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Affärsarenan och normerna: tvisten om tvångslicens för patenterad läkemedel
En sammanfattning

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Den uppsatsen skrevs 2008, som slutförande av min masterexam i Intellectual Capital Management, på Centre for Intellectual Property Studies, i Göteborg.
Den sammanfattningen kompletterar nu 2011, min jurist utbildning vid Handelshögskolan.

Uppsatsen observerar de då senaste utfärdade tvångslicenser av patenterade HIV läkemedel av Thailand och Brasilien. Utfärdandet stöds av Världshandelsorganisations (WTO) reglering om *Trade Related Aspects of Intellectual Property Rights* (TRIPS-avtalet) och orsakade stor internationell debatt och stridande politiska reaktioner.

Det förväntade utfallet med uppsatsen är att analysera sambandet och ömsesidiga konstruktion och ratificering mellan affärsmässiga - och juridiska – arenorna.

De tre arenorna
Lagen och rättigheterna vilka lagen skapar och upprätthåller, som immateriella rättigheterna är inget mer än övertygelser som har etablerats som normer och har kommunicerats och åtgärdats i olika arenor i den mänskliga existensen.
Professor Ulf Petrusson skildrar att lagen om immateriella rättigheterna är accepterade som norm eftersom de är framgångsrikt kommunicerade. Immateriella rättigheterna, så som patent, är konsekvenser från en acceptans av samhället för någonting som är hävdad i olika politiska, legala och affärsmässiga inställningar världen omkring. Den acceptansen kan resultera från manipulation, repression eller från att de tas för givet och självklara. Det resulteras, enligt Petrussons teori, av en kommunikativ insats som investeras på de påstådda rättigheterna. Hans teori, som utgör ramen för detta arbete, exponerar tre strukturella arenor som påverkar den nuvarande kunskapsekonomi.

Den administrativa arenan
Aktörerna i den arenan är till exempel statliga myndigheterna som är nödvändiga för de som vill erhålla vissa rättsliga status, så som patent- och registreringsverket och skatt myndigheter. Den administrativa arenan är fast baserad på Staten, sina institutioner och regleringar, vilket tillåter en lägre nivå flexibilitet.

Den rättsliga arenan
Den arenan utgörs främst av domstolarna men även av aktörer som domaren, jurister och åklagare. I den rättsliga arenan den legala status och rättigheterna upprätthålls och valideras vid tvist mellan patenthavare och de som gör anspråk på det patenterade objektet.

Den affärsmässiga arenan
Den affärsmässiga arenan utgörs av flera strukturer. Några sådana är marknader, innovatörer, nätverk, media, etc. För företag som har en stark fokus och beroendet på immateriella rättigheter, så som läkemedelsföretag, är det viktigt att de andra aktörerna observerar deras rättigheter. Det beror på att det reflekterar deras möjligheter att utföra framgångsrika affärer överhuvudtaget.

Samspelet mellan arenorna
I Petrussons teori ses den administrativa arenan och den rättsliga arenan till stödstrukturer till den affärsmässiga arenan. Vilket orsakar beroendet mellan arenorna.

Intressen från branschens lobbyorganisationer, nationella regeringar från både utvecklade och utvecklingsländer och administrativa och rättsliga myndigheter spelar en stark roll i utfärdandet och utförandet av viktiga internationella dokument som TRIPS-avtalet och Doha deklarationen. Denna uppsatsen avser att visa hur samspelet mellan arenorna har påverkat och har manipulerats med avsikt att stödja olika intressen.

Tvångslicenser
En tvångslicens medför att någon mot patenthavarens vilja får rätt att tillverka kopior av exempelvis läkemedel.

2001 i Doha, som är huvudstaden i Qatar, Världshandelsorganisationen höll en ministerkonferens där antogs deklarationen om TRIPS-avtalet och folkhälsa (Dohadeklarationen). TRIPS betonade att immaterialrättsligt skydd är viktigt för utveckling av nya läkemedel men i Dohadeklarationen poängterades att TRIPS-avtalet kan och bör genomföras på ett sätt som stödjer alla WTO-medlemmars rätt att skydda folkhälsan och främja tillgången till läkemedel. Tvångslicens bestämmelser kommer för att särskilt bekräfta TRIPS-avtalets flexibilitet för dessa syften.

2003 togs ett beslut som möjliggjorde att tvångslicenser kan utfärdas för tillverkning av läkemedel för export till länder som saknar egna möjligheter att tillverka sina egna. Detta betyder att i samband med allvarliga folkhälsoproblem, som HIV, tuberkulos, malaria och andra epidemier, kan kopior av läkemedel importeras med hjälp av tvångslicenser.

Blad drygt tio exemplar på läkemedelspatent tvångslicenseringar runt omkring världen som citeras i den ursprungliga uppsatsen utförskar jag sammanfattningsviss endast den thailändska och den brasilianska.

Thailands tvångslicensering
Sen 2006 har den thailändska regeringen för första gången annonserat tvångslicensering av två patenterade antiretrovirala läkemedel för HIV/Aids patienter. Dessa läkemedel var Efavirenz, tillverkad och marknadsförd av Merck, Sharp and Dohme under namnet Stocrin, och Lopinavir/Ritonavir, tillverkad och marknadsförd av Abbot Laboratories under namnet Kaletra. Regeringen i Thailand har även tvångslicenserat en antikoagulantia för behandling ab hjärtsjukdom Clopidogril, tillverkad och marknadsförd av Sanofi-Aventis under namnet Plavix.

Brasiliens tvångslicensering
Brasilien har också använt patenttvångslicensering för att tillåta lokala läkemedelsleverantörer att producera kopior av HIV/Aids läkemedel. 2001 började Brasilien hota med att använda tvångslicensiering av läkemedel som ”lopinavir”, tillverkade av Abbott Laboratories, ”nelfinavir” från Merck Sharp och ”tenofovir” från Gilead om priserna inte sänktes. Med vid den tiden, på grund av ganska konfidentiella avtal, avhöll Brasilien sig från utfärdandet som sådant.

2007 utfärdar dock Brasilien en tvångslicens om Merck:s efavirenz.

Lagligt stöd för tvångslicensering
TRIPS-avtalet från 1995 är en milstolpe i immateriella rättighetens historia. Det skapar nya möjligheter för verkställighet av immateriella rättigheter på internationell och nationell nivåer

och binder sina undertecknar till normer för skydd av de flesta former av dessa rättigheter. Men framförallt tillåter TRIPS en mycket lättare patentering av läkemedel och läkemedeltillverkningsprocesser än det som stod till buds förut.

En bestämmelse som ger balans till TRIPS-avtalet vad det gäller läkemedels patenterbarhet är den om tvångslicensering. Avtalet uttömmer inte uppräkningen av de omständigheter under vilka tvångslicenser får användas. Men det inrättar förfaranden som undertecknarna förväntas följa när de beviljar tillstånd och ger vissa villkor för detta. De förfaranden och villkor varierar beroende på sammanhang där tvångslicensen är anställd.

Artikel 31 i TRIPS-avtalet medger att medlemsstater har rätt att använda, eller tillåta andra att använda en patenterad uppfinning utan tillstånd från rättighetsinnehavaren om ”lagstiftningen hos en medlemsstat medger annan användning”, men det klargör inte vad en medlems lag måste säga innan sådan användning är tillåten och räknar heller inte vad som är grunderna för rättfärdigande av icke auktoriserade användning. Vissa allmänna villkor för utfärdande av tvångslicens dock anges: nationella nödsituationer, annan extrem brådska, offentlig icke-kommersiell användning, konkurrenshämmande metoder och beroende patent.

Dessa bestämmelser i TRIPS-avtalet avser att ge en tydlig balansgång, inrättande av en medlemsstats rätt att utfärda tvångslicenser medan det försöker skydda rättigheter för den patentinnehavaren.

Vid Världshandelsorganisationens ministerkonferens i Doha 2001 antog WTO:s medlemmar en särskild deklaration om frågor som rör TRIPS-avtalet och folkhälsa. Dohadeklarationen visar att WTO:s medlemmar har överenskommit att i de fall där det finns konflikt mellan immateriella rättigheter och folkhälsa bör den förstnämnda inte utgöra ett hinder för förverkligandet av den senare.

Reaktion till tvångslicensering

Redogörelsen för yttrande om den thailändska och den brasilianska tvångslicenseringen i engelskspråkliga medier är mycket märkligt. Det betecknar en angelägen insats från båda sidor i konflikten att fånga massornas benägenhet. I den ena sidan, den pro läkemedelsföretagen lobbyn försöker, till varje pris, demoralisera den thailändska och den brasilianska regeringen och deras verksamhet om sjukvården samt helheten av systemet för immateriella rättigheter i dessa länder. På den andra sidan står en myriad av aktivister, akademiker och regeringsföreträdare som stödjer och erkänner sig inspirerad av dessa två länders åtgärder.

Analys och Slutsatsen

Thailand och Brasilien var inte de enda länderna att använda sig av patent tvångslicensering åtgärder i allmänhetens intresse för icke-kommersiell användning. Varför har just deras handlingar orsakat så mycket uppståndelse?

2008 när jag undersökte frågan kämpade Thailand för att återupprätta ett demokratiskt politiskt system. Dessutom hade Thailand tvångslicenserat även medicin för hjärtsjukdomar och var på väg att tvångslicensera cancermediciner. Brasilien har en historia av konflikter om tvångslicensiering av patent medicin och ständigheter som korruptionsskandaler och våld i sina städer har placerat landet under bevakelse av den utvecklade världen.

Både Thailand och Brasilien anklagades hårt för brott mot patenträtt. Men i verkligheten hade båda länderna lagligt stöd för sina tvångslicenseringar. Dessutom bryter inte deras agerande med läkemedelsindustripatent, dessa har inte återkallats. De fortsätter att drivas och sina ägare fortsätter vara Merck och Sanofi-Aventis. Merck och Sanofi-Aventis får även royalty baserat betalning på tvångslicenseringar.

Det starka motståndet från industrin och även från några statliga organ mot Brasiliens och Thailands åtgärder är av en sådan kraftfullhet som föreslås ha en avskräckande effekt för mindre ekonomier. Motståndet kanske inriktar sig som exempel för länder som eventuellt överväger liknande åtgärder på folkhälsoområdet men kanske saknar den juridiska eller politiska resurser att försvara sig på den globala scenen. Attackerna mot Brasilien och Thailand kanske är ett exempel på vad som kan göras mot andra länder som vågar göra detsamma.

En av mina viktigare slutsatser från detta är att lagen, på egen hand, inte har styrkan att producera de resultat som den var avsedd för. Lobbyn, dominerande ställning och kommunikativ styrka spelar faktiskt en roll i tvister, även när lagen redan finns.

Frågan om tvångslicensering för patenterat läkemedel har dessutom vunnit en nästan folklig status och har definitivt satt ämnet på det vardagliga diskussionsbordet. Människor som förut kanske inte hade någon åsikt om de immateriella rättigheterna fick veta om konflikten mellan folkhälsan och intressen för vinst, eller var det en konflikt mellan korrupta länder och de som utvecklar botemedel för sjukdomar? Tack vare tvångslicensering för patent och den nu mera aktuella frågan om fildelningen på nätet har medborgare över hela världen fått möjlighet att informera sig om och att bilda sig en uppfattning om immateriella rättigheters paradoxala nyanser. Detta bidrar för en möjlig förbättring av systemet, ett system som har potential att förbättra den mänskliga tillvaron i vår planet.

Master Thesis 20 credits

The business arena and the norms: the dispute over compulsory licensing of patented drugs

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Table of contents

Abstract

The recent issuance of compulsory licenses of HIV patented drugs by Thailand and Brazil, supported on the provisions of the WTO´s Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement), raises great debate in the international arena.

Observing this case, the legal norms on which it is based, examples of different uses of this institute and the contrasting public reactions to the matter, the expected outcome is to appreciate the important relation of mutual construction and ratification between the business and the legal arenas.

As the public priorities of the society and the notion of justice evolve, so do the law and the acceptable ways of enforcing it. The people's understanding of what is right and what is wrong and how they act upon this, influences the concepts of what is legal. What is communicated in the business – and political arena, tends to have direct influence in the public opinion. Which, by its turn, influences the daily events that affect the lives of millions.

The law, on its own, does not have the strength to produce the results it was intended for. Some of the reasons could be the very nature of the law in question, its relation to the society it is intended to rule, the business forces and international relations. The reactions to the use of a legal instrument must be pre analysed and taken into consideration by those that intend to take an innovative step in the international relations and business arenas. As can be seen in this study, the counteract from the lobbyists and from the governments that support them can be fierce and can actually harm the political and social harmony of entire nations.

List of Abbreviations

WTO – World Trade Organization

TRIPS – Agreement on Trade Related Aspects of Intellectual Property Rights

WIPO – World Intellectual Property Organization

WHO – World Health Organization

DSU – Dispute Settlement Understanding

DSB – Dispute Settlement Body

MSF - Médecins Sans Frontières

DNDi - Drugs for Neglected Diseases Initiative

LDCs - Least Developed Countries

DHHS - Department of Health and Human Services of the USA

AGCM - Italian Competition Authority

USTR – United States Trade Representative's Office

IPR – Intellectual Property Rights

CPTECH – Consumer Knowledge on Technology

1 Introduction

The recent issuance of compulsory licenses of HIV patented drugs by Thailand and Brazil, supported on the provisions of the WTO´s Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement), has raised great debate in the international arena. Observing this case, the legal norms on which it is based, examples of different uses of this institute and the different public reactions to the matter, I will appreciate the important relation of mutual construction and ratification between the business and the legal arenas.

1.1 Background

Compulsory license is the term used to describe the mechanisms for non-voluntary authorization to use patents. The most important international norm for the use of compulsory licenses so far is the Article 31 of the TRIPS Agreement, which undertakes "uses of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government". Other important provisions are TRIPS Articles 1, 6, 7, 8, 40, 44 and the provisions of the Doha Declaration on TRIPS and Public Health. These documents of international public law are the guidelines for intellectual property related trade between countries in different stages of development. While the TRIPS Agreement embraces this kind of trade relation in a general perspective, the Doha Declaration discusses the matter of intellectual property related to public health. With this, many attempts for compulsory licensing drugs in the name of the public interest have been made before, until Thailand's actual issuance of compulsory licenses on patented drugs came to light.[1]

By the time of the conclusion of this thesis, the compulsory licensing of patented drugs was still receiving great attention from the international media and the public opinion. Support and criticism have continuously been expressed, causing specially developing countries to refrain from using the legal instrument of compulsory licensing or to justify themselves for doing so. Pharmaceutical companies, the governments of several countries and international bodies join in the discussion of how to balance the patent rights, the public interests and the commercial ends of pharmaceutical research.

1.2 Purpose and delimitations

In the first section of this paper, I will analyze the legal and historical foundations of compulsory licensing of patents from the Paris Convention, to the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement

[1] In late 2006, the Thai government, for the first time, announced its use of the compulsory licensing on two patented anti-retroviral drugs for HIV/AIDS patients (Efavirenz, manufactured and marketed by Merck, Sharp and Dohme as Stocrin, and Lopinavir/Ritonavir, manufactured and marketed by Abbott Laboratories as Kaletra) and another anti-coagulant for treating heart disease (Clopidogril, manufactured and marketed by Sanofi-Aventis as Plavix).

and Public Health. In the third section of this thesis, I will describe Professor Ulf Petrusson´s theory on the three arenas and the interaction between them, as an attempt to understand how is the law, the administration sector and the business arena correlated and mutually influenced. Which can, hopefully, become clearer with the analysis of the recent compulsory licensing of drugs. In the following part, I will provide an account of some of the previous cases of compulsory licensing attempts by other, developed and developing countries. In contrast to those examples, I will then tell about the cases of Thailand and Brazil, which have caused a considerable commotion in the business world and in the international relations of those countries with, specially, the United States government and pharmaceutical industry.

My intention with this narration is to illustrate the dynamic relation between legality and claimed norms. The purpose of this thesis is to understand how the business arena and the legal arena are mutually influenced. By analyzing the compulsory licensing of patented drugs, my intention is to grasp the relation between these two spheres of the intellectual property existence and how they shape and validate each other.

Due to the complexity of such theme as patent compulsory licensing, the following analysis will be limited. The economical and financial aspects of compulsory licensing of patents, valuation, royalty setting, contracts of intellectual property licenses or of acquisition of generic pharmaceutical products and specifics of different national laws will not be deeply analyzed. The events of compulsory licensing of patented drugs also have considerable influence on the incentives the pharmaceutical companies have for research and developing treatments for victims of diseases that tend to occur with more intensity in tropical or less developed countries, such as malaria and tuberculosis – the so called "neglected diseases". This interesting perspective of the clash between profits and public interests in relation to intellectual property rights and more specifically to the monopoly allowed by patent rights, is not be the focus of my thesis. However, this issue will be commented upon.

The audience for this paper might be those interested in compulsory licensing in general and compulsory licensing in the health care industry. And chiefly, those interested in how norms are constructed in that theoretical convergence area where the legal and the business ideals meet.

1.3 Method and Material

I have used customary legal sources such as international agreements, national laws, doctrines, regulations and recommendations from international bodies such as WIPO, WTO and WHO. These sources helped establishing the legal status of the patent compulsory licensing.

Another important modality of source was the international media. I gathered an expressive collection of newspaper articles, blogg postings, white papers from national governments, articles from specialized sources such as from the web sites Intellectual Property Watch and the James Love

blogg that have all presented intensive coverage on the matter. I have also used some polemical advertisements and public statements, some of which I have annexed a copy in the appendix of this thesis, in some cases only as an illustration for the theme and in other cases because those are no longer accessible.

The main theoretic framework of this study has been developed by professor Ulf Petrusson and is taught at the Centre for Intellectual Property Studies, in Gothenburg. One angle of his theory that will be especially considered is the concept of the three structural arenas – legal, business and administrative - where intellectual property is designed, validated and constructed.[2]

[2] Petrusson, Ulf (2004)

2 The Law

This chapter opens with a brief introduction of the dynamic nature of law, followed by an overview of patent law and the regulation on compulsory license of patents. I will introduce the evolution of this legal mechanism from the Paris Convention, to the TRIPS Agreement and the Doha Declaration. The account of these international agreements adds to a rather solid legal construction allowing governments to the use of patents without the consent of the patent holder. It will also be demonstrated that medicines were not subject of patenting until the emergence of the TRIPS Agreement, which is one of the reasons why the compulsory licensing on these patents are so commented and disputed.

As it will be commented upon, the national government can only benefit from the TRIPS provisions if their national laws are timely adapted to comply with the agreement. More on this subject will be discussed in sections 4, 5 and 6.

2.1 The Dynamic Nature of Law

The law is in constant construction and it depends on the people's approval to be efficiently enforced, and its evolution is closely connected to the evolution of the society as a whole. The society's understanding of what is acceptable, what is not acceptable, what is a reasonable punishment and a necessary procedural, is what the written letter of the law is intended to mirror.

In a business perspective, the law is essential for economic prosperity. In the absence of law, order, property rights and contracts it is likely that no one would take the risks for entrepreneurship and improvement. Law is what provides the tools to manage risks and create value. It gives a framework for effectiveness and allows the world to be more predictable, because it states the limits of fairness.

The dynamic nature of the law is that it evolves, as does the humanity. The law of ten years ago is different than the law of today, so is the society. While the law establishes limits to people's behaviour, it is people's behaviour that creates the need for the law. Within its limits, the law allows for evolution, change and adaptation to the development of the business and social environment.[3]

In the context of law, a special form of property is the intellectual property right. This is the area of law which concerns legal rights associated with creative effort or commercial reputations and goodwill[4]. The patent is a strong form of intellectual property because it gives monopoly to its owner. By nature, patents protect ideas, as expressed in the description and claims, but there are several controls on this monopoly right conferred to the patent owner, such as the compulsory licensing. This is an example of the attempt

[3] Bagley, Constance E. (2005)
[4] Bainbridge, D. (2002), p. 3

to provide the law with balance, while allowing great privilege, such as the monopoly right in a patent, the law also offers a valve for such power, that is, the compulsory licensing.

2.2 Compulsory Licensing of Patents

Since its origins, the establishment and spread of patent regimes has been controversial. In Europe, for instance, a major anti-patent movement emerged during the 19th century. At that time, the liberalization of international trade was gathering momentum and patent protection was perceived as an obstacle to it. In 1883, the year of the signature of the Paris Convention, 22 countries had patent systems in place.

One of the issues which seem to have met instability in the international arena has been the patentability of medicines and pharmaceutical processes. As it will be demonstrated in this chapter, up until the advent of the TRIPS Agreement[5], pharmaceutical products were not subject to patentability in a number of countries.

The compulsory licensing in general and particularly on pharmaceutical patents have also been controversy, having received special consideration both in the TRIPS Agreement and the Doha Declaration[6].

In this chapter I will introduce the evolution of the legal treatment to those institutions, by analysing the specificities on this concern from the Paris Convention to the Doha Declaration on the TRIPS Agreement and Public Health.

2.3 The Paris Convention

In 1883, the international meeting known as the Paris Convention had the main purpose of harmonizing the patent laws adopted by various countries in order to facilitate protection of industrial property simultaneously in different states. One of the main objectives of the negotiations was the establishment of a single priority date for patent applications filed in several countries.[7] The awareness that exclusive rights, such as the ones granted by the patent rights, could seriously interfere with the welfare of the countries led to further negotiations at the first International Patent Congress, in Vienna, 1873. There and then, amongst other commitments, it was resolved that the compulsory licensing of patents should be included in the Paris Convention text to be allowed in cases in which the public interest should require it.

[5] Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement)
[6] Doha Ministerial Declaration on the TRIPS Agreement and Public Health (hereinafter "the Doha Declaration").
[7] Bainbridge, David (2002)

The Paris Convention state members conceded that a state had the residual power to override private interests in times of public health or military necessities; however, they were hesitant to adopt express proposals to limit patent rights.[8] By the time of the signature of the Paris Convention the issue of compulsory licensing of patents remained as a possible sanction against abusive patent holders – particularly when they failed to work patents within a member state. The specifics of this possibility were left for the individual legislation of the member states, but the Paris Convention links the compulsory licensing to cases of "abuse". It states as follows:

> "Each country of the union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."[9]

The agreement also creates time restrictions for compulsory licenses applications and gives limitations for the license when the patentee can justify insufficient usage of the patented innovation.

> "A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application, of three years from the date of filing of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons.
> Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license."[10]

The local working requirement and the compulsory licensing system contributed to the public conciliation with the patent system, for being perceived as an efficient way to prevent abuses by the patentee monopoly.

Another matter left for the members to legislate as they wished was the establishment of which industrial sectors were appropriate for patentability. One effect of this discretion was that many member states excluded the pharmaceutical industry from patentability. The general trend was to extend patent protection to processes and not products. Brazil for instance, excluded both pharmaceutical products and processes from patent protection. In India, while patent protection lasted 14 years for products and processes in all other industrial sectors, pharmaceutical products were excluded from patentability and pharmaceutical processes patents lasted for only 7 years.

[8] E. T. Penrose, p. 640
[9] Paris Convention, Article 5A (2)
[10] Paris Convention, Article 5A (4)

In 1986, the Uruguay Round of Trade Negotiations[11] was launched in Punta del Este. At that time more than 50 countries did not recognize patent protection for pharmaceutical products. The criticism against intellectual property protection for medicines was that multinational pharmaceutical companies could abuse their patent rights by:

- Charging high prices for treatments, inclusive for diseases that affect a large number of poor people who cannot afford them;
- Putting pressure on governments to prevent the local manufacture or import of less expensive copied versions of the drugs produced in off-patent countries;
- Undertaking research and development on diseases of minor importance to poor people.[12]

More than a century had passed and the advent of the TRIPS Agreement did not remove the relevance of the Paris Convention for the understanding of compulsory licensing of Patents. As we will see, the TRIPS incorporates, by reference, a number of the Paris Convention provisions.[13]

2.4 The TRIPS Agreement and the Emergence of the Drug Patents

The TRIPS Agreement, which entered into force 1 January 1995, constitutes a milestone in the history of intellectual property. The adoption of this agreement links intellectual property rights to the world trading system, it creates new enforcement opportunities at the international and national levels. The Agreement binds its signatories to standards of protection for most forms of intellectual property rights. Compelling its member states to, for instance, provide patent protection for any invention whether a product (such as a drug) or a process (such as a manufacturing method), not discriminating between different fields of technology, nor between the place of invention nor production[14]. The patent protection granted by the member states has to last for at least 20 years from the date of application.[15] To fall on the scope of patentability, the invention must be new, represent an inventive step and be capable of industrial application.[16]

These stipulations represent a major achievement for the pharmaceutical industry that, with the Paris Convention, could not secure these rights. However, as patents were not available for any pharmaceutical products in some countries in the pre-TRIPS era, a supplementary transitional period has been allowed for countries still not granting patents for pharmaceutical products when the WTO came into force in 1995. A 5-year supplementary

[11] This meeting resulted in part of the embodiment of the final act signed in 1994 in Marrakech, of which the TRIPS Agreement is an integral part.
[12] Roffe, Pedro, pg.10. (2005)
[13] TRIPS, Article 2 (1): "in respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention (1967)."
[14] TRIPS, Article 27.1
[15] TRIPS, Article 33
[16] TRIPS, Article 27.1

period was granted so the affected developing countries should start granting pharmaceutical products patents no later than 2005.[17]

Before TRIPS, the need to ensure access to medicines to the population was the argument for many countries to exclude pharmaceutical products from patentability. Another argument was to protect national pharmaceutical and chemical sectors in a lower stage of development compared to the other countries. However, not only developing countries adopted this strategy. A study published by the United Nations, in 1975, listed the countries that excluded pharmaceutical products as patentable inventions; they were most of the developing countries as well as the Soviet Union, the former socialist countries of Eastern Europe, Austria, Canada, Italy, Japan, Spain and Switzerland.[18]

During the negotiations for TRIPS, the arguments for a strong patent system in developing countries, especially on what it concerns drug patents, were called into question. Some of the issues that were questioned and that played an important role on the outcome of the discussions concerned the following:

- The actual costs of R&D involved in the development of new drugs (especially compared to the marketing costs of pharmaceutical companies);
- The important role that publicly funded R&D plays in the discovery of new drugs;
- The use of patents to protect a myriad of minor developments and prevent or delay the entry of generic products after patent expiry (the strategy known as "evergreen"); and
- The justification for extending to developing countries the same model of patent protection applied in more advanced countries.[19]

These aspects of the pharmaceutical industry have continuously been reason for argument and concern. Another issue that raises great concern and controversy is the neglect, by the pharmaceutical industry, to research and develop cures, relieves or vaccines for the treatment and prevention of those diseases known to occur with more frequency in tropical countries and fall with stronger intensity upon the poor. A study developed by the World Health Organization has estimated that only 4.3% of pharmaceutical R&D expenditure is targeted at those health problems, such as malaria and tuberculosis, which primarily concern low- and middle- income countries.[20] According to Dr. James Orbinski, of the International Council of Médecins Sans Frontières [21], out of 1,393 new drugs marketed between 1975 and 1999, only 16 were for neglected diseases.[22] Yet, these diseases account for over

[17] TRIPS, Article 65
[18] United Nations (1975)
[19] Abbot, M. (2004) pp. 77 -100
[20] World Health Organization (1996).
[21] The Médecins Sans Frontières is an independent humanitarian medical aid agency that is committed to provide medical aid wherever it is needed and to raise awareness of the difficult situation in which those they help live.
[22] Trouiller P, et al. (2002)

10% of the global disease burden. In contrast, over two thirds of new drugs were modified versions of existing drugs, which do little or nothing to change the disease burden. The Drugs for Neglected Diseases Initiative – DNDi[23], says that 90% of investment into health-related R&D has focused on concerns that only affect 10% of the global population.[24]

On the other hand, patents are of great importance for the pharmaceutical industry. Since it relies on the returns from the exploitation of patents to recover investments in research and development and achieve profit. The industry claims that profits provided by global patents are fundamental for the discovery and development of new drugs. One of the arguments pro drug patenting used by the pharmaceutical industry is the dangerous of parallel importing. That is, if developing markets were allowed to copy the drugs, they would be exported to developed countries, obstructing the market were the industry makes the highest profits.

Another complicating aspect in this debate is that other building blocks besides patents, such as market distribution channels, infrastructure, know-how, and costs of production play an important role on drugs accessibility. The middle – and low-income countries representatives claim that by controlling these and yet the patent rights, the pharmaceutical industry is in the position of setting the prices as wishes. The industry, in the other hand, claims that great amounts of medicine and other forms of aid donate to nations in need come to get lost or expired due to corruption and total lack of infrastructure in those nations.

These contrasting points of the debate that took place during the negotiation of TRIPS are still relevant and controversial nowadays, even after the Doha Declaration. These arguments are still been claimed by the actors in the drug patent compulsory licensing debate, despite what is written in the signed international agreements. The strength of the communicative skills of pictures and fierce speeches provided by the actors in this debate tend to overcome the cold letter of the law. But to have a glimpse of the truth in this issue, it is important to know what the law to which most countries[25] have agreed upon says.

The TRIPS Agreement establishes the global possibility for pharmaceutical patents[26], yet it also allows for fundamental flexibilities to the patent rights. According to the agreement, the member governments have to require the patent applicant to disclose details of the invention and they may also require

23 The Drugs for Neglected Diseases Initiative is a non-profit drug development organization focused on improving the health and quality of life of people suffering from neglected diseases. Its main goals are to develop treatment for people suffering from those diseases; advocate on research and development of drugs for those treatments; and, strengthen the existing research capacity in countries where those diseases are endemic.

24 For more information on neglected diseases and the efforts of DNDi go to http://www.dndi.org/index.asp (accessed in November 2008)

25 On 27 July 2007, 151 countries were member of the WTO and therefore bind to the TRIPS Agreement.

26 TRIPS, Article 27.1

the applicant to reveal the best method for carrying it out.[27] The national laws shall prescribe the scope of the patentability criteria, the possibility of establishing exceptions to the exclusive rights[28], such as the working exception, when the government allows researchers to use a patented invention for research, in order to understand the invention more fully; and parallel import of patented products, when they are obtainable in a foreign country at lower prices, when a patent also exists there.[29] The government members may refuse to grant patents for three reasons that relate to public health. These are:

1) Inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health.[30]

2) Diagnostic, therapeutic and surgical methods for treating humans or animals.[31]

3) Certain plan and animal inventions.[32]

The governments may make limited exceptions to patent rights, provided that some conditions are respected. For instance, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent.[33]

TRIPS incorporates a binding and enforceable dispute settlement mechanism[34] to resolve disagreements with respect to compliance with these standards under the WTO Dispute Settlement Understanding (DSU), which creates the Dispute Settlement Body (DSB).[35] The Member States are also entitled to impose retaliatory trade sanctions against another Member State that persists in non-compliance, even in sectors not related to intellectual property[36].

Amongst so many important statements, the TRIPS Agreement affirms that the state members may "*use, or permit others to use, a patented invention without authorization of the right holder*"[37]. This is the consequential statement that enables the compulsory licensing of patents.

2.5 Compulsory Licensing in the TRIPS Agreement

Perhaps one of the most momentous instruments for public policy in the TRIPS Agreement is the provision for compulsory licensing in public interest.

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[27] TRIPS, Article 29.1
[28] TRIPS, Articles 30 and 40
[29] TRIPS, Article 6, and Doha Declaration, Section 5
[30] TRIPS, Article 27.2
[31] TRIPS, 27.3a
[32] TRIPS, Article 27, 3b
[33] TRIPS, Article 30
[34] TRIPS, Article 64
[35] For detailed information regarding the Dispute Settlement Understanding, the main WTO agreement on settling disputes; and the Dispute Settlement Body see http://www.wto.org/English/tratop_e/dispu_e/dispu_e.htm#disputes (accessed on 25 July 2007)
[36] TRIPS, Articles 21(8) and 22(6)
[37] TRIPS, Article 31

Compulsory licensing is an authorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent owner. The patent itself is a concession from a government in favour of a particular person that hence acquires certain exclusive rights in the public interest. The compulsory license is a permission for a third party to make, use, or sell a patented invention without the patent owner's consent – under which generic versions of patented drugs can be produced.

Traditionally, the chief requirement for the issuance of a compulsory license is that attempts to obtain a license under reasonable commercial terms have failed after a reasonable period of time.[38] More specific provisions concerning the compulsory licenses requirements, before the TRIPS agreement were set in the legislation of each state and varied between systems. Some of the traditional examples of situations in which a compulsory license may be granted are lack of commercialization of the invention in the territory of the patent, inventions funded by the government, failure to meet the demand for the product and where the refusal to grant a license leads to inability to exploit an important technological advance or to exploit a development patent. Compulsory licenses have also been used before on other intellectual property rights than patents, for instance, on copyrighted material for educational or non-commercial use.

The text of the TRIPS Agreement does not state the term "compulsory licensing". The title of the Article 31 of the TRIPS Agreement is "Other use without authorization from the right holder"[39], which implicitly deals with compulsory licensing. It also includes use by governments for their own purposes. This thesis will often refer to both uses under the term of compulsory licensing.

The TRIPS did not exhaust the enumeration of the circumstances under which compulsory licenses could be used. But it sets up procedures that governments are expected to follow when granting a license and gives certain conditions for such. The procedures and terms vary depending upon the contexts in which the compulsory license is employed. The Article 31 admits that members have the right to use, or permit others to use, a patented invention without authorization of the right holder "where the law of a member allows for other use"[40], but it does not elucidate what a member's law must say before such use is allowed and it does not enumerate what are the grounds for justification of unauthorized use. Certain general conditions for the issuance of a compulsory license, however, are stated: national emergency, other circumstances of extreme urgency, *public non-commercial use*, anti-competitive practices and dependent patents.

The TRIPS Agreement intends to provide a distinct balancing act, establishing a member state's right to issue compulsory licenses, while attempting to safeguard the rights of the patent holders. As an example of

[38] As the provision in the Paris Convention, seen in the first part of this sub-chapter.
[39] TRIPS, Article 31
[40] TRIPS, Article 31

that, Article 31 (c), (d), (e) and (g) (which will be analyzed further on in this chapter) outline strict restrictions for use of compulsory licenses, notification procedures and royalties to benefit the patent holder. To understand the intentions of Article 31 it is important to see the general objective and principles stated in article 7 and 8 of the TRIPS Agreement, which indicate the balance of interests intended by the agreement.

> Article 7. "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to *a balance of rights and obligations*". (my highlight)

And

> Article 8. "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to *protect public health* and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." (my highlight)

The open list of conditions for issuing a compulsory license, established in the several sections of the Article 31 of the TRIPS Agreement, shows that instead of focusing on enumerating grounds, negotiators concentrated on establishing a mandatory set of conditions for the compulsory licenses issued. The conditions where established so to minimize the negative trade effects of these compulsory licenses. The rules do not prevent member states from granting compulsory licenses, though.
These conditions are:

a) The authorization of compulsory licensing should be considered on its individual merits;[41]
b) Before obtaining a compulsory license, the issuer must attempt to negotiate the license on reasonable business terms with the patent holder and that such efforts have not been successful within a reasonable period of time. Only after having failed to reach an

[41] TRIPS, Article 31 (a)

agreement within a reasonable time can the compulsory license be obtained;[42]

c) There are three possible waivers to the "previous negotiation requirement": national emergency; other circumstances of extreme urgency; or where the proposed use is a public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;[43]
d) The license must be non-exclusive and non-assignable;[44]
e) The scope and duration of the license must be limited to the purpose for which it was authorized[45] and usually must be granted to supply only the issuing Member State's domestic market;[46]
f) When the circumstances leading to the grant of the license cease to exist, so too must the license; and "competent authority" shall have the power to review the continuation of the compulsory licenses;[47]
g) During the entire period of use, the patent holder must be entitled to receive adequate remuneration for that use, taking into account the economic value of the patent;[48]
h) The decision to authorize compulsory licenses and the payment to the patent holder are subject to judicial review;[49]
i) Special consideration should be given in cases where the patent holder is engaged in anti-competitive acts.[50]

The Article 31, the TRIPS Agreement does not define the requirements for declaration of "national emergency", "other circumstances of extreme urgency" or what types of use qualify as "public non-commercial use", in what can be understood as an effort to facilitate the balance of interests that it influences. The agreement is also vague on determining the economic values involved in the compulsory licensing. It demands the use of the balancing test to analyze the economic concerns of the patent holder against the economic capabilities of the license grantor. This balancing test and the final decision is within the capabilities of the Dispute Settlement Body.[51]

[42] TRIPS, Article 31 (b)
[43] TRIPS, Article 31 (b), second part.
[44] TRIPS, Article 31 (d) and (c)
[45] TRIPS, Article 31 (c)
[46] TRIPS, Article 31 (f)
[47] TRIPS, Article 31 (g)
[48] TRIPS, Article 31 (h)
[49] TRIPS, Article 31 (h) and (j)
[50] TRIPS, Article 31 (k)
[51] See DSU, footnote 8, art. 3(2) – The role of the DSB is "… to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretations of public international law"

According to Spennemann and Braun[52] there are a number of practical difficulties for the issuance of compulsory licenses as it is established in the TRIPS Agreement.

Negotiation - Where negotiations to receive prior authorization from the patent owner are required[53], they can be complicated and take a long time to conclude.

Manufacturing - The patent specification may not provide sufficient information to copy the drug. In fact, in the case of some drugs, the most efficient manufacturing process is protected as a trade secret or by a separate patent, which may even be owned by a different company.

Know-how - Many countries may lack professionals who can do the copying, and licensees may not necessarily be able to profitably sell the drug at a much lower price than that of the patent-holding firm.

Business Arena - Politically, it may need substantial courage for a small country to issue compulsory license on a drug patented in the US or in a European Union member state. A good political relationship may be necessary for a guaranteeing access to the markets of the two global economic players. As such, a small country may consider that the trade-offs of issuing a compulsory license outweigh the price reduction of individual drugs.

While the provisions for obligations and flexibilities in the text of the TRIPS Agreement may rest somewhat vague and may leave room for questioning their upholding possibilities and limitations, the outcome of the Doha World Trade Organization Ministerial Conference, the Doha Declaration, clarifies and reinforces the intentions expressed in the Agreement. The most relevant paragraphs of the Doha Declaration for the present study will be analyzed in the section that follows.

2.6 The Doha Declaration on the TRIPS Agreement and Public Health

At the Doha World Trade Organization Ministerial Conference (9-14 November 2001), the WTO members adopted a special declaration[54] on issues related to the Agreement on Trade-Related Aspects of intellectual Property (TRIPS) and Public Health. The discussion for the establishment of the declaration was one of the most important issues at the Conference, which launched a new round of trade negotiations on a broad range of issues[55]. It was the first outcome of a process that started in early 2001,

[52] Roffe, Pedro et all. pg.10.

[53] TRIPS, Article 31(b)

[54] Paragraph 17 of the general Ministerial Declaration states: "We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration".

[55] The Director General of WTO emphasized the importance of this issue on the opening day of the Conference, indicating that agreement on public health and TRIPS was the "deal breaker" of the new round. Pascal Lamy, the EU Commissioner for Trade, stated at the Conference that "… we must also find the right mix of trade and other policies — consider the passion surrounding our debate of TRIPS and Access to Medicines, which has risen so dramatically to become a clearly defining issue for us this week, and rightly so".

when, upon request of the African Group, the Council for TRIPS agreed to deal specifically with the relationship between the TRIPS Agreement and Public Health.

Attempts to parallel import and compulsory license consistently with TRIPS were met with strong objections by state governments and the pharmaceutical industry in the period before the Doha Declaration.[56] One of the most publicized cases illustrating this clash of interests is the one concerning the South Africa's Medicines Act. In 1997, this African law was amended to permit parallel imports and compulsory licensing of pharmaceuticals.[57] The US Government denounced this measure as an infringement of patent rights and the Office of the Trade Representative (USTR) designated South Africa as a Special 301 "watch list" country[58]. At the time, this decision created a debate with so important dimensions that it is believed to have influenced the presidential campaign of former Vice-President Al Gore[59]. The dispute between the countries was basically on the access to drugs at affordable prices through the implementation of TRIPS flexibilities. With the South African recognition of the parallel importation and compulsory licensing of patented pharmaceuticals in its national law, 39 international firms, including the South African Pharmaceutical Manufacturers Association, sued the President Nelson Mandela and the South African Department of Health. This caused an enormous mobilization of the international civil society in favor of Mandela, which resulted on the removal of the legal action against the South African government. Another event that followed the same pattern was the introduction by the United States government of a complaint against the Brazilian government in front of the WTO dispute settlement system. The complaint also founded on the Brazilian attempts to introduce the TRIPS possibilities for compulsory licensing and parallel importing in its legislation.[60] This complaint was also withdrawn.

These are examples of the circumstances that contributed to the awareness that the TRIPS Agreement needed clarification, further discussion and empowerment. The developing countries sought a declaration, not because of the lack of clarity in the Agreement, but as a result of the obstacles that

[56] Roffe, Pedro (2005)

[57] A time line of the disputes over compulsory licensing and parallel importation in South Africa can be found at http://www.cptech.org/ip/health/sa/sa-timeline.txt (accessed in 10 January, 2008)

[58] Idem footnote 57. "April 30, 1999. USTR announces that South Africa is placed on the "watch list" in its Special 301 Review, and schedules an "out-of-cycle" review for South Africa to conclude in September 1999. According to USTR, South Africa's "barriers to trade" are parallel imports, compulsory licensing, registration of generic forms of Taxol, and speaking out at the World Health Assembly. "During the past year, South African representatives have led a faction of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS"."

[59] Abbot, Pedro (2005)

[60] The declared intention of the Brazilian government was to procure anti-retroviral at prices lower than those charged by patent owners, in the framework of its government-supported program against AIDS. The USA withdrew its complaint upon an agreement with the Brazilian government in March 2001.

the authorities in those countries had experience when trying to make effective use of such flexibility at the national level. At the time of the Doha Meeting, access to HIV/AIDS pharmaceutical treatment was (and still is) mostly critical for developing nations. What illustrates this affirmation is that by the end of 2005, 40.3 million people were living with HIV/AIDS, including 17.5 million women and 2.3 million children under the age of 15, 96% of people with HIV live in the developing world, most in the sub-Saharan Africa.[61]

The Doha Declaration includes preambular provisions[62], a provision aimed at confirming the interpretation of certain rules of the TRIPS Agreement[63] and two operative provisions requiring action by the council for TRIPS in relation to countries with no or insufficient manufacturing capacity in pharmaceuticals[64], and for the extension of the transition period for least developed countries (LDCs) in relation to the protection of pharmaceutical products[65]. The first paragraph of the Doha Declaration defines the problems there addressed:

> 1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

The reference to some specific epidemics in the text of the Declaration does not imply that the Declaration is limited to them. It covers any public health problem, including those that may be derived from diseases that affect the population in developing as well and developed countries, such as asthma or cancer. Also, although the access to medicines was the main issue that led to the Doha Declaration, it covers not only medicines, by any product, method or technology for *health care*. Which means that the Declaration applies to pharmaceutical products, processes and uses, surgical, therapeutic and diagnostic methods[66], diagnostic kits as well as medical equipment. And, even though patents are the focus, the Declaration apples to all areas of intellectual property covered by the TRIPS Agreement, including protection of test data submitted for the marketing approval of pharmaceuticals[67].

Paragraphs 2 and 3 of the Doha Declaration express the state members´ view with regard to the role of TRIPS and Intellectual Property Rights in the context of public health. The text of these paragraphs:

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[61] Global Health Council web page http://globalhealth.org/view_top.php3?id=227 (accessed in 01/02/2008)
[62] Doha Declaration, paragraphs 1 to 4
[63] Doha Declaration, paragraph 5
[64] Doha Declaration, paragraph 6
[65] Doha Declaration, paragraph 7
[66] According to Article 27.3(a) of the TRIPS Agreement, member states may exclude these methods from patentability.
[67] Doha Declaration, paragraph 7

> 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
> 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about it effects on prices.

With this statement, the Doha Declaration recognizes that the high prices of medicines caused by patent protection are part of the grave problems that afflict developing countries and least developed ountries and is a concern that needs to be addressed. The text of the paragraph 4 states de recognition that nothing in the TRIPS Agreement shall be interpreted as preventing state members from adopting measures necessary to protect public health, notably compulsory licensing and parallel imports. The text of the paragraph 4 reads:

> "4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members´ right to protect public health and, in particular, to promote access to medicines for all.
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

From this text it is possible to understand that the intention of the members was to indicate that in cases where there is conflict between intellectual property rights and public health, the former should not be an obstacle to the realization of the latter.[68] The Brazilian delegation at the Doha Ministerial Conference that:

> "… In the area of intellectual property, different readings of the TRIPS Agreement have given rise to tensions. To a certain extent, it is natural that conflicts of interests should reflect themselves in divergent interpretations of common rules. But the commercial exploitation of knowledge must not be valued more highly than human life. There are circumstances in which the conflict of interests will require that the State exercise its supreme political responsibility… Brazil promotes and upholds intellectual property rights… However, if circumstances so require it, Brazil, like many other countries, will not hesitate to make full use of the flexibility afforded by the TRIPS Agreement to legitimately safeguard the health of its citizens."

[68] Correa, Carlos M. (2002)

Before the Doha Declaration, it could be argued that the Article 8.1 of the TRIPS Agreement would mean that intellectual property could override public health. That is because one possible interpretations of this article is that public health and other reasons there enumerated permit member states to adopt measures such as commercialization and price controls but not to derogate obligations relating to the availability or enforcement of IPRs. With the paragraph 4 of the Declaration, however, it can be argued that the Article 8.1 of TRIPS would not prevent derogation from certain obligations under the TRIPS if necessary to address public health needs.

The paragraph 5 of the Doha Declaration reflects the concern of the state members with the concept of "flexibility" as applied to the obligations imposed by the TRIPS Agreement. In order to take advantage of these flexibilities, national laws must incorporate the appropriate rules in the form of compulsory licenses, exceptions and other relevant provisions. Those flexibilities are not automatically translated into national regimes and do not protect actors for legal actions based on national laws and regulations that fail to make use of the TRIPS Agreement's flexibilities.

The paragraph 5 o the Doha Declaration has four sub-paragraphs where each supplies a comment to different aspects of the TRIPS Agreement. To simplify the analysis, each sub-paragraph will be analyzed in separate.

> "5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
> a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

This sub-paragraph 5(a) stresses the importance of the Articles 7 and 8 of the TRIPS Agreement for the **interpretation** of the Agreement, especially in relation to the Article 31 of the Vienna Convention on the Law of the Treaties[69]. This means that not only the Doha Declaration can be regarded as

[69]Vienna Convention on the Interpretation of Treaties - Article 31 - General rule of interpretation:
1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;
(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
(a) any subsequent agreement between the parties regarding the interpretation of the treaty

a subsequent agreement to the TRIPS Agreement, having force of law. Also, that such rule should ensure that due deference to national law is given in appropriate cases; that is, that the flexibility given to member states is respected by the DSB.

> "5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (…)
> b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

This sub-paragraph may not develop any substantive means for the interpretation of TRIPS, but it specifically employs the expression "compulsory license", which is not employed in the TRIPS Agreement itself[70].

The **compulsory licensing** is one of the key instruments that may limit the exclusive rights of the patent owner when needs to fulfill certain objectives of public policy, particularly in order to ensure the availability of alternative sources for the supply of medicines at lower prices[71].

This sub-paragraph 5(b) states what is apparent from the Article 31 of the TRIPS Agreement. As seen in the previous section of this thesis, the Article 31 prescribes conditions for compulsory licensing, such as case-by-case determination; prior negotiation – in certain cases – with the patent owner; remuneration; time spam; etc. But it does not limit the grounds on which the compulsory licensing can be granted. Although mentioning some possible grounds for the granting of the licenses, such as emergency and anti-competitive practices, the TRIPS Agreement leaves its state members the freedom to stipulate other grounds, such as public health or public interest.

> "5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (…)
> c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent

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or the application of its provisions;
(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
(c) any relevant rules of international law applicable in the relations between the parties.
4. A special meaning shall be given to a term if it is established that the parties so intended.

[70] The Article 31 of the TRIPS Agreement uses "other use without the authorization of the right holder" to refer to "compulsory licensing".

[71] Velasquez G. (1999)

> a national emergency or other circumstances of extreme urgency."

This sub-paragraph 5(c) reaffirms the right, stated on Article 31(b) of the TRIPS Agreement, to determine "what constitutes a national **emergency** of other circumstances of extreme urgency" as an indubitable right of the member states. This sub-paragraph clarifies that a public health crises can represent a "national emergency or other circumstances of extreme urgency", thus permitting the granting of compulsory licenses when provided for under national law[72]. And, according to Article 31(b) of the TRIPS Agreement, this can be done without the prior negotiation with the patent holder. Furthermore, by referring to "HIV/AIDS, tuberculosis, malaria and other epidemics" as an emergency, signs that an emergency does not have to be a temporary problem, but rather a long-lasting condition, such as the situation of the epidemics mentioned in the sub-paragraph. This is important because it implies that the measures taken to deal with an emergency can be adopted and maintained as long as the underlying situation persists, without temporal limitations. And finally, the sub-paragraph 5(c) establishes that burden on the complaining about the qualification of a specific situation as a "national emergency or other circumstances of extreme urgency" is on the complaining member to prove that this emergency or urgency does not exist.

> "5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (…)
> d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish it own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

The parallel import under an international principle of **exhaustion** is another aspect regarded as a key component of a patent system sensitive to public needs. That is because this principle permits the import of a patented product into a country without the authorization of the titleholder or his licensees, to the extent that the product has been put on the market elsewhere in a legitimate manner[73]. This sub-paragraph support the state members that wish

72 A decision by the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) extended the transition period for least-developed countries to comply their national laws with the TRIPS by seven and a half years, and included commitments on technical assistance to help them prepare to apply the agreement. The transition period was due to expire on 1 January 2006; 11 years after the TRIPS Agreement came into force. Which means that least-developed countries will not have to provide the intellectual property protection, or the flexibilities, covered by the TRIPS Agreement until 1 July 2013 unless they graduate from being least developed. At present, 32 WTO members are least developed. This decision can be found at the WTO web page http://www.wto.org/english/news_e/pres05_e/pr424_e.htm

73 Velásquez, G. (1999)

to apply an international exhaustion principle, stating that is would be legitimate and fully consistent with the TRIPS Agreement to do so.

3 The Three Arenas

The law and the rights it creates and enforces, such as the intellectual property rights and other legal phenomena, are beliefs that have been established as norm and have been communicated and acted upon in different arenas of human existence.

Professor Ulf Petrusson clarifies the idea of intellectual property law being accepted as a norm because of successful communication of beliefs, when he states, "the acceptance of the fact that intellectual phenomena do not exist in themselves is the clarification of the fact that each individual has his or her own substantial perception"[74]. The intellectual property rights, such as patents, are the consequences of an acceptance by society of something that is claimed in different settings of the legal, political and business world. This acceptance can be the result of manipulation, repression or of the fact that the existence of the phenomenon is taken for granted. It is the result of a communicative effort invested upon the claimed rights. The intellectual property rights claims are validated in the daily conflicts and interactions between the stakeholders. For instance, if a patent is challenged in a legal procedure and the sentence for this procedure reinforces the legality of the patent, then the strength of this patent as an accepted norm is increased.

Professor Ulf Petrusson has developed a theoretical framework where the administrative, judicial and business platforms are three structural arenas that influence the present knowledge economy[75].

3.1 Administrative Arena

The actors in the administrative arena are governmental authorities necessary for obtaining certain legal status. Examples of such authorities are the Patent and Registration Offices and Tax Authorities. In order to have a patent granted, one must file for it at a Patent and Registration office and must fulfil the formal requirements for the application to be accepted[76]. Communicating with the Patent and Registration Offices the patentee will be forced to adjust his argumentation to the formal requirements of the institution in order to achieve his objective. The administrative arena is firmly based on the State, its institutions and regulations, its character allows to a lower level of flexibility.

3.2 Judicial Arena

The judicial arena – also called the legal arena in this thesis – primarily comprise of the courts, but also of its actors such as judges, lawyers and prosecutors. In the legal arena the legal status or rights are upheld and validated. When a patent is infringed, the rights holder can be forced to turn

[74] Petrusson, p. 103
[75] Petrusson, pp. 104, 105
[76] The formal requirements for patentability of an invention are novelty, industrial application and non-obviousness.

to the courts to stop the infringement. The infringer then might try to invalidate the patent, and the court will have to decide if the right will be upheld or invalidated. It is crucial for the intellectual property holders to understand the full extension of the legal norms that sustain this arena.

3.3 The Business Arena

The business arena itself consists of several structures and some of them are markets, innovations, networks, the media, etc[77]. Companies that have a strong focus and dependency on intellectual property rights, such as the pharmaceutical companies, it is important that the other actors in the business arena recognize their intellectual properties, because that reflects the possibility of conducting business altogether. If the intellectual property of an actor is perceived to be weak or non-existent it can have serious consequences to the core of the business.

The business arena is international and is more malleable than the other two. The business arena and the political one are closely related and, in this thesis, will be considered as one.

3.4 The Interaction Between the Three Arenas

In Professor Petrusson´s theory, the administrative and the judicial arenas are seen as supporting structures for the business arena[78]. The supporting structures also create a dependency because the construction process in the business arena will be dependent on how the communication is handled in the administrative and the judicial arenas. For instance, the claims in a patent application, the patent law and international agreements such as the TRIPS Agreement, will reflect in the business opportunities for the patent holder.

After the brief exposition of the TRIPS Agreement and the Doha Declaration in this thesis, it is possible to imagine the interaction between the legal and business arena, as well as the administrative aspects of these important international documents. The industry lobby, the national governments interests from both the developing and the developed world, and the legal and administrative protocols influenced the negotiation for the accomplishment of those agreements. For the construction of those statements, the communicative skills of each party played a role that drove the final decisions agreed upon by the member states.

In the following sections of this thesis, I will introduce the case of Thailand's compulsory licensing of HIV/AIDS patented drugs, and how in the interaction between the three arenas communication has been manipulated to support different interests.

[77] Petrusson p.106
[78] Petrusson p.106

4 Examples of Events Related to Compulsory Licensing of Patents

It is untrue that the granting of compulsory licenses is suspect under global trade rules. In fact, it is far more common than many news reports acknowledge. Indeed, the United States has issued several compulsory licenses since June 2006, including compulsory licenses that have benefited Microsoft, DirectTV, Toyota and Johnson and Johnson[79].

This chapter gives an account of some compulsory licensing of intellectual property events around the world, in developed and developing nations, successful and unsuccessful requests for compulsory licensing. One can find that there are compulsory licenses covering a wide variety of technologies, they are based on different legal mechanisms and grounded on different claims. The present account will not be exhaustive; it is intended to bring examples that are more directly related to the questions examined in this master thesis. For this reason, the examples hereby given will concern compulsory licensing of patents on public health interests. With the following information, the reader might share my reflection over which are the reasons why Thailand and Brazil have been subject of such criticism when they were not the only countries to use the compulsory licensing possibility.

4.1 United States of America

Under the USA Law 28 USC 1498, which concerns uses of patents or copyrights, when the use is by or for the government, the US government does not have to seek a license or negotiate for use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright. The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent the use. Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.[80] One example of the government use of this possibility occurred in 2001, when the Department of Health and Human Services (DHHS) Secretary Tommy Thompson used the threat of compulsory licensing to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.[81]

The Bayh-Dole Act gives the US government "march-in right"[82]. It allows

[79] James Love, Racist and Ignorant Reactions on Thailand Compulsory License: http://www.huffingtonpost.com/james-love/racist-and-ignorant-react_b_39618.html

[80] More information about the compulsory licensing for government use in the USA: http://www.cptech.org/ip/health/cl/us-1498.html (accessed in 10/02/2008)

[81] More information about the case known as the "Cipro Patent Dispute" can be found at http://www.cptech.org/ip/health/cl/cipro/talkingpoints.html (accessed in 09/02/2008)

[82] Complete information about the Bayh-Dole Act and the march-in rights can be found at http://www.cptech.org/ip/health/bd/ (accessed in 10/02/2008). Regulations governing the

the federal agency under whose funding agreement an invention was made the right to grant a license to a responsible new applicant if, among other things, the current manufacturer has failed to make the product available to the public on reasonable terms, 18 USC sections 201(f), 203(1)(a), or if action is necessary to alleviate health or safety needs which are not reasonably satisfied by the current manufacturer.[83] In 2001, DHHS used its authority to exercise march-in rights for patents on stem cell lines resulting from publicly funded research and held by the Wisconsin Alumni Foundation as leverage to secure an open license on those patents.[84]

In January 29, 2004, the non-profit corporation Essential Inventions petitioned the DHHS for compulsory licenses to manufacture and sell inexpensive generic versions of latanoprost (Xalatan)[85] and ritonavir (Norvir)[86]. Both drugs were developed with federal funding, and the government has rights through the Bayh-Dole Act to "march in" on the patent rights and license them to another producer. On August 4, 2004, the National Institute of Health (NIH) turned down the request for ritonavir. It has not yet responded to the latanoprost request.[87]

While public criticizing Thailand and Brazil for their compulsory licensing of drug patents, on the 12th of January 2007, Abbott Laboratories lost a bid in a US District Court (the Western District of Wisconsin) for a compulsory license on a patent held by Innogenetics, Inc. A judge and jury said Abbott infringed to manufacture and sell Hepatitis C virus (HCV) genotyping test kits. The compulsory licensing request was an effort to avoid an injunction that would prevent Abbott from using the Innogenetics patent without permission from the patent owner[88].

4.2 Canada

In September 2001, the Ontario Health Minister held a speech concerning the Myriad Gene Patent[89], calling for compulsory licensing of patents on

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procedures for the exercise of march-in rights are at 37 CFR section 401.6.

[83] 18 USC section 203(1)(b)

[84] Extensive discussion on this subject does still take place. Some information about the case can be found at Nature: Focus on Stemcells: http://www.nature.com/nature/stemcells/ (accessed in 10/02/2008)

[85] Xalatan is a medicine for the treatment of glaucoma http://www.drugs.com/xalatan.html

86 Norvir is an antiviral medication in a group of HIV medicines called protease (PRO-tee-ayz) inhibitors. http://www.drugs.com/norvir.html

[87] Miscellanea on Compulsory Licensing Programs: http://www.cptech.org/ip/health/cl/us-misc.html (accessed in 10/02/2008)

[88] Keionline: Abbott Recently Sought Compulsory License in US Patent Dispute: http://www.keionline.org/index.php?option=com_content&task=view&id=43 (accessed in 27/03/2008)

[89] Myriad Genetics Inc., in collaboration with the University of Utah, were the first to sequence the BRCA-1 gene, and applied for patent protection in 1994. Together with the University of Utah Research Foundation and the United States of America, Myriad holds U.S. patents 5747282 and 5710001 on the isolated DNA coding for a BRCA-1 polypeptide and on a screening method. In 1997, together with the Centre de Recherche du Chul in Canada and the Cancer Institute of Japan, they received patent protection on an isolated DNA sequence, asserting rights over a number of mutations in the gene (U.S. Patent

genes relevant to tests for breast cancer. In January 2002, the Ontario Advisory Committee on New Predictive Genetic Technologies published the "Ontario Report to Premiers: Genetics, Testing & Gene Patents: Charting New Territory in Healthcare",[90] which noted that the Doha Declaration calls upon nations to make measures "to protect public health and, in particular, to promote access to medicines for all". Concerning the compulsory licensing, the report concludes:

> "In order to prevent the statement for providing a hollow right, the concept of promoting access to medicines for all must include providing access to the diagnostic procedures necessary to determine when and which medicines to provide. The federal government should, therefore, amend the Patent Act to specifically allow the potential for compulsory licensing of patent relating to the provision of genetic diagnostic and screening test should this power be necessary."[91]

On May 14, 2004, Canada passed BILL C-9, an Act to amend the Patent Act and the Food and Drugs Act, with the purpose to allow Canadian manufactures to export medicines to countries lacking manufacturing capacity. Proposed royalties paid to the patent holder vary according to the importing country's Human Development Index[92]. The benefits of the Act are limited to products listed on "Schedule 1", the list of patented pharmaceutical products that are eligible to be exported under the compulsory license.[93] On October 2007, Canada became the first country to authorize a company to make a generic version of a patented medicine for exporting. The drug, a fixed dose combination product of zidovudine, lamivudine and Nevirapine, is a HIV/AIDS treatment being produced in Canada by Apotex INC, under the name ApoTriavir. It will be exported to Rwanda that said to have the intention to initially import 260.000 packs of the medicine during two years time[94]. A notification to the WTO authorities completes the legal formalities allowing the export. This is the first country

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5693473). Further patent applications were filed on the second gene, BRCA-2, in the U.S. and in other countries (US Patents 5837492 and 6033857).

[90] The full version of the report can be found at http://www.who.int/genomics/elsi/regulatory_data/region/amro/014/en/index.html (accessed in 02/02/2008)

[91] "Ontario Report to Premiers: Genetics, Testing & Gene Patents: Charting New Territory in Healthcare", p.79.

[92] The Human Development Index (HDI), published annually by the UN, ranks nations according to their citizens' quality of life rather than strictly by a nation's traditional economic figures. The criteria for calculating rankings include life expectancy, educational attainment, and adjusted real income.

[93] The Canadian Act to amend the Patent Act and the Food and Drugs Act can be accessed at http://www.parl.gc.ca/common/Bills_ls.asp?Parl=37&Ses=3&ls=C9

[94] Reuters: "Canada grants patent waiver for Rwanda AIDS drug", at http://www.reuters.com/article/health-SP/idUSL0521156720071005 (accessed in 01/11/2007) and "Canada confirms to WTO it will be first to export cheap, generic AIDS drugs" http://aol.mediresource.com/channel_health_news_details.asp?news_id=13514&news_channel_id=16&channel_id=16&relation_id=10584 (accessed in 02/11/2007)

to take action regarding the WTO agreement[95], which has the purpose of facilitating for countries with public health problems to import less expensive generic drugs made under compulsory licensing when they are unable to manufacture the medicines themselves.

4.3 European Union

The subject of compulsory licensing of intellectual property rights and competition law is complex, both under the TRIPS Agreement and the European Law. A number of decisions by the European Court of Justice provide some clarity to the issue. However, as competition law is not the focus of the present study and it would demand specific study and research, I refrain from commenting on this particular modality of compulsory licensing within the European Union.

Nevertheless, compulsory licensing of patented pharmaceutical products is an issue considered with careful attention by European Law. An example of that is the European Community Regulation of the European Parliament and of the Council of 17 May 2006 on "Compulsory Licensing of Patents relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems" [96]. This regulation has the purpose of promoting the harmonization, within the European Union, of the conditions for granting compulsory export licenses for companies that intend to manufacture generic medicinal products for export to developing countries which do not have sufficient production capacity of their own. The regulation also aims to prevent distortion of competition among operators in the single European market and to apply uniform rules in order to avoid the re-import into the European Union of pharmaceutical products manufactured under the compulsory export licenses.

4.4 France

France amended its law No. 92-597 of July 1, 1992,[97] on the Intellectual Property Code to allow the broader use of compulsory licenses – referred to as "ex-officio licenses", and in particular, to authorize the government to issue ex-officio licenses to patents on certain diagnostic technologies. The article L. 613-16 of the amended law provides that:

> "Where the interest of public health demand, and in the absence of a voluntary agreement with the patent holder, the minister responsible for industrial property, may, by order of the minister responsible for public health, request ex-office licenses in accordance with Article L, 613-17 for any patent granted for: a) a medicine, a medical

[95] This WTO agreement, so called "the August 30 WTO deal", can be found at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed in 06/01/2008)
[96] Accessible at http://europa.eu/scadplus/leg/en/lvb/l21172.htm (accessed on 9/02/2008)
[97] A version in English of the French intellectual Property Law can be found at http://www.cptech.org/ip/health/cl/france1.html (accessed in 11/02/2008)

> device, a medical device for in vitro diagnosis, a related therapeutic product; b) processes for obtaining them, or for products necessary in obtaining such medicines of for processes for manufacturing such products; c) a diagnostic method ex vivo." [98]

In October 2001, several notices of opposition to the European patent EP 699 754 held by Myriad Genetics relating to a "method for diagnosing a predisposition for breast and ovarian cancer" were filed at the EPO. In France, the Institut Curie, the Assistance Publique–Hôpitaux de Paris and the Institut Gustave-Roussy, filed a joint notice of opposition. The French Federation of Cancer Centers and the French Hospital Federation, the French Ministries of Public Health and Research, and the European Parliament supported this initiative. Further notices of opposition were filed by a group led by the Belgian Society of Human Genetics that included Belgian and Dutch human genetics centers, as well as by the genetics societies of Germany, Denmark and Great Britain.[99] In a *Communiqué* issued by M. Roger-Gérard Schwartzenberg, the Minister for Research of the French government, he stated that the government was "considering an ex officio license" of the Myriad Genetics' diagnostic testing.[100] In this statement he says:

> "From now on, where the interests of public health demand, in the event of a diagnostic test being made available to the public in insufficient quantity, of inadequate quality or at an abnormally high price, the State will be able to make this test subject to an ex officio license."

4.5 Italy

On February 8, 2006, the Italian Competition Authority (AGCM) closed the investigation into the Glaxo Group's refusal to grant a license to Fabbrica Italiana Sintetici SpA (FIS), for the manufacture in Italy of an active ingredient, Sumatriptan Succinate, used in the production of migraine medicines. According to the AGCM press release[101]:

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[98] vide footnote 84.

[99] More information at www.curie.fr and the patent files and oppositions can be found at www.european-patent-office.org (accessed in 11/02/2008)

[100] The communiqué can be read at http://www.ambafrance-uk.org/Myriad-Genetics-diagnostic-testing.html (accessed in 11/02/2008).

101 AGCM. February 21, 2006. Press Release: Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued. Granting license opens way for manufacture of generic migraine drugs. http://www.agcm.it/agcm_eng/COSTAMPA/E_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/634fe21dc342c220c125711d003692c3?OpenDocument&Highlight=2,patent (accessed in 06/01/2008)

> "To remedy the earlier refusal to license, Glaxo granted the licenses originally requested by FIS, but also set conditions such as to allow the time to be made up which had been lost because of the original refusal. Those conditions include the granting of a number of additional procedural licenses, whereby Glaxo has allowed FIS to save the time otherwise required to research and test and efficient manufacturing process for Sumatriptan Succinate. FIS will this be enabled to offer the active ingredient to manufacturer of generics as early as if Glaxo had never refused the original request for a license".

The AGCM sought to prevent delays in bringing generic pharmaceutical to market, thus paving the way for substantial price reductions. FIS initially used the compulsory license entirely for the export market, supplying generic firms that were selling products in markets outside of Italy (such as Spain), where the patents had expired. It did so outside of the framework of the WTO August 30, 2003 decision on exports on medicines manufactured under a compulsory license[102], which Spain and other EU members had "opted out" as an importer. This was possible in part because the TRIPS waives all restrictions on exports in cases where the licenses were issued to remedy to anticompetitive practices.

Another case of compulsory licensing that took place in Italy, from March 21, 2007, when the AGCM required Merck to "grant free licenses to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate"[103] Finasteride is the active ingredient of a drug marketed initially under the brand name Proscar and Propecia. It is used to treat hypertrophy of the prostate, cancer of the prostrate and male-pattern baldness. The Merck royalty free compulsory licenses were remedies to Merck's earlier refusal to license the patents to Italian manufactures of active pharmaceutical ingredients. Again, the licenses anticipate exports to other European countries.

4.6 Germany

On May 2001, Roche and Chiron reached a licensing agreement for patents on blood screening HIV probe, held by Chiron. With this agreement Roche ended its attempts to obtain compulsory licensing of those patents, which it was doing by means of undertaking the German government to issue a compulsory license for those patents. Chiron and Roche had pending

[102] To be found at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed in 06/01/2008)

[103] AGCM Press Release – Merck – Active ingredients (conclusion of investigation): antitrust authority rules Merck must grant free licenses for the active ingredient Finasteride http://www.agcm.it/agcm_eng/COSTAMPA/E_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/28653b373e56772ac12572ab003a4d68 (accessed in 07/01/2008).

litigation in the USA, Italy, Japan, the Netherlands, Belgium, Germany and Australia regarding the HIV testing technology. Among other provisions of the agreement that settled the dispute, Chiron agreed to grant Roche licenses to manufacture and sell the diagnostic tests.[104]

4.7 India

In February 2005, India amended its patent law, to provide for patent protection for pharmaceutical inventions. The legislation created a mandatory compulsory license for products that were already manufactured and marketed in India. The new provision was added under Section 11 A of the Indian Patent Act read as follows:

> (7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application:
> Provided that the applicant shall not be entitled to institute any proceeding for infringement until the patent has been granted:
> Provided further that the rights of a patentee in respect of applications made under sub-section 2 of section 5 before 1st January, 2005 shall accrue form the date of grant of the patent:
> Provided also that after a patent is granted in respect of application made under sub-section 2 of section 5, **the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceeding shall be instituted against such enterprises"[105]** (emphasis added)

Supported by its national law, the Indian generic-drug industry is one of the largest in the world. As of March 2008, the first compulsory licenses to be issued by the country that were not automatic due to the 2005 law, are of product process patent on two cancer treatment drugs. The Indian Natco Pharma, filed an application for compulsory licensing those medicines that should be exported to Nepal[106].

4.8 Indonesia

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[104] More information and a copy of the license agreement that settled this dispute can be found at http://www.cptech.org/ip/health/cl/recent-examples.html (accessed in 03/02/2008).
[105] The Indian Patent Act 2005, available at http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf
106 The Wall Street Journal: Keen Wait for Outcome of First Case on Compulsory License: http://www.livemint.com/2008/03/06231231/Keen-wait-for-outcome-of-first.html (accessed in 20/03/2008)

On October 5, 2004, Indonesia issued a government use compulsory license to manufacture generic versions of two HIV/AIDS drugs, lamivudine and nevirapine, until the end of the patent term in 2011 and 2012 respectively. The license includes a royalty rate of 0.5% of the net selling value [107] Production of the ARVs has started by PT Kimia Farma.

4.9 Malaysia

On September 29, 2004, the Malaysian Minister of domestic Trade and Consumer Affairs issued a two-year government use compulsory license to import from India didanosine (ddl), zidovudine (AZT) and lamivudine + zidovidine (Combivir) [108]. The Ministry of Health proposed a royalty rate of 4% of the value of the generic product.

4.10 Taiwan

On November 2005, Taiwan issued a compulsory license for patents needed to manufacture and sell generic versions of Tamiflu, a drug for the treatment of avian flu. Taiwan was the first country to employ compulsory licensing to ensure sufficient stockpiles of the drug in the event of a pandemic. However, in an attempt to prevent damage to Taiwan's image in the protection of intellectual property rights, the cabinet's Intellectual Property Office (Tipo) attached a number of conditions to the compulsory license, which officials said would ensure that Roche would not lose profits[109].

[107] Translated text of the license is available at http://www.lists.essential.org/pipermail/ip-health/2004-December/007233.html

[108] Translated text of the license is available at http://www.cptech.org/ip/health/c/malaysia/arv-license.html

109 Financial Times: Taiwan Employs Compulsory Licensing for Tamiflu http://www.ft.com/cms/s/0/cebeb882-5dcb-11da-be9c-0000779e2340.html

5 Thailand's compulsory licensing of HIV/AIDS patented drugs

One of the most important existing medicines for human immunodeficiency virus infection, the HIV, is efavirenz, a non-nucleoside reverse-transcriptase inhibitor that is available since the late 1990s. The efavirenz, in combination with two other medicines, "has become a standard-of-care comparator in clinical trials"[110]. The efavirenz is more complicated to manufacture than some other antiretroviral drugs, therefore it is relatively expensive, particularly for low - and middle – income countries.

In 2006, first-line treatment regimens, that contain, amongst other drugs, 600mg of efavirenz, the usual daily dose for adults, had a median cost of nearly $500 per patient per year in low – and middle - income countries, which represents more than three times the price of some other alternatives[111]. Low-income countries are those with a 2005 gross national income of less than $875 per capita, and middle-income countries are those with a 2005 gross national income of $876 to $10,725 per capita, as defined by the World Bank[112]. In the United States, where Bristol-Myers Squibb markets efavirenz as Sustive, a one-year supply costs about $6,000. In 2006, Merck's official price for the 600-mg of efavirenz in least developed countries was $277 per patient per year. In middle-income countries with an HIV prevalence rate among adults of 1% or greater, such as Thailand, it was also $277.

Since October 2003, Thailand has had a policy of universal coverage for antiretroviral treatment and patients receive their drugs free of charge from the government. Their goal is to reduce the price of efavirenz so the government could provide the medication to additional patients while remaining within its budget for the treatment of HIV/AIDS. At the end of 2005, the estimation was that 580,000 Thais were living with HIV infection[113]. According to the World Health Organization, in June 2006 estimated 89,000 Thais were receiving antiretroviral therapy, which represents about four fifths of those who actually needed it, but less than one quarter of those received regimens that included efavirenz. The majority of the patients received the drug nevirapine, a less expensive non-nucleoside reverse-transcriptase inhibitor that can have negative side effects, including severe rash and hepatotoxic effects[114].

To increase the reach of the treatment with efavirenz so the majority of the patients would have access to it, the Thailand's Ministry of Public Health

[110] Hammer SM. (2006)
[111] Steinbrook, R. (2007)
[112] Data are from the World Health Organization's Global Price Reporting Mechanism on Antiretroviral Drugs. Summary of the report can be found at http://www.who.int/hiv/amds/GRPM_april2006.pdf (accessed on 21 August, 2007)
[113] Data extracted from the Joint United Nations Program on HIV/AIDS. (Accessed in 21 August, 2007) At http://www.unaids.org/en/Regions_Countries/Countries/thailand.asp
[114] World Health Organization. Antiretroviral therapy for HIV infection in adults and adolescents: towards universal access: recommendations for a public health approach. 2006 Revision. At http://www.who.int/hiv/pub/guidelines/en/ (accessed in 21 August, 2007)

issued a compulsory license for the efavirenz[115]. The license had immediate effect and will last until December 31, 2011. It permits the Thai Government Pharmaceutical Organization to import generic efavirenz from India, where the drug is not patented, and also to produce the drug at a time when Merck still has it patented in Thailand.

The consequences of Thailand's action transcend efavirenz and HIV itself. That is because the same rationale Thailand has used to issue this compulsory license can be used again by Thailand itself or by any other country to license additional HIV drugs; drugs for other infectious diseases with public health consequences i.e. malaria, tuberculosis, influenza; or drugs for cancer and other chronic diseases.

Thailand has not only compulsory licensed the patent on the efavirenz. The same was done with Kaletra, another anti-HIV/AIDS drug patented by the US pharma major Abbot Laboratories; and with Plavis, a blood thinner made by Sanofi-Aventis. Thailand's actions in testing and winning the right to use compulsory licenses has received much praise from a large section of activists, patients and academics at home and abroad, it has also received a lot of public criticism and retaliation.

5.1 The Thai National Law regarding Compulsory Licensing

To have the authority to issue a government-sue compulsory license under its own law and to be able to justify it by the flexibilities of the TRIPS Agreement and the statements of the Doha Declaration, as see before, Thailand must have complied with the Agreement in its own national law, adding to it the specificities of the international agreement.

Section 51 of the Thai Patent Act[116] makes clear that the Thailand Department of Disease Control is well within its rights in granting a license for the public purchase and use of generic patented drugs, such as the efavirenz, without further negotiation with the patent holder. The patent holder is given a right to appeal the terms of the license, including its royalty rate. The Department may, however, use the license to begin purchase of generic versions of patented medicines immediately, regardless of whether any dispute may exist or arise as to the reasonableness of the royalty or other terms established in the license.

On 29 November 2006, the Director General of the Department of Disease Control of Thailand announced that is was authorizing the public use of

[115] Announcement of the Department of Disease Control, Ministry of Public Health, Thailand, on the public use of patents for pharmaceutical products. November 29, 2006. At http://www.cptech.org/ip/health/cl/recent-examples.html (accessed on 21 August 2007)

[116] Thai Patent Act B.E.2522

patents on efavirenz to serve its national treatment plan.[117] This notice, grounded by the Article 51 of the Thai Patent Act, states:

> By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), the Department of Disease Control, Ministry of Public Health, thus use the patent right of a medicine called Stocrin® (or efavirenz as a generic name) and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contained within Paragraph 1 of Article 36 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) under these conditions:
> (1) The use of the above patent rights is effective from today to the 31st December 2011.
> (2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 200,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employees medical benefits scheme.
> (3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value of the imported or locally produced Efavirenz will be paid to the patent holder.
>
> The Department of Disease Control, Ministry of Public Health will notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.

Section 51 of Thailand's Patent Act states the right of "any ministry, bureau or department of the Government" "by themselves or through others," to exercise the rights in any patent "for public consumption." This section reads:

> In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay,

[117] The full notice can be found at http://www.cptech.org/ip/health/c/thailand/thaicl4efavirenz.html

> notwithstanding the provisions of Section 46, 47 and 47bis.
> In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis.

This legal provision authorizes the government to use compulsory licensing of patents to carry out any service for public consumption or to meet a list of specific public needs, including to prevent or relieve a severe shortage of drugs or other consumption items. The public notice as showed above contains appropriate statements invoking these authorized grounds. The notice also explains that the license is being used to help carry out a service for public consumption. It tells that the license will be used only for public health services and therefore is clearly aimed for non-commercial purposes and for public interests. This would be sufficient ground for the allowance of the compulsory license. As seen before in the section concerning the Doha Declaration, the WTO state members are not obliged to use the compulsory licensing of patents only in emergency situations of extreme public need, using the license to support a public program that responds to a public need is sufficient ground to justify the issuance of the license.

Nevertheless, the public notice[118] also brings a second ground for the license: to prevent or relieve a severe shortage of drugs or other consumption items. As seen before in this section, the license was needed to solve a shortage of efavirenz for the public treatment programs for the Thai HIV/AIDS patients. The notice explains:

> More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2006 (B.E. 2549) is only 2,796.2 million baht for the target group of 82,000 patients.
>
> The Thai Government has launched a policy of universal access to anti-retroviral since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get access to some effective and safer anti-retroviral. The high price of these patented anti-retroviral has hindered their accessibility under the universal access policy.

[118] Idem footnote 68

> Efavirenz is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of Anti-retroviral. However, the price of the patented Efavirenz is twice of those generics produced by WHO certified GMP factories in India. With this higher price, the budget allocated from the Thai Government can only supply some patients with Efavirenz, whereas the rest has to use other non-patented and more toxic anti-retroviral.

Even though the compulsory license for efavirenz seems to be limited to use in the public health system, according to the Section 51 this use is not necessarily restricted to the public sector. The Thai law states that the purpose of these licenses is to address "a severe shortage of (…) drugs or other consumption items". Hence, Section 51 could be used to authorize a compulsory license for use in the private sector as well, if the purpose is to address a shortage of needed medicines.

Concerning the requirements for prior notice to the patent holder, Section 51 does not require prior negotiation with the patent holder. It requires that the licensing authority "notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis". The exemption from the requirements of Sections 46, 47 and 47bis make clear that the government is not required to wait until "the expiration of three years from the grant of a patent of four years form the date of application", nor to have "made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances."

Regarding the question of royalties, still the Section 51 states that the ministry issuing the patent "shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General". The royalty rate and terms must be either "as agreed upon by the ministry or bureau or department and the patentee or his licensee," or set in the of Section 50, which "shall apply *mutatis mutandis*[119]" The reference to Section 50 means that the authorizing ministry has the right to set a royalty absent agreement with the patent holder, which can be subject to appeal. It states the right of the Director General to set a royalty rate.

The Department of Disease Control fixed a royalty and prescribed conditions of the license in its public notice and stated the intent to "notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately". The negotiations over the terms and royalty of the license should follow the public notice.

If the patent holder and the government would not reach an agreement on the terms and royalty of the license, the patent holder can file an appeal of such terms without affecting the right of the Department to use the compulsory

[119] mutatis mutandis, i.e. with the necessary changes.

license immediately, that is, to purchase the generic medications for its treatment program[120]. The ultimate decision to issue a compulsory license seems to be definitive according to the Thai law.

5.2 Public Reaction

The account of opinion expressions concerning the Thai compulsory licensing activity in the English speaking media is quite extraordinary. It denotes an important effort from both sides of the conflict to captivate the mass preference. In one side, the pro-pharmaceutical companies lobby attempt, at all costs, to demoralize the Thai government and its activities regarding health care system, and the intellectual property system of the country as a whole. On the other side, stand a myriad of activists, academics and government representatives, supporting and admitting to be inspired by the Thai actions.

In this section I will give not but few examples of these two contrasting sides of the public opinion. With this, I intend to demonstrate how the business arena has been moved and manipulated so to disrupt the public understanding of the legal reality, that is, the international understanding expressed in the letters of the TRIPS Agreement and the Doha Declaration. The attempts to convince the public against the rightfulness of the Thai compulsory licensing can indicate a real life expression of the theory of the three arenas[121].

After the notification of the compulsory licensing, the United States government admitted that Bangkok had not violated any laws under the special provisions of the TRIPS[122]. However, the US Trade Representative's Office (USTR) placed Thailand on the 2007´s list of countries that, in general, violate intellectual property rights, the US Government's Priority Watch List[123]. "While the US acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern" [124], states the report, yet without clarifying which were the actions that lacked transparency or due process. Apparently the US wanted Thailand to negotiate with drug companies before issuing a compulsory license, an

[120] Section 50 of the Thai Patent Act states in relevant part: "The decision of the [Department] made under the first paragraph of the Section is appeal able to the Board within sixty days from the date on which such decision is received."
[121] As previously seen in the Section 3 of this thesis.
[122] The copies of the documents sent to the Thai Government by the Congress of the United States, reaffirming Thailand's right to issue the compulsory licensing can be found in the Appendix, Documents I and II.
[123] Announcing the 2007 Special 301 Report, the USTR lists the countries that were "elevated" to the list and those that remain. As well as those that are under "watch". http://www.ustr.gov/Document_Library/Press_Releases/2007/April/SPECIAL_301_Report.html
[124] The USTR 2007 Special 301 Watch List http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file884_11123.pdf

action TRIPS does not require and something Thai officials claimed they tried to do unsuccessfully for two years before issuing the licenses[125].

Another pungent criticism came in the form of a campaign against the actions of the Thai government that ran in advertisements in the Bangkok Post, the Port Today, the Wall Street Journal and other vehicles of the international media. This campaign was leaded by the organization called "USA for Innovation". This organization was apparently lobbying for the US pharmaceutical companies. The only proofs of its existence were a website, a telephone number and an email address[126]. The leader of the USA for Innovation was known to be the former United Nations ambassador Ken Adelman; he is also a senior counselor public relations for a number of drug companies. The campaign states that the actions of the Thai government "hurts Thai patients" and "most of Thailand's AIDS patients will not have access to the world's best medicines". The USA for innovation have launched a website www.thailies.com, which is also out of service today[127]. However, before the web site was extinct, the texts of the posts were copied. The posts in this website accused 10 supposed lies told about the Thai government. An example of the content of this[128]:

> "Is Thailand a poor country that cannot afford Western medicines? In fact, just the opposite is true. Thailand has the 21st largest economy in the world when measured by gross domestic product (GDP) derived from Purchasing Power Parity (PPP) calculations. According to the CIA World Fact Book 2007, Thailand's economy is more productive than over 200 countries -- placing Thailand among the top ten percent of richest countries in the world.
> Earlier this month USTR noted that Thailand continues to suffer from "widespread commercial IPR counterfeiting and piracy." The new Thai military regime, which assumed power by coup last September, has now introduced direct government theft of American innovation into the quickly deteriorating U.S.- Thailand relationship through its theft of the intellectual property of three drugs produced by American and European companies."

The pro-pharmaceutical website claimed that "Thailand's actions violate the TRIPS agreement of the WTO" and "WTO members are not allowed to issue compulsory licenses without full and transparent negotiations". After

[125] IP Watch: Thailand Presents Report on Compulsory Licensing Experience http://www.ip-watch.org/weblog/index.php?p=563
[126] The web site is no longer accessible, but a copy of the referred advertise can be found in the Appendix, Document III.
[127] The USA for Innovation story, provided by 2Bangkok.com, can be seen in the Appendix, Document IV.
[128] More samples of the content of the "thailies.com" website can be found in the Appendix, Document V.

accusing the Thai Public Health Ministry of "threatening to kidnap American tourists", the advertisement goes on to say that the Thai government was "stealing American assets for military benefit". The propaganda went on to state that most Thais that suffer with HIV/AIDS would "not have access to the world's best medicines", because they would be treated with locally manufactured drugs, such as the GPO-Vir. The GPO-Vir is a HIV/AIDS treatment manufactured by GPO, the agency claims that the resistance rate for the drug is of 15%, while a study by the Mahidol University has found that the resistance rate is between 39,6% and 58%.[129]

The criticism against the compulsory licensing of drugs adeptly fluctuates between fact and fiction, mixing legitimate concerns about democracy and military spending with half-truths about the legality of compulsory licensing and the costs of medicines in Thailand. An article published by the Wall Street Journal, amongst other vehicles, by Franklin Cudjoe, from Accra, Ghana, entitled "Curing the Diseases of Poverty"[130], states

> "Last year, the Thai military government declared that it could not afford branded drugs to treat its citizens. So it issued compulsory licenses or patent suspensions, for two AIDS medications and one heart drug and began producing copies locally. Though the quality of the drugs was unknown, the move was hailed by activists as a victory for "patients over patents". But the generals weren't really worried about patients. If public health concerns had been the prime motivation, the Thai government wouldn't have refused the massive price reductions the patent holders had offered.
> (…)
> Far from noble act, Thailand's compulsory licensing was a bold power play to beef up local manufacturing and generate revenues for a corrupt state. Unfortunately for Thai AIDS patients, producing the drugs locally has proved prohibitively expensive and has sharply limited their supply."

Contrasting examples to the above mentioned are the statements that praise and support Thailand's compulsory licensing policy, which have also been significant. "Medicines are a substantial element of health care costs, and it is entirely appropriate and necessary for the government of Thailand to find means of reducing these costs to ensure sustainable financing of health care", said a February letter to the Thai government written by the WHO director-general Dr Margaret Chan, which added that the compulsory

[129] Bangkok Post: GPO may sue US lobby firm (accessed in March 10, 2008) http://www.biothai.org/cgi-bin/content/news/show.pl?0466 and FTA Watch Group: PR War Over Cheap Drugs Causes Anger (accessed in March 10, 2008) http://www.ftawatch.org/cgi-bin/content/newse/show.pl?0745

[130] The Wall Street Journal: Curing the Diseases of Poverty (accessed in January 10, 2008) http://online.wsj.com/article/SB119430106912883083.html?mod=googlenews_wsj

licenses were "fully in line with the TRIPS agreement"[131]. The following fragment of this letter expresses the position of WHO regarding compulsory licensing of medicines and is a good example of the contrasting reactions to Thailand's actions.

> "WHO unequivocally supports the use by developing countries of the flexibilities within the TRIPS agreement that ensure access to affordable, high quality drugs. This includes the use of compulsory licensing, as described in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The decision whether to issue a compulsory license for a pharmaceutical product is a national one. There is no requirement for countries to negotiate with patent holders before issuing a compulsory license. As a global community we need to ensure the right balance between the immediate and urgent pressing need to provide affordable medicines to the many that need them and the need to provide continuous incentives for innovation."

"This can set a precedent, a new understanding, about what developing countries can do under TRIPS", stated Jacques-Chai Chomthongdi, a researcher at Focus on the Global South, a Bangkok-based think-tank. He also said "this is to the advantage of developing countries". Paul Cawthorne of the Medicins Sans Frontieres (MSF) added "other countries will feel more confident in issuing compulsory licenses, rather than threatening to issue them but not doing so due to pressure" [132].

An article by Lara Santoro, published by the Los Angeles Times in 9 October 2007, argued that, "Cheap HIV drugs are more important than patents"[133]. She affirms, "Thailand's move was, and remains, in perfect observance of international Law". She wrote that the Thai government's attempt to acquire a lifesaving drug has caused corporate indignation and government censure not for the standard reason that without the protective role of patents drug makers would fail to recover their research and development costs and consequently stop pursuing new drugs, she claims this cannot be true because "more than half of all antiretroviral drugs patented in the US were researched entirely on US government grants, public money". According to Santoro, the real reason is that "The pharmaceutical industry lives in fear of a cheap drug domino effect. Thailand's compulsory license could inspire the entire continent of Africa – where 70% of the world's 40 million HIV/AIDS cases are found – to issue for a series of drugs".

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[131] A copy of the letter can be found in the Appendix, Document VI.

[132] Human Rights Tribune: Thailand Turns Giant Pharma Killer http://www.humanrights-geneva.info/article.php3?id_article=1649

[133] Los Angeles Times: Cheap Drugs are More Important than Patents http://www.latimes.com/news/opinion/la-oe-santoro9oct09,0,432447.story

The Financial Times published in September 2007 and article called "Big pharma chiefs must look at the world differently to meet health challenges"[134], by Alex Hsieh. He wrote about an interview given by Tachi Yamada, the global health chief of the Bill and Melinda Gates Foundation, he is the for research and development director of GlaxoSmithKline. Dr. Yamada said that "the pharmaceutical industry's future success will require a new generation of executives who can find a fresh way to look at the world's health challenges and its neediest countries", and "pharma was an industry n which it was almost too easy to be successful. It was a license to print money. In a way, that is how it lost its way. (…) It lost contact with the people it was supposed to serve". The author writes that this statement is "best illustrated by the recent spate of compulsory licensing – when poor countries react against pharmaceutical companies´ pricing for crucial drugs, such as HIV/AIDS, by breaking patents".

The discussion is ongoing more than one year after those events took place. The above were only few examples of the statements given at the time of Thailand's compulsory licensing for the three stated drugs. But then, why was the public reaction so strong concerning Thailand's actions? That was not the first and only time compulsory licensing ever took place in the pharmaceutical industry. The following section will give some examples of other countries that also made moves towards this option.

[134] Financial Times: Big Pharma Chiefs must "look at world differently" to Meet Health Challenges
http://pharmaceuticalengineering.blogharbor.com/blog/_archives/2007/9/30/3262801.html

6 Brazil's Compulsory Licensing on HIV/AIDS Patented Drugs

Brazil and Thailand are two of the possibly most controversial countries when it comes to the dealing with patented drugs. Brazil has taken a different path than Thailand did, having finally issued the first compulsory license of a medicine some days after Thailand did so. Previously, Brazil used to "threat" to compulsory license to achieve an advantage in negotiations with the pharmaceutical companies for reduced royalties.

Due this Brazil's threatening, 12 days before President Clinton left office, on January 8, 2001, the USTR filed a complaint against the Brazilian compulsory licensing law in the WTO Dispute Settlement Body[135]. USTR officials called this the "Merck case". The matter was the Article 68 of the Brazilian Patent Act[136], which allows compulsory licenses to be issued in situations where the patent holder does not locally manufacture the patented product (the "local working provision"). The US received a large amount of negative publicity, and on June 25, 2001, the Bush administration withdrew the complaint, after negotiating an agreement with Brazil[137]. Under this agreement, Brazil agreed to provide the US with advance notice if a license is issued under Article 68 of the Brazilian Patent Act, and disputes would be discussed through a bilateral "Consultative Mechanism". The agreement was not made public.[138]

On August 22, 2001, Brazilian Health Minister José Serra announced that the government would issue a compulsory license for the manufacture of the antiretroviral drug nelfinavir, made by Roche and marketed under the name Viracept, for the Brazilian pharmaceutical producer Far Manguinhos, in order to bring costs down 40 percent[139]. On August 28, the two parties resumed talks, and on August 31, they reached an agreement. Roche would sell the drug in Brazil at an additional 40% discount, and Brazil would not issue the compulsory license. This agreement was seen as a relief to the pharmaceutical industry. Already then, the fear was that, if Brazil had carried out its threat to ignore Roche´s patent on Viracept, a host of other developing countries might have followed its lead and begun manufacturing patented drugs for AIDS and other diseases[140].

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[135] The request can be read at http://www.cptech.org/ip/health/c/brazil/Req4EstabPanel.html (accessed in 11/02/2008)

[136] A version in English of selected Compulsory Licensing, Government Use, and Notable Patent Exception Provisions of the Brazilian Intellectual Property Law at http://www.cptech.org/ip/health/cl/brazil1.html (accessed in 11/02/2008)

[137] BBC UK news: US drops Brazil Aids drugs case http://news.bbc.co.uk/2/hi/business/1407472.stm

[138] New York Times: Brazil's AIDS Chief Denounces Bush Position on Drug Patents http://www.nytimes.com/2001/05/03/world/03NATI.html?ex=1202878800&en=aa0ad7ecbac5a923&ei=5070 (accessed in 12/02/2008)

[139] Reuters news: Brazil to Violate Roche Patent on AIDS Drug http://www.cptech.org/ip/health/c/brazil/reuters08222001.html

[140] The New York Times news: Roche reaches accord on drug with Brazil http://query.nytimes.com/gst/fullpage.html?res=9F01E4DC1130F932A3575AC0A9679C8B63

On September 5, 2003, the Brazilian government issued a decree that would allow it to produce or import generic anti-AIDS drugs without the consent of companies holding the patent on those medications. The Health Minister made it clear that the decree was meant to apply to antiretroviral drugs – specifically lopinavir, efavirenz and nelfinavir. The Ministry said in a statement it had negotiated with the name-brand companies in August seeking a reduction of more than 40%, but was offered maximum discount of 6.7%. Brazil and Merck reached an agreement in November, that year[141].

In 2005, the Brazilian Health Minister Humberto Costa signed a decree declaring the patent of Kaletra in the public interest and appropriate for compulsory licensing. A subsequent settlement with Abbott reduced the price of by 46%[142]. In the same year, the government of Brazil declared to be considering compulsory licensing for the manufacture of Viread. In May 2006, Gilead and the Brazilian Health Minister reached an agreement to reduce the price of Viread in Brazil by approximately 50%. This process was viewed with displeasure by the pharmaceutical industry. Brian Kyhos, a spokesman for Abbot Laboratories, said "the government is taking actions that will undermine initiatives seeking new and better treatment for AIDS. The respect to intellectual property is important as it leads to more investments"[143].

In the begging of May 2007, a short while after Thailand's compulsory licensing began, the government of Brazil finally issued a compulsory license on the efavirenz, after negotiations failed to bring about an agreement on price reductions with Merck[144]. Merck said it was "profoundly disappointed" and the US Chamber and US-Brazil Business Council stated that the decision on breaking the patent of Merck's Sustiva (the brand name of efavirenz) was a "major step backward" in intellectual property law and warned it could harm development Brazil is working to attract investment in innovative industries that rely on IP, and this move will likely cause investments to go elsewhere"[145].

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[141] BBC news - New Anti-HIV Drug Deal for Brazil
http://news.bbc.co.uk/2/hi/americas/3281683.stm

[142] PR News - *The Government declares anti-retroviral Kaletra to be of public interest and will produce it in Brazil* http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-25-2005/0003950348&EDATE=

[143] Bloomberg.com - Brazil Deputies Suspend Patents on AIDS drugs
http://www.bloomberg.com/apps/news?pid=10000086&sid=aqtnA4hCov2I&refer=latin_america#

[144] Essential Drugs Organization - Brazilian Government Declares Efavirenz to be of Public Interest
http://www.essentialdrugs.org/edrug/archive/200704/msg00085.php

[145] U.S. Chamber of Commerce Press Statement - *Brazil Takes Major Step Backward on Intellectual Property Rights, Says U.S. Chamber* http://lists.essential.org/pipermail/ip-health/2007-May/011111.html

7 Analysis

After seeing that Thailand and Brazil were not the first countries to use the TRIPS flexibility of compulsory licensing of patents in public interest for non-commercial use, one can wonder why did their actions cause so much commotion.

Thailand is still struggling to restore a democratic politic system[146], which does not necessarily pair with the liberal democratic ideals of the USA and Europe. Furthermore, Thailand did not limit the compulsory licensing for HIV/AIDS drugs. The country also licensed medicine for heart disease and is about to compulsory license cancer drugs. Brazil has a history of conflicts concerning compulsory licensing of medicine patents and many events, such as corruption scandals and urban violence, put the country in "watch" by the developing world[147]. There was quite some discussion in the media when Brazil started threatening to use compulsory licensing, from 2001 and on, but at that time, due to rather confidential agreements, Brazil restrained from the issuance as such, as seen in the previous section. In 2007, however, the right for compulsory licensing was fully applied and the industry seems to have understood the risks of those events.

The publicity given to the matter and the extensive criticism and praise it has received, caused the subject to reach even the population who normally does not take interest in intellectual property issues. Suddenly, those that did not have an opinion about pharmaceutical company business, intellectual property ethic questions or public health care, started discussing the matter and forming opinion in favour or against one or the other side. Another particular of these cases is that the countries responded to the public attacks in the same level, publishing articles and white papers as a response to virtually all manifestation of disagreement towards their actions.

There was a "statement war" in the media. In this war, one side wanted to take full advantage from the possibilities allowed by the international agreements. The other side wanted the public and political opinion to believe that those possibilities are neither fair nor efficient. None of them wanted to harm their own "brand". The issuing countries, such as Brazil and Thailand, do not want to pose as risky for foreign investment, they do not want to be seen as disrespectful of intellectual properties nor of the public best interest. They want investors to trust in their security and legality, and they want their people to trust in their government's intentions. The companies do not want to pose as disregardful of the peoples suffering, they do not want the public to believe that the price charged for life saving medicines is unfairly high and that they are not open for negotiation to reach a price that is convenient to all parties. They do not wish to be seen as the villains in the picture where millions are dying for lack of medicine, and they do not want to decrease profits and endanger their business model. The companies often state to

[146] The Economist – Country Briefings: Thailand
http://www.economist.com/countries/Thailand/profile.cfm?folder=Profile-Forecast
[147] The Economist – Country Briefings: Brazil
http://www.economist.com/countries/Brazil/profile.cfm?folder=Profile-Forecast

remain open for negotiation. “Merck has attempted to negotiate in good faith with the government of Brazil, but a fair offer on Stocrin has been rejected,” it said. “While we remain flexible and committed to exploring a mutually acceptable agreement with the Brazilian government to help the country achieve its objective of universal access to treatment, we believe their action is not in the best interests of patients in Brazil and around the world”[148]. And, “Last year, America’s pharmaceutical research companies invested more than $55 billion to bring new and innovative products to market to provide treatment for virtually every disease known to mankind. This research is costly and time consuming, but it is undertaken because of our industry’s continued commitment to improving and saving lives everywhere”[149], stated Billy Tauzin, from the Pharmaceutical Research and Manufacturers of America.

While some developed countries sustain the vital importance of patent protection for the development and improvement of medicines, other countries, such as Canada, count with pharmaceutical companies, such as Apotex, that manage to take the momentous situation to explore the legality of compulsory licensing and sell inexpensive HIV/AIDS drugs to the least developed world, as seen in section 4.3. With this, the company as well as the country, pose as a politically correct and engaged in the care of those that most need[150].

Both Thailand and Brazil, as seen in the previous sections, were accused of “breaking” the patents of the medicines. But, in the words of Professor Peter Drahos, from the Australian National University, which are valid to Brazil as well as to Thailand, “Brazil’s action will not “break Merck’s Brazilian patent. The patent has not been revoked by the Brazilian government. The patent continues to operate and Merck remains its owner. Merck will receive royalties based on its use”[151].

The strong opposition by part of the industry and even some governmental agencies against the actions of Brazil and Thailand are of such a forcefulness that are suggested to have a discouraging effect for smaller economies considering similar public health actions, but lack the legal or political resources to defend themselves on the global stage. In other words, perhaps those larger, stronger developing countries such as Brazil and Thailand are being opposed in this way so to serve as an example of what can be done to other countries that try to do the same.

The validity of the use of compulsory licenses in accordance to the TRIPS agreement is subtly challenged and a sagacious trade threatening is often the

[148] IP Watch – Brazil Takes Step to Import Cheaper AIDS drugs under Trade Law http://www.ip-watch.org/weblog/index.php?p=614

[149] Phrma – Compulsory Licensing Trend Dangerous http://www.phrma.org/news_room/press_releases/phrma%3a_compulsory_licensing_trend_dangerous/

[150] Essential Drugs: Rwanda to import of patented medicines under compulsory license http://www.essentialdrugs.org/indiadrug/archive/200707/msg00035.php

[151] Idem footnote 149

content of the messages for those that attempt to compulsory license. An example is the view of the Geneva based International Federation of Pharmaceutical Manufacturers and Associations, "Although permitted under specific conditions by the WTO TRIPS agreement, compulsory licensing is not a solution to improve access to medicines. Improved access can only be assured by adequate financing and collaboration with the innovative companies that develop new therapies. Compulsory licensing is a confrontational approach, and may be aimed to benefit local government-owned companies´ commercial interest"[152]. Some pharmaceutical industry representatives have even admitted to put pressure in their governments to "limit or cancel trade agreements that may affect wider economic development"[153].

The communicative efforts to shake the compulsory licensing possibilities become clear when noticing the use of terms such as "breaking the patents" or "revoking the patents" instead of "compulsory licensing of patents". These expressions have different communicative strengths, while international agreements and institutions support compulsory licensing and it implies the payment of royalties; the breaking patents is highly illegal in most countries of the world and it implies complete disrespect to the intellectual property institutions.

Furthermore, the pharmaceutical industry claims to offer the lowest possible prices in the negotiations pre-compulsory license. Dr Krikorian, a researcher at the Research Center on Health, Social and Political Issues, from the university of Paris, said "Brazil achieved lower prices in the past using the threat of compulsory license. However, there has certainly been an erosion of the power of the threats since none of them actually led to a compulsory license. In addition, the prices offered by the companies were clearly not the lowest possible". Dr Krikorian continued his analysis by saying "the most obvious reason [on why Brazil has not issued a compulsory license before] is the fear of an open conflict with the United States. The Thai case, and the recent 301 list report, indeed shows that despite the Doha Declaration and all the commitments made, the US is ready to be extremely aggressive with countries with producing capacity that use compulsory licensing for medicines"[154]. This statement shows that the manoeuvres of the pharmaceutical industry, and of the government of the countries where they are based, even though made in the business arena - which means that no actual legal action is taken - have considerable effects in political and legal decisions. This reaction could mean that the business and political arena can be manipulated by communicative efforts; and that this manipulation can cause effects in the other arenas.

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[152] Idem 115

153 Pharmaceutical Business Review – Breaking Merck Patent May Drive Investment Away from Brazil
http://www.pharmaceutical-business-review.com/article_feature.asp?guid=8A869BFC-88A5-4131-8CA3-231EE6F6E46C

[154] Idem 115

However, the attempt to manipulate the public opinion and to control the actions of other parties is not a guarantee of success, it is still just an attempt to defend ones interests. The truth is that an active example can encourage more than half empty accusations and threatening. The danger is that the argument for previous negotiation, used by the industry, can be ruined by facts. According to Dr Ellen t´Hoen of the Médecins Sans Frotières, the actions of Thailand and Brazil are a lesson for other developing countries that one actually gets lower prices by issuing a compulsory license instead of only threatening to issue one. Brazil has achieved a price for efavirenz of $580 per patient per year earlier when it had threatened to use compulsory license. But this was too expensive compared with the price for generics (Thailand was offered $244 per patient per year after it issued a compulsory license), and thus Brazil has paid too much for too many years[155].

The result of this communicative war, where one side fights for less expensive public health care solutions and the other side fights for the maintenance of a profitable industry, can culminate in what James Love, the director of the Knowledge Ecology International, has predicted in his statement on the compulsory licensing of Efavirenz[156].

> "With Brazil and Thailand expanding the market for generic versions of efavirenz, greater economies of scale should push prices down further, eventually to less than $.24 per day. We hope also that Efavirenz can be included in new generic fixed dose combinations, including those using TDF and FTC, products now sold by Gilead, and licensed to some generic producers in some countries.

James Love also put words to what can be a reason for the negative reaction from the pharmaceutical industry. He said that, at some point, it will be necessary to reassess the business model for medicines in developing countries. “Negotiations with patent owners rarely produce affordable prices. Competition is more effective”, he wrote. And continued advising that Brazil should go far beyond this single product (the efavirenz), and create a system of collective management of intellectual property rights that would extend compulsory license for either all prescription medicines, or a set of essential medicines that includes not only AIDS, but other important health problems, like diabetes, cancer, or heart disease.

This is what Thailand has been doing. As seen previously, at the same moment as the country issued the compulsory licenses on the HIV/AIDS medicines, it did the same on the heart disease drug. Now, in this beginning of 2008, Thailand disputes compulsory licensing three cancer drugs[157],

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[155] Idem 115

[156] James Love – Statement on Brazil and Thailand Compulsory Licensing http://www.keionline.org/index.php?option=com_content&task=view&id=46

[157] Reuters - *Thailand will override cancer drug patents* (March 10, 2008) http://uk.reuters.com/article/healthNews/idUKBKK14764720080310

which will probably continue to raise steaming discussions in the international arenas.

The debate also evolves around the question of who bares the burden of R&D costs for the continuous innovation of medicines, and whether or not the compulsory licensing can indeed represent the end of the incentives for pharmaceutical companies to keep researching for cures or relieves for diseases that attack mostly the developing world, such as malaria, that kills an African child every 30 seconds, and tuberculosis, with which one-third of the world's population is infected[158].

[158] Reuters Foundation's Fact Sheet - Top killer diseases in the developing world. http://www.alertnet.org/topkillerdiseases.htm (accessed on 24 August, 2007)

8 Conclusion

As the public priorities of the society and the notion of justice evolve, so do the law and the acceptable ways of enforcing it. The people's understanding of what is right and what is wrong and how they act upon this, influences the concepts of what is legal. What is communicated in the business – and political arena, tends to have direct influence in the public opinion. Which, by its turn, influences the daily events that affect the lives of millions.

At the time of the conclusion of this study Thailand have just had its presidential elections and the new Minister of Health is about to face impeachment for having started to review the previous government's initiated policy on compulsory licensing.[159] That shows the public disagreement with the government's inability to fight the threats of trade sanction from the developing world. Brazil, in its turn, has ceased the compulsory licensing activities that have received so many previous support and encouragement.

The true reason why the compulsory licensing efforts by the developing countries is received with so much hostility from the developed world is unknown to me. That is, perhaps, one of the further questions that could be examined in a continuation to this thesis.

My most outstanding conclusion after this study is that the law, on its own, does not have the strength to produce the results it was intended for. That probably happens for various reasons, which can, also, be subject of further study. Some of these reasons, I speculate, could be the very nature of the law in question, its relation to the society it is intended to rule, the business forces and international trade relations. I perceived that the reactions to the use of a legal instrument must be pre analysed and taken into consideration by those that intend to take an innovative step in the international relations and business arenas. As seen, the counteract from the lobbyists and from the governments that support them can be fierce and can actually harm the political and social harmony of entire nations. This case of the governmental compulsory licensing of medicines although being of international resonance, can be also illustrative in cases of smaller reach, such as local licensing of patents and other moves that may have legal sustainability but can be vulnerable business and politically wise.

One realization I came to with the analysis of this case is that concepts such as dominant position and communicative strength have indeed played an important role in the reality of the dispute. Even though Thailand and Brazil have the legal right to compulsory license medicine patents, and even though the procedure applied was according to the law, the dominant position of the United States government and of the pharma giants and their strong communicative efforts have, so far, outcome the legal rights.

[159] Thai News Agency: Thai health minister unfazed as voters seek his removal http://enews.mcot.net/view.php?id=3509

I do not think that the compulsory licensing of patented drugs for public non-commercial use, supported by the WTO Agreements, has yet met its end. On the contrary, I believe that much will still happen in this scene. The future events will teach us even more about the international business and political forces, the three arenas where they are displayed and, specially, how can these be used for the final creation of value, for the management of risk and, hopefully, for the development of a global welfare.

No matter what Thailand decides to do regarding the cancer drugs compulsory licensing, or what Brazil decides to do regarding the continuation of its AIDS program, the TRIPS flexibilities and its practical benefits to the population have already been exposed. The reaction of the citizens in Thailand against the apparent desistance of its government to continue what has been started indicates that public awareness has been created. This awareness has the strength to influence the democratic and the social processes of our era.

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10 Appendix

- Document I

Letter from the Congress of the United States to Ambassador Susan Schwab

Thailand Ministry of Public Health and the National Health Security Office. *Facts and Evidences on the 10 Burning Issues Related to the Government Use o Patents on Three Patented Essential Drugs in Thailand: Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent.*

- Document II

Letter from the ambassador Susan Schwab to the Congress of the United States

Thailand Ministry of Public Health and the National Health Security Office. *Facts and Evidences on the 10 Burning Issues Related to the Government Use o Patents on Three Patented Essential Drugs in Thailand: Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent.*

- Document III

USA for Innovation – The Wrong Prescription for Thailand

Bangkok Post – May 11, 2007

- Document IV

USA for Innovation Story

2Bangkok.com (http://2bangkok.com/07/news07apr.shtml) accessed in March, 2008

- Document V

USA for Innovation launches thailies.com

From the extinct www.thailies.com

- Document VI

Letter from Dr. Margaret Chan, WHO Director-General to the Minister of Public Health of the Government of Thailand

Thailand Ministry of Public Health and the National Health Security Office. *Facts and Evidences on the 10 Burning Issues Related to the Government Use o Patents on Three Patented Essential Drugs in Thailand: Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent.*

Document I

Letter from the Congress of the United States to Ambassador Susan Schwab

Congress of the United States
Washington, DC 20515

January 10, 2007

The Honorable Susan C. Schwab
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Schwab:

We are writing to urge that the United States respect the decision of the Thai government to issue a compulsory license on the AIDS drug efavirenz.

Thailand's HIV/AIDS treatment initiative has been recognized as among the most successful in the developing world. By producing generic first-line antiretroviral (ARV) therapies since before the medicines were patented in the country, Thailand's Government Pharmaceutical Organization (GPO) has made treatment widely accessible to tens of thousands of patients in government clinics and hospitals.

However, increasing numbers of Thai HIV/AIDS patients need access to newer, second-line treatment options because they have developed resistance to, or severe side effects from, the first-line regimens. Because second-line drugs, including efavirenz, are under patent in Thailand, they are currently only available from their brand name producers. The high price of these medicines has created a significant obstacle to the expansion and sustainability of the Thai program.

Thailand's November 29 announcement of its intent to issue a government-use compulsory license on efavirenz is a demonstration of its commitment to improve treatment options for the nearly 600,000 Thai citizens living with HIV.[1] As has been demonstrated in many other contexts, the availability of generics greatly lowers the price of HIV drugs over time and increases access to these life-savings medications.

Further, Thailand's action is entirely consistent with international trade rules. The World Trade Organization's 1994 Agreement on Trade Related Aspects of Intellectual Property (TRIPS) specifically permits compulsory licensing, and the 2001 Doha Declaration reaffirmed each country's "freedom to determine the grounds upon which such licenses are granted."[2] Under TRIPS, Thailand is not required to negotiate in advance with the patent holder because the drug will be produced in the near-term future by the GPO and distributed for non-commercial public use by Thailand's national program.[3]

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[2] Paragraph 5(b), 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference – Fourth Session, WT/MIN(01)/DEC/2, 20 November (2001).

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Unfortunately, it is our understanding that the United States government may be attempting to intervene in the Thai government's decision to issue and implement the compulsory license for efavirenz. As you are aware, the Trade Promotion Authority Act of 2002 mandates that United States trade policy respect other nations' public health initiatives under Doha.[4] We therefore call on you to respect the rights of Thailand and other nations to implement important and permitted public health safeguards.

Sincerely,

Tom Allen
Member of Congress

Sander M. Levin
Member of Congress

Henry A. Waxman
Member of Congress

Jim McDermott
Member of Congress

Fortney Pete Stark
Member of Congress

John Lewis
Member of Congress

James P. Moran
Member of Congress

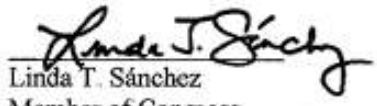
Lloyd Doggett
Member of Congress

Earl Blumenauer
Member of Congress

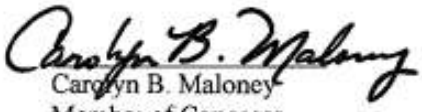
Charles A. Gonzalez
Member of Congress

[4] U.S. Trade Promotion Authority Act (P.L. 107-210), August 6, 2002 § 2102(b)(4)(C)

Betty McCollum
Member of Congress



Linda T. Sánchez
Member of Congress



Carolyn B. Maloney
Member of Congress

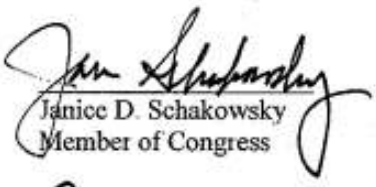
Hilda Solis
Member of Congress

Dennis J. Kucinich
Member of Congress

Barbara Lee
Member of Congress

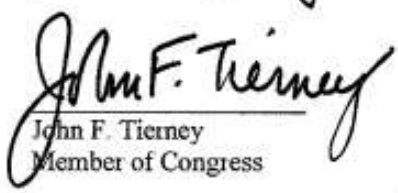
Michael H. Michaud
Member of Congress

Loretta Sanchez
Member of Congress

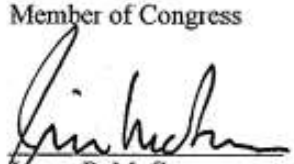


Janice D. Schakowsky
Member of Congress

Maxine Waters
Member of Congress



John F. Tierney
Member of Congress



James P. McGovern
Member of Congress

Document II

Letter from Ambassador Susan Schwab to the Congress of the United States

EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

The Honorable Sander M. Levin
U.S. House of Representatives
Washington, D.C. 20515

JAN 17 2007

Dear Congressman Levin:

Thank you for your letter concerning the Thai Government's announced intention to issue a compulsory license on the AIDS drug efavirenz.

The Administration's trade policy continues to advocate strong protection of intellectual property rights as an essential element in fostering innovation in the development of life-saving medicines, including those medicines necessary in the global fight against HIV/AIDS. Countries like Thailand, facing major public health crises, need to play a role in and benefit fully from the development of new and more advanced treatments. Strong protection of intellectual property, including through patents, remains a vital part of that process.

The Administration also remains fully committed to the flexibilities established within global and national intellectual property regimes enabling countries to address effectively significant public health emergencies. As recognized in the 2001 Doha Declaration, these flexibilities include recourse to the issuance of compulsory licenses. We are continually striving to strike the right balance between strong intellectual property protection as a means of promoting innovation, and appropriate use of flexibilities to address urgent situations. These objectives are both achievable.

With respect to the recent announcement of the Thai Government, we have taken care to respect fully the Thai Government's ability to issue compulsory licenses in accordance with its own law and its obligations as a member of the World Trade Organization (WTO). We have not suggested that Thailand has failed to comply with particular national or international rules. We have indicated that it would be appropriate for the Thai authorities to respond to any requests for direct discussions by concerned stakeholders, including, among others, the patent holder; we have not sought to insert the U.S. Government into any such discussions.

Our trade policy dialogue with Thailand will continue to emphasize the importance of effective intellectual property protection as an element in that country's effort to strengthen its investment climate and promote economic development. We will stress the importance to Thailand of abiding fully by its WTO obligations, but -- as we have done to date -- within the context of a full respect for the Doha Declaration and for Thailand's ability to make appropriate use of the flexibilities embodied in WTO rules.

Again, thank you for your letter and for your views on this important and sensitive issue.

Sincerely,

Susan C. Schwab

Document III

USA for Innovation – The Wrong Prescription for Thailand

The Wrong Prescription for Thailand

Thailand is refusing American and European medical technology at the expense of the poor and sick of Thailand.

These actions hurt jobs and investment in Thailand.

Thailand is now the only country in Southeast Asia on the U.S. Government's Priority Watch List.

Investor confidence in Thailand has plummeted since the announcement to compulsory license American and European drug patents.

Groups in the United States have demanded tariffs and sanctions on major exports from Thailand such as shrimp and gems.

Even worse, these actions hurt Thai patients.

Most of Thailand's AIDS patients will not have access to the world's best medicines.

Instead, the Thai government will provide locally manufactured drugs that have not even been approved by the World Health Organization.

A 2005 study by Mahidol University found that GPO-vir, a copy HIV treatment made by GPO, had between 39.6% and 58% resistance. This is one of the worst cases of HIV drug resistance in the world.

The people of Thailand deserve safer medicines and better public health policy from their leaders.

For more information on this issue, visit **www.USAforInnovation.org**.

Paid for by USA for Innovation

We Urge the Leadership to Protect the People of Thailand.

Document IV

2Bangkok.com – USA for Innovation Story

The USA for Innovation story

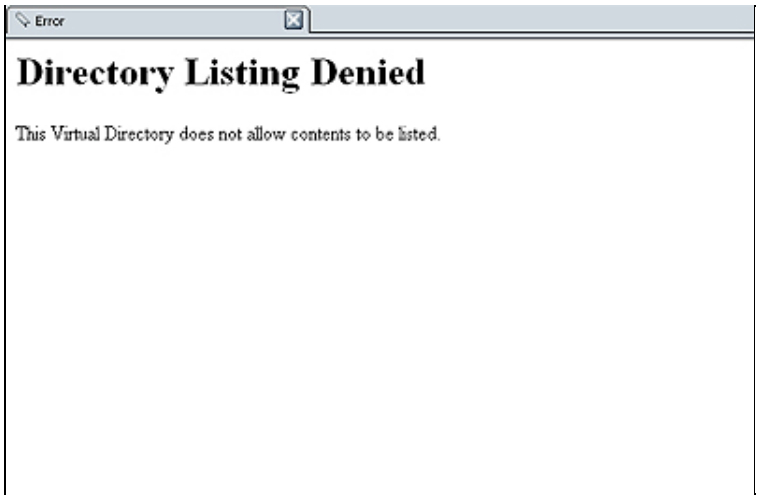
Sincerely yours,

Kenneth L. Adelman,
Executive Director
USA For Innovation

Above: USA for Innovation's Executive Director was Ken Adelman

ThaiMyths.com site gone - September 29, 2007

The ThaiMyths.com site, set up by USA for Innovation, has just disappeared from the net. Previously, USA for Innovation, a short-lived website set up to pressure the Thai regime, stopped posting two days after deposed PM Thaksin ended his association with lobbying group Edelman.



Above: USA for Innovation on August 23, 2007

USA for Innovation finally disappears - August 25, 2007

USA For Innovation was the fake lobbying site set up by PR company Edelman to pressure the Thai military junta. The site pretended to have a long history with many press releases and an on-going mission to target Brazilian and Thai compulsory drug licensing, but the reality is that the site suddenly appeared in April, 2007.

Deposed PM Thaksin reportedly ended his association with Edelman on May 7. USA for Innovation's last post was on May 9. USA for Innovation's sister site, Thaimyths.com, set up to highlight a series of press releases from May 7-18, is still up.

Proof of the big money behind the site was the enlistment of Kenneth Adelman to front the website and even record a YouTube video - "The government of Thailand won't let me talk to the people of Thailand, since they block this YouTube message..."
Inside of Thailand you can download the video here (11MB) and watch it with Miro (formerly Democracy Player).

More about the short history of this mysterious site is below.

Time to accept USA for Innovation for what it is (was) - June 9, 2007

The USA for Innovation site went silent on May 9. The companion site ThaiMyths.com ran from May 7 to May 18 and then went silent as well.

Based on its short history, USA for Innovation is

- an organization with no history before April 2007 (despite a huge directory of press releases, none of these were released to the net on the alleged dates they were created)

- an organization whose web attacks have no precedent in lobbying--except for the lobbying group Edelman which is well-known for creating fake lobbying efforts and planting articles and opinion pieces in the press (just like this).

- an organization that could afford an expensive hired gun like Kenneth Adelman

- an organization that seems satisfied to cease activity on May 18. Thaksin reportedly ended his association with Edelman on May 7.

"Charity" or "corporate-funded campaigning group" - May 11, 2007

From the forum: *The cited article in the Chicago Sun-Times* [Thailand violates drug patents for its own profit] *signs off with:"Philip Stevens is health program director at the International Policy Network, a London-based charity..."*

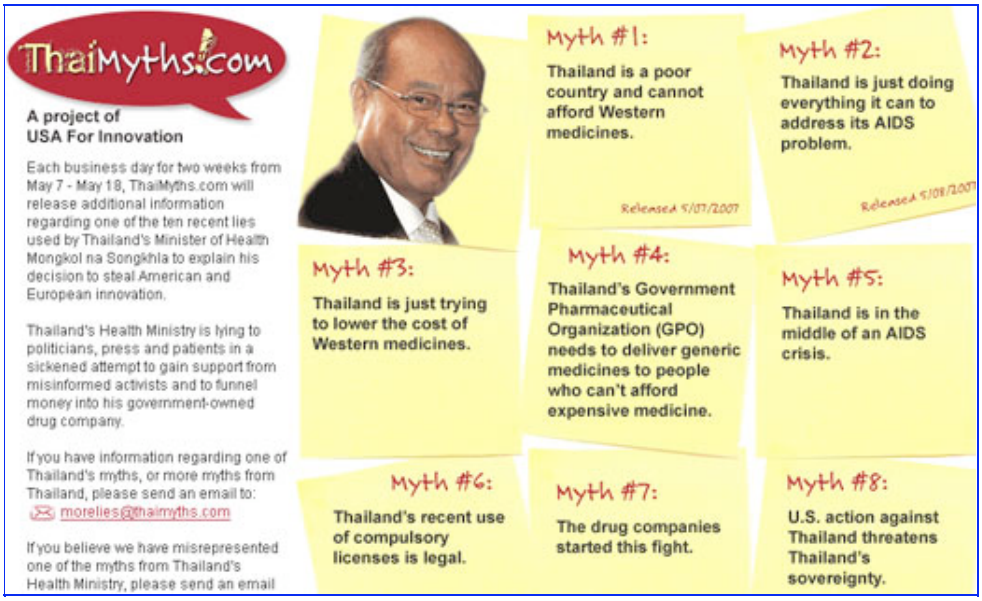
In an opinion piece in *The Nation*, the author is described as "*Philip Stevens is director of the health programme at the International Policy Network, a London-based development think tank.*" This is the same description *Newsweek* uses.

Sourcewatch calls International Policy Network a "corporate-funded campaigning group" that specializes in pharmaceutical and patent issues. Regardless of media outlets' misleading descriptions, the International Policy Network appears to be another lobbying group.

It is interesting how the USA for Innovation ad in *The Nation* on May 9, 2007 (below left) uses the same points as the Philip Stevens' article.

Also: USA For Innovation Announces Advertising Campaign In Thailand - *Bangkok Post*, May 10, 2007
USA for Innovation today announced an advertising campaign in Thailand aimed at highlighting Thailand's theft of American and European medical technology at the expense of the poor and sick. The advertisement, a full-page ad in The Nation, highlights the actions of Health Minister Mongkol Na Songkhla, which hurt jobs, investment and access to safe medicines for the people of Thailand...

Also: A peculiar article from the International Policy Network website: Myths on AIDS prevalence
HIV/AIDS figures in India will have to be drastically slashed as a result of more accurate HIV data. But United Nation's Programme on AIDS (UNAIDS) continues to stand by its exaggerated guesstimates that distort the magnitude of the Indian epidemic...



Above: ThaiMyths.com (also ThaiLies.com)

The media talks about USA for Innovation

Adelman spin the latest attack in the 'war from outside' - *The Nation*, May 11, 2007

...Since his background has been in the field of defence, with close ties to hardcore American conservatives, you must wonder why he dislikes the Thai military regime so much. Don't they belong to the same species - more power and higher military budgets?
But wait a minute, his bio says that he is senior counsellor at Edelman Public Relations. Do you know why now?
Thaksin Shinawatra, the ousted prime minister, hired Edelman Public Relations to represent him and to help prop up his international image. The Nation earlier reported that he signed a public-relations contract with Edelman in a deal worth US$300,000 (Bt10.3 million). Edelman Public Relations was responsible for most of Thaksin's media exposure with CNN, Time magazine, The Wall Street Journal and the like earlier this year when he launched a PR blitz to boost his international image.
...The outsiders set the rules - freedom of expression by YouTube, free trade by the US, high drug costs by pharmaceutical companies - we only have to follow.
Increasingly, we'll face more and more people like Ken Edelman, who has hardly ever set foot in Thailand, but who is willing to crush us to the ground with his black heart.

Ex-president blasts Abbott on standoff with Thailand - *Waukegan News*, May 11, 2007
...Standing next to the Thai health minister, Clinton strongly endorsed decisions by Thailand and Brazil to break patents held by American drug manufacturers to make their own versions of the drugs. The former president also said some of the prices charged by American drug companies are "exorbitant..."

The Nation's statement on USA Innovation ad - *The Nation*, May 12, 2007

USA FOR INNOVATION - GPO may sue over adverts - *The Nation*, May 12, 2007

New 'Thailies' website spurs strong reaction - *Bangkok Post*, May 9, 2007
The government has increased its internet monitoring operations after the American lobby group USA for Innovation announced it had launched a new anti-Thai government website, www.Thailies.com. "We will check the background of the website operator to see if it has any hidden agenda," said government spokesman Yongyuth Mayalap...

Official: U.S. ex-President Clinton backs Thai move to break patents on AIDS drugs - IHT, May 8, 2007
Former U.S. President Bill Clinton supports Thailand's move to break patents on AIDS drugs to lower their cost for poor patients, the Thai health minister said Wednesday.
Public Health Minister Mongkol Na Songkhla, who met with Clinton on Tuesday, is visiting the U.S. to explain Thailand's decision to break patents on three drugs, including the AIDS drugs Kaletra produced by Abbott Laboratories and Efavirenz by Merck. Both are American companies...

Thaksin ends PR contract amid flak - *The Nation*, May 7, 2007
Deposed prime minister Thaksin Shinawatra has terminated his association with United States-based public relations company Edelman...

Thai AIDS activist: US is "devil disguised" - Gay.com, May 3, 2007

Thailand joins China, India among worst copyright offenders - IANS, May 1, 2007
Thailand has joined China, India and nine other countries that top the US list of worst offenders of international copyright rules, the US government said...

Thailand scolded over not honoring patents - *Tribune*, April 30, 2007

Thai coup leaders hire PR company - BBC, April 30, 2007
...It signals a battle over the image of the country, which has been the subject of some recent negative publicity.
Its ousted and exiled former Prime Minister, Thaksin Shinawatra, has hired lobbyists and PR agents in the US...

Above: Part of the full page ad placed in *The Wall Street Journal*

"USA for Innovation" - A made-to-order lobbying effort? - 7:31am, April 29, 2007

A forum thread on this subject is here.

> **Update:** 19:11, April 29, 2007 - Traditional media is beginning to cover this story--along the lines we have laid out here. Just remember that 2Bangkok.com had the story first.

Is "USA for Innovation" a fake lobbying group set up only to attack the current Thai government?

With perfect timing, this new lobbying effort has appeared and targeted the Thai military government. Practically overnight, a Google search returns 24,300 hits for "USA for Innovation" (as of the writing of this article) and they all appear to refer to the press releases this lobbying group has issued over the last few days.

USA for Innovation's sparse website has a news page with occasional press releases going back to 2005, but only the recent Thai patent issue has multiple press releases. There is also a gap, nearly a year long, between press releases from May 2006 to April 2007.

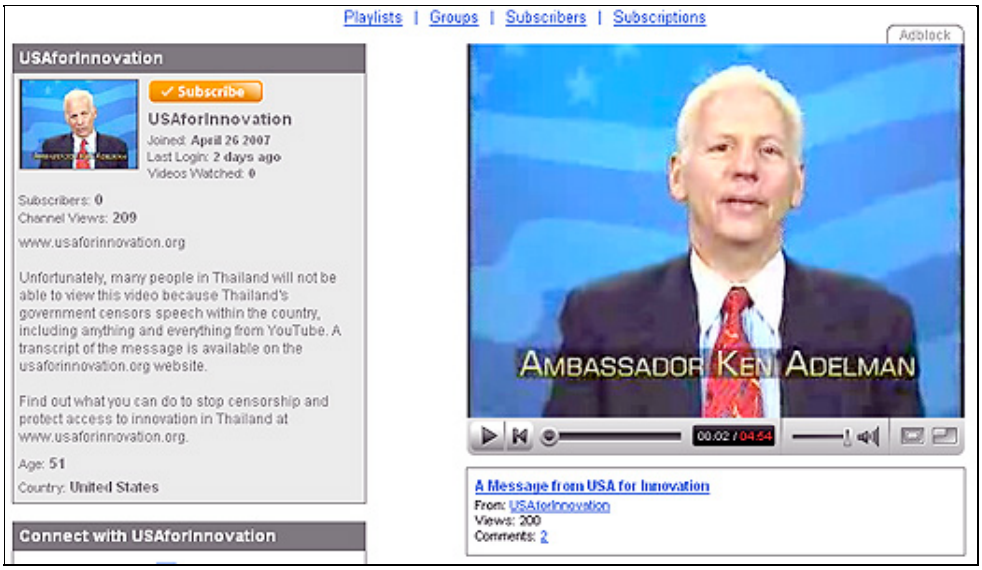
Pre-April 2007 press releases from USA for Innovation do not appear to have been released to PR Web or other press release websites. Pre-April 2007 press releases do not even appear on Google--perhaps indicating they were only recently placed on the website to give USA for Innovation a plausible history before this April. Archive.org shows no activity for the site either.

The broad sweep of issues addressed in both the USA for Innovation website and its *Wall Street Journal* ad is peculiar for a lobbying group that ostensibly is concerned with pharmaceutical issues. Taking the angle of "Slouching towards Burma" and "Radical new regime" could indicate a broader agenda than just focusing on protecting patents. Calling the PM a "Military Dictator," bringing up "targeted 'disappearances'" in the deep south, attacking military spending, and trying to highlight YouTube censorship seems to go far beyond what would be expected from a typical lobbying group attempting a diplomatic solution to a patent issue.

This PR initiative comes at a suspiciously opportune time as pro-Thaksin groups attempt to build on issues from the draft constitution to destabilize the government before the momentous rulings on disbanding the Thai Rak Thai party at the end of May.

According to SourceWatch, USA for Innovation's Executive Director Ken Adelman is also a senior counselor to Edelman. Edelman is the PR firm hired by former PM Thaksin Shinawatra.

2Bangkok.com is attempting to contact USA for Innovation, Edelman, and Baker Botts for comment.



Above: For those of you who cannot see YouTube in Thailand, here is a screen grab of USA for Innovation's site. So far the comments on the clip are overwhelmingly negative. On the USA for Innovation website there is a strangely broad explanation of the YouTube blocking: *Thailand's government censors speech within the country, including anything from YouTube, a service it considers to be dangerous and subversive.*

Some interesting press release from the site:

Thailand's Military is Sucking Money Away from Public Health - April 26, 2007

Military Regime Continues to Censor Free Speech in Thailand - April 26, 2007
USA For Innovation's Executive Director Ken Adelman will today release a message to the people of Thailand regarding the importance of innovation and concerns about the Thai Government's recent endorsement of theft of American intellectual property.
This message will be available via Google's YouTube service this afternoon beginning at 3:00pm PT at the USA For Innovation YouTube website...

Troubles from Thailand - *Washington Times*, April 27, 2007
... Most recently, the government brazenly announced it was breaking patents on drugs produced by Western corporations. And while this action is in line with the rampant theft of U.S. innovation in Thailand, it is also glaringly self-serving. An official Thai spokesman admitted busting patents "will be good for local pharmaceutical companies to improve their capacity." Perhaps unsurprising, one local pharmaceutical supplier happens to be owned by the Thai government, the Government Pharmaceutical Organization.

Document V

USA for Innovation launches thailies.com

USA for Innovation Launches ThaiLies.com

Website Highlights Deceit by Thailand's Minister of Health

WASHINGTON, May 7 /PRNewswire-USNewswire/ -- ThaiLies.com (**http://www.thailies.com**), a project of USA for Innovation, was unveiled today to draw attention to the deceit in Thailand's decision to steal American and European innovation. Each business day for two weeks from May 7 - May 18, ThaiLies.com will release additional information regarding one of the ten recent lies by the Health Minister Mongkol na Songkhla.

Today's Lie

Is Thailand a poor country that cannot afford Western medicines?

In fact, just the opposite is true. Thailand has the 21st largest economy in the world when measured by gross domestic product (GDP) derived from Purchasing Power Parity (PPP) calculations. According to the CIA World Fact Book 2007, Thailand's economy is more productive than over 200 countries -- placing Thailand among the top ten percent of richest countries in the world.

Earlier this month USTR noted that Thailand continues to suffer from "widespread commercial IPR counterfeiting and piracy." The new Thai military regime, which assumed power by coup last September, has now introduced direct government theft of American innovation into the quickly deteriorating U.S.- Thailand relationship through its theft of the intellectual property of three drugs produced by American and European companies.

#1 of 10

Lie: Thailand is a poor country and cannot afford Western medicines.

Fact: Thailand Has One Of The Largest Economies In The World.

Thailand has the 21st largest economy in the world when measured by gross domestic product (GDP) derived from Purchasing Power Parity (PPP) calculations. Many experts believe analyzing economic activity using PPP is the most accurate method because it allows comparisons in living standards by taking into account the relative cost of living and the inflation rates of the countries. According to the CIA World Fact Book 2007, Thailand's economy is more productive than over 200 countries -- placing Thailand among the top ten percent of richest countries in the world.

(CIA Fact Book, Accessed 5/3/07)

Fact: Thailand's Economy Is Growing Faster Than Over 100 Countries Across The Globe.

In 2006, Thailand's economy grew at a 4.8 percent clip -- ahead of 106 other countries around the world. Among the countries whose growth were outpaced by Thailand were the United States (3.4%), Switzerland (2.9%) and the United Kingdom (2.7%).

(CIA Fact Book, Accessed 5/3/07)

Fact: Thailand Has The 17th Lowest Unemployment Rate In The World.

According to the CIA World Fact Book, in 2006 Thailand's unemployment rate was only 2.1 percent -- over half the rate of the United States (4.8%) and about one-third the unemployment rate in Canada (6.4%).

(CIA Fact Book, Accessed 5/3/07)

Fact: Thailand's Exports Total Over $123 Billion -- Ahead Of Almost 200 Countries In The World.

In 2006, it is estimated that Thailand exported $123.5 billion, ahead

of Australia ($117 billion) or India ($112 billion).
(CIA Fact Book, Accessed 5/3/07)
Fact: Thailand's Industrial Production Is Growing At A Faster Rate Than The European Union, Japan, And 100 Other Countries.
In 2006, Thailand's industrial output grew six percent -- double the growth of industrial production worldwide. Thailand's output was well ahead of Japan's 3.2 percent growth and the European Union's 2.6 percent.
(CIA Fact Book, Accessed 5/3/07)
About USA for Innovation and ThaiLies.com
USA For Innovation is a non-profit organization dedicated to the protection of intellectual property and continued innovation around the globe. USA For Innovation educates decision makers, the media and general public about threats to innovation. ThaiLies.com is a project of USA for Innovation intended to expose the web of deceit by Thailand's Health Ministry. For additional information, please contact us at 866-646-8668 or john@usaforinnovation.org.

SOURCE USA for Innovation

back to top

Related links:
- http://www.thailies.com

Document VI

Letter from Dr. Margaret Chan, WHO Director-General to the Minister of Public Health of the Government of Thailand

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 2797
Fax direct: +41 22 791 4846
E-mail :

In reply please refer to: DGO

Your reference:

Mr Mongkol Na Songkhla
Minister of Public Health
Ministry of Public Health
Royal Thai Government
Tivanond Road
Nonthaburi 11000
Thaïlande

7 February 2007

Dear Minister,

It was a pleasure to meet you last week in Bangkok, and I must express my deep appreciation to you and your staff for the warm welcome, hospitality and great efficiency demonstrated throughout my brief visit to Thailand.

It was a great honour for me to have an audience with His Majesty the King, and with her Royal Highness Princess Maha Chakri Sirindhorn, in her capacity as Chair of the Board of Trustees and President of the Prince Mahidol Award Foundation.

I was particularly impressed with the field visit, which provided me with an opportunity to witness the work of dedicated health professionals and the community in Khon Kaen and Nam Phong. The pride and professionalism of the staff and the support of the community was obvious and most encouraging.

I also appreciated the opportunity to hear more about the work of the National Health Security Office and the National Health Promotion Foundation. I was pleased to witness the commitment of the Royal Thai government to universal coverage with effective health care services, and to the health of the people of Thailand. I welcome the increasing budget for the universal coverage scheme, which I know understand amounts to close to 2,000 baht per person per year, and includes treatment for people with HIV/AIDS with antiretrovirals.

cc: The Minister of Foreign Affairs of Thailand, Bangkok
Permanent Mission of Thailand to the United Nations Office at Geneva and the Specialized Agencies in Switzerland

I deeply regret that my comments at the close of the briefing at the National Health Security Office were misrepresented in the media, and may have caused embarrassment to the government of Thailand. They should not be taken as a criticism of the decision of the Royal Thai government to issue compulsory licences, which is entirely the prerogative of the government, and fully in line with the TRIPS agreement.

Thailand is making good progress towards increase budget allocations for health, while simultaneously control rising health care costs with greater efficiency. Medicines are a substantial element of health care costs, and it is entirely appropriate and necessary for the government of Thailand to find means of reducing these costs to ensure sustainable financing of health care.

As I mentioned in the recent Executive Board, I firmly believe that the pharmaceutical industry - generic manufacturers and R&D companies - are part of the solution. I am committed to dialogue with industry to find ways of ensuring that access to high quality essential medicines is not limited by cost considerations. I am equally committed to dialogue with people who suffer from HIV/AIDS and other conditions, and with civil society groups and NGOs.

WHO unequivocally supports the use by developing countries of the flexibilities within the TRIPS agreement that ensure access to affordable, high quality drugs. This includes the use of compulsory licensing, as described in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The decision whether to issue a compulsory license for a pharmaceutical product is a national one. There is no requirement for countries to negotiate with patent holders before issuing a compulsory licence. As a global community we need to ensure the right balance between the immediate and urgent pressing need to provide affordable medicines to the many that need them, and the need to provide continuous incentives for innovation. It is in this regard that I noted that prior negotiations with industry is a pragmatic approach that may ensure countries have access to high quality medicines at affordable prices.

Where there are urgent needs, the bottom line is that people need access to medicines.

I trust this clarifies the position of WHO concerning compulsory licensing of medicines, and I look forward to further opportunities to discuss these important issues with you in the future.

Yours faithfully,

Dr Margaret Chan
Director-General