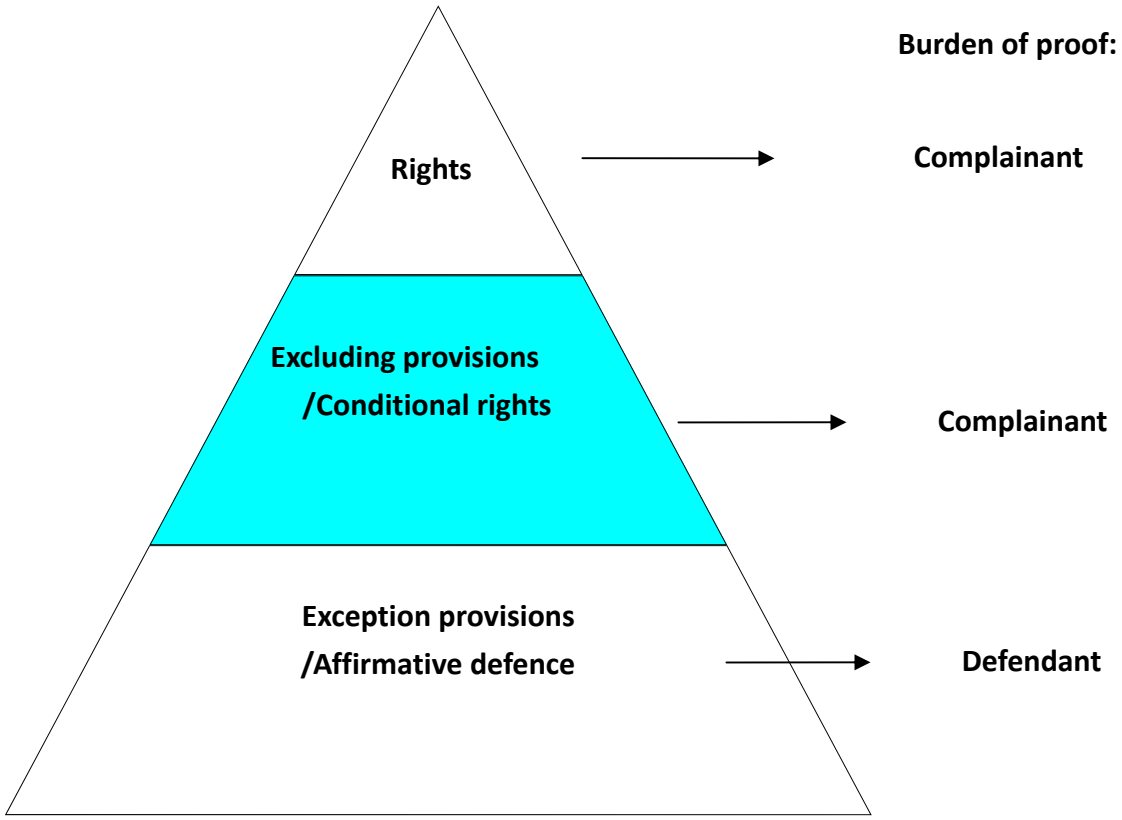
Diagram 1.2.1.2 Exemptions from WTO obligations



[118] Conditional rights are also known as excluding provisions, see Grando, M.T. (2006) "Allocating the Burden of Proof in WTO Disputes: A Critical Analysis", 9(3) *Journal of International Economic Law* 615-656 (Grando); Charnovitz, S. *et al.* (2004) "The Appellate Body's GSP Decision" 3(2) *World Trade Review* 257 (Charnovitz).

[119] See Grando and Charnovitz **n118**.

Diagram 1.2.1.2.1 Legal hierarchy of exemptions from WTO obligations



The distinctions of these exemptions have special implications on their legal status. The Appellate Body of the WTO has distinguished the excluded rights as "conditional rights", which enjoy a higher legal status than "exception provision or affirmative defence" in WTO law.[120] This is often demonstrated by the reversal of burden of proof when cases are associated with conditional rights (See Diagram 1.2.1.2.1).[121] As Grando notes that, "…it implies the existence of a hierarchy between provisions where exceptions are

[120] Charnovitz, S. *et al.*, **n118**.
[121] Grando, **n118**.

placed at a lower level of the hierarchical pyramid".[122] Charnovitz *et al.* note that "conditional rights" in WTO law "are essentially provisions that read as exceptions but which are given a self-standing status in that the conditional rights carves out the general rules so that the general rule and the conditional right apply side by side, in a mutually exclusive manner".[123]

The distinction between "exception rules" and "excluding rules" is significant due to its implication for the legal status of the provision and designates the allocation of burden of proof. The burden of proof is reversed for the complainant in an excluding provision. In the case regarding an exception rule, after the complainant's provision of prima facie evidence, the defendant has the burden of proving that "it has complied with the requirements of the provision establishing an *exception* to that rule". On the contrary, the complainant has the burden to prove that "the defendant does not fall under the situation or has not complied with the requirements of a provision that *excludes* the application to the general rule".[124] For example, if compulsory licensing is deemed as an exception in TRIPS, the invoking party needs to prove that the public health emergency existed when the compulsory licence was issued in its territory; on the contrary, if compulsory licensing is deemed as an excluding provision, the onus is reversed for the complaining party to prove that the public health emergency did *not* exist in the territory of the invoking party when the grant was issued.

After examining the basic principles and exemptions of the WTO, we can now proceed to discuss the scheme of compulsory licensing, which can be deemed as the core

[122] Grando, **n118**.
[123] Charnovitz, S. *et al.* **n118**
[124] Grando, **n118**.

instrument of promoting access to medicines in the TRIPS Agreement.[125]

1.3 Intellectual property under a public health emergency

The protection of IP serves as an incentive for innovation, yet over protection may have adverse effects to innovation as well as undermining humans' right to health.[126] The mechanism of compulsory licensing is considered a typical safety-valve of the exemption rule applied in TRIPS which aims to enhance access to medicines in a public health emergency. However, the criteria to invoke a compulsory licence in TRIPS under a public health emergency have remained undefined which often gives rise to the controversies of the legitimacy of the grant.

We will firstly introduce the TRIPS Agreement and its mechanism of compulsory licensing, and followed by some observations on the malfunction of the current provision in international political settings.

1.3.1 TRIPS Agreement

The TRIPS Agreement is the most comprehensive multilateral agreement on IP protection. It sets minimum standards of protection of patents, copyrights, trademark and other forms of IP based on three core commitments of the WTO: minimum

[125] TRIPS **n1**.

[126] For more information about patents to innovation, see: WHO Report (2006) *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (CIPIH) **n35**; Opderbeck, D.W. (2005) "Patents, Essential Medicines, and the Innovation Game" 58 *Vanderbilt Law Review* 501; Love, J. and Hubbard, T. (2007) "The Big Idea: Prizes to Stimulate R&D for New Medicines" 82 *Chicago-Kent Law Review* 1519; Love, J. (2007) "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D" 40 *U.C. Davis Law Review* 679 (Love Access).

standards, national treatment,[127] and most-favoured-nation treatment.[128] Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. Adherence to TRIPS is a prerequisite for membership of the WTO, and provisions of the agreement can be enforced through the WTO's Dispute Settlement Understanding Mechanism.[129]

The inclusion of pharmaceutical patents in TRIPS is one of the most controversial issues in the TRIPS Agreement. Patent protection on pharmaceutical products was not mandatory prior to the TRIPS regime. Over protection of pharmaceutical patents would significantly increase obstacles to access to medicines. Consequently, after the TRIPS Agreement entered into force, the WHO called upon Member States to ensure access to essential drugs and to explore the flexibilities in the TRIPS Agreement.[130]

We will discuss the objectives and principles of TRIPS in the following section.

1.3.1.1 Objectives and principles of TRIPS

Compulsory licensing, which serves as a means to limit IP, is an exemption from TRIPS obligations. According to the Vienna Convention on the Law of Treaties (VCLT),[131] a treaty needs to be interpreted firstly with a textual approach to search for its natural and ordinary meaning; if it still leaves the meaning ambiguous or obscure, then its context,

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127 See **section 1.2.1.1.1**.
128 See **section 1.2.1.1.1**.
129 See **section 1.2.1.1.2**.
130 See **sections 1.1.2.2 - 1.1.2.4**. World Health Assembly, Resolution 52.19, "Revised Drug Strategy" 24 May 1999. For more information on the discussion on the TRIPS Agreement and pharmaceutical patent protection, see: Sell, S.K. (2003) *Private Power, Public Law: The Globalization of Intellectual Property Rights*, Cambridge: Cambridge University Press; Gamharter, K. (2004) *Access to Affordable Medicines: Developing Responses under the TRIPS Agreement and EC Law*, Horn, Austria: Spriner Wien New York.
131 Article 31 Vienna Convention on the Law of Treaties (VCLT).

subsequent practice, practice of organisations, preparatory work, can be considered to be a supplementary means of interpretation while applying the principles of restrictive interpretation, effective interpretation, and a teleological approach[132]. Thus the interpretation of compulsory licensing needs to be read along with the objectives[133] and purposes[134] of the TRIPS Agreement.

The objectives of TRIPS clearly states that the protection and enforcement of IP should contribute to the mutual advantage of producers and users of technological knowledge and should be conducive to a balance of rights and obligations.[135] Regarding its principles,[136] it stipulates that Members may adopt measures necessary to protect public health, and to promote *public interest* in sectors of vital importance to their socio-economic and technological development.

While the TRIPS Agreement aims at the protection of IP in order to promote technological innovation, it also recognises the flexibilities of the standard of protection in order to balance the rights and obligations of patent holders. Notably, in recent years, scholars have adopted a view from human rights and competition to promote a balance in public and private interests in IP;[137] the role of "public interest" in the public domain

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[132] Brownlie, I. (2003) *Principle of Public International Law* (6th edition) Clarendon Press, Oxford, (Brownlie) pp602-607. For more reference on the interpretation of TRIPS, see: Condon, B.J. (2006) *Environmental Sovereignty and the WTO: Trade Sanctions and International Law*, Transnational Publishers, New York, United States (Condon Sovereignty), pp15-48; Mitchell, A.D. (2007) "The Legal Basis for Using Principles in WTO Disputes" 10(4) *Journal of International Economic Law* 795; Geuze, M. and Wager, H. (1999) "WTO Dispute Settlement Practice Relating to the Trips Agreement" 2(2) *Journal of International Economic Law* 347; Abbott, F. A. (2005) "Toward a New Era of Objective Assessment in the Field of Trips and Variable Geometry for the Preservation of Multilateralism" 8(1) *Journal of International Economic Law* 77 (Abbott Multilateralism); Frankel, S. (2005-2006) "WTO Application of 'the Customary Rules of Interpretation of Public International Law' to Intellectual Property" 46 *Virginia Journal of International Law* 365 (Frankel Interpretation).

[133] Article 7 TRIPS **n1**.

[134] Article 8 TRIPS

[135] Article 7 TRIPS.

[136] Article 8 TRIPS.

[137] See, for example, Maskus, K. E. and Reichman, J. M. (2004) "The Globalisation of Private Knowledge Goods and the Privatisation of Global Public Goods" 7 (2) *Journal of International Economic Law* 279

in the IP regime has also been discussed.[138]

Indeed, the role and function of IP is not only restricted to trade purposes. It is indicated in the objectives and principles of TRIPS that the role of *public interest* could serve as grounds for the legitimate differentiation of IP.[139] For example, if a given product or technology is strongly associated with the reduction or elimination of certain public health risk, it then could receive differential treatment in IP. IP should be able to reflect different dimensions/characteristics of products and technologies in accordance with their implications for society. Particularly, Abbott notes that the WTO Appellate Body adopts a cautious approach against "expansive interpretation of TRIPS obligation". He argues for a broader perspective on IP by stating that "IPRs are not only trade-related. They are also education-related, health-related, nutrition-related, defence-related, environment-related, energy-related and so on".[140]

In addition, Carvalho notes that "Only public interest justifies the taking of private rights by governments".[141] Gervais further argues that the public interest is considered greater with regard to the cases of "life-saving pharmaceutical products in crisis situations".[142] Gervais also contends that Articles 7 and 8 serve as a basis for the interpretation of the TRIPS provisions. Moreover, he argues that Article 7, Article 8 TRIPS and paragraph

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(Maskus/Reichman); MacQueen, H.L. "Towards Utopia or Irreconcilable Tensions? Thoughts on Intellectual Property, Human Rights and Competition Law" and Brown, A. "The Interface between Intellectual Property, Competition and Human Rights: Overview of Field And Proposed Contribution to Knowledge" in Pattanaik, M.K.(ed)(2008) *Human Rights and Intellectual Property*, The Icfai University Press, India.

138 For a detailed discussion on the role of the public domain in a contemporary IP regime, see: Waelde, C. and MacQueen, H. (eds) (2007) *Intellectual Property: The Many Faces of the Public Domain*, Edward Elgar, Cheltenham, UK (Waelde/MacQueen).

139 Articles 7 and 8 TRIPS..

140 Abbott Multilateralism, **n132**.

141 Carvalho, N.P. (2005) *The TRIPS Regime of Patent Rights* (2nd edition) Kluwer Law International, The Hague, The Netherlands (Carvalho).

142 Gervais, D. (2003) *The TRIPS Agreement: Drafting History and Analysis* (2nd edition) Sweet & Maxwell, London, UK (Gervais TRIPS Analysis).

19 of the Doha Ministerial Declaration[143] have "higher legal status not only for the negotiations but in interpreting the Agreement in the context of, e.g., dispute settlement procedures".[144] Hence, the interpretation of compulsory licensing would need to take into account the objectives and principles of TRIPS and the Doha Declaration. Compulsory licensing should be examined through the lens of public health, and be able to reflect the different implications of pharmaceutical products for society.

1.3.1.2Exemptions in TRIPS

In order to balance different social agendas besides individual private rights, TRIPS also introduces exemptions from IP protection. For example, the scheme of "compulsory licensing"[145] is considered an exemption from IP which allows states to grant permission to suspend the "exclusiveness" of patent protection under certain circumstances.[146] Yet the question arises as to the legal status of compulsory licensing: Is compulsory licensing an excluding provision or an exception provision in TRIPS?[147] In other words, can compulsory licensing be deemed as a conditional right[148] or merely an affirmative defence[149] in TRIPS? The legal status of this provision has a direct impact on the definition of WTO Members' entitlements to exercise their sovereignty in issues relating to compulsory licensing in a public health emergency.[150]

Hence, we will examine the general conditions and state practice of compulsory licensing

[143] Doha Ministerial Declaration, WT/MIN(01)/DEC/1, 20 November 2001 "In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension".
[144] Gervais TRIPS Analysis **n142**. *Cf.* **Diagram 1.2.1.2**.
[145] Article 31 TRIPS introduces the scheme of "other use without authorization of the right holder" **n41**.
[146] See **section 4.3.2.2**.
[147] See **section 1.2.1.2**.
[148] Conditional rights, see **n118**.
[149] See **section 1.2.1.2.**
[150] See **section 4.3.2.2.1**.

in the following section. The legal status of compulsory licensing will be further discussed in Chapters 4 and 5.[151]

1.3.2 Compulsory licensing

Compulsory licensing is a means of equity to redress the imbalance of IP protection. Confronted by emergent global public health emergencies in recent years, the issue of compulsory licences has received attention in international societies in relation to drug access in developing countries. For example, the UK Gowers Review has identified that "patent rights are territorial", and suggested that "a single one-size-fits-all approach is inappropriate". It suggests that different IP regimes are more appropriate at different stages of development.[152] It has also expressed concerns that TRIPS may be too restrictive to meet the needs of developing countries in relation to access to pharmaceutical products. The Gowers Review has further identified the conditions of compulsory licensing in TRIPS as a hindrance to the effectiveness of compulsory licensing. It has concluded that proposals to amend TRIPS may be necessary to address public health crises in developing countries.[153]

TRIPS has identified several conditions to grant a compulsory licence: anti-competitive practice, national emergency or other circumstance of extreme urgency, and public non-commercial use.[154]

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151 See **sections 4.3.2.2 and 4.3.2.2.1 and 5.2.1.1**.
152 Gowers Review of Intellectual Property (2006) HMSO, UK, paras 4.56 and 4.57(Gowers Review).
153 Gowers Review, paras 4.64 -4.66 **n152**.
154 Correa, C.M. (2007) *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, New York, United States, p305 (Correa TRIPS).

1.3.2.1Anti-competitiveness

The first condition of compulsory licensing is for "anti-competitive" practice, which is the primary application of compulsory licensing in the US.[155]

1.3.2.1.1 US: March-in rights

The provision of compulsory licensing in the US is mainly applied for anti-competition concerns. In other fields of compulsory licensing, the Bayh-Dole Act provides the primary legal ground for compulsory licensing while the so-called "march-in rights" can intervene where public funding of an invention is involved.[156]

Though the "march-in" rights are covered in the Bayh-Dole act for government to redress the malfunction of patent protection through compulsory licensing; however in practice, the US takes a relatively hard-line position of patent protection on medicines. Empirical studies show that US Government avoids granting a compulsory licence on pharmaceuticals within its march-in rights.[157]

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[155] "Love Access" **n126**. For example, James Love contends that the compulsory licence can be granted for anti-competitiveness if the drug price is unreasonably affordable for most people; if the patent impede the transfer and dissemination of technology, or constitute an abuse of IP rights.

[156] 35 US Code § 200. On 25 October 2005, the US Congress introduced the "Public Health Medicine Act" to provide compulsory licensing of certain patented inventions relating to health care emergency and to ensure that applications under Section 505 of the Federal Food, Drug, and Cosmetics Act that are submitted pursuant to such licences may be approved. This Bill gives the Secretary of Health and Human Service discretion to grant compulsory licenses to address public health crises. The patent holder should be paid a reasonable amount of loyalty as compensation. The Secretary may also issue compulsory licenses without the consent of the patentee to exercise importation of patented pharmaceuticals to address global public health emergencies. The Secretary also has the discretion to adopt measures which fulfil the purpose of Section 505 under the obligations of the TRIPS Agreement. This Bill was proposed in a previous congress session, however, it did not pass to become law. (The Proposed Act of 35 US Code Sec. 158)

[157] For example, on January 29 2004, the nonprofit corporation Essential Inventions (EI) petitioned the US Department of Health and Human Services for compulsory licenses on generic versions of latanoprost (Xalatan) and ritonavir (Norvir), which were both developed with federal funding. Essential Invention asserted that the government has the "march-in right" under the Bayh-Dole Act, and the patent should be licensed to another producer. Yet empirical studies show the government shuns issuing a

1.3.2.2 National emergency or other circumstances of extreme urgency

The condition of "national emergency or other circumstances of extreme urgency" is also regarded as another legitimate situation to issue a compulsory licence in TRIPS. The pandemic outbreak of HIV/AIDS in South Africa, Brazil and Thailand is deemed as typical of the said condition. However, interestingly, in recent years, evidence shows that states tend to deviate from the "national emergency" track in compulsory licensing, and to adopt the third track of "public use" to issue a compulsory licence.

1.3.2.2.1 South Africa

South Africa had faced the pressure of AIDS prevalence in its population and it decided to adopt a law to give the Minister of Health the authority to limit patent rights through compulsory licensing in 1997. The South African Medicines and Related Substances Control Amendment Act[158] soon faced pressure from the international pharmaceutical industry, especially from the US government and EU officials. In 1998, many multinational pharmaceutical companies in a huge number of 42 applicants, filed suit against the South African government.[159] The pharmaceutical industry argued that many provisions of the Amendment Act violated its constitutionally protected property right, especially Section 15(c) which vests the Minister of Health the power to limit patent rights by granting compulsory licences.

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compulsory licence with its march-in right.

[158] South African Medicines and Related Substances Control Amendment Act 1997, Republic of South Africa Government Gazette No 18505, Act No 90, 1997, 12 December 1997.

[159] High Court of South Africa, P*harmaceutical Manufacturers' Association of South Africa et al.* v *President of the Republic of South Africa*, Case No 4183/98, 1998.

After the debates on the Medicine Amendment Act, the South African government decided to tackle the bottleneck of the access to medicines issue with an *anti-competitive* approach,[160] and seemed to successfully bypass the controversies of "national emergency"[161] in compulsory licensing in TRIPS. The approach of examining the exclusive market power of drug firms may provide another window for states to negotiate with the drug firms and to seek to enhance access to medicines.[162]

1.3.2.3 Public non-commercial use

The third condition to issue a compulsory licence is "public non-commercial use".[163] Despite the AIDS outbreak being a legitimate trigger of compulsory licensing, in recent years, Brazil and Thailand both opted for the condition of "public non-commercial use" for granting a compulsory licence on AIDS drugs in order to avoid the implementation of the licence on the ambiguous criterion of "national emergency or other circumstances of extreme urgency" in TRIPS.[164]

Notably in the UK Patent Act, the production or supply of specific drugs or medicine is regarded as "Service of the Crown" and as such as deemed necessary or expedient by the

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160 See **section 1.3.2.1**.

161 See **section 4.1.2** for discussion of "security exception" in GATT **n47**.

162 In 2002, the Treatment Action Campaign gathered 11 complainants and launched a collective complaint with South Africa's Competition Commission against two pharmaceutical companies, GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI). The complaint also accused the two companies of dominating the market by an exclusionary act. GSK and BI were found to have contravened the Competition Act of 1998. http://www.cptech.org/ip/health/cl/recent-examples.html#South; Competition Commission finds pharmaceutical firms in contravention of the Competition Act, 16 October 2003, http://www.cptech.org/ip/health/sa/cc10162003.html; Competition Commission concludes an agreement with pharmaceutical firms, 10 December 2003, http://www.cptech.org/ip/health/sa/cc12102003.html.

163 "Love Access" **n126**. James Love proposes that grounds for compulsory licensing on public interests includes: improved access to medicines; technological innovation; transfer and dissemination of technology, and social and economic welfare.

164 See **section 4.1.2** for discussion of "security exception" in GATT **n47**.

Secretary of State.[165]

1.3.2.3.1 UK: Crown use

In the history of British Patent Law, a special provision of compulsory licences on food and drug patents was maintained during 1919 to 1977.[166] This regime was ended by a Monopolies Commission Report which granted the Secretary of State power to order price reduction on the two leading patented tranquillisers.[167] The order by the Secretary of State led to the introduction of a specific procedure for compulsory licensing which was later incorporated into the Patents Acts 1977.[168]

In Patents Acts 1977, the Comptroller has the power to grant compulsory licences on certain conditions once the patent has been granted for three years.[169] Because UK is a Member State of the WTO, its patent law needs to be in compliance with TRIPS, and bears the obligation to offer patent protection to other Member States.

It is noteworthy that Crown use is a legitimate ground to grant compulsory licences for

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165 UK Patent Act s 56(2). McQueen, H., Waelde, C., Laurie, G., Brown, A. (2010) *Contemporary Intellectual Property: Law and Policy* (2nd edition) Oxford University Press, New York, US, p475 (MacQueen *et al.*). This includes supply of anything for foreign defence purposes, production or supply of specific drugs or medicines, and such purposes relating to the production or use of atomic energy or research.

166 Cornish, W. and Llewelyn, D. (2007) *IP: Patents, Copyright, Trade Marks and Allied Rights* (6th edition), London Sweet & Maxwell, p295 (Cornish/Llewelyn).

167 Tranquillisers Report, H.C. 197, 1973.

168 See PA 1977 ss 48(4), 51, 55-59; Articles 8, 31(k), 40 TRIPS. The Patents Act 1977 differentiates four situations where compulsory licenses can be granted. First is the various grounds set out in section 48 and further divides "the relevant grounds" into two categories by whether the patentee is a WTO proprietor or not. Second follows a report of the Competition Commission; third is for Crown use and fourth is in relation to biotechnology inventions.
Following Directive 98/44/EC, the Legal protection of Biotechnological Inventions, UK amended its patent law to provide for mandatory compulsory cross-licensed of certain biotechnology inventions used for agriculture. The licence is available to plant breeders who demonstrate a technical advance. However, the UK Growers Review on 06 December 2006 noted that the provision is ineffective in the UK. And called for an expanded research exception, to permit broader use of the compulsory licence.

169 Patents Act 1977, s 48.

civil responsibility and is regarded as overriding the private interest of a patentee.[170] Hence, the Crown's powers in domestic administration become very wide due to the vague definition of "national security".[171]

The above example in the developed world show that compulsory licensing has been devised as an instrument to promote the balance of public and private interests; however in the UK, the distinct feature of food and medicines which relate to national security has become blurred. It is also observed that in the developing world, states tend to adopt the "public interest" track instead of the "public health emergency" track in compulsory licensing in order to avoid the controversial interpretation of "emergency" in international law.

1.3.2.3.2 Brazil: Public interest

The severe AIDS pandemic is overwhelming to the national public health system in Brazil. Notably, Brazil has the capacity to manufacture generic versions of AIDS drugs through reverse-engineering, and thus the Brazilian government has reached remarkable success in its AIDS programme by providing free AIDS drugs to any patients who were registered with the public health system from the mid-1990s.[172]

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170 PA 1977, s 55 (1).

171 See: PA 1977 s 59. Special provisions as to Crown use during emergency. Cornish/Llewelyn, **n166** p294. For example, the House of Lords held that the Ministry of Health might authorise an importer to bring in drugs not made by the patents for used in the NHS hospital service. *Cf*: See **section 4.1.2** for discussion of "security exception" in GATT **n47**.

172 The price of AIDS drugs fell by 82 percent over a five year period as a result of generic competition. The AIDS programme has reduced AIDS-related mortality by more than 50 percent between 1995 and 1999. The rate of new infection has been controlled since then. See: Ho'en, E. (2002) "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long way from Seattle to Doha" *Chicago Journal of International Law*; Hestermeyer, H. (2007) *Human Rights and the WTO – the Case of Patents and Access to Medicines*, Oxford, p10 (Hestermeyer).

Nevertheless, Brazil is a Member of the WTO, and it is subject to its obligations in TRIPS. In January 2001, the US officially filed a complaint to the WTO Dispute Settlement Body against Brazil's Intellectual Property Law (IPL) Article 68, which allows compulsory licences to be issued in situations where the patent holder does not locally manufacture the patented product (known as a "local working" provision).[173] The US argued that this provision was a breach of Articles 27 and 28 of TRIPS because it discriminated against locally made and imported products.[174] However, the US received much criticism and was forced to withdraw the case in June. The two WTO Members later resolved their disputes through a bilateral "Consultative Mechanism".[175]

On the other hand, in April 2007, the Minister of Health declared the AIDS drug, Efavirenz to be in the "public interest" domain.[176] The Brazilian Government consequently issued a compulsory licence on Efavirenz to ensure the supply of the drug for its national AIDS programme after a series of negotiations with the patent holder, Merck, broke down in 2010.[177]

Like South Africa's preference for the anti-competitive approach, Brazil also avoided the controversial "national emergency" track in compulsory licensing. They are also followed by Thailand's act of compulsory licensing on the grounds of public non-commercial use.

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[173] See WTO, Request for the establishment of a Panel by the United States, Brazil Measures Affecting Patent Protection, WT/DS199/3, 9 January 2001.

[174] *Brazil – Measures Affecting Patent Protection.* Request for the establishment of a Panel by the United States, WT/DS199/1(2001). See **section 1.2.1.1.1**.

[175] Brazil agreed to notify the US in advance if the compulsory licence is being issued under Article 68. "Examples of Health-Related Compulsory Licenses", http://www.cptech.org/ip/health/cl/recent-examples.html#Brazil

[176] "Brazilian Government Declares Efavirenz to Be of Public Interest", Essentialdrug.Org, 26 April 2007, http://www.essentialdrugs.org/edrug/archive/200704/msg00085.php

[177] "Compulsory Licensing of Efavirenz in Brazil", Access to Pharmaceuticals, 23, February, 2010, http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/

1.3.2.3.3 Thailand: Public non-commercial use

Thailand is the first country to test the boundary of compulsory licensing on the medications for chronic diseases.[178] Likewise, Thailand claimed that its act to grant a compulsory licence on the patented drug for heart disease, Plavix was based on the provision of "public non-commercial use" rather than that of "national emergency or other circumstances of extreme urgency" in TRIPS in 2007.[179]

Civil society and NGO have expressed support for Thailand's move on issuing compulsory license for chronic diseases treatment.[180] Yet critics have accused Thailand's act of compulsory licensing on Plavix as overstepping the appropriate application of compulsory licencing. As a consequence, the patent owner of Plavix, Abbot Laboratories announced that it would no longer market its new pharmaceutical products in Thailand in March 2007, and it even withdrew registration applications of new pharmaceutical products.[181] Moreover, the US placed Thailand on its Special 301 Priority Watch List[182] which was deemed to be a trade sanction due to the compulsory licence in April 2007.[183]

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178 On 25 January, 2007, Thailand granted compulsory licenses on patents for the heart disease drug, Plavix (Clopidogrel bisulfate). At: http://www.cptech.org/ip/health/cl/recent-examples.html#Thailand.

179 Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent, the Ministry of Public Health & the National health Security Office, Thailand, Feb.2007. ISBN 978-974-94591-5-7.

180 See: Knowledge Ecology International Statement on Thailand Compulsory Licenses, 21 January 2007; *Joint Statement by 15 NGOs - Thai civil society supports the health ministers of Thailand and Brazil and calls on pharmaceutical companies and lobbyists to stop abusing their power*, 10 May 2007. See also, Love, J. (2007) "*Recent Examples of the Use of Compulsory License on Patents*" KEI Research Note 2, 8 March 2007.

181 Abbott Pharmaceuticals in Thailand: Fact Sheet, 13 April 2007, http://www.oxfamamerica.org/whatwedo/campaigns/access_to_medicines/news_publications/Abbott%20in%20Thailand.

182 The United States Trade Representatives Office publishes annual "Special 301" review as a means to enforce IP protection worldwide, available at: http://www.ustr.gov/trade-topics/intellectual-property; special 301 report 2010: http://www.ustr.gov/webfm_send/1906.

183 Savoie, B. (2007) "Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition" 48 *Virginia Journal of International Law* 211.

The future of compulsory licensing on chronic diseases still remains unclear. Thailand was the first to test the boundaries of this provision, but it faced the consequence of trade retaliation. Trade sanctions from drug companies would inevitably create chilling effects on governments' acts of compulsory licensing of pharmaceuticals.

1.3.3 The constraints of the current mechanism

It can be observed from the above cases that international work to embody the flexibilities in TRIPS has been less than satisfying, especially in relation to a public health emergency. In recent years, states have shown preference for the "anti-competitive" and "public non-commercial use" tracks instead of resorting to the condition of "national emergency or other circumstances of extreme urgency" in compulsory licensing in order to avoid the undefined and ambiguous characteristics of "national emergency" in WTO law.[184] Their deliberation reflects the controversies of the existing mechanism for fear that conflicts may arise over the interpretation of "national emergency". We will discuss the application of "national emergency" in WTO law in chapter 4. Attention will now be turned to some hidden reasons of the dissatisfactions of compulsory licensing.

[184] See **section 4.1.2**.

1.3.3.1Power imbalance and political reality in "Access to Medicines"

When confronted with a firm pro-IP stance from developed countries which often use trade retaliation in response to a compulsory licensing grant,[185] developing countries are inevitably forced to use compulsory licensing as a defensive bargaining tool.[186] Hence, the compulsory licensing provision has barely been used in practice, as it is often used as a threatening tool to force drug price reductions instead of being a satisfactory and systematic channel to address the "access to medicines" problem.[187] Yet, in John Jackson's analysis of "power-oriented" diplomacy versus "rule-oriented" diplomacy, he argues that the move to a rule-oriented approach was normal evolution in human affairs as well as democractically justified in the economic sphere. A rule-based system which would bring "stability and predictability of government activity" requires that behaviour be based on prescribed principles – that it should not be based on discretionary decision-making or simply on the excise of power.[188] Therefore, a workable and systematic reading of compulsory licensing for tempering IP and health in a public health emergency is desirable with a view to increasing stability and predictability in a rule-based institution.

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[185] For example, the US often uses the Office of the US Trade Representative (USTR) to file complaints to the WTO over TRIPS disputes, or alternatively, it often uses the Special 301 apparatus "Priority Watch List" to pressure developing countries to alter their IP policy. See: Sell Post-TRIPS **n102**. After Thailand's grant of compulsory licences on clopidogrel/Plavix, the US government expressed that the measure appeared to fall within WTO rules. Nevertheless, USTR placed Thailand under 2007 Special 301 "Priority Watch List" surveillance. See: Abbott/Reichman, **n8**.

[186] Cameron, E. (2004) "Patents and Public Health: Principle, Politics and Paradox" 1(4) *Script-ed.*

[187] For example, Brazil and South Africa have threatened granting such licences in order to obtain substantial price reductions on HIV/AIDS drugs. See *Public Health, Innovation and Intellectual Property Rights*, WHO Report of the Commission on Intellectual Property Rights, Innovation and Public Health, **n35**, p117; Abbott/Reichman **n8**.

[188] Jackson, J. H. (1978) "The Crumbling Institutions of the Liberal Trade System" 12 *Journal of World Trade Law* 93:98-101. See also Jackson, J. H. (1979) "Governmental Disputes in International Trade Relations: A Proposal in the Context of the GATT" 13 *Journal of World Trade Law* 1:3-4. For a coercive narrative of TRIPS, see also: Gervais, D. "TRIPS and Development" in Gervais, D. (ed) (2007) *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era*, Oxford University Press, New York, US

1.3.3.2 Failure to declare a public health emergency of international concern

In the domestic context, the declaration of a public health emergency is a prerequisite to empower a state with emergency powers which can invoke relative responses to an emergency. It can then enable government to allocate appropriate resources to combat the epidemic. However, in the TRIPS context, the term "national emergency" appears to be vague and self-defining in WTO law,[189] thus the core issue is how to define "national emergency" in TRIPS? To what extent can a WTO Member exercise a margin of appreciation in compulsory licensing under the state of "emergency"? Taubman stated that: "A calm reading of the plain black-letter text of TRIPS would have mostly settled these questions, but the intensity of the debates created a need for political solution to reinforce the legal reality".[190] In Taubman's words, the Doha Declaration consequently articulated what had been implicit in TRIPS and provided a political gloss on TRIPS.[191] Nevertheless, even after the interpretation of the Doha Declaration, it is still observed that Members appear to have been deliberately bypassing compulsory licensing on the grounds of "national emergency or other circumstances of extreme urgency". This work hence aims to bolster the political and moral basis for using this measure by providing a workable reading of the text.

According to the "Paris Minimum Standards of Human Rights Norms in a State of Emergency"[192] "public emergency" means an exceptional situation of crisis or public

189 GATT XXI **n47**. See **section 4.1.2.1**.

190 Taubman, A (2011) *A Practical Guide to Working with TRIPS*, Oxford University Press, New York, US, (Taubman) p48

191 Taubman pp48-49, **n190** ; *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), adopted by the fourth Ministerial Conference of the World Trade Organization in Doha, Qatar, on 14 November 2001. WT/MIN(01)/DEC/2 of 20 November 2001. See **section 4.3.2.2.1**.

192 Article 1 The Paris Minimum Standards of Human Rights Norms in a State of Emergency. See report

danger, actual or imminent, and an official proclamation of a public emergency will justify the declaration of a state of emergency. Nevertheless, empirical studies suggest that states tend to avoid the declaration of a public health emergency in fear of possible adverse effects. For example, in the past experience of HIV/AIDS pandemic in Africa, states hesitated to declare a state of public health emergency regardless of being urged to by the NGOs and the WHO.[193] Notably, the outbreak of SARS in Asia-Pacific countries including Canada, Hong Kong, China, Vietnam, Malaysia, Australia, Thailand, and Indonesia resulted in huge economic loss from tourism.[194] Hence the identification of a public health emergency is frequently made behind closed doors: the granting of a compulsory licence, however, appears to be less transparent and convincing. Thus a compulsory licence granted for pharmaceuticals in an emergency situation has been controversial due to the unclear trigger threshold for compulsory licensing. A clear and workable framework for the invocation of compulsory licensing in a public health emergency is desired to be developed within the flexibilities in TRIPS.[195]

Compulsory licensing could be viewed as an equity basis to redress the imbalance of IP and health. However, as we have discussed in the previous paragraphs, developing countries have been deterred from resorting to this instrument for political reasons,

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of the 61st conference (Paris 1984) of the ILA Committee of the Enforcement of Human Rights Law; Chowdhury, S.R. (1989) *Rule of Law in a State of Emergency: The Paris Minimum Standards of Human Rights Norms in a State of Emergency*, St Martin's Press, New York, US.

193 "African Countries Urged to Declare HIV/AIDS A National Emergency" WHO/AFRO Press Releases, 24 June 1999; "Mbeki Refuses to Declare Emergency Over Aids" Panafrican News Agency (Dakar), 14 March 2001, available at: http://www.aegis.com/news/pana/2001/PA010316.html.

194 Krauss, C. "The SARS Epidemic: Canada; Toronto Is Stricken from Warning List Issued by WHO" The New York Times, 15 March 2003, available at: http://www.nytimes.com/2003/05/15/world/the-sars-epidemic-canada-toronto-is-stricken-from-warning-list-issued-by-who.html; "Economic Impact of SARS on Tourism in Seven Selected APEC Member Economies", Asia-Pacific Economic Cooperation (APEC), 22nd Tourism Working Group Meeting, June 2003, 2003/TWG22/016.

195 CIPIH Report, **n35** p19. As the WHO Report indicates that "the most significant barrier to the use of compulsory licensing is the absence of simple, straightforward legislative and administrative procedures to put the system into effect". It also suggests that the possible grounds for the issue of licences should be specified and urges to establish clear decision-making processes in order to avoid ambiguity and uncertainty. See **section 5.3**.

specifically on the grounds of "national emergency". In view of the increasing role of the precautionary approach in risk regulation in international law, this work proposes that the precautionary approach be accommodated into the identification of a "national emergency", and serves as a tool to embody the trigger threshold of "national emergency" in compulsory licensing. In so doing, we would also reconcile the WHO and WTO agendas in relation to pandemic preparedness in order to take advantage of the TRIPS flexibilities.[196]

After this background introduction of compulsory licensing in the international settings, we will turn our focus to the development of the precautionary approach in international law in the next chapter.

[196] See **section 5.3**.

2 The Development of the Precautionary Approach in International Law

2.1 Introduction to the precautionary approach

The precautionary approach (PA) has been developed from international environmental protection policy in the past few decades.[197] Its main premise is that where the threat of a particular harm is serious and the damage is irreversible, the notion of precaution should take priority over scientific justification. The background of the PA will be briefly introduced in the following paragraphs.

An evidence-based approach has been central to environmental and public health policy-making; however, it has been identified as outdated and unable to cope with emerging risks in contemporary society. The PA is therefore proposed to supplement the inadequacy of the traditional evidence-based approach.

Notably, the Nuffield Council on Bioethics in the UK has highlighted the importance of precaution when dealing with threats to public health.[198] It points out that "an evidence-based approach to public health policy can be fraught with difficulties". It also states that even when every step has been taken to ensure the validity of the evidence, "in practice it is often incomplete or ambiguous, and usually will be contested".[199] In a public health guidance from the UK National Institute of Clinical Excellence (NICE), it also states: "All evidence requires interpretation as evidence alone cannot determine the content of a recommendation".[200] It has been argued that

197 See **section 2.2**.
198 Nuffield Council on Bioethics, *Public Health: Ethical Issues* (2007) (Nuffield Public Health).
199 Nuffield Public Health, **n198**, p33.
200 National Institute of Clinical Excellence (NICE) Guidance, *Methods for the Development of NICE Public*

policy-making dependent only on scientific evidence is no longer fit for modern society. This is where the PA comes to play as an important role in contemporary public health protection.

Origins of the precautionary approach

The PA first emerged from international environmental protection prior to its application in the protection of human health and food safety. Freestone and Hey have commented on it as "intrinsic to international environmental policy".[201] Freestone further notes the rise of the approach as "one of the most remarkable developments of the last decade, and arguably one of the most significant in the emergence of the new discipline of international environmental law itself".[202] It has arisen as an applied ethic to complement the blind spot of scientific uncertainty or ignorance in the shadow of economic progression,[203] and is often applied to redress the vacuum in circumstances of insufficient scientific evidence.

More specifically within the health sector, precaution has been argued to be one of the

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Health Guidance (2009)(2nd edition) (NICE Methods) p118, available at: http://www.nice.org.uk/media/2FB/53/PHMethodsManual110509.pdf.

[201] Freestone, D. and Hey, E. "Origins and Development of the Precautionary Principle" in Freestone, D. and Hey, E. (eds) (1995)*The Precautionary Principle and International Law*, The Hague, pp3-15 (Freestone/Hey).

[202] Freestone, D. "International Fisheries Law since Rio: The Continued Rise of the Precautionary Principle" in Boyle, A. and Freestone, D. (eds) (1999) *International Law and Sustainable Development*, Oxford, pp135-164.

[203] "Uncertainty" refers to a situation under which it is possible to define all possible outcomes, but where there is no basis for the confident assigning of probabilities.
"Ignorance" refers to a situation under which it is possible neither to assign probabilities nor even to define all possible outcomes. From: Glossery in A. Stirling, *On Science and Precaution in the Management of Technological Risk*, Final Report of a project for the EC Forward Studies Unit under the auspices of the ESTO Network. See also: Gee, D. and Stirling, A. "Late Lessons from Early Warnings: Improving Science and Governance Under Uncertainty and Ignorance" in Tickner, J. A. (ed) (2003) *Precaution, Environmental Science, and Preventive Public Policy*, Island Press, Washington DC, US (Tickner Policy).

fundamentals of public health ethics,[204] it has been characterised as being: "at the heart of medical and public health theory and practice and is an underpinning to many of our current environmental and public health policies".[205] An Australia Judge has also stated that: "the precautionary principle is a statement of commonsense and has already been applied by decision-makers in appropriate circumstances prior to the principle being spelled out".[206]

On the one hand, the PA has been incorporated widely in environmental protection policy in international law and also recognised as a fundamental value in the health regime.[207] On the other hand, it has been criticised as incoherent and leading to paradox.[208] Yet existing formulations of precaution represent a wide range of implications which appear to be confusing and even contradictory. There is no current consensus on using the term "precautionary approach" (PA) or "precautionary principle" (PP) in international law.[209] The debates of the function and application of precaution without a focused target thus result in more myths, and adversely undermine the ground for communication amongst different stakeholders.

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[204] Weed, D. (2004) "Precaution, Prevention, and Public Health Ethics" 29(3) *Journal of Medicine and Philosophy* 313-332; Martuzzi, M. (2007) "The Precautionary Principle: in Action for Public Health" 64 *Occupational & Environmental Medicine* 569-670. See also: Kopelman, L.M. *et al.* (2004) "What is the Role of the Precautionary Principle in the Philosophy of Medicine and Bioethics?" 29 (3) J*ournal of Medicine and Philosophy* 255-258.

[205] Tickner, J. and Kriebel, D. (2006) "The Role of Science and Precaution in Environmental and Public Health Policy" in Fisher, E. *et al.* (eds) *Implementing the Precautionary Principle: Perspective and Prospects*, Edward Elgar Publishing (Fisher PP). Pearce, N. "Public Health and the Precautionary Principle" in Martuzzi, M. and Tickner, J. (eds) (2004) *The Precautionary Principle: Protecting Public Health, the Environment and the Future of Our Children* (WHO).

[206] Justice Stein of the New South Wales (NSW) Land and Environment Court in *Leatch v Director-General, National Parks and Wildlife Service and Shoalhaven City Council*, 23 November 1993, 81 LGERA, 1993, p270, at 282, cited from Trouwborst, A. (2002) *Evolution and Status of the Precautionary Principle in International Law*, International Environmental Law and Policy Series, Kluwer Law International, The Hague, p8. (Trouwborst Evolution)

[207] See **section 2.2**. See also **chapter 3**.

[208] Harris, J, and Holm, S. (2002) "Extending Human Lifespan and the Precautionary Paradox" 17(3) *Journal of Medicine and Philosophy* 355-368.

[209] See **section 2.1.3** for the distinction of PA and PP.

As a WHO report points out: "the problem with the PP definition is not in their accuracy, but that the definitions, possibly any synthetic definition, miss the values and role of the PP as an overarching, inspiring principle in environment and health".[210] The significance of the role of the PA has been blurred after contradictory debates. Therefore, a tailor-made definition in the context of our research is necessary to facilitate further discussion and implementation.[211] Thus, this chapter aims at shaping the contour of the PA in this work by literature review and comparative studies of previous works of philosophers and lawyers.

In this chapter, we will first introduce typical formulations of the PA in the literature, and examine the PA from the perspective of "State's responsibility" in international law. The "precautionary approach" will be the preferred term in this work. We will also revisit the more recent evolution of the PA from international environmental law to international public health law, and then turn to the analysis of philosophical elements of precaution in order to identify general features of the PA defined in this work. By comparing different models proposed by lawyers and philosophers and examining the application of the approach in different realms, this chapter aims to develop a common ground for the understanding of the PA and attempts to redefine it from the international public health perspective in the following chapters.

[210] Report of a WHO Meeting (2005) *Dealing with Uncertainty: Setting the Agenda for the 5th Ministerial Conference on Environment and Health, 2009*, Copenhagen, Denmark, 15-16 December 2005, EUR/06/5067987, at 3 (WHO Uncertainty Report).

[211] See **sections 5.1.2 and 5.2**.

2.1.1 Formulations of the precautionary approach

There exist numerous formulations of the PA in international law. All of them are related to risk management[212] of the environment and health protection in international law. We will first introduce typical versions from international declarations, treaties, and legislations in order to gain an initial impression of precaution. Then the term "precautionary approach" will be preferred in this work for it represents a degree of flexibility and stresses the adaptability in risk management.[213] Following the adoption of the preferred term, the ambiguity of legal status of this approach will also be addressed.[214] The PA is found to have a pervasive influence on risk regulation in international law; however, its application is fraught with fragmentationsin different legal regimes.[215]

Amongst all definitions, Principle 15 of the *Rio Declaration on Environment and Development* appears to be the most well-known version of the PA in international law, which reads:

> In order to protect the environment, the *precautionary approach* shall be widely applied by States according to their capacities. Where there are threats of *serious or irreversible* damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (*emphasis* added)[216]

The Rio Declaration involves a "triple-negative" connotation, which may leave ambiguity in its implication. In view of this, the European Environment Agency (EEA) has

[212] See **n36 section 3.1.3**.
[213] See **section 2.1.3**.
[214] See **section 2.1.3.1**.
[215] See **sections 2.2.4-2.2.4.3**.
[216] The Rio Declaration on Environment and Development, UN Doc.A/CONF.151/26, Vol. I, Annex I, 1992 (*Rio Declaration*).

proposed a more proactive and assertive definition as follows:

> The PP provides justification for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduced, *potentially serious or irreversible threats* to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction (*italics* added).[217]

Another frequently-cited version of the approach, which was developed from the Wingspread Conference in the United States, known as the *Wingspread Statement* reads:

> When an activity raises threats of harm to human health or the environment, *precautionary measures* should be taken even if some cause and effect relationships are not fully established scientifically. (*emphasis* added)[218]

With regard to environmental protection in domestic legislations, the Australian Government defines the PA in its *Intergovernmental Agreement on the Environment* (*IGAE*) as follows:

> Where there are threats of serious irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.[219]

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[217] WHO Uncertainty Report, **n210**.

[218] Wingspread Statement on the Precautionary Principle was established during a conference of experts in Wingspread, Wisconsin, USA in January 1998. The full text of the Wingspread Declaration is reproduced in Raffensperger, C. and Tickner, J. (eds) (1999), *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, Island Press: Washington DC, US, at pp 353-354. According to Naomi Salmon, the version in the Wingspread Statement is generally adopted by non-governmental organisations aiming at a more stringent approach to environmental and health protection. See Salmon, N. (2005) "What's 'novel' about it? Substantial equivalence, precaution and consumer protection 1997-2004", 7(2) *Environmental Law Review* 138-149 n70.

[219] The Intergovernmental Agreement on the Environment (IGAE) signed in May 1992 by all heads of government in Australia. (s 3.5.1).

These formulations lead to different conclusions in their interpretation and application. Some may be justification for doing nothing while others might be justification to intervene to do something. This distinction will be further discussed when we categorise the PA into the "Argumentative version" or the "Prescriptive version".[220]

The PA is perceived by the European Court of Justice (ECJ) as constituting "an integral part of the decision-making process leading to the adoption of any measure for the protection of human health".[221] In addition, Kriebel and Tickner note that the PA seeks to shift health and environmental policy from a strategy of "reaction" to a strategy of "precaution",[222] which would more aggressively cause significant change to the linkage of science and policy.[223]

From the view of regulation, Somsen further argues for "enabling precaution" to be a "morally and legally acceptable principle",[224] which substantively enables regulators to "channel regulatory tilt towards constraints on new technologies".[225] He maintains that "[W]hen under such circumstances uncertainty about the impact of a technology persists, enabling precaution posits that regulators should *temporarily prohibit or constrain that technology* until there is new evidence suggesting no risk or acceptable risk".[226](*emphasis added*)

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220 See **section 2.3.1**.
221 ECJ Case C–236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* (*Monsanto*), ECR 2003 I–08105, adopted 9 September 2003, para 133.
222 Harding, R. and Fisher, E. "Introducing the Precautionary Principle" in Harding, R. & Fisher, E. (1999) *Perspectives on the Precautionary Principle*, The Federation Press, NSW, Australia (Harding/Fisher), ch 1; Tickner, J. and Kriebel, D. "The Role of Science and Precaution in Environmental and Public Health Policy" in Fisher PP **n205** ch.3 ; Kriebel, D. and Tickner, J. (2001) "Reenergizing Public Health through Precaution" 91(9) *American Journal of Public Health* 1351.
223 Kriebel, D. *et al.* (2001) "The Precautionary Principle in Environmental Science" 109(9) *Environmental Health Perspectives* 871.
224 Somsen, H. "Cloning Trojan Horses" in Brownsword, R. and Yeung, K. (eds) (2008) *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Brownsword Technologies), Portland, Oregon US, Hart Publishing (Somsen Cloning).
225 Somsen Cloning **n224** p223.
226 Somsen Cloning **n224** p230.

Moreover, Somsen argues from the perspective of future generations that the costs of "irreversible harm" to the environment are to be borne by future generations who are not represented in current political and legal process. Therefore, precaution arises to give future generations a voice in legal and political processes.[227] This is argued from the angle of inter-generational equity. Somsen further concludes that precaution is used for environmental regulations to help "redress some very clear and serious imbalances that ultimately undermine mankind's chance of survival".[228] Indeed, Somsen's argument focuses on the adoption of a "margin of safety"[229] in environmental and health policy-making which would provide a buffer zone in the situation of scientific ignorance or uncertainty. An ample margin of safety in policy making will still be able to provide sufficient protection to human health in extreme or emergency situation, and to ensure that the scientific advancement would not come at a cost of human health. In order to avoid unpredictable or irreversible damage to human kinds and future generations, the role of PA serves as a mechanism of a safety valve in the regulation of risk posed by modern technologies under globalisation.

2.1.2 The precautionary approach from the perspective of "State responsibility"

The precautionary approach emphasises that when there is a possibility of serious or irreversible harm to the environment, protective action should be taken in advance of scientific proof of harm.[230] From the perspective of *State responsibility* in international

[227] Somsen Cloning **n224** p225
[228] Somsen Cloning **n224** p225
[229] See also **section 3.1.3.2**.
[230] Harding/Fisher, p3, **n222222**.

law,[231] governments may be obliged to act to avoid irreversible damage even under the circumstances of scientific uncertainty. In view of this, Trouwborst contends that the PA taken by states is embodied as "*a right or duty of states*" in international law when the threat to a particular harm crosses the "significant harm" threshold.[232] Trouwborst divides states' precautionary actions into a "right" or a "duty" in accordance with the degree of risk. I wish to adapt Trouwborst's concept of "precautionary rights and duties", but this work will not follow his distinction of a "right" or a "duty" of a precautionary action. Therefore, the terminology of states' "*precautionary entitlements*" is proposed in later discussions.

In addition to the argument in international law, Brownsword proposes a *State stewardship* model in domestic public health regulation, which suggests that a state has a responsibility to protect and promote the conditions of public health, and further requires the state to keep its citizens informed about risks to their health and the channel of democratic participation to improve the conditions of public health.[233] Furthering this argument, the Nuffield Council on Bioethics also promotes the stewardship model of states to impose states to have responsibilities "to look after important needs of people both individually and collectively".[234] This Report distinguishes paternalism and a stewardship model by the emphasis on "seeking the least intrusive way of achieving policy goals, taking into account also the criteria of effectiveness and proportionality".

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231 For more discussion about state responsibility, see, for example: Brownlie **n132** p419; Tinker, C. "State Responsibility and the Precautionary Principle", Freestone/Hey **n201**; Gathii, J.T. (2006) "How Necessity May Preclude State Responsibility for Compulsory Licensing under the TRIPS Agreement", 31 *North Carolina Journal of International Law and Commercial Regulation* 943. Gathii argues some major health pandemics such as HIV/AIDS may provide justification based on the rules of State responsibility under international law to improve affordable access to essential medicines. Crawford, J. (1999) "Revisiting the Draft Articles on State Responsibility" 10(2) *European Journal of International Law* 436.

232 Trouwborst, A. (2006) Precautionary Rights and Duties of States, Martinus Nijhoff Publishers, Leiden, The Netherlands (Trouwborst States). See **section 2.2**.

233 Brownsword, R., "So What Does the World Need Now?" in Brownsword technologies **n224** p46.

234 Nuffield Public Health **n198**.

It also identifies five main elements of the PA: scientific assessment of risk; fairness and consistency; consideration of costs and benefits; transparency, and proportionality.[235]

Further, this Nuffield proposal has recently been picked up by the National Institute for Clinical Excellence (NICE) in the UK with respect to public health.[236] It has acknowledged that the NICE's advisory committees are encouraged to take "non-scientific values" into consideration in "bridging the gaps between the evidence and producing a recommendation".[237] In another NICE report, it stresses the significance of "individual choice and of respecting individual' values, cultural attitudes and religious views".[238] Yet it also mentions that sometimes individual choice may need to be limited for public interests.[239]

From the above observation, it can also be understood that "precaution" has emerged to provide a safety net or a buffer zone between the boundary of risk and safety in the domain of scientific uncertainty. Either from the rule of state responsibility or the perspective of future generations, the PA appears to have a vital role to play in risk management[240] in modern society. However, the term of "precautionary principle" or "precautionary approach" have appeared in the literature in a rather random order. The word "approach" will be distinguished from this work in our discussion below.

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235 Nuffield Public Health, p35 **n198**.
236 NICE Methods, **n200**; see also: Killoran, A. *et al.* (2009) "NICE Update: NICE Public Health Guidance" 31(3) *Journal of Public Health* 451-452.
237 NICE Methods, **n200**, pp118-119.
238 NICE Report (2008) *Social Value Judgements: Principles for the Development of NICE Guidance* (2nd edition) (NICE Judgements), p19, available at: http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp.
239 NICE Judgements, **n238**, p19.
240 See **n36**.

2.1.3 Legal status of the precautionary approach

Precaution appeared in national legislation before it was introduced at the international level,[241] and most states adopt it at the national level more than at international level. It first emerged from environmental protection in Germany; there is also evidence that it had been applied by US courts about health, safety and environmental protection even before the appearance of the concept in Europe.[242]

At the international level, the legal status of PA is not yet settled,[243] but its widespread use has implied that it is recognised as "a legitimate approach in the field of environmental protection".[244] The *European Council Resolution on the Precautionary Principle* notes that the PA is "gradually asserting itself as a principle of international law in the field of environmental and health protection".[245]

Notably in the international economic regime, the Appellate Body suggested that PA has been incorporated in the WTO SPS Agreement;[246] however, its application and legal status appears to be relatively restrictive in WTO law. The Appellate Body in *EC – Hormones* indicated that PA was not yet accepted principle of "general" or "customary

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241 Sands, P. (2003) *Principles of International Environmental Law* (2nd edition) Cambridge University Press, Cambridge, UK (Sands Principles) pp266-279.

242 Perrez, F.X. (2008) "Risk Regulation, Precaution and Trade" in Wuger, D. and Cottier, T. (eds) (2008) *Genetic Engineering and the World Trade System: World Trade Forum*, New York, Cambridge University Press (Perrez Regulation); see also : Ashford, N.A., "Implementing a Precautionary Approach in Decisions Affecting Health, Safety, and the Environment: Risk , Technology Alternatives, and Tradeoff-Analysis" in Freytag, E. *et al.* (eds) (2002)*The Role of Precaution in Chemicals Policy*, Vienna, Diplomatische Akademie, p128, cited from Perrez n23.

243 See, for example: Boutillon, S. (2002) "The Precautionary Principle: Development of an International Standard" 23 *Michigan Journal of International Law* 429;

244 Barton, C. (1998) "The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine" 22 *Harvard Environmental Law Review* 517.

245 *European Council Resolution on the Precautionary Principle*, SN 400/00 ADD 1 20 EN Annex III, adopted 9 December 2000 (Nice) (*EC PP Resolution*), para 3.

246 SPS Agreement, see **sections 2.2.2.2 and 4.2 n39**.

international law" by stating that:[247]

> The status of the precautionary principle in international law constitutes to be the subject of debate among academic, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We noted that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.[248]

While the Appellate Body avoided declaring the legal status of PA, it did imply that "the 'precautionary approach' or 'concept' is 'an *emerging* principle of law' which may in the future crystallize into one of the 'general principles of law recognized by civilized nations' within the meaning of Article 38(1)(c) of the *Statue of the International Court of Justice*".[249] It also mentioned that commentators have noted that there is sufficient state practice of PA, and it can be recognised as *an evolving principle* in international law.[250]

The legal status of the PA has a direct impact on the preference of the term "precautionary approach" rather than "precautionary principle" in this work, which will be addressed in the following section.

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[247] WTO Appellate Body Report, *EC – Measures Concerning Meat and Meat Products* (*EC – Hormones*), WT/DS26/AB/R, adopted 16 January 1998.
[248] *EC – Hormones*, para 123.
[249] *EC – Hormones*, para 122.
[250] *EC – Hormones*, note 92.

2.1.3.1Precautionary principle or precautionary approach?

The distinction between the terms "precautionary principle" and the "precautionary approach" has been a topic of academic debates.[251] Some observe that the Americans prefer the word "approach" in order to underline that they do not accept it has yet gained the status of customary international law, while the Europeans prefer "principle" to emphasise that they accept it as a concept entailing certain legal implications.[252] Birnie *et al.* note that "…European treaties and EC law generally refer to the precautionary principle, whereas global agreements more often refer to the precautionary approach or precautionary measures". [253] Few commentators insist on the significance of distinguishing the precautionary approach from the precautionary principle;[254] however, both terms often appear to be interchangeable.

Mascher has concluded that "there is nothing to suggest that the terms 'precautionary principle' and 'precautionary approach' cannot be used interchangeably".[255] Yet Viscuna has observed that the term "approach" reflects a hint of flexibility of the role of precaution in relation to fisheries management:

> Since scientific uncertainty is normally the rule in fisheries management a straightforward application of the precautionary principle would have resulted in the impossibility of proceeding with any activity relating to marine fisheries. It is on these grounds that the concept of the "precautionary approach" surfaced with a view to provide a more flexible tool for the specific needs of fisheries

[251] For example, see Birnie, P., Boyle, A. and Redgwell, C.(2009) *International Law and the Environment*, 3rd edition, Oxford University Press, New York, US. (Birnie/Boyle/Redgwell) pp152-164.
[252] Perrez Regulation, **n242**. See also: Whiteside, K.H. "Comparing Precaution in the United States and Europe" in *Precautionary Politics: Principle and Practice in Confronting Environmental Risk* (2006) MIT Press, Cambridge, Massachusetts, US (Whiteside Precaution).
[253] For example, see Birnie/Boyle/Redgwell, **n251**.
[254] Birnie/Boyle/Redgwell, **n251**.
[255] Mascher, S. (1997) "Taking a 'Precautionary Approach': Fisheries Management in New Zealand" 14 *European Public Law Journal* 70-79.

management.[256]

It is noteworthy that there is a preference to use the word "approach" rather than "principle" in cases of fisheries management.[257] For example, the 1995 *Convention on Straddling and Highly Migratory Fish Stocks* preferred the term "precautionary approach" by noting "'approach' offers greater flexibility and will be less potentially restrictive than the 'principle'".[258] Judge Laing had expressed in another Separate Opinion the view that "adopting an approach, rather than a principle imports a certain degree of flexibility and tends, though not dispositively, to underscore reticence about making premature pronouncements about desirable normative structures".[259] Judge Treves seems to associate the term "principle" with legally binding, customary status, as opposed to the alleged more neutral "approach".[260] It is therefore observed that the word "approach" receives more acknowledgement than the term "principle" in empirical studies in international environmental protection.

Perrez has concluded that "at the practical level, there is no conflict or contradiction between the terms 'principle' and 'approach'. The debate over whether precaution should be considered a principle or an approach is therefore more to do with symbols and semantics than substance".[261]

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[256] Orrega Viscuna, F. (1999) *The Changing International Law of High Seas Fisheries*, Cambridge University Press, Cambridge, UK.
[257] *Southern Bluefin Tuna Case* (1999) International Tribunal for the Law of the Sea (ITLOS) Nos 3&4, Separate opinion of Judge *Ad Hoc* Shearer. See also: Howarth, W. (2008) "The Interpretation of 'Precaution' in the European Community Common Fisheries Policy" 20 *Journal of Environmental Law* 213.
[258] See FAO, *The Precautionary Approach to Fisheries with Reference to Straddling Fish Stocks and Highly Migratory Stocks* (1994) UN Doc A/CONF.164/INF/8.
[259] Separate Opinion of Judge Laing, *Southern Bluefin Tuna Cases* (*New Zealand v Japan*; *Australia v Japan*), International Tribunal for the Law of the Sea, 27 August 1999, para 19, **n257**.
[260] Separate Opinion of Judge Treves, *Southern Bluefin Tuna Cases* (*New Zealand v Japan*; *Australia v Japan*), International Tribunal for the Law of the Sea, 27 August 1999, para 9, **n257**.
[261] Perrez Regulation **n242**.

In addition, the Nuffield Council suggests that "there is not just one, but several principles or considerations that need to be considered" by adopting the term "precautionary approach" rather than "precautionary principle".[262] As Laurie and Hunter point out, "[T]he Council prefers the term 'precautionary approach' and, in so doing, reflects the Department of Health's framework in suggesting that no one principle or consideration should be applied. The value of these instruments lies in both their procedural and substantive contribution to decision-making process".[263]

In empirical studies, the word "approach" appears to be preferable in international legal instruments in order to avoid extreme versions of the precautionary principle that demand absolute environmental protection regardless of the cost.[264] An extreme version of the precautionary principle shows little acceptance of the cost-effectiveness arguments, and gives no presumption of free trade.[265] However, in this work, the precautionary approach is suggested to be triggered by empirical risk assessment or science-based judgement.[266] The invocation of a PA in compulsory licensing will depend on scientific judgement or certain forms of cost-effectivenss evaluation, tempered by precaution.

Taking into account the factor of risk assessment and the reconciliation of free trade and international health, this work avoids extreme interpretations of the precautionary principle, and will settle at the *moderate* version proposed by the WHO.[267] Hence, the

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262 Nuffield Public Health, **n198**, pp35-36.
263 Laurie, G. and Hunter K. "Mapping, Assessing and Improving Legal Preparedness for Pandemic Flu in the United Kingdom" 10(2) *Medical Law International* 101-137 (Laurie/Hunter).
264 See **section 2.3.3**
265 See **Table 2.3.3.3**
266 See **sections 3.1.3.1; 5.1.3; 5.1.3.2.** The work of the Codex Alimentarius Commission defines "risk assessment" as a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.
267 See **section 2.3.3.3; Table 2.3.3.3**

term "approach" would demonstrate the "moderate" and "pragmatic" nature of this work.

The term "approach" suggests a broader and more adaptive method than the term "principle" which indicates an absolute implication. At the time being, considering the evolving nature and the unsettled debates on the legal status of the precautionary principle as discussed above,[268] and given the political expediency in the international setting, it would be more agreeable to adopt the term "approach" to avoid disagreements in international fora.

The terminology is the first stepping stone of communication amongst different stakeholders, which aims at facilitating future reconciliation in the application of the PA in a public health emergency. Considering the political sensitivities which can be extreme in different worlds of trade, health, IP, and human rights, it would be more satisfactory to all stakeholders to adopt the term "approach" rather than "principle" within the domain of this work.

Based on the above consideration, with a view to reconciling trade and health, a practical and workable reading of the text is sought by this work. Though some may argue that the two terms are interchangeable, the term "approach" appears to be more apt than "principle" in empirical studies in international law. It is also observed that the slight distinction between these two terms is that PP implies a more dogmatic assertion to adopt certain measures to shy away from uncertain risks, while PA reflects a hint of a more flexible application of precaution. We will choose the term "approach" in this

[268] See **section 2.1.3**. The United States and Canada do not yet accept it as "principle" in international law. For example, see WTO Appellate Body Report, *EC – Measures Concerning Meat and Meat Products* (*EC – Hormones*), WT/DS26/AB/R, adopted 16 January 1998, para 122.

work to underscore the adaptability and flexibility of risk management[269] in a public health emergency.

2.2 Origins of the precautionary approach: From international environmental protection to human health and food safety

After having an initial impression of the precautionary approach, we will turn our attention to its origins in international environmental law and recent developments in the protection of human health and food safety.

Prior to the emergence of the PA, the "preventive principle" was documented in the literature.[270] Whereas the preventive principle can be traced back to international environmental treaties since the 1930s,[271] the PA emerged in the context of marine pollution legislation in international law, and "cleaner production" in Europe.[272]

It is therefore important to distinguish "precaution" from "prevention". "Precaution" is relevant in situations of scientific uncertainty, while "prevention" relates to situations in which the risk of potential damage can be determined or identified on the basis of a scientific assessment.[273] The PA therefore is only involved in the condition that there is *scientific uncertainty* concerning the existence or seriousness of a risk. In other words, when a risk can be managed with a quantitative risk assessment (QRA),[274] it is included

269 See **n36**.
270 For example, see: Sands Principles p267 **n2411**.
271 Sands Principles p267 **n241**.
272 Harding/Fisher **n222**. See also: De Sadeleer, N. *Environmental Principles: From Political Slogans to Legal Rules*, Oxford University Press, New York, the United States, pp61-90.
273 Perrez Regulation, **n252**.
274 See **section 3.1.3.1**, **n266**

in the exercise of prevention rather than precaution;[275] on the contrary, if the risk involves scientific uncertainty which cannot be measured by QRA, or the causal relationship has not been established under current pertinent scientific justification, the PA may be introduced to address the need to prevent further damage to human health and safety.[276]

The PA originated from air pollution legislation in Germany in the phrase "Vorsorgeprinzip".[277] Tickner and Kriebel argue for an alternative translation of this word is the "foresight principle" or "forecaring principle" which emphasises an anticipatory action: "a proactive idea rather than precaution, which may sounds reactive and even negative".[278] Birnie *et al.* state that its purpose is "to make greater allowance for uncertainty in the regulation of environmental risks and the sustainable use of natural resources".[279]

The PA is becoming increasing relevant as an international legal measure to guide decision-making in the face of scientific uncertainty. It is reflected in a growing body of legal instruments which form part of developing international customary and treaty regimes.[280] It has been applied in relation to the adoption of measures to address ozone depletion;[281] to protect the marine environment of the North Sea;[282] to prevent the causes of climate change;[283] to regulate handling and use of living modified organisms,[284]

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275 Cameron, J. "The Precautionary Principle: Core Meaning, Constitutional Framework and Procedures for Implementation" (Cameron PP) in Harding/Fisher, **n222**.
276 Cameron PP, **n275**.
277 Harding/Fisher, **n222**.
278 Tickner, J. and Kriebel, D. "The Role of Science and Precaution in Environmental and Public Health Policy" in Fisher PP **n205**.
279 Birnie/Boyle/Redgwell, **n251**.
280 For a detailed review of the origins and history of precaution, see Trouwborst Evolution, **n206**.
281 *Montreal Protocol on Substances that Deplete the Ozone Layer*, 1987.
282 Third North Sea Conference, 1990.
283 The *Rio Declaration on Environment and Development*, 1992; *Framework Convention on Climate Change*, 1992.
284 *Cartagena Protocol on Biosafety*, 2000.

and more recently, to the protection of human health and food safety.[285] It is observed that after the *Rio Declaration*,[286] the PA soon appeared in many dimensions in different legal instruments to meet demands of various risks under scientific uncertainty. For example, the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement),[287] the *Cartagena Protocol on Biosafety* (Cartagena Protocol" or "CPB),[288] the WHO *International Health Regulations* (IHRs),[289] and the *Codex Alimentarius*[290] have further expanded the application of precaution from specific environmental protection to the protection of human health.[291] This will be further addressed in following Chapters.[292]

We will now revisit its development within the United Nations, the WTO and the EC respectively in order to trace its development and to identify recent trends in the protection of international environment with a special regard to the protection of human health and food safety.

2.2.1 United Nations

The precautionary approach has been adopted in international law to put states under a duty to prevent or mitigate transboundary environmental harm caused by activities in

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285 *Treaty on European Union* (*Maastricht Treaty*), 1992; *Stockholm Convention on Persistent Organic Pollutants* (*POPs*), 2001. See European Environmental Agency Report, *Late Lessons from Early Warnings: the Precautionary Principle 1896-2000*, Environmental Issue Report No 22, EEA, Copenhagen 2001.

286 *Rio Declaration on Environment and Development*, the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, 1992 (*Rio Declaration*), UN Doc.A/CONF.151/26, Vol I, Annex I.

287 SPS Agreement **n39**.

288 Cartagena Protocol on Biosafety, see **section 3.2 n46**.

289 See **section 3.1.2**. International Health Regulations (IHRs) **n45** .

290 See website of *Codex Alimentarius* at: http:www.codexalimentarius.net **n36**

291 WTO SPS Agreement, Art. 5.7 **n39**; *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (Montreal 2000), Article 10.6 (Cartagena Protocol/CPB)**n46** ; WHO International Health Regulations (IHRs) Article 43 **n45**; *Codex Alimentarius* Procedural Manual (Codex Manual)**n36**: http://www.codexalimentarius.net/web/procedural_manual.jspm.

292 See Chapters 3 and 4.

territory under their jurisdiction or control. The PA arises to provide regulations on the polluters or the one introduces new technology to bear relevant duties in managing unknown risks associated with their activities.

Many threatening environmental issues such as ozone depletion,[293] climate change,[294] and transboundary waste dumping[295] all require international cooperation. Therefore the United Nations has played an important role in the proliferation of the PA to prevent international environmental deterioration. Though some of the resolutions of the General Assembly may not be legally-binding as treaties, they are recommended to be taken into considerations by the International Court of Justice (ICJ)[296] as a manner in which "the development of international law may be reflected" when disputes arise.[297]

2.2.1.1Legal instruments

The UN General Assembly has adopted the *World Charter for Nature* (*World Charter*) within the framework of the World Conservation Union in 1982, which is also known as "the Magna Carta of ecological environmental policy".[298] Despite the absence of the term "precautionary principle" or "precautionary approach", Principle 11 of the Charter reflects the basic elements of the PA by stating that:

> Activities which might have an impact on nature shall be controlled and the best available

[293] See **n281**
[294] See **n283**
[295] See **n285**
[296] International Court of Justice (ICJ), see **section 2.2.1.1.1**, available at: http://www.icj-cij.org/homepage/index.php?lang=en
[297] *Resolution 29/332*, 29 United Nations General Assembly Official Records (UNGAOR), 1974, Supp31, cited from Trouwborst Evolution **n206**, p149.
[298] *World Charter for Nature, UN General Assembly Resolution 37/7*, Annex B. no 1; Trouwborst Evolution **n206** pp150-152.

technologies that minimize *significant risks* to nature or other effects shall be used, in particular:

(a) Activities which are likely to cause *irreversible damage* to nature shall be avoided;

(b) Activities which are likely to pose a significant risk to nature shall be preceded by an *exhaustive examination*; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed;

(c) Activities which may disturb nature shall be preceded by *assessment of their consequence*s, and environmental impact studies of development projects shall be conducted sufficiently in advance, and if they are to be undertaken such activities shall be planned and carried out so as to minimize potential adverse effects;…(*emphasis* added)

Principle 11 identifies some major factors in the implementation of the PA: significant risks; irreversible damage; cost-effectiveness, and environmental impact assessment (EIA). The European Commission thus referred the *World Charter for Nature* as the first legal instrument to recognise the PA at the international level,[299] and Hohmann concludes that the *World Charter for Nature* is "certainly one of the most important UN documents in which the precautionary principle has been recognized as the central principle of environmental policy".[300] Trouwborst further comments that the precautionary thinking on the international plane has proliferated after the adoption of the *World Charter*.[301]

Further to the completion of the *World Charter*, the UN General Assembly later approved

[299] *EC Communication on the Precautionary Principle*, *Communication COM (2000)1*, p11 (*EC Communication*).
[300] Hohmann, H. (1994), *Precautionary Legal Duties and Principles of Modern International Environmental Law*, Dordrecht, cited from Trouwborst Evolution, **n206** p152.
[301] For example: *United Nations Convention on the Law of the Sea* (1982); *Convention on Early Notification of a Nuclear Accident* (1986); *Convention on the Regulation of Antarctic Mineral Resource Activities* (1988); *Vienna Convention for the Protection of the Protection of the Ozone Layer* (1985); *Protocol on Substances that Deplete the Ozone Layer* (the *Montreal Protocol*, 1987), and *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal* (1989).

Goals and Principles of Environmental Impact Assessment in 1987 and extended the application of the PA into the problems of global climate change,[302] marine resource and large-scale driftnet fishing,[303] sustainable development;[304] hazardous waste and persistent organic pollutants.[305] Relevant cases of *Gabcikovo – Nagymaros* before the ICJ and *Southern Blufin Tuna Case* in the International Tribunal of the Law of the Sea (ITLOS)[306] will be introduced briefly to highlight the fundamental ingredients of the PA.

2.2.1.1.1 Gabcikovo – Nagymaros Case

The International Court of Justice (ICJ) is the principal judicial organ of the United Nations. It was established by the Charter of the United Nations in 1949 to settle legal disputes submitted by states and to give advisory opinions on legal questions. The *Gabcikovo – Nagymaros Case*[307] was heard in the ICJ when Hungary invoked the PA to suspend works of the two barrages for its natural environment in the region affected by the Gabcikovo – Nagymaros Project in consideration of "ecological necessity" in 1989.

Nevertheless, the ICJ found that Hungary did not prove a "real, 'grave', and 'imminent' 'peril' existed in 1989, and the measures taken by Hungary were the only possible

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302 UN General Assembly *Resolution 43/53 on Protection of Global Climate for Present and Future Generations of Mankind* (1988).

303 UN Environment Programme *Governing Council Decision 15/27 on the Precautionary Approach to Marine Pollution, Including Waste-Dumping at Sea* (1989); UN General Assembly *Resolution 44/225 on Large-Scale Pelagic Driftnet Fishing and its Impact on the Living Marine Resources of the World's Oceans and Seas* (1989); UN General Assembly *Resolution 46/215 on Large-Scale Pelagic Driftnet Fishing and its Impact on the Living Marine Resources of the World's Oceans and Seas* (1991), and UN General Assembly *Resolution 59/25* (2004).

304 UN General Assembly *Resolutions S/19-2* (*Programme for the Further Implementation of Agenda 21*, 1997).

305 UN Environment Programme *Governing Council Decision SS II/4 on a Comprehensive Approach to Hazardous Waste* (1990); UN Environment Programme *Governing Council Decision 18/32 on Persistent Organic Pollutants* (1995); UN Environment Programme *Governing Council Decision 19/13 C on Persistent Organic Pollutants* (1997).

306 International Tribunal of the Law of the Sea (ITLOS), see **section 2.2.1.1.2**. http://www.itlos.org/start2_en.html

307 *Gabcikovo – Nagymaros Case* (1997) ICJ Report 7, paras 105-114.(*Gabcikovo – Nagymaros*)

response to it".[308] It was also alleged that an adequate Environmental Impact Assessment (EIA) had not been carried out before the project, but the court did not address the need for prior EIA. EIA is "a procedure for evaluating the likely impact of a proposed activity on the environment".[309] In particular, the Court required the parties to "look afresh" at the environmental impact of the project, and treated prior EIA and subsequent monitoring of the ongoing risks as a continuing obligation throughout the whole project.[310] Birnie *et al.* note that: "If EIA is a necessary precondition for effective notification and consultation with other states, then monitoring may equally be regarded as a necessary element of an effective EIA".[311] It can therefore be suggested that monitoring may also be part of the obligation of due diligence, and needs to be incorporated in a complete EIA through the life of the project.

The *Gabcikove – Nagymaros* case may indicate that the triggering threshold of the PA needs to prove a "real, 'grave', and 'imminent' 'peril'" exists,[312] and the one who carry out the project associated with the risk may be obliged to carry out a prior EIA and subsequent monitoring of the ongoing risks. The ongoing risks need to be constantly evaluated and updated to ensure the adopting measure is proportionate and effective.

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308 The ICJ found that a state of necessity was, on an exceptional basis, a ground recognised by customary international law for precluding the wrongfulness of an act not in conformity with an international obligation, and relied on the formulation of draft Article 33 of the ILC's draft Articles on State Responsibility: (1997) ICJ Report 7 paras 50-2, 54.

309 1991 *Convention on Environmental Impact Assessment in a Transboundary Context*, Article 1 (vi).

310 Birnie/Boyle/Redgwell, pp164-168 **n251**.

311 Birnie/Boyle/Redgwell, pp164-168 **n251**.

312 See **n307**. The ICJ found that a state of necessity was, on an exceptional basis, a ground recognised by customary international law for precluding the wrongfulness of an act not in conformity with an international obligation, and relied on the formulation of draft Article 33 of the ILC's draft Articles on State Responsibility: (1997) ICJ Report 7 paras 50-2, 54.

2.2.1.1.2 Southern Bluefin Tuna Case

The United Nations Convention on the Law of the Sea (UNCLOS) establishes a comprehensive legal framework to regulate ocean space, its uses and resources. It provides for the protection and preservation of the marine environment in particular. The Convention is equipped with several channels for the settlement of disputes: the International Tribunal for the Law of the Sea (ITLOS),[313] the International Court of Justice,[314] an arbitral tribunal constituted in the Convention.

In the *Southern Bluefin Tuna Case*, Australia and New Zealand requested the ITLOS to order "that the parties *act consistently with the precautionary principle* in fishing for Southern Bluefin Tuna pending a final settlement of the dispute" (*emphasis* added).[315] The Tribunal relied on scientific uncertainty of the conservation of tuna stock to justify the grant of *provisional measures* to prevent the stock from further depletion. It stated that "the parties should in the circumstances act with *prudence and caution* to ensure that effective conservation measures are taken to prevent serious harm to the stock of southern bluefin tuna".[316](*emphasis* added)

"Scientific uncertainty" regarding provisional measures to be taken to conserve the stock of bluefin tuna is acknowledged in the case.[317] The *Southern Bluefin Tuna* case thus recognises that the measure to grant a provisional measure can be considered as a legitimate precautionary action in international law.[318]

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313 ITLOS, see **n306**.
314 ICJ, see **n296**.
315 Sands Principles, **n241** p275.
316 *Southern Bluefin Tuna Case* (1999) International Tribunal for the Law of the Sea Nos 3&4, para 77. (Southern Bluefin Tuna) **n257**
317 *Southern Bluefin Tuna Case* (1999) International Tribunal for the Law of the Sea Nos 3&4 **n257**, para 79.
318 *Southern Bluefin Tuna Case* (1999) International Tribunal for the Law of the Sea Nos 3&4 **n257**, Judge Laing at para 17.

In conclusion, the above two cases identify three basic elements of PA which are features formed in other operations of the approach: the triggering threshold of the approach, the duty of scientific assessment and monitoring, and the adoption of provisional measures. Furthermore, in the legislation of the WTO SPS Agreement,[319] the adoption of provisional SPS measures[320] is also considered typical application of the PA. Yet the said provisional measure is subject to the accompaniment of procedural requirements, which will be elaborated in the following sections.[321]

2.2.2 WTO

The precautionary approach has been emerging as a guiding norm in international environmental law, yet its application is relatively more reserved and restrictive in the international economic legal system.[322] This is due to the intrinsic limitations of the WTO whose primary goals are the elimination of any possible restriction to trade and the promotion of a global market.

Interpretations of the PA in the WTO are accompanied by ongoing rulings of the Dispute Settlement Body[323] when any new dispute arises. It is therefore necessary to analyse relevant cases and to sketch the outline of the approach applied by the WTO.

We will examine the development of the PA in the WTO first by introducing the

[319] WTO SPS Agreement **n39**, see **sections 2.2.2.2 and 4.2**.
[320] See **section 4.2.2**.
[321] The set of procedural requirements of the adoption of a provisional SPS measure is addressed in **section 2.2.2.2**.
[322] See **section 5.1.1**.
[323] See **section 1.2.1.1.2**.

mechanism of the SPS Agreement[324] and then by reviewing relevant cases in order to take a closer look at the approach practised by the WTO.

2.2.2.1 Appropriate level of health protection

The WTO has acknowledged Members' rights to determine the level of health protection that they consider appropriate in a given situation. The Appellate Body concluded that the SPS Agreement has incorporated precautionary elements,[325] and noted that the PA is reflected in Article 5.7, in the sixth paragraph of the Preamble and in Article 3.3.[326]

Specifically, the SPS Preamble recognises Members' rights to maintain their appropriate level of protection (ALOP)[327] of human, animal or plant life or health".[328] In addition, the Appellate Body in *EC – Asbestos* also stated: "…we note that it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation".[329] They are entitled to determine their level of health protection according to scientific and non-scientific factors.

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[324] Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) **n39**, **sections 2.2.2.2 and 4.2.**

[325] Birnie/Boyle/Redgwell, **n251**. See also: Bermann, G.A. and Mavroidis, P.C. (2006) *Trade and Human Health and Safety*, Cambridge University Press: New York (Bermann/Mavroidis); Scott, J. (2009) *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* Oxford University Press: New York (Scott SPS); Epps, T. (2008) *International Trade and Health Protection: A Critical Assessment of the WTO's SPS Agreement*, Edward Elgar: Cheltenham UK (Epps SPS); Button, C. (2004) *The Power to Protect: Trade, Health and Uncertainty in the WTO* , Hart Publishing: Portland, Oregon, US (Button Power).

[326] *EC – Hormones*, **n247** para 124 "…the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement. We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3…"

[327] States' "appropriate level of protection" (ALOP) is also understood as individual Member's "acceptable level of protection".

[328] The sixth paragraph of the preamble, SPS **n39**.

[329] WTO Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* (*EC – Asbestos*), WT/DS135/AB/R, para 168 **n110**.

Regarding the non-scientific factors in the determination of ALOP, scholars propose that risk regulation should include public perception of risk which consists of citizens' preferences and domestic demand for regulation. These are supposed to be determined by democratic processes.[330] According to Button's research, non-scientific factors represent social and cultural preferences which consist of the desired level of protection, economic feasibility, popular demands for regulations and the effect of regulation.[331] She further distinguishes various societal preferences into cultural traditions and public fear.[332] Public fear towards different risks varies in different cultures. Similarly, Sunstein also describes people and societies as "selective in their fear".[333]

For example, the Europeans are aware of the residue hormones in beef,[334] while the Americans are afraid of Bovine Spongiform Encephalopathy (BSE).[335] Hence the willingness to accept a particular risk varies in different social contexts. The level of unacceptable health protection is supposed to be determined by the community through an objective scientific assessment and a subjective process of public engagement. These examples illustrate that scientific findings are not the sole factor in risk regulations, civilians' social and cultural preferences in different contexts have arisen to play an important role in the policy-making of risk management. Ideally through public

330 See for example: Bohanes, J. (2002) "Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle" 40 *Columbia Journal of Transnational Law* 323

331 Button Power, **n325** pp102-113.

332 Button Power, **n325** pp102-113.

333 See Sunstein, C. (2005) *Laws of Fear: Beyond the Precautionary Principle*, Cambridge, Cambridge University Press pp13-15(Sunstein PP).

334 *EC – Hormones*, **n247**.

335 Bovine Spongiform Encephalopathy (BSE) is commonly known as "mad cow disease", which was first identified in the UK in November 1986. Scientists suspect that BSE had been transmitted from sheep to cow through contaminated feed. BSE attacks the brain and central nervous system of the host before killing it. The most well-known BSE-related disease that affects people is Creutzfeldt-Jakob Disease (CJD). Researchers conclude that the most likely of CJD is eating meat infected with BSE. Like BSE in cattle, CJD is always fatal to human. See: "'Mad Cow Disease' 1980s-2000: How Reassurances Undermined Precaution" in *Late Lessons from Early Warnings: the Precautionary Principle 1896-2000*, European Environment Agency, Copenhagen 2001; see also: UK Food Standards Agency Website at: http://www.eatwell.gov.uk/healthissues/factsbehindissues/bse/#cat237257; Holer, J. and Elworthy, S. "The BSE Crisis: A Study of the Precautionary Principle and the Politics of Science in Law" in Reece, H. (ed) (1998) *Law and Science: Current Legal Issues Volume 1*, Oxford University Press, New York.

engagement, civilians' social and cultural preferences would serve as legitimate grounds to determine an appropriate level of health protection, yet in the scenario of a public health emergency, the time constraints would often limit public engagement.

In addition to choosing its preferred level of health protection, a WTO Member is also allowed to act with prudence on the basis of *minority* opinion. The Appellate Body further expresses its view on minority opinion.[336] This demonstrates that the right of WTO Members to adopt the level of health protection they deem appropriate or acceptable is respected by the WTO. It also illustrates that Members are not obliged to base their decisions on majority scientific opinion. Further, in situations when both majority opinion and minority opinion are not available or do not exist, the PA comes in to play a vital role in decision-making. In other words, the PA is supposed to be activated within the scope of scientific ignorance or scientific uncertainty.

We will now turn our attention to the WTO SPS Agreement,[337] which is the main instrument of the regulation of health risks in WTO law.

2.2.2.2 SPS Agreement

The SPS Agreement is a more elaborate agreement on human health than the health exception provision in GATT.[338] Originally, health concerns in the GATT only serve as a general exception to the rule of free trade; a Member's right to protect domestic public health was not officially recognised in the traditional GATT framework. It was not

[336] WTO Appellate Body Report, *EC – Asbestos*, para 178, **n110**.
[337] SPS Agreement, **n39**.
[338] See **section 4.1.1**.

until the Uruguay Round of negotiations that the WTO introduced the SPS Agreement for a detailed framework of health protection in the WTO mechanism. On the one hand, the SPS Agreement grants Members the power to protect domestic human health issues and food safety by regulating risks arising from "additives, contaminants, toxins, disease-causing organisms in food, beverages or feedstuffs";[339] on the other hand, Members are obliged to follow relevant requirements in this agreement to avoid trade protectionism.[340]

Article 2 of the SPS Agreement affirms a Member's "right" to take SPS measures "necessary for the protection of human, animal or plant life or health", but the adopted SPS measure needs to meet several requirements:

- They must be applied "only to the extent *necessary* to protect human, animal or plant life or health;
- They must be "based on *scientific principles* and …not maintained without sufficient *scientific evidence*";
- They must not "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevails", and
- They must be "applied in a manner which would not constitute a disguised restriction on international trade".

The Preamble of the SPS Agreement recognises Members' right to maintain the appropriate level of health protection.[341] The international approved standard is

[339] Annex A, Article 1(b) SPS **n39**.
[340] Article 2 SPS **n39**.
[341] See **section 2.2.2.1.**

generally recommended,[342] but Members could adopt their ALOP[343] accompanied by scientific justification based on the relevant international standards.[344] However, the SPS Agreement also provides leeway for a higher level of protection under scientific uncertainty by providing the mechanism of provisional SPS measures.[345] In other words, ALOP may be maintained with scientific justification, but provisional SPS measures may also be adopted if certain criteria are met under scientific uncertainty.[346]

The WTO Appellate Body thus concluded that "These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which *level may be higher* (*i.e., more cautious*) than that implied in existing international standards, guidelines and recommendations" (*italics* added).[347] It also noted that in situations where risks are irreversible, for example, risks identified as life-terminating or damaging to human health, acts from *perspectives of prudence and precaution* may be adopted by responsible governments.[348] In other words, in situations concerning irreversible risks, the standard of application on the PA appears to be more relaxed. Joanna Scott hence contends that when the provisional measure is adopted to protect irreversible or life-threatening damage, Members' obligation to the WTO will be lessened.[349]

As the interpretations of the SPS Agreement depend greatly on the rulings of the Appellate Body, it is necessary to examine typical SPS cases in order to interpret the

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342 Article 3.1 SPS. "International standards, guidelines or recommendations" are issued by the following organisations: the Codex Alimentarius Commission relating to food safety; the International Office of Epizootics relating to animal health and zoonoses; the Secretariat of the International Plant Protection Convention relating to plant health, and other relevant international organizations open for membership to WTO Members. See Article 3 Annex A SPS Agreement **n39**.

343 See **section 2.2.2.1** .

344 Article 3.3 SPS.

345 Article 5.7 SPS.

346 Scientific uncertainty can either be insufficiency in scientific evidence or causal relationship. See **section 2.3.1.2**.

347 *EC – Hormones*, para 124 **n247**.

348 *EC – Hormones*, para 124 **n247**.

349 Scott SPS, Preface to Paperback Edition **n325**.

meanings of the legislation with respect to the PA. We will now familiarise ourselves with the procedural requirements of the health mechanism in the SPS Agreement by examining the following cases.

2.2.2.2.1 Japan – Varietals

In *Japan – Measures Affecting Agricultural Products* (*Japan – Varietals*)[350], the United States filed a complaint against Japan relating to the quarantine requirement imposed by Japan for each variety of certain agricultural products (varietal testing requirements", "VTR). Japanese law provided that the prohibition on imported fruits can be lifted when the exporting country uses an alternative quarantine treatment that meets the same level of protection as the import ban. The United States complained that the testing for each variety of apples was lengthy, costly, and caused unjustifiably delay to market US products.[351] In particular, the United States challenged the requirement that VTR was inconsistent with Japan's obligations under the SPS Agreement.[352]

The Appellate Body in *Japan – Varietals* further found that the application of a precautionary SPS measure needs to meet four requirements:

> Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:
>
> (1) imposed in respect of a situation where "relevant scientific information is insufficient"; and

[350] *Japan – Measures Affecting Agricultural Products* (*Japan – Varietals*), WT/DS76/AB/R, 22 February 1999, para 89.
[351] Under the legal regime, after extensive testing, Red Delicious apples from the United States were approved for import in August 1994; however, separate and different testing for different *varieties* of apples including Gala, Granny Smith, Jonagold, Fuji and Braeburn apples was still ongoing in 1998 when the dispute was being heard in a WTO dispute settlement. Reproduced from Dunoff, J.L. "Lotus Eaters: Reflections on the *Varietals* Dispute, the SPS Agreement and WTO Dispute Resolution" in "Trade/Health", (Dunoff Varietals).
[352] Dunoff Varietals, **n351**.

(2) adopted "on the basis of available pertinent information".

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

(1) "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and

(2) "review[s] the … measure accordingly within a reasonable period of time".

These four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7. [353]

In addition to general requirements of a SPS measure such as *necessity*, *scientific justification*, and *non-discrimination* in international trade,[354] this further set of requirements in the adoption of a provisional SPS measure is identified in the *Varietal* case. This set of requirements specifically demand the provisional SPS measure to be applied in situations of insufficiency of scientific information; based on available pertinent information; the adopting state is obliged to have an ongoing duty to gather updated information for monitoring and review.[355] However, the Apellate Body did not explicitely indicate that there should be downstream obligations to change their policy or behaviour if fresh evidence is discovered.

In other words, in *emergency* situations where adequate risk assessment do not exist due to insufficiency of scientific information, Members can still implement provisional SPS measures based on available pertinent information. But in order to ensure the

[353] *Japan – Measures Affecting Agricultural Products* (*Japan – Varietals*), WT/DS76/AB/R, 22 February 1999, para 89 **n350**.
[354] See **section 2.2.2.2**.
[355] See **section 2.2.1.1.2** for the requirement of ongoing monitoring and assessment.

provisional measure does not constitute unnecessary restriction to international trade, it is noteworthy that after the adoption of a provisional measure, Members are obliged to obtain necessary information for a more objective assessment, and review the measure within a reasonable period of time. This has resonance with the duty to monitor the ongoing risks in the *Gabcikove – Nagymaros* case.[356]

In *Japan – Varietal*s, the Appellate Body noted that the VTR was not legitimate within the scope of Article 5.7. In addition, the Appellate Body found that Japan had not sought to obtain addition information, or to review the VTR within a reasonable period of time.[357] The Appellate Body also explained that "what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure".[358]

The *Varietals* case indicates that the adopted PA should be accompanied with a set of requirements which aims to prevent abuse of this mechanism.

It can also be implied that the PA needs to remain adaptive to the characteristics of each particular risk, but that the adopting states are obliged not to cause any unnecessary interference to international trade. The set of requirements indeed serves as an objective safeguard to avoid misuse of the application of the PA in international trade, and it will further be applied in chapter 5 when the PA is argued to be extended to the

356 See **section 2.2.1.1.1**.
357 Appellate Body Report, *Japan – Varietals* **n350** para 92.
358 Appellate Body Report, *Japan – Varietals* **n350** para 93.

realm of IP policy-making.[359]

2.2.2.2.2 EC – Hormones

In *EC – Measures Concerning Meat and Meat Products (EC – Hormones)*,[360] the European Community invoked the precautionary approach to justify its ban on beef imports from the United States and Canada with artificial hormones, where the impact on human health remains uncertain. The United States and Canada challenged the EC's ban on the sale and import of beef treated with growth hormones as a violation of the EC's obligation in the SPS Agreement.

Notably, the EC did not invoke the PA contained in Article 5.7. The Panel and the Appellate Body then had to explore if there could be elements of the PA in the SPS Agreement beyond what is contained in Article 5.7. They concluded that Article 3.3 allows Members to introduce a higher level of health protection than international standards. It is regarded as not only an exception, but as *a conditional right* or an exclusion in WTO law.[361] It serves as an exclusion to Article 3.1 which expects Members to use international standards. This is to say that the act to adopt a higher level of health protection is a right instead of an exception in WTO law. Put more accurately, the Appellate Body noted that:

> Article 3.1 of the SPS Agreement simply *excludes* from its scope of application the kinds of situations covered by Article 3.3 of that Agreement…Article 3.3 recognizes the *autonomous right* of a

[359] See **section 5.3**.
[360] *EC – Hormones*, paras 120-125 **n247**.
[361] Exclusions can also be regarded as conditional rights in WTO law, which enjoy a higher level of legal status than exceptions. See **section 1.2.1.2** for the discussion of excluding provisions and conditional rights in WTO.

> Member to establish such higher level of protection, provided that that Member complies with certain requirements in promulgating SPS measures to achieve that level. (*emphasis* added)[362]

The Appellate Body suggests that the adoption of a higher level of health protection is an *autonomous right* of Members by excluding the application of Article 3.3 from Article 3.1. If Article 3.3 is treated as an exclusion instead of an exception to Article 3.1, the burden of proof would then rest upon the complaining party. In other words, Canada and the United States have to prove that the EC's ban is inconsistent with its obligations in the SPS Agreement.

The Appellate Body also noted that for "…a measure, to be consistent with the requirements of Article 3.3, [it] must comply with, *inter alia*, the requirements contained in Article 5 of the SPS Agreement".[363] Article 5.1 requires Members to base their SPS measures on risk assessment, yet the Panel and Appellate Body both found that the EC ban was not based on a risk assessment, thus constituted a violation to the SPS Agreement. The Appellate Body thus recommended that the EC bring its SPS measures into conformity with its obligations under the SPS Agreement.[364] This case demonstrates that the importance of states need to base their decisions of a health policy on a risk assessment in order to avoid international conflicts.

[362] WTO Appellate Body Report, *EC – Hormones*, para 104 **n247**.
[363] Appellate Body Report, *EC – Hormones*, para 253.
[364] Appellate Body Report, *EC – Hormones*, para 255.

United States – Continued Suspension of Obligations in the EC – Hormones Disputes (*Hormones II*)[365]

After the publication of the Appellate Body Report in *EC – Hormones*, the EC has initiated 17 scientific studies to assess the risks to human health posed by the hormones at issue.[366] However, the United States and Canada have already requested that the DSB[367] to authorise suspension of the concession in relation to the EC.[368]

The EC objected to the levels of suspension of concessions proposed by the US and Canada, but the US and Canada had both obtained authorisation from the DSB to suspend concessions. The EC then notified the DSB of its adoption of *Directive 2003/74/EC* and relevant reports which considered risk assessments that justified the permanent and provisional import prohibitions under the SPS Agreement. The EC then claimed that it had implemented the DSB's recommendations in the original *EC – Hormones* dispute,[369] and considered the suspensions of concessions by the US and Canada as not justified. However, the US and Canada refused to lift the measure taken to suspend concessions or other obligations, thus the EC filed a complaint.[370]

The Appellate Body noted that at the time of adoption of a provisional SPS measure, the Member in question needs to identify the insufficiencies in the relevant scientific

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365 Appellate Body Repot, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (*Hormones II*), WT/DS320/AB/R, adopted 16 October 2008.
366 Appellate Body Repot, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (*Hormones II*), WT/DS320/AB/R **n365**, para 10.
367 See **section 1.2.1.1.2**.
368 Article 22.2 of the DSU (Understanding on Rules and Procedures Governing the Settlement of Disputes) The WTO Agreement has established the WTO Dispute Settlement Body, which includes dispute resolution panels and an Appellate Body, see the Dispute Settlement Understanding (DSU), Annex 2 to the WTO Agreement. See **section 1.2.1.1.2**.
369 *EC – Hormones,* **n247**.
370 Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (*Hormones II*), WT/DS320/AB/R, paras 8-12 **n365**.

evidence, and the steps it intends to take to obtain the additional information to remedy these.[371] It also stated that "In emergency situations…a Member will take a provisional SPS measure on the basis of limited information and the steps which it takes to comply with this obligation to seek to obtain additional information and review the measure will be assessed in the light of the exigencies of the emergency".[372]

In summary, the *Hormones* case indicates the importance of basing a domestic SPS measure on decent risk assessment. The PA is deemed as a *right* not an exception in the SPS Agreement, however, it will not be accepted as legitimate without some sort of scientific evidence, and risk assessment is regarded as a neutral measurement of the approach. In *Hormones II*, the prerequisites to adopt a provisional SPS measure are further interpreted. In addition to the abovementioned requirements set out in *Varietals*, the Appellate Body mentioned that the adopting state needs to identify the insufficiency of scientific evidence and relevant following actions of monitoring and review at the time of adoption. This shows that states' rights to be precautious link with their duties to continue gathering evidence over time.

2.2.2.2.3 EC – Biotech[373]

The controversies on the risks of genetically modified organisms (GMOs) to human health and environment have been reflected in many anti-GMO campaigns.[374] The EC

[371] Appellate Body Report, *Hormones II*, para 679.
[372] Appellate Body Report, *Hormones II*, para 680.
[373] *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (*EC- Biotech*) WT/DS291/R, WT/DS292/R, WT/DS293/R, adopted 29 February 2006. See also: Covelli, N. and Hohots, V. (2003) "The Health Regulation of Biotech Foods under the WTO Agreements" 6(4) *Journal of International Economic Law* 773-795 (Covelli Biotech).
[374] For example: Greenpeace and Friends of the Earth have clearly expressed their concerns about GMO products. See Greenpeace International, "Say No to Genetic Engineering, at: http://www.greenpeace.org/international/campaigns/genetic-engineering ; see also: Friends of the Earth

as a whole and several independent Member States have invoked the PA to adopt a general moratorium on approvals of biotech products imported from Argentina, Canada, and the United States between October 1998 and August 2003. The moratorium was then challenged by Argentina, Canada and the United States.

The EC has two legal instruments to manage the risks of GMOs, the first one is *EC Directive 2001/18*,[375] which governs "the deliberate release into the environment of genetically modified organisms", and the second is *EC Regulation 258/97*, which regulates "novel foods and novel food ingredients". These instruments set out procedures that need to be followed in order to obtain market approval for biotech products. They also allow Member States to provisionally restrict or prohibit the sale of a GMO product which they have "justifiable reasons to consider that a product which has been properly notified and has received written consent…constitute[s] a risk to human health or the environment".[376]

However, the US, Canada, and Argentina complained that the EC Member States did not adopt the provisional measures with scientific justification.[377] They argued that the EC's approval regime was influenced by public opinions instead of being based on scientific assessment.[378] It was claimed that the EC Member States had violated Article 5.1 and 2.2 of the SPS Agreement, and they applied arbitrary or unjustifiable restrictions on international trade.

Europe European GMO Campaign, at: http://www.foeeurope.org/GMOs/Index.htm.

375 The previous *EC Directive 90/220* (*Directive 90/220*).

376 Article 16, *Directive 80/220*, Article 23, *Directive 2001/18*.

377 Nine safeguard measures were at issue in this case: Australia – T25 maize; Austria – Bt-176 maize; Austria – MON810 maize; France – MS1/RF1 oilseed rape (EC-161); France – Topas oilseed rape; Germany – Bt176 maize; Greece – Topas oilseed rap; Italy – Bt-11 maize (EC-163), MON 810 maize, MON809 maize, T25 maize; and Luxembourg – Bt-176 maize. As cited from Epps SPS, p221 **n325**.

378 Epps SPS, p220 **n325**.

It is noteworthy that the Panel did *not* examine some substantial controversies such as whether biotech products are safe or not; whether the biotech products are "like products" with conventional products,[379] or whether the EC has a right to require the "pre-marketing approval of biotech products".[380] The Panel did address procedural issues in relation to Directive 90/220 and 2001/18 being SPS measures within the meaning of the SPS Agreement.[381] The Panel also found that the approval procedures resulted in *undue delay* to market.[382]

The Panel concluded EC's violations of the SPS Agreement by applying a general *de facto* moratorium on the approval of biotech products. The DSU accordingly presumed the EC to have nullified or impaired benefits accruing to the complaining parties, and requested the EC to bring the relevant measures into conformity with its obligations under the SPS agreement.

In the previous *Asbestos* case,[383] the Appellate Body included a consumer's view in examining the "likeness" of products. It was noted that "consumers are, to a greater or lesser extent, not willing to use products containing chrysotile asbestos fibres because of the *health risks associated with them*". (*emphasis* added)[384] However, the Panel of *EC – Biotech* overlooked the factor of "consumers' taste and habits" in selecting GMOs or Non-GMOs products.

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379 See **section 1.2.1.1.1** for the discussion on "like-product" analysis **n110**.
380 *EC – Biotech*, para 8.3, **n373**.
381 *EC – Biotech*, para 8.4, **n373**.
382 *EC – Biotech*, para 8.6, **n373**.
383 *EC – Asbestos*, **n110**.
384 In particular, in the *Asbestos* case, the Appellate Body took the view of consumers into account when considering the "likeness" of products: "consumers are, to a greater or less extent, not willing to use products containing chrysotile asbestos fibres because of the health risks associated with them". It can be implied that products carrying different health risks may not be classified as "like products".

In summary, the Panel avoided to comment on fundamental controversies of a biotech product, but only chose to examine the procedural legitimacy of the legislation within the scope of the SPS Agreement. It is a shame that the Panel did not analyse if the GMOs are "like products" with non-GMOs, it only noted that the undue delay to market caused by the moratorium is regarded as inconsistent with their obligations in the SPS Agreement. It may be fair to say that the Panel avoided further analysis of the "likeness" of GMOs and non-GMOs partly due to the insufficiency of existing scientific evidence. By the same token, the insufficiency of scientific evidence in such circumstances may be the exact legitimate grounds for the invocation of the PA.

2.2.2.3 Conclusion

Though the WTO has gradually recognised the importance of the precautionary approach in environmental and health protection in recent years;[385] its implementation appears to be rather ambiguous and rigid, which is narrower than what we see under the UN regime due to the inherent constrain of promoting free trade.

From the above SPS cases, it can be observed that the implementation of the PA is

[385] See for example: Cheyne, I. (2006) "The Precautionary Principle in the EC and WTO Law: Searching for a Common Understanding" 8(4) *Environmental Law Review* 257-277; Cheyne, I. (2006) "Risk and Precaution in World Trade Organization Law" 40(5) *Journal of World Trade* 837-864; Cheyne, I. (2007) "Gateways to the Precautionary Principle in WTO Law" 19 *Journal of Environmental Law* 155; Goh, G. (2006) "Tipping the Apple Cart: the Limits of Science and Law in the SPS Agreement after Japan – Apples" 40(4) *Journal of World Trade* 655-686; Johns, F. (2008) "The Risks of International Law" 21(4) *Leiden Journal of International Law* 783-786; Young, M.A. (2007) "The WTO's Use of Relevant Rules of International Law: An Analysis of the Biotech Case" 56(4) *International & Comparative Law Quarterly* 907-930; Peel, J. (2006) "A GMO by Any Other Name…Might Be an SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement" 17(5) *European Journal of International Law* 1009-1031; Covelli, N. and Hohots, V. (2003) "The Health Regulation of Biotech Foods under the WTO Agreements" 6(4) *Journal of International Economic Law* 773-795; Priess, H-J and Pitschas, C. (2000) "Protection of Public Health and the Role of the Precautionary Principle under WTO Law: A Trojan Horse before Geneva's Wall" 24 *Fordham International Law Journal* 519; Bohanes, J. (2002) "Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle" 40 *Columbia Journal of Transnational Law* 323; Segger, M-C and Gehring, M.W. (2003) "Precaution, Health and the World Trade Organization: Moving toward Sustainable Development" 29 *Queen's Law Journal* 133.

comparatively restricted by a set of procedural requirements of the SPS Agreement. Fundamental requirements of the PA are identified in *Japan – Varietals*;[386] the *EC – Hormones*[387] case suggests the importance of basing Member's ALOP on a risk assessment, and the *EC – Biotech*[388] case indicates that a Member's domestic provisional SPS measure should not result in the said product's undue delay to market.

In summary, the Appellate Body adopts a cautious approach in the interpretation of the PA. The PA in the WTO regime appears to be restrained by the tension between health and global free trade. Some features of the PA in the WTO regime can be identified as follows:

- The measure needs to be *necessary* to protect human life or health;
- The measure needs to be consistent with the requirements of *non-discrimination* in international trade, and should not cause any undue delay to market;
- *Provisional measure* needs to be adopted in the situation of insufficiency of scientific evidence;
- Provisional measure needs to be based on available pertinent information;
- The adopting state is required to have an on-going duty of monitoring and review, and anticipated steps of review should be identified at the time of adoption. However, the Apellate Body does not explicitly impose a duty to change approach with the discovery of new evidence.

From the *Biotech* case, it can be observed that the WTO does not directly tackle the health concerns raised by a given product; it only serves as a trade mechanism to regulate

386 *Japan – Varietals* **n350**
387 *EC – Hormones* **n247**
388 *EC – Biotech* **n373**

the free movement of health-related commodities. Under the current framework, products with potential concerns of uncertain impact to human life or health will not be banned in the first place without scientific evidence. In other words, food is assumed not harmful to human health unless proven otherwise.[389]

However, from past experience, many harmful effects with scientific evidence are proved in hindsight. For example, the European Environment Agency has identified twelve "late lessons" from early warnings including the regulations regarding X-rays, asbestos, Sulphur dioxide, chemical contamination, Tributyltin (TBT), Hormones as growth-promoters, mad-cow disease, and so on.[390] Scientific justification for regulations or banning comes after the product entered the market. Unfortunately, the damage is usually irreversible. This is where the PA comes to play a vital role to cover the gap of scientific uncertainty or scientific ignorance before the scientific justification of regulation is completed.

In conclusion, the development of the PA is limited in WTO law, and its function appears to be less than satisfactory in the regulation of the risks to human health. The WTO is inhibited by its limitation of being the main endorser of free trade;[391] therefore any potential restriction to free trade will be substantially restrained. On the other hand, the development of the PA is more vivid and prosperous in the European Union (EU). We now turn our attention to the PA applied in the EU.

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[389] Baetens, F. (2007) "Safety until Proven Harmful? Risk Regulation in Situations of Scientific Uncertainty: the GMO Case" 66(2) *Cambridge Law Journal* 276.

[390] See, for example: European Environment Agency, *Late Lessons form Early Warnings: the Precautionary Principle 1896-2000*, Environmental Issue Report, No 22, Copenhagen 2001(Late Lessons).

[391] See **section 5.1.1**.

2.2.3 European Union

The European Union (EU) or the previous European Community (EC) is the main endorser of the precautionary principle.[392] The word "principle" instead of "approach" is preferred in order to suggest that the employment of "precaution" enjoys a stronger assertion in the EU domain than in other areas. We would thus follow the EU's preference of the term "precautionary principle" (PP) in this section.

The precautionary principle was first developed from environmental protection in *Action Programmes on the Environment* from 1973 to 1992,[393] and following the regulations of new chemicals such as pesticides and antibiotics,[394] wild life,[395] pollution,[396] growth hormones in cattle,[397] and GMOs.[398] The precautionary principle also received recognition in international treaties in environmental protection by the EU.[399] The EC *Communication on the Precautionary Principle* (*EC Communication*)[400] and the Court of First Instance (CFI) of the European Court of Justice (ECJ) have suggested that precaution

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[392] See, for example: Christoforou, T. "The Precautionary Principle in European Community Law and Science" in Tickner, J.A. (ed) (2003) *Precaution, Environmental Science and Preventive Public Policy*, Island Press, Washington DC, US; Tait, J. (2001) "More Faust than Frankenstein: the European Debate about the Precautionary Principle and Risk Regulation for Genetically Modified Crops" 4(2) *Journal of Risk Research* 175-189; Nucara, A. (2003) "Precautionary Principle and GMOs: Protection or Protectionism?" 9(2) *International Trade Law & Regulation* 47-53; Coleman, L.O. (2002) "The European Union: An Appropriate Model for a Precautionary Approach?" Winter, 25 *Seattle University Law Review* 609.

[393] See Trouwborst Evolution n 687 **n206**.

[394] *Directive 67/548 on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Relating to the Classification, Packaging, and Labelling of Dangerous Substances* (1967); *Directive 79/831* (1979); *Council Decision 80/372 Concerning CFCs in the Environment* (1980); Directive 80/778; Regulation 2821/98 forbade the use of several antibiotics in animal feed.

[395] *Directive 79/409 Relative to the Conservation of Wild Birds* (1979); *Directive 92/43 Concerning the Conservation of Natural Habitats and Wild Fauna and Flora* (1992).

[396] *Directive 91/271 Urban Waste Water Directive* (1991); *Directive 96/61 on Integrated Pollution Prevention and Control (IPPC)* (1996).

[397] *Directive 81/602* (1981); *Directive 88/146* (1988); *Directive 88/299* (1988).

[398] *Directive 90/219 on the Contained Use of Genetically Modified Micro-Organisms*; *Directive 90/220 on the Deliberate Release into the Environment of Genetically Modified Organisms*; *Directive 98/81 on the Contained Use of Genetically Modified Micro-Organisms* (1998).

[399] *Convention for the Protection of the Ozone Layer* (1985); *Protocol on Substances that Deplete the Ozone Layer* (1987); the London *Amendments to the 1985 Convention for the Protection of the Ozone Layer and the 1987 Protocol on Substances that Deplete the Ozone Layer*; the *OSPAR Convention*, the *Climate Change Convention*, the *Biodiversity Convention*, and the *Bergen Declaration*. Cited from Trouwborst Evolution, p147 **n206**.

[400] *EC Communication* **n299**. See **section 2.2.3.2**.

applies to all EU policies as a "central plank" of Union policy.[401]

More recently, since the presentation of the Green Paper on the *General Principles of Food Law in the European Union* in 1997 and the Bovine Spongiforme Encephalopathy (BSE) crisis,[402] the EU comprehensively adopts the precautionary principle from the perspective of consumer health in the regulation of food safety.[403] Specifically, the *Codex Committee* on General Principles of the *Codex Alimentarius* Commission states that the precautionary principle might be extended to food safety aspects.[404] Streinz thus comments that the precautionary principle has been extended from the law of public security and environmental law to national and European food law.[405] In particular, the precautionary principle has been established as one of the basic principles in food law in Article 7 of the *Regulation No 178/2002* of the European Parliament and of the Council (Basic Regulation). Article 7 stipulates that:

> In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

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401 *Communication COM (2000) 1*, p12 **n299**; *Alpharma Inc. v Council of the EU* (2002), Case T-70/99, Judgment of the Court of First Instance (Third Chamber), 11 September 2002 (*Alpharma v Council*), at para 135.

402 Bovine Spongiform Encephalopathy (BSE), **n335**.

403 *Green Paper on the General Principles of Food Law in the European Union* (1997) and its Communication on Consumer Health and Food Safety; *Regulation 258/97* of the European Parliament and the Council on novel foods and novel food ingredients (1997); *European Parliament Resolution on the Green Paper on the General Principles of Food Law in the European Union* (1998); *Directive 98/81 on the Contained Use of Genetically Modified Micro-Organisms* (1998); *Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EC* (2001), and *Regulation 1829/2003 on Genetically Modified Food and Feed* (2003). See also: Streinz, R. (1998) "The Precautionary Principle in Food Law" 8 *European Food Law Review* 413.

404 *Codex Alimentarius*, **n36**. Streinz, R. "Risks Decisions in Cases of Persisting Scientific Uncertainty: the Precautionary Principle in European Food Law" in Woodman, G.R. and Klippel, D. (eds) (2009) *Risk and the Law*, Routledge-Cavendish, New York, pp54-55, (Streinz Risk).

405 Streinz Risk , **n404**, pp54-55.

In paragraph 2 of Article 7, it identifies some basic factors in determining the application of the precautionary principle by stating:

> Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

We can find resemblance between this article and the WTO SPS Agreement[406]: Members' right to adopt a higher level of health protection than the international standard is respected; Member States enjoy discretion in determining the appropriate level of health protection in customary international law. They both suggest the precautionary principle should be based on available information; it needs to be adopted on a provisional basis and needs to be reviewed within a reasonable period of time; it needs to be no more restrictive of trade than is required to achieve an appropriate level of health protection, and the adopting state is obliged to conduct a "more comprehensive risk assessment" after invocation. Particularly, the former article further identifies the element of "proportionality", "technical and economic feasibility" and other factors regarded as legitimate. Other legitimate factors are generally referred to as non-scientific factors which include different cultural contexts and civilians' preferences.[407]

406 SPS Agreement, see **section 2.2.2.1 n39**.
407 See **section 2.2.2.1**.

We now examine the current practice of the precautionary principle in the EU and relevant cases in order to get a better grasp of the more active application in the protection of human health and food safety.

2.2.3.1 Appropriate level of health protection

The EU acknowledges that the Union has the right to establish the appropriate level of environmental protection. Specifically, the Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (Treaty on the Functioning of the European Union, TFEU)[408] incorporates the precautionary approach into a high level of safety and consumer protection in order to safeguard human health and environment under the eclipse of scientific progression. For example, the TFEU consists of provisions introduced by the *Maastricht Treaty* which states:

> Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on *the precautionary principle* and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay…In preparing its policy on the environment, the Union shall take account of available scientific and technical data,…the potential benefits and costs of action or lack of action…[409]

[408] Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (Treaty on the Functioning of the European Union, TFEU), at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0047:0200:EN:PDF

[409] Article 191 TFEU.

Moreover, with regard to the level of protection, the TFEU provides that:

> The Commission, in its proposals envisaged in paragraph 1 concerning *health, safety, environmental protection and consumer protection*, will take as a base *a high level of protection*, taking into account in particular of any new development based on scientific facts. (*emphasis* added)[410]

The TFEU acknowledges that "human health" is included in the context of environmental protection which shall be based on the precautionary principle and that preventive action should be taken to avoid environmental damage.[411] Member States of the EU are allowed to take *provisional environmental measures* for non-economic environmental reasons.

Scholars have argued for consistency in the regulations of human health and the environment in WTO laws.[412] "Human health" has been included as a policy objective in environmental protection in the EU legal system. For example, in the *EC Directive 2001/18*, the Commission stipulates that the regulations on genetically modified organisms following the precautionary principle should protect "human health and the environment".[413] "Environment" in international environmental law is broadly referred to as including "air, water, land, flora and fauna, natural ecosystem and sites, human health and safety, and climate".[414] Human health is central to the concerns of environmental protection, thus "human health" is intertwined with "environment" and

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410 Article 114 TFEU.
411 Article 191 TFEU.
412 Green, A. and Epps, T. (2007) "The WTO, Science, and the Environment: Moving Towards Consistency" 10(2) *Journal of International Economic Law* 285 (Green/Epps).
413 *Directive 2001/18* of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council *Directive 90/220*, Part A Article 1.
414 The arbitral tribunal in the 2005 *Iron Rhine* case between Belgium and the Netherlands, para 58, cited from Trouwborst, A. (2006) Precautionary Rights and Duties of States, Martinus Nijhoff Publishers, Leiden, The Netherlands (Trouwborst States) **n232**.

the two cannot be separated. It is self-evident that the application factors of the precautionary principle in the protection of the environment can also have recourse to its application in the context of human health.

2.2.3.2 EC Communication on the Precautionary Principle

The EC issued a *Communication on the Precautionary Principle* (EC Communication)in 2000 to assert its implementation, but like many other legal instruments, avoided defining it.[415] The *Communication* only describes the precautionary principle as having a role "to protect the environment" and it proposes several guidelines for applying the precautionary principle, which consist of the principles of:

- Proportionality;
- Non-discrimination;
- Consistency;
- Cost-benefit analysis;
- Examination of scientific developments, and
- Burden of proof[416]

The *Council Resolution on the Precautionary Principle* was later adopted in Nice, December 2000. The *Resolution* calls on the Commission to "incorporate the precautionary principle, where necessary, in drawing up its legislation proposals and in all its actions", and asks Member States to "ensure the precautionary principle is fully recognised in the

[415] *EC Communication* **n299**. See also: McNelis, N. (2000) "EU Communication on the Precautionary Principle" *Journal of International Economic Law* 545-551.
[416] *EC Communication* **n299**.

relevant *international health*, environment and *world trade fora*" (*emphasis* added).[417] The *Resolution* stresses that the precautionary principle should be fully implemented in areas of international health and world trade specifically.

Attention will now be turned to two typical EU cases which recognise Member States' precautionary entitlements regarding the regulation on food safety and human health.

2.2.3.2.1 Pfizer Animal Health v Council of the EU[418]

Antibiotics added to animal feed have been used as growth promoters to improve weight gain and prevent certain diseases in animals. However, scientists have claimed that the practice results in a risk of resistance to the antibiotics in humans through the food chain. Thus some antibiotics cannot be used effectively in human medicine for certain diseases.[419] The WHO has also recommended the immediate or gradual discontinuance of the practice.[420]

Yet there was no scientific proof of the link between the antibiotics concerned and the resistance of those antibiotics in humans when the ban was implemented. As producers of the said antibiotics, Pfizer Animal Health and Alpharma Inc. brought actions for annulment of the regulation before the Court of First Instance; they claimed that the ban was based on political expediency instead of objective scientific analysis, and

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417 *European Council Resolution on the Precautionary Principle*, SN 400/00 ADD 1 20 EN Annex III, adopted 9 December 2000 (Nice) (*EC Resolution*) **n245** paras 24-25.

418 *Pfizer Animal Health v. Council of the EU* (2002), Case T-13/39 and C-329/99, Judgment of the Court of First Instance (Third Chamber), 11 September 2002, paras 135-173 (*Pfizer v Council*). See also: MacMaolain, C. (2003) "Using the Precautionary Principle to Protect Human Health: Pfizer v Council" 28(5) *European Law Review* 723-734;

419 Press Release No 71/02, Judgments of the Court of First Instance in Cases T-13/99 and T-70/99, Press and Information Division, the Court of Justice of the European Communities, 11 September 2002.

420 WHO *Annual Report of the Monitoring/Surveillance Network for Resistance to Antibiotics 2003* at: http://www.paho.org/English/AD/DPC/CD/amr-lima-2004.htm.

the Council had taken an unrealistic approach to pursue "zero risk". They argued further that the link between the use of certain antibiotics as feed additives and an increase in resistance to those antibiotics in humans remains uncertain.[421]

The Court stated that in cases relating to food safety (in particular the BSE crisis),[422] "it is possible to take preventive measures without having to wait until the reality and seriousness of the risks perceived become fully apparent". The Court viewed that the ban was designed to prevent the risks from the probability of the negative effects of the practice. In relation to the procedural requirements, it explained that the adoption of the preventive measure should be triggered by a risk assessment, which consists of a scientific component and a political component. A scientific component is to carry out a risk assessment, and a political component is regarded as "risk management"[423] in which the public authority can get involved in determining the appropriate measure in response to the degree of risk.

In *Pfizer Animal Health v. Council of the EU*, the Court noted that the Community institutions are entitled to take a preventive measure regarding the use of antibiotics as an additive in feedstuffs according to the precautionary principle enshrined in the EC Treaty.[424] The Court also referred to the provisional communication from the Codex Alimentarius Commission[425] of the Food and Agriculture Organisation of the United Nations and the WHO in relation to identifying the level of risk that will adversely affect the interests of human health.[426] The Court of First Instance stated that "where there

[421] Press Release No 71/02, Judgments of the Court of First Instance in Cases T-13/99 and T-70/99, Press and Information Division, the Court of Justice of the European Communities, 11 September 2002.
[422] BSE, see **n335**.
[423] Risk management **n36.**
[424] *Pfizer v. Council*, para 140 **n418**.
[425] Codex Alimentarius **n36,** see **section 3.1.3**.
[426] *Pfizer v. Council*, para 147 **n418**.

is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".[427]

In relation to the implementation of a risk assessment, it identifies a risk assessment as "determining what level of risk is deemed unacceptable" and as "conducting a scientific assessment of the risks".[428] The Court also stated that a Members' right in determining the appropriate level of health protection is provided in the WTO SPS Agreement.[429] It further noted that the Community institutions have the "powers" conferred by the Treaty "in defining the political objectives to be pursued". The Community institutions are obliged to determine the level of risk (the critical probability threshold of adverse effect on human health) to ensure a high level of human health protection[430]

It concludes that "under the precautionary principle the Community institutions are entitled, in the interests of human health to adopt, on the basis of as yet incomplete scientific knowledge, protective measures which may seriously harm legally protected positions, and they enjoy a broad discretion in that regard".[431]

Relevant cases will also be discussed below with analysis of elements of the precautionary principle.

[427] *Pfizer v. Council*, para 139.
[428] *Pfizer v. Council*, para 149.
[429] *Pfizer v. Council*, para 150.
[430] *Pfizer v. Council*, paras 151-152.
[431] *Pfizer v. Council*, para 170.

2.2.3.2.2 Alpharma Inc. v Counil [432]

In *Alpharma Inc. v Council*,[433] the Court again stressed that the PP is one of the principles on which Community policy on the protection of human health and environment is based.[434] The Court also reaffirmed that the Community Institutions have the "right and obligation" to adopt protective measures they deem appropriate to prevent the risks to human health. The Court emphasised that under the PP, the Community institutions enjoy a broad discretion in their responsibility for defining public health policy and are entitled to adopt protective measures which may seriously harm the interests of human health.[435]

From the above cases, it can be observed that the European Court of Justice ("ECJ") examined the PA from the perspective of Members' powers/rights and obligations.[436] Its rulings reaffirmed that Members enjoy broad discretion in determining appropriate level of health protection, and Members have the powers/rights and obligations to adopt the PA to safeguard public health. In addition, the Court suggested that the measure should be triggered by a risk assessment, which consists of a scientific component and a political component.

However, there is currently no consensus on whether a political component should be included in a risk assessment in international law.[437] Some argue that the subjective element needs to be excluded from a scientific assessment, yet such debates are beyond

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[432] *Alpharma Inc. v Council of the EU* (2002), Case T-70/99, Judgment of the Court of First Instance (Third Chamber), 11 September 2002 (*Alpharma v Council*) **n401**.
[433] *Alpharma v Council*.
[434] *Alpharma Inc. v Council*, para 152.
[435] *Alpharma Inc. v Council*, paras 181 and 318.
[436] See also **section 2.1.2**.
[437] See for example: Motaal, D.A. (2005) "Is the WTO Anti-Precaution?" 39(3) *Journal of World Trade* 483-501, p486 (Motaal Precaution); Cheyne, I (2006) "Risk and Precaution in World Trade Organization Law" 40(5) *Journal of World Trade* 837-864.

the purpose of this work. Besides this debate, its argument of acting from states' rights and obligations echoes scholars' arguments for examining the PA from "States' responsibility" in international law.[438] From the study in previous sections, Trouwborst, Brownsword, and Somsen all contend that the adoption of the PA should be established from the perspective of States' responsibility.[439] In particular, Trouwborst classifies the PA into state's rights and duties considering the impact of the feared threat. If the feared threat is identified as *significant*, then the state may have the *right* to adopt the PA; if the threat is identified as not only "significant" but also "*serious or irreversible*", then the state may have the *duty* to adopt the approach in international law.

In summary, the above cases show that while the causal relationship of adding antibiotics to animal feed and the risks of resistance of human antibiotics is not yet established, the PA is employed to legitimise the ban of using several antibiotics as additives in animal feed. In addition, the Court also stressed that the Community Institutions have the *powers and duties* to adopt the PA to protect public health. The basic elements of the PA can be synthesised as a cumulative list derived from all of the PA discussions so far:

- The adoption of the PA in international law should be established from the view of "*State responsibility*";
- The measure should be *necessary* to protect human life or health;
- The PA is employed within the domain of *scientific uncertainty* or scientific ignorance;
- Non-discrimination to international trade;
- The PA is suggested to be based on a *risk assessment*;
- *Provisional measures* are considered as a means of the PA; however, the adoption of a

[438] See **section 2.1.2**.
[439] See **section 2.1.2**.

provisional measure is suggested to be accompanied with a set of procedural requirements which restrains its use from bringing unnecessary interference to free trade and globalisation;

- The set of procedural requirements of a provisional measure is suggested to include ongoing duties of *monitoring and review* of the measure;
- Non-scientific factors such as *civilians' social and cultural preferences* and *consumers' tastes and habits* should also be taken into account.

2.2.4 Interim conclusion: Limitations of the current precautionary approach

The PA appears to be common sense to the lay public; however, it is often criticised as ill-defined[440] with hindrance to scientific progress and international trade.[441] In addition to the lack of a clear consensus on its definition, PAs in international legal settings are further restricted by trade supremacy and regimes conflict in international law.[442]

2.2.4.1 Trade supremacy in the regulation of uncertain risk

The legal framework for regulating technologies should not be one-size-fits-all, but should be able to reflect the ethical differentiation of technologies in response to their individual implications for society. Legitimate factors to differentiation would include public interests, public policy, national emergency, risk management, and deliberative democracy. These factors are supposed to be weighed against legitimate trade

[440] Peterson, M. (2006) "The Precautionary Principle Is Incoherent" 26(3) *Risk Analysis* 595-601.
[441] See **section 2.3**.
[442] See **sections 2.2.4.1 and 3.3.1**.

objectives on a case by case basis. Yet the concern of risks to human health is often constrained by the primacy of international trade, and the value of free trade surpasses health concerns in the WTO regime. Thus the regulation of uncertain risks is often subordinated to the principles of non-discrimination:[443] products are assumed safe until proven otherwise.[444]

On the one hand, states' discretion on the regulation of health issues is restricted by the universal employment of "international standards", such as the Codex referred to by the SPS,[445] which greatly relies upon scientific evidence in risk management. On the other hand, the establishment of international standards is aimed to be globally applicable; thus this framework of risk management needs to avoid rigidity. It should allow an "ample" or "adequate" margin of safety to be taken by states of different levels of social-economic development.[446] An ample margin of safety to afford the full range of diverse risks to human health, as well as taking into account the flexibilities of individual development and various social-economic backgrounds, should be considered in risk regulation. Therefore, the prevention or reduction of *uncertain risks* to human health ought to be taken into consideration in the protection of public health. Uncertain risks which have the potential to result in *significant* damage to human health should be regarded valid until proven otherwise. The focus on the significance of the potential damage also helps to ensure a proportionate response with respect to any IP rights which might be in play.

For example, the WTO Appellate Body's ignorance of uncertain risks to human health in

[443] See **section 1.2.1.1.1** for the discussion of the principle of non-discrimination.
[444] See **section 2.2.2.2.3**.
[445] See **section 3.1.3** for the Codex Alimentarius; **section 4.2** for the SPS Agreement.
[446] De Sandeleer, N. (2002) *Environmental Principles: From Political Slogan to Legal Rules*, Oxford University Press, New York, United States, p131 (De Sandeleer), p196 **n54**. It is noted that several US environmental statues require protection with an "adequate" or "ample" margin of safety.

failing to address the like-product[447] debate of GMO and non-GMO products in the *Biotech* case implies that the regulation of uncertain risk has not been distinguished in the trade world.[448] It is therefore argued in this work that technologies or products associated with risks to human health *do* pose unique implications to society, thus they should receive differential treatment in order to adopt an ample margin of safety. This is to say that products associated with *significant* risks to human life or health should *not* be categorised as "like products" with other products in international trade. In such case, if the public health risk is derived from harmful products, the IP system may be reflective on the risk by the restriction of the product/technology. By the same token, if the risk is from natural disasters/epidemics, the IP system needs to be reflective on the risk by the promotion of access to the product/technology. (See Figure I. Research parameter: Precaution lens)

Likewise, the IP regime also shows an imbalance of health and trade protection. TRIPS shows a tendency to stress the intact protection of private property rights, while the status of exclusions to IP on grounds of public interests, risks to public health or public policy remains relatively vague in state practice. Yet such legitimate factors which reflect the spirit of public needs would be able to step in to balance rights and obligations of holders and promote the social and economic welfare of IP.[449]

In summary, the function of the PA in the international public health regime should not be eclipsed by such limitations. In order to explore the extent to which the PA should play in the IP regime, we will now turn our attention to the identification of the basic elements of the PA from the analysis of philosophers and lawyers in the following

[447] "Like product" analysis, **n110**.
[448] *EC – Biotech*, **n373**.
[449] Articles 7 and 8 TRIPS. See **sections 1.3.1.2 and 4.3.2.2.1**.

sections.

2.3 Philosophical elements of the precautionary approach

Despite the merit of providing a margin of safety of a PA in public health[450] and environmental protection,[451] its application has been controversial in international trade partly due to the ambiguity of its definition. Fragmentation exists amongst different operations of PAs in international law; therefore, it would be necessary to revisit PAs from philosophical perspectives. We would be able to delineate the classical contour of PAs, and learn different categories and basic features of PAs in the literature. This will help shape a tailored model of the PA in this work.

According to Trouwborst, at least sixteen global and regional environmental treaties and protocols contain reference to the "precautionary principle", "precautionary approach", "precautionary measures" or "precaution" without defining the terms.[452] There are various versions of the PA developed by scientists, philosophers, policy makers, and the lawyers. For example, Sands describes it as: "to provide guidance in the development and application of international environmental law where there is scientific uncertainty".[453] Kriebel *et al.* identify the PA with four central components: "taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation decision making".[454] Moreover, Freestone

[450] See **chapter 3**.
[451] See **section 2.2**.
[452] Trouwborst States, **n232** p22.
[453] Sands Principles, **n241** p267.
[454] Kriebel, D. *et al.* (2001) The precautionary Principle in Environmental Science, 109(9) *Environmental Health Perspective*.

illustrates the essence of precaution as:

> The precautionary approach then is innovative in that it changes the role of scientific data. It requires that once environmental damage is threatened, action should be taken to control or abate possible environmental interference even though there may still be scientific uncertainty as to the effects of the activities.[455]

He further states that "once a risk is identified the lack of scientific proof of cause and effect shall not be used as a reason for not taking action to protect the environment".[456] Perrez further depicts the content of the PA which reflects the recent development in international policy and law as follows:

> If a risk assessment indicates that according to the scientific information available today one cannot exclude the possibility that a certain activity or a certain product may involve unacceptable risk to the environment or, in a certain policy area, to human health, governments may address this potential risk by adopting protecting measures which are intelligible, proportional and coherent with measures adopted in similar situations, and which are not distinguished protectionist restrictions to trade. Moreover, such precautionary measures should be regularly reviewed, and modified in the light of new scientific findings.[457]

Further, Perrez has identified several key elements and criteria relevant to the application of precaution: lack of scientific certainty; precaution as part of risk management; scientific assessment; transparency; intelligibility and review; proportionality; no disguised

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[455] Freestone, D. (1994) "The Road from Rio: Environmental Law after the Earth Submit" 6 *Journal of Environmental Law* 211.
[456] Freestone/Hey **n201**, at 13.
[457] Perrez Regulation, **n252**.

trade restrictions, and in certain policy areas, application to health.[458] He has also noted that the recent development of the application of precaution has been expanded to the protection of human health, such as policy areas of chemicals and waste policies in particular.[459] It is found that the PA has a pervasive influence on health and risk regulation, yet the above descriptions and the trigger threshold of the PA are still in lack of a uniform definition.

There are still numerous definitions of PAs in different contexts in a wide variety of perspectives on risk and sources of risk.[460] Some are simply declaratory while others appear to be more aggressive and demanding of actions. Currently there is no single universal definition of the approach. We will develop a tailored model of the approach after the philosophical and legal analysis in the following sections.

Models of precautionary approaches

In order to examine the PA from philosophical and legal foundations, our discussions will cover the works of both philosophers and lawyers. We will base our following discussion on the models developed by Sandin, Sunstein and Trouwborst, and attempt to interpret and apply the PA in the real world.

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458 Perrez, F.X., "Risk Regulation, Precaution and Trade" in Wuger, D. and Cottier, T. (eds) (2008) *Genetic Engineering and the World Trade System: World Trade Forum*, New York, Cambridge University Press. (Perrez Regulation) **n252**.

459 Perrez, F.X. (2003) "The World Summit on Sustainable Development: Environment, Precaution and Trade – A Potential for Success and/or Failure" 12 *Review of European and International Environmental Law* 12, pp17-18. (Perrez Sustainable)

460 For accounts of more versions of the precautionary principle, see Wiener, J. and Rogers, M. (2002) "Comparing Precaution in the United States and Europe" 5 *Journal of Risk Research* 317, 320-321; Morris, J. "Defining the Precautionary Principle" in Morris, J. (ed) (2000) *Rethinking Risk and the Precautionary Principle* (Butterworth-Heinemann Oxford); Bohanes, J. (2002) "Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle" 40 *Columbia Journal of Transnational Law* 323, 331.

As a philosopher studies the rationale of the PA, Sandin's work of defining the PA has been widely discussed and considered amongst lawyers.[461] His attempt to generalise the formula of various versions of the approach can serve as a foundation for further interpretation. He believes that "the core of the precautionary principle is clearly identifiable, and can be used as a starting point for further discussions".[462] Sandin lists nineteen versions of the precautionary principle with an applied-ethics approach [463]and then proposes the definition of the PA with a simplified formula.[464]

From the perspective of international environmental law, Trouwborst further conducts a detailed legal study on the evolution and the definition of the principle which acts to provide complementary underpinning to Sandin's work.[465] He attempts to define the PA in the context of "a *state's rights and duties*" and thus proposes a formulation of the "Precautionary Tripod". Trouwborst's definition is based on the theme of "*precautionary rights and duties of states*", and he argues that when there are reasonable grounds for concern that significant harm exists, states are deemed to have a customary *right* to act; when the anticipated harm is not only significant but also serious or irreversible, states are considered to have an *obligation* to take action.

Furthermore, Sunstein scrutinises the PA from the perspective of economic analysis of

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461 For example, Sunstein refers to Sandin's definition in Sunstein, C. (2005) *Laws of Fear: Beyond the Precautionary Principle*, Cambridge, Cambridge University Press (Sunstein PP) n9, p16 **n333**; Trouwborst also refers Sandin's work in Trouwborst States p317 **n232**; see also Peterson, M. (2006) "The Precautionary Principle Is Incoherent" 26(3) *Risk Analysis* 595.

462 Sandin, P. (2004) *Better Safe than Sorry: Applying Philosophical Methods to the Debates on Risk and the Precautionary Principle* (Sandin Philosophical Methods), Doctoral Thesis in Philosophy, Royal Institute of Technology, Stockholm, at 23.

463 Sandin, P. (1999) "Dimensions of the Precautionary Principle" 5(5) *Human and Ecological Risk Assessment* 889-907 (Sandin Dimensions).

464 Sandin, P. (2006) "A Paradox out of Context: Harris and Holm on the Precautionary Principle" 15(2) *Cambridge Quarterly of Health Care Ethics* 175-183 (Sandin Paradox).

465 Trouwborst Evolution, **n206**; Trouwborst States, **n232**.

law and argues that it should be transformed into an "Anti-Catastrophe Principle" which emphasises the full range of risk and other side factors, such as cost-benefit analysis, deliberative democracy, and distributive justice.[466] He then provides the definition of the "Anti-Catastrophe Principle" with a "four-if formula".[467] By the Anti-Catastrophe Principle, he also proposes the "Prohibitory Precautionary Approach" (PPA) which favours a flat ban on the product/technology associated with a high probability of a serious harm and the "Information Disclosure Precautionary Approach" (IDPA) which emphasises the duty to disclose fresh evidence to the public by the promoter of a new product/technology.[468]

In order to create a common ground for the definition of thePA, it is necessary to accommodate all the relevant factors relating to the PA in international law, which aim to reconcile health, trade, and IP. Sandin's definition is classic and general; Trouwborst's work formulates the definition from the international public law perspective, and Sunstein's proposal identifies non-scientific factors of the PA in a democratic society. All their models can be complementary and offer new insight into the implementation of the PA in this work.

The definitions of the PA create several categories: this work will examine the PA by major three categories respectively to illustrate some basic characteristics of the approach: the first is "argumentative versions v prescriptive versions" which distinguishes whether different versions require a specific precautionary action to redress a particular risk;[469]

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[466] Sunstein, C. (2005) *Laws of Fear: Beyond the Precautionary Principle*, Cambridge, Cambridge University Press (Sunstein PP) **n333**. See also Sunstein, C. (2009) "Trimming", 122 *Harvard Law Review* 1049 (Sunstein Trimming).

[467] Sandin Dimensions, **n463**.

[468] See **sections 2.3.2 and 2.3.2.2**.

[469] The classification of "argumentative" and "prescriptive" PAs is borrowed from Sandin's definition. See Sandin Dimensions, **n463**.

the second is "prohibitory versions v information disclosure versions" which is developed from Sunstein's Anti-Catastrophe Principle,[470] and the third is "strong versions v weak versions" which can either refer to the triggering threshold or the shift of the burden of proof.

2.3.1 Argumentative v Prescriptive

Sandin classifies the PA into two types: one is an argumentative version and the other is a prescriptive version. The argumentative version of the PA is less problematic than the prescriptive type which prescribes that certain actions should be adopted in order to avoid or decrease risk. Principle 15 of the *Rio Declaration*[471] represents the typical type of the argumentative version which does not demand that certain precautionary action should be adopted, and only functions as a declaratory and directive tool.

On the contrary, the prescriptive versions of the PA focus on the "actions aiming at the prevention of something that is undesirable but not certain to happen". This version of the PA prescribes certain actions that would be interpreted as precautionary to the uncertain risk, and can be interpreted with the four dimensional "if-clause". Sandin contends that the PA can be expressed in the if-clause:

> *If* there is (1) a threat, which is (2) uncertain, then (3) some kind of action (4) is mandatory.[472]

He proposes that the prescriptive formulations of the PA share four common

[470] The classification of "prohibitory" and "information disclosure" PA is borrowed from Sunstein's work on the "Anti-Catastrophe Principle". See Sunstein PP, **n333** p118.
[471] Rio Declaration **n286**.
[472] Sandin Paradox, **n464**.

elements[473]: (1) the threat dimension; (2) the uncertainty dimensions; (3) the action dimension, and (4) the command dimension.

With the exception of the argumentative version of the PA which does not require action to respond to a threat,[474] he argues that all the other different versions of the PA can be recast into the "four-dimensional if-clause" formula, although each element may vary in precision and strength.[475]

Like Sandin's approach, Trouwborst also identifies some key elements of the PA. He refers to the three legs of the "Precautionary Tripod": (1) a threat of harm, (2) uncertainty, and (3) action.[476] Specifically, Trouwborst attempts to define the precautionary action in the context of *rights and duties of states* in international law.[477] According to his argument, if the threat of harm is designated as "serious or irreversible", and where the precautionary action is deemed as a duty and right of the states, the precautionary action is thus identical to Sandin's formulation as a mandatory measure. Trouwborst designates the precautionary action to be within the domain of the "rights and duties of states" when the threat of harm is "serious or irreversible" to the environment. On the other hand, if the threat only crosses the "significant" threshold, the precautionary action then only falls within the domain of "right of states" to adopt measures toward the risk.

Trouwborst's perspective on the definition of the PA suggests that the strength of the precautionary action needs to be adaptive according to the extent and seriousness of the

473 Sandin Dimensions, **n463**.
474 Paragraph 15 of the *Rio Declaration* is the typical version of argumentative PA **n286**.
475 Sandin Dimensions, **n463**. "Strength" means degree of cautiousness.
476 Trouwborst States, **n232** p30.
477 Trouwborst States, **n232**.

particular risk. Once the risk is identified as *significant*, states are entitled to take precautionary action in order to safeguard the environment and human health. His argument is a more sophisticated tool of the prescriptive version of PA in international law. An argumentative version of the PA, which may only be good for lip service, would not be considered in this work due to efficacy concerns. Therefore, we will further adopt Trouwborst's argument to interpret *the entitlements of states to adopt the PA in IP policy-making* in a public health emergency in the following chapters.[478] Attention will be turned to more detailed discussion on the basic elements of the PA, including threat of harm, uncertainty and action, developed from Trouwborst's work in the following paragraphs.

2.3.1.1Threat of harm

Versions of the formulation of the PA exist which do not set out any minimum standard of the anticipated harm, and thus becomes one of the main critiques that the PA could be used as protectionism in international trade. For example, some formulations regarding the degree of harm to health and environment only refer to the vague wording of "unacceptable risk" or "unreasonable and otherwise unmanageable risk",[479] which may result in arbitrary use of this approach.

In order to set apart insignificant risks of harm which consist of inapplicable conditions to invoke the PA, Trouwborst seeks to distinguish "harm that embodies at least some

[478] See **section 5.3**.

[479] Para 111(a) *Land-Based Activities Action Programme* (1995) applies the precautionary principle to radioactive waste storage by outlawing such storage near the coastal and marine environment unless the absence of any "unacceptable risk" is demonstrated. In para104 (b) (i) of the same document, it suggests that priority ought to be given to phasing out chemicals that pose "unreasonable and otherwise unmanageable risks".

degree of significance and harm that does not".[480] It is therefore suggested that the PA cannot be assumed to come into play when the "projected harm is insignificant".[481]

2.3.1.1.1 "Significant" harm as a threshold

Trouwborst suggests that the PA is of relevance only when the feared harm is identified as *significant* and that this should then be considered as a minimum threshold.[482] "Significant" is defined as "extensive or important enough to merit attention" in the dictionary.[483] Some commentators explain that the standard of significance is met when harm is not minor, nor trivial. Some locate it in between "serious" and "minor trouble to be tolerated".[484] The International Law Commission (ILC)[485] has noted that the harm must be "tangible" and "appreciable" but needs not amount to the level of being "substantial".[486] The ILC later describes a threshold of significant transboundary harm as "real" and measurable, but drawn lower than "substantial" or "serious" harm.[487] Trouwborst then concludes that *tangible*, *appreciable* and *measurable* harm instead of minor or trivial harm falls within the context of precaution. This work will also opt for "significant harm" as the minimum trigger threshold of the PA in IP in order to avoid abuse of this approach.

480 Trouwborst States, p47.
481 Trouwborst States, p50.
482 Trouwborst States, p50.
483 Concise Oxford English Dictionary (11th edition) Oxford University Press, Suffolk, UK, p1341.
484 Trouwborst States, pp50-51.
485 International Law Commission (ILC)
486 The commentary to the 1994 International Law Commission *Draft Articles on the Law of the Non-Navigational Uses of international Watercourses*, the commentary to Article 3 paras 13-15 and the commentary to Article 4, para 7.
487 International Law Commission, 2001; commentary to Article 2(a) of the *Draft Articles on Harm Prevention*, para 4.

2.3.1.1.2 "Serious or irreversible" harm as a threshold

One interpretation by the UK government of Principle 15 of the *Rio Declaration*[488] states that: "it is not acceptable just to say 'we can't be sure that serious damage will happen, so we'll do nothing to prevent it'".[489] The UK government declares that the PA "applies particularly where there are good grounds for judging either that action taken promptly at comparatively low cost may avoid more costly damage later, or that irreversible effects may follow if damage is delayed".[490] It suggests that precautionary action needs to be taken when irreversible damage exists.

In the *Gabcikovo – Nagymaros* case,[491] Hungary contended that the impending damage to the Hungarian environment due to the hydrological project was "irreparable and enormous".[492] Similarly, in the *Southern Bluefin Tuna* cases,[493] Australia and New Zealand claimed that the harm which the Japanese experimental fishing programme threatened the tuna stock with, caused "serious or irreversible damage to the environment".[494]

It is noteworthy that in addition to "significant", "serious" or "irreversible" harm, the ILC also mentions the term "grave" as a standard of harm higher than "serious".[495] It

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488 Rio Declaration **n286**.

489 HM Government, *A Better Quality of Life: A Strategy for Sustainable Development for the United Kingdom*, May 1999, at: http://collections.europarchive.org/tna/20080530153425/http://www.sustainable-development.gov.uk/publications/uk-strategy99/index.htm.

490 White Paper: "This Common Inheritance: Britain's Environmental Strategy", September 1990, cited in "Trouwborst States", p58, **n232**. See also: Haigh, N. "The Introduction of the Precautionary Principle into the UK", in O'Riordan, T. and Cameron, J. (eds) (1994) *Interpreting the Precautionary Principle*, London, pp229-251.

491 *Gabcikovo – Nagymaros* case, see **section 2.2.1.1.1 n307**.

492 *Application of the Republic of Hungary v The Czech and Slovak Republic on the Diversion of the Danube River*, para 31, cited from "Trouwborst Evolution", p163, **n206**. See also: *Principles of International Environmental Law IIA: Documents in International Environmental Law*, Sands, P. *et al.* (eds) Manchester 1994, pp693-698.

493 *Southern Bluefin Tuna* cases, see **section 2.2.1.1.2 n257**.

494 Statements of Claim of Australia and New Zealand, *Southern Bluefin Tuna* case, International Tribunal for the Law of the Sea (ITLOS), 15 July1999, paras 63-66, **n257**.

495 International Law Commission, Commentary on Article 1 of the *Draft Articles on Harm Prevention*, 2001, para 2.

can be further concluded that "'serious' is located between 'significant' and 'grave'."[496] However, the triggering thresholds most required are either "significant" harm or "serious or irreversible" harm; "grave" harm is not officially referred in the formulation of the PA.[497]

In summary, the PA should be triggered when the risk from a particular harm is proved to be crossing the "significant" threshold; any risk that is identified as *de minimis* [498] can be disregarded. Further, if the risk is objectively identified as "serious or irreversible harm", then the legitimacy to trigger the PA will increase. In other words, the legitimacy of the precautionary action depends on the extent or the gravity of the potential harm: when the unknown risk is identified as causing "serious or irreversible" harm to human health or the environment, states are not only entitled but may also be required[499] to take precautionary measures to protect their citizens and the environment under their responsibility in international law.[500] Therefore, this work will recommend that "significant harm" as the trigger threshold of the PA in IP. If the harm is identified "serious or irreversible", then the legitimacy of the precautionary action will increase.

A question arises here as to what extent it is left to a state to determine for itself what an *unacceptable* degree of risk is, and when, if ever, a line can be drawn which can be stated with relative certainty to be an objectively unacceptable degree of risk. The level of unacceptable risk should be established through an objective risk assessment and a

496 Trouwborst States, p64, **n232**.
497 However, in the *Gabcikovo – Nagymaros Case*, the ICJ noted that Hungary did not prove a "real, 'grave, and 'imminent' 'peril' existed". See **section 2.2.1.1.1**.
498 Sandin, P. (2005) "Naturalness and *De Minimis* Risk" 27(2) *Environmental Ethics* 191-200 (Sandin De Minimis Risk).
499 See **section 2.3.1**
500 See **section 2.1.2**.

subjective element of risk communication, which focuses on the public's right to information. It is embodied in stimulation of public debates which will be addressed in the following section.[501] This might arguably also be the place where we draw a line between the right of a state to act and the duty of a state to act.

2.3.1.2 Uncertainty

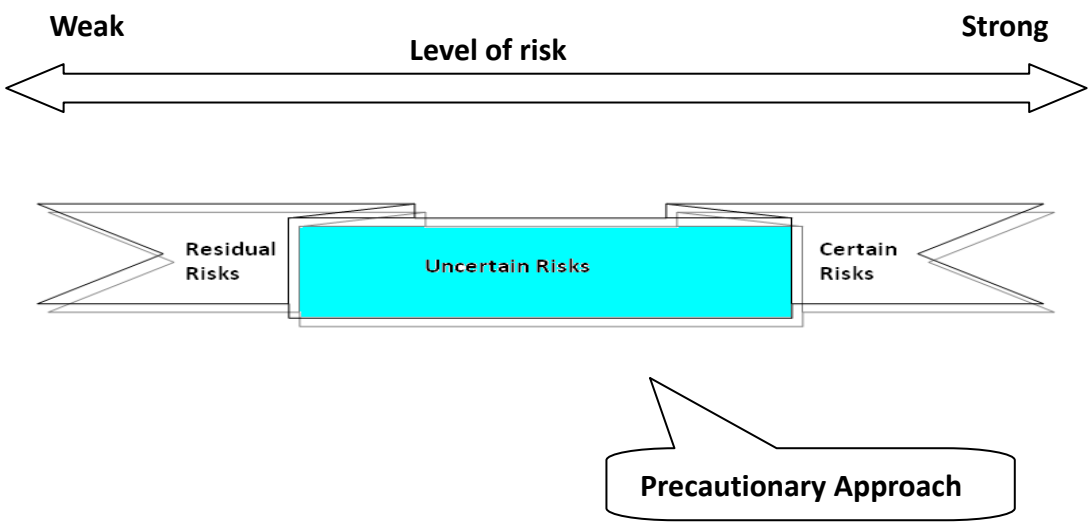
In order to trigger the PA, there must be a basic element of scientific uncertainty. It is of vital importance to set the triggering threshold of the PA on an appropriate level of risk.

De Sandeleer identifies different levels of risks by building a hierarchy of risks:[502]

- Residual risks: these are hypothetical risks, and can be ignored and do not require regulatory measures
- Uncertain risks: this is under the domain of the PA
- Certain risks: this is within the scope of prevention

[501] See **section 2.3.2**.
[502] De Sadeleer, **n54** pp156-161.

Figure 2.3.1.2 Level of risks and the precautionary approach



The aim of a precautionary measure is to invoke the PA in situations of uncertain risks (See Figure 2.3.1.2). Residual risks refer to risks that are small in probabilities which can be ignored and can not be applied in the precautionary model.[503] If the risks are identified as certain, then the prevention principle[504] will play a role in risk management.

The European Commission comments on scientific uncertainty as follows:

> Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationships employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis.[505]

Commentators have further distinguished epistemological uncertainty from ontological

[503] Sandin, P. (2005) "Naturalness and *De Minimis* Risk" 27(2) *Environmental Ethics* 191-200 **n498**.
[504] *Cf*: See **section 2.2** for discussion on prevention v. precaution.
[505] *EC Communication*, **n299**.

uncertainty.[506] Epistemological uncertainty refers to uncertainty due to lack of information, while ontological uncertainty is related to uncertainty due to complexity and variability. However, there appears to be no indication in legal instruments of specific classifications of uncertainty. For example: Principle 15 of the *Rio Declaration*[507] refers to a "lack of full scientific certainty". Similarly, the EC *Communication on the Precautionary Principle* indicates that the precautionary principle is related to situations "where scientific information is *insufficient*, *inconclusive*, or *uncertain*".[508] (*italics* added)

The uncertainty of the cause and effect relationship is one dimension of scientific uncertainty. In *Pfizer Animal Health v EC*[509] and *Alpharma Inc. v EC*,[510] it is noted that there was no scientific proof of any link between the prohibited antibiotics used in animal feedstuffs and the resistance of those antibiotics in humans. Under the circumstance of no available scientific assessment on the causal relationship, the European Council adopted the PA and concluded that the ban was not inappropriated.[511]

However, the risk of harm needs to be a real risk and "more than hypothetical or [a] remote possibility of such harm".[512] In the *MOX Plant* case,[513] Ireland challenged the legitimacy of the authorisation by the British government of a new nuclear fuel processing facility at the Sellafield site on the Irish Sea coast. Ireland claimed that the PA imposed the United Kingdom to "apply caution, and take preventive measures even

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506 See Trouwborst States, pp73-79, **n232**.
507 Rio Declaration **n286.**
508 *EC Communication*, **n299**.
509 See **section 2.2.3.2.1 n418**
510 See **section 2.2.3.2.2 n401**
511 See **section 2.1.1.3.3**.
512 Writing Response of the United Kingdom, para 147, 15 November 2001.International Tribunal for the Law of the Sea (ITLOS) No 10, *MOX Plant Case* (Request for Provisional Measures) (*Ireland v United Kingdom*).
513 International Tribunal for the Law of the Sea (ITLOS) No 10, *MOX Plant Case* (Request for Provisional Measures) (*Ireland v United Kingdom*) **n512**.

where there is no conclusive evidence" of a causal relationship between the operation of the MOX plant and marine environmental hazards. The UK contended that it is "generally accepted that [the PA] can operate only where there are some reasonable grounds for concern". It was therefore argued that the Irish allegation did not pass the test, and there were "no reasonable grounds for believing" that the MOX plant would cause unacceptable changes to the environment of the Irish Sea due to the risks involved being classified as "infinitesimally small".

The European Court of Justice (ECJ) also stresses that precautionary measures cannot be adopted on "purely hypothetical considerations", on "mere conjecture", or be taken "solely on the basis of rumors".[514] The ECJ notes that the Community institutions cannot take a hypothetical approach to risk and cannot make their decision on a "zero-risk" basis.[515] Similar to the implications from the *MOX Plant* case and the abovementioned ECJ cases,[516] Motaal states that the precautionary action needs to be based on "some sort of scientific foundation", and "cannot be based on completely unsubstantiated or unresearched fears".[517] In the WTO regime, the Appellate Body has confirmed that evaluation of the risks of harm can either be expressed quantitatively or qualitatively,[518] and that the report of risks is based on the right to act on the basis of "minority" scientific evidence.[519]

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514 *Alpharma Inc. v Council of the European Union*, Case T-70/99, Judgment of 11 September 2002, paras 155-156, **n401**; *Monsanto Agricoltura Italia and Others*, Case C-236/01, Judgment of 2003, para 106, **n221**; *Commission of the European Communities v Kingdom of Denmark*, Case C-192/01, Judgment of 23 September 2003, para 49; *Commission of the European Communities v French Republic*, Case C-24/00, Judgment of 5 February 2004, para 56.

515 *Pfizer Animal Health v Council*, Case T-13/99, Judgment of 11 September 2002, para 152, **n418**. *Cf.* The WTO accepts that Members can adopt a level of protection on a zero-risk basis. See WTO Appellate Body Report, *Australia – Measures Affecting the Importation of Salmon* (*Australia – Salmon*), WT/DS18/AB/R, adopted 20 October 1998, para 125.

516 *MOX Plant* case, **n512**.

517 Motaal Precaution, at 488, **n437**.

518 WTO Appellate Body Report, *Australia – Measures Affecting the Importation of Salmon* (*Australia – Salmon*), WT/DS18/AB/R, adopted 20 October 1998, paras 123-124.

519 WTO Appellate Body Report, *EC – Hormones*, para 194, **n247**.

In summary, the application of the PA is suggested to be within the domain of uncertain but nonetheless real risks. The PA could be triggered in the circumstances of scientific uncertainty where the threat of harm has crossed the 'significant' threshold. (See Table 2.3.1.2.)

Table 2.3.1.2 The domain of the Precautionary Approach

<table>
<tr><td colspan="2">Risks
Harm</td><td>Residual risks</td><td>Uncertain risks</td><td>Certain risks</td></tr>
<tr><td colspan="2">Hypothetic;
Minor;
Trivial</td><td></td><td></td><td></td></tr>
<tr><td rowspan="4">Real;
Tangible;
Appreciable;
Measurable</td><td>Significant</td><td></td><td rowspan="4">Precautionary
Approach</td><td rowspan="4">Prevention
Principle</td></tr>
<tr><td>Substantial</td><td></td></tr>
<tr><td>Serious/ irreversible</td><td></td></tr>
<tr><td>Grave</td><td></td></tr>
</table>

Scientific uncertainty is a significant factor in the precautionary formulation. The adopting state's duty to review[520] is particularly relevant in updating the situation of scientific uncertainty. If the risk is proved positively harmful after the discovery of ongoing monitoring and review, then the PA should be adapted as a permanent ban; if proved otherwise, the approach should be abolished in due course.

In addition to the criteria of threat of harm and uncertainty, the element of "action" is

[520] See **section 5.3.3**.

also highlighted as an elementary feature of a prescriptive PA, which distinguishes itself from an argumentative PA.

2.3.1.3 Action

In Sandin's formulation, precautionary action is mandatory in prescriptive versions. Likewise, Trouwborst argues that states should have a customary right to act when there are reasonable grounds for concern that significant harm exists, and an obligation to take action when the harm is not only significant but also serious or irreversible. The EU Court of Justice also notes that "a public authority may be *required* to take action even before adverse effects have become apparent" in a situation where the Community institutions make the provisional withdrawal of the authorisations for antibiotics.[521] (*italics* added)

In addition, from past precedents in international law, precautionary actions are required to be effective and proportionate. Effectiveness ensures that the relevant purpose is served. In the *Southern Bluefin Tuna*[522] Order, the ITLOS[523] suggested parties "act with prudence and caution to ensure that *effective* conservation measures are taken to prevent serious harm to the stock of southern bluefin tuna.[524] *Proportionality* ensures that the means can be well-adjusted to fit the purpose. For example, the International Chamber of Commerce states that precautionary action must be "proportionally responsive" to the environmental concern at issue.[525]

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[521] *Alpharma Inc. v Council*, Case T-70/99, Judgment of 11 September 2002, para 355, **n401**.
[522] *Southern Bluefin Tuna*, see **section 2.2.1.1.2 n257**.
[523] ITLOS, **n306**.
[524] Order of 27 August 1999, para 77, **n257**.
[525] International Chamber of Commerce Commission on Environment, A Precautionary Approach: An ICC Business Perspective, 1997, as quoted in Trouwborst States, p150, **n232**.

The European Court of Justice has often emphasised the importance of proportionality in the implementation of the PA by choosing the least restrictive precautionary measure.[526] Under the current trend of globalisation, precautionary measures stipulated in international legal instruments are frequently required to be the least restrictive to international trade or traffic.[527]

Types of precautionary actions

There are many forms of precautionary actions. Typical precautionary measures include precautionary bans,[528] the employment of safety margins,[529] carrying out detailed research on the risk and monitoring,[530] reversal of the burden of proof to the one who promotes a new technology,[531] prior information and consultation, liability and compensation rules, the use of economic instruments like subsidies or taxes, and participatory decision-making procedures.[532] The range of measures taken by states in response to the PA is very wide; Trouwborst further contends that "essentially every type

[526] For example, see para 186 of Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, NS t-141/00, Judgment of the EU Court of First Instance of 26 November 2002.
[527] See also **section 5.3.2.2.1**.
[528] For example: The Moratorium on commercial whaling adopted by the International Whaling Commission (IWC) in 1982; the moratorium on pelagic driftnet fishing agreed by the UN General Assembly; the European Union's *de facto* precautionary moratorium on the marketing of genetically modified food products from 1998, and the precautionary restrictions imposed on emissions of chlorofluorocarbons under the *Montreal Protocol* in order to prevent further depletion of the ozone layer.
[529] For example, the application of ample safety buffers in the setting of catch levels and fishing effort limitations where uncertainty is great; the NAFO Fisheries Commission acknowledges "The more uncertain the stock assessment, the greater the buffer zone should be" in its *Precautionary Approach Framework*. The Framework distinguishes between five different states – the safe zone, the overfishing zone, the cautionary zone, the danger zone and the collapse zone – and sets out the appropriate precautionary management action for each.
[530] For example: the performance of an environmental impact assessment (EIA) and monitoring is required during the period when risk exists. The European Council called on EU member states and the Commission to "attach particular importance to the development of scientific expertise". WTO Members must "seek to obtain the additional information necessary for a more objective assessment of risk" after adopting a provisional SPS measure.
[531] See discussions in **section 2.2.3.2**.
[532] Trouwborst States, p177-178, **n232**.

of environmental measure can be a precautionary measure in the scheme of the precautionary principle".[533]

2.3.2 Prohibitory v Information Disclosure

In addition to the *argumentative* v *prescriptive* versions of the PA, the PA can also be classified into *prohibitory* v *information disclosure* versions according to the severity of the damage which is derived from Sustein's Anti-Catastrophe Principle.

2.3.2.1 Anti-Catastrophe Principle

Sustein has criticised the traditional precautionary principle as having a tendency to lead people to think in terns of the worst-case scenario and also has the risk of over-regulation.[534] Alternatively, he proposes the model of "Anti-Catastrophe Principle" by which the prohibitory PA and the information disclosure PA are developed in accordance with the severity of the anticipated harm.[535] A flat ban on the product/technology is recommended when it is associated with a high probability of serious harm; otherwise, when the risk concerns a relatively lower probability of less serious harm, the promoter of the new product/technology is obliged to monitor and disclose the information of the ongoing risk.[536]

[533] Trouwborst States, p179, **n232**.
[534] Sustein PP, **n333** pp64-88.
[535] Sunstein PP, **n333**.
[536] Sunstein PP p118, **n333**.

2.3.2.2 Trimming exercise

With regard to risk regulation in addition to the Anti-Catastrophe Principle, Sunstein also argues for the concept of "trimming",[537] by which he refers to the seventeen-century "Trimmer[s]", "who tend to reject the extremes and to borrow ideas from both sides in intense social controversies". It is recorded that "Trimmers believed it important to steer between the polar positions and to preserve what is deepest and most sensible in competing positions".[538] Sunstein notes that trimming might be defended as "producing the best outcomes" and "responding to judges' lack of information", and can serve to reduce social exclusion or humiliation. He focuses on the reasons why judges involved in constitutional disputes might choose to trim. He maintains that being "humble and uncertain about the right result", Justices might steer between the poles to minimise possible damages.[539]

In summary, the core concept of the "Trimming" and "Anti-Catastrophe Principle" is to adopt a margin of safety to manage unknown risks. These two concepts are similar to the precautionary measure to adopt a "safety margin"[540] which provides extra buffer zones to minimise the direct impact of risk to environment or human health. They provide a safety net in the blind spot of science to safeguard human health and the environment.

A duty of information disclosure is highlighted in the "Anti-Catastrophe" principle model. Under the IDPA, the party who introduces a new technology should bear the burden to disclose the risk and uncertainties of the technology at issue and leaves the

[537] Sunstein Trimming, **n466**.
[538] Sunstein Trimming, **n466**.
[539] Sunstein Trimming, p1061, **n466.**
[540] See **n529**.

public to decide the margin of safety of the product. It is suggested that a review of the risks and uncertainties can be conducted within a certain period of time to update the relevant scientific information and evaluate its margin of safety. Ideally, relevant scientific justifications should be clearer in time with the advancement of scientific breakthroughs, and the public will be enabled to decide the appropriate margins of safety.

Sunstein's Anti-Catastrophe principle consists of four factors of uncertainty, magnitude of harm, tool, and margin of safety. Particularly, the element of "public engagement" plays a vital role in the determination of an appropriate level of protection and a margin of safety.

2.3.2.3 Public engagement

In the Anti-Catastrophe Principle model, Sunstein highlights the significance of public engagement in a democratic society, which is of particular relevance in risk communication in the structure of risk analysis.[541] It appears to incorporate the subjective element of risk perception into risk management.[542] In this regard, he suggests citizens should get involved with the decision-making process of risk management by deliberating their preferences and values.[543]

"Public engagement" is deemed a fundamental feature of a democratic society. It is mentioned in some international instruments regarding the implementation of the PA.

[541] See **section 3.1.3.1** and **figure 3.1.3.1**.
[542] Risk management, see **n36**.
[543] Sunstein PP, p158, **n333**.

The first official legal instrument to recognise public engagement is the Rio Declaration.[544] It notes that environmental issues are best handled with public participation, and individual's access to information, access to decision-making and access to justice are endorsed. The detailed action plan for the Rio Declaration, Agenda 21, also addresses the importance of access to information. It highlights that the United System should involve the participation of "Major Groups" which include the expertise and views of non-governmental organisations.[545]

Further, public participation is developed as the objective of specific international obligations binding upon the EU and its Member States as a result of the Aarhus Convention.[546] The Aarhus Convention developed a three-pillar structure in its agenda: public access to environmental information; public participation in decision-making and public access to justice in environmental matters.

Public participation involves the following three dimensions: public participation in decisions on specific activities, public participation concerning plans, programmes and policies, and public participation during the preparation of executive regulations and generally applicable legally binding normative instruments.[547] It is stressed that Member

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[544] Principle 10, *Rio Declaration on Environment and Development*, the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, 1992 (Rio Declaration) **n286**.

[545] Section III, *Agenda 21*, see Chapter 27 in particular.

[546] UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Arhus, Denmark, 25 June 1998, (Aarhus Convention). Other references regarding public participation in international/European environmental law including: Jans, J. (2003) "EU Environmental Policy and the Civil Society" in Jans, J. (ed) *The European Convention and the Future of European Environmental Law*, Europa Law Publishing, 2003, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1112424 ; UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (1998), available at: http://www.unece.org/env/pp/documents/cep43e.pdf; UNECE Compliance Committee Report, Compliance with regard to the European Commission, UN doc.ECE/MP.PP/2008/5/Add.10, available at: http://www.unece.org/env/documents/2008/pp/mop3/ece_mp_pp_2008_5_add_10_e.pdf
Council Directive Proposal, Access to Justice in Environmental Matters, COM (2003)624, available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2003/com2003_0624en01.pdf

[547] Article 6, 7 and 8 Aarhus Convention, **n546**.

States are obliged to "promote environmental education and environmental awareness among the public, especially on how to obtain access to information, to participate in decision-making and to obtain access to justice in environmental matter[s]".[548] The public should be allowed to submit any "comments, information, analyses or opinions that it considers relevant" during the process of communication.[549] The public is also engaged during the preparation of regulations and other legal binding rules that may have a significant effect on the environment.[550]

Specifically, it is identified in the Aarhus Convention that "the state of human health and safety" and "conditions of human life" are affected by the environment.[551] It is fair to say that Member States bear the duty to promote health education and health awareness among the public, particularly on how to obtain access to information, to participate in decision-making and to obtain access to justice in health and safety matters.

Further, the TFEU stipulates that citizens "have the right to participate in the democratic life of the Union";[552] the EU institutions need to "maintain an open, transparent and regular dialogue" with civil society, and citizens' initiatives of submission proposals need to be recognised.[553] Therefore, the public should be encouraged to take part in the policy-making of health policy and make a collective informed decision through risk communication on the acceptable level of health protection.

Similarly, at the international level, the concept of public awareness and participation is

548 Article 3.3 Aarhus Convention
549 Article 6.8 Aarhus Convention.
550 Article 6 and 8 Aarhus Convention.
551 Article 2.3(c) Aarhus Convention, **n546**.
552 Article 10.3 TFEU, **n408**.
553 Articles 10.3, 11.2 and 11.4 TFEU, **n408**.

also respected in the *Cartagena Protocol on Biosafety*.[554] The *Cartagena Protocol* is an instrument renowned for its mechanism of regulation on importing genetically modified organisms (GMOs)[555]. The PA has been laid down as a foundation of the mechanism. In addition, the *Codex Alimentarius* [556] also stresses the element of "risk communication"[557] in risk regulation, which indicates the exchange of information between relevant important stakeholders.[558] A more elaborate illustration of the mechanism will be addressed in the following chapter.[559]

In summary, the element of "margin of safety" which is associated with the determination of the appropriate level of protection can be particularly influenced by public engagement. The acceptable level of risk differs in different communities, thus it requires social debates within specific communities to determine the appropriate level of health protection. The stimulation of public debate is an on-going process, and thus no absolute rules or answers to particular issues exist.[560] Constant refining and review are necessary to examine the appropriateness and effectiveness of the adopted approach. We will continue to the discussion of the non-scientific elements of the PA in Chapter 5.

After the introduction of the Prescriptive PA and Information Disclosure PA, the last common classification of the PA is also noteworthy: weak versions v. strong versions are

554 Article 23 *Cartagena Protocol on Biosafety,* **n46**.
555 Living modified organisms (LMOs) resulting from modern biotechnology are broadly equivalent to genetically modified organisms. The difference between an LMO and a GMO is that a LMO is capable of growing, and typically refers to agricultural crops. GMOs include both LMOs and organisms which are not capable of growing.
556 *Codex Alimentariu*, see **section 3.1.3 n36**
557 See **section 3.1.3.1 n36** for risk management.
558 See **section 3.1.3.1 n36.** The text of the *Codex Alimentarius* is available at: http://www.codexalimentarius.net; see also *Codex Alimentarius Procedural Manua*l at: http://www.codexalimentarius.net/web/procedural_manual.jsp .
559 See **section 3.2**.
560 See: Pellerano, M. B. and Montague, P. "Democratic Tools: Communities and Precaution" in Myers, N.J. and Raffensperger, C. (eds) (2006) *Precautionary Tools for Reshaping Environmental Policy*, The MIT Press, Cambridge, Massachusetts, US; Whiteside, K.H. "Precaution and Democratic Deliberation" in Whiteside Precaution, **n252**.

divided either in terms of the trigger threshold or the allocation of burden of proof. We will then conclude with a *moderate* PA in this section.

2.3.3 Strong v Weak

Commentators have expressed the polarities of this spectrum in terms of "strong" and "weak" versions in a great variety of formulations of the approach. Tinker expresses the view that:

> At its *strongest*, the precautionary principle may be interpreted to prohibit virtually all use of natural resources and all human activities of any kind in certain ecosystems. Such a moratorium could continue indefinitely, until such time as sufficient scientific knowledge develops about the effects of such activities or use. At its *weakest*, the precautionary principle may be mere hortatory language intended to guide states as they adopt national legislation and plans, allowing a permissive approach to use of resources and human activities and a balancing of interests which may favour development or quality of life choices over conservation of biodiversity or other preventive action.[561]

Some commentators avoid using potentially negative connotations associated with the terms "weak" and "strong". For example, VanderZwaag refers to different strengths of formulations as "ecocentric" or "strict", and "utilitarian" or "permissive" and the like.[562] This work follows a traditional classification and divides the "weak" and "strong" versions in terms of two criteria: the trigger threshold and burden of proof, and then concludes with an alternative version of the "*moderate*" PA.

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[561] Tinker, C. "State Responsibility for Biological Diversity Conservation under International Law" in Freestone/Hey, pp53-72, **n201**.

[562] VanderZwaag, D. (1994) "The Implications of the Precautionary Principle for the Canadian Environmental Protection Act (CEPA)", at: http://www2.ec.gc.ca/cepa/ip18_01.html#j26.

2.3.3.1 Trigger threshold

The standard to distinguish strong and weak versions of the PA is whether precautionary measures are required once a certain risk is identified or only permitted in the absence of scientific certainty.[563] In the context, a prescriptive version of the approach is referred to a strong one, and an argumentative version is accordingly a weak one.[564] The strong PA requires mitigating action by those who created the damage or risk;[565] the weak PA merely prevents lacks of scientific certainty from postponing mitigating measures.[566]

Further, a strong version implies that once a certain minimal threshold of risk is met, "a fundamental rethinking of regulatory policy" is required.[567] As Freestone notes: "once a risk is identified the lack of scientific proof of cause and effect shall not be used as a reason for not taking action to protect the environment".[568] Hence, Ervin and Welsh define the strong version of the PA as:

> [S]etting certain thresholds of scientific uncertainty and hazardous potential, which once met, would allow regulators to take appropriate regulatory actions (e.g., impose a ban on the introduction of a new technology), irrespective of the costs – measured in terms of benefits forgone.[569]

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563 Kolitch, S. "The Environmental and Public Health Impacts of US Patent Law: Making the Case for Incorporating a Precautionary Principle" 36(1) *Environmental Law* 221-256.

564 See the above discussion on prescriptive v argumentative versions of the approach in **section 2.3.1**.

565 For example, the strong precautionary principle is provided in the *Treaty on the European Union*, as amended by the *Maastricht Treaty*, 07 February 1992, Article 130r.

566 For example, the embodiment of the weak precautionary principle articulated in the Preamble of the *United Nations Convention on Biology Diversity*: "Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measure to avoid or minimize such a threat".

567 Sunstein PP, p18, **n333**.

568 Freestone/Hey, p13, **n201**.

569 Perez, O. (2007) "Anomalies at the Precautionary Kingdom: Reflections on the GMO Panel's Decision", 6(2) *World Trade Review* 265-280. Welsh, R. and Ervin, D.E. "Precaution as an Approach to Technology Development: the Case of Transgenic Crops", 31(2) *Science, Technology and Human Values* 153-172.

Likewise, the TFEU describes the strong version as:

> Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectifies at source and that the polluter should pay.[570]

Sunstein notes that: "The most cautious … weak versions suggest, quite sensibly, that a lack of decisive evidence of harm should not be a ground for refusing to regulate". Consequently, he refers to the *Rio Declaration*[571] as a weak version of the PA. On the contrary, a strong version of the PA is more aggressive than the *Rio Declaration* because it is not limited to threats of serious or irreversible damage. For instance, the *Wingspread Declaration*[572] does not require the element of "serious or irreversible damage" as the trigger threhsold.

Under international customary law, a weak version or an argumentative version of the PA would not be able to impose a duty on states to be responsible for the protection of human health and the environment in its domain, thus the adoption of a weak version would probably only be lip service and a declaratory tool of policy-making without any mechanism of enforcement. It is therefore suggested by this work that the employment of the PA would achieve relatively satisfactory efficiency with a *strong* or a *prescriptive* version of the approach.

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[570] Article 191.2 TFEU, **n408**.
[571] Rio Declaration **n286**.
[572] Wingspread Statement on the Precautionary Principle **n218**.

2.3.3.2 Burden of proof

A strong version of the PA sometimes refers to the reversal of burden of proof on the proponents of a new technology. As Sands notes the PA would "tend to shift the burden of proof and require the person who wishes to carry out an activity to prove that it will not cause harm to the environment".[573] However, its application is far more complicated in court than in theory and is under debate.[574] Jones and Bronitt note that: "precaution, it has been argued, has the potential to strike at the heart of this evidential problem by modifying the burden of proof that objectors must satisfy".[575] Thus the reversal of burden of proof is context-dependent and should be considered on a case by case basis.

In WTO law, if the PA is regarded as an *exclusion* to other Members' obligations[576], then the defendant party enjoys the shift of burden of proof; if the PA can be treated as an *exception* to Members' obligations, then the burden of proof still lies with the defendant party. This distinction has been addressed in the previous section where we discussed the implication of the *EC – Hormones* case.[577] In particular, in the *EC – Biotech* case,[578] the Panel recognised the adoption of a provisional SPS measure as "a *right* and not an exception from a general obligation" under the SPS Agreement.[579] It implies that the

[573] Sands Principles, **n241** at 273
[574] For more discussions on the burden of proof of the precautionary principle, see Jones, J. and Bronitt, S. "The Burden and Standard of Proof in Environmental Regulation: the Precautionary Principle in an Australian Administrative Context" in Fisher PP, **n205**.
[575] Jones, J. and Bronitt, S. "The Burden and Standard of Proof in Environmental Regulation: the Precautionary Principle in an Australian Administrative Context" in Fisher PP, **n205** at 139.
[576] See **section 1.2.1.2**.
[577] See **section 2.2.2.2.2**.
[578] *EC – Biotech*, **n373**
[579] *EC – Biotech*, **n373** paras 7.2969 and 7.2973.

burden of proof is to be shifted to the complaining party.[580] The allocation of burden of proof will be further examined in following chapters when we explore the difference in legal status between exceptions and exclusions to WTO obligations in WTO law.[581]

2.3.3.3 Moderate PA

It is noteworthy that in addition to the traditional classifications of weak and strong precaution which represent two extremes, the WHO has proposed "*Moderate Precaution*" which consists of presumptions about interventions being under "weak precaution" but which allow flexibility in order to shift the burden on a case by case basis.[582] Table 2.3.3.3 demonstrates that "*Moderate Precaution*" appears to hit the balance of the extreme versions of precaution, while it accommodates the strengths of weak and strong versions by balancing the burden of proof, and giving considerations of free trade and individual preference. In the context of *moderate precaution*, precautionary action can only be adopted as a *last resort* to prevent misuse or protectionism under globalisation. It can be concluded that this version has resonance with the requirement of proportionality and will sit well in the trade world.

[580] See **section 1.2.1.2**.
[581] Chapter 4.
[582] WHO *The World Health Report 2002 – Reducing Risks, Promoting Healthy Life*, WHO, Chapter Six, "Strengthening Risk Prevention Policies", p151.

Table 2.3.3.3. Contrasting views of the role of precaution within different views of regulation

Weak Precaution	***Moderate Precaution***	**Strong Precaution**
Intervention only on positive scientific evidence and demonstrated cost-effectiveness	Presumption about interventions as under "weak prevention", but with case by case flexibility to shift burden of proof	Risk creator has to demonstrate safety of activity. Little acceptance of cost-effectiveness arguments.
Presumption of risk management. Banning very rare.	Underlying presumption of risk management. Banning possible, but only as *last resort*.	Presumption of risk avoidance. Banning very likely.
Presumption of free trade based on objective scientific criteria. Individual preferences and societal concerns given no weight.	Underlying presumption of *free trade* on the basis of scientific criteria. Recognition that individual preferences and societal concerns do matter.	No automatic presumption of free trade. Individual preferences and societal concerns are dominant.

(Adapted from WHO *The World Health Report 2002*, p151)

Now the general features of the PA will be identified by comparative studies of the abovementioned models.

2.3.4 Comparisons of the precaution formula

We can compare Sunstein's four factors of the Anti-Catastrophe Principle[583] with Sandin's formulation of prescriptive versions of the PA [584] and Trouwborst's

[583] Anti-Catastrophe Principle, see Sunstein PP, **n333**
[584] Sandin Dimensions, **n463**

Precautionary Tripod.[585] They all identify the basic elements of harm, uncertainty and the introduced tool/measure. There is a slight difference in their construction of the PA where Sunstein puts more weight on the magnitude of potential harm; likewise, Trouwborst focuses on the distinction of "significant" harm and "serious or irreversible" harm, while Sandin *et al.* ask which type of hazards should apply in the formula. Sunstein further proposes the concept of "margins of safety"; Sandin *et al.* stress different types of measures applied under various conditions, and Trouwborst argues for the PA to be established from the perspective of *the rights and duties of states*.

This work focuses on the comparative study of these three models of the PA and seeks to develop further refinement to fit into the application of a public health emergency of international concern (PHEIC)[586]. A normative prescriptive version of the PA is emerging from the above studies in the following outlines:

- The fundamental elements of the PA consist of the trigger threshold, scientific uncertainty, and the precautionary action;
- The adoption of the PA is required to be proportionate and efficient;
- The PA is more efficient as a prescriptive version than an argumentative one;
- The PA adopted in international law can be established from the perspective of a state's rights and duties;
- The adopting state bears the duty to carry out on-going monitoring and review of the measure and the feared risk;
- Non-scientific factors such as cost-benefit analysis and public engagement can be included in the consideration of the PA.

[585] Trouwborst States, **n232**
[586] Public health emergency of international concern (PHEIC), see **section 3.1.2.1**.

Based upon these analyses, we will redefine the PA in the IP regime from the aspect of public health emergency in Chapter 5.

Sunstein's proposal appears to fit in modern democratic society, yet the distinction between "high probability of a serious harm" and "low probability of a less serious harm" fails to enclose a full range of risks. For example, risks of "low probability of a serious harm" exist in a risk spectrum which is not yet categorised in his model. The case of imposing an importing ban on beef due to the outbreak of "mad cow disease"[587] in the country of origin falls within the domain of "low probability of a serious harm".

Sunstein's incorporation of the extra factors such as cost-benefit analysis, deliberate democracy, and distributive justice provides practical policy guidance on the implementation of the approach in contemporary society. This category of the PA focuses on people's right to information and the allocation of burden of proof,[588] which are of vital importance in a democratic society, yet they still need to be accommodated in a given scenario in accordance with the characteristics of a specific risk. In the circumstance of a public health emergency, it may not have sufficient time to carry out proper public engagement; however, the duty of review and information disclosure could still be imposed on the adopting party after the invocation of the approach.

In summary, in order to have an effective PA, a *prescriptive* and *information disclosure* version will be opted in this work. Further, a *moderate* PA is preferred with a view to avoid extreme versions and also to take concerns of free trade into account.

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[587] BSE **n335**.
[588] See **section 2.3.3.2**.

2.4 Conclusion

We have introduced the origins and recent development of the PA.[589] It has been proliferated in international environmental protection in the past few decades. Evidence shows that the implementation of the PA has also been extended to the scope of human health and food safety in international law. States are allowed to determine their own appropriate level of health protection to adopt the PA in international customary law.[590]

The PA has a pervasive influence on risk regulation particularly in the fields of protection of the environment, human health, and food safety. However, it is also found that though precautionary thinking is recognised in the WTO, the PA is restrained by the tension between global trade and health. The application of the PA is required to be accompanied by Members' obligation of non-discrimination [591] and is least-restrictive to trade. Particularly, WTO Members are bound to follow a set of procedural requirements relating to sanitary or phytosanitary measures while the adoption of the PA to prevent possible abuse.[592]

2.4.1 Scholarly approaches taken

We have also reviewed scholars' proposals on the definition of the PA. Evidence shows that adopting the term "approach" instead of "principle" will be more practical in an international setting for it implies a rather flexible spirit, and would be more adaptive in

589 See **section 2.2**.
590 See **sections 2.2.2.1 and 2.2.3.1**.
591 See **section 1.2.1.1.1**.
592 See **sections 2.2.2.2 and 2.2.2.3**.

the current political setting.[593] In order to underscore the adaptability of the employed precaution, the term "precautionary approach" is preferred in this work. Specifically, based upon the abovementioned formulations of the PA, this work will be developed from the foundation of "*States' precautionary entitlements*",[594] which was based on Trouwborst's theory of "*precautionary rights and duties of states*"[595] in international law. Trouwborst divides states' precautionary actions into "rights" or "duties" in accordance with the gravity of the anticipated harm, yet this work considers "significant harm" (to human health) as a general reasonable trigger threshold of the PA. Whether to follow his distinction of precautionary "rights" or "duties" according to the severity of the harm is not within the domain of this work.

In the above discussion, a model of the "prescriptive" and "information disclosure" versions[596] of the PA will be preferred. However, the element of "public engagement" of risk management may not be carried out due to the inherent limitations of an emergency, but the burden of "information disclosure" may still be imposed on the adopting party to avoid abuse of the PA. Further, the model of a *moderate* PA[597] will also be considered, which aims to avoid extreme versions of the approach and serves to reconcile different stakeholders. It is noteworthy that the invocation of the PA depends greatly upon the adopted measure and the characteristics of each individual threat. Therefore the elements of the approach are identified as a general template, and still need to be adapted in the context of each particular risk.

593 See **section 2.1.3**.
594 See **section 2.1.2**.
595 See **section 2.1.2 n232**.
596 See **sections 2.3.1.**
597 See **section 2.3.3.3 n582**.

2.4.2 Elements of the moderate precautionary approach

We have also reviewed different definitions of the PA proposed by philosophers, lawyers, and scientists. Three categories of the PA have been reviewed; it can be concluded that the basic elements of the PA consist of: (1) threat of harm; (2) uncertainty; (3) precautionary action. We have also identified other basic elements of the PA in this work, which are supposed to act well in the interplay of health, trade, and IP. In summary, the adaptive version of the *moderate* PA consists of the following elements:

- A precautionary action is established from the perspective of a *state's precautionary entitlements* in international law;[598]
- States enjoy a broad margin of appreciation in exercising their precautionary entitlements;[599]
- The adoption of the PA should be *necessary* to protect human health or safety;[600]
- The adoption of a *provisional measure* is a means to the approach;[601]
- The said PA should be based on a *risk assessment*;[602]
- The adoption of the PA should take *proportionality* into account, which needs to be employed as a *last resort*;[603]
- The PA should be in compliance with Members' obligation of "Non-discrimination" in WTO. The approach should not consist of any disguised restriction and should be *least restrictive* to international trade;[604]
- Uncertainty: The PA should be applied within the domain of *scientific uncertainty*;[605]

598 See **section 2.1.3**.
599 See **sections 2.2.2.1 and 2.2.3.1**.
600 See **section 2.2.2.3**.
601 See **sections 2.2.1.1.2 and 2.2.2.3**.
602 See **sections 2.2.1.1.1 and 2.2.2.3**.
603 See **section 2.3.3.3**.
604 See **section 2.2.2.3**.
605 See **section 2.3.1.2**.

- Threshold of harm: The PA *may* be triggered when the unknown harm crosses the threshold of "*significant*" level of harm;[606]
- Action: The PA should include an *effective* precautionary action;[607]
- Ongoing duty of monitoring and review: According to the Information Disclosure PA, the adopting state bears the duty to update relevant information on the said measure;[608]
- Burden of proof: The PA allows a reversal of burden of proof on a case-by-case basis.[609] Particularly in an Information Disclosure PA, the onus is often shifted to the one promoting a new product/technology, which implies that the party who introduces/increases risks to society bears the burden of proof.
- Other non-scientific factors such as public participation;[610] *consumers' tastes and habits*, and *civilian's social and cultural preferences* could be taken into account on a case-by-case basis.[611] However, in the situation of an acute health emergency, the integration of public participation may be seriously restricted due to time constraints.

The PA from the perspective of a public health emergency will be further defined to reshape the IP policy through the lens of precaution in following chapters. After reviewing the development of the PA, we will assess how the PA has been developed to date in the international public health regime in the following chapter.

606 See **section 2.3.1.1**.
607 See **section 2.3.1.3**.
608 See **sections 2.2.1.1.1 and 2.2.2.3**.
609 See **section 2.3.3.2**.
610 See **section 2.3.2.3**.
611 See **sections 2.2.2.1 and 2.2.3.**

Part 2: The current landscape

3 Precautionary Approach in Practice: International Public Health

The purpose of this chapter is to examine the value and reflect on the current operation of the precautionary approach (PA) in the international public health regime. These comprise the discussions of the legal mechanisms in the WHO system and one of the most renowned multilateral environmental agreements (MEAs) on the PA, the Cartagena Protocol on Biosafety.

The current practice of international health protection has incorporated the essence of precaution by adopting particular health measures for an appropriate level of health protection. Typical examples of the PA implemented in international health can be found in legal instruments such as the *International Health Regulations* (IHRs)[612]; *Codex Alimentarius*,[613] and the *Cartagena Protocol on Biosafety* (CPB)[614], which will also be assessed against the analysis and template developed in the previous chapter. We will examine the practice of precaution in each instrument in the following sections. Relevant employment of the PA by the WHO will first be discussed.

3.1 WHO

The WHO stands as the primary international organisation for addressing global health concerns. The WHO is established under the UN system as the highest directing and coordinating authority of the health-related issues for the world's population. The goal of the WHO is to ensure the right of everyone to the enjoyment of the *highest attainable*

612 International Health Regulations (IHRs) **n45**.
613 Codex Alimentarius **n36.**
614 Cartagena Protocol on Biosafety (CPB) **n46**.

standard of physical and mental health (the right to health).[615] The protection and promotion of human health and safety is regarded as the first priority in the WHO regime, thus the concept of precaution has been widely promoted in the WHO system.

3.1.1 The precautionary approach in the WHO

As discussed in the previous chapter, the WHO has proposed the version of "*Moderate Precaution*"[616] by taking into account the requirements of "free trade" in order to reconcile trade and health. In the fourth Ministerial Conference on Environment and Health, it was noted that:

> We affirm the importance of the precautionary principle as a risk management tool, and we therefore recommend that it should be applied where the possibility of serious or irreversible damage to health or the environment has been identified and where scientific evaluation, based on available data, proves inconclusive for assessing the existence of risk and its level but is deemed to be sufficient to warrant passing from inactivity to policy alternatives.[617]

It stressed that the guidelines to the implementation of the PA need to consider the element of cost-benefit analysis, possible legal constraints, and impediment to free trade.[618] Further, the WHO organised an expert meeting on precautionary policies in environment and health in 2005. The consequent "Dealing with Uncertainty" report

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[615] The State Parties of WHO adopted important principles in regard to public health that are enshrined in the preamble to its Constitution. Hence, the Constitution establishes as a fundamental international principle that enjoyment of the highest attainable standard of health is not only a state or condition of the individual, but "… one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition…".

[616] See **section 2.3.3.3**.

[617] WHO *Fourth Ministerial Declaration on Environment and Health*, EUR/04/5046267/6, Budapest, Hungary 23-25 June 2004, para 17a.

[618] WHO *Fourth Ministerial Declaration on Environment and Health*, EUR/04/5046267/6, Budapest, Hungary 23-25 June 2004, para 17c.

(WHO Uncertainty Report)[619] was published to identify major urgent questions about uncertainty and precaution in the WHO.

The WHO has acknowledged the PA as a risk management tool, and thus recommended that it should be adopted under scientific uncertainty where serious or irreversible damage to health has been identified. The Uncertainty Report discusses some relevant tools about the implementation of the PA such as: risk assessment, cost-benefit analysis, uncertainty analysis, alternative assessment, and public participation tools. Its aim is to provide guidance as well as to facilitate the implementation of the PA as a tool to protect public health. It starts with adopting the definition proposed by the European Environment Agency (EEA) which is deemed a more proactive definition than other versions of the PA.[620] Particularly, compared to the moderate PA developed in the previous chapter, the element of "alternative assessment" is a unique feature which could term the version a "constructive" instead of a "restrictive" PA for it evalutes a whole range of alternatives at the time risks are identified. This approach would "change the current focus from studying the risk to investigating the solutions".[621]

The main instruments containing the PA in the WHO regime are the International Health Regulations (IHRs)[622] and the Codex Alimentarius (Codex)[623]. The IHRs are equipped with the scheme of "additional health measures" which serves as a tool to minimise risks of virus transmission, and the Codex Alimentarius consists of the

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619 *Dealing with Uncertainty: Setting the Agenda for the 5th Ministerial Conference on Environment and Health, 2009*, Report of a WHO Meeting, EUR/06/5067987, Copenhagen, Denmark, 15-16 December 2005 (WHO Uncertainty Report) **n210**.

620 *Dealing with Uncertainty: Setting the Agenda for the 5th Ministerial Conference on Environment and Health, 2009*, Report of a WHO Meeting, EUR/06/5067987, Copenhagen, Denmark, 15-16 December 2005, p3 (WHO Uncertainty Report). See **section 2.1.1 n210**.

621 WHO Uncertainty Report, **n210**, p22.

622 See **section 3.1.2**.

623 See **section 3.1.3**.

structure of "Risk Analysis" which incorporates the precautionary thinking in the regulation of food safety. We will first introduce its relevant application in the IHRs in the following sections in order to examine the role of science in the containment of global virus transmission.

3.1.2 The precautionary approach in the International Health Regulations

The WHO Constitution and the United Nations Charter vest WHO to adopt treaties and regulations to which State Parties subscribe.[624] The *International Health Regulations* (IHRs) are one of the major United Nations agreements that have attempted to regulate the activities of State Parties as they relate to infectious diseases which have been revised to meet the emergence of newly discovered infectious diseases such as SARS in 2002 and the highly virulent strain of bird flu in 2003. The IHRs were revised in 2005 to follow a precautionary thinking in its legal framework in order to ensure the effectiveness of global virus surveillance.[625] The purpose of the IHRs is to ensure maximum security against the international spread of diseases with a minimum interference with world traffic.[626]

Under the WHO mechanism, the IHRs aim at preventing and responding to acute public health risks that have the potential to spread rapidly across borders. The IHRs build an international network of virus surveillance, and oblige State Parties to notify the WHO with the occurrences of notifiable diseases.

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[624] Forrest, M. (2000) "Using the Power of the World Health Organization: The International Health Regulations and the Future of International Health Law", 33 *Columbia Journal of Law and Social Problems* 153.

[625] The IHRs were revised in 2005, and entered into force in 2007 **n45**.

[626] Article 2 IHRs.

In the era of globalisation, fast-spreading diseases have been aided by international travel and trade in foods and services amongst countries and continents. Efficient disease containment greatly depends upon immediate global cooperation.[627] In order to build global health security, states are granted a margin of appreciation in determining the adoption of additional public health measures which aims at achieving an appropriate or acceptable level of protection (ALOP).[628] States may be more cautious in containing virus transmission than international standards require. Specifically, the concept of precaution has been embodied in the IHRs which will be addressed in the following sections.

3.1.2.1Public health emergency of international concern(PHEIC)

The PA employed in the IHRs acts to provide a safeguard to human health by allowing prompt response to managing risks under a public health emergency of international concern (PHEIC).[629] We will first discuss the definition of "public health emergency of international concern" before introducing states' duties and rights[630] in the IHRs and the mechanism of additional health measures.[631]

[627] WHO Report (2007) "Issues Paper – Invest in Health, Build a Safer Future" p16.
[628] "Appropriate level of protection" is also understood as "acceptable level of protection". See **sections 2.2.2.1 and 2.2.3.1**.
[629] See **section 3.1.2.1**.
[630] See **section 3.1.2.2**.
[631] See **section 3.1.2.4**.

3.1.2.1.1 Definition of PHEIC

The IHRs are equipped with a reporting structure to oblige State Parties to notify WHO of all events which may constitute a PHEIC within its territory.[632] The IHRs define a public health emergency as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health threat risk to other States through the international spread of disease [;] and (ii) to potentially require a coordinated international response".[633] A "public risk" means "a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger".[634]

3.1.2.1.2 Scope of PHEIC

After the revision in 2005, the scope of IHRs has covered a broader range of notifiable diseases to reduce the rate of global virus transmission.[635] The scope of notifiable diseases encompasses both imminent and potential risks; it also includes a large range of newly emerging diseases including natural and artificial threats. State Parties are required to notify the WHO of all events that may constitute a PHEIC.[636] In general, the IHRs categorise the notifiable diseases into three classes: (1) known diseases whose outbreaks are unexpected and serious, such as a new influenza strain or SARS; (2) known diseases with a demonstrated ability to become emergencies, including the plague or

[632] See Articles 7- 9, and Annex 2 IHRs.
[633] Article 1 IHRs.
[634] Article 1 IHRs.
[635] Annex II IHRs.
[636] WHO website (2005) "What Has Changed in the International Health Regulations", available at: http://www.who.int/csr/IHRS/revisionchange/en/print.html, The decision instrument identifies a limited set of criteria that will assist State Parties in deciding whether an event is notifiable to WHO.

Ebola; and (3) unknown or potential threats or any other kind.[637]

After receiving the notification of a potential PHEIC, the WHO will begin an investigation and deploy response teams through systems such as the *Global Outbreak Alert and Response Network* (*GOARN*),[638] which is a technological collaboration of existing institutions and networks aiming at rapid identification, confirmation and response to a PHEIC. The Director-General of the WHO will determine whether an event constitutes a PHEIC in accordance with the criteria and procedures set out in these Regulations on the basis of the information received.[639]

3.1.2.1.3 Example of a PHEIC

A recent declaration of a PHEIC had been made from a Swine Influenza A (H1N1) outbreak reported in Mexico and the United States. After receiving notification of a PHEIC, the Director-General soon convened a meeting of the Emergency Committee to assess the condition on 25 April 2009. The Committee decided that the situation constituted a PHEIC after reviewing all available relevant information, and the Director-General also determined that the event constituted a PHEIC.[640] Following the WHO's determination and announcement of the state of a PHEIC, public health officials in the United States soon declared a national public health emergency in preparation for following public health strategies.[641]

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637 Annex II IHRs.
638 http://www.who.int/csr/outbreaknetwork/en/.
639 Article 12 IHRs.
640 Statement by WHO Director-General, 25 April 2009, available on WHO Website, Swine Influenza, http://www.who.int/mediacentre/news/statements/2009/h1n1_20090425/en/index.html.
641 "U.S. Declares Public Health Emergency over Swine Flu", *N.Y. Times*, 26 April 2009, available at: http://www.nytimes.com/2009/04/27/world/27flu.html.

The emergency declaration in the United States was to empower the government to stockpile sufficient antiviral drugs with public resource reallocation. Other countries have opted for travel bans, plans for quarantine, pig culling, and banning foreign pork imports etc.[642] States have been vigilant and have made every possible effort towards the health threat, yet not every response is deemed legitimate under the rationale of international law: some responses are criticised as over-reactive. For example, Russia's ban on pork imports from Mexico and the United States is regarded as groundless as the H1N1 virus cannot be transmitted by pork. The ban on pork imports therefore may violate Article 17(d) of the IHRs which indicates that any health measure needs to be *least-restrictive to international trade and traffic*. It will also be regarded as incompliance with its obligations under the WTO if Russia is a Member of the WTO.[643]

After a brief introduction of a PHEIC, we will now examine State Parties' rights and duties under a PHEIC in the following section.

3.1.2.2 The duties and rights of State Parties

The purpose of the IHRs is to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.[644] The IHRs establish guidelines on the WHO's role and responsibilities in the event of a PHEIC, as well as outline the roles and obligations of WHO State Parties when addressing such crises.

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642 "The World Response to Flu Crisis", *BBC News*, 9 May 2009, available at: http://news.bbc.co.uk/1/hi/world/americas/8022516.stm.

643 Fidler, D. P. (2009) "The Swine Flu Outbreak and International Law", 13 (5) *ASIL Insights*, available at: http://www.asil.org/insights090427.cfm.

644 Article 2 IHRs.

The IHRs formally grant the WHO authority to issue recommendations for State Parties to follow.[645] The WHO may make standing recommendations of appropriate health measures for State Parties' routine or periodic application, and temporary recommendation for adopting additional health measures.[646] These are established in the context of the defined rights and duties of State Parties:

3.1.2.2.1 Duties of surveillance and notification

The IHRs impose obligations on the State Parties of the WHO. Annex 1 of the IHRs spells out the "core capacity requirements for surveillance and response", and details State Parties' obligations under the IHRs. It places duties on State Parties by building a streamlined event reporting system and by importing binding aspects of international law into the health regulations.[647] The IHRs' goals include the avoidance of "unnecessary interference with world trade and travel",[648] and appear to give public health higher priority over commercial interests.[649]

Further, the decision instrument in Annex II identifies a limited set of criteria that will assist State Parties in deciding whether an event is notifiable to the WHO. The criteria are:

- Is the public health impact of the event *serious*?

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645 Mack, E. (2006) "The World Health Organization's New International Health Regulations: Incursion on State Sovereignty and Ill-fated Response to Global Health Issues" 7 *Chicago Journal of International Law* 365.

646 Articles 16 and 43 IHRs.

647 Milano, T.J. (2006) "Understanding And Applying International Infectious Disease Law: U.N. Regulations During An H5N1Avian Flu Epidemic" 6 *Chi.-Kent Journal of International &Comparative Law* 26. (Milano Regulations)

648 Article 2 IHRs.

649 Milano, T.J. (2006) "Understanding And Applying International Infectious Disease Law: U.N. Regulations During An H5N1Avian Flu Epidemic" 6 *Chi.-Kent J. Int'l &Comp. L.* 26 **n647**.

- Is the event unusual or unexpected?
- Is there a *significant risk* of international spread?
- Is there a significant risk of international restriction(s) to travel and trade?[650]

In other words, once the health impact of an event is identified as *serious*; the risk of international spread and the risk of international restriction(s) to travel and trade are *significant*, State Parties are obliged to notify the WHO if the event is unusual or unexpected. This also suggests that the WHO adopts the PA of imposing State Parties' duty to notification when the health impact of an unusual or unexpected event crosses the "serious" threshold and the risk is identified as "significant".[651] Albeit this appears to be deviated from the example of Information Disclosure PA, which favours a shift of the burden of proof to the one who introduces a new product/technology.[652] It could be understood that the invoking party may be in a better position to collect relevant information of the risk in an emergency.

And like the previous WHO "*Moderate Precaution*" model,[653] this IHRs decision instrument also takes the impact to free trade into account by asking the question: "Is there a significant risk of international restriction(s) to travel and trade?" Through this instrument, we can again observe that the WHO aims to reconcile health protection and free trade by adopting a moderate approach of precaution. We can conclude that the deployment of the PA in international public health law is tailored in order to conform to the requirements of global free trade and travel. The adopted precautionary measure to avoid health risks is expected to be "no more restrictive of international traffic and

650 Annex II IHRs.
651 See **section 2.3.1.1**.
652 See **section 2.3.2**.
653 See **section 2.3.3.3**.

trade" than available alternatives that would achieve the appropriate level of health protection.[654]

3.1.2.2.2 Rights to quarantine

The IHRs also lay out the rights that State Parties have with respect to the WHO and clarify domestic rights relating to public health emergencies. As indicated in the IHRs, "States...have the sovereign rights to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations".[655] The IHRs vest State Parties with the "right to quarantine" which allows them to take some action to restrict and protect its population as it sees fit, and the WHO is not in a position to uniformly constrain quarantine policy.

The 2003 SARS outbreak in Singapore illustrates State Parties' right to quarantine clearly.[656] Possible patients were required to report to treatment centres; carry out quarantine with electric tagging, and destroy contaminated property. All of these abovementioned measures are adaptive to circumstances in individual states and are deemed acceptable under the IHRs. However, every procedure to enforce quarantine will inevitably brings compromise of civilians' human rights protection to a certain extent. It is therefore required that the health measures need to be "not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level

654 Article 17 (d) IHRs.
655 Article 3.4 IHRs.
656 In April 2003, Singapore amended its Infectious Disease Act to "require persons with [possible SARS] to report to designated treatment centres, …enforce home quarantine with electronic tagging and forced detention, and allow the quarantine and destruction of SARS-contaminated property". "Milano Regulations, n 28; See also: Sapsin, J.W. *et al.* (2004) "SARS, Public Health, and Global Governance" 77 *Temple Law Review*155, 159-161.

of health protection".[657]

3.1.2.3 Precautionary entitlements to achieve a higher level of health protection

A state's right to determine its appropriate level of health protection has been paid due respect in international law.[658] Under the IHRs, State Parties may also enjoy the right to choose its appropriate level of health protection; they are free to choose the same or greater level of health protection than WHO recommendations.[659] There are *two tracks* in determining an appropriate level of health protection: Member States may either choose to follow the WHO's recommendations to adopt a general public health measure; or to adopt an additional health measure to achieve a greater level of health protection. (Table 3.1.2.4) The application of additional health measures can be deemed as another face of the PA in international health, which will be introduced in the following paragraphs.

3.1.2.4 Additional health measures

As mentioned above, the IHRs attempt to balance a State Party's right and duty in international law while implementing the PA in global disease surveillance networks. A State Party may still choose to adopt additional health measures for an appropriate level of health protection under scientific uncertainty.[660] The imposition of additional public

[657] Article 17(d) IHRs.
[658] See **sections 2.2.2.1 and 2.2.3.1**.For example, the WTO recognised Members' right to pursue a higher level of health protection in *EC - Hormones*, Appellate Body Report, para 124. Article 95.3 of the *EC Treaty* also provides that: "The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking into account in particular any new development based on scientific facts".
[659] Article 43.1 (a) IHRs.
[660] Article 43.2 IHRs.

health measures represents the respect of State Parties' autonomy and sovereignty under a PHEIC for it further embodies the precautionary thinking in the IHRs. Even in the situation of insufficient scientific evidence, when the public health risk cannot be scientifically assessed or quantified, additional health measures can still be imposed but subject to timeous review upon available information from the WHO or other convincing organisations. The adoption of such *additional health measures* is considered the application of the PA. This version of PA could be considered a prescriptive and moderate verion in light of our discussion in the previoud chapter,[661] which requires a precautionary action and minimum interference to international trade, albeit that the onus appears to remain on the invoking party.[662]

An additional health measure can be adopted even under insufficiency of scientific evidence of a public health threat. However, in order to prevent the public health measures being applied arbitrarily, the imposition of such measures needs to be based upon scientific principles or scientific evidence, available information from the WHO or other relevant convincing organisations[663] Moreover, a state which implements this additional public health measure bear the duty to review the measure within three months to make sure that the public health measure is consistent with the advice of the WHO and the criteria set in Article 43.2.[664]

Further, the issue of a temporary recommendation needs to avoid unnecessary interference with international traffic.[665] Additional health measures can be implemented under WHO's temporary recommendations in response to specific health risks or a

661 See **sections 2.3.1 and 2.3.3.3.**
662 See **section 3.3.1**.
663 Article 43.2 IHRs.
664 Article 43.6 IHRs.
665 Article 15.2 IHRs.

PHEIC.[666] A higher level of health protection may be also accepted on the condition of the health measures not be more restrictive of international traffic and not more invasive or intrusive to individuals than reasonable alternative that would achieve appropriate level of protection.[667] In determine whether to adopt additional public health measures; State Parties need to consider scientific principles, available scientific evidence of a risk to human health, the available information, and specific guidance of advice from the WHO.[668] In other words, State Party can still adopt a temporary health measure based on available pertinent information if scientific evidence is insufficient. Scientific evidence is not necessary required in the employment of an additional health measure.

In addition, in order to avoid misuse of this provision, if an additional public health measure adopted significantly interferes with international traffic,[669] the implementing state bears the duty to provide the WHO with the public health rationale and relevant scientific information within 48 hours.[670] State implements the additional public health measure is also obliged to review the measure within three months to make sure the public health measure consistent with the advice of the WHO and the criteria set in Article 43.2.[671]

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666 Article 43.1 IHRs.
667 Article 43.1 IHRs
668 Article 43.2 IHRs.
669 Significant interference generally means refusal of entry or departure of international travelers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours. Article 43.3 IHRs.
670 Article 43.5 IHRs. "Significant interference with international trade" means the conditions of refusal of entry or departure of international travelers, baggage, cargo, containers, conveyances, goods, and the like, or their delay for more than 24 hours.
671 The criteria set in Article 43.2 means: (a) scientific principles; (b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organisations and international bodies; and (3) any available specific guidance or advice from the WHO.

Table 3.1.2.4 Two tracks of implementing public health measures in the IHRs

<table>
<tr><td></td><td colspan="2">Two Tracks of Implementing Public Health Measures in the IHRs</td></tr>
<tr><td></td><td>General public health measures</td><td>Additional health measures</td></tr>
<tr><td>Principles
§3</td><td colspan="2">1. Respect for the dignity, human rights and fundamental freedom of persons.
2. Guided by the UN Charter and the WHO Constitution.
3. Universal application.
4. States have the sovereign rights to legislate and to implement legislation in pursuance of their health policies.</td></tr>
<tr><td>Legal ground</td><td>1. Routine or periodic application (§23-34) ; or
2. from the WHO’s standing recommendation toward a specific public health risk (§53)</td><td>1. From the WHO’s temporary recommendation toward a PHEIC (§15.1) ; or
2. State Parties implement health measures in accordance with their relevant national law and obligations under international law, in response to specific public health risks or a PHEIC. (§43.1-2)</td></tr>
<tr><td rowspan="4">Public health measures</td><td>Health measures on arrival and departure (§ 23)</td><td rowspan="4">1. Based on scientific principles, scientific evidence, scientific information, and WHO guidance or advice (§43.1-2);
2. Shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection(§43.1)
3. Review: shall review the measure within three months taking into account advice from the WHO and the criteria of §43.2. (§43.6)
4. Consultation: with impacted State Party (§43.7)</td></tr>
<tr><td>Special provisions for conveyances and conveyance operators (§24-29)</td></tr>
<tr><td>Special provisions for travelers (§30-32)</td></tr>
<tr><td>Special provisions for goods, containers, and container loading areas (§33-34)</td></tr>
</table>

3.1.2.5 Elements of the precautionary approach in the IHRs

The surveillance network and the mechanism of additional health measures both demonstrate the significance of precaution in the IHRs. On the one hand, State Parties enjoy their sovereignty upon the implementation of public health policies in adopting the PA; on the other hand, they are required to act according to the principle of the IHRs, which aims to minimise the interference of international traffic and trade as well as retaining the full respect for the dignity, human rights and fundamental freedom of individuals.[672]

In summary, in order to achieve a greater level of health protection than the WHO's recommendations, the State Parties are entitled to adopt the PA under prescribed conditions. The elements of the PA in the IHRs include:

- Uncertainty: the PA is applied when there is insufficient scientific evidence in virus surveillance and notification, which is based on scientific principles; available scientific evidence of a risk to human health, or where such evidence is insufficient, available information from the WHO and other organisations, WHO guidance;[673]
- Harm: *Significant* risk of *serious* harm to human health;[674]
- Action: the adoption of additional health measures;[675]
- Duty to review: The adopting Party should provide health rationale and review the said measure within 3 months;[676]
- Burden of proof: the adopting State Party should provide public health rationale

[672] Article 3.1 IHRs.
[673] Article 43.2 IHRs.
[674] See **section 3.1.2.2.1**, Annex II IHRs.
[675] Article 43 IHRs.
[676] Article 43.6 IHRs.

and relevant scientific information;[677]

- No more restrictive of international trade and no more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.[678]

Being compared with the PA model in the previous chapter, the PA in the IHRs shares the similarities of a prescriptive and a moderate version of the PA, which demands that the precautionary action is triggered at the "significant risk of serious harm" threshold as well as causing minimum interference to international trade. However, it is also noteworthy that the IHRs version appears to deviate from the typical Information Disclosure PA, and that the onus remains on the party invoking the precautionary measure.

After the introduction of the PA in the IHRs, it is also noteworthy to discuss the employment of the approach in the regulation of food safety in the WHO regime.

3.1.3 The precautionary approach in the Codex Alimentarius

The Codex Alimentarius Commission is set up by the WHO and Food and Agriculture Organization of the UN (FAO)[679] to develop food standards, guidelines and related texts under the Joint FAO/WHO Food Standard Programme. It establishes the structure of "*Risk Analysis*"[680] for application in the framework of the Codex Alimentarius. States are not forced to follow the Codex guidelines and standards for they appear to be

[677] Article 43.5 IHRs.
[678] Article 43.1 IHRs.
[679] Food and Agriculture Organization of the United Nations (FAO), http://www.fao.org/ .
[680] See **section 3.1.3.1**.

voluntary in international law; however, under the requirements of the WTO SPS Agreement, the Codex guidelines are mandated to harmonise states' national law into Codex.[681] This is to say that under the international economic settings and the pressure of WTO DSB mechanism,[682] countries are often left with no option but to be in compliance with the standards of the Codex Alimentarius. Therefore the Codex Alimentarius has emerged as the official international standard in food safety after the WTO SPS agreement coming into force in 1995.[683]

The PA is not officially introduced in the Codex Alimentarius system; yet the term "precaution" is identified as an "inherent element" of risk analysis in the *Codex Alimentarius Commission Procedure Manual* (*Codex Manual*).[684] In situations where health risks exist but scientific data are insufficient; the Codex Alimentatius Commission will not provide a "standard" but a related "text" which is based on available scientific information.[685]

Further, the adoption of a "Safety factor" is deemed as a form of precautionary measures in international law. In other words, the PA appears in the guise of the "Safety factor" when scientific uncertainty abounds; specifically, the structure of "Risk Analysis" implies that the precautionary thinking is at the stage of risk management.[686] This will be addressed below.

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681 Article 3.1 SPS Agreement requires states to base their sanitary and phytosanitary measures on international standards. Article 3 in Annex A SPS Agreement identifies the Codex Alimentarius Commission as the international standards for food safety. See also: Verkerk, R. (2009) "Codex Alimentarius: Focus on True Threats, not Disinformation" 77 *Caduceus* 24 (Verkerk Codex).

682 See **section 1.2.1.1.2**.

683 See **section 2.2.2.2**.

684 Codex Alimentarius Commission Procedural Manual (18th edition) Joint FAO/WHO Food Standards Programme, FAO, Rome, 2008 (Codex Manual) **n36**.

685 Codex Manual, **n36** p77.

686 Codex Alimentarius Commission Procedural Manual (18th edition) Joint FAO/WHO Food Standards Programme, FAO, Rome, 2008 (Codex Manual) **n36**.

3.1.3.1Risk Analysis

The Codex Alimentarius defines the structure of risk analysis, which is comprised of risk assessment, risk management and risk communication.[687] Each is defined by the FAO in the following paragraphs (Figure 3.1.3.1):

- Risk assessment [688] consists of four steps: hazard identification; hazard characterisation; exposure assessment, and risk characterisation. Risk assessment includes quantitative assessment and qualitative expressions of risk.
- Risk management[689] is the process of "weighing policy alternatives to accept, minimize or reduce risks and to select and implement appropriate options".
- Risk communication[690] is a process of exchanging information and opinion on risk among various stakeholders. [691] This can also be understood as "public engagement"[692] in the context of deliberate democracy.

[687] Report of the Joint FAO/WHO Expert Consultation, *Application of Risk Analysis to Food Standards Issues*, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3 (Food Standard) p6; Codex Manual **n36** p68.
[688] Report of the Joint FAO/WHO Expert Consultation, *Application of Risk Analysis to Food Standards Issues*, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3 (Food Standard) p6; Codex Manual **n36** pp69-70.
[689] Report of the Joint FAO/WHO Expert Consultation, *Application of Risk Analysis to Food Standards Issues*, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3 (Food Standard) p6; Codex Manual **n36** pp70-72.
[690] Report of the Joint FAO/WHO Expert Consultation, *Application of Risk Analysis to Food Standards Issues*, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3 (Food Standard) p6; Codex Manual **n36** p72.
[691] Report of the Joint FAO/WHO Expert Consultation, *Application of Risk Analysis to Food Standards Issues*, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3.
[692] See **section 2.3.2.3**.

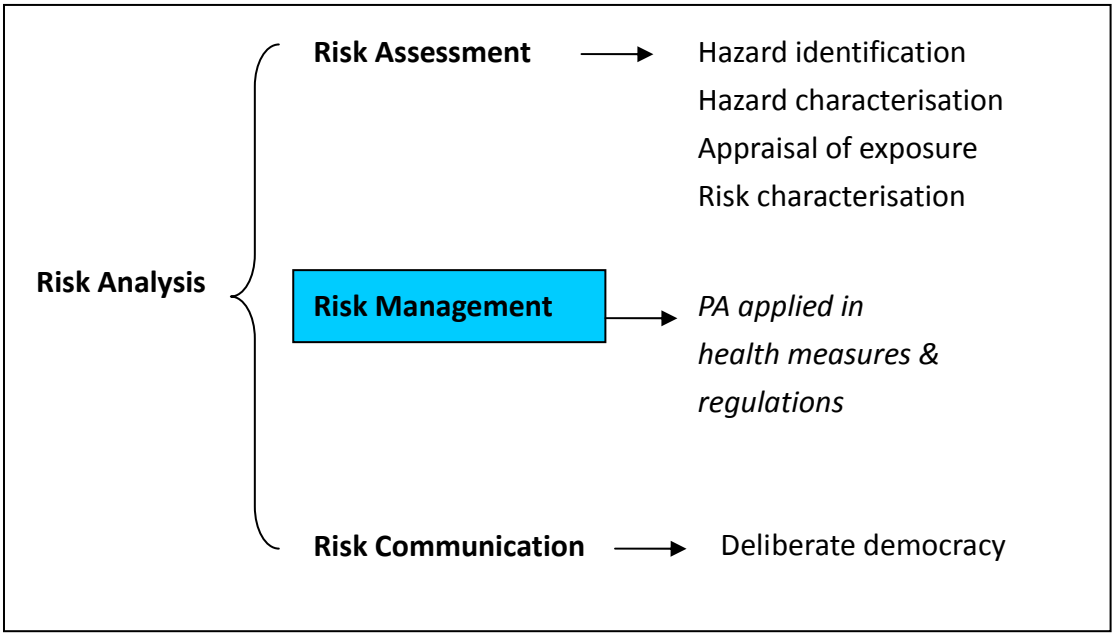

Figure 3.1.3.1. Risk Analysis

Notably, the EU also recognises that the PA should be considered in the structure of risk analysis which is comprised of three elements including risk assessment, risk management and risk communication.[693] The EC's *Communication from the Commission on the Precautionary Principle* identifies four stages of risk assessment which should be performed before a precautionary action is taken: "hazard identification, hazard characterisation, appraisal of exposure, and risk characterisation".[694] The PA is deemed particularly relevant to risk management for adopting public health measures after a scientific evaluation of a potential public health risk (See Figure 3.1.3.1). Specifically, the embodiment of the PA in the Codex Almentarius is the adoption of a "Safety factor" in establishing a health standard at the stage of risk management. Therefore the PA in the Codex could also be deemed as a prescriptive PA which requires a precautionary action to be employed.

[693] Communication from the Commission on the Precautionary Principle, Commission of the European Communities (CEC), Brussels, 2 February 2000, **n299**.
[694] Annex III Communication from the Commission on the Precautionary Principle, Commission of the European Communities (CEC), Brussels, 2 February 2000, **n299**.

3.1.3.2 The adoption of the "Safety factor" and "Additional safety factor"

The employment of safety margins is deemed as a typical precautionary action in international environmental protection.[695] Based on the same concept, in the process of risk management, the Joint Expert Committee on Food Additives (JECFA) of The Codex Alimentarius Committee uses the "Safety Factor" as a margin of safety in establishing the standard of an Acceptable Daily Intake (ADI). The ADI is estimated by JECFA on "the amount of a food additive, expressed on a body weight basis, which can be ingested daily over a lifetime without appreciable health risk".[696]

In the determination of the standard of an ADI, the "Safety factor" can be used in three folds: first, to choose a low "no toxic effect" level as the "no-observed-effect level";[697] second, an additional safety factor is often used by assuming humans are *ten times more sensitive* than experimental animals, which introduces a 10-fold variation in sensitivity in the human population.[698] Third, it is also noted in a report of the Codex Alimentarius that a "temporary ADI" which takes into account relevant public health risks and food technological aspects often uses an *additional safety factor*.[699] A "temporary ADI" is defined by JECFA if the use of the substance is safe over a short period of time, but the safety data are insufficient to conclude that use of the substance is safe over a lifetime. In this

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[695] See **section 2.3.1.3.1** for the discussion of different types of precautionary actions. Trouwborst States, pp177-179 **n232**.

[696] WHO Environmental Health Criteria document No 70, *Principles for the Safety Assessment of Food Additives and Containments in Food*, Geneva, 1987.

[697] If a toxic effect is found at the 2 % level and a "no toxic effect" at 1% level, the 1% level will be the "no-observed-effect level". In this case, the no-observed-effect level lies between 1% and 2% levels, if no toxicological evaluations are done at intermediary levels, the choice of the 1% level as the no-observed-effect level introduces a safety factor. See Codex Alimentarius Document, *Guidelines for Simple Evaluation of Food Additive Intake*, CAC/GL 03-1989, p3 (Codex Guidelines).

[698] Codex Alimentarius Document, *Guidelines for Simple Evaluation of Food Additive Intake*, CAC/GL 03-1989, p3.

[699] Codex Alimentarius Document, *Glossary of Terms and Definitions* (Residues of Veterinary Drugs in Foods), CAC/MISC 5-1993, amended 2003, pp2-3 (Codex Glossary).

case, a "higher-than-normal safety factor" is used in establishing a temporary ADI.[700]

Hence, the spirit of precaution, particularly a prescriptive version of the PA, has been reflected in the Codex system. We can therefore identify the relevant features of the PA in the Codex Almentarius in the following section.

3.1.3.3 Elements of Risk Analysis

The Codex identifies the basic features of a risk analysis as follows:[701]

- The adoption of a "Safety factor" of an ADI and an "additional safety factor" of a temporary ADI is a form of a *prescriptive PA* in the Codex Alimentarius;[702]
- The standards or guidelines need to be evaluated and reviewed "in the light of newly generated scientific data".[703] This requirement is consistent with the requirements of an "Information Disclosure" PA, which demands that the precautionary measure is continually monitored.
- These guidelines and standards are based on principles of scientific analysis and evidence;[704]
- Health and safety aspects decisions should be based on risk assessment;[705]
- Legitimate factors relevant for the health protection of consumers and fair trade

[700] Codex Alimentarius Document, *Glossary of Terms and Definitions* (Residues of Veterinary Drugs in Foods), CAC/MISC 5-1993, amended 2003, p3.
[701] *Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* , Decision of the 21st Session of the Commission, 1995, and the *Statement of Principle Relating to the Role of Food Safety Risk Assessment*, Decision of the 22nd Session of the Commission, 1997. See Appendix: General Decisions of the Commission in Codex Manual, **n36**.
[702] Codex Glossary **n699** pp2-3.
[703] Codex Manual, **n36**, p68.
[704] *Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* , Decision of the 21st Session of the Commission, 1995, See Appendix: General Decisions of the Commission in Codex Manual, **n36** p171.
[705] *Statement of Principle Relating to the Role of Food Safety Risk Assessment*, Decision of the 22nd Session of the Commission, 1997. See Appendix: General Decisions of the Commission in Codex Manual, **n36** p 173.

need to be considered;[706]

- Legitimate concerns of governments when establishing domestic legislation need to be considered;[707]
- Health measures should not create unjustified barriers to trade;[708]
- Health measures should be applied consistently, openly, transparently and be documented;[709]
- Recognising a "functional separation of risk assessment and risk management";[710]
- Considering the function of "food labelling" and constrains of the production or processing methods in developing countries.[711]

In summary, the Codex Alimentarius recognises that the PA is applied in scientific uncertainty and is to be triggered by risk assessment. The Codex also favours a prescriptive PA which introduces a precautionary health measure; the duty of constant monitoring from an Information Disclosure PA and the duty of minimising unjustified barriers to trade from a moderate PA are recognised. However, in terms of allocation of the burden of proof, the Codex does not explicitly address whether a shift of the burden of proof is allowed. This may be referred back to the WTO SPS Agreement when disputes arise.

When scientific uncertainty persists, the Codex Alimentarius will not provide specific

706 Codex Manual, **n36** p71.
707 *Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* Decision of the 21st Session of the Commission, 1995, See Appendix: General Decisions of the Commission in Codex Manual, **n36** p171.
708 Codex Manual, **n36** p71.
709 Codex Manual, **n36**, p68.
710 Codex Manual, **n36**, p69.
711 *Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* , Decision of the 21st Session of the Commission, 1995, See Appendix: General Decisions of the Commission in Codex Manual, **n36** p172.

guidelines or standards but only relevant text based on available information.[712] The structure of risk analysis indicates that the PA is particularly relevant to the stage of risk management. Though the PA is not officially written into the Codex Alimentarius, the requirements of its application appear to be more elaborate than the previous instrument in the IHRs. Common factors of the PA identified by the Codex Alimentarius and the IHRs include: the basis of scientific assessment or scientific information;[713] considering updated data by review and evaluation;[714] taking globalisation into account by demanding the precautionary action does not create an unjustified barrier to trade.[715] It also requires that the approach should be consistent, open and transparent.[716]

In addition, it is also noteworthy that the Codex Alimentarius recognises the function of "food labelling"[717] which may act to address the controversies of unknown risks to human health, such as food labelling on GMO products.[718] When scientific evidence is insufficient or incomplete, food labelling may serve as a means to inform consumers to distinguish potential health risks associated with a specific product.[719]

After the discussion of the WHO's regulation on food safety, we will visit another important multilateral environmental agreement (MEA) regarding the regulation of the trans-boundary movement of biotechnology products. Attention will be turned to the Cartagena Protocol of which the PA is identified as playing a profound role in regulating

712 Codex Manual, **n36** p69.
713 *Statement of Principle Relating to the Role of Food Safety Risk Assessment*, Decision of the 22nd Session of the Commission, 1997. See Appendix: General Decisions of the Commission in Codex Manual, **n36** p 173; Article 43.2 IHRs **n45**.
714 Codex Manual, p68; Article 43 IHRs .
715 Codex Manual, p71; Article 43.1 IHRs.
716 Codex Manual, p69; Article 42 IHRs.
717 Codex Manual, p138.
718 See **section 2.2.2.2.3**.
719 See relevant discussion in Cheyne, I. (2009) "Proportionality, Proximity and Environmental Labelling in WTO Law" 12 *Journal of International Environmental Law* 927.

health risks arising from biotechnology products.

3.2 Cartagena Protocol on Biosafety

In addition to the WHO system, many multilateral environmental agreements (MEAs) also incorporate the PA in their mechanisms to regulate risks to health and the environment.[720] The Cartagena Protocol on Biosafety (CPB) is the first international instrument which provides a regulatory framework relevant to the PA to reconcile free trade and environmental protection.[721] The use and release of genetically modified organisms (GMOs) in contemporary biotechnology has been aggressively expanding, however, the extent to which GMOs pose risks of adverse effects on human health still remains uncertain.[722] Therefore trade conflicts have arisen over the regulation and labelling of GMOs products. It is in this context that the Cartagena Protocol arises to provide a regulatory framework for the international trading of biotechnology products. The objective of the Cartagena Protocol is:

> to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.[723]

[720] For example: 1992 Convention on Biodiversity (CBD), the 1992 Framework Convention on Climate Change, the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Hazardous Substances, the 1996 Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter. See also **section 2.2**; Bernasconi-Osterwalder, N. *et al.* (2006) (eds) *Environment and Trade: A Guild to WTO Jurisprudence*, Earthscan, London UK, pp266-267 (Bernasconi-Osterwalder WTO)

[721] Cartagena Protocol on Biosafety (CPB). It was adopted at the Conference of the Parties to the Convention on Biodiversity on 29 January 2000, and entered into force on 11 September 2003 **n46**.

[722] See **section 2.2.2.2.3**.

[723] Article 1 CPB.

The CPB seeks to protect biological diversity from the potential risks posed by living modified organisms (LMOs) resulting from modern biotechnology.[724] An LMO is defined in the Protocol as "any living organism that possesses a novel combination of genetic material obtained through the use of modern technology".[725] Modern technology means the application of in vitro nucleic acid techniques and cell fusion that overcome natural physiological reproductive or recombination barriers. Techniques used in traditional breeding and selection are excluded from the definition.[726]

3.2.1 The Advanced Informed Agreement (AIA) procedure

The Protocol devises the *Advance Informed Agreement* (AIA) procedure as a new information sharing mechanism under the Biosafety Clearing-House; this avails the contracting parties to conduct a risk assessment of imported LMOs.[727] The handling, use, or trans-boundary movements of LMOs that may have an adverse effect on the conservation and sustainable use of biological diversity can be regulated according to the PA.[728]

Under the AIA rules, the exporter is required to send written notification of the intended export to the importer.[729] The notification must contain specific information including a risk assessment[730] about the potential adverse effects of the imported LMOs.[731] The importer is obliged to acknowledge receipt of the notification and to take a decision of

724 See **n555**.
725 Article 3(g) CPB.
726 Article 3(i) CPB.
727 The AIA procedure is set out in Articles 7-10, and Article 12 of the Cartagena Protocol, which forms the core of the Protocol.
728 Article 1 CPB.
729 Article 8 CPB.
730 Article 5, Annex I (k), and Annex II(j) CPB.
731 Annex I, para (k) CPB.

whether to allow import within 270 days.[732] The importer can either: (1) approve the import and any subsequent imports; (2) prohibit the proposed import; (3) request additional information, or (4) extend the period for decision making.[733] The importer has to set out the reasons for its decision unless the consent to import is unconditional.[734]

The mechanism of the AIA procedure still leaves a fair degree of flexibility for the importing state, for example, Parties my proceed according to the domestic regulatory framework,[735] adopt simplified procedures,[736] or enter into bilateral and regional agreements as long as these are consistent with the objective of the Protocol.[737]

3.2.2 Precaution in the Cartagena Protocol on Biosafety

The AIA procedure requires that an import decision must be based on a risk assessment. A decision to ban or restrict the import of an LMO under the AIA procedure needs to be based on a "risk assessment carried out in a scientifically sound manner".[738] Due to the lack of a clear consensus on the precise requirements for a risk assessment, the Protocol also sets out general principles, methodology, and points to a proper risk management.[739] It allows parties to take precautionary measures by stipulating:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism…shall not

[732] Article 10.3 CPB.
[733] Article 10.3 CPB.
[734] Article 10.4 CPB.
[735] Article 9.2(c) CPB.
[736] Article 13.1(b) CPB.
[737] Article 14.1 CPB.
[738] Article 10.1, Article 15, and Annex III CPB.
[739] Annex III CPB.

prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism…in order to avoid or minimize such potential adverse effects.[740]

The Protocol is considered the most elaborate agreement on the PA in international law. It aims for the development of LMOs to be based on the PA to safeguard public health concerns from unknown risks of a novel technology.[741] The notion of precaution has a pervasive influence on the CPB. Elements of the PA are reflected in several provisions of the Protocol, such as:

- The preamble, reaffirming "the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development[742]";
- Article 1, indicating that the objective of the Protocol is "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development";
- Article 10.6 and 11.8, which states "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question, in order to avoid or minimize such potential adverse effects."; and
- Annex III on risk assessment, which notes that "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk".

740 Article 10.6 and 11.8 CPB.
741 Winham, G. (2003) "International Regime Conflict in Trade and Environment: the Biosafety Protocol and the WTO" 2(2) *Word Trade Review* 131.
742 The Rio Declaration on Environment and Development, UN Doc.A/CONF.151/26, Vol I, Annex I, 1992, (*Rio Declaration*). See **n286**.

Notably, the PA invoked in the CPB as an operational device to protect human health appears to have significant flexibility. The CPB follows the *Rio Declaration on Environment and Development* using the phrase "precautionary approach" to describe the adoption of a precautionary concept on environmental and health protection.[743] However, the Cartagena Protocol appears to be a stronger version[744] than the Rio Declaration since it does not have the threshold requirement of "threats of serious or irreversible damage" and "cost-effective measures".[745]

The PA is adopted in the CPB as legitimate grounds to take a precautionary measure and is further limited by two conditions: the obligation of the importer to review the decision with new scientific information,[746] and the need for the measure to be only imposed to the extent necessary to prevent adverse effects within the territory of the importer.[747] It is noteworthy that "social-economic considerations" also have a role to play in reaching an import decision regarding the value of conservation and sustainable use of biological diversity in the CPB. In addition, the parties are also "encouraged to cooperate on research on any social-economic impacts of LMOs, especially on indigenous and local communities".[748]

The implementation of a precautionary measure is required to be in accordance with a risk assessment, but the importer's obligation to review does not have a specific time

[743] The Rio Declaration on Environment and Development, UN Doc.A/CONF.151/26, Vol I, Annex I, 1992, (*Rio Declaration*). See **n286**.
[744] The distinction of "Strong or Weak versions" of the precautionary approach is addressed in **section 2.3.3**.
[745] Mackenzie, R. and Eggers, B. (2000) "The Cartagena Protocol on Biosafety", *Journal of International Economic Law* 525-543 (Mackenzie/Eggers).
[746] Articles 12 CPB.
[747] Article 16(2) CPB.
[748] Article 26 CPB. Covelli Biotech, **n373**

limit. In other words, the importer is not burdened with an ongoing obligation to keep the measure under review unless requested by the exporter to do so.

In summary, the features of the PA in the Cartagena Protocol comprise of the following considerations:

- The trade decision is made under scientific uncertainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO;
- Risks of an LMO to human health;
- The import decision is based on a risk assessment;[749]
- The risk assessment of the importing product can be expected to be carried out by the exporter.[750] In other words, the burden of proof appears to be laid on the exporter;
- Importer's duty to review the decision;[751]
- Trade measures need to be imposed only to the extent *necessary*;[752]
- Other "social-economic considerations", especially on indigenous and local communities.[753]

These features indicate that the PA in the CPB is also a prescriptive one by which the import decision is triggered by risk assessment. It appears to be a relatively strong version of the PA; however, it also states that a trade measure can only be imposed to the extent *necessary* to prevent potentially adverse effects on biological diversity. It may be fair to say that this version is more akin to the Information Disclosure PA with an

749 Article 5 CPB.
750 Annex I (k), and Annex II(j) CPB.
751 Article 12 CPB.
752 Article 16(2) CPB.
753 Article 26 CPB.

emphasis on the duty to review as well as a shift of burden of proof.

3.3 Conclusion

3.3.1 Regimes conflict and precautionary approaches

It is observed that the discrepancies of PAs exist not only between national and international planes; regimes conflict[754] also appears in individual legal instruments in international law.[755] Research shows that *domestic* health or environmental regulations often allow a comprehensive employment of a PA to safeguard human health;[756] however, at the *international* level, when global trade interests are involved, and the risks are often undervalued, the application of a PA in the protection of public health thus appears sporadically.

3.3.1.1 IHRs v SPS Agreement

The features of PAs in the IHRs[757] are similar to those in the WTO SPS Agreement.[758] These are both *prescriptive* and *moderate* version of the PA; the need of information disclosure is also recognised in both instruments. Some common elements of scientific uncertainty have been identified; risks to human health; based on available information; the adoption of a specific health measure for a higher level of health protection, the adopting party is obliged to review the measure within three months, and the measure

[754] Helfer, L.R. (2004) "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" 29 *Yale Journal of International Law* 1 (Helfer TRIPS) **n16**.
[755] See **section 3.3.2**.
[756] De Sadeleer, p196; Sunstein, C.R. (2010) "Irreversibility" Law, Probability and Risk, 4 July 2010 (Sunstein Irreversibility).
[757] IHRs, **n45**.
[758] SPS agreement, **n39**.

should not be more restrictive to international trade.[759] However, there are three major differences between these two instruments:

- The burden of proof appears to remain on the invoking state in the IHRs.
- Regarding the enforcement mechanism, the IHRs are only equipped with consultation between states,[760] while the WTO Members can resort to its Dispute Settlement Body,[761] which is regarded as binding and effective in international dispute settlements. State Parties of both organisations may choose the WTO DSB for an efficient resolution. The WTO enforcement mechanism plays an important role in ensuring states take measures in compliance with the IHRs.[762]

3.3.1.2 Catagena Protocol v SPS Agreement

The most prominent regimes conflict appears in the Cartagena Protocol[763] and the WTO SPS Agreement. The Cartagena Protocol has potential inconsistency with the SPS Agreement in the banning regulation of importing GMOs. The PA invoked in the Cartagena Protocol is an operational device with more flexibility to safeguard human health. Specifically, the procedural requirements of GMO importation are more stringent in the AIA procedure[764] in the Cartagena Protocol than those in the SPS Agreement. The burden of proof under the Cartagena Protocol appears to be allocated on the exporting party since the Protocol allows the importing party to require a risk assessment from the exporting party.[765] The importing party may also require the

[759] See **sections 3.1.2.5 and 4.2.3**.
[760] Article 43.4 IHRs.
[761] DSB, see **section 1.2.1.1.2**.
[762] Tigerstrom, B. (2005) "The Revised International Health Regulations and Restraint of National Health Measures, 13 *Health Law Journal* 35
[763] CPB, see **section 3.2 n46**.
[764] See **section 3.2.1**.
[765] Article 15.2 CPB.

cost of risk assessment to be borne by the exporting party.[766] State Party of both legal instruments may find conflicts in prescribing relevant national laws.[767]

Further, the implementation of a precautionary measure is not necessarily based on scientific justification; the obligation of the importer to review does not have a specific time frame in the Cartagena Protocol; while in the SPS Agreement, any provisional measure is obliged to be reviewed within a *reasonable period of time*.[768] According to the Cartagena Protocol, the importer does not have an ongoing obligation to keep the measure under review unless requested to do so by the exporter.[769] For example, the EC was challenged by the US, Canada, and Argentina in the recent WTO *EC – Biotech* case[770] on its regulations of GMOs imports. The EC claimed that its import suspension of GMOs was consistent with its obligations in the CPB, while the US, Canada and Argentina accused its "undue delay" as a violation of the requirements in Article 8 and Annex C (1)(a) of the SPS Agreement.

In order to avoid inconsistency with other international agreements, the Preamble of the Cartagena Protocol suggests that trade and environmental agreements should be mutually supported, and the interpretation of the Protocol should not lead to a change in the rights and obligations under existing international agreements. A complementary relationship between trade-related provisions of environmental treaties and WTO law has been implied, and conflicts should be avoided through conciliatory interpretation.[771] However, in terms of dispute resolution, similar to the clash of the IHRs and the SPS

766 Article 15.3 Cartagena Protocol.
767 Covelli, N. (2003) "The Health Regulation of Biotech Foods under the WTO Agreements" 6(4) *Journal of International Economic Law* 773.
768 Article 5.7 SPS.
769 Article 12 CPB.
770 *EC – Biotech*, WT/DS 291, WT/DS292, WT/DS293, **n373**.
771 Mackenzie/Eggers, **n745**.

Agreement, states of these two legal regimes will also resort to the WTO for enforcement. It is therefore proposed to harmonise the requirements of the PA in the two organisations to avoid conflicts and contradiction in international public health law.

Evidence shows that the PA has been widely practised in the regulation of health risks arising from virus transmission and biotechnology in international public health law. Although being employed without a uniform name, prescriptive PAs have appeared in different guises of risk management in contemporary society. The IHRs[772] incorporate the mechanism of the adoption of "additional health measures"[773] which aims to prompt detection of disease transmission;[774] the *Codex Alimentarius*[775] consists the structure of "risk analysis" which focuses on managing the risk from food;[776] the adoption of "Safety factor" or "Additional safety factor"[777] for the establishment of a temporary ADI,[778] and the Cartagena Protocol[779] includes an "Advance Informed Agreement" (AIA) system[780] which attempts to monitor the transboundary movement of GMO products.[781] All the above devices are deemed as the employment of a *prescriptive* PA and risk management in the international public health regime.

772 IHRs, **n45**.
773 See **section 3.1.2.4**.
774 See **section 3.1.2.3**.
775 Codex Alimentarius, **n36**.
776 See **section 3.2.1**.
777 See **section 3.1.3.2**.
778 See **section 3.1.3.2**.
779 Cartagena Protocol on Biosafety (CPB) **n46**.
780 See **section 3.2.1**. Articles 7-12 CPB.
781 See **section 3.3.1**.

3.3.2 Elements of the precautionary approach in the international public health regime

In summary, it can be concluded from the above discussions that a single approach which comprises a *prescriptive, information disclosure and moderate* version of the PA is preferred in the international public health law regime. A precautionary measure triggered by risk assessment is essential in this model, a need to restrain the use to avoid unnecessary interference to international trade and trafiic is identified, and the requirement of information disclosure is recognised, albeit that the shift of burden of proof is to be determined on a case-to-case basis. To conclude, the PA employed in international public health law comprises the following common features characteristics:

- Scientific uncertainty or potential adverse impact to human health;[782]
- Additional health measures or additional safety factors can be adopted;[783]
- Risk assessment is suggested to be a trigger of a health measure; if scientific evidence is insufficient to carry out a full risk assessment, the health measure should be based on scientific principle, available pertinent information or suggestions from international organsiations;[784]
- Duty to review the health measure within a reasonable period of time;[785]
- The health measure should be *necessary* , which means the health measure should be no more restrictive of international trade and traffic than reasonably available alternatives;[786]
- Other legitimate concerns including the protection of consumers, fair trade,

[782] See WHO Uncertainty Report **n210**; Article 1 IHRs; Codex Manual, **n36** p77; Article 10.6 and 11.8 CPB.
[783] See **sections 3.1.2.4, 3.1.3.2 and 3.2.1**.
[784] Article 43.2 IHRs; *Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* , Decision of the 21st Session of the Commission, 1995, See Appendix: General Decisions of the Commission in Codex Manual, **n36** p171; Article 5 CPB.
[785] Article 43.6 IHRs; Codex Manual, **n36**, p68 ; Article 12 CPB.
[786] Article 43.1 IHRs; Codex Manual, **n36**, p71; Article 16.2 CPB.

government domestic regulation, social-economic impact may also be taken into account.[787]

It is noteworthy that the health measure should pay due respect to free trade and avoid creating unnecessary barriers to international trade.[788] This has resonance with the WHO "*Moderate Precaution*"[789] model which aims to reconcile health protection and global free trade. It can therefore be assumed that a *prescriptive, moderate* model as well as an information disclosure model which has a special emphasis on the duty to review, could sit well in the trade word.

In order to have a better grasp of the operation of the PA under the tension of health and trade, we will proceed wth an exploration of the PA in the WTO regime, which will be contrasted with the common features identified in the health sphere in this chapter. The differences will be further analysed and an argument for the preferred model of the PA in the IP regime will be set out.

[787] Article 26 CPB; Codex Manual, **n36**, p71; *Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account* , Decision of the 21st Session of the Commission, 1995, See Appendix: General Decisions of the Commission in Codex Manual, **n36** p171.
[788] See **n784**.
[789] See **section 2.3.3.3**.

4 The Precautionary Approach in Practice: International Economic Law

The WTO has a very different mandate from the WHO, but it has become one of the most important international organisations affecting international health issues due to its effective mechanism for dispute settlement.[790] The winning party may be granted legitimate cause to issue trade sanction on the other party under the WTO DSB, as discussed in the previous chapter, Members of different organisations will resort to the WTO for resolving health-related trade disputes.

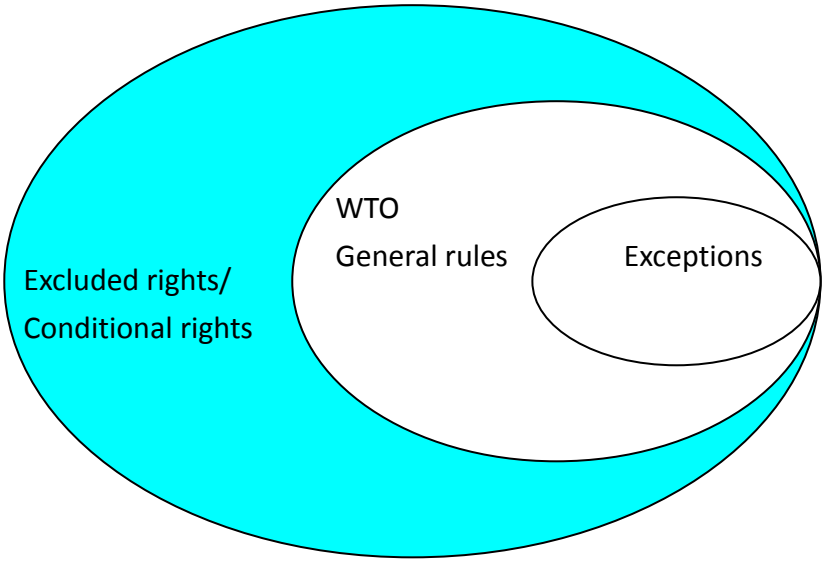
The WTO is the major institution that promotes global free trade. Its aim is to minimise trade barriers among countries in oreder to progress maximum economic interests.[791] Trade liberalism, global market access and the elimination of tariffs as barriers to global trade and non-tariff barriers are primary concerns of the WTO.[792] In order to preserve certain non-economic values including the protection of human health and environment under global world trade, the WTO system creates specific rules exempting Members from compliance with the general rules of its "free trade" principle.[793]

The PA provides a safety margin and appears in the WTO as an exemption to free trade rules; however, this comes in different guises under different headings. Each iteration of the PA carries different weight in its legal instrument. Some appear in the exception provisions; others are reflected in the excluding provisions as the so-called "conditional

[790] Kelly, C.R. (2006) "Power, Linkage and Accommodation: The WTO as an International Actor and Its Influence on Other Actors and Regimes" 24 *Berkley Journal of International Law* 79. See **section 1.2.1.1.2**.
[791] See relevant introduction of the WTO in **section 1.2.1**.
[792] See **section 1.2.1.1**.
[793] See **section 1.2.1.2**.

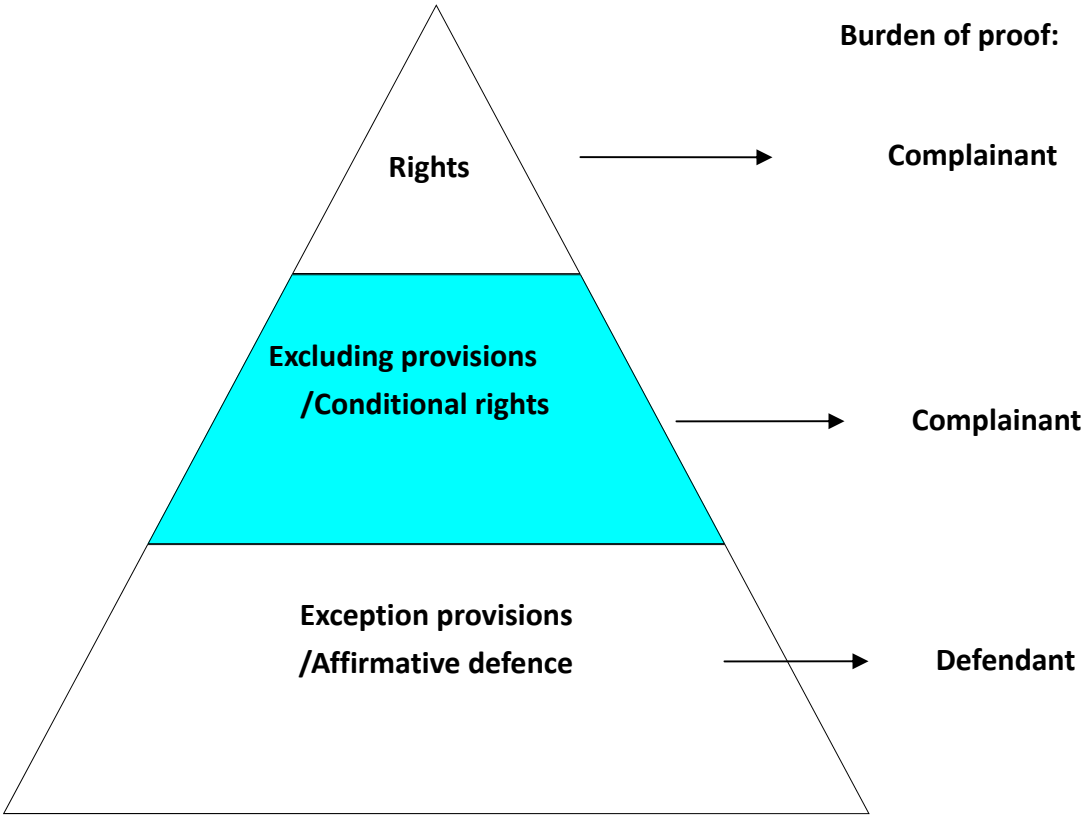
rights",[794] which enjoy a higher status in legal hierarchy (see Diagram 1.2.1.2 and Diagram 1.2.1.2.1).[795]

Diagram 1.2.1.2 Exemption from WTO obligations



[794] See **section 1.2.1.2** for the discussion of "conditional rights" **n118**.
[795] See **section 1.2.1.2**.

Diagram 1.2.1.2.1 Legal hierarchy of exemptions from the WTO obligations



Interpretation of exception rules

The understanding and interpretation of a treaty or an agreement shall be referred to its objectives and purposed in goodwill throughout the legal structure. According to "general rules of interpretation" in the Vienna Convention, "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".[796] In other words, the whole legal structure which should be taken into account including its preamble, annexes, further instruments, subsequent agreements, subsequent practice and any relevant rules

[796] Article 31 VCLT **n131**.

of international law. Moreover, when the textual approach referred to above still leaves the meaning ambiguous or obscure, then the preparatory work of the treaty may be used as a further means for interpretation.[797]

In this chapter, we will examine the PA in the WTO regime, specifically in the General Agreement on Tariffs and Trade (GATT),[798] the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[799] and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[800] We shall see that, in contrast to the examples in the previous chapter, the PA has an ambiguous appearance in the WTO regime, as it is not often recognised as being within the domain of exceptions or exclusions to Members' obligations. However, the PA is found to have a more assertive presence in the SPS Agreement, while WTO Members' determination to adopt a higher level of health protection has been recognised as a "right" instead of a "defence" in the trade world.

In addition to examining current operation of the PA as a means to protect international health, this chapter also considers the extent to which precaution should play a role in contemporary IP systems. Similar to the approach taken in examining precaution in the GATT and SPS,[801] this chapter will also visit the practice of the PA in the IP regime by means of scrutinising exemptions in TRIPS in the context of risk and health management.[802] The PA in TRIPS is also found to be ambiguous; yet the contour of the

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797 Brownlie, I. (2003) *Principles of Public International Law* (6th edition) Oxford, p27 (Brownlie Principles) **n132**. Brownlie stated that, "legitimate interests may play a role in creating exceptions to existing rules and brings about the progressive development of international law".

798 The General Agreement on Tariffs and Trade (GATT 1947" or "GATT) **n47**.

799 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) **n39**

800 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C to WTO Agreement **n1**.

801 See **sections 4.1 and 4.2**.

802 See **section 4.3**.

PA can still be delineated by means of analysing the legal status of obligations and exemptions in the TRIPS. We will see that, instead of seeking a new legal doctrine for addressing Members' reluctance to rely on compulsory licensing on the grounds of a public health emergency, a PA reading of the existing text would significantly contribute to the enhanced use of other existing tools and stronger political and/or ethical arguments of this measure.[803]

We will first introduce the PA in the GATT which appears in the context of "health exception provision"[804] and "security exception provision"[805] in the General Agreement.

4.1 Precaution in the General Agreement on Tariffs and Trade

Precaution appears under the heading of "exceptions" in the GATT. Though the wording of the GATT does not include explicit requirement of the role of science and precaution, it appears in the articles that WTO Members (Members) are left with sufficient space to employ precautionary measures to protect human life or health.[806] These include the health exception and the security exception;[807] both are comprised of exemption to free trade and suggest the rationale of risk management on health and security grounds. Limited exceptions to general rules in the WTO regime are deemed legitimate while taking account of the interests of third parties.

[803] For example, **section 5.2.1.2** deals with the "like-product" analysis borrowed from the *Asbestos* case, and enables a new reading of the discrimination/differential treatment disctinction made in the case with reference to TRIPS Article 27.1.
[804] GATT XX(b) **n47**.
[805] GATT XXI **n47**.
[806] Bernasconi-Osterwalder, N. *et al.* (2006) *Environment and Trade: A Guide to WTO Jurisprudence*, Earthscan, London, UK (Bernasconi-Osterwalder WTO) **n720**, p257.
[807] Article XX (b) and Article XXI GATT.

The role of risk and precaution has been emerging as a topic of contentious debate in relation to the health exception provision of WTO law. Prominent cases have arisen in recent years to test the clash of free trade and health protection.[808] The WTO appears to be willing to leave leeway for health protection under scientific uncertainty in the trade world. However, the application of the PA on health and security grounds has been restrictive and limited for fear of such use resulting in protectionism.

According to the rationale of the PA, health and security measures are expected to be promptly adopted to cope with uncertain risks before the advent of the disaster. Though its argument appears to legitimise exemption under the rules of free trade; however, if being adopted arbitrarily without transparency, the PA is susceptible to the operation of unilateral protectionism in international trade. Hence its application has been hesitatant and fragmented in the WTO due to the lack of a clear definition and a harmonised mechanism for invocation.[809]

4.1.1 Health exception in GATT

Article XX (b) concerns measures which are "*necessary* to protect human, animal or plant life or health". Members have the autonomy to adopt necessary precautionary measures to protect human, animal or plant life or health. The Appellate Body has also

[808] *EC – Asbestos*, *EC – Hormones*, *Canada – Pharmaceutical patents*, *India – Pharmaceutical patents*, *EC – Biotech, and EC – Continued Suspension(Hormones II). European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* (*EC – Asbestos*), WT/DS27/AB/R, adopted 25 September 1997; *EC – Measures Concerning Meat and Meat Products* (*EC – Hormones*), WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998; *Canada – Patent Protection of Pharmaceutical Products* (*Canada – Pharmaceutical Patents*), WT/DS114/R, adopted 17 March 2000; *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (*India – Patents*), WT/DS50/AB/R, adopted 16 January 1998; *EC – Measures Affecting the Approval and Marketing of Biotech Products* (*EC – Biotech*), WT/DS291/R, WT/DS292/R, WT/DS293/R, adopted 29 September 2006; *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (*Hormones II*), WT/DS320/AB/R, adopted 16 October 2008. See **section 2.2.2.2**.

[809] See **section 5.1.1.2**.

ruled that some important principles developed from the SPS Agreement[810] are equally applicable under the health exception provision.[811]

4.1.1.1 Purpose of the health exception provision

The policy objective pursued by the precautionary measure must be the protection of life or health of humans, animals or plants, and the said measure must be *necessary* to fulfill the policy objective. The precautionary health measure inconsistent with the WTO obligations should be examined for its legitimate objectives within the interpretation of Article XX (b), and it should pass the necessity test and the proportionality test in order to prevent abuse of this article.[812]

4.1.1.2 Precautionary measures under the health exception provision

Typical trade measures adopted to restrict free trade on health grounds include the banning or restrictions on imported products which may constitute a risk to human health. Import bans or restrictions on products such as cigarettes, gasoline, asbestos,

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[810] SPS Agreement **n39**. See **sections 2.2.2.2 and 4.2**.

[811] WTO Appellate Body Report, *EC – Asbestos,* paras 167; 168; 178. Bernasconi-Osterwalder, N. *et al.* (2006) *Environment and Trade: A Guide to WTO Jurisprudence*, Earthscan, London, UK (Bernasconi-Osterwalder WTO) p257.

[812] In *United States – Standards for Reformulated and Conventional Gasoline* (*US – Gasoline*), the Appellate Body stated: "In order the justifying protection of Article XX may be extended to it, the measure at issue must not only come under one or another of the particular exceptions – paragraphs (a) to (j) – listed under Article XX; it must also satisfy the requirements imposed by the opening clauses of Article XX. The analysis is, in other words, two-tiered: first, provisional justification by reason of characterization of the measure under Article XX (g); second, further appraisal of the same measure under the introduction of Article XX". *United States – Standards for Reformulated and Conventional Gasoline* (*US – Gasoline*), WT/DS2/AB/R, adopted 20 May 1996. The Appellate Body has further adopted a "weighing and balancing" process as a *proportionality test* to relax the *necessity test* after *EC – Asbestos*. *European Communities – Measures Affecting Asbestos or Products Containing Asbestos* (*EC – Asbestos*), WT/DS135R; WT/DS135/AB/R. For a more detailed introduction on the necessity test in the WTO regime, see: Kapterian, G. (2010) "A Critique of the WTO Jurisprudence on 'Necessity'" 59(1) *International & Comparative Law Quarterly* 89 (Kapterian Necessity).

and retreaded tyres arguably fall within the scope of "the protection of life or health of humans". However, such trade measures are hardly regarded as legitimate after the strict scrutiny of the necessity test and the proportionality test. We will examine relevant cases respectively in the following sections in order to learn that only trade bans with scientific justification as well as without unnecessary intervention to trade will pass the scrutiny. Hence the space for the PA is rather vague and narrow and depends greatly upon the Panel's interpretation of the necessity test.

4.1.1.2.1 Thailand – Cigarettes

In *Thailand – Restrictions on Importation of Internal Taxes on Cigarettes* (*Thailand – Cigarettes*),[813] the US argued that Thailand's quantitative restriction on the importation of cigarettes was inconsistent with the General Agreement. The Panel asked the WHO to comment on the health effects of cigarette consumption while considering the legitimacy of Thailand's restrictive measure.[814] The Panel "accepted that smoking constituted a serious risk to human health and that consequently measures designed to reduce the consumption of cigarettes fell within the scope of Article XX (b)".[815] However, the Panel further concluded that there were other reasonable alternative measures consistent with the General Agreement,[816] hence the restrictive measure failed to meet the *necessity* test.

[813] *Thailand – Restrictions on Importation of Internal Taxes on Cigarettes* (*Thailand – Cigarettes*), GATT BISD 37S/200, 7 November 1990.
[814] GATT Panel Report, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarette*, 7 November 1990, BISD 37S/200, paras 50-57.
[815] GATT Panel Report, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarette*, 7 November 1990, BISD 37S/200, paras 73 and 75.
[816] GATT Panel Report, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarette*, 7 November 1990, BISD 37S/200, para 81.

4.1.1.2.2 US – Gasoline

In *United States – Standards for Reformatted and Conventional Gasoline* (*US – Gasoline*),[817] the Panel made an important clarification on the requirement of necessity: it is not the necessity of the policy objective to be examined, but the necessity of the disputed measure at issue to be examined. Consequently, the Panel examined whether there were reasonable alternative measures available which were "consistent or less inconsistent" with the General Agreement.[818] The Panel agreed the measure to decrease the consumption of gasoline to reduce pollution, but the US failed to prove the necessity of the applied measure. Therefore the US Gasoline Rule was found to be inconsistent with the necessity requirement in the WTO.

4.1.1.2.3 EC – Asbestos

The *EC – Measures Affecting Asbestos and Asbestos-Containing Products* Case (*EC – Asbestos*)[819] reaffirmed that a higher level of health protection of individual Member could be sustained by the PA in WTO law.[820] Asbestos has been long known for causing significant threat to human health. Exposure to chrysotile asbestos may increase the risk for asbestosis, lung cancer, mesothelioma or pneumocomiosis. These negative effects are also identified in a study by the WHO.[821]

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[817] WT/DS2/R, Report of the Panel, 29 January 1996; WT/DS2/AB/R, Reports of the Appellate Body, 29 April 1996.

[818] Panel Report, *US – Gasoline*, para 6.25.

[819] *European Communities – Measures Affecting Asbestos or Products Containing Asbestos* (*EC – Asbestos*), WT/DS135/R; WT/DS135/AB/R **n110**.

[820] *EC – Measures Affecting Asbestos and Asbestos-Containing Products* (*EC – Asbestos*), WT/DS135/AB/R, **n110**. See also: Segger, M-C and Gehring, M.W. (2003) "The WTO and Precaution: Sustainable Development Implications of the WTO Asbestos Dispute" 15 *Journal of Environmental Law* 289; Ruessmann, L.A. (2002) "Putting the Precautionary Principle in Its Place: Parameters for the Proper Application of a Precautionary Approach and the Implications for Developing Countries in Light of the Doha WTO Ministerial" 17 *American University International Law Review* 905 (Ruessmann).

[821] WHO International Programme on Chemical Safety (IPCS), *Environmental Health Criteria 203 – Chrysotile*

In *EC – Asbestos*, France banned the importation and sale of asbestos from Canada for the reason of public health protection. France's ban of asbestos was proved without discrimination to both domestic and imported asbestos. However, Canada argued that the asbestos it exported was a "like product"[822] to substitute products used in construction and thus it should receive no less favourable treatment under the National Treatment[823] standard in GATT.[824] Canada claimed that the measure was inconsistent with France's obligations under WTO law, but France's ban was proved legitimate after reasonable scientific evidence was provided on chrysotile-cement products to the DSB.

In addition, the Appellate Body adopted a "*weighing and balancing process*" as the *proportionality* test to supplement the necessity test.[825] In other words, the Appellate Body takes more factors into consideration in determining the necessity of a measure. Besides "the difficulty of implementation" of the alternative measure, the Appellate Body also referred to two factors in the weighing and balancing process: "contribution of the measure to the realisation of the value pursued" and "importance of the value pursued".[826]

Notably, the Appellate Body identified that several principles developed from the cases under the SPS Agreement were equally applicable under GATT XX. These include:

Asbestos (1998), para 144.

822 "Like product", see **section1.2.1.1.1 n110**.

823 See **section 1.2.1.1.1**.

824 Howse, R. and Turk, E. "The WTO Impact on Internal Regulations: A Case Study of the Canada – EC Asbestos Dispute" in Bermann, G.A. and Mavroidis, P.C. (eds) (2006) *Trade and Human Health and Safety*, Columbia Studies in WTO Law and Policy, Cambridge University Press, New York.

825 The Appellate Body report of *Korea – Beef* was the first WTO ruling to introduce some relaxing elements into the necessity test. *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (*Korea – Beef*), WT/DS169/AB/R, adopted 10 January 2001, para 161.

826 Neumann, J. and Turk, E. (2003) "Necessity Revisited: Proportionality in World Trade Organization Law after *Korea – Beef, EC – Asbestos and EC- Sardines*" 37(1) *Journal of World Trade* 199-233.

Members have the right to establish their appropriate level of health protection;[827] risks to human, animal or plant life or health must be assessed; risk assessment can be qualitative or quantitative; Members can rely on majority scientific opinions or minority opinions to adopt a trade measure.[828]

4.1.1.2.4 Brazil – Retreaded Tyres

Retreaded tyres are produced by reconditioning used tyres. In *Brazil – Measures Affecting Imports of Retreaded Tyres* (*Brazil – Retreaded Tyres*),[829] the EU challenged Brazil's restrictions on imported retreaded tyres from the EU. However, Brazil claimed that the ban was justified by Article XX(b) GATT, and argued that the import ban was aimed at reducing public health risks. Brazil contended that the import ban was designed to reduce waste tyre volume to reduce the incidence of dengue, cancer, environmental contamination, and other associated risks.[830] Brazil argued that waste tyre accumulation threatened public health because it fuels mosquito-borne diseases and releases toxic chemicals into the environment.[831] Brazil also submitted that it had suffered from epidemics of dengue, which the WHO has identified as "a major international public health concern".[832] Brazil explained that the ban was necessary and played an important part in the reduction of dengue. It was claimed that, following the Panel's statement in *EC – Asbestos*,[833] the interests protected by the ban (the preservation of human life and

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827 See **section 2.2.2.1**.
828 WTO Appellate Body Report, *EC – Asbestos,* paras 167; 168; 178; Bernasconi-Osterwalder, N. *et al.* (2006) *Environment and Trade: A Guide to WTO Jurisprudence*, Earthscan, London, UK (Bernasconi-Osterwalder WTO) **n720** p257.
829 *Brazil – Measures Affecting Imports of Retreaded Tyres* (*Brazil – Retreaded Tyres*), WT/DS332/R WT/DS332/AB/R, adopted 3 December 2007.
830 WTO Panel Report, *Brazil – Retreaded Tyres*, **n829**, para 4.11.
831 WTO Panel Report, *Brazil – Retreaded Tyres*, **n829** para 4.12.
832 WTO Panel Report, *Brazil – Retreaded Tyres*, **n829**, para 4.28; WHO, *Guidelines for Treatment of Dengue Haemorrhagic Fever in Small Hospitals* (ix) (1999).
833 *EC – Asbestos*, **n110**.

health through the elimination, or *reduction* of health risks) were "both vital and important in the highest degree",[834] and "they weigh substantially in favour of the necessity of the measure".[835]

On the other hand, the EU argued that the ban did not contribute to health and environmental protection. The EU claimed that there were no "well-known and life-threatening health risks" posed by retreaded tyres,[836] and the EU contested that the real aim of the import ban was not the protection of health but the protection of Brazil's domestic industry.[837] Though Brazil imposed a ban on imported tyres, the court still granted a number of injunctions applied by local retreaders which was deemed by the Appellate Body as "being applied in a manner that constitutes arbitrary or unjustifiable discrimination",[838] and thus it was not able to prevent the continued importation of used tyres.[839]

In summary, the Panel and the Appellate Body found that the ban was necessary to protect human, animal, or plant life and health.[840] However, the Panel also found that the quantity of imports of used tyres to local retreading industry still seriously undermined the purpose of the ban,[841] thus the ban was deemed to fail to meet the requirements of the *Chapeau* of the GATT XX(b) and constituted *arbitrary or unjustifiable discrimination*, or a disguised restriction to trade.[842]

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834 WTO Panel Report, *Brazil – Retreaded Tyres*, para 4.16.
835 WTO Panel Report, *Brazil – Retreaded Tyres*, para 4.44.
836 WTO Panel Report, *Brazil – Retreaded Tyres*, para 4.18.
837 WTO Panel Report, *Brazil – Retreaded Tyres*, para 4.19.
838 WTO Appellate Body Report, *Brazil – Retreaded Tyres*, para 258.
839 Epps, T. (2008) *International Trade and Health Protection: A Critical Assessment of the WTO's SPS Agreement*, Edward Elgar Publishing, Cheltenham, UK, pp222-224 (Epps SPS) **n325**.
840 WTO Panel Report, *Brazil – Retreaded Tyres*, para 7.215.
841 WTO Panel Report, *Brazil – Retreaded Tyres*, para 7.355.
842 WTO Panel Report, *Brazil – Retreaded Tyres*, para 7.356.

4.1.1.3Rules and principles of the precautionary approach in the health exception provision

From the above discussion, the structure of Article XX (b) includes the provision and the *Chapeau*. The examination of the disputed measure consists of three steps: first, to review whether the objective of the measure falls within the domain of the protection of "human, animal or plant life or health"; second, the *Chapeau* requires that the applied measure should be *least inconsistent* with the obligations and be *least restrictive to trade*. The disputed measure should be applied in a non-discriminative way, and any disguised restriction on international trade is considered inconsistent with the *Chapeau*. Third, an analysis of weighing and balancing has been adopted by the Appellate Body to balance the values of the protected objectives and the cost of trade restriction.[843] The Appellate Body started to take into account several other factors to relax the necessity test. Specifically, in *Brazil – Retreaded Tyres*, Brazil recalled the factors in determining the necessity of a measure as follows:

- The importance of the interests protected by the measure;
- The contribution of the measure to the end pursued;
- The trade impact of the measure; and
- The existence of reasonably available alternative measures.[844]

In other words, the applied measure will be accepted as legitimate if it is considered *least restrictive to free trade*. If there exists an alternative measure that would achieve the same goal and is less restrictive to trade, then the alternative measure should be determined if

[843] Weighing and balancing process, see **n826**.
[844] WTO Panel Report, *Brazil – Retreaded Tyres*, para 4.38.

it is reasonably available.[845] Moreover, the Appellate Body has introduced a weighing and balancing process as a proportionality test into the necessity analysis. Any trade restriction aimed at protecting human health has to be in proportion to the benefits arising from the protection of human health.

In summary, article XX(b) GATT appears to leave a fair space for Members' discretion in adopting the precautionary health measures; however, after the interpretation of the Appellate Body, the space of the PA is rather narrow and rigid. All of the above cases except *EC – Asbestos*[846] failed to pass the scrutiny of "the necessity test". Though the necessity test has been relaxed after the introduction of a weighing and balancing process for the proportionality test after *EC – Asbestos*; the necessity test including the proportionality test, still appears to be a relatively rigid and scientific-based approach to examine the legitimacy and validity of a trade measure to avoid hidden protectionism.

The PA in the health exception is also a *prescriptive* version; due to the strict scrutiny of the necessity test of a precautionary measure, it could be deems as a *weak* PA. The burden of proof remains on the adopting state: states who adopt the PA bear the onus to prove the necessity of the precautionary measure. Nevertheless, the interpretation of this article has recourse to the rationale of the SPS Agreement. It can be suggested that the PA in the GATT is expected to be congruent to its application in the SPS Agreement.

Attention will now be turned to the discussion of the security exception provision in the GATT.

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[845] WTO Panel Report, *Brazil – Retreaded Tyres*, para 4.38.
[846] *EC – Asbestos* **n110**.

4.1.2 Security exception in GATT

Contrary to the rigid application of the health exception provision, the invocation of the security exception provision appears to be rather broad and self-defining. The security exception provision lacks a clear mechanism, thus WTO Members enjoy a broad range of discretion in determining their "security interests". They are vested legitimate grounds to take actions which *they consider necessary* for the protection of their essential security interests. Consequently, the dispute settlement relies much on diplomatic pressure, which ultimately depends on the power of the state.

Provisions involve "national security" in the WTO laws including GATT XXI, GATS XIV *bis* (1),[847] TRIPS 73(b) (iii), and Agreement on Government Procurement 23 (1). GATT XXI is a basic template for discussing "national security", and considered more relevant to risk management and the PA in WTO law. We will examine the mechanism of the security exception in GATT, and visit current state practice in the following paragraphs.

4.1.2.1Purpose of the security exception provision

Definition and Controversy

Article XXI (b) GATT allows Members to adopt or maintain measures relating to

[847] General Agreement on Trade in Services (GATS). Services from architecture to voice-mail telecommunications and to space transport are also included into the production of most goods after Uruguay round of negotiation.

fissionable materials; measures relating to trade in arms or in other materials, directly, for military use, and measures taken in time of war or other emergencies in international relations which "it considers necessary of the protection of its essential security interests". Unlike Article XX, Article XXI does not have a chapeau to prevent misuse of abuse of the exceptions in Article XXI.[848] Members can apply Article XXI to protect their essential interests as *they considers necessary*.[849] The definitions of the terms and criteria of Article XXI deliberately remain vague in order to maintain flexibility which Members can resort to in times of emergency. This also implies that states are allowed to have a greater margin of appreciation in exercising their *precautionary entitlements* to protect public interest of security under emergency situations.[850] It may be fair to say that states' precautionary entitlements, or in Trouwborst words, states' precautionary rights and duties,[851] are deemed legitimate especially in a public health emergency. States' discretion in granting a precautionary compulsory licence based on their precautionary entitlements in international law will be discussed in later chapters.[852] However, the uncertainties of Article XXI have also resulted in obstacles and restrictions to trade which WTO Members may use for protectionism unilaterally.

As Cann has noted:

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[848] Bossche, P. (2008) *The Law and Policy of the World Trade Organization - Text, Cases and Materials* (2nd edition) Cambridge University Press, New York, US, pp664-669 (Bossche WTO) **n109**.

[849] The distinction between "necessary" and "it considers necessary" has been previously discussed by the International Court of Justice (ICJ). In *Military and Paramilitary Activities in and against Nicaragua*, the ICJ held that it did indeed have jurisdiction to determine whether the measures taken by the US fell within the the security exception, whether the measures proposed to protect those security interests were "not merely useful but 'necessary'". The Court recognised the distinction of "necessary" and "it considers necessary", and concluded that: "the issue of whether a measure is necessary to protect the essential security interests of a party is *not*…purely a question for the subjective judgment of the party; the text does not refer to what the party 'consider necessary' for that purpose." (*emphasis added*) *Nicaragua* v *United States of America*, International Court of Justice, 27 June 1986.

[850] See **section 2.1.2**.

[851] See **section 2.1.2**.

[852] See **section 5.2.1.1**.

> … although Article XXI was not designed to create a "policy" exception, or to create a mechanism by which one nation could impose its social, political, or economic ideology on another, it is conceivable that Article XXI will be invoked for the wrong reasons. More significantly, Article XXI will continue to serve as a generally unspoken basis for the unilateral imposition of restrictive trade measures for non-economic purposes. These measures, often imposed without identifiable standards and without any accountability or effective retaliatory remedy, undermine[ing] the cooperative integrative purposes of the world trade system.[853]

The lack of clarity on the subjective phrasing of "it considers necessary"; "essential security interests" and "other emergency in international relations" makes the interpretation of this statue ambiguous. Therefore, the concepts of "security", "diplomatic policy", and "economic welfare" are often understood with confusion. However, Article XXI functions as a safety valve in the GATT. Members will be unwilling to participate in this trade agreement if it does not provide any flexibility reserved for exercising Members' autonomy in times of emergency.

Hence, the security exception provision has been drafted without a clear mechanism on purpose. Relevant cases of the provision further indicate that the provision is adopted within a rather broad spectrum, and that the resolution of disputes depends greatly on informal diplomatic negotiation. The PA in the security exception provision therefore appears to enjoy a broad application.

[853] Cann, W.A. Jr. (2001) "Creating Standards and Accountability for the Use of the WTO Security Exception: Reducing the Role of Power-Based relations and Establishing a New Balance between Sovereignty and Multilateralism" 26 *Yale Journal of International Law* (Cann).

4.1.2.2 Precautionary measures under the security exception provision

4.1.2.2.1 Sweden – Import Restrictions on Certain Footwear

In *Sweden – Import Restrictions on Certain Footwear*,[854] the Swedish Government introduced a trade measure of a global quota system for leather shoes, plastic shoes and rubber boots from 5 November 1975.[855] The global quota system for shoes was introduced in order to allow time to "remedy the serious difficulties" that had arisen in this sector of the shoe industry.[856] The Swedish Government claimed that the continued decrease in domestic shoes production had become a critical threat to the emergency planning of Sweden's economic defence, and it felt "compelled to resort to temporary emergency measures to prevent a further deterioration of the domestic production capacity of shoes and rubber boots".[857]

Although GATT XIX provides regulations regarding emergency action on imports of particular products, many contracting parties questioned the legitimacy of Sweden's act to invoke Article XXI. In recognition of international disapproval, Sweden promptly held negotiations and withdrew its measure of its quota system on shoes. This case demonstrates the importance of diplomatic pressure on the process of dispute settlement in Article XXI. An economic emergency within a specific industry may not therefore be a legitimate cause to trigger the security exception provision.

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[854] L/4250, 17 November 1975

[855] Although Sweden never formally invoked Article XXI, its position was supported by the exception.

[856] Notification by the Swedish Delegation, Introduction of a Global Import Quota System for Leather Shoes, Plastic Shoes and Rubber Shoes, L/4250, p2.

[857] Notification by the Swedish Delegation, Introduction of a Global Import Quota System for Leather Shoes, Plastic Shoes and Rubber Shoes, L/4250, p3.

4.1.2.2.2 Helms – Burton Act

The dispute settlement between the US and the EU about the *Helms-Burton Act*[858] also demonstrates that the judgements of the WTO restrain Members from abusing the mechanism of the national security exception.

On 20 February 1996, Cuba shot down two civil unarmed airplanes that violated Cuban airspace, the US soon adopted the *Helms-Burton Act* to impose economic sanctions on an extraterritorial basis to certain companies in other countries who trade with or invest in Cuba as a diplomatic revenge.[859]

The *Helms-Burton Act* is not consistent with Members' commitment to the WTO because it is motivated by foreign policy objectives, which are against the underlying principles of trade liberalisation in the WTO trading system. The *Helms-Burton Act* led to serious rejections from the US' primary trading partners including the EU, Canada, and Mexico. The EU filed a complaint against the *Helms-Burton Act* to the DSB[860] of the WTO, and a Panel was held to settle this dispute.[861]

The US claimed that the legislation of the *Helms-Burton Act* was based on the ground of national security to invoke GATT XXI, and it asserted that it was not within the authority of the WTO to decide the domain of national security interests of the US.[862] There were also fierce debates about whether Cuba could constitute a real threat to

858 Cuban Liberty and Democratic Solidarity (Libertad) Act of 1996 (*Helms–Burton Act*).
859 Lindsay, P. (2003) "The Ambiguity of GATT Article XXI: Subtle Success or Rampant Failure?" 52 *Duke Law Journal* 1277 (Lindsay).
860 Dispute Settlement Body (DSB), see **section 1.2.1.1.2**.
861 WTO Panel Named in Helms–Burton Dispute; Dispute Settlement Body, Minutes of Meeting, WTO/DSB/M/78.
862 Guy de Jonquie'res, "US Dodges Brussels Onslaught: Washington Buys Time as Anti-Cuba Law Dispute Goes to World Trade Body" *Financial Times* (London), 21 February 1997, 6.

national security from both international and domestic critics.[863]

It seemed that the US held back on this Act because it would possibly challenge its legitimacy on the application of Article XXI by the DSB judgment, so the US negotiated with the EU and reached an agreement in April 1997.[864] The EU promised to cease the procedure to the DSB Panel, and the US agreed to suspend the application of Title III and IV of the *Helms-Burton Act*.[865] The case was closed due to the Panel being suspended for over twelve months.[866]

The resolution of the dispute on the *Helms-Burton Act* further demonstrates a peculiar approach to the dispute settlement in GATT XXI. Disputes in the WTO system can be resolved by other means of diplomatic negotiation as well as by the legal process in the DSB.[867] This may well be true if a dispute arises regarding the application of a PA in this provision. The trigger of a PA appears to be lower due to the subjective standard "it considers necessary", and without a proper risk assessment and a clear allocation of burden of proof, the dispute settlement would inevitably depend greatly upon political means. Resolutions using diplomatic approach indeed provide more flexibility in negotiations, and can be resolved more from a public point of view which would be

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[863] Whether Cuba really represents a national security threat to the United States is an issue that is still being debated. At least one person suggests that perceptions of Cuba's threat linger from the Cold War and are maintained for political reasons (e.g., the common belief that Florida is an important swing state). See Lindsay, P. (2003) "The Ambiguity of GATT Article XXI: Subtle Success or Rampant Failure?" 52 *Duke Law Journal* 1277 note149.

[864] Lindsay, **n859**.

[865] Under the *Helms-Burton Act*, the president has the authority to suspend application of Title III for up to 6 months if he gives notice to the appropriate congressional committees and "[the] suspension is necessary to the national interests of the United States and will expedite a transition to democracy in Cuba", 22 U.S.C.A. §6085(c) (West Supp.2002). The president may make additional suspensions as necessary.

[866] See WTO, Communication from the Chairman of the Panel, U*nited States – The Cuban Liberty and Democratic Solidarity Act*, WT/DS38/5 (1997).

[867] For a discussion of the argument for and against the legalism embodied in the WTO Dispute Settlement Understanding, see Movsesian, M.L. (1999) "Sovereignty, Compliance, and the World Trade Organization: Lessons from the History of Supreme Court Review" 20 *Michigan Journal of International Law* 775,791-95.

more likely to reach mutual consensus. The strengths of the dispute settlement from diplomatic negotiations are not easily achieved by official judicial review. However, diplomatic negotiation also depends greatly upon the power of a state. Therefore, a weak state is forced to give in under a powerful economic influence of a strong state.

4.1.2.3 Rules and principles of the application of the precautionary approach under the security exception

From the experience of the *security exception* in Article XXI GATT,[868] we can see that a "one-size-fits-all" approach is not necessarily best for Members' administration under a national emergency. States prefer to have more flexibility in their interpretation of "national security" and "essential security interests" which also have ambiguous implications.[869]

GATT XXI is used as leeway for states to exercise their authority when they think necessary under circumstances of emergency. This could be linked to the discussion of a state's rights and duties above.[870] When "national security" or "essential security interests" are threatened by a particular health risk, states are granted with more margin of appreciation in the interpretation of the PA that they adapt.

In addition, a PA is only used as a policy tool in risk management while its application is to ensure that the concept of "precaution" is employed under uncertainty.[871] Hence, similar to the function as a safety valve of GATT XXI in WTO, the vagueness also demonstrates that a PA may be applied with flexibility and a state's margin of discretion

[868] GATT XXI is regarding the security exceptions to Members' obligation in the GATT.
[869] See **section 4.1.2.3**.
[870] See **section 2.3.1**.
[871] Motaal Precaution, **n437** pp483-501.

in risk management according to a state's own particular policy objectives.

The current situation of a lack of a uniform definition as well as an ambiguous legal status of PAs does not deter the widespread application in risk management. A one-size-fits-all approach of the PA does not always satisfy the challenges of the multi-dimension character of risks. Consequently, a tailor-made definition for a specific health risk will be proposed in Chapter 5 in order to facilitate further application and communication.

GATT XXI is a highly controversial provision in the WTO regime due to its ambiguity of interpretation. Although its phrasing appears to be of broad interpretation, in reality its application needs to pass political scrutiny found in international settings. There are also follow-up discussions regarding the limitations of this article. For example, Hahn argues that this article was not designed to include the "socio-economic consequence" resulting from the operation of GATT principles, nor was it designed to provide safeguards for "vital industries" or to allow for the use of other protectionist measures.[872] He holds that Article XXI is not absolutely "self-defining", and he suggested that Members should be required to provide the relevant facts and reasons with the proposed measure for protection of their essential security interests.[873]

In addition, in a later Decision which was adopted by Contracting Parties, the interests of third parties which may be affected was reckoned to be taken into consideration, and appropriate guidelines on the obligation to inform other affected contracting parties were established for its application. The Contracting Parties decided that, "contracting

[872] Hahn, M.J. (1991) "Vital Interests and the Law of GATT: An Analysis of GATT's Security Exception" 12 *Michigan Journal of International Law* 558 (Hahn).
[873] Hahn, **n872**.

parties should be informed to the fullest extent possible of trade measures taken under Article XXI", and all contracting parties affected by such action should retain their full rights under the General Agreement.[874]

The General Agreement acknowledges that the contracting party has the autonomy on the discretion of measures which involve its own essential interests. Nevertheless, the applied measure should be used as *a last resort* in order to prevent abuse of the provision.[875] Therefore it is imperative that a certain degree of judicial review remains to safeguard the provision from being abused or used arbitrarily. From case precedents and state practice of the security exception provision, if Members are to apply the PA under the national security provision, some clarifications about the ambiguity in the article can be demonstrated in the following analysis:

- Members have the *autonomy* to invoke GATT XXI and apply certain measures to protect their essential security interests;
- Members have the discretion to interpret their "essential security interest" while taking into account the requirements in GATT XXI;
- Members are expected to avoid "broad interpretation" to prevent the abuse of GATT XXI, and conform to the jurisprudence of "limited interpretation of exceptions" in WTO laws;[876]

[874] Decision Concerning Article XXI of the General Agreement, Decision of 30 November 1982, General Agreement on Tariffs and Trade, L/5426, 2 December 1982. Available at: http://www.wto.org/gatt_docs/English/SULPDF/91000212.pdf .

[875] In the discussion on the complaint by Czechoslovakia against export restrictions imposed by the US, it is noted that: "…every country must be the judge in the last resort on questions relating to its own security. On the other hand, every contracting party should be cautious not to take any step which might have the effect of undermining the General Agreement". Corrigendum to the Summary Record of the Twenty-second Meeting, Contracting Parties Third Session, General Agreement on Tariffs and Trade, GATT/CP.3/SR.22, Corr.1, 20 June 1949, available at: http://www.wto.org/gatt_docs/English/SULPDF/90060101.pdf .

[876] McRae, D.M. "GATT Article XX and the WTO Appellate Body", in Bronckers, M. and Quick, R. (eds) (2000) *New Directions in International Economic Law*, Kluwer Law International, The Hague, pp235-236.

- The adopted measure proposed under GATT XXI should be proportionate to the threat to Members' essential interests;
- Members are expected to inform other affected Members and the WTO;
- Affected Members retain their full rights in WTO, such as the right to request a consultation and the process of Dispute Settlement in the WTO;
- The WTO has the authority to review the disputed measure proposed by GATT XXI, but the WTO is intrinsically not an appropriate mechanism to settle such highly political disputes.[877]

Again, the PA in the security exception tends to be a *prescriptive* one which adopts a precautionary measure; it can also be understood as relevant to the *information disclosure* PA for it expects the invoking state to inform other affected states and the WTO. In terms of a strong, weak or moderate version, the vague and subjective trigger "it considers necessary" may initially indicate a relatively strong PA; however, evidence shows that the international political atmosphere indeed plays an important role in the moderation of a strong PA. In order to avoid international conflict, it may be fair to say that a *moderate* PA is more favourable than a strong PA.

Basically, Members prefer to reserve the ambiguity and flexibility of GATT XXI in order to exercise their autonomy and fulfil the needs of national essential interests in the circumstances of emergency. Members are left with a greater margin of appreciation in the exercise of the PA under this heading. Nevertheless, due to the intrinsic limitations of an unclear mechanism for operation and the subjectivity of interpretation, it will

[877] Horng, D-C. (2005) "The Research Regarding National Security Exception in WTO" 17 *The Chinese (Taiwan) Yearbook of International Law and Affairs* 165-211 (in Chinese: 洪德欽 "WTO 有關安全例外條款之研究" *中國國際法與國際事務年報* 第十七卷 頁 165-211).

inevitably depend more on the international political setting rather than the WTO DSB[878] to resolve such disputes.

4.1.3 Interim conclusion: Principles of the application of the PA under WTO exception provisions

The PA under the exception headings in the WTO system includes the health exception provision and the security provision. Both are *prescriptive* versions of the PA. The interpretation of the Appellate Body shows that the PA in the health exception appears to be a *weak* version, while it appears to be a relatively *strong* one in the security exception, albeit that some moderation from the international political settings exists. Both have the prerequisite of "necessary": the definition of "necessary" in the health exception rule is considered objective and requires scientific justification. In contrast, the definition of "it considers necessary" in the security exception appears to be self-defining and leaves more flexibilities for Members' discretion. This is to say that the PA may enjoy broader employment in the security exception; however, the lack of a transparent mechanism in the security exception provision inevitably results in controversies which may only be resolved through political negotiation.

It has been stated previously that, exception rules in WTO law are expected to be applied strictly. Though Members enjoy a certain degree of autonomy to interpret the PA within the domain of the security exception, they are still under pressure from the international political setting. The application is also required to be "limited interpreted"[879] and adopted as *a last resort*.[880] The invoking Member bears the burden of

[878] DSB, see **section 1.2.1.1.2**.
[879] See **n876**.
[880] See **n875**.

proof and is expected to inform other affected Members to the fullest extent possible.[881]

In addition to the limited application of precaution in exception provisions in GATT, the SPS Agreement, which is considered as the most elaborate agreement on health issues in WTO law, is thought to embody the PA in the guise of provisional SPS measures. The Appellate Body has also indicated that the principles developed from the SPS Agreement are equally applicable under GATT XX. It appears that different versions of the PA operate within the WTO regime. We now turn to the discussion of relevant mechanisms of SPS measures in order to unveil a more concrete structure of the PA in the WTO.

4.2 Precautionary entitlements in the SPS Agreement

As mentioned above, the PA appears in the form of the health exception operated in the WTO and is often limited and requires scientific justification. However, in order to safeguard human health under the circumstances of scientific uncertainty, the concept of precaution has been incorporated into the SPS Agreement as a *right* instead of a mere exception to Members' obligations by means of the adoption of provisional SPS measures.[882] The PA in the SPS Agreement therefore enjoys higher legal status than in the GATT exceptions in WTO legal hierarchy. (See Diagram 4.2) This is to say that Members are allowed to exercise their *precautionary entitlements* if certain criteria are fulfilled. The adoption of provisional SPS measures to cope with uncertain threat to health is the main feature of the PA in the SPS Agreement.[883]

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[881] See **n874**.
[882] For the precautionary rights of states, see **sections 2.2.2.2 and 2.2.2.2.2**.
[883] Birnie/Boyle/Redgwell, **n251**.

Diagram 4.2 Precautionary actions in WTO exceptions and the SPS Agreement

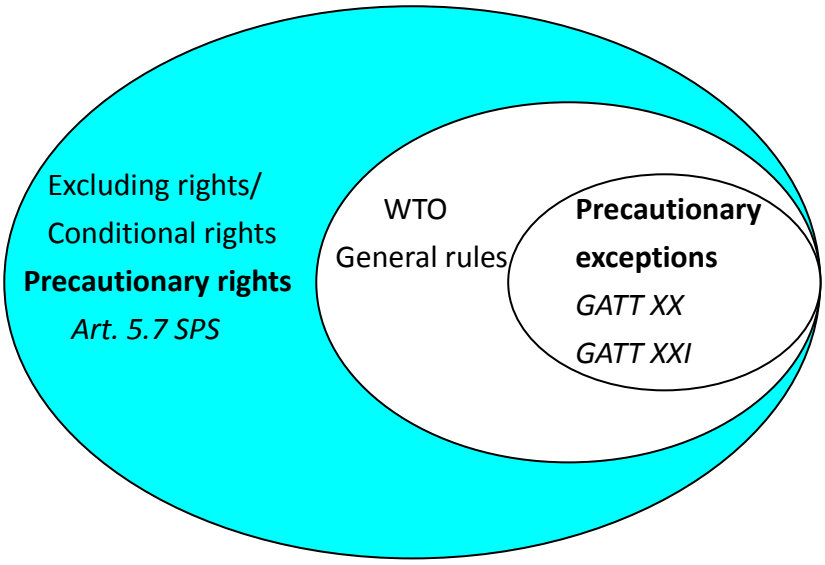
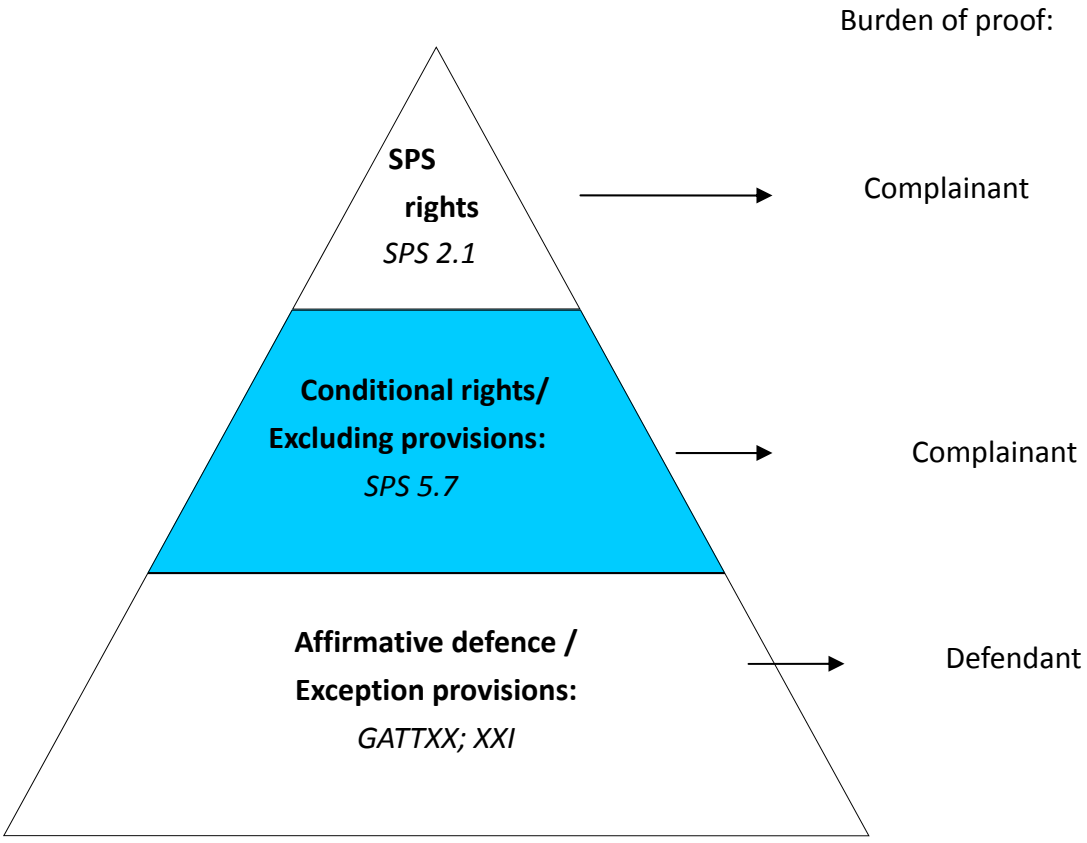


Diagram 4.2.1 Legal hierarchy of the precautionary approach in the WTO



As different PAs exist in both exception provisions and excluding provisions in WTO law, they can be further distinguished in terms of legal status. The PA in exception provisions only acts as an affirmative defence with which the onus remains on the defendant; on the contrary, the PA in excluding provisions can also be understood as a "conditional right" in WTO which enjoys a shift of the burden of proof. In other words, when the PA is identified as a "conditional right", the burden of proof is reversed onto the complaining party. For example, a precautionary measure in the health or security exception could only serve as a defence if the defendant is able to prove the necessity of the health measure; however, if a precautionary SPS measure (or a provisional SPS measure)[884] is deemed a conditional rights by the WTO, it enjoys a higher level of legal status, and the complaining party bears the onus to prove that the adopted measure is inconsistent with Members' obligations to the WTO.

The SPS Agreement aims to help WTO Members set up a standard system of risk management on imported food and produce.[885] It also requires Members to conform to their obligations in WTO law to ensure that the principle of non-discrimination is protected.[886] In addition, to dealing with the situation of scientific uncertainty, the PA is embodied in the SPS Agreement through the imposition of a provisional SPS measure to manage uncertain health risks under a public health emergency.[887] The WTO Appellate Body has identified the function of provisional SPS measures as "a temporary 'safety valve' in situations where some evidence of a risk exists but not enough to complete a full risk assessment under a health emergency".[888] It further stated that "In emergency

[884] Article 5.7 SPS.
[885] See **section 2.2.2.2**.
[886] See para 1 of the preamble SPS; **section 1.2.1.1.1**.
[887] Article 5.7 SPS.
[888] Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute (Hormones II)* **n365** WT/DS320/AB/R, para 678.

situations, for example, a WTO Member will take a provisional SPS measure on the basis of limited information".[889] Therefore, it can be argued that this version of PA is closest to the version that exists in compulsory licensing on the grounds of a public health emergency. If the legal status of compulsory licensing is also a "conditional right" instead of being an "affirmative defence",[890] the PA model in the SPS Agreement can then can be mapped in the compulsory licensing scenario.

4.2.1 Purpose of the SPS Agreement

The purpose of the SPS Agreement is to improve the human health, animal health and phytosanitary situation of WTO Members, and also to ensure that the SPS measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members.[891] The SPS Agreement was devised to introduce more elaborate rules for the application of the health exception rules in GATT XX(b) which relates to the use of sanitary or phytosanitary measures.[892] There is potential overlap between GATT XX(b) and the SPS Agreement. GATT XX(b) appears to cover general health measures that Members might adopt, while the SPS Agreement relates specific to sanitary and phytosanitary measures. The SPS Agreement articulates that SPS measures which conform to the relevant provisions of the SPS Agreement need to be in accordance with Members' obligation under GATT XX(b).[893] In other words, the SPS Agreement and the health exception in GATT stand in a mutually-supportive way.

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[889] Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute (Hormones II)*, **n365** WT/DS320/AB/R, para 680.
[890] See **sections 4.3.2.2.1 and 5.2.1.1**.
[891] Para 1 Preamble SPS Agreement.
[892] Preamble of the SPS Agreement.
[893] Article 2.4 SPS Agreement.

4.2.2 Precautionary SPS measures

Under the SPS Agreement, a WTO Member is allowed to set its own health standard as long as the measure is applied by risk assessment based on scientific evidence.[894] Applications of international standards of health protection to the process of risk management are encouraged.[895] However, a higher standard of protection than the international standard may also be accepted as a *conditional right*[896] in conjunction with a valid risk assessment and scientific evidence.[897] Alternative measures can also be accepted as an equivalent if Members can prove they provides the same standard of health protection and are least restrictive to trade.[898]

Specifically, the Appellate Body suggested that the PA is reflected in three articles in the SPS Agreement:[899]

- The sixth paragraph of the Preamble: Members can retain their appropriate level of health protection;[900]
- Article 3.3: Members can introduce a higher level of health protection under scientific justification, and
- Article 5.7: Members can adopt provisional SPS measures to manage health risks if scientific evidence is insufficient.

These articles all recognise the *rights* of Members to determine the appropriate level of public health protection in WTO law.[901] The Appellate Body has recognised the

894 Articles 2.2, 5.2 SPS Agreement. See **section 2.2.2.1**.
895 Articles 3.1, 3.2, 3.3 SPS Agreement.
896 Conditional rights, see **n118**.
897 Articles 3.3 and 5 SPS Agreement.
898 Article 4 SPS Agreement.
899 WTO Appellate Body Report, *EC – Hormones*, para 124.
900 See **section 2.2.2.1**.
901 See also Appellate Body Report, *EC – Asbestos*, WT/DS135/AB/R, **n110** para 168, "…we note that it

"autonomous right" of a Member to establish a higher level of health protection.[902] Under the scheme of the SPS Agreement, Members can follow two tracks in order to adopt a SPS measure, track one is to follow available international standards; track two is at the discretion of Members, if Members wish to adopt a higher level of health protection for their population, scientific justification must be satisfied with risk assessment and scientific evidence. WTO Members are not prohibited from adopting a level of zero risk.[903]

In order to meet the requirements of adopting a higher level of health protection, Members need to take into account the objective of minimising negative trade effects.[904] Members are obliged to avoid arbitrary or unjust discrimination in the determination of the appropriate levels of health protection in different situations.[905] Relevant economic factors should also be assessed: the potential loss of production or sales in the event of the entry; the spread of a pest or disease; the costs of control for the importing Member, and the cost-effectiveness of alternative approaches should be included.[906]

Furthermore, the PA has been embodied in provisional SPS measures in the SPS Agreement to manage unknown risks to human health. Provisional SPS measures can be adopted with a lack of scientific evidence in order to minimise the risk of a public health threat.

The mechanism of provisional SPS measures was initially drafted to be used in

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is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation". See **section 2.2.2.1**.

[902] Appellate Body Report, *EC – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para 104 **n247** 錯誤! 尚未定義書籤。.

[903] Appellate Body Report, *Australia – Salmon*, WT/DS18/AB/R, para 125 **n515**

[904] Articles 5.3 - 5.6 SPS Agreement.

[905] Article 5.5 SPS Agreement.

[906] Article 5.3 SPS Agreement.

emergency situations where, for example, the spread of a disease has to be stopped urgently before it is feasible to complete a risk assessment.[907] A Member may adopt provisional SPS measures on the basis of available pertinent information. In order to avoid misuse of this article, after the adoption of a provisional SPS measure, Members are still obliged to seek to obtain necessary additional information for a more objective risk assessment, and bear the duty to review the SPS measure within a reasonable period of time.[908]

4.2.3 Rules and principles of the application of the precautionary approach in the SPS Agreement

As mentioned above, there are two tracks to adopting SPS measures, one is the general SPS measure, and the other is an expedient track for adopting provisional SPS measures. The SPS Agreement sets the basic rights and obligations of Members,[909] and affirms that Members "have the right" to take SPS measures "necessary to protect human, animal or plant life or health".[910] In order to meet the following requirements, general SPS measures must:

- be applied "only to the extent necessary to protect human, animal or plant life or health";[911]
- be "based on scientific principle and …not maintained without sufficient scientific evidence";[912]

[907] Marceau, G. and Trachtman, J. "A Map of the World Trade Organization Law of Domestic Regulation of Goods" in Bermann, J. and Mavroidis P. (eds) (2006) *Trade and Human Health and Safety*, Cambridge University Press, New York, USA. See also: **section 2.2.2.2**.
[908] Article 5.7 SPS. See **section 2.2.2.2**.
[909] Article 2 SPS Agreement.
[910] Article 2.1 SPS Agreement.
[911] Article 2.1 SPS Agreement.
[912] Article 2.2 SPS Agreement.

- not "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail",[913] and
- not "be applied in a manner which would constitute a disguised restriction on international trade".[914]

Further, the SPS Agreement defines the necessity test in a way that any alternative measure:

- must achieve "the appropriate level of sanitary or phytosanitary protection";
- must be "reasonably available taking into account technical and economic feasibility", and
- is "significantly less restrictive to trade".[915]

Hence, the necessity test in the SPS Agreement is considered more flexible than that in GATT XX(b).[916] It includes the consideration of technical and economic feasibility of Members, and the alternative measures needs to be "significantly" less restrictive to trade.[917] However, Members are obliged to base their SPS measures on certain risk assessments that indicate the necessity of the measures to reach appropriate levels of health protection.[918]

Again, the PA in the SPS Agreement is a *prescriptive* version, by which states can adopt provisional SPS measures. It could also be understood as a *moderate* PA, for the

[913] Article 2.3 SPS Agreement.
[914] Article 2.3 SPS Agreement.
[915] Footnote 3 SPS Agreement.
[916] See **section 4.1.1.3**.
[917] Footnote 3 SPS Agreement.
[918] Article 5.1 SPS. For a more detailed differentiation of the necessity test in GATTXX(b) and the SPS Agreement, see Kapterian Necessity, **n812**.

necessity test is relatively more relaxed than it is in the health exception. It is also akin to the *information disclosure* PA for an emphasis on the duty of the adopting state to monitor and review the adopted measure is made. It is noteworthy that due to the legal status of a provisional SPS measure being within the domain of "conditional rights" in the WTO, the burden of proof is therefore reversed to the complaining state.[919]

The SPS Agreement articulates that SPS measures which conform to the relevant provisions of the SPS Agreement shall be in accordance with Members' obligations under GATT XX(b).[920] Yet the allocation of burden of proof in the SPS Agreement is different from that in the GATT XX(b) due to their different legal status.[921] (See Diagrams 4.2 and 4.2.1) The right to adopt SPS measures is deemed as an "autonomous right" by the WTO,[922] while GATT XX(b) is deemed an exception to any existing rule.[923] Under the current rule, the burden of proof lies with the defendant who invokes an exception, but the burden of proof is on the complainant who challenges the measure which is adopted following an autonomous right. Therefore, the complaining party has to prove the adopted measure is not consistent with the SPS Agreement. A SPS measure is assumed consistent with the SPS Agreement if the complainant fails to prove otherwise.

In sum, three versions of PAs have been examined in the WTO context, which can be further distinguished by their legal status (see Table 4.2.3). These are all *prescriptive* versions, while PAs in the exception provisions are only affirmative defences, but in the

[919] See **Diagram 4.2.1**.
[920] Article 2.4 SPS.
[921] Grando, **n118**.
[922] Article 2.1 SPS Agreement.
[923] Charnovitz, **n118**, at 257.

SPS Agreement it is a *conditional right*. WTO Members' *right to protect* public health has been recognised and developed in the SPS Agreement, and thus the PA in the SPS Agreement is more concrete and sophisticated than others. It appears that the PAs in WTO exceptions are at two extremes, and that the PA in the SPS Agreement appears to be a *moderate* mechanism.

Table 4.2.3 Precautioanry approaches in the WTO

Version of PA		**Prescriptive**	**Information Disclosure**	**Reverse burden of proof**	**Strong/ Weak/ Modearte**
Exception provision	**Health exception**	V			Weak
	Security exception	V	V		Strong
Excluding provision (Conditional right)	**Provisional SPS measures**	V	V	V	Moderate

It is also noteworthy that in order to avoid misuse and create unnecessary substantial barriers to trade, the invocation of a provisional SPS measure is subject to a set of procedural requirements which aims to avoid disguised protectionism in international economic law.[924] Whether this set of procedural requirements could be accommodated into the IP regime will be explored further, especially through the application in

[924] See **section 2.2.2.2**.

compulsory licensing in Chapter 5.[925]

We now turn our attention to the PA in TRIPS.

4.3 Precautionary entitlements in TRIPS

The role of science has been discussed in the context of the granting of patent rights; for example, the morality or patentability of stem cell, human genome and biotechnology has been subject to great debate.[926] However, the study from the view of the PA or risk management after IP granting has seldom been carried out. This section therefore aims to explore the PA in TRIPS with a special emphasis on compulsory licensing. It is argued that a risk factor arising from the PA has a role to play in the IP regime, and particularly, and that in compulsory licensing of pharmaceutical patents under a public health emergency it is essential and legitimate in contemporary society.[927]

The TRIPS Agreement requires WTO Members to provide minimal standard of IP protection on commodities including pharmaceutical products. Though the TRIPS Agreement has created flexibilities in its mechanism in order to protect human health, the comprehensive protection of IP has given rise to many ethical debates. Notably, the issue of the protection of pharmaceutical patents has drawn commentators' attention to

[925] See **section 5.3**.
[926] See: MacQueen, H, Waelde, C. & Laurie, G., Brown, A. (2010) *Contemporary Intellectual Property: Law and Policy* (2nd edition) Oxford University Press, New York, United States, Chapter 12 **n165**; Laurie, G. (2004) "Patenting Stem Cells of Human Origin" European Intellectual Property Review 59-66; Laurie, G.T. "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" in McLean, S. (ed) (1996) *Contemporary Issues in Law, Medicine and Ethics*, Chapter 12; Porter, G. *et al.*(2006) "The Patentability of Human Embryonic Stem Cells in Europe" 24 *Nature Biotechnology* 653-655; Koopman, J. "Human Rights Implications of Patenting Biotechnological Knowledge" in Torremans, P. (ed) (2008) *Intellectual Property and Human Rights: Enhanced Edition of Copy Right and Human Rights*, Kluwer Law International, The Netherlands.
[927] See **section 5.3**.

the interpretation of the flexibilities of the TRIPS mechanism.[928] These flexibilities include compulsory licensing and parallel import. Yet the international political atmosphere and the WTO retaliation mechanism[929] have deterred Members from taking full advantage of the flexibilities recognised in the TRIPS Agreement.

In the following section, we will explore another guise of precaution first by visiting the flexibilities in the TRIPS on health and security grounds. Similarly to the PA in GATT[930] and the SPS Agreement,[931] in terms of legal status, PAs in the TRIPS can be further distinguished into exceptions[932] and exclusions[933] to IP. (See Diagram 4.2) Exclusions enjoy a higher legal status than exceptions. (See Diagram 4.2.1) Particularly, the granting of a compulsory licence is argued to be exclusion to IP[934] and a precautionary entitlement of states through the interpretation of the Doha Declaration.[935] This section also observes a trend to adopt the PA in recent state practice of the employment in the mechanism of compulsory licensing.[936] First of all, we will introduce the health and security exception provisions in TRIPS.

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928 For interpretation of TRIPS, see for example: Gervais, D.J. (ed)(2007) *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era*, Oxford University Press, New York, U.S. (Gervais IP); Gervais, D. (2003) *The TRIPS Agreement: Drafting History and Analysis* (2nd edition) Sweet & Maxwell, London, UK (Gervais TRIPS) **n142**; Carvalho, N.P. (2005) The TRIPS Regime of Patent Rights (2nd edition) Kluwer Law International, The Hague, The Netherlands (Carvalho) **n141**; Malbon, J. and Lawson C. (eds) (2008) *Interpreting and Implementing the TRIPS Agreement: Is it fair?* Edward Elgar, Cheltenham, UK.

929 See **sections 1.2.1.1.2. and 1.3.3.1**.

930 See **section 4.1**.

931 See **section 4.2**.

932 See **section 4.3.1**.

933 See **section 4.3.2**.

934 See **section 4.3.2.2**.

935 See **section 4.3.2.2.1**. Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)

936 See **section 4.3.2.3**.

4.3.1 Public health exceptions in TRIPS

The understanding of the exception rules in the TRIPS Agreement is essential to comprehend the limitations of Members' obligations in WTO law. If Members' specific determination of the level of IP protection falls within the scope of exceptions, it would not be deemed non-compliant to its obligations in the TRIPS.

4.3.1.1 Exceptions to rights conferred

TRIPS exceptions are applied with significant limitations. Examples of legitimate exceptions to patent rights include experimental use exceptions, research or teaching exceptions and the Bolar exception.[937] While an experimental use exception aims for technology innovation, a research and teaching exception is for diffusion of knowledge, the Bolar exception is created to promote competition and access to medicines in particular. The interpretation of the scope of Article 30 TRIPS is in the WTO Panel Report on *Canada - Patent Protection of Pharmaceutical Products* (*Canada – Pharmaceutical Patents*).[938]

4.3.1.1.1 Canada – Pharmaceutical Patents

The WTO Panel had specifically discussed the interpretation of the wording of "limited exception" in Article 30 of the TRIPS Agreement in *Canada – Patent Protection of*

[937] The Bolar exception is also known as an "early working" exception which allow generic drug producers to initiate the process of marketing approval of generic drugs before the expiry date. It helps the consumers to obtain generic drugs at lower prices immediately thereafter. Bolar exception has been established in many countries to promote access to medicines and to support the development of a generic pharmaceutical industry

[938] *Canada - Patent Protection of Pharmaceutical Products* (*Canada – Pharmaceutical Patents*) WT/DS114/5, WT/DS114/R, 12 March 2000.

Pharmaceutical Products (*Canada – Pharmaceutical Patents*)[939].

On 11 November 1998, the EC and their Member States filed a complaint to the Dispute Settlement Body (DSB)[940] of the WTO against Canada's Patent Act regarding the protection of inventions in the area of pharmaceuticals. Canada's Patent Act Section 55.2 creates some exceptions to patent protections under certain circumstances. The first paragraph of Section 55.2 is known as the "Regulatory Exception", which is regarding the exception of users related to the development and submission of information required under domestic law, and the second paragraph is the "Stockpiling Exception", which provides legitimate grounds for competitors in the market to manufacture and stockpile the patented product before its patent expires.

In *Canada – Pharmaceutical Patents*, the examination of exception to IP is subject to the "three-step test". Firstly, the exception needs to be limited; secondly, the exception needs "not unreasonably conflict with a normal exploitation"; thirdly, the exception does "not unreasonably prejudice the legitimate interests of the right holder, taking account of the legitimate interests of third parties".[941]

The EC alleged that the exception violated Canada's obligation under Article 28.1 with Article 33 of the TRIPS Agreement. Canada asserted that the word "exception" in TRIPS Article 30 should be interpreted according to the conventional dictionary definition, such as "confined with definite limits", or "restrictive in scope, extent,

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939 Correa, C.M. (2007) *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, New York, United States, p305 (Correa TRIPS) **n154**

940 See **section 1.2.1.1.2**.

941 *Canada - Patent Protection of Pharmaceutical Products* (*Canada – Pharmaceutical Patents*) WT/DS114/5, WT/DS114/R, 12 March 2000, para 7.20. Exceptions to copyright are also limited by the "three-step test". These are contained in Articles 13; 26(2), and 30 TRIPS. See Gervais, D. (2005) "Towards a New Core International Copyright Norm: The Reverse Three-Step Test" 9 *Marquette Intellectual Property Law Review* 1.

amount". However, the EC interpreted the word "limited" to connote a narrow exception, which could be described such as "narrow, small, minor, insignificant or restrictive".[942] The Panel agreed with the EC and adopted the narrow interpretation of the word "limited". The Panel concluded that the interpretation "should be justified in reading the text literally, and focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact".[943]

The *Canada – Pharmaceutical Patents* case indicates that the exception in TRIPS 30 should be interpreted in a restrictive manner, and the exception should not curtail substantial rights of the patent holder. This case shows that the PA in Article 30 TRIPS is a *prescriptive* but *weak* version. The exception rule in the TRIPS, like its application in the General Agreement,[944] is again required to be applied restrictively.

4.3.1.2 Security exceptions in TRIPS

Further to the above discussion with respect to the security exception in the GATT, it is observed that the concept of "national security" has shifted from a purely military to a much broader concept, which Gross *et al.* argue encompasses almost all areas of human endeavor.[945] One of the most important causes for the transition of the concept of national security is the reality of increasing global interdependence. National security consideration constitutes one of the general exceptions to international trade agreement in GATT Article XXI, and the language used has been described as "broad, self-defining,

[942] WTO Panel Report, *Canada – Pharmaceutical Patents*, para 7.28.
[943] WTO Panel Report, *Canada – Pharmaceutical Patents*, para 7.31.
[944] See **section 4.1.3**.
[945] Gross, O. and Aolain, F.N. (2006) *Law in Time of Crisis: Emergency Power in Theory and Practice*, Cambridge University Press. (Gross/Aolain)

and ambiguous".[946]

In the IP regime, Article 73 of the TRIPS Agreement is another provision which allows Members to take action deemed necessary for the protection of "essential security interests" in particular situations. The provision states that the Agreement cannot be construed as preventing Members from taking action in pursuance of a Member's obligation under the UN Charter for the maintenance of international peace and security.[947] The wording of this article echoes GATT XXI[948] and thus the jurisprudence developed thereof may be of relevance for the interpretation of Article 73 of the TRIPS Agreement.

According to the above discussion of security exception in GATT XXI, Members are left with a considerable margin of appreciation in the interpretation of "national security interests"; however, their determination may not be exempt from the scrutiny of the international political settings and the Dispute Settlement Body (DSB)[949] of the WTO. Further, as Correa maintains that "a health crisis or a natural disaster may justify the invocation of such an exception",[950] a public health emergency of international concern (PHEIC)[951] thus may constitute legitimate grounds for security exception in WTO laws. In the context of major human rights conventions, national security is also viewed as a legitimate ground for restricting certain rights and freedom. Cases before the European Court of Human Rights have demonstrated states' wide discretion in the sphere of

946 See **section 4.1.2**. Jackson, J.H. (1997) *The World Trading System: Law and Policy of International Economic Relations* (2nd edition) Cambridge, MA: MIT Press.
947 Correa TRIPS, p520 **n154**.
948 See **section 4.1.2**.
949 See **section 1.2.1.1.2**.
950 Correa TRIPS, p520, **n154.**
951 See **section 3.1.2.1**.

national security as grounds for limiting human rights.[952] It may also be argued that states are left with a broader margin of appreciation in trimming IP in association with security concerns. Following Sunstein's theories of "Anti-Catastrophe Principle" and the "Trimming exercise" as discussed in previous sections,[953] IP protection may need to steer between the polar positions to minimise possible damages. A safety margin is recommended to be adopted in the IP regime in times of emergency.

However, the PA adopted under an exception provision is still only deemed as an "affirmative defence" to the obligations in the TRIPS.[954] Therefore, the burden of proof lies with the defendant to prove the existence of a public health emergency.[955] The trimming measure of IP in the security exception is assumed inconsistent with the obligations in the TRIPS unless the defendant can prove otherwise.

PAs which are within the domain of excluding provisions, namely the *conditional rights* in the IP regime are discussed below.

4.3.2 Public health exclusions in TRIPS

4.3.2.1 Exclusions of patentable subject matter

According to Article 27.2 of the TRIPS, "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is *necessary* to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment".[956] WTO Members may

[952] Gross/Aolain, pp218-9 **n945**.
[953] See **sections 2.3.2.1 and 2.3.2.2**.
[954] See **section 1.2.1.2**.
[955] See **section 1.2.1.2**.
[956] See: Carvalho, N.P. (2005) *The TRIPS Regime of Patent Rights* (2nd edition) Kluwer Law International, The Hague, The Netherlands (Carvalho), **n141**. Regarding the necessity test in this article, Carvalho suggests

choose to adopt precautionary exclusions to patentable subject matter based on morality, public order (or public policy), public health, and serious environmental harm.[957] Morality might simply be a principled objection to an invention; however, precaution implies a desire to eliminate or prevent a risk. In other words, precautionary actions based on risk assessment or evaluation of available pertinent information would appear to be a means of risk management.

"Human health" is considered as a sub-species of *ordre public*.[958] The European Patent Office (EPO) has distinguished "*ordre public*" relating to public interests from morality, which is referred to the physical integrity of individuals.[959] For example, the issues of the patentability of human genetics[960] and software patent protection[961] have recently drawn the debates on the legitimate exclusion to IP on morality grounds.

It is observed by Correa that WTO Members enjoy a wide range of discretion in

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that the necessity test in Article 27.2 implies a two-step test, and needs to be applied with the criteria that are available in the WTO system. These includes considering Article 2.2 SPS Agreement and Article 2 of the WTO Agreement on Technical Barriers to Trade (the TBT Agreement). See Carvalho, pp209-210.

957 For the moral exceptions in WTO, see: Kolitch, S. "The Environmental and Public Health Impacts of US Patent Paw: Making the Law for Incorporation a Precautionary Principle" 36(1) *Environmental Law* 221-256; Diebold, N. F. (2008) "The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and the Undermining Mole" 11(1) *Journal of International Economic Law* 43.

958 Correa TRIPS, p289 **n154**.

959 Correa TRIPS, p288 **n154**.

960 For the limitations on patent rights, see: MacQueen, H. , Waelde, C. and Laurie, G., Brwon, A. (2010)Contemporary Intellectual Property: Law and Policy (2nd edition) Oxford University Press, New York, United States, chapter 12 **n165**; see also: Brownsword, R. (2004) "Regulating Human Genetics: New Dilemma for A New Millennium" 12(14) *Medical Law Review*; Rowlandson, M. (2010) "The Order Public and Morality Exception and its Impact on the Patentability of Human Embryonic Stem Cells" 67 *European Intellectual Property Review*.

961 Leith, P. (2007) *Software and Patents in Europe*, Cambridge University Press, New York, United States; Leith, P. (2004) "Software Patents" JISC Briefing Paper, available at: http://www.jisclegal.ac.uk/Portals/12/Documents/PDFs/softpatentsleith.pdf ; Guadamuz, A. (2006) "The Software Patent Debate" 1(3) *Journal of Intellectual Property Law & Practice* 196-206; Taylor, R. (2009) "In Practice: Legal Update: Hard Choice over Software" 3 *Law Society Gazette*; Grosche, A. (2006) "Software Patents, Boon or Bane for Europe?" 14 *International Journal of Law and Information Technology* 257; Freedman, C.D. (2000) "Software and Computer-Related Business-Method Inventions: Must Europe Adopt American Patent Culture?" 8 *International Journal of Law and IT* 285; Park, J.(2005) "Has Patentable Subject Matter Been Expanded?—A Comparative Study on Software Patent Practices in the European Patent Office, the United States Patent and Trademark Office and the Japanese Patent Office" 13 *International Journal of Law and Information Technology* 336.

determining the situation of "*ordre public*" according to their particular values and social background that needs special protection. Specifically, he argues that "a country devastated by an epidemic may consider that adopting measures to combat it may be a matter of '*ordre public*'".[962] This is to say that states may have the autonomous right to employ health measures to contain virus transmission on "*order public*" grounds in times of public health emergencies. This echoes the argument of the legitimacy of a state's trimming exercise of IP under a pending threat to national security interests.[963]

In addition, many nations have incorporated the PA to protect human health in their patent laws to varying degrees.[964] For example, in the patent code of India, a provision states: "an invention the primary or intended use of which would be contrary to law or morality or injurious to public health".[965] It is also noteworthy that Brazilian patent law provides a number of statutory exclusions from patentability, essentially limiting the definition of patentable subject matter to exclude various categories of inventions for policy reasons.[966] Particularly, the National Health Vigilance Agency (ANVISA)[967] is established as a unique scheme to deliberately trim IP protection prior to patent granting on public health grounds, which can be deemed as adopting a margin of safety in the IP regime.[968] The mechanism of ANVISA will be addressed briefly in the following section.

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962 Correa TRIPS, p288, **n154**.
963 See **section 4.3.1.2**.
964 See Patents Throughout the World (West 2004), Kolitch PP p245 note 156 **n6**.
965 India Patent Act of 1970, chapter II, sec 3(b). Other nations whose patent laws are known to include a statutory public health exclusion are Costa Rica, Ghana, Iran, Japan, Kenya, South Korea, Mongolia, Mozambique, Nepal, Nicaragua, Panama, Peru, Portugal, Saudi Arabia, Somali, Taiwan, Thailand, Trinidad and Tobago, Uruguay, and Vietnam. See Patents Throughout the World, West 2004.
966 In Brazilian law, the following are not patentable: anything contrary to morals, standards of respectability and public security, order and health; substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus; and all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability-novelty, inventive step and industrial application-provided for in Article 8 and which are not mere discoveries.
967 Available at: http://www.anvisa.gov.br/eng/index.htm.
968 Regarding the trimming exercise of the precautionary approach, see **section 2.3.2.2**.

4.3.2.1.1 Brazil National Health Vigilance Agency

Due to the highly prevalence rate of HIV/AIDS in its population, Brazil has been proactive at the forefront of advancing the "right to health" in international society. It has adopted a series of reforms in patent law to promote access to medicines.[969] A self-invented scheme of ANVISA is introduced to incorporate a role for the health agency into the process of pharmaceutical patent granting.[970] ANVISA has the veto power on patent granting when it considers the said patent is harmful to human health. This scheme is also regarded as an action to take full advantage of the flexibilities in TRIPS on health and security considerations.

Prior consent mechanism of ANVISA as a precautionary action for the pre-grant exemptions

The Brazilian exclusions to patentable subject matter are typical of precautionary exclusions in the patent laws for WTO Members. The ANVISA has included public health concerns to limit patent applications on public health grounds. The aim of this trimming exercise of IP granting is to provide an *additional safety factor* in the IP regime,[971] thus it can be deemed as a precautionary measure. According to the legislation, "the concession of patents for pharmaceutical products and processes will depend on the prior approval of ANVISA".[972] The prior consent mechanism of "anuencia previa"

[969] For example, Law 10196/2001 has introduced restrictive and amendments to Patent Law 9279/96.
[970] Chaves, G. C. (2007) "Case Study on the Use of TRIPS Flexibilities in Brazil", Access to Medicines, Human Rights and Trade Rules: Comparative and International Perspectives, Beijing, 29 October 2007.
[971] For the measure to adopting an "additional safety factor", see the discussion of the precautionary approach in Codex Alimentarius in **section 3.1.3.2**.
[972] Article 229-C of Law 9.279/96.

(prior approval) from ANVISA has been adopted to examine substantive patentability criteria from 2003.

In other words, the creation of "anuencia previa" requires two government agencies, the National Institute for Intellectual Property (INPI) and ANVISA to work together in the examination and granting of pharmaceutical patents.[973] The significance of the prior consent requirement is that it partly vests "the competence of regulating pharmaceutical patent applications within ANVISA".[974] ANVISA has the veto power over the granting of any pharmaceutical patent while considering the impact on societal interests relating to public health of a pharmaceutical patent.[975] The requirement of "anuencia previa" has been a novel programme to differentiate pharmaceutical patent application from other patents, which can be seen as a precautionary measure to manage risk to human health. "The prior approval" of ANVISA was devised to suggest the unique and important implication of pharmaceutical patents for society, and to ensure that the granting of pharmaceutical patents receives special examination. However, this consequently gives rise to a question: Is it acceptable in the WTO that pharmaceutical patents are not regarded as "like products" with other patents and receive differential market treatment?[976]

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[973] Murphy, B. (2005) "Brazil's Anuencia Previa: How Brazil's Unique Pharmaceutical Patent Law Illustrates that the United States and Brazil Continue to Disagree on TRIPS' Flexibilities to Protect Access to Essential Medicines".

[974] Rodrigues, E.B.Jr. and Murphy, B. (2006) "Brazil's Prior Consent Law: A Dialogue between Brazil and the United States over where the TRIPS Agreement Currently Sets the Balance between the Protection of Pharmaceutical Patents and Access to Medicines", 16 *Albany Law Journal of Science & Technology* 423 (Rodrigues/Murphy).

[975] Rodrigues/Murphy, **n974.**

[976] According to Article 27.1 TRIPS, which is related to the obligation of non-discrimination, it requires that "patents shall be available and patent rights enjoyable without discrimination" as in the field of technology. The rationale of the prior consent requirement is that it regards pharmaceutical inventions in relation to public health concerns as having a special impact on public interests, thus should not be deemed as "like products" with other technology inventions. See **n110 section 2.2.2.2.3** for the more discussions on "like products"; see **section 5.2.1.2 and below** for the argument on the legitimacy of differential treatment for health technologies associated with risks to human health.

Purpose and defect of ANVISA

The novel device of ANVISA aims to pursue the harmonisation of IP granting and public health by limiting pharmaceutical patentability when taking into account societal interests relating to public health of a pharmaceutical patent from the notion of risk management and precaution. ANVISA has the veto power if the granting of a particular pharmaceutical patent is considered contrary to public health. It appears to have wide discretion on the term of "contrary to public health" while it adopts a strict standard in consenting to the patentability of health-related inventions.

However, there still exist some problems in the mechanism which also attract discussion and criticism. In addition to the legitimacy issue on the distinction of the "likeness" of pharmaceutical patents and other patents,[977] the main conflict is the different mandates and responsibilities of INPI and ANVISA which create tension in the process of granting patents. INPI's primary goal is to apply the norms of Brazil's Industrial Property Law, which is industry-oriented and adopts guidelines more similar to that of developed countries. Yet, ANVISA's purpose is "to protect the health of the public" and "to control products and services that involve risk to the public health".[978] Consequently, the review of ANVISA is based on a public health oriented guideline which adopts a stricter standard in consenting to the patentability of inventions that meet higher standards of non-obviousness and novelty.[979] If the two institutions have disagreements with a patent application, the process is blocked and results in a delay of the grant. TRIPS requires that procedures concerning the enforcement of IP rights

[977] See further discussion in **section 5.2.1.2.1**
[978] Articles 6 and 8 Law N^{0} 9782/99.
[979] Rodrigues/Murphy, **n974.**

shall not entail unwarranted delays,[980] yet the conflicts of INPI and ANVISA could have significant resultes in the delay of granting in some applications. Therefore it may cause "undue delay" to the market for a significant period.[981] This results in a possible violation to the TRIPS.

In summary, though the effectiveness and possible violations of the TRIPS of ANVISA remain to be explored, the reform of pharmaceutical patenting in Brazil demonstrate that developing countries have strived to take full advantage of the flexibilities in TRIPS. The prior consent requirement suggests ANVISA is a *presecriptive* PA. The ANVISA scheme can be categories as a *strong* PA due to the wide discretion in consenting to the patentability of inventions. In addition, ANVISA also requires a manufacturer to present relevant documents in the registration process at ANVISA.[982] It could then be understood that ANVISA reflects an *Information Disclosure* PA.

In addition to the prior consent requirement of ANVISA, which may be regarded as a trimming exercise[983] in the application process of IP on health grounds; the scheme of compulsory licensing could be regarded as another trimming exercise in IP protection after patent granting. Attention now will be turned to the mechanism of compulsory licensing in the TRIPS.

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980 Article 41.2 TRIPS.
981 See *EC – Biotech* for the discussion of "undue delay" to market in **section 2.2.2.2.3**.
982 Resolution – RDC n^0 25, 9th December 1999. Available at: http://www.anvisa.gov.br/legis/resol/25_99rdc_ing.htm
983 See **section 2.3.2.2**.

4.3.2.2 Compulsory licensing

TRIPS provide flexibilities for governments to fine-tune the exclusive protection granted in order to meet other social agendas. It allows governments to evoke suspension on the exclusiveness of patent holders' rights during certain periods in national emergencies provided certain conditions are fulfilled.[984] The relationship between TRIPS and public health has been widely discussed with regard to developing countries,[985] but has hardly been explored in a developed country setting. However, in recent years, the use of compulsory licensing to redress health concerns is increasing in developed countries due to the emergent PHEIC[986] under globalisation. For example, France has implemented an *ex officio* licence for national public health reasons in its patent act,[987] and Belgium has proposed a special compulsory licence regime for national health reasons.[988]

In the case of "other use without authorisation of the right holder" in Article 31 TRIPS, also known as "compulsory licensing", the exclusiveness of patent rights may be temporarily suspended to meet the needs of public interest under a public health emergency. Compulsory licensing can be regarded as a tool to limit IP protection in an

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[984] See **section 1.3.2**.

[985] For a discussion on asymmetrical power relations in international IP, see: Sell, S.K. (2004) "The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions" 77 *Temple Law Review* 363; Sell, S.K. (2002) "Post-TRIPS Developments: The Tension between Commercial and Social Agendas in the Context of Intellectual Property" 14 *Florida Journal of International Law* 193 (Sell Post-TRIPS)**n102**; Helfer, L.R. (2004) "Regime Shifting: the TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" 29 Y*ale Journal of International Law* 1 (Helfer TRIPS) **n16**.

[986] See **section 3.1.2.1**.

[987] Article L. 613-16 of Law No. 92-597 of July 1, 1992, on the Intellectual Property Code (as last amended by Law No. 96-1106 of December 18, 1996): "Where the interests of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to *ex officio* licenses in accordance with Article L. 613-17 in the event of such medicines being made available to the public in insufficient quantity or quality or at abnormally high prices, by order of the Minister responsible for industrial property, at the request of the Minister responsible for health".

[988] Overwalle, G.V. "Reshaping Bio-patents: Measures to Restore Trust in the Patent System" in Somsen, H. (ed) (2007) *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents,* Edward Elgar Cheltenham UK.

attempt to achieve a better balance of rights and obligations of IP.[989] From the lens of risk management, the provisional suspension of the exclusiveness of patent protection in a public health emergency can be regarded as a precautionary measure in IP.[990] It has been adopted as a means to redress the dilemma of "access to essential medicines" in a public health emergency, yet its operation has been highly controversial.[991]

Taubman noted that the Doha Declaration has provided a political solution to these debates;[992] however, it is still observed that, even with the interpretation of the Doha Declaration, Members still tend to bypass this measure on the grounds of public health emergency or other circumstances of extreme urgency.[993] The following section will review the Doha Declaration and the more recent development of compulsory licensing in empirical studies. This suggests that a PA reading of the text would practically meet the need for stronger political and moral arguments for this measure, which is not only in line with the Doha Declaration, but also workable within the existing legal framework.

Compulsory licensing as a precautionary action for the post-grant exemptions

In view of this, it can be argued that, under certain circumstances, compulsory licensing on pharmaceutical patents under a public health emergency can be regarded as a precautionary health measure as it is a provisional measure to suspend the exclusiveness

989 Article 7 TRIPS.
990 See **section 4.3.2.3**.
991 See **sections 1.3.3, 1.3.3.1 and 1.3.3.2**.
992 Taubman, A (2010), *A Practical Guide to Working with TRIPS*, Oxford University Press, New York, US, pp48-49 **n190**
993 See **section 1.3.3**

of IP protection due to the greater need of public health.[994] Similar to the abovementioned precautionary measures,[995] the precautionary granting of a compulsory licence is required to be accompanied by a series of procedural requirements to restrain excessive abuse.[996] Under current international law, states are free to determine their appropriate level of health protection[997] and thus have the discretion to strike a balance between public health and IP protection.

The function of compulsory licensing could also be understood from the above-mentioned concept of "Trimming" proposed by Sunstein,[998] which argues for a safety net in emergency situations. In extreme situations, compulsory licensing may be chosen; states may be left with no other choice but to "trim" IP protection to safeguard public interests of health and security. Compulsory licensing thus offers a margin of safety under a public health emergency where the exclusiveness of IP could be temporarily suspended to safeguard public health.

It can be further argued that even in situations where there is a lack of information, "being humble and uncertain about the right result";[999] it may still lead states to choose to trim IP protection to minimise possible damage to public health. It can be suggested that in uncertainty of extreme situations, it is appropriate to steer between the polar situations of IP protection. Questions arise that ask what kinds of measures might be deployed in the trimming exercise? What limits or flexibilities might be used to avoid polarisation? Such concerns and the policy-making of IP protection in a public health emergency will be further addressed in chapter 5.

994 See **section 5.3** for the development of this argument.
995 See **section 2.3.1.3**.
996 See **sections 5.3.1, 5.3.2, 5.3.3, 5.2.4 and 5.3.5**.
997 See **sections 2.2.2.1 and 2.2.3.1**.
998 See **section 2.3.2.2**.
999 Sunstein Trimming, **n466** p1061.

The conditions and procedures prior to the granting of a compulsory licence are set out in Article 31 TRIPS. For instance, the proposed user needs to obtain authorisation from the right holder on reasonable commercial terms and conditions unless a national emergency or other circumstances of extreme urgency exist. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as is reasonably practicable. The scope and duration of such use needs to be limited to the purpose for which it was authorised; such use needs to be non-exclusive; it requires to be authorised primarily for the supply of the domestic market, and adequate remuneration needs to be paid to the patent right holder. Moreover, granting of a compulsory licence is subject to judicial review or other independent review by a higher authority.

As a general rule, it requires the competent authorities of the WTO Members to decide each compulsory licensing case and establish conditions that are intended to prevent the granting of sweeping compulsory licences across a broad range of inventions. For example, in subparagraph (b) of Article 31, before an application may be considered, the proposed user must first obtain a voluntary licence on reasonable terms and conditions within a reasonable period of time. The requirement of the obligation of the proposed user to first make an effort to obtain authorisation from the right holder can be waived in cases of national emergency or other circumstances of extreme urgency, yet similar to the security exception in GATT, the condition of "national emergency or other circumstances of extreme urgency" is not clearly defined in TRIPS.

In the later round of negotiations in Doha in 2001, WTO ministers stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports

public health.[1000] It has emphasised that the TRIPS Agreement should not prevent member governments from acting to protect public health. It also affirms governments' right to use the agreement's flexibilities, such as compulsory licensing. The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) will be introduced in the following section.

4.3.2.2.1 Doha Declaration on the TRIPS Agreement and Public Health

In agreeing to launch a new round of WTO trade negotiations, trade ministers adopted the "Declaration on the TRIPS Agreement and Public Health" (Doha Declaration) on 14 November 2001. [1001] The Declaration sought to alleviate developing countries' dissatisfaction with the TRIPS regime. It committed members to the interpreting and implementing of the agreement to support public health and to promote access to medicines.[1002] It also affirmed the *right* of WTO Members to use the flexibilities in the TRIPS Agreement to promote these goals.[1003]

[1000] *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), adopted by the fourth Ministerial Conference of the World Trade Organization in Doha, Qatar, on 14 November 2001. WT/MIN(01)/DEC/2 of 20 November 2001 **n27**

[1001] WTO Document, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 14 November 2001. See also: WHO Report, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Correa, C. M. (2002) , WHO/EDM/PAR/2002.3 (Correa WHO); Abbott, F.M. (2002) "The Doha Declaration on the Trips Agreement and Public Health: Lighting A Dark Corner at the WTO" 5(2) *Journal of International Economic Law* 469; Sun, Haochen (2004) "The Road to Doha and Beyond: Some reflections on the TRIPS Agreement and Public Health" 15 *European Journal Of International Law* 123; Baker, B.K. (2004) "Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" 14 *Indiana International and Comparative Law Review* 613; Ansari, N. (2002) "International Patent Rights in a Post-Doha World" 11 *WTR Currents: International Trade Law Journal* 57; Attaran, A. (2002) "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options under WTO Law" 12 *Fordham Intellectual Property, Media and Entertainment Law Journal* 859; Chang, S. W. (2007) "WTO for Trade and Development Post Doha" 10(3) *Journal of International Economic Law* 553.

[1002] Para 4 Doha Declaration, **n27**.

[1003] Para 4 Doha Declaration, **n27**, see also: Fergusson, I. F. "The WTO, Intellectual Property Rights, and the Access to Medicines Controversy" *CRS Report for Congress*, available at: www.au.af.mil/au/awc/awcgate/crs/rs21609.pdf .

For example, the Doha Declaration which stresses WTO Members' right to take advantage of the flexibilities of TRIPS has resonance with the flexibilities used to protect public health in Article 27.2 TRIPS:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, 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. In this connection, we reaffirmed the rights of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.[1004]

The interpretation of the Doha Declaration implies that Members' right in deciding the appropriate level of protection is an "*autonomous right*" and deciding the exclusion to patent rights is conferred. On the one hand, from the view of state *sovereignty* and national autonomy in international law, the Doha Declaration has reaffirmed that the granting of a compulsory licence under a public health emergency falls within the scope of domestic sovereignty.[1005] State sovereignty has been adopted as a reason to limit Members' obligations in the WTO.[1006] On the other hand, this also has resonance with the argument of state responsibility and the protection of civilians when an unknown risk to human health is suspected.[1007]

[1004] Para 4 Doha Declaration, **n27**.

[1005] For discussion on state sovereignty, see: Brownlie, I. (2003) *Principle of Public International Law* (6th edition) Clarendon Press, Oxford, p287; Raustiala, K. (2003) "Rethinking the Sovereignty Debate in International Economic Law" 6 (4) *Journal of International Economic Law* 842; Oesch, M. (2003) "Standards of Review in WTO Dispute Resolution" 6 (3) *Journal of International Economic Law* 635; Cottier, T. (1998) "The Relationship between World Trade Organisation Law, National and Regional Law" 1(1) *Journal of International Economic Law* 83; Condon, B.J. (2006) *Environmental Sovereignty and the WTO: Trade Sanctions and International Law*, Transnational Publishers, New York, United States (Condon Sovereignty) **n132**.

[1006] Condon Sovereignty, **n132**, p233.

[1007] See **section 2.1.2** for the discussion of "State responsibility".

The Doha Declaration has stated that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted;[1008] each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency. It articulates 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.[1009] In view of this, Carvalho notes that "WTO Members are entitled to rely on their own legal system and practices" to issue compulsory licences.[1010]

In addition, WTO Members' right to determine an appropriate level of health protection has been reaffirmed.[1011] Members are allowed to take a more cautious approach to health risk than the international standard. Specifically through the interpretation of the Doha Declaration, arguably, it can therefore be implied that the notion of precaution has been incorporated, or at least accepted in TRIPS.

The declaration also reminds Members to apply the customary rules of interpretation of public international law: each provision of the TRIPS Agreement needs be read in the light of the objectives and principles of the Agreement as stated in Articles 7 and 8 of the general provisions in the Agreement.[1012] The objectives of the TRIPS Agreement clearly state that the protection and enforcement of IP should contribute to the mutual advantage of producers and users and in a manner conducive to "social economic

[1008] Para 5 (b) Doha Declaration.
[1009] Para 5 (c) Doha Declaration.
[1010] Carvalho, N.P. (2005) *The TRIPS Regime of Patent Rights* (2nd edition) Kluwer Law International, The Hague, The Netherlands (Carvalho) **n141**, p151.
[1011] For example, the Appellate Body in *EC – Asbestos* stated that, " …we note that it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation". Appellate Body Report, *EC – Asbestos*, WT/DS135/AB/R, para 168. See **sections 2.2.2.1 and 2.2.3.1**.
[1012] Para 5 (a) Doha Declaration. See **section 1.3.1.1**.

welfare", and a balance of rights and obligations. In Article 8 regarding its principles, it stipulates that Members may adopt measures "necessary to protect public health", and to promote the "public interest" in sectors of vital importance to their socio-economic and technological development.

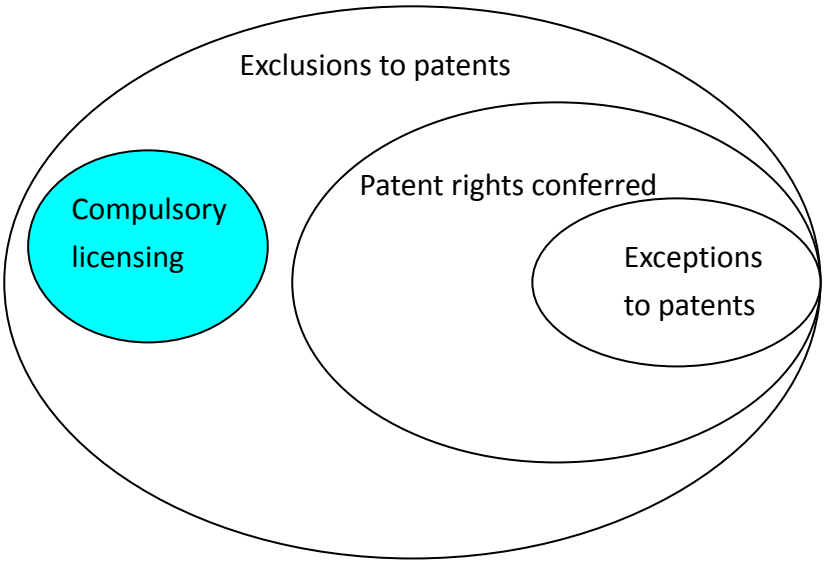
Further, the principles of the TRIPS Agreement states that Members may adopt measures "necessary to protect public health", yet, according to the interpretation of the Doha Declaration, the necessity test in Article 8.1 TRIPS has distinguished itself from that of GATT XX (b).[1013] The interpretation of paragraph 5(c) of the Doha Declaration implies that the granting of a compulsory licence is a *conditional right*,[1014] or an "exclusion provision" in TRIPS, (See Diagram 4.3.2.2.1) which enjoys a higher legal status in the WTO legal hierarchy than "exception provisions", the so-called "affirmative defence" in the general exception provision.[1015] (See Diagram 4.3.2.2.1.1)

In addition, Correa also argues that paragraph 5(c) of the Doha Declaration shows an important and different implication from the GATT/WTO jurisprudence of "the necessity test" outside of the TRIPS context.[1016] Likewise, Carvalho also notes that "the word 'necessary' seems to be redundant in Article 8.1 and … [has] no practical

[1013] See **section 4.1.1.3**.
[1014] See **n118** for conditional rights in the WTO.
[1015] The distinction between "excluding provision" (conditional rights) and "exception provision" (affirmative defence), see the introduction of this chapter and Grando; Charnovitz **n118**.
[1016] Correa, C.M. (2002) "Implications of the Doha Declaration on the TRIPS Agreement and Public Health" *Health Economics and Drugs*, EDM Series No12, at 16-17 (Correa Implications). He also notes that: first, it clarifies that "public health crises" can represent "a national emergency or other circumstances of extreme urgency", and exempt the proposed user of prior negotiation with the patent holder in such conditions. Second, the reference to "HIV/AIDS, tuberculosis, malaria and other epidemics" indicates that the emergency could be a long-term situation. See **section 4.1.1** for the discussion of the "necessity test" in exception provisions. The necessity test of the health exception rule outside the TRIPS context in WTO jurisprudence appears in GATTXX (b), which requires the adopting Member to bear the burden of proving the necessity of the measure. It should be examined by the objective of the said health measure and the *Chapeau* of the provision. Furthermore, the Appellate Body has introduced a balancing and weighing process as a proportionality test to supplement the necessity test.

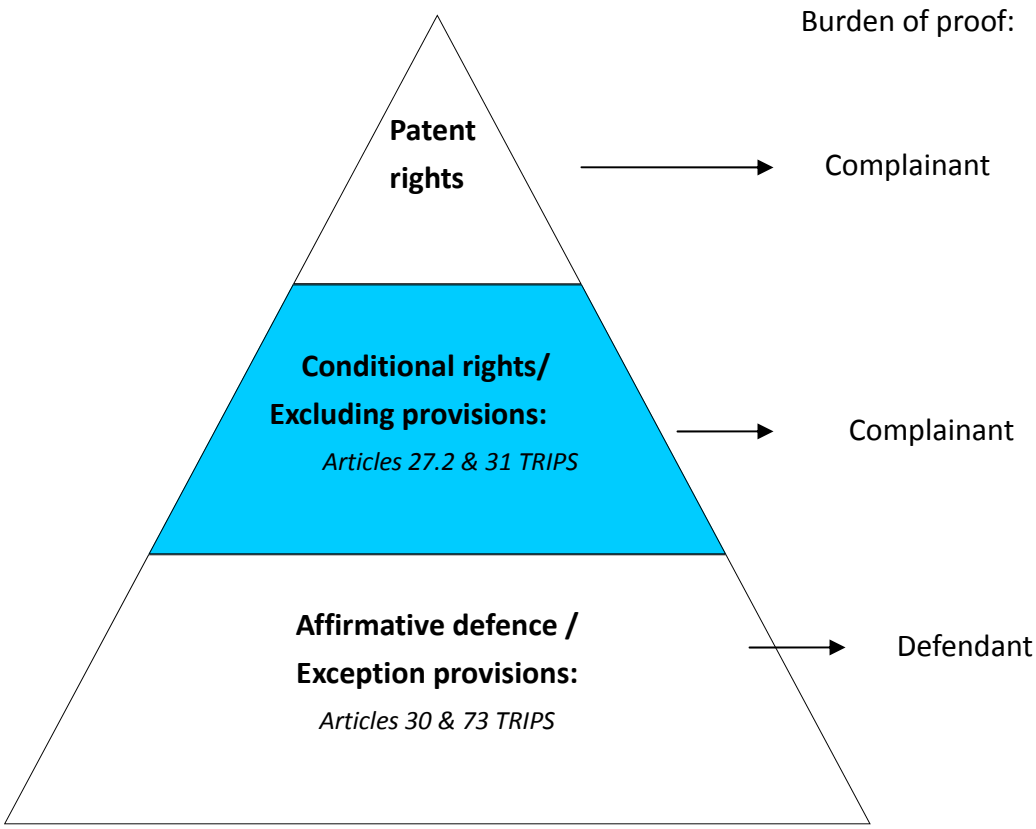
meaning".[1017] From the above analysis, it can therefore be concluded that the burden of proof of such cases is reversed to the complaining Member of compulsory licensing to prove that such emergency conditions do not exist with the accused party.[1018]

Diagram 4.3.2.2.1 Exemptions of WTO patent rights



[1017] For discussion of the health exception in GATT and Article 8 TRIPS, see: Carvalho, N.P. (2005) *The TRIPS Regime of Patent Rights* (2nd edition) Kluwer Law International, The Hague, The Netherlands **n141**.
[1018] Correa Implications, **n1016**.

Diagram 4.3.2.2.1.1 Legal hierarchy of the precautionary approach in TRIPS



In summary, the Doha Declaration has reaffirmed that a WTO Member has the right to determine the grounds to grant a compulsory licence. The right to determine an appropriate level of health protection is regarded as an "autonomous right" in WTO law which therefore requires the complainant to bear the burden of proof proving that the defendant does not fall under the emergency situation. A Member who wants to file a complaint against the invoking Member bears the burden of proof under the interpretation of this paragraph.[1019]

[1019] For a further discussion of allocation of burden of proof in WTO laws, see Grando, M. (2006) "Allocating the Burden of Proof in WTO Disputes: A Critical Analysis" 9 *Journal of International Economic Law* 615, **n118**.

From this perspective, the WTO appears to open a door for public health concerns to legitimise the flexibilities which Members can apply to their discretion.[1020] This also manifests in Members' autonomy being paid due respect in the public health dimension of international economic law.[1021] In particular, Bloche argues that the WTO system has come to treat protection of health as a *de facto* interpretative principle when disputes arise over Members' treaty obligations. He notes that especially after the global AIDS pandemic, world politics has pushed the WTO to identify an emerging pattern of deference to *national autonomy* when Members' domestic health policies conflict with other values protected by trade agreements.[1022] It is also noteworthy that the ongoing amendment of Article 31(f) which introduces a notification system is also an attempt to embody the flexibilities in TRIPS.[1023] It is in this context that this work has observed a trend of promoting access to medicines and adopting the PA in compulsory licensing in state practice.

In summary, in terms of legal status, the PA in compulsory licensing is akin to the PA in the SPS Agreement:[1024] both are exclusions to Members' obligations to the WTO. It can further be concluded that precautionary compulsory licensing is a *prescriptive* PA; it can also be categorised as an *information disclosure* PA for the adopting state needs to notify the right holder and also bears the responsibility to review the grant in due course.[1025] Further, in order to achieve a *moderate* PA, it is suggested that the template in the SPS

[1020] Sherman, P. B. (2004) "Pandemics ad Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs" 41 *American Business Law Journal* 353.
[1021] *Cf.* See **section 4.2.3** for WTO Members' right to establish their level of health protection. For example, the Appellate Body in *EC – Hormones* noted that, "…Article 3.3 recognizes the autonomous right of a Member to establish such higher level of protection" **n247** 錯誤! 尚未定義書籤。 Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, para 104.
[1022] Bloche, M. (2002) "WTO Deference to National Health Policy: Toward an Interpretive Principle" *Journal of International Economic Law* 825-848 (Bloche Deference).
[1023] See WTO website: http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm
[1024] See **section 4.2.3**.
[1025] Paras (b) (g) (i) of Article 31 TRIPS.

Agreement is adapted in the application for a precautionary compulsory licence. This will be explored in the following chapter.

Attention will be paid to relevant cases where the PA has been accommodated into the IP regime in the following section.

4.3.2.3 Trend of compulsory licensing

The implementation of compulsory licensing seems to broaden its scope in states' practice. In recent years, it had been applied to cope with potential disease outbreaks under the threat of Anthrax in the US and Canada,[1026] as well as the avian flu in Taiwan.[1027] Moreover, Thailand granted compulsory licensing on a heart disease drug by claiming that heart disease has resulted in a national financial emergency.[1028] However, despite the interpretation of the Doha Declaration, there is still no objective mechanism for the invocation of a compulsory licence, thus such application still gives rise to debates on the legitimacy of the grant.[1029] Relevant cases are introduced in the following sections.

4.3.2.3.1 United States and Canada

In 2001, the US and Canada were threatened with a terrorist attack of a particular strain of anthrax that would be resistant to penicillin and other common antibiotics, but possibly treatable by ciprofloxacin, an antibiotic which is patented under a German

[1026] See **section 4.3.2.3.1**.
[1027] See **section 4.3.2.3.2**.
[1028] See **section 4.3.2.3.3**.
[1029] See also **sections 1.3.3.1. and 1.3.3.2**.

company, Bayer Inc. The recommended stockpiles for ciprofloxacin (Cipro) did not exist and the patent owner could not meet the demand for nearly two years. In the fear of an imminent outbreak, the US public health authorities considered calling off the protection of the Cipro patent under Bayer, but decided to wait rather than to buy readily available generics from outside the US.[1030]

At the same time, under the threat of a possible outbreak, the Canadian government also considered issuing a compulsory licence for the generic manufacture of the antibiotic Cipro.[1031] The conflict ceased when both the US and Canada reached an agreement with Bayer who promised a price reduction on the drug.[1032] This anthrax case may imply that the threat to a possible pandemic outbreak is a legitimate ground for compulsory licensing on patented drugs.

4.3.2.3.2 Taiwan

The WHO, on its website, has consistently warned that there has been a high possibility of an avian flu outbreak since spring 2005, and should a serious outbreak happen, the high mortality rate of avian flu H5N1 could result in millions of deaths worldwide.[1033] The WHO considered the H5N1 outbreak to be a phase 3 "pandemic alert phase" in 2005,[1034] which means that a virus new to humans is causing infections, but does not spread easily from one person to another.[1035] The WHO thus recommended that

[1030] "America's anthrax patent dilemma" BBC News, 23 October 2001, available at: http://news.bbc.co.uk/1/hi/business/1613410.stm .
[1031] "Ciprofloxacin: the Dispute over compulsory licenses", CPTech website, available at: http://www.cptech.org/ip/health/cl/cipro/ .
[1032] Bayer press release on Cipro deal, 25 October 2001, available at : http://lists.essential.org/pipermail/ip-health/2001-October/002261.html
[1033] See WHO website: http://www.who.int/crs/disease/avian_influenza/en/index.html.
[1034] WHO "Pandemic Phase", see **section 3.2.3.4.2**.
[1035] WHO (2005) "WHO global influenza preparedness plan: The role of WHO and recommendations for national measures before and during pandemics", Department of Communicable Disease, Surveillance

countries should stockpile the appropriate antiviral at least sufficient for 10 percent of the population, to contain the virus spread.[1036]

Tamiflu (Oseltamivir), the patented drug under Roche is regarded as the most effective antiviral treatment for H5N1, and was in short supply in 2005 when the WHO made its recommendation. Roche, as the single manufacturer, was increasing its production capacity, but still could not meet the global demand in the world for several years.

To secure sufficient stockpiling of Tamiflu, after negotiations with Roche broke down, Taiwan's Department of Health (DOH) considered it necessary to obtain compulsory licensing on the antiviral to eliminate possible shortages in the stock of the Tamiflu due to an outbreak or Roche's failure to timeously supply the antiviral. Consequently, the DOH filed the compulsory licensing application with the Taiwan Intellectual Property Office (TIPO). According to the requirement of Article 76 of the Patent Act, TIPO granted compulsory licensing on Tamiflu on 25 November 2005, which was the first case of compulsory licensing in the light of a threat of an avian flu pandemic.[1037] The grant took effect immediately and operated until December 2007 unless there was some licensing agreement reached between Roche and DOH.[1038]

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and Response, Global Influenza Programme, WHO/CDS/CSR/GIP/2005.5, p6.

[1036] WHO (2005) "WHO global influenza preparedness plan: The role of WHO and recommendations for national measures before and during pandemics", Department of Communicable Disease, Surveillance and Response, Global Influenza Programme, WHO/CDS/CSR/GIP/2005.5.

[1037] TIPO Rule No. 09418601140, 8 December 2006.

[1038] There were several preconditions accompanied by this grant:

- The grant shall take effect immediately and operate through 31 December 2007 to meet the needs and only the needs of the national preparedness plan;
- The antiviral made under the compulsory licensing must not be deployed until after the stock of the Tamiflu which DOH procured from Roche is drawn in full;
- The compulsory licensing may be terminated if Roche agrees to release its patent on Tamiflu to Taiwan;
- Taiwan's drug firms can make Tamiflu for domestic use only, and
- TIPO recommends that Roche and the DOH negotiate the remuneration under the compulsory licensing as soon as possible.

According to the WHO, the potential H5N1 outbreak was a phase 3 pandemic alert phase in 2005, which means that a virus new to humans is causing infections, but does not spread easily from one person to another.[1039] The evolution of mutation of the virus to the next human-to-human phase is not predictable under current technology. It is a complicated problem involving international IP, international economics, public health, and science. Under such global risks, every government would face the dilemma of balancing the industrial development of the pharmaceutical sector with public health needs.

The issue is how to properly apply the concept of "national emergency"[1040] under international economic law, and how to validate the granting ofcompulsory licensing. Taiwan's government claimed that the grant was based upon special consideration of scientific and non-scientific factors. It was claimed that its special geographical location and diplomatic isolation were the main factors in rendering the grant.[1041]

Since 2003, Taiwan did not have a bird flu outbreak unlike neighbouring Southeast Asian countries,[1042] but it claimed that it was under high risk for surveillance of the pandemic due to its special geographical location and not being a member state of the WHO. In the past event of a SARS outbreak, Taiwan was excluded from the global disease surveillance system, and could not receive support from the WHO in the first place because it was not a member of the WHO.[1043] In light of the past experience of isolation from the international surveillance network, Taiwan's government considered

[1039] See **section 3.1.2.4.2** Current phase of alert in the WHO global influenza preparedness plan, available at: http://www.who.int/csr/disease/avian_influenza/phase/en/
[1040] See **section 4.1.2**.
[1041] TIPO Rule No. 09418601140, 8 December 2006.
[1042] Bird flu broke out in Southeast Asia, the more deadly bird flu H5N1 had killed more than 109 people in Indonesia, Vietnam, Cambodia, Thailand, and China. See: http://www.who.int/crs/disease/avian_influenza/country/cases_table_2006_04_12/en/index.html.
[1043] Taiwan had been rejected as a member of the WHO due to China's opposition.

that the threat of the possible outbreak constituted the condition of "national emergency" and that it was necessary to take extra caution in preparation of the upcoming outbreak of avian influenza. Taiwan claimed that its dilemma of diplomatic and political isolation required extra protection for the preparation of the disease outbreak. In order to stockpile enough doses of Tamiflu to prepare for a pending pandemic, the DOH insisted that the compulsory licensing of Tamiflu was legitimate and necessary.

The validity and legitimacy of granting a compulsory licence for a potential public health threat requires further scrutiny, although the previous US and Canadian cases on Cipro seem to indicate that the absence of a bird flu outbreak is not an excuse to prevent Taiwan from considering that this risk of a potential outbreak constitutes a national emergency under TRIPS Article 31(b). The above Cipro cases in consideration of the granting of a compulsory licence under the anthrax threat seem to suggest that the so called "national emergency" is not necessarily to be an ongoing catastrophe.[1044]

4.3.2.3.3 Thailand

Thailand is the first country to test the boundaries of compulsory licensing on medications for chronic diseases. On 25 January 2007, Thailand granted compulsory licences on patents for the heart disease drug, Plavix (Clopidogrel bisulfate).[1045] Thailand

[1044] See **section 4.3.2.3.1**.

[1045] It was under the following conditions:(1) The use of the above Patent rights is effective from now until the patent expired or no essential need.(2) The use of the provision of generic drugs of Clopidogrel is unlimited for patients covered under the National Health Security Act B.E.2545, Social Security Act B.E.2533 and Civil Servants and Government Employees Medical Benefit Scheme, but is under doctors' judgment.(3) A loyalty fee of the Government Pharmaceutical Organisation's (GPO) total sale value will be paid to the patentee. "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand", Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent, the Ministry of Public Health & the National Health Security Office, Thailand, February 2007. ISBN 978-974-94591-5-7.

claimed that its act to grant a compulsory licence on Plavix was based on the provision of "public non-commercial use"[1046] rather than that of "national emergency or other circumstances of extreme urgency"[1047] in TRIPS Article 31 (b). Thailand argues that the production of the generic Plavix by the government-owned Government Pharmaceutical Organisation (GPO) under compulsory licence constitutes a "public non-commercial use". Thailand also alleged that under TRIPS 31(b), the requirement of prior negotiation was waived in cases of public non-commercial use, and that this provision only obliged the government to inform the patentee promptly.

On the one hand, civil society and the NGO have expressed support for Thailand's move on compulsory licensing for chronic diseases treatment.[1048] On the other hand, critics have confronted Thailand's act of compulsory licensing on Plavix as overstepping the appropriate application of compulsory licensing.

However, there was a consequence after the grant: The patent owner of Plavix, Abbot Laboratories announced it would no longer market new pharmaceutical products in Thailand, and it withdrew seven registration applications for four new pharmaceutical products.[1049] In April 2007, the US placed Thailand on its Special 301 Priority Watch List

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1046 See **sections 1.3.2.3 and 1.3.2.3.3**.

1047 See **section 1.3.2.2.**

1048 For example, Knowledge Ecology International (KEI) applauds the decision by the Thailand's Ministry of Health, and they "expect that Thailand will issue other compulsory licence[s] on medicines in the future." The Joint Statement by 15 NGOs claims that the Minister for Public Health has acted accruing to the flexibilities laid out in Article 31(b) of the TRIPS Agreement, and even the US has ever applied the flexibilities in the past. They called the attempt to attack the legitimacy of the decision "insulting and mischievous". Knowledge Ecology International Statement on Thailand Compulsory Licenses, 21 January 2007; *Joint Statement by 15 NGOs - Thai civil society supports the health ministers of Thailand and Brazil and calls on pharmaceutical companies and lobbyists to stop abusing their power*, available at: http://lists.essential.org/pipermail/ip-health/2007-May/011155.html ,10 May 2007. See also, Love, J. Recent Examples of the Use of Compulsory Licensed on Patents, *KEI Research Note* 2, 8 March 2007.

1049 Abbott Pharmaceuticals in Thailand: Fact Sheet,13 April 2007, http://www.oxfamamerica.org/whatwedo/campaigns/access_to_medicines/news_publications/Abbott%20in%20Thailand

which was deemed to be a trade sanction.[1050]

The future of compulsory licensing on chronic diseases still remains unclear. Thailand gave the first shot at testing the threshold of the provision, but it also experienced the backfire of trade retaliation. Trade sanctions and retaliations from drug companies may create chilling effects on the following governments' acts of compulsory licensing on pharmaceuticals.[1051] The hidden pressure still shows that the pharmaceutical IP issue is intrinsically an international wrestle which involves enormous political power and economic profits.

However, the above cases have shown a trend in adopting a PA into compulsory licensing. The recent occurrence of public health emergency also demonstrates that the employment of compulsory licensing on pharmaceuticals is no longer limited to developing countries; developed countries could also face the dilemma of patent right protection and the access to drugs debates under a public health emergency. Both the United States and Canada threatened to issue compulsory licences on Cipro against at the time of the Anthrax threat,[1052] and Taiwan granted a compulsory licence on Tamiflu in preparation for a possible avian flu outbreak.[1053] These cases also imply that the incorporation of precaution in compulsory licensing has been a pragmatic option to tackle a public health emergency. Moreover, from the perspective of states' duties and rights,[1054] states may be obliged to take certain precautionary health measures to protect

[1050] Special 301 Priority Watch List, see Sell Post-TRIPS, **n102**.
[1051] See: "Thailand Avoids Compulsory Licence on Cancer Drug; 3 More Drugs Undecided" Intellectual Property Watch, 31 January 2008, available at: http://www.ip-watch.org/weblog/2008/01/31/thailand-avoids-compulsory-licence-on-cancer-drug-3-more-drugs-undecided/ .
[1052] See **section 4.3.2.3.1**.
[1053] See **section 4.3.2.3.2**.
[1054] See **sections 2.1.2 and 2.3.1.1** for a detailed discussion on "states' precautionary rights and duties".

their civilians under a public health threat, even if there is not full scientific certainty.[1055] In order to minimise Members' reluctance of compulsory licensing, this work focuses on the enhanced use of the existing tools and stronger political and ethical arguments for this measure rather than on the exploration of a new legal doctrine.[1056]

4.3.3 Comments to the precautionary approach in TRIPS

Patent protection is like a two-edged sword, pharmaceutical patents are indeed vital to the innovation of new technology on drug production, but how to strike the right balance between the right to health and patent protection is debatable. International pharmaceutical industries strive to reduce the practice of compulsory licensing by urging that the scope of compulsory licensing should be limited to certain diseases.[1057] They claim that the necessary investment in the research and development of new drugs is the main reason for the high cost of antivirus.[1058] However, in most developing and under-developed countries, the enormous health burden appears to be too overwhelming to consider the protection of IP.[1059]

[1055] Ruessmann, L. (2002) "Putting the Precautionary Principle in its Place: Parameters for the Proper Application of a Precautionary Approach and the Implications for Developing Countries in Light of the Doha WTO Ministerial" 17 *American University of International Law Review* 905-949 **n820**.

[1056] For example, chapter 5 deals with the justification of the need for differential treatment for medical technology in compulsory licensing by establishing how the "like-product" analysis enable a new reading of the discrimination/differential treatment distinction made in TRIPS Article 27.1.

[1057] In order to limit the scope of granting compulsory licences, the EU and the US have attempted to negotiate a list of diseases for which compulsory licences would be given. See, for example, Outterson, K. (2008) "Should Access to Medicines and TRIPS Flexibilities be Limited to Specific Diseases?" 34 *American Journal of Law and Medicine 279*; *Communication from the European Communities and Their Members to the TRIPS Council Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (2002) Brussels, 20 June 2002.

[1058] For innovation of new drugs, see: Love, J. and Hubbard, T. (2007) "The Big Idea: Prizes to Stimulate R&D for New Medicines" 82 *Chicago-Kent Law Review* 1519.

[1059] For "access to medicines" issues, see Nanda, N. and Lodha, R. (2002) "Making Essential Medicines Affordable to the Poor" 20 *Wisconsin International Law Journal* 581; Mercurio, B. (2006) "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" 5 *Northwestern University Journal of International Human Rights* 1; Love, J. (2007) "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D" 40 *U.C. Davis Law Review* 679; Opderbeck, D.W. (2005) "Patents, Essential Medicines, and the Innovation Game" 58 *Vanderbilt Law Review* 501.

The controversy on the inclusion of pharmaceutical products in the IP regime has raised huge ethical controversies. From a historical perspective, many countries with the most innovative pharmaceutical industries did not provide pharmaceutical patents until the industries were established.[1060] TRIPS is the first international agreement that provides patent protection on pharmaceutical products, and it has been challenged by the developing world for offering excessive patent protection for life-saving drugs which has led to the putting off of efficient therapy for the resource-poor patients.

It is in this context that the scheme of compulsory licensing has been devised in order to resolve the dilemma between human rights to health and IP. However, in empirical studies, it has been scarcely used, especially on the grounds of "national emergency or other circumstances of extreme urgency".[1061] Instead of serving as an objective and transparent mechanism to redress the imbalance of IP, compulsory licensing has been constantly used as a diplomatic threatening tool for drug price reduction in many countries.[1062] Therefore the consequences of its application rely much on power play in international settings.[1063]

From the above analysis based on the distinction of "excluding provisions" and "exception provisions" in WTO law,[1064] the mechanism of compulsory licensing can be

[1060] For example, France, Germany, Italy, Sweden and Switzerland had resisted providing patents on pharmaceutical products for a long time before their industries had grown to a significant size. Alsegard, E. (2004) "Global Pharmaceutical Patents after the Doha Declaration – What Lies in the Future" 1(1) *SCRIPT-ed*. See **sections 5.2.1.2 and 5.2.1.2.1**.
[1061] See **sections 1.3.3, 1.3.3.1 and 1.3.3.2**.
[1062] Including South Africa, Brazil, Thailand, US and Canada. See: Abbott, F. and Reichman, J. (2007) "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions" 10 *Journal of International Economic Law* 921.
[1063] See **section 1.3.3.1**.
[1064] See **section 1.2.1.2**, **Diagram 1.2.1.2** and **Diagram 1.2.1.2.1**.

considered an exclusion to IP, which is deemed as Members' "conditional right"[1065] in the WTO regime.[1066] Members are entitled to exercise this right to establish their appropriate level of protection by means of compulsory licensing if certain conditions are satisfied. The question of how best to achieve Members' appropriate level of protection by compulsory licensing then arises.

The Doha Declaration has clarified and interpreted on the terms of compulsory licensing. It has reaffirmed Members' autonomy in determining the appropriate level of health protection under a public health emergency, such as AIDS/HIV, tuberculosis, malaria, and other epidemics. Paragraph 5(c) of the Declaration indicates that the device of compulsory licensing has an important and different implication from the WTO jurisprudence of "the necessity test". It also implies that Article 31 is as an "excluding provision", which excludes other provisions in the TRIPS Agreement. It suggests that the right to grant compulsory licences is an "autonomous right" in the WTO. Charnovitz *et al.* have described an excluding provision (also called conditional right) standing in a mutually exclusive manner with the general rule.[1067] In view of the principles of exception rules applied in the WTO system, a Member is required to prove that the adopted health measure is *necessary* in order to eliminate public health risk through scientific justification. However, compulsory licensing can be deemed as an "excluding provision", thus the burden of proof is laid on the complainant who needs to provide evidence that a public health emergency does not exist. In this analogy, compulsory licensing is deemed in compliance with the obligation of the TRIPS Agreement unless the complainant proves otherwise.

[1065] Conditional rights, see **n118**.
[1066] See **section 4.3.2.2.1**, **Diagram 4.3.2.2.1** and **Diagram 4.3.2.2.1.1**.
[1067] Charnovitz, p257, **n118**.

However, application of compulsory licensing on pharmaceuticals has always been controversial in international fora due to its lack of a clear threshold for invocation. Resourced-poor states are hesitant and reluctant to invoke the provision in fear of trade retaliation from developed states. In order to promote a balanced trimming exercise of IP and restrain a sweeping use of the PA in compulsory licensing, an objective and transparent mechanism is required to prevent its abuse. Relevant conditions to restrict the application of the PA will be further addressed in the following chapter.[1068]

4.4 Conclusion

The WTO has arisen to play an important role in international organisations with respect to world health due to its effective enforcement mechanism.[1069] Members of different international organisations choose to resort to the WTO for dispute settlement on international health issues. The rationale of the PA is particularly related to risk management under globalisation, which appears under different headings in WTO law. This chapter has examined the relevant WTO instruments of the PA in the GATT,[1070] the SPS Agreement,[1071] and the TRIPS Agreement;[1072] and concludes that the concept of precaution has been incorporated into human health protection in WTO law. Yet its application is somewhat fragmented with different weights given to different headings.[1073]

There are two forms of operation of the PA according to its legal status in the WTO regime: one is in the guise of exception provisions, and the other excluding provisions.[1074]

[1068] See **section 5.3**.
[1069] See **section 1.2.1.1.2**.
[1070] See **sections 4.1.1 and 4.1.2**.
[1071] See **sections 4.2.2 and 4.2.3**.
[1072] See **section 4.3.3**.
[1073] See **section 5.1.1.2**.
[1074] See **section 1.2.1.2**.

The PA appearing as an excluding provision enjoys higher legal status than that of an exception provision.

It has been observed that the PA appears as an exception in the GATT,[1075] while the application of a health exception is rigid and subject to scientific justification;[1076] the exercise of the security exception is broad and self-defining.[1077] Both provisions are vague in the embodiment of the PA; lack an objective mechanism for operation, and are restricted by their limited legal status.[1078] On the contrary, the PA in the SPS Agreement is accepted as a *right* or a *conditional right* of WTO Members,[1079] which is equipped with a more sophisticated operation to accommodate precaution and enjoys higher legal status than the GATT instruments in the trade world.[1080]

Similarly, the PA in TRIPS can also be divided into exception provisions and excluding provisions.[1081] Particularly, this chapter scrutinises the mechanism of compulsory licensing and argues that the concept of precaution has been incorporated into compulsory licensing after the specific interpretation of the Doha Declaration.[1082] The Doha Declaration has indicated the flexibilities of compulsory licensing which may have implications for the PA in health risk management in TRIPS. It is argued that WTO Members have the precautionary entitlement to grant a compulsory license under a public health emergency. In addition, recent state practice has also demonstrated a trend towards the employment of the PA which broadens the scope of compulsory

[1075] See **sections 4.1.1. and 4.1.2**.
[1076] GATT XX(b), see **section 4.1.1.3**.
[1077] GATT XXI (b), see **section 4.1.2.3**.
[1078] See **section 4.2**, **Diagram 4.2 and Diagram 4.2.1**.
[1079] Conditional rights, see **n118, section 4.2.3**.
[1080] See **section 4.2**, **Diagram 4.2 and Diagram 4.2.1**.
[1081] See **section 4.3.2.2.1, Diagrams 4.3.2.2.1 and 4.3.2.2.1.1**.
[1082] See **section 4.3.2.2.1**.

licensing in promoting access to medicines.[1083] Hence, it is therefore important to apply the scheme of compulsory licensing in a way that differs from the traditional approach of "the necessity test" in other WTO exception rules.[1084]

Specifically, the schemes of provisional SPS measures and a precautionary grant of compulsory licensing share the common characteristics of risk management in WTO law. They are both provisional health measures adopted under a public health emergency within the domain of scientific uncertainty. These two instruments can be regarded as the excluding provisions in WTO law;[1085] both enjoy a higher legal status than the exception provisions.[1086] States' domestic sovereignty and flexibilities in discretion should be paid due respect when confronting a public health emergency.

In summary, the mechanism of compulsory licensing on pharmaceutical patents under a public health emergency can be considered related more to the scheme of the provisional SPS measures due to their legal status and common characteristics of the rationale of risk management in a public health emergency. Accordingly, WTO Members may argue for a precautionary entitlement to trim IP through compulsory licensing in a public health emergency. The mechanism of provisional SPS measures is suggested to be adapted into the precautionary granting of a compulsory licence. In view of this, further recommendations to refine and to embody the PA in TRIPS will be made in the following chapter to accommodate the PA into compulsory licensing.

1083 See **sections 4.3.2.3.1, 4.3.2.3.2 and 4.3.2.3.3**.
1084 See **n1017 and n1018**.
1085 See **Diagrams 4.2 and 4.3.2.2.1**.
1086 See **Diagrams 4.2.1 and 4.3.2.2.1.1**.

Part 3: Recommendations

5 The Precautionary Approach in Intellectual Property

5.1 Redefining the precautionary approach in international public health

After examining current practice of the precautionary approach (PA) in the international public health and the WTO regimes, a model of the PA adopted in the mechanism of compulsory licensing will be developed in this chapter.

The focus of this chapter is to argue for an adequate margin of safety in the contemporary IP regime. It is suggested that technologies or products associated with risks to human life or health should be granted differential treatment, particularly in compulsory licensing in TRIPS. The differential treatment is justified by the rationale of precaution and risk management in WTO law.

This distinction of "differential treatment" and "discrimination" in WTO law is based on the legitimate factor of safety and the PA;[1087] therefore we will also explore the extent to which the adoption of the PA of pharmaceutical technology should be granted legitimate "differential treatment" in the trade world. It is further argued that a *fast track* to compulsory licensing can be employed when the said technology is strongly associated with the elimination of *significant* / *serious* / *irreversible* damage to human life or health.

This chapter is divided into three parts. First, in view of the current limitations of being subordinated to free trade and regimes conflict in international law which have been addressed in previous chapters,[1088] a tailored model of the PA will be proposed.

[1087] See **section 1.2.1.1.1** for the discussion of the principle of non-discrimination in WTO law.
[1088] See **sections 2.2.4.1. and 3.3.1**.

Second, the proposed model of the PA will be applied in the IP regime to redefine the compulsory licensing provision in TRIPS. It is argued that pharmaceutical technology should receive differential treatment by adopting the PA into compulsory licensing on the rationale of precaution and risk management. Lastly, an expedient track of compulsory licensing on pharmaceutical patents based on the PA is also developed with sub-conditions in order to prevent abuse of this article.

In order to facilitate future application of the PA in the IP regime, a redefinition of the PA will be developed in this context to build a common ground for an objective implementation in the following section.[1089] This redefinition will be further recast into the IP regime by means of adopting a margin of safety in the mechanism of compulsory licensing on pharmaceutical patents.[1090]

5.1.1 Redefinition

As our discussion suggests, the PA is not opposed to science and evidence; rather it supplements the blind spot or ignorance of science.[1091] It is used as a policy tool in risk management while its application is to ensure the concept of a "safety factor" employed in circumstances of scientific uncertainty or insufficiency in scientific evidence. In other words, the PA is supposed to stand side by side with science and evidence; both act in a mutually supportive way to provide a safeguard to human health in case of scientific uncertainty.

[1089] See **section 5.1.2**.
[1090] See **section 5.2**.
[1091] See **section 2.1.1**.

To avoid possible controversies on the applications of the PA which may amount to discrimination[1092] in free trade, I propose to develop a structural mechanism for a systematic application which starts with a scientific evaluation of risk.[1093]

Moreover, from the previous analysis,[1094] the definition of the PA in the international public health law regime tends to be a *prescriptive* one,[1095] which requires specific public health measures to be instituted to regulate the unknown risks to human life or health. An *information disclosure* version could also shed some light on our model with regard to its mandate for the introducing party of a new product or technology to monitor and disclose any risk to the public. We also favour a *moderate* version[1096] as a strong version of the PA tends to opt for intervention regardless of potential costs and a weak version does not require any action for intervention. A moderate version would therefore reconcile both extremes, and it is in favour of adopting the least restrictive measure (LRM) to free trade,[1097] given that globalisation has risen to play an important role in international health.[1098]

Consequently, a revised formulation based on Sandin's prescriptive version can be further illustrated by:[1099]

[1092] See **section 1.2.1.1.1**.

[1093] As the EC Communication has suggested, this mechanism should also includes the sub-principles of proportionality, non-discriminatory, consistency, review, and transparency. *Communication from the Commission on the Precautionary Principle*, Commission of the European Communities, Brussels, COM/2000/1, 2 February 2002, **n299**.

[1094] See **section 2.4.1**.

[1095] See **section 2.3.1**.

[1096] See **section 2.3.3.3**.

[1097] See **section 5.3.2.2.1**.

[1098] See **section 1.1.1.2**.

[1099] According to Sandin's formulation of Prescriptive Precautionary Principle, which is consist of four common elements: (1) a threat, which is (2) uncertain, then (3) some kind of action (4) is mandatory. Sandin, P. (1999) "Dimensions of the Precautionary Principle" 5(5) *Human and Ecological Risk Assessment*, 889-907 **n463**.

Diagram 5.1.1.1 PA formula

> (1) a health threat, which is (2) under scientific uncertainty, then (3) some public health measure for achieving an appropriate level of protection (4) should not be postponed.

Moreover, the requirement for minimising restriction to international traffic and trade can also be accommodated into the formula. Thus this refined version of the PA from an international health law perspective can be elaborated as follows:

Diagram 5.1.1.2 Redefinition of the PA in international health law

> When confronted with *significant* threats of harm to human health, scientific uncertainty should not postpone the adoption of a precautionary public health measure for an *appropriate* level of public health protection while avoiding *unnecessary* interference to international trade.

I suggest that the PA should be triggered once the unknown risk is identified as passing the *significant* threshold.[1100] States have the precautionary entitlement[1101] to adopt health measures to achieve their appropriate level of public health protection.[1102] However, considering the possible adverse effects of interference to international trade, I also suggest that the health measure be a *least restrictive* approach to trade.[1103] It is suggested

[1100] See **section 2.3.1.1.1**.
[1101] See **section 2.1.2**.
[1102] Appropriate level of protection (ALOP), see **sections 2.2.2.1 and 2.2.3.1**.
[1103] See **section 5.3.2.2.1**.

that applications of the PA in international public health can be recast using this formula. Some additional conditions including the duty to review, cost-benefit analysis, public engagement and the burden of proof may be imposed respectively according to the various characteristics of individual health risk. Specifically, the examination of compulsory licensing through the lens of precaution will be addressed in the following paragraphs.[1104]

5.2 Redefining the precautionary approach in intellectual property

The Doha Declaration has reaffirmed Members' *conditional rights*[1105] to determine the appropriate level of health protection in the IP regime, which therefore appears to accommodate the concept of precaution into the TRIPS Agreement.[1106] WTO Members have the conditional rights to show more caution when adopting a higher level of health protection than international standards suggest. Particularly, after the interpretation of the Doha Declaration,[1107] it can be argued that the scheme of compulsory licensing can be understood and rephrased from the perspective of precaution as follows:

[1104] See **section 5.3**.
[1105] Conditional rights, see **n118**.
[1106] See **section 4.3.2.2.1**.
[1107] Doha Declaration, see **section 4.3.2.2.1 n27**.

Diagram 5.2 Redefinition of compulsory licensing through the lens of states' precautionary entitlements

When confronted with a public health emergency, on the basis of the best information available, there are reasonable grounds for concern that *significant* harm to human life and health may occur, scientific uncertainty should not prevent states' precautionary entitlements from adopting a temporary limitation on the exclusiveness of pharmaceutical patents to prevent/abate this harm for achieving an appropriate level of public health protection while avoiding unnecessary interference to international trade.

In other words, the PA could enable states to adopt a safety margin in compulsory licensing when the harm has crossed the *significant* threshold,[1108] but the scientific evidence is not yet fully established.[1109] The PA model adapted in compulsory licensing which introduces a more objective mechanism to trigger the grant and would boost states' confidence in granting a compulsory licence in the preparatory stage of a public health emergency.

5.2.1 A PA reading of compulsory licensing

A PA reading of compulsory licensing would make ample allowance for safety in the IP regime in times of emergency. The precautionary action of adopting "additional

[1108] See **section 2.3.1.1.1**.
[1109] See **section 2.3.1.2**.

conservatism" is regarded as the embodiment of the PA in the structure of risk analysis.[1110]

In order to examine the legitimacy of adopting the PA and the structure of *risk analysis* in compulsory licensing, the legal status of this provision will first be reviewed.[1111] We will then be able to explore to what extent WTO Members can exercise their *precautionary entitlements* in the determination of granting a compulsory licence in a public health emergency.

We will also need to discuss whether the adoption of the PA and the structure of *risk analysis* in this provision will constitute "discrimination" in the WTO regime.[1112] If the adoption can demonstrate legitimate differential treatment, it will then not be seen as "discrimination" by the WTO. In order to identify whether the impact of adoption results in "discrimination" or "differential treatment", we need to introduce the existing tool of the "like-product" analysis to distinguish both concepts in WTO law.[1113] Furthermore, we would also need to discuss the legitimacy of differential treatment for pharmaceutical technologies associated with significant risks to human life or health by means of the examination of the impact of health technologies for society.[1114]

Finally, the following sections also address the fact that a sound framework for the PA in compulsory licensing should be accompanied by a set of sub-conditions based on the elements we developed from previous chapters. These requirements aim to prevent

[1110] Goldstein, B. and Carruth, R.S. (2004) "The Precautionary Principle and/or Risk Assessment in World Trade Organization Decisions: A Possible Role for Risk Perception" 24(2) *Risk Analysis* 491-499, at 492. For example, this application is employed as a typical adoption of an "additional safety factor" in the Codex Alimentarius. See **section 3.1.3.2**.

[1111] See **section 5.2.1.1**.

[1112] See **section 1.2.1.1.1** for the discussion of the principle of non-discrimination in WTO.

[1113] See **section 5.2.1.2.1**.

[1114] See **section 5.2.1.1.2**.

possible abuse of this provision and minimise conflicts in international trade.

5.2.1.1 Compulsory licensing as a state's conditional right in TRIPS

As we have discussed in the previous chapter,[1115] through the clarification of the Doha Declaration,[1116] compulsory licensing falls within the *rights* of WTO Members; put more specifically, it is identified as a *conditional right* in WTO jurisprudence.[1117] This is to say that states have *sovereignty* in the determination of compulsory licensing once certain conditions are satisfied. These sub-conditions will be further addressed in the following paragraphs.[1118]

In addition, it is also argued in the previous chapter that compulsory licensing can at times be deemed to be a form of precautionary measure which serves to constrain private IP protection in times of public health emergency. It is articulated in TRIPS that in the case of "a national emergency or other circumstances of extreme urgency", individual patent protection may be provisionally limted for the greater needs of the public.[1119] This is to say that compulsory licensing can serve as a means for a state to achieve the nation's appropriate or acceptable level of health protection (ALOP).[1120] By adopting the PA and the structure of risk analysis in compulsory licensing, this work would embody the flexibilities in TRIPS and boost states' confidence in granting a compulsory licence in a public health emergency. Based on the argument of

[1115] See **section 4.3.2.2.1**.
[1116] Doha Declaration, see **section 4.3.2.2.1 n27**.
[1117] See **section 4.3.2.2.1, section 1.2.1.2, Diagrams 1.2.1.2 and 1.2.1.2.1** for the discussion of conditional rights, **n118**.
[1118] See **section 5.3 and below**.
[1119] Article 31 (b) and (c) TRIPS. See **section 1.3.1.1** for the discussion of the role of public interest in IP.
[1120] Appropriate level of protection (ALOP), see **sections 2.2.2.1 and 2.2.3.1**.

"*precautionary entitlements of states*",[1121] states may choose to grant a compulsory licence when the risk of harm to public health is identified as passing the "signifiant" threshold.[1122]

Besides, in terms of "State responsibility" in international law as well as their obligations in the IHRs,[1123] every government has responsibilities to safeguard the global virus surveillance network by sharing viruses or specimens and protecting its civilians from virus attack by securing an essential drug supply under the threat of a potential public health emergency.[1124] Specifically, the WHO has advised states to start the stockpiling of essential medicines and vaccines during the preparation period of a disease outbreak;[1125] it would then be necessary to resort to compulsory licensing to ensure sufficient drug supplies within a limited period of time prior to an actual pandemic outbreak. Therefore, it would be of vital importance to invoke the PA and adopt a safety margin in compulsory licensing in the preparedness for a public health emergency.

5.2.1.2 Legitimacy of differential treatment for health technologies associated with risks of significant damage to human life or health

According to Article 27.1 TRIPS, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology". The disctinction of discrimination and differential treatment was discussed in the *Canada* –

[1121] See **section 2.3.1**.
[1122] See **section 2.3.1.1.2**.
[1123] See **section 2.1.2** and **section 3.1.2.2.1** for the discussions of states' duties in the IHRs.
[1124] See **sections 3.1.2.2.1** IHRs; WHO *Ethical Considerations in Developing a Public Health Response to Pandemic Influenza* (WHO Ethical Considerations) pp17-19.
[1125] *WHO Global Influenza Preparedness Plan: The Role of WHO and Recommendations for National Measures before and during Pandemics* (WHO Preparedness), WHO report, WHO/CDS/CSR/GIP/2005.5, pp22-39.

Pharmaceutical Patents Case, where the Panel expressly indicated that these two terms are different concepts.[1126] We will examine whether adopting the PA for health technologies in compulsory licensing will constitute discrimination in WTO law.[1127] In other words, if the differential treatment of health technologies in compulsory licensing can be justified on the basis of the PA and the rationale of risk management in the WTO, it would not be deemed as "discrimination" to other technologies in the trade world.

5.2.1.2.1 Differential treatment and discrimination in international trade

"Discrimination" is illustrated in the context of "like-product" analysis as follows in the WTO system:

> The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment *no less favourable than* that accorded to *like products* of national origin in respect of all laws, regulation and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. (*italics* added)[1128]

Under the non-discrimination principle, if two products are treated as "like products",[1129] then the foreign like products should not receive less advantageous treatment than the domestic products. In other words, any "differential treatment" to market will only be legitimised if the two products are categorised as "unlike" products.

[1126] *Canada – Pharmaceutical Patents*, **n941, para 7.94**
[1127] See **section 1.2.1.1.1** for the discussion of the principle of non-discrimination in WTO law.
[1128] GATT III:4 **n47**.
[1129] See **section 1.2.1.1.1 n110** for the discussion of the "like product" analysis.

Yet Howse notes that the non-discrimination provisions in Article 27.1 TRIPS are very different from those typically found in other WTO treaties.[1130] Article 27.1 TRIPS bans the discrimination with regard to the "fields of technology", while typical non-discrimination provisions in other WTO treaties are with respect to the prohibition of discrimination between domestic and foreign products. Howse states that:

> based on legitimate social and economic objectives, a Member may well wish to limit intellectual property rights in one particular industrial sector – generic medicines is of course a classic example. The importance of *health concerns* in this sector might well argue in favour of limits that it would be inappropriate to impose across the board on all sectors.[1131] (*italic* added)

Hence, Howse argues that a WTO Member may enjoy regulatory autonomy in the limitation of IP with regard to issues of health concerns. It is also noted on the Trans-Atlantic Consumer Dialogue that

> Article 27.1 should not be interpreted as requiring a 'one size fits all' patent law. The language in Article 27.1 …should not be interpreted as preventing countries from addressing public interest concerns in patents, when provisions to address those public interest concerns are consistent with the TRIPs framework. Article 30 of the TRIPs regarding exceptions to patent rights should be interpreted to permit countries to address public interest concerns, including those specifically related to fields of technology.[1132]

[1130] Howse, R (2000) "The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times" 3(4) *Journal of World Intellectual Property* 493-508 (Howse Generic Medicines).

[1131] Howse Generic Medicines, **n1130** p505.

[1132] Trans-Atlantic Consumer Dialogue, *Recommendations on Health Care and Intellectual Property*, Doc No Health-4-00, *Early Working of Patents and Research Exceptions*, February 2000. (Trans-Atlantic Consumer Dialogue) Available at: http://tacd.org/index.php?option=com_docman&task=cat_view&gid=76&Itemid=40

It is suggested that the policy-making of IP and fields of technology is within Members' regulatory autonomy. Health technologies, which are stongly associated with risk to human life and health, would contribute to legitimate social and economic objectives.

For example, in *Canada – Pharmaceutical Patents*, Cuba as a third party, presented arguments in favour of differential treatment of pharmaceutical product inventions by noting that: "The subject of patent protection for pharmaceutical products had always warranted special attention from the legislative and doctrinal point of view, a fact easily attributed to the nature of the products involved and their social impact".[1133] It also restated the Panel's observation of the complex issues concerning the scope of patent protection of pharmaceutical products in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*.[1134] Moreover, Cuba identified the "*particularity*" of the pharmaceutical sector by recognising its fundamental role for research; the "vulnerability" to imitation; the unique market and competition model, and its subjection to strict control by the public authorities.[1135]

Thus, based on the above arguments and the "like-product" analysis in the *Asbestos* case,[1136] a health/risk factor could as well legitimately distinguish fields of technology. Regrettably, the Panel did not consider whether measures limited to a particular area of techonology are "discriminatory", or whether "under certain circumstances they may be justified as special measures needed to restore equality of treatment to the area of technology in question".[1137] There appears to be certain scope for the distinction of discrminination and justifiable differential treatment. Therefore, I propose to adopt the

[1133] *Canada – Pharmaceutical Patents*, **n938,** para 5.18.
[1134] *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (*India – Pharmaceutical Patents*), WT/DS50/R, 5 September 1997, para 8.29.
[1135] *Canada – Pharmaceutical Patents*, **n938 ,** para 5.18.
[1136] *EC – Asbestos*, **n110**
[1137] *Canada – Pharmaceutical Patents,* fn439, **n938 .**

"like-product analysis" as an objective threshold device to differentiate the "unlikeness" of health technologies and other technologies in order to explore the extent to which health technologies could be granted legitimate differential treatment in compulsory licensing.

5.2.1.2.1.1 Health risks as a legitimate factor of the like-product analysis

In order to establish the legitimacy of differential treatment of technologies referred in *Canada – Pharmaceutical Patents*,[1138] the WTO Appellate Body's examination of "like products" can shed some light on the standards of the distinction between "differential treatment" and "discrimination".[1139]

The Appellate Body in the *Asbestos* Case interpreted "like products" as "products [that] share a number of identical or similar characteristics or qualities".[1140] It also suggested "similar" or "identical" as a synonym of "like". The Appellate Body described a determination of "likeness" as "a determination about the nature and extent of *a competitive relationship* between and among products" (*italic* added).[1141] The Appellate Body also identified the following four criteria to analyse the "likeness" of products:

- The properties, nature and quality of the products;
- The end-uses;
- Consumers' tastes and habits – more comprehensively termed "consumers' *perception and behaviour* – in respect of the products", and

[1138] *Canada – Pharmaceutical Patents*, **n941.**
[1139] *EC – Asbestos*, **n110.**
[1140] *EC – Asbestos*, para 91.
[1141] *EC – Asbestos*, para 99.

- The tariff classification of the products.[1142]

Particularly, the Appellate Body took into account "health risk" factors relating to the product while considering the "physical properties" and "consumers' perception and behaviour" of the product. It stated that "We are very much of the view that evidence relating to the *health risks associated with a product* may be pertinent in an examination of 'likeness' under Article III:4 of the GATT 1994" (*emphasis* added).[1143] Therefore, the Appellate Body took the carcinogenicity or toxicity as a highly significant physical difference in examining the physical properties of a product.[1144] It is suggested that the product associated with health risks to human life and health is deemed "physically very different" from other products which have no such health implications.[1145] Products which are associated with health risks to human health thus are regarded "unlike" products to other products which are not associated with such risks. The carcinogenicity or toxicity of a product thus serves as a legitimate ground to differentiate products in the trade world.

Further, in the recent *Philippines – Taxes on Distilled Spirits Case* (*Philippines – Spirits*),[1146] the Appellate Body reminded us that competitveness is the key to the "likeness" analysis by saying that:

> We understand that products that have very similar physical characteristics may not be "like", within the meaning of Article III:2, if their competitveness or substitutability is low, while products that present certain physical differences may still be considered "like" if such physical differences have a

[1142] WTO Appellate Body Report, *EC – Asbestos*, para 85.
[1143] WTO Appellate Body Report, *EC – Asbestos*, para 113.
[1144] WTO Appellate Body Report, *EC – Asbestos*, para 114.
[1145] WTO Appellate Body Report, *EC – Asbestos*, paras 121-122.
[1146] *Philippines – Taxes on Distilled Spirits* (*Philippines – Spirits*), WT/DS396/AB/R, WT/DS403/AB/R, adopted 21 December 2011.

limited impact on the competitive relationship and among the products.[1147]

Using this analogy, it could well be suggested that if the competitivenss or substitutability between technologies is low, even if they have very similar physical characteristics, they may not be "like" in WTO/GATT jurisprudence.

5.2.1.2.1.2 Differential treatment v Discrimination

The Appellate Body in *Canada – Parmaceutical Patents* suggested that "differential treatment" needs to be discerned from "discrimination". It stated:

> The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Article 3 and 4, do not use the term "discrimination". They speak in more precise terms. The ordinary meaning of the word "discriminate" is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of *the unjustified imposition of differentially disadvantageous treatment….The standards by which the justification for differential treatment is measured are a subject of infinite complexity.* "Discrimination" is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision than the concept contains. (*Italics* added)[1148]

It also noted that "Article 27 [TRIPS] prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced

[1147] *Philippines – Spirits*, **n1146** , para 120.
[1148] WTO Panel Report, *Canada – Pharmaceutical Patents*, para 7.94.

locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas".[1149] The Appellate Body articulated that the standards to distinguish "differential treatment" and "discrimination" are a matter of complexity, which may suggest that multiple factors are involved in the determination of the boundaries between these two concepts. It also stressed that the term "discrimination" needs to be avoided if the "differential treatment" of a particular technology is justified with a precise and legitimate factor.

For example, the health impact on society of a health technology may serve as a legitimate factor for the differentiation of technologies. A product or a technology which is associated with significant health risks in terms of either introducing or eliminating health risks could be granted differential treatment in international trade. Following on from the Doha consensus where the Ministers explicitly stated that no country should be prevented from taking measures for the protection of health at the levels it considers appropriate;[1150] the Doha Declaration again articulated that TRIPS should be interpreted and implemented in a manner supportive of Members' rights to protect public health.[1151] Members retain the right to determine the appropriate level of health protection; matters of public health concerns are legitimately within the domain of Members' regulatory authority.

With regard to pre-grant issues, the "like-product" analysis developed from WTO/GATT jurisprudence may enable a new reading of the discrimination/differential treatment distinction in TRIPS Article 27.1. Differential treatment of health

[1149] WTO Panel Report, *Canada – Pharmaceutical Patents*, para 7.92.
[1150] Doha Ministerial Declaration, WT/MIN(01)/DEC/1, 20 November 2001, para 6, **n143**
[1151] *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), adopted by the fourth Ministerial Conference of the World Trade Organization in Doha, Qatar, on 14 November 2001. WT/MIN(01)/DEC/2 of 20 November 2001, para 4..

technology which is strongly associated with risk will not amount to discrimination to the field of technology, when these technologies have low competitiveness or substitutability.[1152] In order to improve clarity, it is suggested that the text of Article 27.1 TRIPS be revised as follows to afford a sophisticated distinction of dirscrimination and differential treatment:

> …., patents shall be available and patent rights enjoyable without *unjustifiable* discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

In other words, though patents are to be granted to all fields of technology, Members could still enjoy their regulatory sovereignty to differentiate between technologies on legitimate grounds in accordance to their particular needs. By the same token, in post-grant exemptions, specifically in compulsory licensing, it may be suggested that medical technology could also receive *justifiable* differential treatment and that the exclusiveness of pharmaceutical patents would be temporarily limited on the legitimate grounds of eliminating health risks to the public.

5.2.1.2.2 Different implications of health technologies associated with risks to human life or health

The principle of national treatment requires that imported like products should receive no less favourable market treatment than domestic products.[1153] However, if a particular technology cannot be treated as "alike" other technologies based on certain legitimate factor, for example, public health, then the differential treatment of the said technology will not amount to discrimination.

[1152] See **section 5.2.1.1.1.1**; **n1147**
[1153] Article III: 4 GATT, see **section 1.2.1.1.1**.

It is therefore contended in this work that when health technologies associated with risks of *significant* impact to the maintenance of human life or health, the unique association of the health risks and the said technology then consists of very different physical properties from other technologies. We now consider the Appellant Body's *like-product* analysis as a threshold device to distinguish health technologies which are strongly associated with the elimination of significant risks to human health from other technologies.[1154]

5.2.1.2.2.1 Like-product analysis

When *health risk* is regarded as a legitimate factor in the "like product" analysis in the Appellate Body's ruling,[1155] it can further be argued that health technologies strongly associated with the elimination of risks to human life or health can be distinguished from other technologies in the same "likeness" analysis.[1156] If two products are deemed "unlike" following the likeness analysis, differential treatments of these products are subsequently legitimate. Likewise, if two technologies are identified "unlike" after the examination of the likeness analysis, differential treatment of these technologies would be legitimate. For example, if a certain pharmaceutical technology, which acts as a vital instrument to control or eliminate the spread of an acute infectious disease, could be categorised as "unlike" information technology; the differential treatment of the given pharmaceutical technology in the context of compulsory licensing would then not amount to discrimination.

[1154] See **sections 1.2.1.1.1 and 5.2.1.2.1.1** for the discussion of the likeness analysis, **n110**.
[1155] There are four criteria to scrutinise the likeness of products. See **section 5.2.1.2.1.1**, **n1154**.
[1156] See **section 1.2.1.1.1** for the discussion of the likeness analysis.

In view of this, the likeness analysis can demonstrate the "unlikeness" of health technologies associated with the elimination of significant risks to human life and health and other technologies which are not directly relevant to health and security. Given its immense impacts on human life or health, it can therefore be argued that the PA granted on the said health technologies could constitute legitimate differential treatment rather than discrimination in international trade.

5.2.1.2.2.2High level of health protection

As we mentioned earlier, states are free to achieve their appropriate level of protection (ALOP) in international law.[1157] In a contemporary society confronted by various risks arising from new technologies or the mutation of diseases, states have the responsibility to pursue a *high* level of health protection in their risk regulatory frameworks in order to cope with uncertain threats to human life and health. The protection of human health is given the *highest* priority in certain international legal instruments. For example, the UN International Covenant on Economic, Social and Cultural Rights (ICESCR) articulates that states need to "recognize the right of everyone to the enjoyment of the *highest* attainable standard of physical and mental health" (*italics* added).[1158] More specifically, EU institutions are required to seek to achieve a *high* level of security,[1159] public health protection[1160] and consumer protection,[1161] and the WTO recognises

[1157] See **sections 2.2.2.1 and 2.2.3.1**.
[1158] Article 12 *International Covenant on Economic, Social and Cultural Rights*, adopted and opened for signature by the United Nations General Assembly Resolution 2200A (XXI) on 16 December 1966, entered into force 3 January 1976 (ICESCR)
[1159] Article 67.3 *Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union* (TFEU) **n408**
[1160] Articles 114.3 and 168.1 TFEU.
[1161] Articles 114.3 and 169.1 TFEU.

Members' policy to pursue "zero risk" health protection.[1162]

Regarding domestic risk regulations, the highest French administrative court also took a PA concerning AIDS-contaminated blood. It was concluded by *Commissaire du Gouvernement Legal* that: "In a situation of risk, a hypothesis that has not been invalidated should provisionally be considered valid, even if it has not been formally demonstrated".[1163] In other words, when risks to human life or health are involved, a government may be legitimate in taking extra caution before a full scientific assessment of the risks has been carried out.

It is also noteworthy that historically speaking, Section 41 of the UK Patent Act 1949 distinguished foods, medicines, and surgical devices from other patented products to ensure a favourable use of compulsory licensing.[1164] It was articulated that those patents concerning foods, medicines, and surgical devices should be "available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights".[1165] However, after the accession to the WTO, the UK Patent Act was amended to abolish those provisions which singled out foods, medicines, and surgical devices patents for a strong presumption in favour of compulsory licensing.[1166]

Nevertheless, it can still be observed that the value of the distinction of "foods, medicines, and surgical patents" from other patents is that it recognises that these

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[1162] WTO Appellate Body Report, *Australia – Salmon*, **n515** para 125; *EC – Asbestos*, **n1100** paras 168, 174.
[1163] Quoted from De Sandeleer, N (2002) *Environmental Principles: From Political Slogan to Legal Rules*, Oxford University Press, New York, United States, p131 (De Sandeleer) **n54**.
[1164] See **section 1.3.2.3.1**. Cornish, W. and Llewelyn, D. (2007) *IP: Patents, Copyright, Trade Marks and Allied Rights* (6th edition) London Sweet & Maxwell, p295 (Cornish/Llewelyn) **n166**; Scherer, F. M. and Watal, J. (2002) "Post-TRIPS Options for Access to Patented Medicines in Developing Nations" 5(4) *Journal of International Economic Law* 913-939, p918 (Scherer/Watal).
[1165] See Scherer/Watal, **n1164** p918.
[1166] Scherer/Watal, **n1164** p918. Medical methods and the treatment of humans or animals may still be excluded from patentability. See Article 27.3 TRIPS.

products are highly associated with public and national security interests which are concerned with the population's health and are essential interests of a nation. Regrettably, the unique properties of those products have been overshadowed by the "non-discrimination" umbrella after accession to the WTO,[1167] and their relevance to public policy has been made indistinct.

Paradoxically, under the free trade blanket, humans are even more vulnerable to health risks arising from globalisation including increasing international disease transmission, bioterrorism, and unknown risks accompanied with emergent technologies,[1168] for the new arising risks are often constantly evolving and difficult to predict or track down.

Further, though public health exclusions are not explicitly articulated or reflected in the compulsory licensing provision, the health exclusions in the patentability clauses do indicate the unique properties of health technologies in the IP regime. Public health exclusions from patent protection are still articulated in the patentability clauses in TRIPS. WTO Members may exclude from patentability inventions which are deemed "necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health" and "diagnostic, therapeutic and surgical methods for the treatment of human or animals".[1169] Accordingly, in view of a harmonious interpretation of TRIPS, health technologies associated with the elimination of significant risks to human health could also be distinguished from other technologies in compulsory licensing.

[1167] See **section 1.2.1.1.1** for the discussion of the principle of non-discrimination.

[1168] For example, a wide range of fears and uncertainties about the potential consequences of novel technologies including nuclear accident, Genetically Modified Foods, BSE, and nanotechnologies have been the subject of academic debates. See **n335 n555**; see also the special edition of "Nanotechnologies, Risk and Society" (2007) 9(2) *Health, Risk & Society*; (2002) 13 *Risk: Health, Safety & Environment*; Mehta, Michael D. (2001)"Public Perceptions of Genetically Engineered Foods: Playing God or Trusting Science" 12 *Risk: Health, Safety & Environment* 205.

[1169] Articles 27.2 and 27.3 TRIPS.

It is therefore appropriate to restore the incommensurable value of human life and health in the global trade net. More specifically in the IP regime, the employment of the PA to adopt a margin of safety would facilitate the balance of public and private interests. In terms of the objective to protect human life or health, which is no longer limited to the legal status of exception to trade, but has officially evolved and been recognised as a *right* or a *conditional right* in the world trade system.[1170] Moreover, based on the rationale of state responsibility and state stewardship of safeguarding public health,[1171] states may be obliged to seek a high level of health protection as well as to protect the population from pending health threats in international law. They are free to exercise their *precautionary entitlements* to safeguard their civilians when confronted by unknown risks,[1172] of which the damages are identified as crossing the *significant* threshold.[1173]

Based on the above analysis, different technologies indeed have various implications for society. For example, Abbott contends that "Inventions are not neutral with respect to field of technology", he suggests that technologies associated with public interests and security including education, health, nutrition, defence, environment, and energy play an important role in IP which are not restricted to trade purposes.[1174] Therefore, inventions which have fundamentally different implications for public health may be distinguished from other inventions based on the differentiation of technologies.

Hence, in order to protect the public interests of health, technologies which have a direct

[1170] See **n118**. The adoption of SPS measures to achieve an appropriate level of health protection is also considered a conditional right of states. See **section 4.2.2** for the adoption of SPS measures.
[1171] See **section 2.1.2**.
[1172] See **section 2.1.2** for the discussion of precautionary rights and duties of states
[1173] See **section 2.3.1.1** for the trigger threshold of the precautionary approach.
[1174] Abbott, F. A. (2005) "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" 8 (1) *Journal of International Economic Law* 77 (Abbott Multilateralism) **n132**

impact on reducing significant risks to human life or health can be argued to be granted legitimate differential treatment based on the rationale of the PA and risk analysis in the trade context.[1175] Precaution and risk management can serve as legitimate grounds in the differentiation of health technologies in the IP regime. This is to say that by adopting the PA in the health-related trade measure, human life or health can still be safeguarded under *unknown risks* to human life or health. After all, health is an indispensible and vital element to the sustainability of a human being; the value of human health and security is too profound to be overshadowed by free trade. By adopting the PA as a safety factor in the trade regime, we will be able to redefine different social and economic implications of a public health emergency, and ultimately, the trade rules in a contemporary IP system.

5.2.1.2.2.3Conclusion

I argue that when a particular technology is associated with the elimination of significant risks to human health, the differential treatment can be justified considering its unique physical properties and consumers' perceptions and behaviour.

The current mechanism of compulsory licensing in redressing the access to medicines issues has been criticised as unsatisfactory,[1176] and that the provision has been acting as a bargaining tool in states' power play instead of providing a clear structure for invocation in the international economic law regime.[1177] Therefore, in order to reflect the unique properties of health technologies for enhancing the access to medicines, as well as to

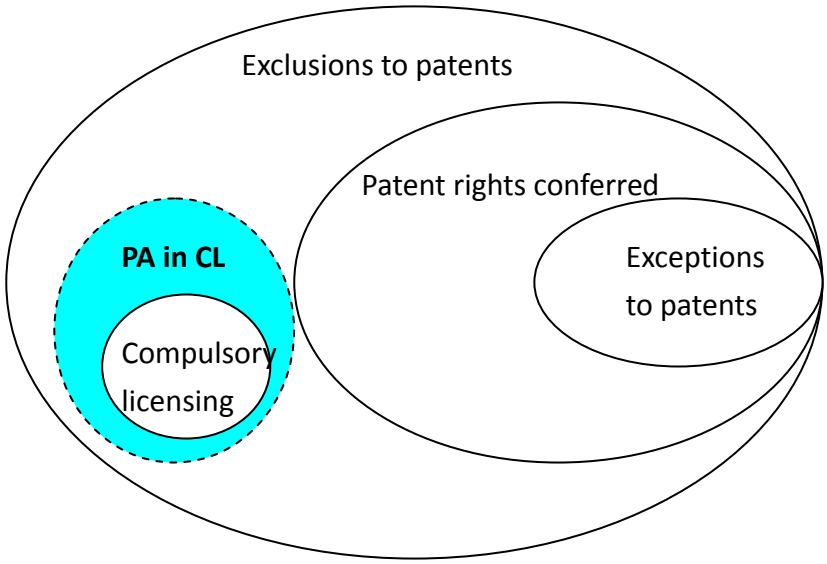
[1175] See **section 3.1.3.1** for the discussion of the structure of risk analysis.
[1176] See **section 1.3.3**.
[1177] See **section 1.3.3.1**.

have a coherent interpretation and application of the PA in international law, it is suggested that the PA should be incorporated into the framework of compulsory licensing. We will apply this argument by adopting differential treatment of the PA on health technologies in compulsory licensing in the following sections.

5.3 Differential treatment of adopting the precautionary approach in compulsory licensing of pharmaceutical patents

The differential treatment in international trade can be demonstrated by the adoption of the PA in risk regulation. It is argued in this work that the adoption of a *differential track* of compulsory licensing on pharmaceutical patents in a public health emergency can be justified by the above analysis. (See Diagram 5.3)

Diagram 5.3 The precautionary approach in compulsory licensing and exemptions to patent rights



In this diagram, I demonstrate that the PA can be incorporated in compulsory licensing by establishing a differential track dealing with technologies strongly associated with the elimination of significant risks to human life and health. In short, I argue that the protection of public health and security can serve as a legitimate factor for differential treatment in compulsory licensing.

Based on the proposed model of the PA in chapter 2, I will proceed to establish a framework of the PA in compulsory licensing in the following paragraphs. First of all, the trigger threshold, or the domain to invoke the PA in compulsory licensing needs to be considered as follows.

5.3.1 Trigger threshold

As we have discussed above, the application of the PA should be based on uncertain risks which are *real, tangible* rather than hypothetic, minor, or trivial.[1178] The PA is suggested to be invoked when the threat of harm passing the "*significant*" threshold.

5.3.1.1 Trigger threshold of the precautionary approach in "Pandemic Phase"

The imposition of public health measures involves significant costs, and policy-makers need to ensure that a cost-benefit option is made available regardless of limited resources in the event of a pandemic. According to the WHO, "Because little may be known about the virulence and transmissibility of the next influenza pandemic virus until it has

[1178] See **section 2.3.1.2** and **Figure 2.3.1.2**. See also: Gostin, L.O. (2000) *Public Health Law: Power, Duty, Restraint*, California University Press. Chapter 4, "Public Health Regulation".

started spreading widely, judgments about the likely effectiveness and benefits of public health measures will often be difficult and may change over time".[1179] It is therefore necessary that an evidence-based approach following the WHO's guidance plays an essential role in the battle against global transient virus mutation. States can follow the WHO's recommendation at any specific pandemic phase and make their best decisions on health measures based on available pertinent evidence.[1180]

However, if it is a condition that a state can only act after scientific justification or full materialisation of a potential disease outbreak, it may be too late to respond to the immediate threat. An evidence-based approach in international health protection may be central to public health strategies, but it has been identified as insufficient in order to cope with emergent and re-emergent public health risks.[1181]

In times of rapid virus transmission, sufficient time to prepare and respond is the key to successful technical surveillance and stockpiling of vaccines and medicines. Therefore the PA is considered essential to risk management of a public health emergency. For example, the WHO has given specific instructions and advice regarding particular public health objectives at each pandemic phase.[1182]

The recommendation of stockpiling antiviral drugs sufficient for a state's population has

[1179] WHO Report (2007) "Ethical Consideration in Developing Public Health Response to Pandemic Influenza" (WHO Ethical Consideration) **n1124** p3.
[1180] Current WHO Phase of Pandemic Alert, available at: http://www.who.int/csr/disease/avian_influenza/phase/en/index.html. See **section 1.5.2.2**; "WHO Global Influenza Preparedness Plan: the Role of WHO and Recommendations for National Measures before and during Pandemics" (WHO Influenza Preparedness), WHO/CDS/CSR/GIP/2005.5 **n1125**.
[1181] See **section 2.1**.
[1182] WHO Report (2005) "WHO Global Influenza Preparedness Plan – The Role of WHO and Recommendations for National Measures before and during Pandemics" (WHO Influenza Preparedness) WHO/CDS/CSR/GIP/2005.5 **n1125.** The WHO global influenza preparedness plan includes six phases in a pandemic scale, divided into three periods: the inter-pandemic period, the pandemic alert period, and the pandemic period (**Table 3.1.2.4.2**). Current Pandemic Phase Alert is also posted on the WHO website. http://www.who.int/csr/disease/avian_influenza/phase/en/.

been on the WHO's main agenda. Specifically, from phase 3 of a pandemic alert period onwards, the major objective regarding antiviral drugs is to coordinate positioning of a possible global stockpile; from phase 4 of a pandemic alert period, one of the national objectives is to assess and facilitate wider usage of antivirus and vaccines in later phases.[1183] States are recommended to prepare sufficient stockpiles of antiviral drugs and vaccines as a precaution.

In order to keep alert to the evolution of new influenza virus strains and to build a surveillance network, the WHO has developed the website "Global Outbreak Alert & Response Network" (GOARN) to keep track of the virus activities globally.[1184] Guidance has been issued on the preparedness for the influenza virus outbreak for states to follow since 2005.[1185] A table of pandemic phases is published by the WHO which divides the pandemic phases into six stages (see Table 5.3.1.1). The table of pandemic phase is used as a tool to inform states of the updated threat of the virus. Each designation of phases is determined by the Director-General of the WHO.[1186]

According to the hierarchy of risks,[1187] the risks in the "Inter-pandemic phase" are residual risks, the risks in the "Pandemic alert" phase are uncertain risks, and the risks in the "Pandemic" phase are certain risks. The PA is applied under the stage of scientific

[1183] WHO Guidance Document "Pandemic Influenza Preparedness and Response: A WHO Guidance Document" Global Influenza Programme, April 2009 (WHO influenza Guidance), p38, at: http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html ; WHO Report (2005) "WHO Global Influenza Preparedness Plan – The Role of WHO and Recommendations for National Measures before and during Pandemics" WHO/CDS/CSR/GIP/2005.5. See **n1125** pp23-27.

[1184] Global Outbreak & Response Network (GOARN), WHO, available at : http://www.who.int/crs/outbreaknetwork/en/

[1185] WHO Global Influenza Preparedness Plan, WHO/CDS/CRS/GIP/2005.5.

[1186] WHO/CDS/CSR/GIP/2005.5. The distinction between phase 1 and phase 2 is based on the risk of human infection or disease resulting from circulating strains in animals. The distinction between phase 3, phase 4 and phase 5 is based on an assessment of the risk of a pandemic. The factors for consideration include current scientific knowledge of the "rate of transmission; geographical location and spread; severity of illness; presence of genes from human strains; other information from the viral genome; and/or other scientific information".

[1187] See De Sadeleer, **n54** p157. See **section 2.3.1.2** for the discussion of the risk hierarchy.

uncertainty or insufficiency of scientific evidence when the risks to human life or health are identified as crossing the significant threshold.[1188] I suggest that the PA should be triggered in the "Pandemic alert" phase when risks are uncertain, but a possibility of human-to-human transmission has been identified as increasing.

Hence, the PA would be triggered between phases 4 to 5 where scientific certainty of a disease outbreak is not inevitable, but there is increased evidence of human-to-human transmission. At both phases 4 and 5, the WHO and states should have started stockpiling sufficient medications for the population to combat the virus spread.[1189]

It is also noteworthy that the WHO also issued a "Checklist for influenza pandemic preparedness planning" and recommended that states should devote time to preparing for an emergency in different pandemic phases.[1190] The aim of this checklist is to equip states with sufficient capacity of virus surveillance and secure adequate medical treatment.[1191] For example, to increase and deploy the vaccine supply is one of the objectives of phase 4 of the pandemic phase.[1192] It may be legitimate to say that the precautionary granting of a compulsory licence could be triggered from phase 4 onwards.

[1188] See **section 2**.

[1189] WHO/CDS/CSR/GIP/2005.5. For example, the WHO needs to review and update recommendations for pandemic vaccine use strategies with partners; States need to review and assess vaccine use strategy following the recommendations.

[1190] "WHO Checklist for Influenza Pandemic Preparedness Planning" Epidemic Alert & Response, Department of Communicable Disease, Surveillance and Response, Global Influenza Programme (WHO Influenza Checklist), WHO/CDS/CSR/GIP/2005.4, 2005.

[1191] WHO/CDS/CSR/GIP/2005.5, WHO global influenza preparedness plan-the role of the WHO and recommendations for national measures before and during pandemics, March 2005.

[1192] WHO/CDS/CSR/GIP/2005.5, 27.

Table 5.3.1.1 Trigger threshold of the PA in phase of pandemic alert (Adapted from "Current WHO phase of pandemic alert")

Pandemic alert	Virus evolution	Level of risk to human	Phase
Inter-pandemic phase	No new influenza virus subtypes have been detected in humans.	Low risk of human cases	1
New virus on animals, no human cases	No new influenza virus subtypes have been detected in human, but a circulating animal influenza virus subtype poses a substantial risk of human disease.	Higher risk of human cases	2
Pandemic alert New virus causes human cases	Human infection(s) with a new subtype, but no human-to-human spread.	Very limited or no human-to-human transmission	3
	Small cluster(s) with limited human-to-human transmission but spread is highly localised.	Evidence of increased human-to-human transmission	4
	Larger cluster(s) but human-to-human spread is still localised.	Evidence of sign human-to-human transmission	5
Pandemic	Increased and sustained transmission in general population.	Efficient and sustained human-to-human transmission	6

PA

5.3.1.2 Based on risk assessment or available pertinent information

According to the rationale of risk analysis, a scientific evaluation of the risk is suggested to be accompanied by the invocation of a precautionary grant.[1193] If a full risk

[1193] See **sections 2.4.2, 3.3 and 4.2.3**. For example, more specifically in the SPS Agreement, the evaluation of the risk for a provisional SPS measure should be conducted in either two aspects: "the likelihood of entry, establishment or spread of a pest or disease" or "the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs". In the CPB, the importer's decision on whether to approve the import should be based on a risk assessment. In the IHRs, the adoption of an additional public health measure should consider scientific principles, available scientific evidence of a risk to human health, available information and special guidance from the WHO. These both demonstrate that the trigger of the precautionary approach should be based on objective scientific grounds, and that the health risk must be

assessment cannot be produced due to time constraints or insufficiency of scientific evidence, relevant available information should also be taken into account. Therefore the implementation of the PA should start with a risk assessment or a valuation based on available pertinent information in order to identify the degree of scientific uncertainty at each stage.

In the circumstances of a public health emergency, the provisional granting of compulsory licensing can still be adopted prior to the completion of a full risk assessment, but it is expected to be subject to a limited duration and timeous review.[1194] If a full risk assessment cannot be carried out due to incomplete scientific evidence, then the decision should be triggered by available pertinent information from international organisations, for example, the recommendations from the WHO. Therefore, the objective suggestions from international organisations play a vital role when disputes arise.

If the time restraint is urgent and it is not possible to conduct an evaluation of risk, I also suggest that the state officially announces a public health emergency to prove the said risks exist.[1195] In most cases when states are reluctant to declare a national emergency due to other considerations,[1196] in order to increase transparency, I suggest that they can publish government statements about their objectives in adopting the measure of granting a compulsory licence.[1197]

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an "ascertainable risk".
SPS Agreement, Annex A. 4; CPB, Article 15.2; IHRs, Article 43.2; WTO Appellate Body Report, *US – Continued Suspension (Hormones II)*, **n365** para 530.

[1194] See **section 5.3.3**.

[1195] For example, the WHO recommended that African states declared HIV/AIDS "a national emergency" in 1999.

[1196] See **section 1.3.3.2**.

[1197] Such considerations were taken into account in *Canada – Certain Measures Concerning Periodicals* for the purpose of showing that imported split-run and domestic non-split-run magazines were substitutable. WT/DS31/AB/R, AB-1997-2, 30 June 1997.

5.3.2 The precautionary action

Governments have a duty and right to protect public health in an emergency. On the one hand, under the rationale of "States' responsibility/stewardship",[1198] states have a *duty* to "take *whatever steps are necessary* to ensure that everyone has access to health facilities, goods and services so that they can enjoy…the highest attainable standard of physical and mental health". (*emphasis* added)[1199] The WHO also identified a government's leadership in the responsibility of national preparedness and response.[1200]

On the other hand, states are also granted a margin of discretion within their sovereignty in determining the appropriate method to achieve the highest level of attainable health protection.[1201] Further, the UN General Comment sets out states' rights and obligations in the realisation of people's right to health in the following paragraph:

> The most appropriate feasible measures to implement the right to health will vary significantly from one State to another. Every State has a *margin of discretion* in assessing which measures are most suitable to meet its specific circumstances. (*emphasis* added)[1202]

In other words, under the rationale of international law, states have the responsibility to protect the public interest of health as well as to enjoy their autonomy in the

[1198] See **section 2.1.2**.
[1199] Para 53 UN document, "General Comment No 14: the Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)", adopted by the Committee on Economic, Social and Cultural rights on 11 May 2000, E/C.12/2000/4, 11 August 2000, (General Comment No 14)
[1200] WHO Guidance Document "Pandemic Influenza Preparedness and Response: A WHO Guidance Document" Global Influenza Programme, April 2009 (WHO influenza Guidance) **n1183**, pp16-17.
[1201] See **sections 2.2.2.1 and 2.2.3.1**.
[1202] Para 53 UN document, "General Comment No 14: the Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)", adopted by the Committee on Economic, Social and Cultural rights on 11 May 2000, E/C.12/2000/4, 11 August 2000, (General Comment No 14) **n1199**.

determination of adopting health measures. This also has resonance with the Doha Declaration which has reaffirmed that "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".[1203]

5.3.2.1 The precautionary entitlements of states' on compulsory licensing

Once the threat of harm is identified as significant; states enjoy the *conditional rights* to grant a compulsory licence in order to achieve an appropriate level of health protection. In order to avoid abuse of this mechanism, the compulsory licensing grant still needs to be examined by the necessity test in the WTO context.

5.3.2.2 The necessity test

The interpretation of the necessity test in the WTO exists in the necessity provisions in different WTO agreements.[1204] Considering the necessity test in the GATT, the Appellate Body adopted the three-step necessity test to examine if the health measure is necessary in the public health exception provision.[1205] Comparatively, the necessity test in the SPS Agreement has slightly different phrasing: Members need to ensure that their SPS measure is applied *only to the extent necessary* to protect human, animal or plant life and health.[1206] Members also need to ensure that such measures are *not more trade-restrictive*

[1203] Para 5(b) Doha Declaration **section 4.3.2.2.1 n27**.
[1204] Kapterian, G (2010) "A Critique of the WTO Jurisprudence on 'Necessity'" 59(1) *International & Comparative Law Quarterly* 89-127.
[1205] See **section 4.1.1.3**. Examining whether the goal of the measure falls within the protection of human health; examining if the measure constitute discrimination to international trade; the weighing and balancing test of the interests furthered by the challenged measure.
[1206] Article 2.2 SPS.

than required to achieve their appropriate level of SPS protection, taking into account technical and economic feasibility.[1207]

In addition, the WTO Appellate Body noted that the more important the protected interests are; the easier a measure designed as an enforcement instrument would be accepted as necessary.[1208] It was stated that the value of "the preservation of human life and health" is "vital and important in the highest degree"[1209], and it also indicated that in situations where risk of irreversible damage to human life and health are concerned,[1210] the threshold to apply the PA will be more relaxed. This suggests that the necessity test in issues dealing with life-threatening or life-terminating situations does not follow the typical necessity test in the GATT.

Further, scholars contend the necessity test in TRIPS has an important and different implication from the typical necessity test outside the TRIPS context.[1211] Consequently, I suggest the necessity test of a compulsory licence dealing with a public health emergency does not follow the typical necessity test in the GATT. Considering its legal status as a conditional right in the WTO, which is similar to the provisional SPS measures,[1212] I suggest that the grant of compulsory licensing, following the requirement of of a SPS measure being "not more trade-restrictive than required" would still need to be examined through the least restrictive measure (LRM) test in order to prove the necessity of the said grant.

1207 Article 5.6 SPS.
1208 WTO Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (*Korea – Beef*) WT/DS161/AB/R, adopted 11 December 2000 **n825**, para 162.
1209 WTO Appellate Body Report, *EC – Asbestos*, para 172, **n110**.
1210 WTO Appellate Body Report, *EC – Hormones*, para 124 **n247**.
1211 See **section 4.3.2.2.1** for the comments from Correa and Carvalho. Correa, C.M. (2002) "Implications of the Doha Declaration on the TRIPS Agreement and Public Health" *Health Economics and Drugs*, EDM Series No. 12, at 16-17 (Correa Implications); Carvalho, N.P. (2005) *The TRIPS Regime of Patent Rights* (2nd edition) Kluwer Law International, The Hague, The Netherlands. See **n141**.
1212 See **sections 4.2.3 and 4.4**.

5.3.2.2.1 Least restrictive to international trade

Given that compulsory licensing and SPS measures share the legal status of Members' conditional rights in the WTO;[1213] we can interpret the necessity of a compulsory licence in view of the necessity test in the SPS Agreement. A Member's SPS measure is deemed necessary until the complainant proves otherwise through the least restrictive measure (LRM) test.[1214] A compulsory licence is deemed necessary until the complaining party proves otherwise through the least restrictive measure (LRM) test. This is to say that the adopted health measure should be least trade restrictive, and no other alternative measure exists to achieve the appropriate level of health protection.[1215]

Accordingly, in order to examine if the compulsory licence is the least restrictive measure, the complaining party needs to prove a *reasonable available alternative* measure existed. Such reasonable available alternative measure must: (1) achieve the appropriate level of public health protection, (2) be significantly less restrictive to trade and (3) be technically and economically feasible.[1216]

In summary, we need to remember that the value of human life or health is of vital interests to the highest degree, and that the necessity test is more relaxed when human health or safety is a concern. A compulsory licence is deemed *necessary* unless the complaining party proves a reasonable available alternative existed.

[1213] See **n118.**
[1214] Kapterian, G (2010) "A Critique of the WTO Jurisprudence on 'Necessity'" 59(1) *International & Comparative Law Quarterly* 89-127.
[1215] See footnote 3 of Article 5.6 SPS Agreement **n39**.
[1216] See **section 4.2.3**.

5.3.3 Duty to review

The granting of a precautionary compulsory licence is an expedient action that is only justifiable when the scientific evidence about a risk remains unclear or insufficient. It is suggested that at the time of adoption how often the measure should be subject to review should be specified.[1217]

5.3.3.1 The grant should be provisional

The precautionary measure should not be adopted once and for all, and the provisional approach reflects the nature of precautionary measures.[1218] Its function is similar to the issuing of preliminary injunctions in environmental cases, which could be issued before a full environmental impact assessment is completed in order to prevent further irreparable damage.[1219]

De Sadeleer notes that: "Precaution is seen as a temporary measure pending further scientific information".[1220] Sandin also contends that "the time factor" is associated with the duty to review which plays an important role in the PA.[1221] He argues that "precaution is warranted only when information about the possible threat is lacking", and that information changes over time. Due to the special characteristics of transient mutation of a virus in a pandemic, the time factor is vital in the preparedness for a public

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1217 See *Japan – Varietals* and *EC – Hormones* II in **sections 2.2.2.2.1 and 2.2.2.2.2**.
1218 The provisional nature of the precautionary approach, see **sections 2.4.2 and 4.2.3**.
1219 Sunstein Irreversiblity, **n756**. For example, the UNCLOS recognised the adoption of provisional measures as an employment of the precautionary approach, and the WTO SPS Agreement also articulates that "a Member may *provisionally* adopt SPS measures on the basis of available pertinent information". (*emphasis* added) See: **section 2.2.1.1.2**. *Southern Bluefin Tuna Case*; Article 5.7 SPS Agreement.
1220 De Sadeleer, **n54**, p110.
1221 Sandin, P. (2006) "A Paradox out of Context: Harris and Holm on the Precautionary Principle" 15(2) *Cambridge Quarterly of Health Care Ethics* 175.

health emergency.

5.3.3.1.1 Transient mutation of virus

Speed and time play a dominant role when humans compete with the unpredictable mutation of a novel influenza virus strain.[1222] The mutation of the influenza virus is the core challenge to the containment of a pandemic. The influenza virus has been difficult to control due to its multitude of virus makeup.[1223] The evolution and potential damage of the new type of virus strain is unpredictable, and there may be a significant period of time to stay on guard and prepare for the next outbreak.[1224] One flu virus can easily swap genetic information with another, and changes in their genetic makeup would make them more deadly.[1225]

Hence, "the time factor" of a potential disease outbreak should be taken into account in risk management. Further, provisional public health measures should be subject to review with updated scientific justifications within a reasonable period of time.

[1222] In order to secure the timeous supply of the vaccine and antivirus once the disease occurs, the WHO works on keeping track of the latest information on viruses and aims to have a better grasp of the virus through close monitoring and assessment of the threat globally. For example, the WHO has developed an "Influenza virus tracking system" after the Convention of "Intergovernmental meeting on Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccine[s] and other benefits" on 21-23 November 2007. The tracking system is an interim electronic system for WHO members, which offers the latest indications of the H5N1 virus and relevant information on vaccines. The Influenza Virus Tracking System, WHO, http://www.who.int/fluvirus_tracker.

[1223] The term H5N1, H1N1 and so on refer to a virus' ability to enter and leave host cells. H and N are the virus's surface proteins haemagglutinin and neuraminidase. Each H and N is quite distinct, and immunity to one strain is not carried to another. See: "The Predictable Pandemic", *New Scientist*, 2 May 2009, p6; "Pandemic's Progress: We Saw it Coming" *New Statesman*, 4 May 2009, pp14-15.

[1224] The duty to review within a reasonable period of time becomes essential when facing an unpredictable and transient health threat, such as in health measures which aim to contain a rapid virus outbreak in the IHRs and the SPS Agreement.

[1225] "More Than 2 Billion People Worldwide Could Get it. Thousands of Schools May Shut down. And Millions Will Need to Be Vaccinated – Twice: Inside the Fight against a Flu Pandemic" *Time*, 24 August 2009, pp15-19.

5.3.3.2 Ongoing duty of monitor and review

A precautionary measure should be provisional; by the same token, it requires constant review to reassure that the measure is up to date and remains legitimate and proportionate. Under the circumstances of scientific uncertainty of a health threat, the precautionary granting of compulsory licensing devised for a higher level of protection is required for timeous review.[1226] Sunstein's notion on the *Information Disclosure Precautionary Principle* (IDPP) also puts emphasis on the disclosure and distribution of knowledge of the risk before the specification of public policies.[1227] The Commission for the European Union also acknowledges the principle of "examination of scientific developments" which highlight the time factor and the development of scientific knowledge.[1228] Consequently, a timeous review with the latest scientific evidence or scientific information is considered essential during a public health emergency.

Before the actual outbreak of a public health emergency, the cumulative scientific information can indicate the proper response on every pandemic phase. After the granting of a precautionary compulsory licence at pandemic phases 4-5,[1229] the WHO

[1226] For example, a provisional SPS measure is subject to a review within a reasonable period of time; an additional public health measure in the IHRs should be reviewed within three months. However, the duty of review in the CPB appears to be less demanding as it does not designate a specific time span for review and is only subject to the exporter's request. The WTO Appellate Body also confirmed that the temporal issue should proceed on a case by case basis which includes the consideration of the difficulty in obtaining the additional information and the characteristics of the measure. It may be interpreted that the duty to review can be imposed according to the characteristics of the health risk and government's policy objectives. See: Article 5.7 SPS Agreement; Article 43 IHRs.; Scott, J. *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (2009) Oxford University Press. New York, p123 (Scott SPS). WTO Appellate Body Report, *Japan – Measures Affecting Agricultural Products (Japan – Agricultural Products II)*, WT/DS76/AB/R, adopted on 19 March 1999, para 93.

[1227] Sunstein PP, p118, **n333**.

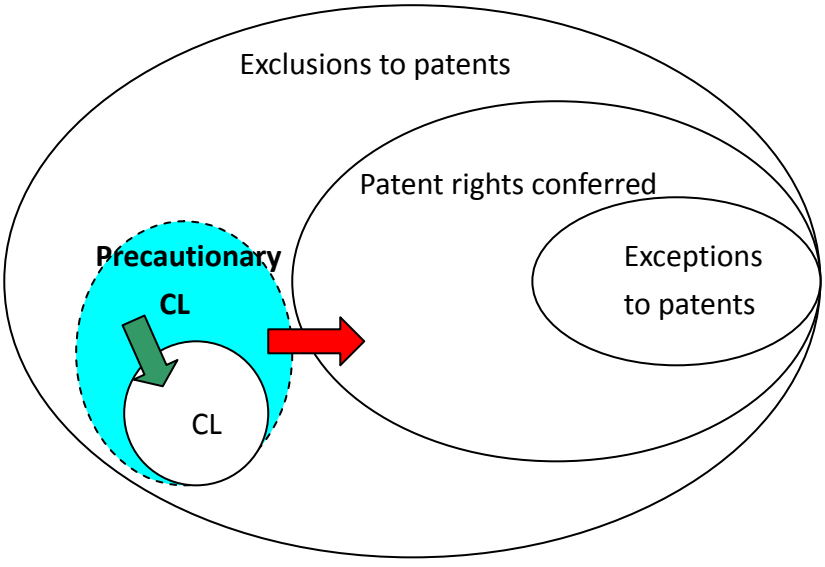
[1228] Communication from the Commission on the Precautionary Principle, Commission of the European Communities (EC Communication), Brussels, 2 February 2000. The EC Communication on the precautionary principle addresses the importance of advancement on scientific findings by expressing that health measures need to be "modified or abolished by a particular deadline, in the light of new scientific findings". It is also noted that "However, this is not always linked to the time factor, but to the development of scientific knowledge".

[1229] See **section 5.3.1**.

and states shall still review and update information at each pandemic phase.[1230]

According to TRIPS, the duration of the compulsory licensing should be limited, and it should be subject to judicial review or other independent review by a "distinct higher authority" within the Member.[1231] Consequently, for a transparent and systematic application, it is suggested that the precautionary grant should be subject to review along with the latest knowledge and development on the new virus strain, and a scientific evaluation should be carried out at pandemic phases 4 and 5 in order to identify the degree of scientific uncertainty and to reassure the legitimacy of the grant. It would become an ordinary grant once the risks have been proved certain; on the contrary, it would need to be revoked or terminated if the threat of harm was proved to be below the *significant* threshold (see Diagram 5.3.3.2.)

Diagram 5.3.3.2 Review of a precautionary compulsory licence (CL)



[1230] WHO/CDS/CSR/GIP/2005.5. For example, the WHO needs to review and update recommendations for pandemic vaccine use strategies with partners; states need to review and assess vaccine use strategy following the recommendations.
[1231] Article 31 (c), (i) TRIPS.

5.3.4 Other non-scientific factors

The value of the PA is that it leaves a margin of safety and provides a channel for present and future generations to get involved with the decision making of risk policies. It recognises the limitations of science, and incorporates other non-scientific factors in risk management, such as, public opinions as supporting evidence in the regulation of risks. The objective of risk management also aims to engage the lay public to increase transparency in the decision making process.[1232] The public engagement of policy making also reflects the value of respect and democracy in contemporary society. It empowers the lay public to make a collective informed decision on their vital interests of health and security.[1233]

However, in a public health emergency bound by the intrinsic limitation of time restraint, it is somehow unimaginable to carry out proper public engagement for pandemic preparedness, and public engagement could only come at a rather late stage as a form of "Amicus Briefs" after a dispute has arisen.[1234] Given the limited time of granting a precautionary compulsory licence, it is still noteworthy that the granting needs to take non-scientific factors into consideration in different social contexts. This would include the respect of patients as main consumers of pharmaceuticals[1235] and civilians' special social and cultural preferences.[1236]

[1232] A WHO draft stated that: "By involving a wide range of stakeholders in the process, the Precautionary Framework requires clarification of stakeholder interests as well as transparency in the way decisions are made". "Stakeholders' engagement" is deemed as a core element of the WHO "Risk Management Framework for Uncertain Risks" and the "Precautionary Framework for Public Health Protection" of the draft, 2 May 2003, (WHO Precautionary Framework). Available at: http://www.who.int/peh-emf/meetings/archive/Precaution_Draft_2May.pdf

[1233] See **section 2.3.2.3**.

[1234] See **section 5.3.4.3**.

[1235] See **section 5.3.4.4.1**.

[1236] See **section 5.3.4.2**.

5.3.4.1 Consumers' perception and behaviour

The WTO Appellate Body highlighted that consumers' tastes and habits are "very likely to be shaped by the health risks associated with a product which is known to be highly carcinogenic".[1237] Thus the health effects of a product play an important role in distinguishing the likeness of products.[1238] In addition, based on the above like-products analysis, health risks associated with a given product would influence consumer behavior.[1239] It is particularly noted by the Appellate Body that: "If the risks posed by a particular product are sufficiently great, the ultimate consumer may simply cease to buy this product".[1240]

The Appellate Body seems to subsume the health effect factor within the physical property and consumers' perception and behaviour criteria in the "likeness" analysis.[1241] In the consideration of the health effect and consumers' perception of the precautionary granting of a compulsory licence, we would first need to take patients' perspectives into account in policy making.

5.3.4.1.1 Patients as main consumers of pharmaceuticals

Patients are a unique group of consumers who are much more vulnerable and sensitive to pharmaceutical products than other customers of certain products. Pharmaceuticals are indispensable, and most of the time irreplaceable to patients unless they choose to

1237 WTO Appellate Body Report, *EC – Asbestos*, **n110**, para 122.
1238 See **section 5.2.1.2.1.1**.
1239 See **sections 5.2.1.2.1.1 and 5.2.1.2.2.1**.
1240 WTO Appellate Body Report, *EC – Asbestos*, para 122.
1241 Bernasconi-Osterwalder, N. *et al. Environment and Trade*, **n720**, p13.

give up their fight for life. The consumers of pharmaceuticals are the *patients inflicted by certain diseases*, who are apparently distinctive from other ordinary groups of customers on the market. Therefore, patients' perspectives need to be taken into account in the transaction of pharmaceuticals through the interpretation of international trade rules.

In other words, the transaction of pharmaceuticals cannot be seen as an ordinary carefree pleasure of open-market shopping behaviour; patients need to be diagnosed first to get prescriptions from professional healthcare providers before having access to drugs. They have no other available alternatives but to survive on these prescriptions in order to maintain fundamental wellbeing. This threshold to access and the characteristic of indispensableness can also be regarded as unique physical properties of pharmaceutical products. This also indicates the given drugs' predominant position on the market, through which they enjoys exclusive patent protection for over 20 years, and most of the time, do not share *a competitive relationship* with other generic drugs.[1242]

Hence, considering the vulnerable position of patients and the non-competitiveness of patented drugs on the market, governments should be able to distinguish the "unlikeness" of pharmaceutical patents and other patents. A precautionary track for compulsory licensing on pharmaceutical patents would not amount to discrimination in international trade.

[1242] See *EC – Asbestos*, para 99. "Thus, a determination of 'likeness' under Article III:4 is, fundamentally, a determination about the nature and extent of a competitive relationship between and among products".

5.3.4.2 Civilians' social and cultural preferences

Risk assessment can be used as a means to assess health risks as well as to provide a form of reasoning in a regulatory system,[1243] but as Gostin notes: "policy in the real world is confounded by scientific uncertainties, human values, and political compromises".[1244] Hence, it is difficult to fully understand the risk posed to the community's health. He also notes that scientists understand risk according to probabilistic assessment, but the lay public's understanding of risk "includes personal, social, and cultural values".[1245]

Consequently, the public's view arises to complement the limitations and possible blind spot in science. As Breyer questions whether the risk policy tends to regulate low risks, but fails to regulate more serious health threats,[1246] there may be gaps among the risks identified by scientists and the real existing threats to human health. Besides, Sunstein's argument of "deliberative democracy" in the process of risk management also implies that citizens are not merely consumers; the regulatory choices should respect and be made after citizens' preferences and values.[1247] However, as time restraint is a vital feature of an "emergency", it may not be realistic to expect a proper consultation on the public's perception of the evidence. Such consideration, therefore, is inevitably beyond the context of risk management.

[1243] Gostin, L.O. (ed) (2002) *Public Health Law and Ethic: A Reader*, University of California Press, Berkeley and Los Angeles, California, US, London, England, pp127-130, (Gostin Reader). He identifies philosophical inquiry, risk assessment and cost-benefit analysis as criteria to assess the worth of public health intervention.

[1244] Gostin, L.O. (ed) (2002) *Public Health Law and Ethic: A Reader*, University of California Press, Berkeley and Los Angeles, California, US, London, England, p139 (Gostin Reader).

[1245] Gostin, L.O. (ed) (2002) *Public Health Law and Ethic: A Reader*, University of California Press, Berkeley and Los Angeles, California, US, London, England, p128 (Gostin Reader).

[1246] Breyer, S. "Breaking the Vicious Circle: Toward Effective Risk Regulation" in Gostin, L.O. (ed) (2002) *Public Health Law and Ethic: A Reader*, University of California Press, Berkeley and Los Angeles, California, US, London, England, pp140-144, at 143 (Gostin Reader).

[1247] Sunstein PP, **n333.**

Indeed, risks have their unique cultural implications that are deeply rooted in specific social, historical and geographical contexts. A WHO Report has stated that: "once people frame a risk issue, it is very difficult to change their mind; therefore, technical risk assessments are largely irrelevant to people".[1248] Perceptions of risks vary from region to region, and variations should be allowed to reflect the diversity in different cultural contexts. Such variations would play an important role in deliberation when disputes arise in international trade.

Moreover, Button observes that: "Many cultures have particular practices that may seem irrational to the outsider".[1249] Due to different cultural backgrounds, some cultures are better prepared to overlook some risks, and some are more cautious in response to other risks due to inherent vulnerabilities. Various factors of civilians' social and cultural preferences would include individual state public policies in national IP and social welfare system, the provision of healthcare and national health insurance.

In summary, due to special social and cultural backgrounds, states may need to adopt a broader margin of safety based on their preferred policies of risk management in IP protection within the flexibilities of TRIPS.[1250] Moreover, it is specifically argued by Correa that "a country devastated by an epidemic may consider that adopting measures to combat it may be a matter of '*order public*'".[1251] Developing countries may exercise domestic sovereignty and conditional rights[1252] in the WTO system to trim/limit certain IP protection in their legal system in order to safeguard their essential security interest in

[1248] WHO Report "Precautionary Policies and Health Protection: Principles and Applications" Report on a WHO Workshop, Rome, Italy, 28-29 May 2001, EUR/02/5027100, (WHO Applications), p10.
[1249] Button, C. (2004) *The Power to Protect: Trade, Health and Uncertainty in the WTO*, Studies in International Trade law, Hart Publishing, Oregon USA (Button) **n325** pp107-108.
[1250] TRIPS, **n1**.
[1251] Correa TRIPS, p288, **n154**.
[1252] Conditional rights, see **n118**.

public health.[1253] This view also has resonance with the Doha debate which implies that states enjoy the entitlements to determine the grounds to issue a compulsory licence in a health emergency.[1254] Consequently, in disease-stricken areas such as Southeast Asian and South Sahara African countries, a state's particular geographical or political situation under an acute disease trans-border transmission may constitute a legitimate cause of the precautionary granting of compulsory licensing.[1255]

Non-scientific factor after a dispute has arisen

5.3.4.3 Amicus Briefs in WTO dispute settlement

While the unknown risks are not acute, for example, where public health risks are posed by biotechnologies or nanotechnologies; government could provide channels for public participation to express their concerns and perspective toward the unknown risks.[1256] However, in situations of a health emergency, for example, during the rapid virus transmission phase, there may not be sufficient time to engage the public in achieving a decisional communication. Accordingly, public participation of compulsory licensing in a public health emergency would come at a rather late stage after the licence was issued and a dispute has arisen. The system of *Amicus Briefs*[1257] in the WTO dispute

[1253] See **section 4.3.2.1.1** for the discussion of Brazilian Agency of Sanitary Vigilance (ANVISA). See also Carvalho, p151, **n141**.
[1254] Doha Declaration, see **section 4.3.2.2.1 n27**.
[1255] See **sections 3.1.2.1.3 and 4.3.2.3.2** for discussions of Swine Flu outbreak in the US and Mexico, and Bird Flu warnings in Taiwan and Southeast Asian countries.
[1256] Bruce, A. "The Public domain: Ideology vs. Interest" in Waelde, C. and MacQueen, H. (2007) *Intellectual Property: The Many Faces of the Public Domain*, Edward Elgar, Cheltenham, UK **n138**. Public participation involves the following three dimensions: public participation in decisions on specific activities, public participation concerning plans, programmes and policies, and public participation during the preparation of executive regulations and generally applicable legally binding normative instruments. Public participation involves the following three dimensions: public participation in decisions on specific activities, public participation concerning plans, programmes and policies, and public participation during the preparation of executive regulations and generally applicable legally binding normative instruments. See: Articles 6, 7 and 8 Aarhus Convention, **n546**.
[1257] Bernasconi-Osterwalder, N. *et al.* (2006) *Environment and Trade: A Guide to WTO Jurisprudence*, Earthscan, London, UK, Chapter 8 (Bernasconi-Osterwalder) **n720**.

settlement process[1258] would serve as a means to engage the public opinions on the interpretation of the trade rules of IP; however, the WTO dispute settlement body has the discretionary power to accept this information.[1259]

WTO Members have a legal right to participate as parties or third parties in a certain dispute. The submission of amicus briefs in WTO dispute settlement system thus provides the rout of public engagement of compulsory licensing. Further, both WTO Members and non-Members could submit *amicus curiae* (friend of the court) *briefs* to the dispute settlement body (DSB) over the dispute of a compulsory licence.

An amicus brief is a written document, submitted by WTO Members and non-Members including businesses, civil society groups and individuals as an interested non-party of the dispute. It can be a document or simply a letter to the DSB.[1260] This provides the only approach for non-government organisations to have a say in a particular dispute in the world trade forum.

The WTO Panel has the discretionary power to seek information and technical advice from any individual or body which it deems appropriate.[1261] The communication with the Members for information is also addressed in the working procedures of the Appellate Body.[1262] It is further provided in the Working Procedures for Appellate Review that:

1258 WTO Dispute Settlement Body, see **section 1.2.1.1.2**.

1259 Bernasconi-Osterwalder, N. *et al.* (2006) *Environment and Trade: A Guide to WTO Jurisprudence*, Earthscan, London, UK, (Bernasconi-Osterwalder), pp317-319. See WTO Appellate Body Report, *United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom* (*US – Lead and Bismuth Carbon Steel*) WT/DS138/AB/R, adopted 10 May 2000, paras 40-41.

1260 Bernasconi-Osterwalder, p318, **n720**.

1261 Article 13 of the Understanding on Rules and Procedures Governing the Settlement of Disputes, The World Trade Organization Agreements, Annex 2 (DSU).

1262 Article 17.9 DSU.

> In the interests of fairness and orderly procedure in the conduct of an appeal, where a procedural question arises that is not covered by these Rules, a division may adopt an appropriate procedure for the purposes of that appeal only, provided that it is not inconsistent with the DSU, the other covered agreements and these Rules.[1263]

Hence, the Appellate Body is also free to choose "whether or not to accept and consider any information [in an amicus brief] that is pertinent and useful in an appeal".[1264] When a dispute arises on the legitimacy of compulsory licensing of particular drug in a public health emergency, non-state actors could also submit their amicus briefs as an interested non-party of the dispute. It can be anticipated that not only the civil society but also non-state actors such as the WHO, the WIPO, the World Medical Association and Medicines Sans Frontieres will have a say in promoting access to medicines in such disputes.[1265] In summary, the system of amicus briefs only plays a supplementary role in the interpretation of compulsory licensing which is aimed at increasing transparency in the dispute settlement process of a grant, but the Panel and Appellate Body have the final discretionary power to accept and consider amicus briefs attached to a party or third-party's submission.[1266]

In short, the incorporation of non-scientific factors in the granting of a precautionary

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[1263] Rule 16(1) Working Procedures for Appellate Review, World Trade Organization, WT/AB/WP/5, 4 January 2005.

[1264] Appellate Body Report, *United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom* (*US –Lead and Bismuth Carbon Steel*), WT/DS138/AB/R, adopted 10 May 2000, para 39. Cases relevant to Amicus Briefs include *EC – Hormones*, para 155-156; *US – Shrimp/Turtle I*, paras 7-10, 79-91; *Japan – Varietals*, paras 118-131; *Australia – Salmon*, paras 7.8-7.9; *EC – Asbestos*, paras 6.1-6.4, 8.12-8.14, 50-57. See Bernasconi-Osterwalder, N. *et al.* (2006) *Environment and Trade: A Guide to WTO Jurisprudence*, Earthscan, London, UK, Chapter 8 (Bernasconi-Osterwalder), pp317-362.

[1265] See **section I.2.2** for the discussion of non-state actors in the access to medicines campaign.

[1266] Bernasconi-Osterwalder, **n720** p323.

compulsory licence under a public health emergency is still vague. Governments may not have sufficient time to gather the public perceptions of evidence due to the time constraints. However, policy makers should bear in mind that the different transaction model implies a very distinct feature of drugs from other products on the market; the non-competitiveness of a patented drug could also be a legitmate factor in granting differential treatment in the interpretation of IP rules. In addition, civilians' special social, geographical and cultural preferences should also be taken into account in the decision-making of a precautionary compulsory licence. Lastly, the public can still submit their perceptions to the WTO dispute settlement body after a dispute on the legitimacy of a compulsory licence has arised.

5.4 Conclusion

This chapter has demonstrated that the PA can be accommodated into compulsory licensinge within the current flexibilities in TRIPS. It is argued in this chapter that in an extreme situation, the precautionary granting of compulsory licensing may offer a *margin of safety* to promote public health protection by means of provisional limitation on IP. IP policy making may choose to "trim" the exclusive patent protection in extreme situations such as a public health emergency.

This chapter has also argued that, from the rationale of risk analysis and the PA, health technologies associated with significant risk to human life or health may receive differential treatment in the IP regime. Such ethical differentiation of granting an expedient track of compulsory licensing on health technologies would not constitute discrimination and could be justified on the rationale of risk management in WTO law.

The elements of the PA in compulsory licensing can be demonstrated as follows:

- The Trigger threshold: The invocation of a precautionary compulsory licence should be between phases 4-5 at the WHO's pandemic phases when the risk has passed the "significant" threshold, and should be based on risk assessment or available pertinent information.
- The granting of a precautionary compulsory licence as a precautionary action: The precautionary granting of a compulsory licence is a state's conditional right in WTO, but it still has to be least restrictive to international trade. In other words, it should be used as a last resort; there should be no other available alternatives to relieve the burden of disease.
- Duty to review: The adopting state bears the ongoing duty to monitor the risk and review the grant. The grant should be abolished after the risk has been identified as non-significant.
- Other non-scientific factors: The role of public engagement in a public health emergency is limited due to time constraints. However, Governments should bear in mind that differential treatment of a patented drug may be legitimate due to its non-competitiveness on the market. Civil society can still submit their opinions to the WTO dispute settlement body after a dispute has arisen.

Lastly, given the precautionary grant of a compulsory licence is within the domain of conditional rights of WTO Members, the burden of proof would be reversed to the complaining party to prove that the public health emergency does not exist in the invoking state and the grant is not least restrictive to trade. The precautionary grant of a compulsory licence should be presumed legitimate unless the complaining party proves otherwise.

Part 4: Conclusion

6 Conclusion

6.1 Thesis overview

This work has developed a means to encourage states in taking advantage of the flexibilities of compulsory licensing in TRIPS to promote access to medicines in a public health emergency.

6.1.1 Problem and solution

This work began with a discussion of the malfunction of the compulsory licensing provision between the tension of international health and international trade, especially in the context of IP.[1267] Compulsory licensing indeed has a positive impact on the moderation of public and private interests in IP protection,[1268] yet some unsatisfactory implications on the condition of "national emergency or other circumstances of extreme urgency" has been identified due to the inherent limitations of the WTO and the international political settings.[1269] Compulsory licensing has failed to meet the proper needs to promote access to medicines in circumstances of a public health emergency. Though the Doha Declaration in 2001 has reaffirmed states' right to grant a compulsory licence, developing countries are still deterred from resorting to this mechanism due to possible trade retaliation from developed countries. This work therefore adopts the PA and the structure of risk analysis as a means to help states embody the flexibilities of IP in the Doha Declaration. This mechanism will also serve as a foundation to boost states' confidence in granting a compulsory licence in a public health emergency.

[1267] See **sections 1.3.3-1.3.3.2**.
[1268] See **sections 1.3.2-1.3.2.3.3**.
[1269] See **sections 1.3.3.1 and 1.3.3.2**.

After the Doha Declaration, the world has experienced a series of pandemic attacks which force us to contemplate the significance of the PA and risk management in a risk society. This also implies that risk management based on the rationale of the PA has a role to play in the interface of international health and IP. This work, therefore, proposes to incorporate the structure of risk analysis into the IP regime in order to accommodate sufficient margin of safety in a risk society.[1270] Particularly, the PA has thus been adopted to supplement the gap in scientific evidence and to serve as a safety valve in compulsory licensing in the preparedness for a public health emergency.[1271]

The WHO has also suggested that states take full advantage of the flexibilities in the TRIPS Agreement in order to promote access to medicines, yet empirical studies show that states are still hesitant to grant a compulsory licence based on the condition of "national emergency or other circumstances of extreme urgency".[1272] They prefer to use other tracks such as "anti-competitiveness"[1273] and "public non-commercial use"[1274] to avoid conflicts in international trade. Hence, this work has attempted to redefine the condition of "national emergency or other circumstances of extreme urgency" through the lens of precaution and risk management,[1275] and to reaffirm states' precautionary entitlements to grant a compulsory licence as part of a preparedness plan following the WHO's recommendation in a public health emergency.[1276] Instead of pursuing stronger legal arguments, this work focuses on a PA analysis which would bolster the political and/or moral basis for compulsory licensing in a public health emergency.

[1270] See **sections 5.2 and 5.2.1**.
[1271] See **sections 5.3-5.3.5**.
[1272] See **sections 1.3.2.2.1, 1.3.2.3.2 and 1.3.2.32.3**.
[1273] See **section 1.3.2.1**.
[1274] See **section 1.3.2.3**.
[1275] See **section 5.1.2**.
[1276] See **section 5.2.1.1**.

6.1.2 Approach adopted

In pursuing this solution, we started with the review of the PA from the perspective of "State responsibility" in international law, and particularly, we also found that the "State stewardship" model of public health policy-making has been developed at the domestic level.[1277] With respect to these, we have also looked at the international level in the context of the different legal instruments available to examine the current practice of the PA.[1278] By means of a philosophical review of the PA,[1279] we have also developed a *moderate* model of this approach in the domain of our research.[1280]

This work has reviewed the PA employed in international public health[1281] and international trade.[1282] It was noted that the PA has been widely practised in the realm of human health and safety. International legal instruments have adopted the PA and the structure of risk analysis to safeguard human health and safety. Yet we also found regimes conflict and inconsistencies in relation to the PA in different legal regimes,[1283] particularly in the WTO regime, that the legal status of the PA has been an issue of debate.[1284] This is even more ambiguous in TRIPS. Thus our work has focused on the extent to which the PA could be incorporated into the IP regime in relation to human health and security with an emphasis on the compulsory licensing provision.

In developing this solution, this work has analysed the legal status of the PA in different

[1277] See **section 2.1.2**.
[1278] See **sections 2.2-2.2.3.2.2**.
[1279] See **sections 2.3-2.3.3.3**.
[1280] See **section 2.3.3.3**.
[1281] See **chapter 3**.
[1282] See **chapter 4**.
[1283] See **section 3.1.1.**
[1284] See **section 2.1.3 n252**.

WTO instruments, especially in the GATT and the SPS Agreement.[1285] We have also explored the possible interpretation of compulsory licensing regarding "national emergency and other circumstances of extreme urgency" by means of the lens of precautionary entitlements in the WTO regime.[1286] We have also proposed a comparative study of exemptions in the WTO obligations,[1287] which also have resonance with exemptions to the TRIPS obligations in terms of legal status.[1288]

This approach has also been examined to reaffirm states' *precautionary entitlement* to grant a compulsory licence through the interpretation of existing international instruments. It aims to act as an underpinning to states' act of compulsory licensing when states adopt the precautionary granting of a compulsory licence following the conditions developed in chapter 5.

6.1.3 Proposals and arguments developed

First, this work noted that states enjoy the precautionary entitlement to take measures to achieve their appropriate level of public health protection.[1289] **Secondly**, I developed a *moderate and prescriptive* version[1290] of the PA delineating the trigger threshold of significant risk of harm,[1291] uncertainty,[1292] and action[1293] along with other non-scientific factors[1294] for future application in the context of my research. I argued that this model of the PA could be recast into various risks with minor alterations of the

1285 See **section 4.2, Diagrams 4.2 and 4.2.1**.
1286 See **section 5.2**.
1287 See **section 4.2, Diagrams 4.2 and 4.2.1**.
1288 See **section 4.3.2.2.1, Diagrams 4.3.2.2.1 and 4.3.2.2.1.1**.
1289 See **sections 2.1.2, 2.2.2.1 and 2.2.3.1**.
1290 See **sections 2.3.1 and 2.3.3.3**.
1291 See **sections 2.3.1.1-2.3.1.1.2**.
1292 See **section 2.3.1.2**.
1293 See **section 2.3.1.3**.
1294 See **sections 2.3.2-2.3.2.3**.

sub-conditions depending on different characteristics of each given risk.

I also noted that states have *precautionary rights and duties* in international law to safeguard public health in the examination of the legal instruments of the IHRs,[1295] the Codex Alimentaius, [1296] and the Cartagena Protocol on Biosafety. [1297] Following the examination of instruments in relation to the PA in the WTO, it was noted that the PA in the SPS Agreement enjoys a higher legal status, namely the excluding provision/conditional rights in the WTO legal hierarchy, than in the exception provisions in GATT.[1298] **Thirdly**, I therefore argue that WTO Members enjoy precautionary entitlements in exercising their conditional rights[1299] in achieving an appropriate level of public health protection.

I have also borrowed the WTO legal hierarchy to illustrate exemptions to IP in TRIPS.[1300] Considering the legal status of compulsory licensing, I have looked into the interpretation of the Doha Declaration and the principles and goals of TRIPS.[1301] **Fourthly**, therefore, it was argued that compulsory licensing, like the provisional SPS measures, enjoys a higher legal status as an excluding provision, which can be deemed as a conditional right of WTO Members'.[1302] Then I argue that a compulsory licence granted under specific conditions would be considered in compliance with Members' obligations in TRIPS unless a complaining Member proves otherwise.[1303]

1295 See **section 3.1.2.2**.
1296 See **section 3.1.3.2**.
1297 See **section 3.2.1**.
1298 See **section 4.2**, **Diagrams 4.2 and 4.2.1**.
1299 Conditional rights, see **n118.**
1300 See **section 4.3.2.2.1 and Diagram 4.3.2.2.1**.
1301 See **section 4.3.2.2.1 and Diagram 4.3.2.2.1.1**.
1302 See **section 5.2.1.1**.
1303 See **section 5.3.5**.

This work has also examined whether the adoption of the PA in compulsory licensing would constitute discrimination in TRIPS. It was then stressed that the risk factor could legitimise differential treatment in WTO law.[1304] **Fifthly**, I have therefore argued that the risk factor could legitimise differential treatment in the adoption of the PA in compulsory licensing of a pharmaceutical patent with regard to taking an expedient trigger to invoke "national emergency or other circumstances of extreme urgency".[1305] **Finally**, I also took compulsory licensing in pandemic preparedness as an example to examine the precautionary model I developed in the previous chapters. Following a risk assessment or an objective evaluation of a pandemic based on the WHO's recommendations,[1306] I have concluded that under certain conditions,[1307] states can invoke compulsory licensing in a pandemic preparedness plan to exercise their precautionary entitlements in TRIPS to achieve an appropriate level of public health protection.

6.2 Some challenges and responses

6.2.1 A better approach than the Doha Declaration?

The Doha Declaration[1308] indeed sought to relieve the disease burden of developing countries by means of providing a signpost in the access to medicines debates, yet due to political restraints in international settings, this declaration nevertheless fails to realise the goal it had promised. Most developing countries are still deterred from seeking the flexibilities in TRIPS fearing that trade retaliation would follow.[1309] This work has thus proposed a means to embody the flexibilities in the Doha Declaration in relation to its

[1304] See **sections 5.2.1.2.1.1 and 5.2.1.2.2**.
[1305] See **section 5.3**.
[1306] See **sections 5.3.1 and 5.3.1.1**.
[1307] See **sections 5.3.2-5.3.5**.
[1308] Doha Declaration, see **section 4.3.2.2.1 n27**.
[1309] See **sections 1.3.3-1.3.3.2**.

interpretation of "national emergency or other circumstances of extreme urgency" in compulsory licensing.

This work has also equipped states with a model to embody their *precautionary entitlements* in order to claim their conditional rights to compulsory licensing in a public health emergency. However, it is beyond the content of this work to address the political reasons underlying a state's decision to grant a compulsory licence. This work has only provided a policy tool for states to realise their conditional rights in the WTO/TRIPS regime. It would ultimately depend on individual state's policy-making in IP and risk management, taking all factors into consideration, to decide if this approach would be best adopted in a preparedness plan for a public health emergency.

6.2.2 Non-scientific factors?

This work has suggested that states trigger the precautionary granting of a compulsory licence with a scientific risk assessment or scientific information, yet other non-scientific factors in their IP/risk policy-making exist. For example, a state's particular value and social background,[1310] political and geographic context[1311] may render the said state to also base its decision upon civilians' social and cultural preferences.

Unlike other unknown risks which may be regulated along with public engagement, an acute public health emergency technically could not afford proper public engagement due to time restraints. Hence, public engagement comes at a rather late stage in the form of amicus briefs to the WTO DSS[1312] after a dispute is filed. Yet, it is fair to say

[1310] Correa TRIPS, p288, **n154**.
[1311] See **section 4.3.2.3.2**.
[1312] WTO Dispute Settlement System (DSS) or Dispute Settlement Body (DSB), see **section 1.2.1.1.2**.

that governments would still need to take the comments of the civil society,[1313] particular from patients' perspectives,[1314] into consideration in its IP/risk policy-making. It may also be further explored whether "anticipatory engagement" is possible in a public health emergency.

6.3 Beyond this work

This work has argued for an expedient trigger threshold of compulsory licensing when dealing with a preparedness plan for an acute public health emergency. In order to examine if a different trigger threshold of the said compulsory licence would constitute discrimination in TRIPS, this work has also explored the legitimate differentiation of health technologies from other technologies. I have adapted the "like-product" analysis from the WTO DSS as a threshold device into the discussion of the differentiation of pharmaceutical technologies. However, the question of the PA still exists in the case of chronical disease, for example, the Thai Government's compulsory licence of heart disease drugs.[1315] There may be arguably more room to engage the public in the debates of compulsory licensing on non-acute conditions, but it is beyond the domain of this work. Regarding the compulsory licensing on acute disease drugs, new questions will arise in interpreting the legitimate differentiation of health technologies.

For example, I have argued that a differentiation should be made when health technologies are *strongly* associated with *significant* risks to human life and health. Yet, next question moves to the identification and interpretation of the concept of "*strongly*

[1313] See **section 5.3.4.1.**
[1314] See **section 5.3.4.1.1**.
[1315] See **section 4.3.2.3.3**.

associated with *significant* risks to human life and health". Again, this should be based on scientific evidence or pertinent scientific information, which is carried out by convincing organisations, to increase transparency and objectivity.

Our discussion in the context of TRIPS and the Doha Declaration has concluded that this proposal may be found to be consistent with the obligations of a state under the TRIPS/WTO framework. If a Member makes a complaint to the WTO DSS with regard to a compulsory licence, he needs to prove that the public health emergency did not exist in the invoking state as well as that the granting of a compulsory licence was not a least-restrictive measure. The invoking party may submit their objective risk assessment or relevant information/recommendations from the WHO regarding the public health emergency to defend their cause.

In addition to compulsory licensing, this work could serve as a foundation to further explore the extent to which the PA would be better accommodated in the IP regime, for example, other exception and excluding provisions in TRIPS in order to enhance access to essential medicines. It can be anticipated that the employment of the PA in the IP regime would serve to promote a balance in the rights and obligations of patent holders, and legitimise a safety factor in the trade world. Hopefully, we would then be equipped to distinguish technologies which are associated with public interest and security and have fundamentally different implications to society from other technologies in IP.[1316]

Finally, moving beyond our discussion of the health technology, the contribution of this

[1316] Abbott, F. A. (2005) "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" 8 (1) *Journal of International Economic Law* 77 (Abbott Multilateralism), **n132**.

work could also be explored in relation to other technologies associated with the reduction or elimination of risks to the environment or technologies which aim to redress climate change and other environmental concerns. This would then require more detailed investigation of the "significant implications" of environmental technologies and the strength of the link between the said technology and the risk.

6.4 Closing thought

This work has developed a solution based on the PA in order to revisit public health emergency in TRIPS when national policy-makers are in a position to resort to the granting of a compulsory licence in an acute emergency situation. Throughout, this work has drawn upon philosophical and legal implications of the PA, as well as used existing international legal instruments with regard to health and security to illustrate that the PA and the rationale of risk management could be incorporated into the IP regime in order to take the full advantage of the TRIPS flexibilities.

The final message is straightforward: a safety factor based on the PA is strongly recommended to be accommodated into the compulsory licensing mechanism. This work has reviewed the rationale of this approach, the objectives and the principles, as well as exemptions to obligations in the TRIPS Agreement, hence, it has concluded that the granting of a compulsory licence in a public health emergency falls within the domain of *conditional rights* in the WTO framework, compulsory licensing is deemed consistent with a state's obligations under TRIPS unless a complaining Member proves otherwise. A model of the PA has been developed which is fit for purpose in its chosen realm of application and which could serve to ensure that two worlds – trade and health – need not collide.

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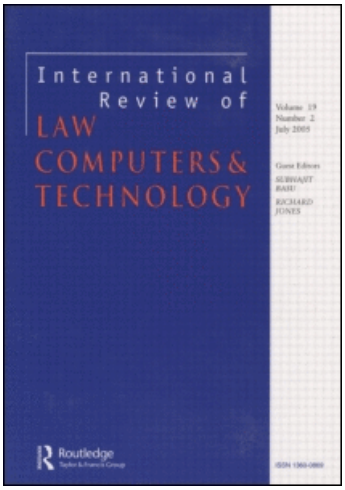

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The precautionary approach under the right to health dilemma

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The precautionary approach under the right to health dilemma

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This paper examines the mechanism of compulsory licensing after the interpretation of the Doha Declaration. It argues that the notion of precaution has been incorporated into the Trade Related Aspects of Intellectual Property Rights Agreement through the exclusion of patentable subject matter and the interpretation of the Doha Declaration. In addition, state practice in recent years also demonstrates that precaution has been implemented into the application of compulsory licensing under a public health emergency. This paper scrutinises the health exceptions in World Trade Organization laws and suggests that the device of compulsory licensing is related to the scheme of provisional sanitary and phytosanitary measures which reflects the spirit of precaution.

Keywords: precaution; compulsory licensing; health exception

Health exceptions operated in World Trade Organization (WTO) law are often limited and require scientific justification. For example, health measures of the General Agreement on Tariffs and Trade (GATT) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) are deemed legitimate on the basis of scientific evidence. However, in order to safeguard human health under the circumstances of scientific uncertainty, the concept of precaution has been incorporated into the SPS Agreement by means of the mechanism of provisional SPS measures which reflects the precautionary approach. Moreover, the Doha Declaration on the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health (Doha Declaration) has reaffirmed WTO Members' (henceforth Member refers to WTO Member) sovereignty on health protection under a public health emergency, and thus the precautionary approach is arguably implied in compulsory licensing. Article 5.7 SPS was initially drafted to be used in emergency situations where, for example, the spread of disease had to be stopped urgently before it may be feasible to complete a risk assessment.[1] While being developed as an expedient tool under an emergency, Article 5.7 of the SPS Agreement shares similar characteristics with the jurisprudence of the mechanism of compulsory licensing under a public health emergency. The paper observes that the scheme of provisional SPS measures and the mechanism of compulsory licensing are both health measures devised to deal with public health risks in emergency conditions, and thus proposes a comparative study of the two devices from the perspective of precaution.

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1. Compulsory licensing

The TRIPS Agreement provides flexibility for governments to fine-tune the exclusive protection granted in order to meet other social goals. It allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right holder does not supply the invention, provided certain conditions are fulfilled. In the case of 'other use without authorisation of the right holder', which is understood as 'compulsory licensing', the protection of the exclusive rights may be suspended under certain conditions. For instance, the pharmaceutical patent protection can be suspended during a limited period of time to meet the needs of public interests under a public health emergency.

Compulsory licensing can be regarded as Members' autonomous right and exclusion to the IP regime which aims at the balance of rights and obligations of intellectual property (IP) protection. It has been applied as a means to redress the dilemma of 'access to essential medicines' and pharmaceutical patent protection in a public health emergency, yet its operation has been highly controversial. It is therefore suggested that the notion of precaution in health exceptions in WTO laws can shed some light on the operation of compulsory licensing.

1.1. *Mechanism in TRIPS*

The supplementary conditions and procedures in prior to grant compulsory licence are detailed in Article 31 – TRIPS. For instance, the proposed user needs to make an effort to obtain authorisation from the right holder on reasonable commercial terms and conditions unless in the case of a national emergency of other circumstances of extreme urgency. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable. The scope and duration of such use shall be limited to the purpose for which it was authorised; such use shall be non-exclusive; it shall be authorised primarily for the supply of the domestic market, and adequate remuneration shall be paid to the patent right holder. The compulsory licence is subject to judicial review or other independent review by a higher authority.

As a general rule, it requires the competent authorities in the Member country to decide each compulsory licensing case and establishes conditions that are intended to prevent the granting of sweeping compulsory licences across a broad range of inventions. In subparagraph (b), before an application may be considered, the proposed user must first seek to obtain a voluntary licence on reasonable terms and conditions within a reasonable period of time. The requirement of the obligation of the proposed user to first make an effort to obtain authorisation from the rights holder in case of national emergency can be waived under Article 31(b) of the TRIPS Agreement, but the condition of 'national emergency or other circumstances of extreme urgency' is not clearly defined in the TRIPS Agreement. In the later round of negotiations in Doha in 2001, ministers stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health – by promoting both access to existing medicines and the creation of new medicines.[2] It emphasises that the TRIPS Agreement should not prevent Member governments from acting to protect public health. It affirms governments' right to use the agreement's flexibilities, such as compulsory licensing and parallel importing. After the Doha Declaration and following international state practice, it is suggested that there is a growing trend to broaden the flexibilities in the TRIPS agreement to promote access to medicines.[3]

1.2. *Doha Declaration*

In agreeing to launch a new round of trade negotiations, trade ministers adopted a 'Declaration on the TRIPS Agreement and Public Health' (Doha Declaration) on 14 November 2001. The Declaration sought to alleviate developing-country dissatisfaction with the TRIPS regime. It committed Members to interpret and implement the agreement to support public health and to promote access to medicines for all. It also affirmed the right of Members to use the flexibilities in the TRIPS agreement to promote these goals.

The interpretation of the Doha Declaration suggests that a Member's right in deciding appropriate level of protection is an 'autonomous right'. The Appellate Body in *EC – Asbestos* also stated that, ' . . . we note that it is undisputed that Members have the right to determine the level of protection of health that they consider appropriate in a given situation'.[4] The Doha Declaration states that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency. It articulates that public health crises, including those relating to human immunodeficiency virus (HIV)/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. It also reminds Members in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the objectives and principles of the Agreement. While the TRIPS Agreement aims at the protection of intellectual property rights in order to promote the technology innovation, it also recognises the flexibilities of the standard of protection in order to balance rights and obligations of patent holders.

The Doha Declaration has reaffirmed that a Member has the right to determine the grounds to grant a compulsory licence, and thus a Member can be more cautious about their chosen level of health protection. The right to determine an appropriate level of health protection is regarded as an 'autonomous right' in WTO law. From this perspective, the WTO seems willing to open a door for public health concerns and legitimate the flexibilities that Members can apply at their discretion. This also manifests that Members' autonomy has been paid due respect in the public health dimension of the international economic law regime. After the global auto-immune disease syndrome (AIDS) pandemic, world politics has pushed the WTO to identify an emerging pattern of deference to national autonomy when Members' domestic health policies conflict with other values protected by trade agreements.

2. Precaution and health exception in WTO

Trade liberalism, global market access and the elimination of tariffs as barriers to global trade and non-tariff barriers are the primary concerns of WTO. In order to balance different interests, WTO provides limited exceptions allowing Members to take account of certain values that compete or conflict with free trade, but the application to the exception rules are usually strictly restricted. However, there still exist health risks under scientific uncertainty, and the device of a provisional SPS measure offers leeway for Members' discretion under the scientific uncertainty. From the perspective of flexibilities in the free trade regime, this paper observes that the interpretation of the Doha Declaration appears to indicate that the application of compulsory licensing is more related to the model of a provisional SPS measure than the mechanism in GATT Article XX (b). We now turn our attention to the application of GATT Article XX (b).

2.1. *GATT XX (b)*

Article XX (b) concerns measures which are 'necessary to protect human, animal or plant life or health'. Members can adopt necessary public health measures to protect human, animal or plant life or health. In order to prevent abuse of exception rules, Article XX sets out a two-tier test for determining whether a measure applied is necessary to the policy which the Member attempts to protect. The Appellate Body has further adopted a 'weighing and balancing' process in the necessity test after *EC – Asbestos*.

2.1.1. *Purpose*

The policy objective pursued by the measure must be the protection of life or health of humans, animals or plants, and the measure must be necessary to fulfill the policy objective. A public health measure inconsistent with the WTO obligations should be examined for its legitimate objectives within the interpretation of Article XX (b), and it should pass the necessity test. For example, in *Thailand – Restrictions on Importation of Internal Taxes on Cigarettes*,[5] the Panel 'accepted that smoking constituted a serious risk to human health and that consequently measures designed to reduce the consumption of cigarettes fell within the scope of Article XX (b)'. The Panel noted this provision allowed the Contracting Parties to give priority to health over trade liberalisation, but the Panel further concluded that the applied measure needed to be necessary.

2.1.2. *Measures*

In *Thailand – Cigarettes*, the USA accused that Thailand's prohibition on the importation of cigarettes was inconsistent with the General Agreement on Tarrifs and Trade (GATT). The Panel concluded that the restrictive measure failed to meet the necessity test.

In *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*: France banned the importation and sales of asbestos for the reason of public health protection. Canada accused that the measure was inconsistent with the WTO law, but France's banning was proved legitimate after providing reasonable scientific evidence on chrysotile-cement products to the Dispute Settlement Body (DSB). The Appellate Body adopted the 'weighing and balancing process' as the proportionality test to supplement the necessity test. Besides 'the difficulty of implementation', the Appellate Body also referred to two factors in the balancing process: 'contribution of the measure to the realisation of the value pursued' and 'importance of the value pursued'.[6]

In *Brazil – Measures Affecting Imports of Retreaded Tyres*,[7] The EU challenged Brazil's restrictions on imported retreaded tyres from the EU. Although Brazil argued that the import ban was aimed at reducing public health risks, the EU accused that the ban was not contributing to health and environmental protection. The Appellate Body held that the ban failed to meet the requirement of the *Chapeau* of the GATT XX and constituted arbitrary or unjustifiable discrimination, or a disguised restriction to trade.

2.1.3. *Rules and principles*

The structure of Article XX (b) includes the provision and the *Chapeau.* The examination of the disputed measure consists of three steps: first to review whether the objective of the measure falls within the domain of the statute; second, the requirements in the *Chapeau* need to be fulfilled. The *Chapeau* requires the applied measure should be least inconsistent

with the obligations and be least restrictive to trade. The disputed measure should be applied in a non-discriminative way and any disguised restriction on international trade is considered inconsistent with the *Chapeau.* Third, an analysis has been adopted by the Appellate Body to balance the values of the protected objectives and the cost of the trade restriction. The Appellate Body started to take into account several other factors to relax the necessity test. The factor to relax the necessity test in a health exception includes: the difficulty of implementation, contribution of the measure to the realisation of health protection, and importance of the health pursued.

In other words, the applied measure will be accepted as legitimate if it is considered the least restrictive to free trade. If there existing an alternative measure that would achieve the same goal and is less restrictive to trade, then the alternative measure should be determined if it is 'reasonable available'. Moreover, the Appellate Body has introduced a weighing and balancing process into the necessity analysis. Any trade restriction aimed at protecting human health has to be in proportion to the benefits arising from the protection of human health.

In sum, all the above cases except *EC – Asbestos* related to public health exception in GATT XX (b) have failed to pass the scrutiny of 'the necessity test'. The necessity test has been relaxed after the introduction of a weighing and balancing process of the proportionality test after *EC – Asbestos*. However, the necessity test including the proportionality test, is deemed as a relatively rigid and scientifically based approach to examine the legitimacy and validity of an international trade measure. Members do not enjoy a significant margin of appreciation in determining the appropriate level of health protection under the necessity test.

The application of Article XX (b) has been restrictive and requires an objective standard to pass the necessity test. Among the above WTO cases only the *Asbestos* case passed the examination for France's provision of scientific justification. Moreover, the examination of the applied measure has been influenced by mechanism of the SPS Agreement which sets out more detailed requirements of a health measure. The SPS Agreement requires health measures to be under scientific justification except for the imposition of the provisional SPS measures which accepts measures on the basis of scientific uncertainty. The implementation of provisional SPS measures is deemed more flexible with States' discretion.

2.2. *SPS*

The SPS Agreement aims at helping Members set up a standard system of risk management on imported food and produce, but the agreement also requires Members to conform to its obligations in WTO law to ensure the spirit of non-discrimination is protected. While adopting a SPS measure, a Member country has the obligation to ensure that the measure applied should be in a non-discriminatory way. In addition, to deal with the condition of scientific uncertainty in the process of risk management, the precautionary principle is incorporated into the SPS Agreement through the imposition of a provisional SPS measure in Article 5.7 to accommodate health risks under emergency. The Appellate Body has identified the function of provisional SPS measures under a health emergency.

2.2.1. *Purpose*

The purpose of the SPS Agreement is to improve the human health, animal health and phytosanitary situation in Member countries, and also to ensure the SPS measures are not applied in a manner that would constitute a means of arbitrary or unjustifiable

discrimination between Members. The SPS Agreement was devised to introduce more elaborate rules for the application of the GATT XX (b) which relates to the use of sanitary or phytosanitary measures. There is potential overlap between GATT XX and the SPS Agreement. GATT XX appears to cover general health measures that Member countries might adopt, while the SPS Agreement relates specificly to sanitary and phytosanitary measures. Article 2.4 of the SPS Agreement articulates that SPS measures which conform to the relevant provisions of the SPS Agreement shall be in accordance with Member countries' obligations under GATT XX (b).

2.2.2. *Measures*

Under the SPS Agreement, Members are allowed to set their own health standards as long as the measures are applied by risk assessment based on scientific evidence. International standards are encouraged to be applied to the process of risk management. However, a higher standard of protection than the international standard may also be accepted with risk assessment and scientific evidence. The measure applied should be least restrictive to international trade. Members are required to notify other Members about any change or new SPS measures. Alternative measures can be accepted as equivalent if Members can prove it provides the same standard of health protection and is proved least restrictive to trade.

From the abovementioned statutes, the rights of Members to determine the appropriate level of public health protection are recognised. Members can have two tracks to adopt an SPS measure: track one is to follow available international standards; track two is at the discretion of Members, if Members wish to adopt a higher level of public health protection for their population, scientific justification must be satisfied with risk assessment and scientific evidence. The Appellate Body has recognised the 'autonomous right' of a Member to establish a higher level of health protection in Article 3.3. According to the requirements of Article 5.3–5.6, Members should take into the account the objective of minimising negative trade effects while achieving the appropriate level of SPS protection. Members shall also avoid arbitrary or unjust discrimination at the levels to be considered appropriate in different situations.

In order to minimise the risk of a public health threat, relevant SPS measures can also be adopted even in lack of scientific evidence. The mechanism of provisional SPS measures is regulated in Article 5.7. The mechanism of provisional SPS measures was initially drafted to be used in emergency situations where, for example, the spread of a disease had to be stopped urgently before it may be feasible to complete a risk assessment. In cases where relevant scientific evidence is insufficient, Members may adopt provisional SPS measures on the basis of available pertinent information. After the adoption of a provisional SPS measure, Members are obliged to seek to obtain necessary additional information for a more objective risk assessment, and bear the duty to review the SPS measure within a reasonable period of time. Thus, the spirit of the precautionary principle is considered to be included in the WTO regime with the statute of the provisional SPS measure.

2.2.3. *Rules and principles*

There are two tracks to adopt SPS measures, one is for adopting general SPS measures, and the other is an expedient track for adopting provisional SPS measures. Article 2 of the SPS Agreement sets out the basic rights and obligations of Members. It affirms Members 'have the right' to take SPS measures 'necessary to protect human, animal or plant life or health'.

In particular, general SPS measures should meet the following requirements: they must (1) be applied 'only to the extent necessary to protect human, animal or plant life or health'; (2) be 'based on scientific principle and ... not maintained without sufficient scientific evidence'; (3) not 'arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail', and (4) not 'be applied in a manner which would constitute a disguised restriction on international trade'. Members are obliged to base their SPS measures on certain risk assessments that indicate the necessity of the measures to reach appropriate level of health protection.

The requirements of adopting provisional SPS measures are set out in Article 5.7. The rulings of WTO also interpret the ambiguity of the provision. The imposition of provisional SPS measures is limited within the domain of 'insufficiency of scientific evidence'. There are further preconditions in adopting a provisional SPS measure. In *Japan – Measures Affecting Agricultural Products II*,[8] the Appellate Body found that Article 5.7 is available subject to the satisfaction of four cumulative requirements: (1) relevant scientific evidence is insufficient; (2) the measure is adopted on the basis of available pertinent information; (3) the Member seeks to obtain the additional necessary information for a more objective risk assessment, and (4) the Member reviews the measure accordingly within a reasonable period of time. After the adoption of a provisional SPS measure, Members are obliged to obtain more information for a risk assessment and for reviewing the measure in a period of time. If scientific evidence is sufficient to carry out a full risk assessment, the provisional SPS measure is bound to be either abolished or made permanent.

2.2.4. *Precaution in SPS*

The precautionary approach or the precautionary principle has been developed from international environmental protection. Despite of its widespread application in environmental protection, its definition is nonetheless universal. Paragraph 15 of the Rio Declaration on Environment and Development provides the most well-known definition of the principle, which reads

> where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[9]

The precautionary principle emphasises that when there is a possibility of serious or irreversible harm to the environment, protective action should be taken in advance of scientific proof of harm. Governments may be obliged to act to avoid irreversible damage even under the circumstances of scientific uncertainty. The WTO Appellate Body has indicated that the precautionary principle finds its reflection in the SPS Agreement.[10] In particular, Article 5.7 SPS is seemed to incorporate the precautionary approach through the introduction of provisional health measures under the circumstances of insufficient scientific evidence. The acceptance of the precautionary principle in the WTO laws remains limited at the time being, but it can serve as a means of risk management to explore the political relationships between the various perspectives and competing interests in society.

3. Precaution in TRIPS

The TRIPS Agreement is the most comprehensive multilateral agreement on IP. It is a minimum standards agreement, which allows Members to provide more extensive

protection of IP. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. Articles 30 and 31 TRIPS are typical exclusions to the patent protection for public interests or other social agenda.

3.1. *Article 30*

Under the current TRIPS mechanism, there is still some exclusion from patentability which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Many nations incorporate precautionary measures in their patent laws to varying degrees. For example, Brazilian patent law provides a number of statutory exclusions from patentability, essentially limiting the definition of patentable subject matter to exclude various categories of inventions for policy reasons. The Brazilian exclusions to patentable subject matter are typical of precautionary exclusions in the patent laws of WTO Member states. In general, Member states have adopted precautionary exclusions to patentable subject matter based on five criteria: morality, public policy (or public order), legality, public health and environmental harm. For example, in the patent code of India, a provision states: 'an invention the primary or intended use of which would be contrary to law or morality or injurious to public health'. Exclusions to patentability can be regarded as typical applications of the precautionary approach in the TRIPS Agreement.

3.2. *Article 31*

The mechanism of compulsory licensing in the TRIPS Agreement can also be considered an exclusion to IP in the world trade system, but the application of compulsory licensing on pharmaceuticals has caused great debates in the international legal forum as a result of its lack of a clear threshold for invocation. The Doha Declaration has interpreted and clarified the specific terms of compulsory licensing. It has reaffirmed Member states' autonomy in determining the appropriate level of health protection under a public health emergency, such as AIDS/HIV, tuberculosis, malaria, or other serious epidemics. It implies Article 31 as an excluding provision, which excludes other provisions within the TRIPS Agreement. It further suggests that the right to grant compulsory licences is an 'autonomous right' of WTO Members. The Doha Declaration has reaffirmed Members' rights to determine the level of health protection, which therefore implies the concept of precaution in the TRIPS Agreement. It can be argued that the scheme of compulsory licensing can be rephrased as: 'When confronted with public health emergency, scientific uncertainty should not prevent the implementation of compulsory licensing for an appropriate level of health protection'.

In view of the principles of the exception rules applied in the WTO system, a Member state is required to prove that the applied public health measure is necessary to eliminate the public health risk through scientific justification. The SPS, along with the health exception rule of GATT XX (b), the public health measure applied should pass the 'necessity test', which is regarded as an objective standard. The SPS Agreement expects international standards or higher standards of public health protection with scientific justification to be applied among Members, while it also provides the mechanism on provisional measures under the circumstances of uncertainty in scientific evidence. The Doha Declaration demonstrates that the invocation of compulsory licensing is different from the jurisprudence of the above health exception rules. Paragraph 5 (c) of the Declaration indicates that the

device of compulsory licensing has an important and different implication from the WTO jurisprudence of 'the necessity test'.[11] Therefore, the burden of proof is laid on the complainant who needs to provide evidence that the public health emergency does not exist. The compulsory licensing is deemed compliant with the TRIPS Agreement unless the complainant proves otherwise.

From the above observation, the implementation of compulsory licensing can be argued to be more related to the device of provisional SPS measures than other general health measures in WTO law. Provisional SPS measures that introduce health measures under emergencies echo the essential needs of compulsory licensing under a public health emergency. This paper therefore suggests that compulsory licensing, similar to the provisional SPS measures, can be interpreted to reflect the spirit of the precautionary approach. It can be further argued that the precautionary approach has been implied in the TRIPS Agreement through the mechanism of compulsory licensing after the interpretation of the Doha Declaration.

4. Conclusion

The device of compulsory licensing aims at redressing the dysfunction of IP protection. It can be applied to promote access to medicines under a public health emergency. This paper scrutinises the mechanism through the interpretation of the Doha Declaration and argues that the concept of precaution has been incorporated into the TRIPS Agreement. It is therefore important to apply the scheme in a way that is different from the traditional approach of 'the necessity test' in other WTO jurisprudence areas. The standard of applying GATT Article XX (b) and the general health measures in the SPS Agreement requires scientific justification, and its application is highly limited. In contrast, the right to grant a compulsory licence is implied as a Member's 'autonomous right' through the interpretation of the Doha Declaration. It has been distinguished from other general health exception rules in WTO law. The implementation of compulsory licensing, which respects states' sovereignty and flexibilities in discretion, is thus more related to the device of provisional SPS measures. The Doha Declaration has indicated that the flexibilities of compulsory licensing imply a precautionary approach in health risk management in the TRIPS Agreement. However, the invocation of compulsory licensing still requires a clear trigger threshold and often gives rise to controversies on the legitimacy of the grant; therefore the interpretation and further exploration of the precautionary approach in the TRIPS Agreement is desired to prevent potential conflicts in international law.

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