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TRIPS, a TRIPS-plus strategy and global health

The complex relationship between intellectual property protection, development, and the promotion of global health. Is co-existence possible?

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Abstract

Many developing countries cannot provide their population with proper medical care or access to medication. International trade intends to assure peace and prosperity, and to increase access to desired products. Consequently, international trade should be able to help solve the problem of insufficient access in underdeveloped nations. This 'simple' equation is complicated by the fact that the developed world seem to be convinced that innovation is a necessity for economic development and prosperity. Industrialized nations believe in a legal system with strong and enforceable intellectual property rights that ensures inventors profit as an incentive for further research and innovation. This perception is generally not shared by the developing world, where most countries consider relaxed intellectual property regimes a necessity for development. Developing countries generally lack the necessary resources to develop their own intellectual property, but still desire access to lifesaving drugs. An obvious approach to improve this global health problem would be to keep prices on medication to a minimum. This is where the conflict between the promotion of global health and protection of intellectual property begins. If manufacturers of pharmaceuticals are not provided with a period of limited competition, they do not have an equally strong incentive to develop new medications. Restriction in competition is very likely to cause higher prices than if the pharmaceuticals were subject to free competition. The crucial international policy question is how to manage the tradeoff between higher prices today, in exchange for innovation tomorrow. The TRIPS agreement and its minimum requirements for IPR protection can be seen as an attempt to compromise this conflict within the multilateral WTO trade system. It is however quite evident that the compromises have not been satisfactory to either the industrialized or the developing world. Many developing countries argue that the regulation does not emphasize development enough and that TRIPS values profit over health protection. They therefore strongly advocate that health shall be recognized as a human right.

This debate has pushed the WTO towards a more health-friendly interpretation of its trade agreements, for example by allowing a broader use of compulsory licenses for lifesaving drugs, which allows the WTO member to set aside the commercial interests of the patent owner, in order to provide its population with a social benefit. A specific declaration on TRIPS and Public Health has also been issued, emphasizing that TRIPS should not prevent WTO members from taking measures to protect public health, and that this should be a guiding principle to TRIPS interpretation. Consequently it is obvious that pressure from the developing world has pushed the WTO to reinterpret TRIPS into a more health-friendly agreement than before.

The increased health focus in the multilateral sector has given many developed countries an incentive to enter into bilateral trade agreements that just add IPR provisions on top of the requirements from multilateral agreements. This way developed countries can take advantage of their bargaining powers and push harder IP rights without the restraints of multilateral treaty-making within the WTO. This development, called the TRIPS-plus strategy, is a serious threat to the success and credibility of multilateral cooperation within the WTO, and has the potential to seriously undermine the steps taken towards a more global health oriented world. The greatest upcoming challenge for the WTO will be how to treat the trend of bilateralism without losing any members, or its status as a strong international organization. No doubt, innovation can provide development and IPR protection does provide an efficient way to achieve innovation. But considering how the profit incentive so profoundly interfere with promotion of global health, it must be possible to find a compromise in order to promote global health and innovation at the same time. If health had the status of a human right and equal enforceability of a civil right, measures necessary to protect global health would easily trump profit incentives. This would require strong safeguards so that health protective measures never become a cover up for trade protectionist measures. Primarily, in order to create sustainable trade liberalization, the wealth and economic growth that innovation provides should be invested into development and promotion of global health.

Acronyms and abbreviations

AB	Appellate Body (WTO)
ARV	Anti-retroviral
Comment 14	General Comment No.14: <i>The Right to the Highest Attainable Standard of Health</i> (UN)
CSDH	Commission on Social Determinants of Health (WHO)
CSR	Corporate social responsibility
DDA	Doha Development Agenda (WTO)
DSU	Dispute Settlement Understanding (WTO)
DSB	Dispute Settlement Body (WTO)
ECOSOC	Economic and Social Council
EU	European Union
FTA	Free trade agreement
GATT	General Agreement on Tariffs and Trade (WTO)
GATS	General Agreement on Trade in Services (WTO)
GDP	Gross domestic product
HDI	Human development index
IAVI	AIDS Vaccine Initiative
ICCPR	International Covenant on Civil and Political Rights (UN)
ICESCR	International Covenant on Economic Social and Cultural Rights (UN)
IMF	International Monetary Fund
IPR	Intellectual property right
LDC	Least-developed country
MDGs	Millennium Development Goals
MFN	Most favored nation
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organization
PTA	Preferential trade agreement
R&D	Research and Development
RTA	Regional trade agreement
SES	Socioeconomic status
SPS	Agreement on Sanitary and Phytosanitary Measures (WTO)
TRIPS	Trade-Related Aspects of Intellectual Property Rights (WTO)
UN	United Nations

UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNCED	United Nations Conference on Environment and Development
UNDHR	Universal Declaration of Human Rights
UNDP	United Nations Development Program
UNHRC	United Nations Human Rights Commission
USTR	United States trade representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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1. Introduction

In a world where globalization has evolved from a theoretical model into an unstoppable process, international trade and economic integration are crucial parts in the attempt to stabilize world order. Through globalization a lot of issues that used to be subject only to national policy, have been given increased global impact and therefore gradually created a need to regulate on an international level. The two policy areas of interest for this thesis are **trade** and **health**. The economic benefits of liberalizing international trade through the removal of barriers to trade are long since recognized. Some even believe that trade liberalization is the primary tool for social and economic development. Simultaneously the issue of public health has been highlighted as a public good and is even considered by many as a human right. The result of this increased awareness is a wide, complex and ever-growing body of international cooperation and regulation regarding as well international trade, as international public health.

1.1 *Topic motivation*

There is an inherent conflict between liberalized trade and public health that can aggravate the simultaneous fulfillment of these goals. With a free market world order, there is always the issue of the profit motive over trumping the interest of global health. An illustrative example is the epidemic of the infectious disease of HIV/Aids. Drugs against infectious diseases have extremely high development costs compared to expected financial return. Countries that require access to this kind of drugs the most, generally do not have the competence to develop the drugs themselves, nor the resources to import them. Pharmaceutical companies want a return on their investments and are more likely to develop lifestyle drugs over lifesaving drugs. This means that the public health interest of providing poor countries with access to medicines is threatened by the liberalization of trade in drugs. A feature of today's industries that makes the situation even more complex is the protection of IPRs in pharmaceuticals. The developed world claims that IPR protection is necessary to promote innovation and that without innovation there would be no drugs at all. Through the WTO and the TRIPS agreement, IPR protection has become an integral part of international trade law. The main part of the world is now obliged to follow the regulation and its requirements of minimum protection for IPRs. Even though the WTO opens up new development possibilities for the developing world through increased market access, strong IPRs make it very hard for developing countries to adhere to its obligation to protect health.

1.2 Regulatory background

The most striking conflict between IPR protection and global health promotion is that TRIPS prevents the supply of generic copies of a new drug. If the drugs needed to fight a disease are protected by strong IPRs, it is even more expensive for developing countries to import the drug, to obtain a license to manufacture the drug. The WTO has gradually become more aware of this conflict and has tried to compensate for this obstacle in the fight for public health. One attempt towards a more health protective approach has been to allow compulsory licenses during public health emergencies, such as the HIV/Aids epidemic. This opens up the possibility for companies manufacturing generic drugs to be able to provide more affordable medicine. Initially, this possibility was limited to domestic use, which meant that a manufacturer was unable to export generic drugs under a compulsory license. The problem with this solution is that most LDCs do not have the resources necessary to make use of a compulsory license by themselves. The Doha Declaration initiating the latest and current round of WTO negotiations took this a little bit further and declared that export of products made under a compulsory license, may be exported to LDC's.

1.3 Problems

The urgent public health question is however if these latest measures are enough. For one thing, there is an uncertainty to the legal standing of the results from the Doha round so far. The relevant declaration is not yet formally ratified as an integral part of the WTO system. The biggest issue is the fact that many of the industrialized nations are pushing for even stronger international IPRs. Many believe that developing countries, during the Uruguay round leading up to the WTO, were basically forced to agree to the TRIPS agreement in order to get access to all the other advantages that the WTO could offer. The current negotiation round within the WTO was supposed to be more focused on the developing countries, the role and consequences of IPR protection was supposed to be back on the agenda. Despite the longest round of negotiations so far, real success is yet to come. Progress is most likely delayed by the fact that most developed countries consider the multilateral IPR protection offered by the WTO to be too weak, contrary to the goal of the Doha agenda. In fact, many large and influential industrialized nations have chosen to enter into a so called TRIPS-plus strategy, using their unequal bargain power to enter into bilateral agreements with small developing countries and thereby imposing even stricter IPRs through a country-by-country approach. The complexity of the conflict adds on when taking into account the fact that all evidence suggests that it is very hard to achieve maximum development potential with strong IPR protection. Basically all current industrialized nations became industrialized with almost no protection for new and

increased innovation so that they could innovate as much as possible. So the question really comes down to if it is possible to combine liberalized trade with strong IP rights, and still expect the kind of social and economic development necessary to fulfill the goals and obligations of international public health agreements.

1.4 Problem statements and purpose of thesis

With these dilemmas, complicated relations and versatile considerations in mind, the main purpose of this thesis is to analyze the following problems:

- (1) What role does global health promotion play in global development;
- (2) Can developing countries reach their development potential with strong international agreements on IPR protection;
- (3) Has the multilateral remedies implemented to comply the TRIPS agreement with protection of global health had any impact – if so, what kind;
- (4) Has the recent trend towards a bilateral TRIPS-plus strategy counteracted multilateral attempts for IPR protection to co-exist with the promotion of development and global health; and
- (5) Is it possible to regulate trade and IPR protection so that it contributes to sustainable trade liberalization?

1.5 Method

The research method for this thesis is a relatively traditional legal dogmatic approach with interdisciplinary features due to the highly political nature of the topic. The primary sources have been relevant international agreements, publications from the WTO and other international organizations, as well as a wide range of as well legal as political doctrine.

1.6 Disposition

For a better overview of the relevant issues, the thesis is divided into 5 different parts. Due to the complexity of the topic, the first parts are quite comprehensive. The intention is to give the reader a thorough understanding of the background to the conflict and all factors that impact the relationship between the policies.

- **Part I**, the introductory chapters 2-4, provides a theoretical and contextual framework for the thesis. It gives an overview of both motives, goals and potential downsides to international trade and trade agreements, followed by an introduction to globalization and

development and how these concepts are influenced by trade liberalization as well as an introduction to how important promotion of global health really is.

- **Part II**, chapter 5 and 6, introduces the concept of health as a human right, international cooperation and agreements on promotion of global health, the connection between the WTO and global health and a brief introduction to the TRIPS agreement.
- **Part III**, chapter 7-10, gives a closer look on the TRIPS agreement and why it is a potential conflict to global health promotion. It also describes the rationale behind IPR protection, how IPRs are connected to trade and how they became a regulatory matter within the WTO.
- **Part IV**, chapter 11-13, closer describes the impact the TRIPS agreement has had on developing countries in general and the health of their populations in particular developing world and how the WTO has tried to reconcile TRIPS and global health protection. It also presents the recent development towards a TRIPS-plus strategy and compares the strengths and weaknesses of multilateral and bilateral cooperation.
- Lastly, in **part V** and chapter 14, the findings from previous chapters are discussed and some conclusions and suggestions are provided.

PART I

2. International trade

There are many aspects and theories on the effects and consequences of international trade; positive as well as negative. This chapter provides a brief introduction to the basic arguments from both an economic and a political point of view.

2.1 Comparative advantage and other economic benefits of trade

From an economic perspective, trade is thought to increase economic well-being, welfare and income. Economic evidence for these positive effects of trade is mainly based on the theory of comparative advantage which suggests that cross-border trade increases the overall income of a country.¹ According to this theory a country has a comparative advantage “*in producing a good, if the relative cost of producing the good, that is, its opportunity cost in terms of other goods forgone, is lower than it is abroad.*”² Countries tend to export goods they have a comparative advantage in and import goods they do not have a comparative advantage in.³ Basically this means that if a nation opens its borders to trade, available production possibilities will increase, which allows the country to specialize in the production of those goods and services in which it has a comparative advantage.⁴ In addition to the increase in overall welfare for both trading parties, international trade also provides a more efficient distribution of resources and creates economies of scale.⁵ When a nation opens its borders for trade to flow freely, competition generally increases and creates lower prices on products, which is beneficial for consumers.⁶ Tariffs on imported products on the other hand, protect domestic companies that would otherwise face competition and raises prices for domestic consumers compared to the world market price where the products are subject to competition.⁷

2.2. Non-economic advantages of trade

Economic advantages aside, trade can: improve friendly relations between nations; reduce the

¹ Page 10, Guzman/Pauwelyn

² Page 69, Oxford Dictionary

³ Page 69, Oxford Dictionary

⁴ Page 13, Guzman/Pauwelyn

⁵ Page 30, Guzman/Pauwelyn

⁶ Page 18, Guzman/Pauwelyn

⁷ Page 495, Rivera-Batiz/Oliva

likelihood of armed conflict; stimulate stability, freedom and democracy; contribute to cultural exchange and enable technology transfer.⁸ If trade can create these advantages, why is it that countries do not open their borders completely and allow free flow of products? If the economic impacts of trade are this positive, why do governments still adhere to protectionist measures and barriers to trade?

2.3 Arguments against free trade

Even though free trade and comparative advantage can contribute to growth and economic development, it does not promise a fairly distributed increase of income.⁹ To create a 'just' system, it is necessary to redistribute resources. The theory of comparative advantage also generally assumes that workers can be easily replaced into where they are most useful.¹⁰ Consequently, one common argument against trade is that countries want to protect domestic industries and the jobs that they offer and thereby be able to correct distributional effects.¹¹ Along with the desire to protect domestic jobs comes the intention of protecting wages. In many developed countries there has also been some resistance towards trading with developing countries, because of a fear that such a trade would drive down the salaries in the developed countries.¹² Generally this point of view is refuted by statements saying that the amount of trade with developing countries is too small, or the importance of imports from developing countries is not significant enough to make an impact on domestic wages in developed countries.¹³ Other common domestic objections to liberalized trade origin in a desire to address domestic market failures, protect infant industries from international competition, improve a country's own terms of trade or collect revenue to the government through the use of tariffs, protection from imports that are seen as a threat to a nation – either by being a risk to health, environment, national culture, security or public moral and so on.¹⁴

2.4 Politics over economic theory – protectionism

Regardless of political views, it is fairly accurate to say that economists are virtually unanimous that international trade is beneficial to growth and essential for sound economic policies.¹⁵ The fact that governments still keep barriers to trade despite this fairly sound economic theory is probably

⁸ Page 30, Guzman/Pauwelyn

⁹ Page 10, Guzman/Pauwelyn

¹⁰ Page 16, Guzman/Pauwelyn

¹¹ Page 30, Guzman/Pauwelyn

¹² Page 96, Rivera-Batiz/Oliva

¹³ Page 96, Rivera-Batiz/Oliva

¹⁴ Page 30, Guzman, Pauwelyn

¹⁵ Page 42, Guzman/Pauwelyn

easiest explained by political pressure. It is important to remember that politics and policies of trade do not necessarily correspond with what is thought to be the most advantageous solution according to economic theory, there are many other aspects to consider in policy making.

2.4.1 Collective action and free riding

A collective good, or a public good, is something that, when provided to a group, all members enjoy equally.¹⁶ One would think that the more people that would gain from a collective good, the harder the public would work a policy assuring this good. The reality is that due to the problem of collective action, small and well-organized interests groups generally have a disproportionate influence over policy compared to the large, unorganized mass that would benefit more from a certain policy. The economist Mancur Olson explains this by referring to the nature of collective goods - the larger the group, the smaller the individual gain.¹⁷ Since everyone gains equally from a collective good regardless of contribution, large groups generally suffer from a free riding problem.¹⁸ This means that the group will suffer from the people who rely on others to contribute and just join in for the free ride. In a small group, the individual gain can be much greater and thereby an incentive for greater individual sacrifices when trying to achieve the benefit, which also limits the possibility of free riding.¹⁹

2.4.1.1 A collective action problem in trade

The problem of collective action and free riding is true also when it comes to trade. Liberalized trade could create the collective good lower consumer prices. Unfortunately consumers make up a large and poorly organized group, and the respective individual gain for each consumer is so small that they are unlikely to care enough to fight for lower tariffs on trade. A domestic company with a more or less un-threatened market position with barriers to trade on the other hand, risk losing a great deal on increased competition. Lobbyist groups that represent this industry that risks facing serious competition without protective measures, is generally sufficiently well-organized and politically influential to be able to steer policy towards more protectionist measures, compared to the unorganized consumers.²⁰ The fact that governments can be influenced by interest groups does not mean that social welfare is not a political goal, only that consumers have a much harder time communicating what would enhance their social welfare.²¹ It should of course be noted that far

¹⁶ Page 466, Canon, Coleman, Mayer

¹⁷ Page 467, Canon, Coleman, Mayer

¹⁸ Page 468, Canon, Coleman, Mayer

¹⁹ Page 469, Canon, Coleman, Mayer

²⁰ Page 495, Rivera-Batiz/Oliva

²¹ Page 528, Rivera-Batiz/Oliva

from all consumers believe that trade liberalization should be a prioritized goal for the government even if they realize the effect of lower prices. For example, a consumer might doubt the government ability to control the distributional effects that that increased competition will have and if consumers believe that trade is hurtful to them, the government will act protectionist regardless of economic arguments. Hence, there is an inherent tension between the economic incentives to liberalize trade and reduce trade barriers on the one hand and political pressure for protectionism on the other hand.

3. International trade agreements

Since the Second World War the world has seen a dramatic decline in tariffs and trade barriers as well as a dramatic increase in trade.²² The connection between these events is clear.²³ Free trade agreements such as GATT and later the free trade organization WTO with its many trade related agreements have been the two main contributors to the dismantling of tariffs, but they have not put an end to protection, merely led to other forms of protection but steered it towards a certain direction.²⁴

3.1 Why liberalized trade through international agreements?

A government that does not cooperate with other nations is likely to try to improve its own position in the market and try to gain a competitive advantage by adopting trade barriers and export subsidies. If all countries only sought to enhance its own market position like this, a situation called the prisoner's dilemma is very likely to occur. In this scenario no single country gains a market advantages; instead all countries impose high tariffs and export subsidies and everyone loses.²⁵ Governments that are aware of the costs that trade restrictions can bring, have a great incentive to cooperate and coordinate trade policies with each other.²⁶ Multilateral and bilateral negotiations regarding trade liberalization through the reduction or elimination of trade barriers in the global economy have taken place since the 1940's.²⁷ Historically international trade has been liberalized gradually through several rounds of negotiations. The fact that liberalization is gradual and not immediate can be explained by the costs associated with adjustments, as well as a country's desire

²² Page 411, Rivera-Batiz, Oliva

²³ Page 1 Guzman/Pauwelyn

²⁴ Page 411, Rivera-Batiz, Oliva

²⁵ Page 518, Rivera-Batiz/Oliva

²⁶ Page 552, Rivera-Batiz/Oliva

²⁷ Page 418, Rivera-Batiz/Oliva

to avoid abrupt changes in income distribution that new competition may bring about.²⁸ An underlying motive for these negotiations has been the possibility of the optimal economic conditions that free trade under perfect competition can bring.²⁹ The goal of these negotiations is generally to try to avoid the costly effects of a prisoner's dilemma situation by committing to a trade agreement.³⁰

3.2 The GATT

In 1947, the signatures from 25 governments created the first multilateral agreement ever devoted to set principles for international trade and to coordinate trade opening among its members.³¹ This was the creation of GATT, an agreement on trade in goods. GATT was the result of a failed attempt to create a world agency for trade as part of the Bretton Woods plan to stabilize the global financial situation by the creation of the World Bank and the UN.³² The UN council ECOSOC initiated the establishment of an International Trade Organization, ITO, which led to a series of negotiations resulting in the adoption of GATT at the UN Conference on Trade and Employment in 1948.³³ The ITO never became reality, which meant that GATT was given the part of both a trade agreement, as well as a substitute for the intended organization.³⁴ GATT was created because of an international desire to avoid trade losses in forms of optimal tariffs for individual countries, because countries wanted to make a commitment against domestic interests, and finally to pursue foreign policy on peace and security.³⁵ The most important reason to its creation was likely a desire to dissolve a number of protectionist trade policies that had been built up during the economic depression in the 1930's.³⁶ The completion of GATT initiated a series of negotiations called rounds with the goal of eliminating barriers to trade. All of the eight negotiation rounds that the GATT sponsored produced a binding trade liberalization agreement signed by all members.³⁷ The latest completed round of negotiations was the Uruguay round. This was the longest round of negotiations, 1986 to 1994, but it also brought about the greatest change by creating a new multilateral trade agency – the WTO – that completely replaced the institutional structure of the GATT.³⁸

²⁸ Page 421, Rivera-Batiz/Oliva

²⁹ Page 418, Rivera-Batiz/Oliva

³⁰ Page 552, Rivera-Batiz/Oliva

³¹ Page 4, Gervais

³² Page 4, Gervais

³³ Page 4, Gervais

³⁴ Page 591, Rivera-Batiz/Oliva

³⁵ Page 197, Irwin, Mavroidis, Sykes

³⁶ Page 197, Irwin, Mavroidis, Sykes

³⁷ Page 591, Rivera-Batiz/Oliva

³⁸ See the Marrakesh agreement establishing the WTO

3.3. The WTO

The end of the Uruguay round resulted in the Marrakesh Agreement, also called the WTO Agreement, establishing the free trade organization WTO in January 1995. The WTO replaced GATT as an international organization, but the GATT still exists as the WTO's umbrella treaty for trade in goods.

3.3.1 What is the WTO and what does it do?

The WTO is a multilateral trade organization of permanent character that deals with the rules of international trade on a global level.³⁹ The organization has legal personality and the same international status as the IMF and the World Bank.⁴⁰ With 153 members across the world, the WTO and its agreements cover a significant portion of the global trade.⁴¹ The main purpose of the WTO system is to *“help trade flow as freely as possible – so long as there are no undesirable side-effects – because this is important for economic development and well-being.”*⁴² To fulfill this purpose the WTO provides an institutional framework for the conduct of trade relations among its members in matters related to the WTO agreements and related legal instruments.⁴³ The framework facilitates the implementation, administration and operation of the WTO agreement and its annexes as well provides a forum for trade negotiations for its members regarding both existing agreements, as well as potential future agreement.⁴⁴ A crucial feature of the WTO system that makes it stand out from almost all other international cooperation is that it is equipped with a strong dispute settlement mechanism that simplifies the possibility to effectively enforce the obligations of its agreements. This dispute settlement process is governed by the DSU and provides a solution if, and when, member states find themselves in a dispute regarding the interpretation of any of the WTO agreements.

3.3.2 Agreements of the WTO

Originating from the GATT, which only dealt with trade in goods, the WTO has developed tremendously and its agreements now cover everything from trade in goods and services, agriculture, intellectual property, clothing, banking and more. The three main areas of regulation are trade in (1) goods, (2) services, and (3) intellectual property. Each of the three main areas is

³⁹ Page 1, Understanding the WTO

⁴⁰ Art VIII:1, WTO Agreement, Art II:5, WTO Agreement

⁴¹ www.wto.org

⁴² Page 10, Understanding the WTO

⁴³ Art II:1, WTO Agreement

⁴⁴ Art III:1, 2 and page 80, Guzman/Pauwelyn

respectively governed by the three WTO core agreements GATT, GATS and TRIPS. These three agreements are annexed to the WTO agreement, making them an integrated and legally binding part of the WTO agreement.⁴⁵ Membership into the WTO is one single undertaking so anyone who wishes to become a member has to accept basically all agreements connected to the WTO agreement.⁴⁶

3.3.3 Structure of the WTO

The leadership of the WTO derives from its members.⁴⁷ The highest decision making authority lies with the Ministerial Conference that consists of minister representatives from all members. The Ministerial Conference meets at least every two years and has the highest responsibility to carry out the functions of the WTO, and take the actions necessary.⁴⁸ In between the Ministerial Conferences the General Council are in charge of carrying out these responsibilities.⁴⁹ The Council also consists of representatives from all members, but generally on a lower level such as ambassadors or delegates. Hence, all major decisions within the WTO are entered into by all members jointly and usually through a consensus process where each member has one vote.⁵⁰ Apart from these bodies, the three core agreements, GATT, GATS and TRIPS, all have respective councils that, with guidance from the General Council, oversee the function of the agreements.⁵¹

3.3.4 Fundamental principles of the WTO

Despite the wide range of subject areas governed by the agreements under the WTO scope, there are some fundamental principles that can be found throughout all of the agreements and that provide the agreements with a sense of unity and base for the multilateral system.⁵² The most foundational principle of the WTO is trade without discrimination. This principle can be divided into two equally important categories⁵³:

- (1) the *most favored nation (MFN)* principle, which mean that members cannot discriminated against its WTO trading partners - any concession made to another WTO member must immediately apply to all other members as well; and
- (2) the principle of *national treatment*, which means that any imported goods or services from

⁴⁵ Art II:2, WTO Agreement

⁴⁶ Page 96, Guzman/Pauwelyn. Two plurilateral agreements are optional for states joining the WTO.

⁴⁷ Page 101, Understanding the WTO

⁴⁸ Art IV:1, WTO Agreement

⁴⁹ Page 101, Understanding the WTO, Art IV:II, WTO Agreement

⁵⁰ Art IX:1, WTO Agreement

⁵¹ Art IV:5, WTO Agreement

⁵² Page 10, Understanding the WTO

⁵³ Page 10, Understanding the WTO

another WTO member must be given equally beneficial treatment as domestic goods and services.⁵⁴

Besides these fundamental principles, the WTO core principles also advocate a gradually freer trade through negotiations; predictability through binding and transparency; promotion of fair competition, as well as encouragement of development and economic reform.⁵⁵

3.3.5 Other relevant features of the WTO

An important characteristic that made the WTO successful enough to attract 153 members, is the '*reciprocal exchange of market access concessions*', which basically means that through the WTO, governments can open up new markets for its domestic exporters and thereby overcome pressure from domestic lobbyists rooting for trade barriers to protect its industries from competition.⁵⁶ The WTO system is producer driven by favoring export politics over import politics, it is completely mercantilist, and the system also has a tendency to mistrust domestic politics with a general belief that national parliaments would regress to protectionism without the rules of the WTO.⁵⁷ It is also important to remember that the WTO is not a completely uncontroversial organization. Many have questioned its motives and instruments to liberalize trade, especially when it comes to protection of the interests of developing countries. The fact that the WTO has given out a publication with statements that the WTO claim are common misunderstandings about the WTO, says a lot about the extent of these concerns.⁵⁸ In the publication the WTO contradict such claims as: that WTO advocate free trade at any cost; that commercial interest take priority over development and that the WTO dictate governments on issues such as food safety, human health and safety.⁵⁹

4. Globalization and development

In order to properly analyze the consequences of international free trade agreements it is important to have an understanding of the concepts globalization and development. Free and liberalized trade is crucial components in the globalization process that highly influence countries' development potential. Since countries development is also highly dependent on the health of its population, any strategy to promote global health must also take the effects of liberalized trade and globalization into consideration.

⁵⁴ Page 11 ??, Understanding the WTO

⁵⁵ Page 12, Understanding the WTO

⁵⁶ Page 87, Guzman, Pauwelyn

⁵⁷ Page 87, Guzman, Pauwelyn

⁵⁸ 10 Common misunderstandings about the WTO

⁵⁹ Page 100, Guzman/Pauwelyn

4.1 What is globalization?

Globalization is a term used widely and often without a definition. If a definition is provided it is often vague and unspecific and can be anything from a very broad, such as *“arrange of processes that is changing the boundaries that separate human societies from each other and can lead both to interconnectedness and new divisions”*⁶⁰, to more specific, such as *“a strategy of development based on liberalization of markets and the assumption that free flow of trade, finance and information that will produce the best possible outcome for economic development.”*⁶¹ The Oxford Dictionary of Economics simply describes globalization as *“the process by which the whole world becomes a single market”*, meaning that *“goods and services, capital and labor are traded on a worldwide basis, and information and the result of research flow readily between countries”*.⁶² Regardless of how one chooses to define the process or strategy of globalization, it is clear that it is here to stay. Technology or information cannot be confined within borders, the interdependence between nations regarding trade is enormous, and the global economic integration is only expanding. There really is no way of turning back the process, only to try to identify its effects and consequences and try to handle it from there. It is also evident that globalization is not new phenomena, but compared to previous periods of globalization, today's has a whole different breadth, speed and intensity of movements.⁶³ The WTO, with its liberalizing trade agreements, has been very influential to this process. It is however a long way to go before the world economy is completely globalized. Restricted mobility in labor and an underdeveloped infrastructure in most LDC's are the current main obstacles to economic globalization, so technically only the rich and industrialized countries can truly be called globalized.⁶⁴

4.2 What is development?

The meaning of the term 'development' is in no way clearly defined and is used in a number of different way by scientists, experts and organizations to explain a wide range of situations or processes. To make it a bit clearer, development is commonly divided into three categories: (1) economic development; (2) human development; and (3) sustainable development.⁶⁵ Sustainable development is not the focus of this thesis, but for informational purposes, it is seen as a supplement to economic and human development by also taking into account environmental aspects into the

⁶⁰ Page 16, Lee, McMichael, Butler, Ahern, Bradley

⁶¹ Page 288, Velásquez, Boulet

⁶² Page 197, Oxford Dictionary on Economics

⁶³ Page 17, Lee, McMichael, Butler, Ahern, Bradley

⁶⁴ Page 197, Black

⁶⁵ Page 272, Dutfield, Suthersanen

measurement of development.⁶⁶

4.2.1 Economic development and trade liberalization

In the economic context, development describes a country's measurable economic performance relative to the performance of other countries.⁶⁷ Economic performance can with advantage be measured in growth, which is defined as “*an increase in an economic variable, normally persisting over successive periods.*”⁶⁸ Examples of measurements in growth that is fairly easy to comprehend, is growth in GDP or growth in income. So how can free trade enhance economic development? When perfect competition prevails, free trade is considered the best policy, but when international trade takes place in imperfectly competitive markets with other trade distortions, appropriately imposed trade restrictions can in principle, but not necessarily, improve trade restrictions.⁶⁹

4.2.1.1 Innovation and knowledge as a part of economic development

Many countries believe that innovation, the creation of knowledge and intellectual property, is a crucial factor to the creation of economic growth and wealth, mainly because original and exclusive knowledge is something that is crucial to be a strong international competitor on any market.⁷⁰ If this is true, it is not farfetched to believe that cross-border access to knowledge and information exchange will be crucial components in international economic development.⁷¹ There is also a general belief in developed countries that a transformation from an economy based on production and “real” property, into an economy with higher focus on innovation of intellectual property, requires a highly developed protection and enforcement for IPRs.⁷² When it comes to innovation, patent rights are the most important IPRs and the industries in research and development strongly advocate that patent protection is crucial to innovation and development of new products.⁷³ This type of protection of IPRs is not exactly uncontroversial in terms of its impact on development and will be examined in more detail further down in this thesis.

4.2.2 Human development

Some consider economic growth to be a sufficient measure of the development of a nation or region. Another perception is that other factors than pure monetary ones must be taken into account

⁶⁶ Page 272, Dutfield, Suthersanen

⁶⁷ Page 272, Dutfield, Suthersanen

⁶⁸ Page 204, Black

⁶⁹ Page 411, Rivera-Batiz, Oliva

⁷⁰ Page 5, Dutfield, Suthersanen

⁷¹ Page 521, Bettcher, Yach, Guindon

⁷² Page 7, Dutfield, Suthersanen

⁷³ Page 527, Bettcher, Yach, Guindon

in order to get a more comprehensive and thorough picture of development. Human development can be seen as a supplement to economic development by also taking social welfare considerations into account when measuring development.⁷⁴ Instead of only measuring economic growth, it has been advocated to measurement through HDI as a better indicator of development.⁷⁵ The HDI measures a country's average achievements in human development by dividing it into three dimensions: “a long and healthy life; knowledge; and a decent standard of living.”⁷⁶ This index has both a component that measures income in form of GDP per capita as well as a non-income component that measures things like life expectancy, literacy and the number of children enrolled in school.⁷⁷ The UNDP defines human development as “*creating an environment in which people can develop their full potential and lead productive creative lives in accord with their needs and interests*”.⁷⁸ With this kind of definition, development entails so much more than economic growth and focus is instead on the process of increasing human choices. In order to be able to make choices and make decisions for oneself, a human being must have the most basic capabilities for development, that is to be able to “*lead long and healthy lives, to be knowledgeable, to have access to the resources needed for a decent standard of living and to be able to participate in the life of the community.*”⁷⁹ In 1992, the UNCED announced The Rio Declaration⁸⁰ for future global sustainable development, which was the first time the international community acknowledged a 'right to development'.⁸¹ The concept is very vague and is most likely a compilation of international obligations as well as both collective and individual human rights, but nevertheless it is still recognition for the need of development.⁸² Hence, human development is closely intertwined with the realization of human rights; the two concepts interact and help realize each other.⁸³

4.3 The need for development – actions and recipients

With approximately 1 billion people in the world that live on less than 1 dollar a day as well as 2 out of 5 humans that live on less than 2 dollars a day, there is an obvious need for both economic

⁷⁴ Page 272, Dutfield, Suthersanen

⁷⁵ Originating from the capability approach by Amartya Sen. See his book *Development as Freedom*, Oxford University Press, 1999, for further information.

⁷⁶ <http://hdr.undp.org/en/statistics/indices/>

⁷⁷ Shivirisani

⁷⁸ <http://hdr.undp.org/en/humandev/>

⁷⁹ <http://hdr.undp.org/en/humandev/>

⁸⁰ Report of the United Nations Conference on Environment and Development, Annex I: Rio Declaration on Environment and Development, A/CONF.151/26, Vol I, 12 August 1992

⁸¹ Page 11, Boyle, Freestone

⁸² Page 12, Boyle, Freestone

⁸³ <http://hdr.undp.org/en/humandev/>

and human development.⁸⁴ Countless international efforts are being made to try to accomplish this development through different international organizations and agreements. The progress that these programs and efforts have had is not to be dismissed lightly. The WHO world health report from 2008 give an illustrative example through the mortality rate in children; if the current number of child deaths would have been as high as it was in 1978, there would have been 16.2 million deaths globally in 2006 - the real number was 9.5 million deaths, illustrating a number of 18 329 saved lives every day.⁸⁵ The problem is though that this progress has not been distributed equally over the globe. The decline in child mortality has unfortunately been much lower in low-income countries than it has been in rich countries.⁸⁶ With more than a third of child deaths caused by malnutrition and statistics showing that one in four children in developing countries are underweight⁸⁷, the connection is not too hard to understand. It is evident that all improvements that have been made in the area of global health has been very unequal where some parts of the world have made great progress, while other parts have simply stood still or even regressed.⁸⁸

4.3.1 Developing countries and progressive realization

Even though international agreements generally place obligations equally on all its members, the world recognizes the increased need for development in certain poor and underdeveloped countries. Almost all international agreements that provide obligations acknowledge this special need, recognize the need for progressive realization and therefore often provide developing countries with extended time limits to comply with the provisions of the agreement.⁸⁹ The division between developed and developing country is based on the principle of self selection, which means that it is the country itself that decides if it should be classified as a developing or a developed country.⁹⁰ This also means that another country can contest to the classification if they do not believe that a country should be given the benefits that a developing country receives in the international arena.⁹¹ The poorest countries on earth, the LDCs, are recognized by the UN and are given additional provisions to comply with international obligations.⁹²

⁸⁴ Page 624, Guzman, Pauwelyn

⁸⁵ Page 2, WHO world health report 2008

⁸⁶ Page 2, WHO world health report 2008

⁸⁷ Page 12, UNMDG Report 2009

⁸⁸ Page xii, WHO world health report 2008

⁸⁹ Concerning progressive realization, see for example the ICESCR and page 25, Human Rights: An Introduction, Health and Human Rights, International Federation of Red Cross & Red Crescent Societies & Francoise-Xavier Bagnoud Center for Health and Human Rights. For example of extended time limits, see art 65 and 66 of the TRIPS agreement.

⁹⁰ Page 624, Guzman, Pauwelyn

⁹¹ Page 624, Guzman, Pauwelyn

⁹² Page 626, Guzman, Pauwelyn

4.4 International initiatives for development

As a matter of enormous urgency, it is no wonder that a number of strategies are in action to fight poverty, infectious diseases and increase the economic well-being of the world's population.

4.4.1 The Millennium Development Goals

During political and economic reforms between 1980's up until 2000 – world leaders committed to eradicate poverty⁹³. This was soon followed by the UN Millennium Summit establishing the MDGs in combat of poverty, hunger, disease and many other factors that impacts development. The commitment to these goals is probably the most significant attempt towards global development and an actual sincere attempt to address the problems of inequality and poverty. New financial mechanisms of development were offered and the UN and G8 took an initiative to fight three specific diseases that are a major cause of low life expectancy in huge parts of the developing world.⁹⁴ The MDG initiative really brought put the issue of inequality into focus of international social policy-making and with global health as a main objective.⁹⁵ It also helped authorities in the health area to expand the understanding of the concept of health. The MDG's do not define health as narrow as increased disease control and higher survival rates; they treat health also as a necessity of life, highly valued in society.⁹⁶

4.4.2 UNCTAD

One important organization in the work for development in a globalized world is the UNCTAD, established in 1964. The mission of this UN agency is to promote “*development-friendly integration of developing countries into the world economy.*” and its work is mainly focused on ensuring that “*domestic policies and international actions are mutually supportive in bringing about sustainable development.*”⁹⁷ The UNCTAD collects economic data and analyze development strategies with the purpose of providing the international community with a better understanding of how to handle the effects of globalization.⁹⁸ To communicate the results of its work, the UNCTAD annually publishes a Trade and Development Report. As a contribution to the international debate on globalization, UNCTAD also has a program on Globalization and Development strategies where it promotes policies for economic growth and development by regularly examining the “*trends and*

⁹³ International Summit on Social Development, Copenhagen 1995 – first UN conference on social development

⁹⁴ Page 665, Walt, Buse

⁹⁵ Page xix, WHO world health report 2008

⁹⁶ Page xx, WHO world health report 2008

⁹⁷ <http://unctad.org/Templates/Page.asp?intItemID=1530&lang=1>

⁹⁸ <http://www.unctad.org/Templates/Page.asp?intItemID=3820&lang=1>

*prospects in the world economy” and “undertaking studies on the requirements for successful development strategies and on the debt problems of developing countries.”*⁹⁹

4.4.3 UNDP

Another important UN agent for development is the UNDP, the UN network for global development that advocates for change and help provide countries with the knowledge, resources, and experience necessary to be able to achieve increased development. The UNDP has a crucial role in coordinating efforts to reach the MDGs and offer nations help with: the buildup of democratic governance, reduction of poverty, prevention and recovery from a crisis, governance of environmental, energy and HIV/Aids challenges, and assist developing countries on how to attract and use international aid effectively.¹⁰⁰ For a long time, the developed world has seen aid as the primary measure to assist any countries in need. According to the WHO, global aid will still play a role in the assurance of progress and development in the future, but one that is highly supplemental and secondary to exchange, joint learning and global governance.¹⁰¹

4.4.4 Corporate Social Responsibility

Apart from state cooperation through agreement and international agencies, it has also become more and more common with large multinational companies to be more active in their CSR measures. For example, in 2004 Coca Cola agreed to treat all their African employees infected with HIV with ARV drugs on the expense of the company.¹⁰² Another example can be found in some pharmaceutical companies that lowered their prices on ARVs after pressure from different organizations such as the UNAIDS.¹⁰³

4.5 Impact of globalization and trade liberalization on development

It is controversial what impact globalization and trade liberalization has on the poor population in developing countries and scholarly evidence point in many directions. Some researchers find that there is no evidence suggesting that open international trade has a significant negative impact on the income of poor, while others claim that an open international trade led to a higher inequality.¹⁰⁴ The connections are not entirely clear, but since trade liberalization is probably only going to be more and more extensive, it is important to learn the effects of it and try to enhance its benefits, and

⁹⁹ <http://unctad.org/Templates/StartPage.asp?intItemID=2874&lang=1>

¹⁰⁰ <http://www.undp.org/about/>

¹⁰¹ Page xix, WHO world health report 2008

¹⁰² Page 667, Walt, Buse

¹⁰³ Page 667, Walt, Buse

¹⁰⁴ See for example page 21, Dollar and Kraay

reduce any potential concerns.

4.5.1 Trade liberalization as an instrument to reach development

The considerable amount of research that identifies liberal trade as a positive instrument, indicate that liberalized trade promote development and social welfare through the reduction of poverty and the increase of overall personal wealth.¹⁰⁵ This means that restricted trade does not provide an optimal allocation of resources and is costly to welfare. Costs to welfare can be calculated very statically by simply measuring the gap between price and marginal cost due to trade restrictions on the one hand, and the elasticity of demand and supply and the volume of trade on the other hand; generally through a percentage of a nation's GDP.¹⁰⁶ Trade restrictions can also create distortions to the social welfare of a nation through reduced access to new technologies, products or specialized inputs.¹⁰⁷

4.5.1.1 Example from trade liberalization in developing countries

In the 1980s there was a debt crisis in many developing countries that made way for a wave of trade liberalization.¹⁰⁸ China, India, Brazil, Thailand, Argentina and Bangladesh (six globalizing countries that together account for over half of the population of the developing world) all sharply reduced tariff rates and increased trade in relation to their GDPs in the 1990's.¹⁰⁹ The relation between trade liberalization, growth and national poverty in these six globalizing countries was examined in an economic study by Dollar and Kraay where the main conclusion was that trade liberalization accelerated both the growth rate and the rate of poverty reduction.¹¹⁰ The study showed that the average income of the poorest 20% of a country on average fall or rise at the same rate as the average income falls or rises.¹¹¹ This research was based on numbers from a time period over 40 years and they found this to be true in all regions and income levels as well as in normal times or times of crisis. Their research also found that economic policies that were pro-growth (such as a low inflation, respect for the rule of law and openness to international trade) in general raised average income without any systematic distributional effects.¹¹² Most significantly, their research indicates that an openness to trade on average increases the income of the poor to the same extent as any other household. Consequently their research supports the view that liberalized trade decrease

¹⁰⁵ Page 253, Bloche, Jungman

¹⁰⁶ Page 420, Rivera-Batiz, Oliva

¹⁰⁷ Page 421, Rivera-Batiz, Oliva

¹⁰⁸ Page 425, Rivera-Batiz, Oliva

¹⁰⁹ Page 425, Rivera-Batiz, Oliva

¹¹⁰ Page 425, Rivera-Batiz, Oliva

¹¹¹ Page 25, Dollar, Kraay

¹¹² Page 25, Dollar, Kraay

poverty and thereby contributes to development. Dollar and Kraay do not suggest that increased growth is the only measure necessary to improve poverty, but since their research demonstrate that economic growth on average benefit the poor equally to the rest of society, they believe that any strategy to reduce poverty should be dedicated to create an increased growth.¹¹³ WTO supports this point of view with research stating that average life expectancy has risen as a reflection of the growth in average income per capita.¹¹⁴ This is further supported by the UN MDG report of 2009, stating that the recent global economic crisis increased the anticipated number of people living in extreme poverty in 2009 by 55 to 90 million people globally.¹¹⁵

4.5.1.2 Other prerequisites for development

Growth and economic development is dependent on diffusion of technology and the capacity of a country to command new technologies.¹¹⁶ Globalization of scientific knowledge and diffusion of technology could have positive implications for health for example by distance learning for poor and remote communities.¹¹⁷ In order to be able to enjoy the economic and social development that diffusion of technology could bring, most developing countries need to improve their technological base.¹¹⁸ Information technology is a powerful force in both social and economic development and it is therefore highly important to improve developing countries capacities to be able to use this technology.¹¹⁹ Globalization of trade also enhances the importance of international standards and legal instruments, introducing for example obligations regarding food safety or other standards that could improve the health of a population.¹²⁰ *“Good governance within each country and at the international level is essential for sustained economic growth and development.”*¹²¹ Policies and instruments in a development strategy, such as macroeconomic tools, trade and education policies, as well as investments in infrastructure are all closely intertwined and interact with each other. Finally, it is also a matter of security. A country in peace is much more susceptible to growth than a nation of conflicts.¹²² According to the WHO, a civil war reduces the growth of a country with approximately 2.3% per year for a typical duration of seven years, resulting in a country that is 15%

¹¹³ Page 25, Dollar, Kraay

¹¹⁴ Page 4, WHO world health report 2008

¹¹⁵ Page 6, UNMDG Report 2009

¹¹⁶ Page 529, Bettcher, Yach, Guindon

¹¹⁷ Page 522, Bettcher, Yach, Guindon

¹¹⁸ Page 529, Bettcher, Yach, Guindon

¹¹⁹ Page 522, Bettcher, Yach, Guindon

¹²⁰ Page 522, Bettcher, Yach Guindon

¹²¹ From the Sao Paolo consensus, <http://www.unctad.org/Templates/Page.asp?intItemID=3820&lang=1>

¹²² Page 6, WHO world health report 2008

more poor.¹²³

4.5.2 Trade liberalization in conflict with development and health improvement?

Despite a number of benefits, there are both winners and losers as a consequence of the distributional effects of globalization. It is clear that global change affects individuals and populations differently depending on their socioeconomic status.¹²⁴

4.5.2.1 Inequality, lack of resources and exposure

Globalization has actually led to a widening of income inequality. Average income in already high-income countries increase faster than average income in low-income countries which consequently lead to higher disparities between the most and the least healthy.¹²⁵ Both individuals in less developed parts of the world, as well as their governments lack the material resources to do the investments necessary to protect health.¹²⁶ By definition, globalization opens up borders, which makes people more exposed sensitive to health threats. Open borders lead to an increased risk of infectious diseases spreading faster and wider because no nation can contain within its own premises.¹²⁷ Open borders also allow harmful products, such as tobacco, to spread into new parts of the world that might not be sufficiently informed or enlightened of its consequences to regulate their existence appropriately.¹²⁸

4.5.2.2 Impact on power structures

Globalization also affects the power structures of the world. On the one hand it is fairly obvious that a more interconnected world places more power in the hands of fewer people, and on the other hand globalization may have a democratizing effect through a positive impact on development.¹²⁹ Healthy and informed people have a better chance of influencing their everyday life. Another issue regarding power is that globalization and trade liberalization reduces state involvement in the economic integration. It limits possibilities for governmental subsidies for example health policies and weakens state influence.¹³⁰

4.5.2.3 Is economic growth and development really connected?

While doing research for the UNDP, economists George Gray Molina and Mark Purser found that

¹²³ Page 6, WHO world health report 2008

¹²⁴ Page 17, Lee, McMichael, Butler, Ahern, Bradley

¹²⁵ Page 4, WHO world health report 2008

¹²⁶ Page 6, WHO world health report 2008

¹²⁷ Page 552, Bettcher, Yach Guindon

¹²⁸ Page 552, Bettcher, Yach Guindon

¹²⁹ Page 18, Lee, McMichael, Butler, Ahern, Bradley

¹³⁰ Page 288, Velásquez, Boulet

changes in the income based and the non-income based parts of the HDI are not related and thereby caused huge disturbance in the generally accepted view that human development will follow economic growth.¹³¹ The two researchers tracked changes in income and non-income components of the HDI separately. Their results indicate that the enormous achievements in health and education has had next to nothing to do with globalization and that the credit instead should go to governmental decisions to expand education and health systems, as well as international efforts to increase access to vaccines and antibiotics.¹³² Their conclusion was that economic growth and human development are not enhanced by the same forces, and that acceleration in life expectancy and literacy as a result of urbanization and declining fertility rates, is driven by individual and household decisions about fertility and female schooling.¹³³

4.5.3 Conclusions on the relationship between trade and development

Due to power shifts, overlapping mandates, competition, poor coordination and governance and so on, the world has seen a shift from a predominantly vertical power to a more horizontal phase; it is not only cooperation between national governments that influence public health policy any more, many other actors have entered the arena in different ways.¹³⁴ It is likely that the continuing development for health cooperation move towards increased vertical public-private partnerships at both local and global level.¹³⁵ At first glance this would seem great simply because the world get more actors trying to solve the problems with global health. There is however a potential problem with such a development; the international community does not have a good way of ensuring corporate compliance to international regulation. There is also the issue of potential hidden agendas in NGOs considering the low transparency due to the lack of obligation for them to reveal their true intentions. If they are profit driven organizations, they answer to no one but their stockholders. Regardless of how, it is evident that countries need to cooperate internationally. A nation aiming for development of course has to base its strategy on the specific needs and circumstances of that nation, but adherence to international cooperation with its rules and regulations, is at least as important if the country want to become a stable economic force in a globalized economy.¹³⁶ Finally, an insufficient economic growth is inescapably connected to a decrease in resources for health protection, which means that every program or measure to try to decrease health inequality,

¹³¹ Shivrisani

¹³² Shivrisani

¹³³ Shivrisani

¹³⁴ Page 674, Walt and Buse

¹³⁵ Page 675, Walt and Buse

¹³⁶ <http://www.unctad.org/Templates/Page.asp?intItemID=3820&lang=1>

has to take the creation of peace and a stable society into account in order to create an environment that actually can invest in education, the health sector and all other parts of society that are essential to assure development.¹³⁷

4.6 Global health and development

Being healthy is a necessity to be able to participate in society. Being able to work, vote, and all other aspects of leading a normal life, all require a stable physical health as well as access to a safe and functioning health system. Without a healthy population a country cannot build a functioning legal and administrative infrastructure to manage a domestic government, let alone enter into cooperation with other states about global concerns. Hence, any serious development strategy must entail a forceful plan to improve global health. In the late 1990's, the WHO initiated the Commission on Macroeconomics and Health, which managed to show that ill health was a cause of poverty and that intervention to prevent and treat disease was cost-effective.¹³⁸ Even though there are significant evidence to the role of liberalized trade and economic growth as a contributing factor in development, a pure market driven approach to development will not be able to see the nuances and potential contradictions of development.¹³⁹ Improvement of social conditions, such as global health, along with liberalization of markets is the most sustainable way of assuring a more equal globalization.¹⁴⁰

4.6.1 Health as a global public good?

In a globalized world, health policy issues are no longer confined within borders. With increased trade and movement, the health of a nation is affected by many factors with international origin that need trans-border cooperation. The most illustrative example is of course the matter of communicable diseases that almost never can be handled by a single nation.¹⁴¹ Since the interest of improving health is international, one could almost assume that global health is a global public good.

4.6.1.1 What is a global public good?

According to the UNDP, a public good is a good/benefit that, unlike private goods, cannot be restricted. It is available to all, and the benefit is not limited to the consumption of one individual; it

¹³⁷ Page 6, WHO world health report 2008

¹³⁸ Page 664, Walt, Buse

¹³⁹ Page 522, Bettcher, Yach, Guindon

¹⁴⁰ Page 529, Bettcher, Yach, Guindon

¹⁴¹ Page 3, Woodward and Smith

is non-excludable and non-rival.¹⁴² To be a *global* public good it also has to be universal in terms of countries, people and generations.¹⁴³ Global health does not fall directly under this category, but it can provide effects that resemble a global public good. The prevention of certain communicable diseases has both individual and global benefits. Considering the cumulative economic effect on national/regional health in terms of loss of production and income that an unhealthy population causes, there are substantial potential gains in health improvement.¹⁴⁴ An excellent example is the issue of HIV/Aids. This disease causes a considerable decrease in life expectancy and thereby decreases income of both the individual and the country.

4.6.1.2 *Public goods and the prisoner's dilemma*

Public goods generally suffer from a collective action problem.¹⁴⁵ The community as a whole is better off if public goods are provided, but in order to avoid free riding and the prisoner's dilemma, collective action is required. The prisoner's dilemma can basically be defined as lack of communication in a group as well as lack of information about each participant's actions, combined with the lack of enforcement mechanisms. The political process necessary to ensure an international collective action is fundamental to securing a global public good. The problem of collective action becomes even more complex when it comes to a global issue. The absence of a global government makes global public goods hard to finance and enforce.

4.6.2 **Socioeconomic factors to health**

Inequalities in health that can be avoided exist both between and within countries and originate in the social and economic conditions people live in, which determine their so called social economic status, SES. This status also include levels of income and education and help assess what risk people have of being exposed to a certain disease as well as what kind of access to treatment they will have.¹⁴⁶ Components of a population's SES are often more important contributors to their health status than medical care itself.¹⁴⁷ The WHO defines social determinants of health as “the conditions in which people are born, grow, live, work and age, including the health system.”¹⁴⁸ WHO also conclude that it is primarily these determinants that are responsible for health inequities. In 2005 the WHO established CSDH with the purpose to provide advice on how to reduce these

¹⁴² Page 4, Woodward and Smith

¹⁴³ Page 4, Woodward and Smith

¹⁴⁴ Page 10-12, Woodward and Smith

¹⁴⁵ See section 2.4.1 supra

¹⁴⁶ Page 252, Bloche, Jungman

¹⁴⁷ Page 252, Bloche, Jungman

¹⁴⁸ http://www.who.int/social_determinants/en/

inequities. In August the Commission launched a final report with three overall goals: (1) improve daily living conditions; (2) tackle inequitable distribution of power, money and resources; and (3) measure and understand the problem and assess the impact of action.¹⁴⁹ The CSDH believes that positioning health equity as a key performance indicator in all social and economic policy making could potentially create significant reductions in health inequalities.¹⁵⁰ It is statistically clear that poor social and economic circumstances throughout life affect the health of an individual; “further down the social ladder” life expectancy is lower and diseases are more common.¹⁵¹ Statistic findings also show that almost all diseases and causes of death show differences in SES.¹⁵² Where an individual is hierarchically positioned in society can have both a direct effect on the health of the individual, as well as an indirect effect through SES related differences in physical and social environment, health behaviors or personality.

¹⁴⁹ http://www.who.int/social_determinants/en/

¹⁵⁰ Page 1171, Marmot, Bell

¹⁵¹ Page 10, Wilkinson, Michael Marmot

¹⁵² Page 181, Adler, Boyce, Chesney, Cohen, Folkman, Kahn, Syme

PART II

5. Health as a human right

The need to improve social determinants of health is since long highly recognized in the international community and there are strategies and battles fought on multiple fronts to try to find the best solution on how to improve the health of the globe. A significant part of this fight is the attempt to get health internationally recognized as a human right.

5.1 Human rights

Human rights are rights that all individuals are equally entitled to simply because they are human.¹⁵³ International human rights law basically governs what the government *can*, *cannot*, and *should* do for its citizens.¹⁵⁴ All human rights imposes three main obligation on the member states: (1) A duty to respect the rights – member states may not interfere with an individual enjoying its human rights; (2) A duty to protect the rights – this means that the member states have to prevent its citizens from other interference with the rights, for example from the private sector; and (3) a duty to fulfill the rights.¹⁵⁵ It is not enough just to prevent from interfering in enjoyment of rights; member states have to take positive measures to facilitate the possibility to enjoy all human rights.¹⁵⁶

5.2 UNDHR - international framework for human rights

When the UN was created in 1945 after the Second World War, the UNC applied an obligation on all member states to respect human rights and dignity. In 1948 this aspirational statement was crystallized into the Universal Declaration of Human Rights.¹⁵⁷ This declaration has been ratified by most nations in the world and even though it is not a legally binding treaty, it is the cornerstone of all human rights.¹⁵⁸ The declaration did not have an immediate effect. After World War II, the main focus and allocation of resources for development was put into technology and scientific progress and there was a period of almost declining interest in human rights. Eventually the interest

¹⁵³ Page 8, Gruskin, Tarantola

¹⁵⁴ Page 8, Gruskin, Tarantola

¹⁵⁵ Page 30, Gostin

¹⁵⁶ Page 8, Gruskin, Tarantola

¹⁵⁷ Page 8, Gruskin, Tarantola, Page 22, International Federation of Red Cross & Red Crescent Societies & Françoise-Xavier Bagnoud Center for Health and Human Rights

¹⁵⁸ Page 8, Gruskin, Tarantola

resurfaced and the idea of turning UNDHR into a legal binding and enforceable treaty emerged. The political climate during the cold war caused polarized views on what human rights were, so when UN finalized its work it resulted in two different treaties: the ICCPR, and the ICESCR adopted in 1966.

5.2.1 ICCPR and ICESCR

The ICCPR govern civil and political rights that are normally classified as 'negative rights' that provide protection from what the government may do to an individual¹⁵⁹, while the ICESCR protects economic, social and cultural rights, normally called 'positive rights' that inflict duties for the state to provide services to their citizens.¹⁶⁰ The ICCPR requires immediate guarantee from its member states, while the rights under ICESCR can be progressively realized.¹⁶¹ Due mainly to unequal resources among the member states, the UN uses the idea of progressive realization to allow member states to progress towards the goal according in its own pace without being in violation of international law immediately.¹⁶² Each covenant is governed by a committee that monitors its implementation. Unlike the ICCPR, the ICESCR does not have a mandatory individual complaint mechanism to enforce the rights, but just recently an optional protocol for the ICESCR was opened, which allows individual complaints of member states' violations to the ICESCR.¹⁶³ Despite the division into two treaties, in international law, both sets of rights are considered equal and interdependent of each other.¹⁶⁴ The UNDHR, ICCPR and ICESCR are jointly referred to as the International Bill of Human Rights.¹⁶⁵

5.3 Health as a human right under international regulation

Promotion and protection of human rights is fundamentally linked to the promotion and protection of health.¹⁶⁶ Art 25 of the UNDHR begins with the statement: *“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the*

¹⁵⁹ Page 29, Gostin

¹⁶⁰ Page 29, Gostin

¹⁶¹ Page 25, International Federation of Red Cross & Red Crescent Societies & Francoise-Xavier Bagnoud Center for Health and Human Rights

¹⁶² Page 14, International Federation of Red Cross & Red Crescent Societies & Francoise-Xavier Bagnoud Center for Health and Human Rights

¹⁶³ OP-ICESCR, opened for signature, September 24th 2009

¹⁶⁴ Page 30, Gostin

¹⁶⁵ Page 23, International Federation of Red Cross & Red Crescent Societies & Francoise-Xavier Bagnoud Center for Health and Human Rights

¹⁶⁶ Page 11, International Federation of Red Cross & Red Crescent Societies & Francoise-Xavier Bagnoud Center for Health and Human Rights

event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.” This broad and unspecified human right is further defined in article 12 of the ICESCR: *“1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”* The phrasing 'highest attainable standard' leaves room for a reasonableness standard, which means that the member states shall try to level the playing field regarding factors that they can control.¹⁶⁷ Article 12 further states that this shall be done with the *“maximum available resources to the highest attainable resources”*. Recently the UN issued a resolution on *“The right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”* showing just how pressing the issue is.¹⁶⁸

5.3.1 How is the right to health defined?

Despite this extensive legal framework, there has been a lot of debate if health really is a right and if so, how to define it. What obligations does it really impose on the member states? When the WHO was started in 1946 it defined health as a *“state of complete physical, mental a social well-being, and not merely the absence of disease or infirmity”*¹⁶⁹. Neither the 1948 UNDHR nor the 1966 ICSECR adopted a clear definition of health. Nevertheless, a clear definition is important to clarify obligations, establish enforcement of the obligations and procedures to identify violations of them.¹⁷⁰ In 2000 the CESRC issued Comment 14 to help straighten out some of these question marks.¹⁷¹

5.3.1.1 Comment 14 – the right to the highest attainable standard of health

Issued by the UN in 2000, Comment 14 is probably the most authoritative statement on the meaning of the right to health.¹⁷² Section 1 of Comment 14 states the following definition: *“Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conduce to living a life in dignity. The realization of the right can be pursued through numerous, complementary approaches... Moreover, the right to health includes certain components which are legally enforceable.”* Comment 14 describes the four most important parts of the normative content of ICESCR as (1)

¹⁶⁷ Page 1156, Yamin

¹⁶⁸ Resolution 58/173

¹⁶⁹ Preamble of WHO constitution of 1946

¹⁷⁰ Page 29, Gostin

¹⁷¹ General Comment No 14, The right to the highest attainable standard of health: . 11/08/2000 E/C.12/2000/4. (General Comments)

¹⁷² Page 29, Gostin

availability, (2) accessibility, (3) acceptability, and (4) quality.¹⁷³ This essentially means that all basic conditions necessary for health shall be available and accessible to all individuals in the member states and that all health services are as well ethically and culturally appropriate as scientifically and medically appropriate.¹⁷⁴ Comment 14 defines some core obligations in order to move up the bare minimum for progressive realization and provide guidelines on how to progressively realize these goals. It should be noted that for many developing countries, even the core obligations can be almost impossible for many developing countries. The perhaps most important accomplishment of Comment 14 is that it clarifies that 'the highest attainable standard of physical and mental health' is not confined to the right to health care, but on the contrary, that the right *“embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health...”*¹⁷⁵ This support the notion that a true realization of equal global health will require that the world take action on the underlying social determinants of health.

5.4 International protection of the right to health

States have a natural responsibility for the health within their own borders but due to the increasingly global nature of health issues, states cooperate to achieve the best coordinated results. States generally cooperate by transferring knowledge and by building up a consensus on a global health issue that quite often result in an agreement or understanding of some sort.¹⁷⁶ International cooperation on health protection has a long history. Already between the years of 1851-1909, ten different international meetings were held to deal with the epidemics of plague and cholera and eventually resulted in international agreements on common approaches for control and treatment of infectious diseases.¹⁷⁷

5.4.1 The UN and the WHO

The main agreements on the right to health have been negotiated under the UN umbrella. Current international cooperation in protection of health is primarily done through the UN agency WHO specifically designated to coordinate international health activities, although a significant number of UN organizations have missions that in some way concern the protection or development of global

¹⁷³ Page 29, Gostin

¹⁷⁴ Page 29, Gostin

¹⁷⁵ Comment 14, point 4.

¹⁷⁶ Page 657, Walt, Buse

¹⁷⁷ Page 654, Walt, Buse

health.¹⁷⁸ All members make contributions to the work of the WHO based on the size of its population and wealth, but they all have equal voting rights before an understanding.¹⁷⁹ The biggest problem with the WHO as an agency in protection of health is that the agreements that the WTO govern really does not have satisfactory enforcement mechanisms.

5.4.2 Other international cooperation for health

Due to overlapping mandates and poor coordination within the UN organizations, it is highly likely that the role of the UN in the international area will be diminished as the importance of horizontal cooperation increases.¹⁸⁰ Other international actors that strive to protect the interest of global health, such as bilateral organizations, NGO's, representatives from the corporate sector and different institutions that help with providing financial mechanisms - such as the World Bank and the global fund to fight aids tuberculosis and malaria, are likely to play a greater part.¹⁸¹ Private companies are becoming more and more important through a stronger CSR culture. Considering that some powerful multinationals have an annual turnover way higher than the GDP of low-income countries, they could become very influential.¹⁸²

5.5 Problems with the right to health approach

There are a number of challenges to the right to health approach. Health is by far universally recognized as a human right. The US, maybe the most influential nation in the world, signed the ICESCR in 1977 but has yet to ratify and thereby make it legally binding.¹⁸³ Neither do health protecting agreements generally have a strong enforcement mechanism. Many question if health really can be considered a right if no efficient legal remedy exist.

5.5.1 'Social clauses' as a way to ensure enforcement?

As shown above there is some evidence that suggest that liberal economic trade will undermine public health by increasing social inequalities. A huge concern is that agreements on social obligations generally do not have the same enforcement mechanisms as trade agreements do. One suggestion on how to solve this problem is to include so called 'social clauses' into international trade agreements.¹⁸⁴ These clauses would basically consist of already existing international

¹⁷⁸ Page 651, Walt, Buse

¹⁷⁹ Page 653, Walt, Buse

¹⁸⁰ Page 674, Walt, Buse

¹⁸¹ Page 652, Walt, Buse

¹⁸² Page 667, Walt, Buse

¹⁸³ See ICESCR, <http://treaties.un.org/doc/publication/mtdsg/volume%20i/chapter%20iv/iv-3.en.pdf>

¹⁸⁴ Page 245, Labonte

obligations, for example from UN multilateral declarations that are currently basically unenforceable due to the lack of an international government of any sort. By including these obligations as a 'social clause' into enforceable trade agreements, the global economy could promote both health as well as a more socially just world.¹⁸⁵ Current international trade agreements often do contain provisions that take health into consideration and sometimes allow for exceptions in the liberalizing trade obligations if it is necessary to protect a domestic interest in health protection.¹⁸⁶ These provisions definitely need to be strengthened or clarified in order to realize a more sustainable globalization, but at the same time it is important to ensure that they are not used as a cover for trade protectionism.¹⁸⁷

5.5.2 Health as an interpretive principle?

An alternative to the 'right to health approach' is to see protection of health as a guiding principle for all interpretation of international agreements. Some authors claim that the WTO praxis has developed exactly this way.¹⁸⁸ Even though this principle is nowhere to be found expressly within WTO documents, many AB decisions have had this approach towards interpreting national health regulations and their compliance with WTO agreements.¹⁸⁹ Reports from the AB is technically not binding to anyone but the parties of the dispute, but naturally WTO members rely on reasoning from previous reports when they are parties to a settlement themselves. The DSU also require the AB to promote “*security and predictability*” in its dispute settlement.¹⁹⁰ This means that any interpretation in an adopted report de facto becomes a part of the *acquis* of the WTO system and thereby has some value as precedent and that a specific legal issue will most likely be resolved the same way in a later case.¹⁹¹ Since precedents are given this much value, health could definitely become a solidified interpretive principle in any WTO disputes.

6 The WTO and global health

The WTO has been seen by many as a threat to global health due to a perception that the purpose and regulation of the WTO conflicts with national efforts to protect the lives and health of their

¹⁸⁵ Page 245, Labonte

¹⁸⁶ A very good example of this is art XX of the GATT agreement with general exceptions and that the DSU now interpret WTO obligations with health protection as a guiding principle.

¹⁸⁷ Page 530, Bettcher, Yach, Guindon

¹⁸⁸ See especially Bloche, Jungman, *Health Policy and the World Trade Organization*

¹⁸⁹ Page 259, Bloche, Jungman. See for example of WTO “case law”, see EC-Asbestos or EC-Hormone Beef.

¹⁹⁰ Art 3.2 DSU, page 131-132, Guzman, Pauwelyn

¹⁹¹ Page 132, Guzman, Pauwelyn

domestic population.¹⁹² Opponents to globalization see corporate globalization as the primary cause to income inequality around the world and believe that the WTO is the main source to corporate globalization.¹⁹³ Some even argue that the WTO promotes the interests of multinationals and rich countries over the poor, and that the language of the treaties and the dispute settlement mechanism completely neglect the issues of health and human welfare.¹⁹⁴ At the same time other economic theories suggest that trade liberalization and economic development have a positive impact on the social determinants of health that are necessary in order to realize the right to health. Inequality and income disparity could very well be cause by different rates of growth in different nations. Since one of the benefits of trade is increased growth, the international trade agreements under the WTO can actually be seen as a necessary, yet insufficient, condition for global equality.¹⁹⁵ Increased awareness of the connections between global health and international trade, combined with the potential ramifications of the HIV/Aids epidemic, has placed health as a more and more central trade issue. The WTO has recently both taken and been given an increased role in the health debate. Changes to trade agreements, as well as changes to the interpretation of the agreements, have followed this debate.

6.1 Protection for health within the WTO system

The current round of negotiations in the WTO system, the Doha round, launched in 2001 with the intention of being the 'Development round' in order to support developing countries to reach their development potential.¹⁹⁶ This clearly shows a more comprehensive understanding of the connections between trade and social development. However, the WTO system does not recognize health as a human right the way the UN system does.¹⁹⁷ In fact the ministerial Conference at Doha actually expressly declined to recognize such a right after a group of developing countries suggested an inclusion of a reference to the right to health "*as affirmed in the International Covenant on Economic, Social and Cultural Rights.*" in a proposal for the Ministerial Declaration on the TRIPS agreement and public health.¹⁹⁸ The WTO does not have the authority to form its own health policies, but there are indications towards a WTO practice of recognizing health as a soft, unenforceable right by making it state practice to treat protection of social and economic rights as a

¹⁹² Page 250, Bloche, Jungman

¹⁹³ Page 300, Ostry

¹⁹⁴ Page 251, Bloche, Jungman

¹⁹⁵ Page 300, Ostry

¹⁹⁶ Page 626, Guzman, Pauwelyn

¹⁹⁷ Page 251, Bloche, Jungman

¹⁹⁸ TRIPS Proposal:Draft Ministerial Declaration: Proposal from a Group of Developing Countries, page 267 Bloche, Jungman

directive and interpretive principle when complying with the WTO obligations.¹⁹⁹

6.2 Provisions in the WTO agreements in protection of health

At the first glance, the WTO agreements are extremely vague on how they try to balance health protection against other trade issues. Neither the Marrakesh Agreement nor any of the major agreements under the WTO umbrella contain provision stating that protection of health is a purpose or even an interpretive principle of the agreements. The GATT, GATS and SPS Agreements do however have very general provisions that allow trade restrictions in order to reduce any risks to health.²⁰⁰

6.2.1 GATT art XX b and subsequent cases

Art XX b is the general safety clause of the GATT agreement and has been the origin to many DSU disputes. It allows the WTO parties to take trade restricting measures, or other provisions that may be prohibited by the GATT agreement, as long as they are “*necessary to protect human... life or health.*”²⁰¹ If a country takes such a measure that another contracting party considers unnecessary, the WTO dispute settlement mechanism is the appropriate mean to settle the issue. If a panel is commissioned, it shall make an 'objective assessment' of facts and law to determine the necessity of the health protective measures taken.²⁰² This means that the decision to restrict trade to protect health needs to be based on some scientific evidence and supported by research data of a health risk in order to be justified, but it is generally not required that the decision is based on a majority scientific opinion.²⁰³ A very famous case involving interpretation of GATT, art XX b, is the **EC – Asbestos** case where the AB concluded that “*WTO members have a right to determine the level of protection of health that they consider appropriate in a given situation.*”²⁰⁴ This case is significant because it highlights the importance of health as a multilateral goal and its supremacy compared to other social goals. The more important end, the easier the WTO system can accept measures taken to protect this end.²⁰⁵ In another WTO dispute, the case of **EC-Hormones**, the AB came to the conclusion that health was no less vital in the context of SPS and food safety than in the trade related GATT context. Art 5 of the SPS requires a risk assessment that the EC-Hormones ruling specify; a contracting party has to reach a threshold level of risk in order to justify any trade-

¹⁹⁹ Page, 261, Bloche, Jungman

²⁰⁰ Page 259, Bloche, Jungman

²⁰¹ Art XXb, GATT

²⁰² Art 11, DSU, page 254, Bloche, Jungman

²⁰³ Page 254, Bloche, Jungman

²⁰⁴ Page 254, Bloche, Jungman, Dispute DS135

²⁰⁵ Page 255, Bloche, Jungman

restricting regulation.²⁰⁶ The risk assessment does not have to be based on 'mainstream' scientific opinion, but some supporting research data is necessary.²⁰⁷ It also has to be a rational relationship between the risk assessment and the protective measure taken.²⁰⁸

6.3 TRIPS – the biggest conflict between the WTO system and global health protection

Despite the provisions in the WTO agreements in protection of health, there is one part of the WTO system that is highly questioned for its compliance with international protection of global health: the TRIPS agreement. TRIPS is one of the three main agreements and was added to the WTO system with the end of the Uruguay round. The main purpose of TRIPS is to oblige all WTO members to offer all other members a minimum standard of protection for intellectual property.²⁰⁹ When TRIPS was included into the WTO package, it was the first time IP rules were integrated into the multilateral trading system.²¹⁰ It was an attempt to narrow the gap between IPR protections over the world by establishing common international rules.²¹¹ TRIPS was controversial when it was created, and it continues to divide its evaluators. What is it about this agreement that can make some people call it “*the greatest trade agreement in history*” while others see it as a “*TRAP*” to both developed and developing countries?²¹² For example some believe that when the agreement was drafted, far more attention was paid to satisfy the pharmaceutical and entertainment industry than to create an IP regime that was beneficial to public health, education, food security and the interests of developing countries.²¹³ Since medications usually contain a number of protected IPRs, the greatest conflict between the WTO and health protection is generally trade with medications that have the potential to save lives.

6.3.1 Purpose and coverage of TRIPS

The main purpose of TRIPS is to oblige all WTO members to offer a minimum standard of protection for intellectual property.²¹⁴ The agreement covers the three most economically important areas of IP (patent, copyright and trademarks) as well as some additional specific IPRs.²¹⁵ The

²⁰⁶ EC-Hormones, AB Report 1998, paragraph 186

²⁰⁷ EC-Hormones, AB Report 1998, paragraph 194

²⁰⁸ EC-Hormones, AB Report 1998, paragraph 193

²⁰⁹ Page 39, Understanding the WTO

²¹⁰ Page 39, Understanding the WTO

²¹¹ Page 39, Understanding the WTO

²¹² Page 1, El Said

²¹³ Page 12, Dutfield, Suthersanen

²¹⁴ Page 39, Understanding the WTO

²¹⁵ Page 597, Guzman, Pauwelyn

agreement both incorporates the IP conventions that were in action when TRIPS was entered into as well as adds some new substantive obligations - giving it a much broader scope than previous agreement in this field.²¹⁶ The agreement permits the members to implement a more extensive protection for IPRs than TRIPS requires, and the freedom to decide the most appropriate way to effectuate the provisions.²¹⁷ The agreement does however entail some rules that are intended to assure that all member give effective domestic enforcement to its provisions and any disputes between the members regarding the provisions are to be settled under the WTO system, governed by the DSU.²¹⁸ According to the WTO, the underlying philosophy behind TRIPS is to attempt to “*strike a balance between long term social objective of providing incentives for future inventions and creation and the short term objective of allowing people to use existing inventions and creations.*”²¹⁹ An important principle throughout TRIPS is that any protection of IP should contribute to innovation and transfer of technology.²²⁰ Starting with the GATT and its trade policies, TRIPS is a revolutionary example of how the WTO switched focus in policy to a more positive regulation of as well substantive provisions, as well as legal procedures.²²¹ Its belonging in the WTO structure has been severely questioned, much due to a sometimes very limited relationship to trade.²²² In fact, due to the exclusivity of IPRs, they can be seen as a per se restriction to trade.²²³ Considering this, what reasons could there have been to include protection of IP into a multilateral trade organization that advocates minimized barriers to trade?

²¹⁶ Art 2 TRIPS, page 597, Guzman, Pauwelyn

²¹⁷ Art 1.1 TRIPS

²¹⁸ Page 597, Guzman, Pauwelyn

²¹⁹ Page 1, TRIPS and pharmaceutical patents

²²⁰ Page 40, Understanding the WTO

²²¹ Page 296, Sylvia Ostry

²²² Page 296, Sylvia Ostry

²²³ Page 1080, Weissman

PART III

7 IP protection rationale

Intellectual property can, simply put, be explained as “*legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields*”²²⁴ or as “*creations of the mind*” such as inventions, literature, art work and design.²²⁵ Protection of IP generally consists of an exclusive but limited statutory right for the creator or producer of the intellectual property, to control the use the property.²²⁶ The economically most important IPRs are patents, copyrights and trademarks and the implementation of these rights were of great influence during the industrialization of Europe and North America.²²⁷

7.1 The exclusivity of IPRs

The justifications to the exclusive nature of IPRs can be divided into three categories.²²⁸ (1) Incentive and motivation; (2) Fairness; (3) Economic benefit. Being given an IPR can be seen as an incentive given to inventors in order to encourage them to create more inventions. Incentive is only a good justification for exclusive IPRs assuming that a high quantity of inventions is beneficial to society. The societal benefit is normally argued with the fact that an applied and commercialized invention could contribute to economic and social development.²²⁹ In order to be innovative and create opportunities through new technologies, companies have to invest quite a lot of money into R&D. Exclusive IPRs assure control over the economic use of the invention. If companies do not expect a return on their investments, they are not likely to do the R&D necessary for the creation of new inventions. It could also be argued that justice requires IPRs to be exclusive and that it would not be fair or morally right if the creator or owner of a certain IP would not be able to benefit from it without protection from attempts to violate it and benefit themselves. Finally, IPRs have the exclusive feature with the economic argument that it prevents free riding, optimize resource allocation and avoid market failure. This justification is built on the assumption that knowledge is a public good. Free riding is a big problem in countries with weak IPRs because imitators can then quickly and cheaply copy products based on the inventions of others and sell them domestically or

²²⁴ Page 3, WIPO Intellectual Property Handbook: Policy, Law and Use

²²⁵ Page 590, Guzman/Pauwelyn

²²⁶ Page 3, WIPO Intellectual Property Handbook: Policy, Law and Use

²²⁷ Page 590, Guzman/Pauwelyn

²²⁸ Page 590, Guzman/Pauwelyn

²²⁹ Page 3, WIPO handbook

in another country with weak IPRs.

7.2 The connection between IP and trade

It is obvious that the IPRs have become significantly more important in commercial settings. With globalization and trade liberalization, markets become more receptive to competition. When companies feel the pressure to be competitive in order to survive, they have to be innovative and creative to be original and beat the competition.²³⁰ The value of new high technology products increase when more innovation, research and development are put into them, which means that ideas and knowledge are becoming increasingly important factors to trade.²³¹

7.2.1 IPR protection in importing countries

Since it can generally be assumed that a company will only invest a lot in R&D for new innovations if they are protected by strong IPRs, the protection of IPRs in other countries is probably a very important factor when they decide if and where to they will export products resulting from that research. If other countries than the country where the producing company is located also have strong IPRs, it could encourage the company to export its products to that country because it does not fear free riding. Hence, strong international IPRs could increase the flow of products between nations and thereby have a positive impact on international trade. At the same time, a company that is given domestic exclusive IPRs for their products are more likely to try to prevent the import of any products that might be a violation on their domestic rights. Instead of increasing the flow of trade, this could create barriers and thereby have a negative impact on international trade. IPRs have both the potential to increase innovation, as well as the tendency to increase prices.

7.3 Interests of the industrialized world to regulate IPR protection

The increased role of IP in commercial trade brought substantial changes to the IP regulation in developed countries since the 1960's and 1970's.²³² It has led to (1) a widening of the subject matter that can be protected; (2) creation of new rights, and a; (3) progressive standardization of IPRs.²³³ The extent of IP protection naturally varies around the world, so when IP protected products, as well as the IPRs themselves, became increasingly important to trade, the issue of IPRs eventually made its way onto the international trade negotiations tables. Important and influential multinationals and

²³⁰ Page 590, Guzman/Pauwelyn

²³¹ Page 39, Understanding the WTO

²³² Page 22, Dutfield, Suthersanen

²³³ Page 22, Dutfield, Suthersanen

huge enterprises in industrialized countries believed that weak IPRs in developing countries caused them a lot of financial losses through imitations and counterfeiting and managed to pressure their governments to push the issue of global standardization of IPRs.²³⁴ Especially the US and the EU governments started to pursue an international agenda to harmonize the IPR protection levels internationally despite a very reluctant and resisting attitude from the developing world.²³⁵

7.3.1 Development of industrial pressure for international IPRs

One of the main reasons to why the developed world advocated to include IPRs under a multilateral forum is that they were pushed by domestic interest groups.²³⁶ One interest group that had major impact is the US pharmaceutical industry. Already in 1985 the US pharmaceutical industry campaigned to persuade developing countries to adopt patent laws formed in the same way as US patent laws.²³⁷ Their strategy was twofold: both to persuade the US policy makers to force the policy makers of the developing world to adopt the US type of patent rules, and to convince the governments of developing countries about the advantages of such a patent system.²³⁸ In fact, many former governmental officials went to work for the US trade association for the pharmaceutical industry and allowed the association to become a very prominent and aggressive lobbyist group in Washington that even managed to acquire seats on important advisory boards that shape government policy.²³⁹ Lobbyists also funded academic studies to prove the advantages of strict patent protection, frequently appeared before Congressional committees about the need to secure greater patent protection abroad and managed to frame other countries' protection for IPRs as being an issue that concerned US trade policy.²⁴⁰ Despite the fact that the pharmaceutical industry received harsh critique for inflating domestic prices, the industry was very successful in making its own goal of strict international protection of intellectual property into a main goal for US international economic policy.²⁴¹

7.3.2 Governmental actions as a result of industrial pressure

The changes in international trade policy that the industry managed to bring about resulted in unilateral, regional and multilateral action from the US government. Unilaterally, the USTR put high pressure on individual developing countries to change their policies into strict patent laws

²³⁴ Page 2, El Said

²³⁵ Page 2, El Said

²³⁶ Page 1, El Said

²³⁷ Page 1085, Weissman

²³⁸ Page 1085, Weissman

²³⁹ Page 1085, Weissman

²⁴⁰ Page 1086, Weissman

²⁴¹ Page 1086, Weissman

similar to the US system; regionally IP protection became an important part of the NAFTA agreement and the US proclaimed that it would be included into all regional trade agreements that the US would be a party to; and finally and most importantly to this context; multilaterally the US government started to insist that IP protection should be included into the Uruguay round of multilateral trade negotiations.²⁴² By the time the GATT contracting parties met in Punta del Este, Uruguay to launch a new round of trade negotiations, US corporations and governments had managed to forge a broad, cross-sector alliance and developed a coordinated strategy to advocate a standardization of international IP protection.²⁴³

7.4 Why negotiations in the trade context?

In order to be able to analyze the impact and consequences of the TRIPS agreement, it is important to understand why the developed world wanted to push the issue of IPR protection on the multilateral arena in general and in the context of trade negotiations in particular.

7.4.1 Previous unilateral attempts for IPR protection

Unilaterally the US has a long tradition of trying to impose its own IP protections onto other countries. Authorized by Section 301 of the Trade Act of 1974, the USTR office started in the mid 1980's to create so called 'watch lists' with countries that did not fulfill their requirements for protection of US IPRs.²⁴⁴ Countries that made the list were informed that if their IP laws were not reformed into providing more protection, the US would impose trade tariffs on any of their exporting goods going into the US.²⁴⁵ Many countries were listed but the main targets were the developing countries that had been able to start up domestic pharmaceutical industries, such as India, Argentina, Brazil, Taiwan, and Thailand, whose competition could become a threat to US manufacturers. Especially Brazil and India were starting to become important forces when it came to organizing the developing countries for multilateral trade negotiations.²⁴⁶ The threat, or maybe even realization, of trade sanctions led to a change in policy in both Thailand and Taiwan. When it came to Brazil, the US had to realize the threat and imposed high tariffs on certain Brazilian imports; even then the Brazil only changed their IP laws marginally and it did so under wild and loud objections.²⁴⁷ India and Argentina were able to essentially resist the US pressure.

²⁴² Page 1086, Weissman

²⁴³ Page 32, Dutfield, Suthersanen

²⁴⁴ Page 1088, Weissman

²⁴⁵ Page 1088, Weissman

²⁴⁶ Page 1088, Weissman

²⁴⁷ Page 1090, Weissman

7.4.2 Transfer into the multilateral arena

It is not hard to comprehend why IP protection became a multilateral issue. Even though the US unilateral enforcement approaches through Section 301 had proven to be successful and provided the US an opportunity to set an example to the rest of the world by attacking selected foreign pharmaceutical regimes, it was still a slow and inefficient process to target countries one by one.²⁴⁸ It became more and more obvious that a more cohesive approach was necessary to create a harmonized and standardized protection of IP. However, why the developed world chose international trade negotiations under the GATT as the forum for the multilateral negotiations about IP protection is a slightly more complex issue.

7.4.3 WIPO or GATT?

IP was not an internationally unregulated issue before the TRIPS agreement emerged. The perhaps most commercially important agreements were, and still are, the Paris Convention on patents, and the Berne Convention on copyrights. Both are governed by WIPO, the specialized UN agent for IP established in 1967 and entered into force in 1974.²⁴⁹ WIPO administers 24 multilateral agreements and would have been a more obvious choice of international cooperation to govern a negotiation of an international agreement about IPR protection. WIPO did however have a big flaw according to the industrialized countries; it did not offer a strong enough enforcement mechanism.²⁵⁰ Even the original GATT agreement had an enforcement mechanism and it seemed likely that the WTO system would entail an even stronger. The fact that WIPO did not offer an enforcement mechanism made regulation of IPR protection under the GATT/WTO instead of WIPO very important also to US multinational pharmaceuticals and entertainment or software industries.²⁵¹ Unlike WIPO, the WTO system also offered the opportunity to gather all main IPRs in one single agreement which no one could opt out from if they wanted to become members in the WTO.²⁵² This meant that an international agreement under the WTO would globalize high standards of IPR's much faster than the WIPO administered conventions could.

8 The Uruguay round and IPRs – the great bargain

In September 1986, the round of multilateral trade negotiations that would turn out to be the most

²⁴⁸ Page 1092, Weissman

²⁴⁹ Page 29, Dutfield, Suthersanen

²⁵⁰ Page 29, Dutfield, Suthersanen

²⁵¹ Page 296 Ostry

²⁵² Page 32-33, Dutfield, Suthersanen

groundbreaking ever, was launched with the Ministerial Conference in Punta del Este, Uruguay.²⁵³ It was intended to have started earlier but the parties had difficulties in agreeing on what to include into the negotiation agenda. The agenda that was finally accepted basically covered all thinkable trade policy issues but one of the new areas to be negotiated that really stood out from the others was of course the regulation of IPRs.²⁵⁴

8.1 Continuation of the forum question

The inclusion of IPR standards into the negotiation about the GATT framework was far from obvious. Developing countries were originally a lot more in favor of continuing to use WIPO as the main agency for IPR regulation because it was more sympathetic to their demand and because they believed that they would be able to have a greater influence there.²⁵⁵ Many developed countries did however feel that it was a necessity to combine IP and trade. Japan and the US tried to use the upcoming Ministerial Conference in Punta del Este to place this issue on the agenda by submitting proposals to the Preparatory Committee that negotiations should cover all IPRs and their enforcement.²⁵⁶ This was quickly followed by proposals from Brazil and Argentina opposing the inclusion of IPRs into a new round of negotiations, but the issue was already on the table.²⁵⁷ The debate if GATT negotiations really were the best forum for regulation of IPRs continued for a long time into the Uruguay round. Even as late into the negotiation round as 1990, Chile suggested that any proposals of IP regulation that came up during the GATT negotiation rounds should be directed to WIPO.²⁵⁸ After the developed world initiated intense pressure, promised trade concessions in other areas, and assured that unilateral and bilateral pressure would seize, developing countries finally began to give into an incorporation of IPR protection into the multilateral trade system.²⁵⁹

8.2 Scope of the agreement

The original purpose of an agreement on IPRs was to prevent the trade in 'counterfeit goods'.²⁶⁰ The negotiations did however result in a lot broader and more comprehensive agreement with common international trade rules for IPRs that among other things established a minimum level of protection

²⁵³ Page 18, Understanding the WTO

²⁵⁴ Page 18, Understanding the WTO

²⁵⁵ Page 2, El Said, page 1093, Weissman

²⁵⁶ Page 10, Gervais

²⁵⁷ Page 10, Gervais – proposals in footnote 35-38

²⁵⁸ Page 1093, Weissman

²⁵⁹ Page 2, El Said

²⁶⁰ See the Punta del Este Declaration, page 33, Dutfield, Suthersanen

and thereby narrowed the gaps in global IPR protection.²⁶¹ How was this possible?

8.2.1 Developed world v developing world?

As negotiations proceeded it became obvious that many countries were set on an agreement for IPR protection that was a lot more comprehensive than originally intended.²⁶² By 1988 many developing countries showed great concern of a too comprehensive agreement on IPR protection because of a fear that such an agreement could seriously damage their access to technology transfer, and increase the costs of crucial agriculture and pharmaceutical products.²⁶³ In 1989 came the first suggestion to, by reference, include any agreement on IP that the negotiations might result in, into GATT. Almost immediately India tried to prevent this by stating that GATT rules should only apply in cases of trade distortion and requested that more favorable treatment for developing countries.²⁶⁴ That year the EU and the US both delivered very detailed drafts for an IPR agreement, which basically became the basis for the final TRIPS agreement.²⁶⁵

8.2.2 Drafting the agreement

There were basically two approaches to how the formation of an agreement should be done. The first one was built on the proposals from the EU and the US and entailed a single agreement that would cover acquisition and enforcement of all IPRs, a long with a reference making all GATT/upcoming WTO provisions applicable.²⁶⁶ The other approach represented the position of the developing countries that opposed a single agreement and instead suggested that the provisions should be separated into two different agreements, one for trade in counterfeit and one on “*availability, scope and use of IPRs*”.²⁶⁷ As the negotiations during the Uruguay round preceded the role and purpose of an IPR agreement evolved, so did the positions of the developing world. By 1989, the ambivalence and hostility from early days of negotiations started to evaporate and the developing countries became less resistant to the idea of one agreement.²⁶⁸

8.2.3 The great bargain

The broad trade negotiation agenda of the Uruguay round opened up opportunities for linkage-

²⁶¹ Page 39, Understanding the WTO

²⁶² Page 14, Gervais

²⁶³ Page 14, Gervais

²⁶⁴ Page 15, Gervais

²⁶⁵ Page 15, Gervais

²⁶⁶ Consolidated document W/76, page 18, Gervais

²⁶⁷ Page 18, Gervais

²⁶⁸ Page 593, Guzman, Pauwelyn

bargain diplomacy.²⁶⁹ This means that in the context of GATT, the industrialized countries were able to offer the skeptic developing world concessions, in for example textiles and agriculture, in exchange for their acceptance of internationally strong IPRs, which very likely helped pave the way for the attitude change.²⁷⁰ The change in attitude from the developing countries basically has two possible explanations: (1) either they were willing to accept TRIPS as a part of the WTO package because they believed that the other parts of the WTO would provide benefits that would outweigh any potential economic or social costs, that TRIPS might cause; or (2) they found both TRIPS and the WTO package as a whole unsatisfactory, but could not really see an alternative but to agree to it due to the temptation of market access in developed countries combined with the threat of higher trade barriers and sanctions if they did not agree to it.²⁷¹ Since the final results of the negotiations was a single agreement regulating all provisions concerning IPRs as well as a reference to all GATT provisions, it seems fair to say that the interests of the industrialized countries came were the ones that were protected the most.

8.3 Compliance exemptions

The negotiating parties did realize that it would be difficult for anyone to assure immediate compliance to the TRIPS agreement, and that developing countries would face even higher difficulties. Because of this developed countries were given a grace period of one year to adapt their domestic regulation to the provisions of TRIPS after it took effect in January of 1995, developing countries were given a transition period of five years and LDCs a period of eleven years, which later was extended by 10 additional years for pharmaceutical patents, thereby giving them until 2016 to fully comply.²⁷²

9 Important regulation in TRIPS

For the purpose of this thesis there are three main areas of importance of the TRIPS regulation: (1) obligations and principles that explain what minimum protection means for the different types of IPRS; (2) provisions to assure effective enforcement; and (3) exceptions to the obligations and other considerations that may be taken into account.

²⁶⁹ Page 33, Dutfield, Suthersanen

²⁷⁰ Page 33, Dutfield, Suthersanen

²⁷¹ Page 593, Guzman, Pauwelyn

²⁷² Page 43, Understanding the WTO

9.1 Obligations to protect

TRIPS for example defines what kind of IPRs that the member states are obliged to protect, what criteria that should be fulfilled in order to gain protection, for how long protection has to be offered, and how far the protection reaches. Since patent rights is the IPR of highest interest for this thesis, only the TRIPS obligations for this kind of IPR will be described in short. Patent rights have to be offered to protect both products and processes in a non-discriminatory way as long as the product or process is a novelty, an invention, and is useful/has industrial applicability.²⁷³ The protection has to last a minimum of 20 years.²⁷⁴

9.2 Enforcement

How members need to enforce IPRs is the most emphasized part of TRIPS. The agreement requires that all member states have procedures available that permit effective action against any act of infringement into a protected IPR.²⁷⁵ Both civil and criminal procedures need to be provided.²⁷⁶ All procedures in case of a conflict regarding an IPR must be fair and equitable and cannot be unnecessarily complicated, costly or time consuming.²⁷⁷ Judicial authorities in the member states must have the power to provide the different remedies to anyone whose right has been violated. Infringers can for example be required to pay damages that compensate the right holder for any injuries suffered due to the infringement.²⁷⁸

9.3 Exceptions and other considerations

TRIPS offer its member governments some alternatives when forming their own domestic IP regulation. In some cases they have the right to refuse protection of an IP, in other they may allow limited exceptions to the exclusiveness of an IPR and sometimes they may even ignore the exclusiveness altogether and permit a so called compulsory license to an IPR. Art 31 of TRIPS is basically a reminder to the contracting parties that they may adopt measures necessary to protect public health and nutrition, and promote the public interest in sectors of vital importance to their socio-economic and technological development, as long as such measures are consistent with the provisions of the agreement.²⁷⁹ It is in no way mandatory for the members to take measures like

²⁷³ Art 27.1 TRIPS

²⁷⁴ Art 33, TRIPS

²⁷⁵ Art 41.1 TRIPS

²⁷⁶ http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

²⁷⁷ Art 41.2 TRIPS

²⁷⁸ Art 45.1 TRIPS

²⁷⁹ Art 8.1 TRIPS

this, but the provision highlights the socioeconomic welfare implications that IPRs can have.²⁸⁰

9.3.1 Protection refusal

The IPR that may cause the most trouble for protection of public health is the patent right. As an attempt to soften these effects, TRIPS allow contracting parties to refuse applicants a patent right for three reasons that relate to public health. (1) if it is necessary to prevent commercial exploitation of an invention in order to properly protect human, animal or plant life²⁸¹; (2) if the patent application concerns a method of treatment of humans or animals²⁸²; and (3) certain plant and animal inventions in general.²⁸³

9.3.2 Limited exceptions – art 30

TRIPS also allow the members to provide limited exceptions to patents rights as long as the exceptions do not unreasonably conflict with normal exploitation of the patent or prejudice the legitimate interests of the patent holder.²⁸⁴ Under this provision members may give so called 'research exception' that allow researchers to use patented inventions for research intended to understand the invention more fully.²⁸⁵ This article also provide for what is generally called the Bolar provision or regulatory exception that refer to governmental permission to manufacturers of generic alternatives to use a patented invention. For example this can be used to obtain marketing approval for their own product based on the permission given to the patent holder and to be able to develop a generic alternative before the patent right expires so that the generic version can be released onto the market as soon as the patent protection has expired.²⁸⁶

9.3.3 Compulsory license – art 31

TRIPS art 31 does not use the term compulsory license, instead it calls the phenomena “*other use without authorization of the right holder*”, but the two descriptions are basically interchangeable. TRIPS does not specifically list what reasons contracting parties may have that could justify a compulsory license, but it does provide some non-exhaustive examples such as national emergencies, circumstances of extreme urgency and anti-competitive practices.²⁸⁷ Issuance of a

²⁸⁰ Page 34, Dutfield, Suthersanen

²⁸¹ Art 27.2, TRIPS

²⁸² Art 27.3a, TRIPS

²⁸³ Art 27.3b, TRIPS

²⁸⁴ Art 30.1

²⁸⁵ Page 3, TRIPS and pharmaceutical patents

²⁸⁶ Page 3, TRIPS and pharmaceutical patents. The article itself does not specifically state that this is allowed, but this has been found to be in compliance with TRIPS in the WTO dispute ruling *Canada v Patent Protection for Pharmaceutical Products*.

²⁸⁷ Art 31b TRIPS

compulsory license has to be made on a case by case basis and the intended user normally has to have tried to first obtain a voluntary license from the right holder, but this requirement can be waived in case of a national emergency, situations of extreme urgency or cases of public and non-commercial use.²⁸⁸ In any case, the right holder has to be paid adequate remuneration for the unauthorized use of the IPR, which should consider the economic value of the authorization.²⁸⁹

9.4 Parallel importing

Another feature that can have significant impact on the exclusiveness of a right holder is the fact that TRIPS does not forbid members to adopt any laws on IP that allows parallel import that leads to an exhaustion of rights.²⁹⁰ This means that members are allowed to have IP laws that permit importation of IP protected goods that were legally placed on the market in a foreign country, for example medicines that are cheaper in another country than in their own, and thereby undercutting the price of the same patented drug on the domestic market.²⁹¹

10. The potential conflict between IPR protection and development of global health

A 2002 report from CIPR²⁹² expressed serious doubt that current international IP regulation could be in the interest of the poor and makes a strong argument that the ‘one-size fits all’ approach to regulation is not suitable when the required levels of protection are as high as today, with the potential of becoming even higher.²⁹³ CIPR argue that since both scientific and technological capacities vary along with social and economic structures of nations, the optimal IP protection should also vary between nations.²⁹⁴ Considering this, a multilateral harmonization of IPR’s could be harmful to global health development.

10.1 Pharmaceutical patents

The most infected debate about IP protection and its potential inhibition for global health lies in pharmaceutical patents. An illuminating example of this conflict can be found in the millions of

²⁸⁸ Art 31a, b TRIPS

²⁸⁹ Art 31h TRIPS

²⁹⁰ Art 6, TRIPS

²⁹¹ Page 34-35, Dutfield, Suthersanen<

²⁹² UK Commission on IPRs – government sponsored commission with the mandate to look into how IPRs could work better for developing countries and poor people and to provide balanced and evidence based recommendations and suggestions, page 27 Dutfield

²⁹³ Page 276, Dutfield

²⁹⁴ Page 276, Dutfield

people who die or suffer from diseases where medication actually exist that could help or even cure their conditions, but the people suffering for some reason do not have access to them.²⁹⁵ The most obvious explanation as to why people do not have access to these medications is lack of resources or simply put – poverty. Individuals in developing countries lack the finances necessary to pay for the medicine that they need and their governments generally lack the resources to build up the infrastructure that is needed to manufacture and distribute the medicines. An obvious approach to the reach improvement to this global health problem would be to try to keep prices on medication to a minimum; this is where the conflict with IP protection begins.

10.1.1 Patent protection and price escalation

Patents and other IPRs are meant to stimulate investment in R&D as well as promote a widespread commercialization of new technologies that could be useful to society.²⁹⁶ The patent right assures return on the R&D investment by providing the innovator with a temporary market exclusivity.²⁹⁷ Since pharmaceuticals have very high R&D costs relative to all other production costs, the patent right gains even higher importance, because if drug manufacturers are not provided with a period of limited competition, the possibility of regaining their investments diminish and they do not have an equally strong incentive to develop new medications. However, due to the restriction in competition, patent protection is very likely to cause higher prices on pharmaceutical products than if they were subject to free competition on the market.²⁹⁸ Exactly how much a patent protection impacts the price of a pharmaceutical product is hard to say, it is not as easy as to say that pharmaceuticals are always more expensive with a patent right and cheaper without, but if the patent restrict competition, it will probably raise the prices.²⁹⁹ There are several documented situations where excessive pricing due to patent protection have been the cause to why a patient has not been able to access life-saving drugs.³⁰⁰ At the same time it has been argued that patent protection does not have a retroactive effect and thereby cannot affect the prices on products that already are available on the market, and that pharmaceuticals generally exist in a regulatory environment that determines prices, so that stricter patent protection therefore cannot cause higher drug prices.³⁰¹ Since one way to improve global health is to increase access and lower prices, the big conflict between global health and IPR protection comes down to the interest of new innovation,

²⁹⁵ Page 312, Dutfield

²⁹⁶ Page 947, Trouiller, Torreele, Olliario, White, Foster, Wirth, Pécoul

²⁹⁷ Page 947, Trouiller, Torreele, Olliario, White, Foster, Wirth, Pécoul

²⁹⁸ Page 314, Dutfield, Suthersanen

²⁹⁹ Page 314, Dutfield, Suthersanen

³⁰⁰ Page 947-948, Trouiller, Torreele, Olliario, White, Foster, Wirth, Pécoul

³⁰¹ Page 528, Bettcher, Yach, Guindon

versus the interest to avoid cost escalation.³⁰²

10.1.2 Higher prices than R&D costs justify?

The pharmaceutical industry normally defends itself against any critique concerning high prices with a reference to their high R&D costs. It is however important to remember that a significant part of the R&D funding come from governmental sources.³⁰³ Most new scientific discoveries are made by public institutes, such as universities, who then license the rights to private companies for development and exploitation.³⁰⁴ Additionally, pharmaceutical companies often include a number of aspects into their calculated R&D costs that might inflate the numbers significantly, such as running costs, overheads, spill-over's and inefficiency.³⁰⁵ Moreover, the pharmaceutical industry has a long standing reputation of being among the most profitable industry sectors in the world.³⁰⁶ All of which could be argued against their statement that their high prices are justified.

10.1.3 Poor patent quality

The number of patents that are issued for genuinely new inventions is quite low; most patent applications are minor developments where the 'innovation' relies on previous innovations and generally available techniques.³⁰⁷ This leads to poor patent quality and a significant increase in patent coverage, which creates barriers for competitors that the 'new' technique might not really justify.³⁰⁸ Some even argue that large companies have learned how to exploit soft patent standards and less than thorough patent application examinations in order to gain as many patents as possible and thereby delay potential generic competition.³⁰⁹ This problem deserves some special attention in developing countries that do not have well developed competition laws to fight this type of behavior. Especially since it is quite common that the agency or authority responsible for granting patents in many developing countries do not really perform a substantive examination before a patent is granted, making the application more of a registration.³¹⁰ Combined with international regulation that require tough enforcement of patent rights, this unsophisticated way of granting patents causes a risk of asymmetry in the system, where it is easy to be granted a patent right but

³⁰² Page 527, Bettcher, Yach, Guindon

³⁰³ Page 527, Bettcher, Yach, Guindon

³⁰⁴ Page 784, Correa

³⁰⁵ Page 947, Trouiller, Torreele, Olliaro, White, Foster, Wirth, Pécoul

³⁰⁶ Page 947, Trouiller, Torreele, Olliaro, White, Foster, Wirth, Pécoul

³⁰⁷ Page 785, Correa

³⁰⁸ Page 785-786, Correa

³⁰⁹ Page 785, Correa

³¹⁰ Page 789, Garrison

very hard to challenge it.³¹¹ Considering this, developing countries could partly fight the poor access to medication through a re-evaluation and development of the process of patent examination, and approval of an application.³¹²

10.1.4 Research priorities

Pharmaceutical companies could also be criticized for their research priorities; not enough attention is aimed at life-saving drugs with low profit incentives. The general response from the pharmaceutical industry to this critique is that the patent-protected monopoly pricing is necessary to promote research on breakthrough drugs of value to all.³¹³ There is however overwhelming evidence that there generally is not enough focus on the most needed medication, even despite the patent incentive. Very little resources are spent on research for drugs that treat diseases that affect the poor in disproportional ways.³¹⁴ Development of medicines for tropical diseases basically stand still and only receive a fraction of funding compared to research for treatment of lifestyle diseases such as obesity and impotence.³¹⁵ It is however hard to say if patents are the cause of this development. With a free market world order the companies will pursue profit for their shareholder over global health and research is bound to focus on areas where there is money to be made.³¹⁶ One could argue that if patent rights were created to serve the public interest, more should be done to encourage the pharmaceutical companies to do research in areas where the public need it the most.³¹⁷

10.2 IPRs only a public good in industrialized countries?

Some argue that patent protection can be a public good, but only for industrialized nations and huge multinationals.³¹⁸ It is highly questioned if IPRs really create an incentive for pharmaceutical industries to develop the drugs that the developing world really needs since it is only the cheaper drugs that have any chance of being used on a scale large enough to make a profit.³¹⁹ It is however possible that the mere development of new drugs can lead to enhanced welfare through increase in

³¹¹ Page 789, Garrison

³¹² Page 786, Correa

³¹³ Page 257, Bloche, Jungman

³¹⁴ For example – 95% of all cases of tuberculosis occur in the developing world and no new drugs for this disease has been developed since 1967. Page 313, Dutfield, Suthersanen

³¹⁵ Page 946, Trouiller, Torreele, Olliaro, White, Foster, Wirth, Pécoul

³¹⁶ Page 313, Dutfield, Suthersanen, Page 946, Trouiller, Torreele, Olliaro, White, Foster, Wirth, Pécoul

³¹⁷ Page 314, Dutfield, Suthersanen

³¹⁸ Page 528, Bettcher, Yach, Guindon

³¹⁹ Page 527, Bettcher, Yach, Guindon

consumer surplus.³²⁰ In order to improve access to drugs in poor countries, it is probably not enough to rely on merely the pharmaceutical companies and the R&D incentive that patent rights provide. The industry itself is of course a necessary prerequisite for drug development, but if the goal is development of cheap drugs in order to fight global health problems, it is necessary to invest money in public health programs, for example through international aid and different collaborations between the private and public sector with focus on CSR.³²¹

³²⁰ Page 528, Bettcher, Yach, Guindon

³²¹ Page 529, Bettcher, Yach, Guindon

PART IV

11 The impact of TRIPS on the developing world

Aware of the inherent conflict between protection of IPRs and the promotion of global health, it is time to analyze what impact the most comprehensive international agreement on IPRs has had on global health in general and in the developing world in particular. Does the classic IP rationale work in developing countries? Does stronger protection for IPR inhibit development and public health, or are IPRs a necessary component to innovation stimuli and thereby increased economic development and general wealth? Representatives from developing countries keep expressing concern that TRIPS causes increased prices of medical technologies, pharmaceuticals and educational materials in developing countries and blocks the highly essential transfer of technology.³²²

11.1 A weaker voice in international IP regulation?

Some argue that developing countries had more influence in multilateral cooperation on IPRs before TRIPS and its minimum standards.³²³ Developing countries used to have the possibility to opt out or make reservations to international IP regulation if they believed that the agreement would hurt their special needs as a developing country, but when TRIPS included IP regulations into the WTO system and the 'take it or leave it' approach of the single undertaking, this possibility disappeared.³²⁴ Before TRIPS, developing countries only had to decide if they wanted to participate in multilateral IP regulation, but after TRIPS the strategy has to be to find the most efficient and appropriate way to participate in order to defend their interests.³²⁵

11.2 Patent rights and pharmaceuticals

On the surface it appears that TRIPS require the member states to offer equal patent protection for pharmaceutical products and other technological products. However, some argue that pharmaceutical products are not 'ordinary consumer products' due to their life saving potential.³²⁶ Patients that want to be cured have to buy the drugs, patent protected or not. Therefore, the major public policy issue regarding TRIPS is developing countries' right to develop generic, low-price

³²² Page 37, Dutfield, Suthersanen , page

³²³ Page 20, Dutfield, Suthersanen

³²⁴ Page 20, Dutfield, Suthersanen

³²⁵ Page 20, Dutfield, Suthersanen

³²⁶ Page 290, Velásquez, Boulet

pharmaceuticals when necessary to prevent a public health crisis. It is obvious that patent right was the IPR where industrialized and developing countries were the most divided prior to TRIPS.³²⁷ Critics generally opposed patents for pharmaceutical products more than the pharmaceutical process, for example countries such as India that previously only provided patent protection for pharmaceutical processes, claim that that strong patent system for products establishes a monopoly that causes price escalation.³²⁸

11.2.1 TRIPS and price escalation

The available economic evidence on what impact patent rights have had on pharmaceutical prices is highly polarized, but the risk of higher prices is daunting.³²⁹ For example, an Argentinean study from 2000 indicated that prices would increase with 270% if product patents were to be introduced.³³⁰ Developing countries are already disadvantaged. Even though the prices of a drug may be nominally cheaper in a developing country compared to a developed country, the income rate and purchasing power in a developing country is generally much lower, which makes the actual cost for the domestic population is much higher in developing countries compared to the developed world.³³¹ Furthermore, one should take into consideration that a consumer usually does not even have the possibility to decide what pharmaceutical product to buy; the decision lies rather with the physician that prescribes the drug than with the consumer.³³²

11.3 Corporate environment – lack of generic competition

Once a patent right expires, generic competitors normally enter the market in numbers to raise the competition. In developed countries, such as the US, generic producers generally enter the market for a certain drug with much lower prices than the existing brand competitors and the prices normally drop even further when more and more generic competitors enter the market.³³³ TRIPS is criticized for making it more difficult for generic drug manufacturers to compete with the patent protected drugs. Once a pharmaceutical company is granted a patent in a poor developing country, which often lack an adequate patent process, TRIPS provides the pharmaceutical company with the patent protection and strong enforcement mechanisms that generics have a really hard time to

³²⁷ Page 289, Velásquez, Boulet

³²⁸ Page 527, Bettcher, Yach, Guindon

³²⁹ Page 527, Bettcher, Yach, Guindon

³³⁰ Page 527, Bettcher, Yach, Guindon

³³¹ Page 1125, Weissman

³³² Page 291, Velásquez, Boulet

³³³ Page 1124. Weissman

compete with.³³⁴ This could cause a situation where big multinational pharmaceutical companies that control strong and important IPRs, eventually build up the strength to overpower minor countries. Since companies are not parties to the WTO system they cannot be in breach of the agreements and thereby not held accountable under the dispute settlement system. So far the WTO system does not offer a solution to this problem.

11.3.1 Other concerns with generics and patented products

Even after the patent right has expired patent holders have the advantage of name recognition, consumer confidence and relations with the medical staff that prescribe pharmaceuticals.³³⁵ This means that a patent holder may be able to sell their product at a higher price than justifiable to a large segment of the market even after the patent is expired, unless a country does not act to make the market more accessible to generic competitors. On the contrary it could be argued that competition desired to create lower price, can be created between patented products that are substitutable to one another, but it is clear that even if this might create some competition, it does not create the same price fall as when a generic enters the market and consequently does not have the same pro-competitive effects as the existence of generics does.³³⁶ From a social point of view, substitutable patented drugs are also an unnecessary use of resources, since the money invested in the R&D for a substitutable drug could have been used for other more socially beneficial causes.³³⁷

11.4 Potential benefits from a weaker IP regulation than TRIPS

Limited patent rights would be beneficial to two specific groups in the developing world: consumers in need of pharmaceuticals and domestic generic drug manufacturers.³³⁸ Consumers would benefit from lower prices and increased access, and drug manufacturers by being able to compete on a free market without the limitation of exclusive rights.

11.4.1 Lower prices

Weak patent regimes and increased competition can decrease prices on pharmaceuticals, thus create a more affordable health care. If generic production is encouraged, either through lack of limited patent protection, or through compulsory licenses, competition will rise and prices will fall.³³⁹ Research has shown that prices for pharmaceutical drugs vary widely from one country to another

³³⁴ Page 257, Bloche, Jungman

³³⁵ Page 1125, Weissman

³³⁶ Page 1126, Weissman

³³⁷ Page 1126, Weissman

³³⁸ Page 1124, Weissman

³³⁹ Page 1124, Weissman

and that “*direct price controls, bulk purchasing, promotion of the use of generics and abolishing patents*” all have the effect of lowering prices.³⁴⁰ A huge factor to the price differences is the existence of, or lack of, a national drug policy.³⁴¹ If developing countries can manage to form effective national drug policies, they will be a lot closer to the goal of more affordable health care. Illustrative examples from the effects of measures like this can be found in Canada, India and Argentina. Canada used a compulsory licensing system in 1983 which had tremendous effects on pharmaceutical prices.³⁴² The average price of compulsorily-licensed drugs sold in Canada was approximately half the price of the US price for the same drugs. India adopted price controls and only acknowledged process patents, which turned Indian drug prices from among the highest in the world to among the lowest, while Argentina simply did not offer patents, and drove down the prices considerably.³⁴³ It is hard to argue with the fact that generic producers creates lower prices, not even the industry denies it, but high prices are still defended with the argument that pharmaceutical drug manufacturers have to regain their investments.

11.6 Compulsory licenses – not enough protection?

Art 31 of TRIPS allow for unauthorized use of existing patents by government or governmentally approved third parties in certain circumstances and is a highly controversial provision. Its virtues and effects have been argued for a long time.

11.6.1 Compulsory licenses and the Uruguay round

During the Uruguay round, the questions of compulsory licenses was central and stirred up emotion. Developing countries on the rise, such as Brazil and Korea, strongly argued in favor of compulsory licenses, while most of the developed world try to narrow down this exception as much as possible, for example by limiting a compulsory license to the domestic market.³⁴⁴ During a meeting in 1990, a group of developing countries, with Brazil and India as leaders, made a strong move for the inclusion of compulsory licenses as well as exceptions to patentability in protection of public interest, health or nutrition.³⁴⁵ This organized pressure from the developing world forced the rest of the world to, at least partially, cave in to their demands.

³⁴⁰ Page 1124, Weissman, see the research by Schut and Van Bergeijk

³⁴¹ Page 1124, Weissman, see the research by Schut and Van Bergeijk

³⁴² Page 1125, Weissman

³⁴³ Page 1125, Weissman

³⁴⁴ Page 15, Gervais

³⁴⁵ Page 20, Gervais

11.6.2 Potential benefits of compulsory licenses

Compulsory licenses have proven to be a very useful way of enhancing access to drugs that are crucial when fighting global health challenges, but normally are restricted due to patent protection.³⁴⁶ Compulsory licenses normally open up competition, which lowers prices, but it is in no way a universal remedy.³⁴⁷ Certain features to the provision limit its potential significantly. Normally a license applicant first has to negotiate with the patent holder for a voluntary license, which could be very time consuming. Additionally, once a manufacturer has been granted a compulsory license and gained access to the patent description, it might not provide enough information for them to be able to copy the drug, or a country might not have chemists qualified enough to copy the patent.³⁴⁸ It does however seem as if the mere threat of a potential compulsory licenses can enhance countries' bargaining positions.

11.7 Moral arguments – a hypocritical developed world?

When issuing a compulsory license, the WTO member in question set aside the commercial interests of the company that own the patent, in favor of some kind of social benefit for its population. Some argue that governments have a human right obligation to put the lives of their citizens before the commercial interest of foreign companies, and that this is reason enough to permit compulsory licenses.³⁴⁹ The developed world in general, and the US in particular, is extremely critical to developing countries issuing compulsory licenses for a certain drug during a public health crisis.³⁵⁰ Sometimes this point of view has been criticized for being hypocritical and that they would act the exact same way if the tables were turned.

11.7.1 The Cipro case – a hypocritical example?

An example of hypocrisy from the developed world can be found in the so called Cipro case concerning the US and the anthrax threat they were subject to in 2001.³⁵¹ Faced with an imminent threat to its population, the US government decided to stock as much as possible of the drug that was considered to be the most efficient one against anthrax, which happened to be a drug called Cipro, manufactured by the pharmaceutical company Bayer's.³⁵² In order to accomplish this goal governmental officials threatened Bayer and said that if they did not reduce the price on Cipro with

³⁴⁶ Page 319, Dutfield, Suthersanen

³⁴⁷ Page 319, Dutfield, Suthersanen

³⁴⁸ Page 319, Dutfield, Suthersanen

³⁴⁹ Page 315, Dutfield, Suthersanen

³⁵⁰ Page 315, Dutfield, Suthersanen

³⁵¹ Page 315, Dutfield, Suthersanen

³⁵² Page 315, Dutfield, Suthersanen

at least 50%, the government would simply take the drug from its source. Government officials also threatened to ask Congress to pass a bill that would remove any obligations the government normally would have to compensate Bayer for the fact that the government would simply ignore their patent right.³⁵³ This strategy was very successful and the US government managed to negotiate a really good deal.³⁵⁴ Despite their own actions when faced with this type of public health threats, they still try to pressure developing countries not to issue compulsory licenses to generic drug producers even though several public health threats could be partly neutralized.

11.8 Is development really possible with strong IPRs?

Can the developed world really demand strong IPRs from the developing world when they themselves build up their industry through imitation and weak IPRs?

11.8.1 IP regulation and economic development

Historically national IPRs have not been especially strong until a country reaches a certain level of economic development, but then they are strengthened. Current industrialized countries have generally had weak patent protection in key parts of their economy in order to gain an advantage when building up industrial and technological capacities.³⁵⁵ Basically all industrialized countries built up their capacity through imitation.³⁵⁶ Globalization and the spread of IPRs have created a whole new economic and social arena, which has a high impact on the goal of equitable access to health and drugs.³⁵⁷

11.8.2 Domestic industries

Research suggests that domestic pharmaceutical industries can provide benefits to its nation that is not possible with multinationals simply because their objectives tend to coincide.³⁵⁸ Domestic companies are generally more likely to: promote development of local technology infrastructure; be in favor of generics; and adjust their technology to local needs, simply because they want to avoid dependence to foreign companies for their technology supply.³⁵⁹ Limited patent rights are a good way of creating a domestic pharmaceutical industry, but it does not provide a universal solution.³⁶⁰

³⁵³ Page 315, Dutfield, Suthersanen

³⁵⁴ Page 315, Dutfield, Suthersanen

³⁵⁵ Page 289, Velásquez, Boulet

³⁵⁶ Page 1126, Weissman

³⁵⁷ Page 291, Velásquez, Boulet

³⁵⁸ See study of Turkey by Kirim, page 1126, Weissman

³⁵⁹ See study of Turkey by Kirim, page 1126, Weissman

³⁶⁰ Page 1126, Weissman

Some studies even suggest that domestic manufacturers in developing countries eventually turn to the same type of anticompetitive behavior as many of the multinational pharmaceutical companies.³⁶¹ Velásquez suggests that every developing country should incorporate a strategy on how to deal with globalization into a national pharmaceutical policy within their national health policy.³⁶²

12 Attempts to comply TRIPS to with international public health obligations

The WHO intended TRIPS to consider more than just IPR regulation, social consideration was also to be possible. Criticism that this attempt was not enough, has urged the WHO to adjust the provisions of TRIPS into a more health-friendly agreement more in compliance with existing international obligations for global health protection.

12.1 Original provisions and exceptions for global health protection

According to the WTO, the obligation in TRIPS to provide minimum IPRs is balanced out by provisions that allow for other considerations and a wider perspective.³⁶³ TRIPS assume that inventions and creativity should contribute to social and technological benefits, as well as an opportunity for governments to be flexible with the regulation when necessary to achieve social goals.³⁶⁴ The WTO also highlights that the TRIPS way to regulate IPRs can in fact promote social goals through the requirements of disclosure in exchange for protection, and the limited time period of protection.³⁶⁵ TRIPS offer the possibility of exceptions to exclusive rights and the institute of compulsory licenses specifically for health protection.³⁶⁶ Despite this original attempt to balance out the agreement, countries still found themselves stuck between the pressure to honor international IPRs, and their wishes to uphold strategies on how to fight public health problems.

12.1 1 Brazil and access to HIV/Aids drugs - Illustrative example of a conflict between TRIPS and the protection of public health

Since 1996, Brazil has had a governmental policy to guarantee free and universal access to ARV

³⁶¹ See study of Turkey by Kirim, page 1126, Weissman

³⁶² Page 291, Velásquez, Boulet

³⁶³ Page 1-2, TRIPS and pharmaceutical patents

³⁶⁴ Page 1-2, TRIPS and pharmaceutical patents

³⁶⁵ Page 1-2, TRIPS and pharmaceutical patents

³⁶⁶ See section 9.3 supra

treatment for HIV/Aids.³⁶⁷ Brazil has a quite developed pharmaceutical industry and to reduce costs of the drug distribution, it has favored domestically produced drugs but high demand has forced some import.³⁶⁸ The policy has been very successful in reducing the number of deaths, hospital admissions and treatment costs but its continuation was threatened by the high costs of imports from international pharmaceutical companies.³⁶⁹ Even though Brazil has its own domestic provisions about compulsory licenses, it is a member of the WTO and has to follow the provisions of TRIPS and is thereby limited its regulation on compulsory licenses. However, the mere threat to break patents has proved to be a successful tool in negotiations with international pharmaceutical companies. In February 2001, Brazil made public that it intended to break patents on ARV drugs produced by the pharmaceutical companies Merck and Roche if they did not lower their prices.³⁷⁰ Faced with this threat Merck lowered its prices by 60%, but offers from Roche were considered too low.³⁷¹ The US answered with a WTO panel request to judge the compatibility of Brazilian patent law with TRIPS. However, in April 2001, the UNHRC approved a resolution that established access to medical drugs during pandemics such as HIV/Aids, as a basic human right.³⁷² After that the US withdraw its panel request, Roche lowered the prices on their drugs, and Brazil abandoned any plans to break the patent.³⁷³ This conflict likely contributed to an increased realization in developed countries that enormous challenges to global health, such as the AIDS pandemic, actually can be a threat to social and political stability and thereby national security, and thereby a new concern for public health issues. Shortly after the conflict in Brazil, the WTO took steps to try to prevent this from happening again.

12.2 TRIPS and the Doha agenda

At a Ministerial Conference in Doha, Qatar in 2001, the WTO members decided to launch a new round of trade negotiations, and to try to improve implementation of the already existing agreements; this entire plan is called the Doha Development Agenda.³⁷⁴ TRIPS was a hot topic for the agenda and the idea was to address three different concerns with the controversial IPR agreement: (1) how to deal with ‘non-violation complaints’ - disputes due to a lost benefits even when no one has violated the agreement; (2) technology transfer to LDCs; and (3) TRIPS and its

³⁶⁷ Page 1862, Galvao

³⁶⁸ Page 1863, Galvao

³⁶⁹ Page 1862, Galvao

³⁷⁰ Page 1864, Galvao

³⁷¹ Page 1864, Galvao

³⁷² UN resolution 2001/33

³⁷³ Page 1864, Galvao

³⁷⁴ Page 77, Understanding the WTO

impact on public health.³⁷⁵ A separate declaration on how to treat TRIPS in the context of public health was a common goal for the member states at the 2001 conference, but they were in no way united on what this declaration should entail.³⁷⁶ The developing countries were relatively united in trying to clarify a more limited scope of IP protection for pharmaceuticals, while developed countries advocated for an interpretation that in no way would undermine the IP protection that TRIPS provides.³⁷⁷ The conference eventually resulted in three statements that in some way concerned IP: (1) the Ministerial Declaration to launch a new round, more commonly called the Doha Declaration; (2) a decision about implementation issues with special attention to LDC countries and their special needs³⁷⁸; and finally the most significant one in this context, a declaration on the TRIPS Agreement and Public Health.³⁷⁹ The Doha round is still going on, thereby surfacing as the longest WTO round of negotiations so far, even longer than the Uruguay round. The WTO will probably face enormous difficulty trying to realize the DDA.

12.2.1 The Doha Declaration

This declaration is a ministerial interpretation of the TRIPS agreement with the main message that it is important to implement and interpret TRIPS in a way that supports public health, specifically by promoting access to pharmaceuticals, as well as encouraging new medicines.³⁸⁰ With consideration to the special needs of LDCs, the Doha declaration also extends the exemption on compliance regarding pharmaceutical patents for LDCs until January 1, 2016.³⁸¹

12.2.2 Declaration on TRIPS and Public Health

This specific declaration on TRIPS and Public Health emphasizes that TRIPS should not prevent WTO members from taking measures to protect public health, and that this should be a guiding principle for TRIPS interpretation.³⁸² The declaration also affirms members' rights to use the agreement flexibly and clarifies how the flexible alternatives, such as compulsory licenses and parallel importing, can be used.³⁸³ Especially important is the fifth paragraph of the declaration that establishes that members have the freedom to determine what qualifies as a "*national emergency or*

³⁷⁵ Page 77, 82, Understanding the WTO

³⁷⁶ Page 43, Gervais

³⁷⁷ Sykes

³⁷⁸ This decision reaffirmed the mandatory nature of art 66.2 TRIPS that states that developed members shall "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDCs in order to enable them to create a sound and viable technological base". Page 37-38, Dutfield, Suthersanen

³⁷⁹ Page 37-38, Dutfield, Suthersanen

³⁸⁰ Page 82, Understanding the WTO

³⁸¹ Page 48, Gervais

³⁸² Page 52, Gervais

³⁸³ Page 82, Understanding the WTO

other circumstances of extreme urgency”, when issuing compulsory licenses.³⁸⁴ The declaration provides some guidance and exemplifies public health crises “*relating to HIV/Aids, tuberculosis, malaria and other epidemics, as an example of a national emergency or other circumstances of extreme urgency*”.³⁸⁵ Members’ freedom also extends to the right to establish individual domestic provisions for exhaustion of IPRs. This means that if a national law says that an IPR is exhausted with the first legal sale anywhere in the world, the product can then be legally exported to a country that normally has a higher price on that product.³⁸⁶ Consequently, it is obvious that pressure from the developing world has pushed the WTO to reinterpret TRIPS into a more health friendly agreement than before. It does not however go so far as recognizing health as a human right, the Doha declaration in fact explicitly declines to do so.³⁸⁷

12.2.2.1 Legal significance or political strategy?

The formal legal significance of the Doha declaration, compared to the rest of the WTO agreements is relatively uncertain. The WTO members have agreed to officially amend the Declaration into the TRIPS agreement so that the declaration itself would receive the same legal standard, and be relied upon in any potential DSU conflict, but this decision is yet to be ratified of a sufficient number of members.³⁸⁸ The question is if the declaration nevertheless could be a legally binding document. The Marrakesh agreement provides information on what is to be considered legally binding under the WTO system. Since the ministerial conference is the highest decision making authority in the WTO, a ministerial decision is an obvious example of a legal binding document.³⁸⁹ Declarations are not explicitly included as a ministerial decision, but neither are they excluded, so the Doha Declaration could very well be seen as a ministerial decision.³⁹⁰ The fact that some documents during the negotiation rounds, contrary to the declaration on TRIPS and public health, actually were named decisions, thereby clearly indicating a binding intention, contradicts the theory that declarations are to be considered binding ministerial decisions.³⁹¹ On the other hand, when a declaration is taken under consensus, like this one was, there is more reason to believe that it could

³⁸⁴ Page 320, Dutfield, Suthersanen

³⁸⁵ Page 320, Dutfield, Suthersanen

³⁸⁶ Page 320, Dutfield, Suthersanen

³⁸⁷ Footnote 130, Bloche, Jungman

³⁸⁸ A formal change to the agreement requires that 2/3s of all members ratify the amendment. So far 28 countries plus the EU has ratified it, which is not sufficient with 153 members.

http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

³⁸⁹ Art IV:1, Marrakesh Agreement

³⁹⁰ Page 208, Charnowitz

³⁹¹ Page 208, Charnowitz

be legally binding and not only of political significance.³⁹² The only obvious conclusion to draw from this is that the legal standing of the Declaration is uncertain.

12.2.2.2 Interpretive weight

Even if the declaration is not seen as an official and binding WTO decision, it could have important weight as an interpretive document relevant to a dispute settlement.³⁹³ The declaration could be considered as a “*subsequent agreement regarding interpretation*” or subsequent practice, according to art 31.3 of the Vienna Convention on the Law of Treaties, which is the primary tool for international agreement interpretation. Regardless if the declaration is classified as legally binding or merely a strategic political stand point; it likely has so much weight and influence that there will not be any complaints within the WTO dispute settlement system on any issues in the declaration.³⁹⁴

12.2.3 2003 WTO decision/waiver and 2005 amendment

Even after the Doha declaration, it was still very hard for the LDCs to access drugs, simply because they did not have the capability to manufacture themselves, and because TRIPS, article 31 only allow compulsory licenses “*predominantly for the supply of the domestic market*”. The Declaration on TRIPS and Public health did not solve this problem. It did recognize it, stating in paragraph 6 that “*WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement*” and instructed the TRIPS council to “*find an expeditious solution to the problem*”.³⁹⁵ These instructions resulted in the 2003 decision by the WTO members to increase the possibilities to import generics that had been manufactured under a compulsory license, for countries that could not manufacture themselves. The decision waived three provisions in the TRIPS agreement: (1) article 31 f , which means that any contracting party now has the right to export generics manufactured under a compulsory license in order to meet the needs of an importing country; (2) the obligation of remuneration was also waived for the importing side in order to avoid double payment; the exporting side still has to pay remuneration; (3) export constraints were waived for developing countries and LDCs so that they can export within regional trade agreements.³⁹⁶ All LDC countries are free to use these waivers at any time and upon notification to the TRIPS council, but all eligible importing members are also welcome to take advantage of these provisions.³⁹⁷ The remuneration

³⁹² Page 208, Charnowitz

³⁹³ Page 208, Charnowitz

³⁹⁴ Page 219, Carmen Otero

³⁹⁵ Page 320-321, Dutfield, Suthersanen

³⁹⁶ 2003 WTO decision/waiver – WT/L/540 and Corr.1

³⁹⁷ Paragraph 2, page 321, Dutfield, Suthersanen

that the exporter is now solely responsible for must take into account the “*economic value to the importing member of the use that has been authorized in the exporting member.*”³⁹⁸ When the council decision of 2003 implemented these waivers, they were intended to be interim with the goal to amend them to TRIPS. A formal decision to amend the changes to the agreement was reached in December 2005³⁹⁹, but is yet to enter into force. The decision needs to be formally accepted by 2/3 members to enter into force and currently there are 28 countries plus the EU that have formally accepted it.⁴⁰⁰ The deadline to accept the decision was originally 1 Dec, 2007, but after two extensions, it is now 31 Dec, 2011.⁴⁰¹

12.3 Effects of the decisions following the Declaration

The most significant impact that the 2003 waiver and 2005 decision has had on the promotion of global health, is that it enables countries to export essential drugs and medicines manufactured under a compulsory license to a country in desperate need for the drugs, but without necessary manufacturing capacities. The ratification rate has been very low so far and there are not many examples of countries that have taken advantage of this opportunity. One probable cause to this is that there really is no good way of prevent re-export of these cheaper compulsory license manufactured drugs since TRIPS allow parallel import and rely on the principle of exhaustion.⁴⁰² This means that drugs exported to a LDC in crisis, can be legally re-exported to any country and sold just as cheap there and thereby undermining the patented drug in that country. It is likely that the problem of re-export is a major cause to why so few member states have accepted the decision so far. Another reason could be that developing countries know that many powerful developed countries do not encourage usage of the provisions and therefore resist the opportunities due to fear of retaliation. Further cause could be that despite attempts to simplify, the process is still quite complex and countries that need generic drugs the most had a hard time with the administrative process. Clearly this is not a completely uncomplicated process. The 2005 amendment is not a perfect attempt to improve access to lifesaving drugs in the most remote parts of the world, but never the less a genuine attempt and a step in the right direction. Unfortunately recent FTA's have a tendency to include chapters regulating IPRs in a different way than the TRIPS amendment, which seem to reflect a deliberate attempt to undermine anything that the international community can

³⁹⁸ Paragraph 3, page 322 Dutfield, Suthersanen

³⁹⁹ Decision WT/L/641

⁴⁰⁰ http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

⁴⁰¹ http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

⁴⁰² See paragraph 9.3.4 on parallel importing

achieve multilaterally.⁴⁰³ The next chapter will examine how this is possible, why it is done, and what potential consequences this could have.

13 Recent developments; a TRIPS-plus strategy

It is clear that recent development within the WTO IPR system has been towards a stronger consideration of health protection, mainly pushed by the developing world. It is also clear that the developed world fear that multilateral IPR protection will be so diminished that their interests are no longer sufficiently protected. Many developed countries, the US in particular, have taken the position that TRIPS was insufficient protection and advocate even stronger IPRs. Due to this division in the multilateral arena, the recent trend has been a movement towards more bilateral agreements between developed and developing countries on stronger and more comprehensive IPR protection than the TRIPS agreement provide. This is the so called the TRIPS-plus strategy. The burning question is if the multilateral strategy to increase access to medicine by decreasing the power of strong IPRs through extending the scope of the compulsory licenses, is working, or if it is neutralized by the bilateral TRIPS-plus strategy that some industrialized countries are currently enacting.

13.1 Why a TRIPS plus strategy through bilateral agreements?

Most developing countries believed that the TRIPS agreement would be the final stop for international regulation of IPRs and that by giving this concession; they would avoid further pressure from the developed world.⁴⁰⁴ Many developed countries, the US in particular, did promise not to act unilaterally or bilaterally if the Uruguay round of negotiations would result in a multilateral trading system.⁴⁰⁵ Despite the fact that the Uruguay round resulted in a very comprehensive multilateral trading system, the US as well as the EU, have entered into a number of bilateral trade agreements with developing countries and LDCs outside the multilateral forum.⁴⁰⁶ After seemingly quite unsuccessful WTO negotiations during the Doha round, for example in Cancun in 2003, the USTR actually took an opposite position compared to previous statements and declared that the US would continue to pursue unilateral and bilateral initiatives for, among other things, stronger IPR protection.⁴⁰⁷ Despite the Uruguay round promises, it is fairly obvious that

⁴⁰³ Page 323, Dutfield, Suthersanen

⁴⁰⁴ Page 54, El-Said

⁴⁰⁵ Page 56, El-Said

⁴⁰⁶ Page 56, El-Said

⁴⁰⁷ Page 57, El-Said

large parts of the developed world only saw TRIPS as the first step towards a more comprehensive global protection of IPRs more or less equivalent to Western standards of IPR protection.⁴⁰⁸

13.1.1 Multilateral arena closed

Since the developing countries were so successful in organizing themselves towards further development of IPR protection within the WTO system, and actually even managed to limit its reach in favor of health protection, it is likely that developed countries believed that international achievements no longer could be achieved multilaterally, and that bilateralism and trade sanctions were the only remaining alternatives.⁴⁰⁹ These bilateral agreements generally have a regular trade issue as its main concern, but incorporate provisions highlighting the importance of IPR protection with the “*highest international standards and levels of protection*”; effectively demanding stronger IPR protection than TRIPS require and thereby causing the so called TRIPS-plus effect.⁴¹⁰ Some go so far as to say that most developing countries have been pressured or coerced to enter into these agreements by its industrialized counterparts.⁴¹¹ True or not, it is clear that bilateral and regional agreements have been a successful way to get developing countries to agree to IPR protection beyond the requirements of TRIPS.⁴¹²

13.2 What is a TRIPS-plus strategy?

Since the TRIPS agreement require a minimum standard of IPR protection, any subsequent bilateral agreement where WTO members are involved can only create stronger IPR protection than TRIPS.⁴¹³ This means that any agreement of that kind is generally part of a TRIPS-plus strategy. A TRIPS-plus provision can both increase the protection level for right holders, as well as reduce a limitation or exception given by the TRIPS agreement.⁴¹⁴ Pressure to interpret the TRIPS agreement as narrow as possible, or to disregard transition period privileges, could also be seen as a TRIPS-plus effects.⁴¹⁵ These TRIPS-plus provisions generally reduce the ability that developing countries have to protect different public interests.⁴¹⁶ This means that attempts to enhance global IPR protection further than the TRIPS agreement could seriously damage developing countries in their effort to achieve technological progress and development, and thereby counteract any positive

⁴⁰⁸ Page 54, El-Said

⁴⁰⁹ Page 60, El-Said

⁴¹⁰ Page 56, El-Said

⁴¹¹ Page 57, El-Said

⁴¹² Page 41, Dutfield, Suthersanen

⁴¹³ Page 3, Dutfield, Suthersanen

⁴¹⁴ Page 3, Dutfield, Suthersanen

⁴¹⁵ Page 57, 58, El-Said

⁴¹⁶ Page 3, Dutfield, Suthersanen

effects from measures taken in protection of global health within the WTO.⁴¹⁷

13.2.1 Examples of TRIPS-plus strategies

There is no single definition of what a TRIPS-plus effect is since it differs from country to country, but some examples can be given of how bilateral agreements can increase a country's IPR protection:

- By extending patent and copyrights to new kind of subject matters⁴¹⁸;
- By disclaiming rights (provided by the TRIPS agreement) to exempt certain things from their national IPR regime, for example plant and animal patents from their national patent laws.⁴¹⁹ Sometimes the exceptions that developing countries disclaim or narrow are even things that are still exempt in US or European IPR regimes⁴²⁰;
- By extending the minimum time period of protection. For example protection of industrial designs, have in many cases been extended from the TRIPS requirement of 10 years, to a fifteen year term of protection;⁴²¹
- By including a requirement to join a specific international IP agreement, such as a WIPO treaty with TRIPS plus provisions, into a trade agreement;⁴²²
- By strengthening already strong TRIPS enforcement provisions or by including other dispute settlement procedures than the WTO DSB system for the interpretation and implementation of that specific agreement. This is often changed to dispute settlement through arbitration, which forces weaker states to solve disputes in a much more sophisticated environment than they have resources for.⁴²³

13.3 Forum management - multilateral v bilateral trade agreements

Recent development has shown a trend towards bilateral FTAs over multilateral agreements for international trade cooperation, especially in the IP area. This trend is an example of a strategy called forum management, or forum shifting, which basically means that countries are aware of the fact that the place of negotiations can have a huge impact on the outcome, and therefore tries to steer the negotiations towards a forum which they believe can provide the best outcome.⁴²⁴

⁴¹⁷ Page 54, El-Said

⁴¹⁸ Page 41, Dutfield, Suthersanen

⁴¹⁹ Page 57, El-Said

⁴²⁰ Page 41, Dutfield, Suthersanen

⁴²¹ Page 58, El-Said

⁴²² Page 41, Dutfield, Suthersanen

⁴²³ Page 59, El-Said

⁴²⁴ Page 41, Dutfield, Suthersanen

Basically all countries have a forum management strategy, but in general only strong countries can fulfill it, while weaker countries need to cooperate in groupings to even have a chance of successful forum management.⁴²⁵ Both multilateral cooperation and PTAs can liberalize trade by helping governments resist political pressure from domestic interest groups that desire more trade restrictive policies.⁴²⁶ So what is the difference between bilateral and multilateral trade cooperation and what consequences could the trend towards bilateralism have?

13.3.1 Multilateralism

The WTO, as the world's leading trade organization, is based on multilateralism. With its basic principles of non-discrimination and MFN, it seeks non-preferential trading arrangement for all members. This is to be contrasted to any PTA that provides advantages only to its parties. Basically, multilateral trade agreements seek global trade liberalization. A multilateral agreement includes a much larger number of countries, which causes longer period of negotiations, especially when the countries strive to achieve consensus as within the WTO system. The long negotiations are however a natural consequence from the comprehensive and complex nature of a multilateral agreement.⁴²⁷ Some argue that trade liberalization through multilateral agreements does not create as high income increase and growth rate as PTAs do, but since the evidence of growth and income increase is much more solid and reliable when it comes to multilateral liberalization compared to liberalization through PTAs, this statement is still very controversial.⁴²⁸ Multilateralism is also considered the best way to avoid a prisoner's dilemma.⁴²⁹

13.3.2 Bilateralism, regionalism and PTAs

PTAs, bilateral and regional trade agreements reduce barriers to trade on a preferential, rather than universal, basis and their increase since the 1980's is highly significant to global trade development.⁴³⁰ Members to a PTA are generally geographically natural trading partners, such as NAFTA and the EU.⁴³¹ The bilateralism trend causes block formation between countries and parallel negotiations to the multilateral cooperation. There are a number of explanations and reasons to why states enter into PTAs: (1) want to manage market power; (2) desire to raise income and growth; (3) as a reaction to delayed multilateral negotiations; (4) because it can be beneficial to

⁴²⁵ Page 40-41, Dutfield, Suthersanen

⁴²⁶ Page 543, Rivera-Batiz, Oliva

⁴²⁷ Page 537, Rivera-Batiz, Oliva

⁴²⁸ Page 536, Rivera-Batiz, Oliva

⁴²⁹ Page 536, Rivera-Batiz, Oliva

⁴³⁰ Page 534-35, Rivera-Batiz, Oliva

⁴³¹ Page 536, Rivera-Batiz, Oliva

different political interests; (5) as an insurance against foreign protection, and finally; (6) it can provide them with enhanced security.⁴³² Regardless of what reasons a single state may have to enter into a PTA, they have different consequences in the international arena.

13.3.2.1 Benefits of PTAs and bilateralism

Trade liberalization through bilateral and regional negotiations are generally considered to be faster and cheaper than multilateral trade liberalization, especially considering the consensus requirement within the WTO system that often causes long delays.⁴³³ PTAs have shown trade liberalizing effects in the shape of actual tariff reductions or MFN tariff reduction.⁴³⁴ The more members to a PTA, the more it can gain trade liberalization. PTAs are also valuable because they allow groups of countries to negotiate and regulate on trade issues beyond what was possible to agree on multilaterally.⁴³⁵ In some cases, such as the issue of IP regulation, regional negotiations have opened up and paved the way for multilateral negotiations.⁴³⁶ PTAs that are open to include developing countries could potentially provide developing countries with stronger negotiation positions than in a multilateral context.⁴³⁷

13.3.2.2 Drawbacks with non-global trade liberalization

International cooperation on a smaller, preferential basis is not without its own complications. The negotiations are not always fast and smooth just because there are fewer participants, they can also be delayed when the parties disagree on complex issues.⁴³⁸ And even though regional agreements and closer economic integration can benefit its participants, it can sometimes hurt the trade interests of other countries.⁴³⁹ From a global trade liberalization perspective, larger PTAs are more problematic because their members have a greater incentive to increase tariffs against non-members and cause a situation of a prisoner's dilemma, unlike a multilateral system that is as globally beneficial as possible.⁴⁴⁰ When a PTA grows, it gains more economic and political power and could potentially be so strong that it could be able to block multilateral agreements that hurt some of their members.⁴⁴¹ Consequently, the greatest danger with bilateralism and PTAs is that it could

⁴³² Page 534-35, Rivera-Batiz, Oliva

⁴³³ The Uruguay round for example, took almost 10 years to complete.

⁴³⁴ Page 558, Rivera-Batiz, Oliva

⁴³⁵ Page 64, Understanding the WTO

⁴³⁶ Page 64, Understanding the WTO

⁴³⁷ Page 557, Rivera-Batiz, Oliva

⁴³⁸ Page 537, Rivera-Batiz, Oliva

⁴³⁹ Page 64, Understanding the WTO

⁴⁴⁰ Page 558, Rivera-Batiz, Oliva

⁴⁴¹ Page 558, Rivera-Batiz, Oliva

undermine incentives and political support for multilateral and global trade liberalization. Non-global trade liberalization creates the problem of multiple and overlapping jurisdictions, as well as draws attention and resources from the multilateral negotiations.

13.3.3 Bilateralism - complement or competition to multilateralism in the trade context?

The reason as to why bilateralism is a controversial issue is that it causes both trade liberalization and trade distortion at the same time. Economic integration between the members in a PTA contributes to trade liberalization, but at the same time a PTA causes economic distortion by discriminating against non-members. Bilateralism has mostly been the forum management strategy of the US and the EU, even though the US has been slightly more aggressive.⁴⁴² It is however very unlikely that these two huge trade actors would abandon the multilateral arena completely. It is much more probable that their forum management strategy is to push stronger IPRs in as many forums as possible.⁴⁴³ So the key question in the debate on international cooperation is if bilateralism, regionalism and PTAs compete with multilateral trade liberalization, or if it can be seen as a complement to multilateral cooperation? A PTA or customs union between members within the WTO would, due to its inherent discriminatory nature, technically violate the fundamental MFN principle.⁴⁴⁴ Art XXIV of GATT provides an exception that nevertheless makes it possible. As long as free trade prevails and a PTA formation does not increase barriers to trade with other members, the WTO allows it. The crucial requirement is that trade between a non-PTA member and a PTA member cannot be any more restrictive.⁴⁴⁵ This provision is however not very efficiently enforced and a clarification of under what conditions members may enter into a PTA has been an important topic during the Doha round. A clarification and strengthening of this provision could be an important part solution to the prisoner's dilemma problem.⁴⁴⁶ Consequently, the WTO is not completely against regional liberalization, despite its potential threats to the multilateral system. The official view of the WTO is that “*regional integration should complement the multilateral trading system, not threaten it.*”⁴⁴⁷ Since 1996 the WTO has a RTA committee in place with the mission to examine regional trade groups, evaluate their compliance with WTO rules, and try to predict how they will affect the multilateral trading system, as well as how the relationship between

⁴⁴² Page 42, Dutfield, Suthersanen

⁴⁴³ Page 42, Dutfield, Suthersanen

⁴⁴⁴ Page 64, Understanding the WTO

⁴⁴⁵ Page 64, Understanding the WTO

⁴⁴⁶ Page 558, Rivera-Batiz, Oliva

⁴⁴⁷ Page 64, Understanding the WTO

regional and multilateral agreements should be treated.⁴⁴⁸ Additionally, regionalism does not always have to cause a prisoner's dilemma. An example of successful regional trade liberalization is the EU: a customs union that has eliminated internal tariffs but at the same time maintained the volume of trade with the rest of the world. Under such circumstances, the union will benefit from trade liberalization without causing harm to its non-members.⁴⁴⁹ In some cases regionalism and PTAs can actually promote multilateral trade liberalization. By weakening the position of domestic lobbyists that seek trade protectionism, strengthen export lobbies and reduce internal tariff rates, they can help to level out the playing field and prepare its members for further and more widespread liberalization.⁴⁵⁰ In sum, there is no simple or obvious answer to what kind of international trade cooperation and agreement that can produce the very best solution. What kind of negotiations and type of agreement for each specific situation is most likely a result of a cost-benefit analysis, where regionalism is preferred when the costs of multilateral negotiations are considered too large in relation to its expected benefits?⁴⁵¹

13.4 Possible consequences for the developing countries from the TRIPS plus strategies

So what impact does the trend towards bilateralism and PTAs in the area of international IP regulation have on developing countries and LDCs? Generally these agreements are bilateral with a country-by-country approach basically just adding more provisions on top of the requirements from multilateral agreements.⁴⁵² Every accomplished bilateral agreement can thereafter be used as a basis and reference for negotiations with another country, giving the TRIPS-plus strategy a very comprehensive effect.⁴⁵³ Developing countries are widely considered to be pressured into these bilateral TRIPS-plus agreements by the developed world through threats of trade sanctions and aid suspensions.⁴⁵⁴ This strategy is possible with the help of vague provisions in the TRIPS agreement that open up the possibility to regulate on different interpretations of the agreement.⁴⁵⁵ By systematically pushing bilateral agreements on developing countries, the developed world, with the US and the EU as frontiers, has created an enormous negotiation advantage compared to the

⁴⁴⁸ Page 64, Understanding the WTO

⁴⁴⁹ Page 563, Rivera-Batiz, Oliva

⁴⁵⁰ Page 569, Rivera-Batiz, Oliva

⁴⁵¹ Page 570, Rivera-Batiz, Oliva

⁴⁵² Page 60, El-Said

⁴⁵³ Page 60, El-Said

⁴⁵⁴ Page 61, El-Said

⁴⁵⁵ Page 60, El-Said

developing countries that basically cannot control the continuing development single-handedly.⁴⁵⁶ The developing world can try to resist this kind of systematic pressure through regional alliances, but often the penetration of these alliances is a deliberate strategy by the developed world.⁴⁵⁷ The recent wave of bilateral agreements can be seen as a part of a competitive liberalization policy by the developed world. This basically means that the developed world believes that the best way to gain liberalization is to activate unilateral, bilateral and multilateral measures simultaneously; they believe that they are both complementary and mutually reinforcing.⁴⁵⁸ In the TRIPS-plus strategy context, this means that bilateral agreements are pushed to create a competitive environment between the developing countries, which the developed world hope will stimulate equal result in a different market.⁴⁵⁹ If one developing country submits to the pressures for stronger IP protection it automatically becomes more attractive to the investments of, and trade relations with, the industrialized world. If the rest of the developing world does not want to lose this business and these investments, they are almost forced to follow in its footsteps despite any unwanted consequences that may follow. What these bilateral agreements have done is basically to shift the IPR debate from the multilateral arena of the WTO to a much less transparent state-to-state forum. The bilateral agreements are also exempt from the reach of the WTO dispute settlement mechanism, which leaves the developing world with a lot less tools to fight any abusive behavior from its counter-parties.⁴⁶⁰

13.4.1 WIPO of new importance in a TRIPS plus strategy?

The TRIPS-plus strategy is actually being pushed in the multilateral context as well as the bilateral. Negotiation processes are currently taking place in the WIPO framework and are likely to result in agreements with TRIPS-plus standards.⁴⁶¹ The biggest fear with these negotiations is that they will result in treaties that basically eliminate, or severely diminish, any flexibility that developing countries currently have to implement IPRs in a way that is reconcilable with their development goals.⁴⁶² In order to keep some development perspective and not solely a business perspective on international IPRs, it is important to: increase developing countries participation and influence in WIPO, make room for development oriented organizations, thoroughly define WIPO's mandate from the UN, and assure that WIPO cannot be pressured by huge industrial players lobbying for a

⁴⁵⁶ Page 61, El-Said

⁴⁵⁷ Page 61, El-Said

⁴⁵⁸ Page 4, Chan

⁴⁵⁹ Page 5, Chan

⁴⁶⁰ Page 62, El-Said

⁴⁶¹ Page 20, Dutfield

⁴⁶² Page 20, Dutfield

stronger business perspective.⁴⁶³ Through increased access to expertise from NGOs or private individuals, developing countries have been able to give more realistic and technically correct proposals, both to WIPO and to the WTO when it comes to taking such interests as public health into account in international IP regulation.⁴⁶⁴ With this business oriented development in mind, both the developing world and development organizations probably need to offer WIPO even stronger attention than what is currently done.

⁴⁶³ Page 20, Dutfield

⁴⁶⁴ Page 276, 277 Dutfield

PART V

14 Discussion and Conclusions

The main purpose of this thesis was to analyze (i) if developing countries actually can reach their development potential with current international agreements on IPR protection; (ii) the connection between IPRs and global health; (iii) how well the remedies implemented to comply IPR regulation with the protection of global health has worked, and; (iv) what implications the recent trend towards more comprehensive bilateral agreements in protection of IP might have on this debate. In this final and conclusive part of the thesis I will present my own thoughts on the problems these issues have presented throughout the thesis, and the difficulties I believe they will present to the world, as well as offer some thoughts on how international cooperation and regulation on trade, IPRs and global health could, or maybe even should, proceed.

14.1 Problems with global health protection in the trade context

Through the course of this thesis, a number of problematic issues have been identified that I intend to comment on briefly in this chapter.

14.1.1 Overlapping mandates and weak authority for health protection

Health protection has an enormous disadvantage compared to trade and IPR regulation when it comes to governance. The united organizational structure of the WTO gives it the strong and persuasive features necessary to act on a multilateral level and achieve solutions with a wide consensus basis. They also have the benefit of receiving basically all resources that every country dedicates to trade and IPR regulation. On the contrary, protection of global health is scattered on many different organizations and actors, which creates a lot more difficulty in managing the tasks onto the appropriate organization. Since the resources for health protection is limited, they often end up competing against each other instead of complementing each other's missions.

14.1.2 Health not recognized as a human right

If the world is serious in wanting to eradicate global health problems and place the health issue on equal standing with any trade concerns I also believe that it is crucial to give global health the status of a human right that it so well deserves. Progress has been made, the promotion of global health can almost be claimed to be a guiding principle for interpretation of WHO agreements, but it is not

enough. Real results require a comprehensive action plan. In many circumstances, global health is considered a human right. If this was a universal truth, it would not be too hard to argue that a human right, such as access to lifesaving drugs, should always trump an economic argument, such as the need to recoup investments in research and development. But this is not a universally recognized right, in fact the context of trade, many countries have specifically denied this right, which makes the conflict somewhat imprecise. With no real international obligation, some would probably consider the right to health to be nothing but a moral argument. Combined with the fact that there is a very poor coordination of efforts to protect public health and many overlapping mandates to international health regulation, international trade regulation has the upper edge in any conflict.

14.1.3 Weak enforcement for social rights v strong enforcement within the WTO

It is however not enough that health is recognized as a human right if the right cannot be properly enforced. I strongly believe that it is essential to give global social rights the same strong and forceful enforcement mechanisms as rights given in global trade agreements. I believe that the world has proven that it does not have enough respect for the fact that all international agreements rely on the fundamental principle of international law, *pacta sunt servanda* - the content of the agreement shall be respected by all parties to the agreement. If an international agreement does not have a strong enforcement mechanism, it is very easy for its parties to disregard from compliance when it does not suit them to comply. Even if the entire international community were to recognize health as a human right from the number of international document that, if nothing else, at least are aspirational, these agreements, covenants and declarations generally do not have a strong enforcement mechanism. So when faced with the conflict between an aspirational obligation without an enforcement mechanism, and a 'harder' obligation from a binding trade agreement with a very strong enforcement mechanism, it is not hard to see that the trade obligation is much more likely to prevail. As we have seen, the enforcement possibility is one of the main reasons to why the industrialized world pushed for an IPR regulation within the WTO system instead of a separate international context such as WIPO. If we keep building strong enforcement mechanisms for the 'harder' commercial international undertakings but at the same time almost unpunished can avoid strict compliance to the 'softer' social obligations, it is like international law ranks its own regulation into different categories – the ones that are worth ensuring compliance with and the ones that really only serve as guiding principles. And guiding principles, in all its glory, comes with its limitations. Even though it is excellent that some fundamental principles in protection of human rights and social responsibility pervade through all international cooperation, it is still not enough if we

seriously want to prevent the worst distributional effects of free trade in a market that is not completely free competition.

14.1.4 Different attitudes on IP protection

It is evident that developing and developed countries have very different attitudes towards IP protection, and thereby very different ways of looking at the TRIPS agreement. Some countries have the approach that TRIPS was as far as they could possibly stretch in terms of IP regulation, while others believe that this is only a step on the way towards a much more comprehensive multilateral regulation. This is a profound difference in the fundamentals of IP protection that does not offer a simple solution or is very likely to change as long as there are developing countries.

14.1.5 Uncertain legal significance of health protective measures

Recently, there has been more multilateral consideration to health protection within the IPR context, most likely after groups of developing countries have organized and pushed the issues during the Doha round. These considerations manifest themselves in the health protective amendment to TRIPS taken to prevent the health damaging effects of the TRIPS agreement by widening the right to use compulsory licenses and simplify the export of generics. The amendment is definitely a step in the right direction, but due to a lack of sufficient ratification, the amendment has an unclear legal significance within the WTO system and it is uncertain what weight the amendment would carry in a dispute settlement.

14.1.6 TRIPS plus strategy towards bilateral agreements

Even if the amendment to TRIPS with more multilateral consideration to health protection would work, there is still the huge issue of the development towards bilateral IPR agreements, pushed by strong developed countries that believe that TRIPS does not offer enough IPR protection and try to find a new forum for negotiations. TRIPS plus strategies seriously threaten all multilateral efforts to create a global IPR regulation more considerate to global health.

14.1.7 Partial liberalization not beneficial for development

Economic evidence show that trade liberalization contributes to economic development by growth enhancement, which generally is a prerequisite for social development, but not enough to improve global health equality. To achieve sustainable trade liberalization, it is important to start to implement 'healthy' international trade policies. It is also highly necessary to assure that the international trade agreements that contribute to liberalization actually are advantageous to all countries that participate and not just to an elite few. If trade liberalization does not contribute to a

wide economic development that reduces poverty and raises income, it will not promote public health in general. This is one of the reasons as to why bilateral trade agreements and PTAs are not as beneficial to growth and development as a multilateral agreement is. A multilateral agreement simply works on a broader arena with a wider scope and authority and can reach a wider circle of people. Economic evidence does not really suggest anything else than that PTAs at its best does not hurt non-members. It is per definition only trade liberalizing to a limited number and not in any way beneficial to non-members.

14.1.8 Limited power of the WTO

Despite the fact that the trend towards more bilateral cooperation could be a significant threat to the authority of the WTO, the organization is probably not very likely to go rough on members that enter into bilateral agreements on IPRs. The WTO is in a very delicate situation with the so far quite unsuccessful Doha agenda and will probably not risk upsetting powerful members too much because if members start to pull out of the WTO, it could threaten the very existence of the organization and I believe that IP is probably considered a minor area within the WTO compared to the rest of the free trade agreements and it is more likely that the GATT and GATS provisions are considered to be so important that they need to be protected at any cost, it is too important to keep the core trade agreements to get into a fight about the compliance of bilateral IP agreements at this moment. Maybe if the Doha round eventually turn into something substantial, the WTO will yet again have the authority to push for a stricter compliance from all members and a more clarified view on how to treat bilateral competition. But until then, the fragile WTO will not go too hard on bilateral agreements in conflict with WTO principles due to fear of commitment. I think that the WTO will be very pragmatic and argue that regionalism is not that bad, and try to see the positive effects of it. If not, the WTO will at least try to put a positive spin on it, simply because the WTO thinks that regional agreements are not going away, they are hard to prevent, and the WTO is afraid that members will drop out if they are not allowed to continue with regional or bilateral agreements. Considering the latest development in the Doha round, which has been quite unsuccessful in reaching sufficient consensus for an agreement, there might be some truth to this. It is probably crucial for the WTO to find a way to enforce this demand for no less favorable treatment for members and regulate WTO members' use of regionalism in a way that is clear and does not repel any members.

14.1.9 WIPO as a potential stronger actor in the arena

Considering the structure of the WTO and the difficulties to form new agreement with the consensus approach, I also believe that WIPO is likely to become a stronger player again. Despite

the inclusion of IPRs into the WTO umbrella, industrialized countries have kept the option of using IPR negotiations within WIPO as a part of their forum management strategy. They needed to keep the door open for other negotiation forums if the WTO and TRIPS did not satisfy their needs. Unfortunately it is not as easy for the developing countries to organize within WIPO. Their limited resources for multilateral are likely to be put into the WTO more than WIPO since this is where they have already invested a lot of time and energy and have a better chance of voicing their opinions.

14.2 What could be done within the international community to better comply IP regulation with protection of global health?

So the question really comes down to if it is possible to combine liberalized trade with strong IP rights and still expect the kind of social and economic development necessary to fulfill the goals and obligations of international public health agreements? How can we find a way to regulate trade of intellectual property so that it contributes to sustainable trade liberalization?

14.2.1 Future development and measures of the WTO

WTO could try harder condemning bilateral agreements that do not agree with them, with the risk of losing parties. At the same time it could be a way for them to show strength and that the WTO will not go down without a fight. One possibility could be to try to improve health protection within other areas, for example try to reach an agreement on minimum safety conditions for labor within the member states, before a product may be exported. This is just as much a trade issue as IPRs were. It is fairly obvious that TRIPS the way it was originally interpreted was a big problem for developing countries. Recent years several steps have been taken to try to neutralize any bad effects that the agreement might have on public health policy. The problem still remains however what legal status these measures really have, they are not formally ratified as an amendment to TRIPS and therefore they are not subject to the WTO dispute settlement mechanism. So a member could most likely not drag another member that is in non-compliance with the un-ratified TRIPS amendment in front of a DSU panel in order to prevent this non-compliance. Until the amendment is fully integrated to TRIPS, this is a huge issue, and fact of the matter is that we do not know if the amendment will ever be integrated into TRIPS since it is not certain that enough countries will ratify it. Nevertheless, if the amendment is ratified, some progress has been made to neutralize the unwanted effects on public policy but a huge issue still remains – the matter of regional or bilateral agreements. If powerful industrialized nations cannot keep a strong enough IP protection through the multilateral system, they will proceed pushing the issue through other channels until they have

their way. The current multilateral trading system does not really have a good way of handling the presence of competing bilateral or regional agreements and it is my belief that the WTO does not really dare to take on the fight during current circumstances. I do not really think that it is a deliberate strategy from the WTO to play some kind of a double jeopardy by attempting to increase access with this exception for the least developed countries, but at the same time prevents this by allowing bilateral trade agreements. This feels like a strange strategy to me considering that regionalism can be such a forceful threat to multi-nationalism. Supporting regionalism and bilateralism too much would be like making itself superfluous as a strong future player on the international arena. I rather believe that the power position of the WTO is questioned enough considering its lack of progress during the current Doha round, and that it considers it necessary to allow the presence of bilateral and regional agreements on IP in order to keep some power in other trade issues. Unfortunately I do not think that this strategy will prevail. I believe that this type of power play will rather lead up to a short term loss, long term loss situation. I think that the WTO need to act strongly and forcefully and try limiting the potential harmful effects that bilateral and regional IPR agreements could have – the exact same effects as the ones the WTO itself has tried to prevent. Since it is mainly the rich and powerful industrialized members such as the US and the EU that are using their power as leverage to get developing countries to enter into these agreements, it is necessary to try to get the developing countries that oppose this kind of behavior organized so that they get enough power to put up a fight at the negotiation tables. It is also of the utmost importance that the Doha round gets a re-boost and is vitalized in some way. If there could come out one successful agreement in a nearby future, I think that would make a huge difference in regaining people's confidence in both the WTO and the multilateral system itself.

14.2.2 Measures within areas of international cooperation for health protection

The whole problem with international law and any kind of social ambitions that entails from it, is that basically everyone can agree in theory that this is a great goal or right, but when it comes down to actually delivering something most nations fall short. Everybody wants a share of the advantages that an agreement creates, but hardly anyone is prepared to pay the prize that committing to the obligations will entail. I personally believe that no significant change will happen unless health is recognized worldwide as a human right, the US ratifies the ICESCR and an effort is made to coordinate health protection with a strong enforcement mechanism so that the “softer” right in an agreement for social development can be given just as strong status as the provisions of a commercial agreement. I believe that the best way to do this is to work on getting the entire international community to recognize health as an inalienable human right with all the obligations

that follow. Not just access to health care, but to everything that is a necessity to realize one's health. However, this is most likely somewhat of a utopia, and something that probably will not happen in a while. A first step in the mean time could be to consider protection of health as an interpretive principle, as there have been tendencies towards within the WTO system. This would allow for national variations in how to prioritize based on different resource availability, risk perceptions and balancing between other domestic goals.

14.3 The crucial relationship between IPR regulation, trade and health protection

The big policy question for IPR regulation is to learn how to deal with the tradeoff between higher prices today in exchange for innovation tomorrow, which basically is the argument from the industry. High R&D costs that new pharmaceuticals need, will lead to high prices for consumers so that the industry can recoup its investments. If sustainable trade liberalization is going to be a goal, it is absolutely crucial to create a competitive environment to counteract this negative price effect that IPRs have for consumers in developing countries. Even though the world sees a lot more active NGOs fighting for better global health and huge multinational companies take on a more active role in their CSR, it is still highly crucial that nations on a governmental level also take their responsibility if we are really serious in complying with the international agreements and undertakings in protection of health. Not only for pragmatic reasons such as it would be so much easier to trade with a country where the population is healthy enough to be educated and build up a functioning administrative and legal system, but also because it is the morally right thing to do. It is likely that the continuing development for health cooperation is increased public-private partnerships at both local and global level. Even though it is good that the attempt to improve global health receives more attention and more resources, there are some potential problems with this future. Besides the fact that global health strategies already struggle with bad coordination and overlapping mandates due to an abundance of actors, the international community does not have a good way of ensuring corporate compliance to international regulation. When the actors are states or cooperating states, there are still matters of international law that can be used as tools to force compliance onto disobedient states. It is evident that countries cannot reach their maximum development potential with strong IPRs. To achieve social development and global health, innovation and growth cannot be the only guiding principles. At the same time it is important to remember that some countries might try to use protection of public health as a cover for trade protectionism because they want to try to get a market advantage for their domestic industries. It is

therefore important to find safeguards to prevent this kind of behavior. For example standards as to when certain protectionist measures are allowed and so on. In the words of Aristotle, “Wealth is evidently not the good we are seeking, for it is merely useful for the sake of something else.”⁴⁶⁵ In this case, increased wealth can, and should, become the tool to achieve global health and development.

⁴⁶⁵ Book I, Chapter V, Aristotle's *Nicomachean Ethics*

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