COMPULSORY LICENSING AND AFFORDABILITY OF MEDICINES UNDER THE TRIPS REGIME: A CASE STUDY OF THAILAND

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DECLARATION

I declare that the thesis entitled **"Compulsory Licensing and Affordability of Medicines under the TRIPs Regime: A Case Study of Thailand"** submitted by me for the award of the degree of **Master of Philosophy** of Jawaharlal Nehru University is my own work. The thesis has not been submitted for any other degree of this University or any other university.

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CERTIFICATE

We recommend that this thesis be placed before the examiners for evaluation.

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Dedicated to my grandfather

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CONTENTS

Abbreviations

AIDS	: Acquired Immuno Deficiency Syndrome
APIs	: Active Pharmaceutical Ingredients
ARV	: Antiretroviral drug
CL	: Compulsory License
CPB	: Cost-Plus Based
DALY	: Disability-Adjusted Life Year
FTA	: Free Trade Agreement
GATT	: General Agreement on Tariff & Trade
GNI, PPP	: Gross National Income, Purchasing Power Parity
GPO	: Government Pharmaceutical Organisation
GSP	: Generalised System of Preferences
HAART	: Highly Active Antiretroviral Therapy
HAI	: Health Action International
HIV	: Human Immunodeficiency Virus
HS	: Harmonised System
ISIC	: Standard International Trade Classification
LPG	: Lowest Priced Generic Equivalent
MBP	: Market-Based Pricing
MoPH	: Ministry of Public Health
MPR	: Median Price Ratio
MRP	: Maximum Retail Price
MSH	: Management Sciences for Health
NLEM	: National List of Essential Medicines
NNRTIs	: Non-Nucleoside Reverse Transcriptase Inhibitors
OB	: Originator Brand
QALY	: Quality-Adjusted Life Year
SEARO	: South East Asia Regional Office
TRIPs	: Trade Related Intellectual Property Rights
UHC	: Universal Health Coverage
UMIC	: Upper Middle Income Countries
USD	: United States Dollar
USTR	: United States Trade Representative
WHO	: World Health Organisation
WTO	: World Trade Organisation

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Chapter 1

Introduction

"*Whatever our political leanings, everyone is basically a socialist when it comes to healthcare: we all feel nervous about profit taking any role in the caring professions, but that feeling has nowhere to go. Big pharma is evil: I would agree with that premise. But because people don't understand exactly how big pharma is evil, their anger and indignation get diverted away from valid criticisms—its role in distorting data, for example, or withholding life-saving AIDS drugs from the developing world—and channeled into infantile fantasies.*" (taken from ***Bad Pharma*** by Ben Michael Goldacre)

Despite the different health care systems that exist worldwide, we all depend on for-profit pharmaceutical companies to develop and market new medicines. I would like to focus on the second evil deed (as Goldacre puts it) of the pharmaceutical giants of withholding essential medicines from the developing world and examine how far compulsory licensing has been effective in tackling the problem of inaccessibility of life saving drugs. Thailand is considered for the study to analyse the impact of compulsory licensing since it has adopted the measure a number of times in the 2006 – 2008 period, and has succeeded to a great extent in making those medicines available to the ailing millions. While examining the details of this success story, we also consider the limitations of compulsory licensing in the context of rising Free Trade Agreements and discuss the role of measures other than compulsory licensing in enhancing medicine accessibility.

1.1 Background

The issuance of compulsory licenses can be seen as an open decision by the Thai government to withdraw from the "one leg on two boats" policy it had followed not deliberately, but due to coercion by the United States and developed world on one hand and obligation to the public on the other. A brief account of the health care and patent policies Thailand has followed will substantiate this.

1.1.1 Thailand at a Glance

Thailand (formerly known as Siam), officially the Kingdom of Thailand, is a country located at the centre of the Indochina peninsula in Southeast Asia. It is a newly industrialized country with a population of 67.9 million people (2012)[1], with 33.3 million males and 34.6 million females and Gross Domestic Product (PPP) of 646 billion in Current International $. The World Bank in 2011 has upgraded Thailand to the category of Upper Middle Income Countries.[2] As per the World Development Indicators database, released by the World Bank on 1 July 2011, the country's Gross National Income Per Capita in 2010 is US$ 4210 and 8240 (International $) according to the Atlas method and Purchasing Power Parity (PPP) respectively. Another noteworthy feature is that Thailand is an export led economy, with export amounting to more than two-thirds of the Gross Domestic Product (GDP).[3]

Historically, Thailand is not a politically stable kingdom. From the early twentieth century to the end of the Second World War, the economy had been gradually integrating to the global system. In 1932, the people of Siam gained their first constitution through a 'bloodless revolution' carried out by the "Khana Ratsadon" group of military and civilian officials, ending centuries of absolute monarchy and giving way to the constitutional monarchy which continues even today. General Luang Phibunsongkhram who became Prime Minister in December 1938 steered the modernization of Thailand. . In 1939, the country's name was changed from Siam to *'Prathet Thai'* or *'Thailand'* meaning the *'land of the free'*. And today the 'land of free' is known for the "free health coverage" scheme it has implemented.

[1] "Thailand at a Glance" published in the Bank of Thailand website, http://www.bot.or.th/English/EconomicConditions/Thai/genecon/Pages/index.aspx (accessed on 29th April, 2013).
[2] Thailand Country Overview, http://www.worldbank.org/en/country/thailand/overview (accessed on 2nd May 2013).
[3] Thailand's Universal Coverage Scheme: Synthesis Report (May 2012).

1.1.2 Health as a Basic Right

In 1997, a Constitution was drafted by the popularly elected Constitutional Drafting Assembly, and hence popularly called the "People's Constitution". It is, in fact, with the Peoples Constitution that health care gained a place in the Thai Constitution as the 'Right of Thai Citizens', even though a departmental agency was established way back in 1888, and the present Ministry of Public Health had been established in 1942.

Section 52 under Chapter III- Rights and Liberties of the Thai People in the Constitution of the Kingdom of Thailand, 1997 reads as follows:

Section 52: A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from public health centres of the State, as provided by law.

The public health service by the State shall be provided thoroughly and efficiently and, for this purpose, participation by local government organisations and the private sector shall also be promoted insofar as it is possible.

The State shall prevent and eradicate harmful contagious diseases for the public without charge, as provided by law.

Besides, Chapter V on Directive Principles of Fundamental State Policies includes the following declaration on the provision of health care.

Section 82: The State shall thoroughly provide and promote standard and efficient public health service.

These rights found their way to the present constitution with much better and more elaborate provisions to assure health care for all.

Part 9: Rights to Public Health Services and Welfare in the Constitution of the Kingdom of Thailand, 2007 (B.E 2550) reads as follows:

Section 51: A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from State's infirmary. The public health service by the State shall be provided thoroughly and

efficiently. The State shall promptly prevent and eradicate harmful contagious diseases for the public without charge.

Section 52: Children and youth shall enjoy the right to survive and to receive physical, mental and intellectual development potentially in suitable environment with due regard to their participation. Children, youth, women and family members shall have the right to be protected by State against violence and unfair treatment and shall have the right to medical treatment or rehabilitation upon the occurrence thereof. An interference and imposition of rights of children, youth and family members shall not be made except by virtue of the law specially enacted for the maintenance of family institution or utmost benefit of such person. Children and youth with no guardian shall have the right to receive appropriate care and education from the State.

Section 53: A person who is over sixty years of age and has insufficient income for living shall have the right to welfare, public facilities and appropriate aids from State.

Section 54: The disabled or handicapped shall have the right to get access to, and to utilise welfare, public facilities and appropriate aids from State. A person of unsound mind shall have the right to appropriate aids from State.

Section 55: A person who is homeless and has insufficient income for living shall have the right to appropriate aids from State.

Besides the provisions in the Constitution of the Kingdom of Thailand, the National Health Security Act, 2002 promises to ensure the 'right to health' for Thai citizens and the government adopted a policy of Universal Access to Antiretroviral Drugs (ARVs) for AIDS patients in Oct 2003.

1.1.3 Evolution of Thai Patent System

The first patent act, Thai Patent Act B.E. 2522 (A.D. 1979) came into effect on 12 September 1979, after the expiration of one hundred and eighty days of its publication in the official Government gazette (on 16 March 1979). Since Thailand has never endured

colonial rule, its patent law did not evolve from colonial influences.[4]The prime objective of the Thai Patent System (1979) is to "promote inventive activities within Thailand and to induce transfer of technology from abroad". The process of producing, maintaining or improving the quality of a pharmaceutical product or ingredient was granted protection, but pharmaceutical products or ingredients themselves are not considered eligible for patent protection. So 'product patenting' was not allowed. Moreover, it is clear from the inclusion of provisions like Compulsory Licensing that the Thai patent System is committed to the prevention of anti-competitive practices and in ensuring the protection of the public interest at large. But Thailand has revised its patent system two times to make it tighter.

The first amendment in1992 was not just a revision, but the culmination of long years of lobbying by Pharmaceutical Research and Manufacturers of America (PhRMA) and the coercive measures of the United States. PhRMA filed a petition with the US government to withdraw the benefits under the Generalised System of Preferences (GSP) to the Kingdom of Thailand in May 28, 1987. The Government of Thailand reciprocated this by arguing that it is not possible for a developing country like Thailand to provide the same level of protection as does the US and as a development tool, the patent system must be in tune with the levels of social, economic and industrial development of the country. PhRMA continued to make allegations and filed a GSP petition under Section 302 of the US Trade Act alleging that the Government of Thailand didn't provide adequate and effective patent protection for pharmaceutical products. As a sort of punitive move, Thailand was placed on the "Priority Watch List" in the Special 301provision of the 1988 Trade Act of the US (Markandya 2001). In April 1992, Thailand was named as Priority Foreign Country under Special 301 for lack of copyright and patent protection.[5] In the meantime, the Thai Supreme Court released a report entitled "National Experience on Judiciary and Intellectual Property System" (in September 1992). It categorically states "Thailand is not ready to change and improve the level of (pharmaceutical) patent protection", in other words, to move from the Act of 1979 which "intends to protect the

[4] See http://www.thailawforum.com/articles/jakpat1.html

[5] Based on 2010 Special 301 Report on Copyright Protection and Enforcement. The "special 301" section is used as a market weapon against countries which don't respect the American market rules.

public" to the new Act of 1992 which "aims to protect the investors". However, Thailand was being forced by "countries who own technologies of producing pharmaceutical products to improve patent law for the exchange of trade benefits". The Government of Thailand finally gave in.

They revised the Thai Patent Act B.E 2522 and passed the Thai Patent Act B.E. 2535 (AD 1992). The amendment came into force on 30 September 1992. Following are the changes that were made:

- Introduction of Product Patents, so that pharmaceutical products or ingredients were no longer prohibited from being patented.
- Extension of the patent protection period from 15 to 20 years
- Narrowing of the scope of Compulsory Licensing, practically making it a nominal provision. Section 46 and 48 of the 1979 Act facilitating compulsory licensing after 3 years from the grant of a patent were repealed
- Parallel Imports were banned.
- The law also created a Pharmaceutical Patent Review Board, which was given powers to award compulsory licenses on the grounds that a product is excessively priced in the Thai market. The Board was invested with authority to require cost and pricing information and allow penalties for failure to supply sufficient information.
- The law was, however, not applied retroactively, which meant the process patents granted prior to 1992 could not be extended to product patents.

Besides, with an intention to obtain two-year exclusive marketing rights, American pharmaceutical firms with the support of their national government pressurized the Thai public authorities and finally ensured the implementation of a Safety Monitoring Programme (SMP) in1992.[6] When a pharmaceutical product is subject to safety monitoring period, generic products of the originator brand could not be registered. In effect, SMP will grant the patent applicant almost the same benefit as EMRs do. Exclusive Marketing Rights (EMRs) is a provision to confer exclusive right to sell or

[6] See http://www.cptech.org/ip/health/c/thailand/thailand.html

distribute the product of invention normally for a period of 5 years during the transitional period. Like EMRs, under SMP system also new drugs are first registered with conditional approval. The USTR and PhRMA continued to monitor Thailand. In September 1993 Thailand was removed from the Priority Foreign Country List and once again placed in the Special 301 "Priority Watch List". After the enactment of a new copyright law, USTR moved Thailand into the category of Special 301 "Watch List" in 1994.

In 1993 in Thailand the number of yearly new HIV infections was more than one lakh.[7] Many of the anti-retroviral drugs used as a part of highly active antiretroviral therapy (HAART) were patented. Since the health insurance system in Thailand in the early nineties was not that developed, a majority of the people had to spend out of their pockets. The Thai NGO Coalition on Aids, the Drug Study Group (Thai NGO) and Medecins Sans Frontiers (MSF) all tried their best to pressurize the government to issue compulsory license for Didanosine – the first case of demand for a compulsory license. Didanosine (ddI, DDI), the second drug approved for the treatment of HIV infection in many countries, including in the United States on October 9, 1991, was developed by the National Cancer Institute (NCI). Since NCI does not market products directly, the National Institutes of Health (NIH) awarded a ten-year exclusive license to Bristol-Myers Squibb Co. (BMS) to market and sell ddI as Videx tablets.[8] Being patented, Videx was priced very high. But the Royal Thai Government was unwilling to award a compulsory license for fear of trade sanctions by the USTR.[9]

Meanwhile the World Trade Organisation (WTO) was constituted and the Agreement on Trade Related Intellectual Property Rights (TRIPs) came into being in1995. Instituting TRIPs complaint patent system became the order of the day. In the 301 Review released by USTR on May 1, 1998, it was noted that Thailand also needed to pass a TRIPs-consistent patent law (including abolition of the Patent Review Board). Further, in the 'Special 301 Annual Review' issued on April 30, 1999, the USTR, while appreciating the

[7] Thailand's Response to HIV/ AIDS: Progress and Challenges (UNDP Report, 2004)
[8] See http://en.wikipedia.org/wiki/Didanosine
[9] Trade Sanctions refers to the trade penalty imposed by one nation onto one or more other nations.

Thai Government's agreement to implement an IPR Action Plan embodying a number of priority reforms, including enactment of a world class patent law, criticized Thailand for its policies on copyright. Under such pressure amendments were made in the Thai Patent Act and the new and improved version, Thai Patent Act B.E 2542 (1999) came into being on September 27, 1999. The new Patent Act, which is still in force, was totally TRIPs compliant. Notable changes incorporated were:

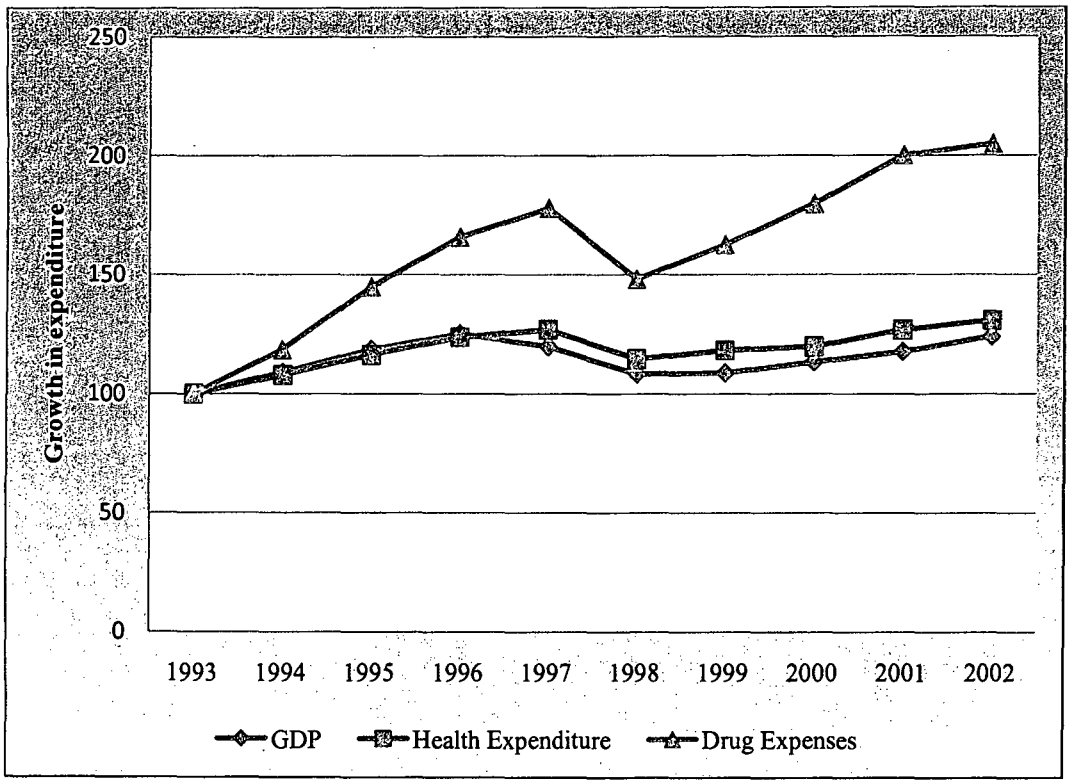
- Introduction of the principle of national treatment.
- Elimination of the working requirement of the patent, so that the importation of patented products by the patentee is considered as 'working the patent'.
- Abolition of the Pharmaceutical Patent Review Board.

1.1.4 Aftermath of the Stringent Patent Regime

The aftermaths of these amendments are rather apparent. Thailand which didn't have a properly developed domestic pharmaceutical industry experienced deterioration in its health environment. Out of pocket expenditure increased drastically due to the lack of generic versions of the patented drugs. Drug expenses increased at a faster rate compared to the rate of growth of health expenditure.

Figure 1.1 shows the impact of introducing product patents in the pharmaceutical industry. In a decade the drug expenses doubled. Prohibition of the production and importation of generic versions of patented drugs due to implementation of 'product patent system' resulted in a surge in the spending on drugs, attributed to the rise in the price of medicines.

Figure 1.1: Growth of Real - term Expenditure on Drugs, Health and GDP, 1993 – 2002 (1993 price = 100)



Source: Thailand Health Profile 1998-2000, released by Ministry of Public Health, Thailand
Note: For comparison health expenditure of 1993 were set at 100. (Table is given in Appendix I).

Table 1.1 presents the data on expenditure on health care and drugs. Expenditure data on drugs is available only from 1983. Both the actual values and values deflated with 1988 as base year are presented here. Expenses on medicines as a percentage of health expenditure is a matter for concern here. The data shows that till 1993 it was mostly falling, but after that it showed an increasing trend till 2001, with 1998 being the only exception. This may be due to a decline in the ability to purchase drugs by the people as a result of the fall in income due to the economic downturn. Over the next seven years, the drug expenditure part of health care expenses increased around 10%, though there is are fluctuations across years.

Table 1.1: Expenditures on Drugs and Health, 1980-2008 (in billion Baht)

Years	Health Expenditure (HE)		Drug Expenditure (DE)		DE as percentage of HE
	Actual Values	Values (1988 prices)	Actual Values	Values (1988 prices)	
1980	25315	34916			
1981	31755	40415			
1982	34873	42246			
1983	41181	48131	16686	19505	40.52
1984	52241	60187	20629	23767	39.49
1985	59265	66824	26317	29674	44.41
1986	66060	73275	18669	20708	28.26
1987	75704	80184	21352	22616	28.73
1988	89968	89968	26674	26674	29.65
1989	105091	99033	33763	31817	32.13
1990	125302	111635	35369	31511	28.23
1991	138818	116955	39464	33249	28.43
1992	157965	127368	42770	34486	27.08
1993	184062	143634	42364	33059	23.02
1994	199949	149962	52823	39617	26.41
1995	227477	161255	68437	48514	30.08
1996	257507	172438	81440	54536	31.63
1997	282001	178935	92728	58838	32.88
1998	276090	162025	82888	48643	30.02
1999	284235	166284	91208	53359	32.09
2000	299757	172671	102400	58986	34.16
2001	321239	182108	116767	66194	36.35
2002	335393	188879	120290	67742	35.87
2003	372160	205718	144085	79646	38.72
2004	395018	212397	172734	92877	48.73
2005	437275	225099	186331	95919	42.61
2006	497102	244471	207906	102247	41.82
2007	544451	261742	261770	125844	48.08
2008	588154	268287	272841	124457	46.39

Source: Thailand Health Profile 2008-2010, released by Ministry of Public Health, Thailand

Table 1.2 provides the proportion of public and private expenditure in the overall health expenditure. Since splitting up the expenditure on drugs into the public and private shares in drug expenditure, which would provide a proper picture of the impact of the rise in drug prices on the people, is not available, health expenditure is used as a proxy here.

Table 1.2:Proportion of Overall Health Expenditure by Different Sources in Thailand 1980-2008 (1988 prices)

Year	Public Sector (%)							Private Sector (%)			Int.Aid (%)
	MoPH	Other	CSBS	SEBS	WCF	SS	Total	PHI	HH &Em	Total	
1980	17.76	8.73	2.61	0.44	0.4	0	29.93	0.88	67.75	68.63	1.44
1981	17.55	7.98	3.13	0.53	0.47	0	29.66	0.89	66.85	67.75	2.59
1982	19.07	8.14	3.5	0.58	0.44	0	31.73	0.91	66.27	67.18	1.09
1983	19.19	7.61	3.6	0.6	0.5	0	31.5	0.85	66.7	67.55	0.95
1984	16.5	6.64	3.43	0.57	0.48	0	27.61	0.9	70.73	71.63	0.76
1985	15.26	6.27	3.64	0.61	0.4	0	26.18	0.92	72.14	73.06	0.76
1986	14.04	6	3.93	0.66	0.33	0	24.96	0.95	73.32	74.27	0.77
1987	12.58	5.39	3.74	0.63	0.36	0	22.7	1	75.63	76.63	0.67
1988	11.53	4.82	3.51	0.59	0.39	0	20.83	1.06	77.76	78.81	0.35
1989	11.16	4.23	3.35	0.56	0.38	0	19.69	1.11	78.97	80.07	0.24
1990	12.95	3.64	3.44	0.58	0.35	0	20.96	1.12	77.77	78.89	0.15
1991	14.82	3.39	3.69	0.62	0.45	0.56	23.52	1.11	75.17	76.28	0.19
1992	15.58	3.06	3.71	0.62	0.48	1.3	24.75	1.12	73.91	75.03	0.23
1993	17.87	2.68	4.3	0.7	0.5	1.34	27.39	1.12	71.33	72.45	0.15
1994	19.67	2.78	4.98	0.83	0.58	1.89	30.73	1.15	68.04	69.19	0.08
1995	20.15	2.94	4.91	0.82	0.6	1.75	31.17	2.19	66.6	68.79	0.04
1996	21.69	3.02	5.28	0.94	0.62	2.42	33.97	2.44	63.57	66.01	0.01
1997	24.44	2.55	5.5	0.98	0.7	3.63	37.8	2.66	59.5	62.16	0.03
1998	23.57	2.08	5.95	1.02	0.59	2.77	35.98	2.82	61.17	63.99	0.03
1999	22.1	2.14	5.34	0.89	0.49	2.7	33.66	2.88	63.45	66.33	0.01
2000	21.02	2.07	5.69	0.54	0.42	3.21	32.95	2.43	64.6	67.03	0.02
2001	19.16	2.22	5.97	0.94	0.4	4.22	32.91	2.61	64.42	67.03	0.06
2002	21.25	2.05	6.1	0.92	0.36	3.35	34.41	2.9	62.58	65.48	0.11
2003	19.92	2.31	6.09	1.07	0.4	4.06	34.37	2.99	62.47	65.45	0.18
2004	19.68	1.79	5.01	1.04	0.38	3.94	32.38	3.18	64.04	67.22	0.4
2005	19.65	1.39	6.62	0.86	0.34	4.02	33.41	3.17	63.24	66.41	0.18
2006	21.55	1.79	7.45	1.62	0.34	4.23	37.78	2.06	60.03	62.1	0.17
2007	23.82	1.9	8.54	1.63	0.32	3.98	40.84	2.04	56.95	58.99	0.16
2008	24.34	2.02	9.41	1.67	0.29	4.04	42.23	2.3	55.31	57.6	0.17

Source: Thailand Health Profile 2008-10, released by Ministry of Public Health, Thailand

Note: MoPH - Ministry of Public Health, CSBS – Civil Servant Benefit Scheme, SEBS – State Enterprise Benefit Scheme, WCF – Workers' Compensation Fund, SS – Social Security, PHI- Private Health Insurance, HH & Em – Households and Employers, Int. Aid- International Financial Aid.

The table shows the proportion of health expenditure classified according to funding sources. It covers a period of around three decades till 2008 (the data is available only till 2008 since the latest Health Profile Report has not yet released). Once UHC was implemented, over 900 drugs included in the National List of Essential Medicines (NLEM, in which many patented drugs too are included) were provided for free to the ailing Thai population. As seen in the table, the coverage of public health insurance schemes (CSBS – Civil Servant Benefit Scheme, SEBS – State Enterprise Benefit Scheme, WCF – Workers' Compensation Fund, SS – Social Security) increased from less than 3.5 percent in 1980 to around 10 percent in 2000. Most of these schemes cover expenditures on medicines, and among them, CSBS gives uncapped coverage too. But a majority of the population remained outside this safety net till 2000. Even though the Ministry of Public Health spends on drugs by providing free drugs through public health care institutions, they constitute a small component of the total health budget. The Health Budget can be split up into budget allocation on hospitals, outpatient services at health centres, public health services, health research, and other health activities.[10] Among these, the outpatient services at health centers and public health services together constitute 25 – 30 percent of the total health budget in most of the years (till 2001) and hence government drug spending which constitutes just a part of it can't reduce the burden of drug expenses which ultimately falls on the shoulder of the patients. The formulation and implementation of Universal Health Coverage Scheme (2002) increased the public sector share in overall health expenditure from 32 percent in 2000 to 42 percent in 2008. The national public health insurance schemes were entitled to full access of all the medicines in the National List of Essential Medicines. The Thai government was also committed to the policy of universal access to antiretroviral drugs (ARV) for HIV/AIDS patients as of 2003. Among the health insurance packages, all except CSBS have capped coverage. Anyway spending on medicines whether it is by government or by individuals is increasing, mostly owing to rise in the prices of drugs.

[10] Based on Thailand Health Profile Report, 2001 – 2004.

1.1.5 Infusion of Compulsory Licensing Provision into the World Order and into the Thai Patent System

The series of negotiations that occurred in Montreal, Geneva, Brussels, Washington, D.C., and Tokyo following the Eighth GATT Round, otherwise known as the Uruguay Round, ultimately resulted in the signing of twenty agreements in Marrakesh. Thus came into being the World Trade Organization upon its entry into force on January 1, 1995, replacing the *General Agreement on Tariffs and Trade* (GATT) system, as an authority to supervise and liberalise international trade.

I would like to note some of the key aspects of the declaration adopted at Marrakesh.

- *"……This has marked a historic step towards a more balanced and integrated global trade partnership……"*(Para 4)
- *"Ministers recall that the results of the negotiations embody provisions conferring differential and more favourable treatment for developing economies, including special attention to the particular situation of least-developed countries. Ministers recognize the importance of the implementation of these provisions for the least developed countries and declare their intention to continue to assist and facilitate the expansion of their trade and investment opportunities……"*(Para 5)

This expressively illustrates the concern of the signatories of the agreement have for the developing and the least developing countries, though that was destined to remain largely on paper only.

The provision of "Compulsory Licensing" gained cognizance in world trade as a part of the TRIPS agreement. Under Section 5: Patents of Part II of the TRIPs Agreement appears Article 31 (incorporating the Compulsory Licensing provision) though the word 'compulsory license' is used nowhere in the document. I would like to term the concerned article 'veiled beauty', since it limits the exclusive rights bestowed upon patent holders by most of the other provisions and thereby provides an escape route from the anti-competitive practices of the IPR holders. Its 'beauty' lies in the very interpretation and execution of the provision. (Article 31 is given in Appendix II).

But it took almost ten years for the development of Compulsory license as a full-fledged provision. Have made its entry into the TRIPS Agreement in 1995 as "*Other Use Without the Authorization of the Right Owner*", the provision sparked off debates and controversies regarding many of the clauses in the article. Though twelve conditions are mentioned for the implementation of the same, it didn't provide proper provision for the execution of the same in countries with insufficient or no manufacturing capacities in the pharmaceutical sector. Similarly questions were raised about the definition of "national emergency and other circumstances of extreme urgency". Hence to sort out the confusion, the Ministerial Conference convened in Doha in November 2001 made a "Declaration on the TRIPs Agreement and Public Health".

The Doha Declaration recognised 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. It stressed the need for the TRIPS Agreement to be part of the wider national and international action in addressing these problems. The Declaration ensured that interpretation and implementation of the TRIPs Agreement should be in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. And it reaffirmed the right of the WTO members to use TRIPs flexibilities to the fullest. The paragraph 5 of the declaration uses the word "Compulsory License" and provides all WTO members with the right to grant the same and the freedom to determine the grounds upon which such licences can be granted. Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution for the WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector who find difficulties in making effective use of compulsory license.

Paragraph 6 of the Doha Declaration led to further developments. A WTO TRIPs Council Decision entitled "Implementation of Paragraph 6 of Doha Declaration on the TRIPs Agreement and Public Health" was released on 30 August 2003. It provided a waiver from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products. As per the Council Decision, the

obligations of an exporting member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member, in accordance with the notification (specifying the details of import) made by the importing country to the Council of TRIPs.[11]

Besides, the licensee had to post all the details of the license and that of the concerned product on its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this decision. Inorder to avoid double payment, where a compulsory license is granted by an exporting member under the system set out in the decision, an adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Moreover, the importing member's obligation of paying the same will be waived.[12]

Most part of the 30 August 2003 Council decision made its way to Article 31bis (See Appendix III). Thus a full-fledged compulsory licensing provision was incorporated. And all the TRIPS complaint countries including Thailand have incorporated it into their national patent systems.

In 2006, the Thai government employed the TRIPs flexibility provision, Compulsory License, to find a way out of the runaway rise in drug expenses, especially due to the exorbitant prices charged for patented drugs. The Thai government issued compulsory licenses to enable import and local production of seven medicines that were patented in Thailand.

[11] Based on the Implementation of Paragraph 6 of Doha Declaration on the TRIPs Agreement and Public Health (30 August 2003).
[12] See supra note 11.

1.2 Rationale of the Study

The Compulsory License provision can be described as the "light at end of the tunnel" for the TRIPs-compliant developing countries. Though the provision is applicable to all the WTO members, it is criticized a lot when employed by developing countries to cater to their public health needs. As mentioned above, Thailand is a developing country (though categorized as Upper Middle Income country recently in 2011) and its use of the compulsory licensing provision is claimed to be effective and successful. But when we examine the question of accessibility of a medicine to the public, especially in a developing country, we should check the capability of the population to afford purchasing them out of their pockets, which is unavoidable in most of these countries. The distribution of income is one of the important factors that determines the accessibility of medicines across patients. When something is provided free, we may tend to ignore this issue.

According to Thai Budget records, in the year 2000 (before the initiation of UHC), the share of functional allocation of budget expenditure for Community and Social services was 43.6% (Education 25.6%, Health 7.4%, Social security 5.4%, Housing, community and amenity affairs and services 4.3%, & Religious, cultural and recreation affairs 0.7%) and for Economic services 22.1%. UHC was implemented in 2002 and by 2004; the proportion of budget expenditure on Health and Social Security rose to 8.4% and 7.32% respectively, which can be considered positive. But the fact is that it is just a reallocation among the various categories of expenditures on Community and Social services which remained at 42.5% (2004). The expenditure on housing, community and amenity services has come down to 1.99% that of education to 24.4%. Similar is the case in 2007 when allocation for health increased to 9.5 % and that for Community and Social services increased from 39.9% to 41.8%, but the proportion allocated to Economic Services fell from 25% to 21.2%. Both social and economic services are meant for improving the welfare of the society. Expenditure on economic services is directed at land management, provision of land to farmers, forestry, fisheries, industrial research and development, public works and so on. So ultimately what is happening is a reallocation or a governmental choice of better health or shelter or food for the public.

Hence it may be better to check whether compulsory licensing helps the population to access medicines out of their own means which also, in a way, results in similar reallocations within the household as happens with government. But then, we can see the true contribution of compulsory licensing in addressing the question of accessibility given the economic situation of the country.

1.3 Outline of the Study

To check the effectiveness of compulsory licensing in satisfying the need for accessing life saving drugs at cheaper prices, I have taken the case of Thailand to analyse whether its success story would remain so if the medicine had not been provided free, given income distribution. The relevance of domestic production in enhancing accessibility of medicines is examined. And a comparative analysis has been undertaken of India and Thailand to see how alternative policies help in bringing down medicine prices.

The Thesis is structured as follows: Chapter 2 presents a review of the existing literature. Chapter 3 presents the analysis done to check the accessibility of the six drugs for which compulsory licenses were issued for various quintiles of population if they are paying for the medicine on their own. Besides this, the trends of domestic pharmaceutical production in Thailand and its dependence on imports are analysed to check whether there has been any improvement in the context of issuance of compulsory license. Chapter 4 presents a comparative analysis of medicine prices in India and Thailand and enquires into the reasons for the wide gap that exists. Chapter 5 summarizes the findings of the study along with some suggestions.

Chapter 2

Literature Review

Availability of good quality medicines, including vaccines, at affordable prices is expected to be a required feature of the public health system of any country. But in most developing countries, an individual's access to medicine largely depends on his purchasing power which, in turn, is determined by the pattern of the distribution of income within a country. The Millennium Development Goal (MDE) 8.E expresses a global commitment to ensure that access to essential affordable medicines is achieved by 2015. To achieve this goal, an increase in spending on medicines in low and middle income countries is required. Besides, conscious and deliberate measures to foster domestic pharmaceutical production and to control the exorbitant rise in medicine prices need to be taken. In 1977 the World Health Organisation published the first model list of essential medicines, and in 1981 the WHO Action Programme on Essential Drugs was launched. Thereafter many countries adopted essential drug policies. But not many systematic studies have been undertaken on the drug situation in the global and national levels.

It is in 1988 that the "World Drug Situation" was first published by WHO which forms the baseline survey for many of the studies that were happened afterwards. According to the report, the world consumption of medicines had increased from US$ 43 million (1976) to US$ 94.1 billion (1985) with an average increase of 9.1%, but at the same time the consumption gap had widened further, leaving 75% of the world population living in the developing countries consuming just 21% of the world's drugs. Besides this, there existed the problem of irrational use of medicines in developing countries. Antibiotics are often the single largest group of drugs purchased in developing countries and there are many instances of its inappropriate use. Self medication is another problem which is pretty grave in developing countries, since many ethical drugs are also dispensed over the counter without medical prescription. And production was concentrated in a few developed countries, with around 90% of the production in seven of them in 1980: United States (30%), Japan (24%), the Federal Republic of Germany (13%), France (9%), the United Kingdom (6.4%), Italy (6%) and Switzerland (4%).

The second review of the global pharmaceutical scenario by the WHO, the "World Medicine Situation" came out in 2004. It presented the available evidence on global production, research and development, international trade and consumption of pharmaceuticals and drew on studies and surveys in the WHO member states to examine the state of national medicines policies. The report found that the relative market share of major medicine producing countries had been stable over the decade with two-third of the value of medicines produced globally being accounted for by firms with head quarters in just five countries – the USA, Japan, Germany, France and the UK. At the same time, large volume markets of lower-price medicines developed in the highly competitive domestic markets of India and China. But the report did not attempt to deal in a comprehensive way with a number of key policy issues in medicines policy, such as parallel trade, intellectual property rights, counterfeiting, or corporate pricing strategy.

Another noticeable development that occurred during the decade which contributed much to the understanding of global medicine accessibility was the combined initiative undertaken by the World Health Organisation (WHO) and Health Action International (HAI) to measure and monitor medicine prices and affordability in very systematic manner. The manual entitled "***Medicine Prices - a New Approach to Measurement***" and accompanying Workbook, the first version of which was developed in 2003 and revised in 2008 by the WHO/HAI presented a new and effective approach for measuring and monitoring the prices of medicines. This approach involved systematic surveys to collect accurate data and reliable information on a standard list of medicines, comparisons using international reference prices of innovator and of generic equivalent medicines, sector-wise price comparisons (e.g. public, private for-profit, private not –for-profit sectors), affordability comparisons and identification of components making up the final price. For affordability analysis, instead of comparing medicine prices with an index price, the cost of a course of therapy for important conditions are compared with the daily wage of the lowest paid government worker. Many surveys are conducted using the WHO/HAI standardized methodology and all of them are available in the HAI official website. The standardized method developed by them and the surveys undertaken using it formed the basis for many of the further studies in this direction. Some of these studies provided me insights for my own study.

Alexandra Cameron et.al (2009) undertook a secondary analysis of medicine availability in 36 developing and middle income countries using the data from 45 national and sub national surveys done using the WHO/HAI methodology. The results of the analysis done for 15 medicines included in at least 80% of the surveys and four individual medicines showed that the mean availability of generic medicines in the public sector was lower than that in the private sector in all WHO regions, ranging from 29.4% in Africa to 54.4% in Americas. The average median price ratio for public procurement turned out to be 1.11, but the purchasing efficiency ranged from 0.09 in Sudan to 5.37 times the international reference price in Nigeria. Many medicines were not consistently available in the public sector. Besides, low procurement prices did not always translate into low patient prices. And in the private sector, wholesale mark-ups ranged from 2% to 380%, whereas retail mark-ups ranged from 10% to 552%. The percentage difference in price between originator brands and lowest-priced generics was over 300% in lower-middle income and low income countries. All these made treatments for acute and chronic illness largely unaffordable in many countries.

Alexandra Cameron et.al (2011) conducted another study to investigate the potential differences in the availability of medicines for chronic and acute conditions in low and middle income countries. The study is very relevant in this age of epidemiological transition wherein chronic conditions account for one-third of the Disability Adjusted Life Years (DALYs) in low-income countries and for nearly two-thirds in middle-income countries. Data comprising of 30 commonly-surveyed medicines (15 for acute and 15 for chronic conditions) obtained using the WHO-HAI methodology was used for the study. The study showed that medicines for chronic conditions are less available than those for acute conditions which have traditionally been the focus of the health system in these countries. And there seems to exist an inverse association between country income level and the availability gap between groups of medicines, especially, in the public sector.

The latest edition of World Medicines Situation (2011) consisting of fifteen parts is a very detailed one. As per the report, 16 percent of the world's population living in high-income countries accounts for over 78 percent of the global expenditures on medicines. Per capita pharmaceutical expenditures ranged from US $7.61 in low income countries to

US $ 431.6 in high income countries, with a considerable variation between income groups in each country. Pharmaceutical spending as a share of total health expenditure ranges from a mean of 19.7% in high income countries to a mean of 30.4% in low income countries with poorer countries spending proportionately more of their health budget on medicines than on the wealthier ones. Regarding availability of medicines, the public sector availability of the originator brand is low since most governments are favouring the purchase and distribution of generic equivalents. The public sector availability of generic medicines ranges from 32% in the Eastern Mediterranean[13] to 58% in Europe, with a large variation being observed across the individual countries in all regions. And the private sector availability of generic medicines is higher than that in the public sector in all regions.

Sooksriwong C et.al (2009) have undertaken a study under the auspices of the Thailand Food and Drug Administration with the co-operation of the Mahidol University to document the situation of medicine prices in public and private health sectors in Thailand. Here too the standardized methodology developed by WHO-HAI has been employed. The public sector procured generics and innovator brands at 1.46 and 3.3 MPR (Median Price Ratio) while patients paid 2.55 and 4.36 MPR respectively. At the same time private pharmacies procured lowest price generics at 1.48 MPR and innovator brands at 9.67 MPR, and were selling them at 3.31 MPR and 11.6 MPR respectively. As a result of no medicine pricing policy in Thailand, it was found that across public and private sectors, different public hospitals, and different private pharmacies, the same products are procured and sold to patients at different prices. The median mark-up for innovator brands were 31% in the public sector and 22% in the private sector, whereas for the lowest priced generics, the median mark-up turned out to be 80% in the public and 96% in the private sector.

On August 30, 2003, the World Trade Organisation accepted a set of new rules enhancing the scope of compulsory licensing provision and making it full-fledged by letting countries with insufficient productive capacity to import generic versions and thereby

[13] WHO Member States are grouped into six regions – Africa, Americas, South-east Asia, Europe, the Eastern Mediterranean and the Western Pacific.

improving the accessibility of medicines. Together with the provision emerged controversies relating to it, notably its negative impact on innovation. In my thesis, I would like to relate the question of medicine accessibility with TRIPs flexibility provision, Compulsory Licensing, to check the effectiveness of the provision in achieving the same. For a comprehensive literature review on various aspects of compulsory licensing, it is essential to consider both formal papers and grey literature dealing with its impact on pharmaceutical innovation and on medicine prices, accessibility and so on.

Clien (2003) performed an empirical analysis on six cases of compulsory licenses in the pharmaceutical sector issued in the United States by the Department of Justice in the 1980s and 1990s. She analyses the rates of innovation within each therapeutic area before and after the issuance of compulsory licences and finds that there is no systematic evidence that individual companies reduce their investment in R&D after being affected by a compulsory license. She also discusses how the structure and implementation of compulsory licenses can affect R&D. According to her, the impact of compulsory license on R&D depends on two important factors: a) how predictable the compulsory license is and b) the relative importance of the market for the affected product. She suggests that based on past experience, compulsory license need not result in a decline in innovation and that policy options for increasing access to medicines deserve greater exploration. But this study did not take into account the impact of the royalty level at which the license is set.

A Kommerskollegium (National Board of Trade, Sweden) report (2008) on the WTO decision on compulsory licensing provides a comprehensive sketch of the prerequisites for the implementation of compulsory licenses, their effects and the possible future challenges. The economic requisite is that there should be a new producer capable of producing and selling the medicine at a price much lower than the patent price. The political requisite is that the issuance should not result in reciprocal measures like trade sanctions from high income countries. Besides, an importer country is dependent on the exporting country for granting compulsory licenses. In fact, a favourable political climate is inevitable since the political situation surrounding compulsory licenses can influence the decision of the exporter. While noting the legal prerequisite, this document points to

one of the main issues of relevance today, which is the impact of Regional Free Trade Agreements and the resultant TRIPS-plus provisions. For the implementation of compulsory licenses, the provision regarding the issuance of the same should not be contradicted by other international commitments. Moreover the tendency of more and more developing countries, which are capable of generic production (like India), becoming TRIPS compliant and the highly concentrated nature of the pharmaceutical industry through mergers and acquisitions limit the possibility of implementation of the provision.

Outterson (2009) in his paper deals with one of crucial misinterpretations regarding the application of the compulsory licensing provision. This provision is seemed to be misunderstood, perhaps deliberately, by the developed world with an intention to limit its application to certain infectious diseases. Outterson describes in length the negotiating history of article 31 and effectively substantiates the fact that TRIPS flexibilities have never been limited to any specific set of diseases nor to any specific set of nations. He says that the point is more nuanced. The Doha Declaration mentions specific diseases in two contexts- in paragraph 1 and in paragraph 5 (c), but neither of them operates as a disease-based limitation on compulsory license. The Doha declaration 5(c) notes that "..... public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency." He argues that the *ejusdem generis* interpretation rule might give members additional flexibility with regard to epidemic diseases, without any limitation on the application of Article 31 to other diseases.

While considering the case of compulsory licensing in Thailand, the two documents which deserve special mention and need to be reviewed are the two White Papers published by the Thai government. These are two authentic documents regarding the issuance of compulsory licenses in Thailand and are publicly available. Along with the white paper relevant documents like official orders declaring the issuance of compulsory license, copies of various correspondences at higher levels regarding this, etc have been released publicly.

The First White Paper regarding compulsory licensing published in February 2007 (just after the issuance of the first set of compulsory licenses) tries to answer ten burning issues (questions) related to the government's use of patents issued. It explains the rationale of the decision and the circumstances that led to it. Some of the points worth-mentioning are clarifications provided by this document on the major controversies regarding the government's decision. The criteria for deciding the drug to be issued with compulsory license are well-defined and are compliant with international law. Besides, in deciding the royalty rates, specific norms were being followed and the pharmaceutical firms were being informed about the government proposal so that they can formally intimate any disagreement they may have. The white paper also claimed that the government's use of patents does not touch the existing market of the originator brand. It stated that the government's use of patents is meant to meet the needs of those who never had access to these drugs before. Realising that the initiative for negotiation reached nowhere the government decided to go ahead with the issuance of compulsory license, but kept the floor open for discussion and negotiation even after the issuance of the same.

The Second White Paper (February 2008) published after the issuance of the second set of compulsory licenses states that the processes to decide upon the government's use of patents started in September 2007. Here too all four anti-cancer drugs issued with compulsory licenses satisfied the criteria required for the issuance of the same. To survey the quality of the generic drugs to be imported, the Health Minister along with a technical team visited the Indian firms. The procurement process was governed by the Government Pharmaceutical Organisation's (GPO) procurement rules and regulations, and had been undertaken through a transparent system of open bidding. Besides, the GPO was conducting quality surveillance of randomized samples of imported drugs to ensure drug quality. Moreover strict measures were being employed to avoid the over-the-counter sale of compulsory licensed drugs. They were available by medical prescription only and must be prescribed by specialist doctors. These drugs were to be supplied only to contracted hospitals under the national health security system.

In effect these two white papers served as the government's declaration justifying its decision to issue compulsory licenses along with a narration of the circumstances that led to the issuance of the same.

Suwit Wibulpolprasert et.al (2011) analysed the policy processes that led to the granting and implementation of the government use licenses to enable the import and the production of generic versions of medicines patented in Thailand. The paper demonstrates that implementation of compulsory license was the successful application of the well-known conceptualization -*"the triangle that moves the mountain"*- the philosophical and strategic approach to policy advocacy by Dr Prawase Wasi. His triangular model is an effective bridging of three powers: (a) knowledge and evidence generated by research and analysis, (b) mobilization of civil society and public support, and (c) leadership of policy makers and politicians which together lead to the resolution of seemingly insurmountable problems. Focusing on the strategies for the effective implementation of compulsory licenses, they urged fostering collaboration between the government authorities, civil society organisations, foreign experts and international agencies in the relevant fields to mobilize broad based support from other countries and actors besides adequate management capacity at the national level and appropriate institutional mechanisms.

Yamabhai et.al (2011) analysed the health and health related economic impacts of the government use licenses issued in Thailand. Their study adopted a five-year timeframe for assessment commencing from the time of the grant of the government use licenses. The study revealed that as a result of the granting of the government use licenses, an additional 84,158 patients were estimated to have gained access to seven drugs over five years. Health gains from the use of the seven drugs compared to their best alternative accounted for 12,493 QALYs (Quality Adjusted Life Years) gained, which translates into quantifiable incremental benefits to society of USD 132.4 million. Besides they found that Thailand's overall exports increased overtime, although exports of the three US GSP withdrawal products to the US did decline. As a whole the public health benefits of the government use licenses turned out to be positive as per this study.

The reports and studies on the global medicine situation present the trend and pattern of medicine accessibility across the world among countries of different income strata and also the accessibility of medicines for different disease groups (chronic & acute) and the trends of global pharmaceutical production. Regarding the impact of compulsory licensing on improving medicine accessibility, the studies undertaken so far, especially for Thailand, praise the provision without going much into the details of how the government made it a success story. In Thailand's case, the presence of Indian firms who were ready to export the lower priced generic equivalents since those drugs were not patented there and the fact that the Thai government was paying for all the medicines for which compulsory licenses were issued ultimately made it a great success. Anyway it is true that when a compulsory license is issued, there results an improvement in the accessibility of medicine to which it is issued due to the price reduction brought about by the entry of generic versions.

I would like to analyse the effects of issuance of compulsory licensing provision in Thailand taking into consideration the pattern of their income distribution. Inorder to check the impact of compulsory license alone in answering the medicine accessibility question, I assume that the medicines are not provided for free. Moreover the trends in domestic production need to be analysed. I would also consider some alternative policies which can work as a solution to the problem of higher prices by incorporating a comparative analysis with India which has tried some of them.

Chapter 3

Compulsory Licensing and Its Impacts

3.1 Introduction

A Compulsory License is a permission granted by the government to allow someone other than the patent holder to produce a patented good or replicate the process without the consent of the patent owner. When a government itself uses, or authorizes a third party to use, a patented invention for government purposes, without the permission of the patent holder, it is called government use. In Thailand all the compulsory licenses were issued as government use licenses meant for non-commercial purposes. Hence the impact of a compulsory license on accessibility of a medicine to the public has not been analysed from the perspective of a Thai citizen. The application of the compulsory licensing provision with the government as sole supplier importing the medicine at a lower price and making it available to already recorded patients has been claimed as a great success in Thailand.

Many studies have been done checking the net benefits of the compulsory licensing provision by analysing health and health-related economic benefits that Thailand has gained out of the issuance of the license, but without going into the details of budget allocation. When we look at the budget allocation, we find that the share of expenditure on health affairs and services has increased only from 7.4% to 9.5% in 2007. Total spending on social and community services has also increased by only 2 percentage points over the same period, accompanied by a fall in the proportion of spending on economic services from 25% to 21.2%. Social and economic services both constitute the developmental spending of the government. If the government starts choosing between them and health spending for the whole population, both have and have nots, without checking affordability, it will amount to a socially regressive allocation of resources. In 2006 around 96% of the people in Thailand had health insurance coverage, when the government issued the first compulsory license. Among them 94.6% were covered by one or other public health insurance programme of the country. When government use of licenses was implemented, the concerned medicines were provided for free to all those

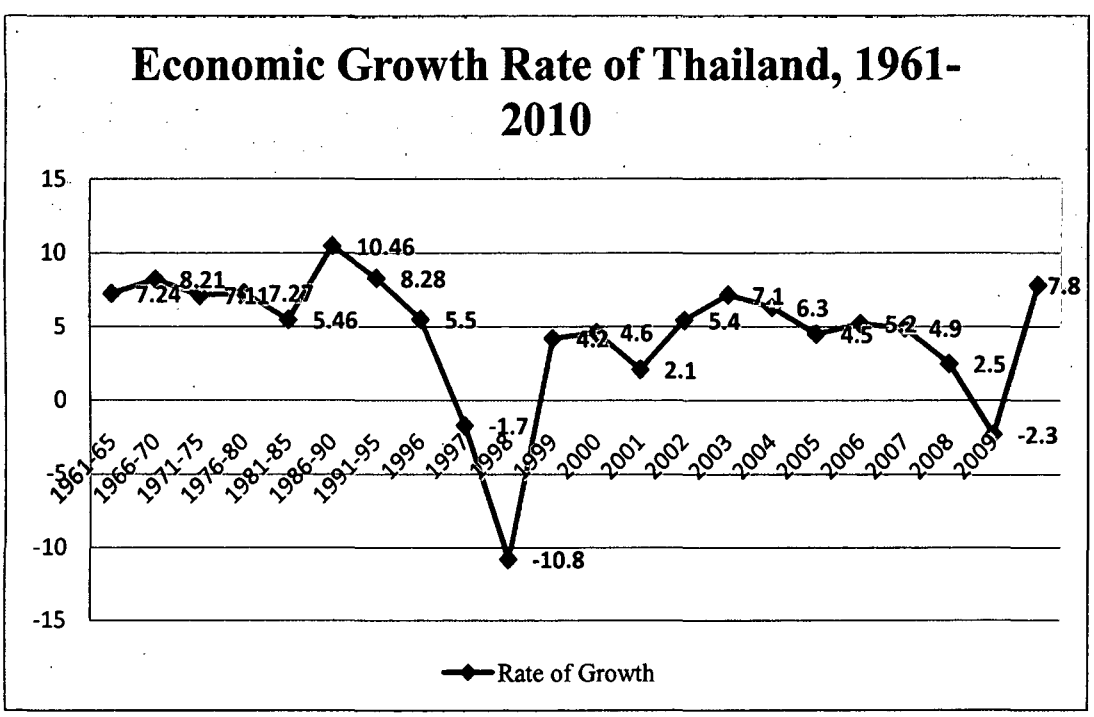
who were insured under the national public health insurance schemes. While the attempt at universal coverage had its justification, in practice the uninsured ones, though few in number, remained unaccounted and the insured ones who were capable of paying the reduced prices were also provided with free medicines.

Because of the above mentioned reasons, I felt it is necessary to analyse the impact of compulsory licensing in enhancing the affordability of medicines from the perspective of Thai citizens to see the real benefits compulsory licenses bestowed upon them, given the economic situation and income distribution of the country.

3.2 Trends of Thailand's Growth and the Pattern of Income Distribution

Thailand belongs to the group of Upper Middle income countries, with its growth story closely related to the East Asian growth story, joined the group of High Performing Asian Economies (HPAEs) in the 1980s.

Figure 3.1: Thailand's Growth Performance, 1961-2010

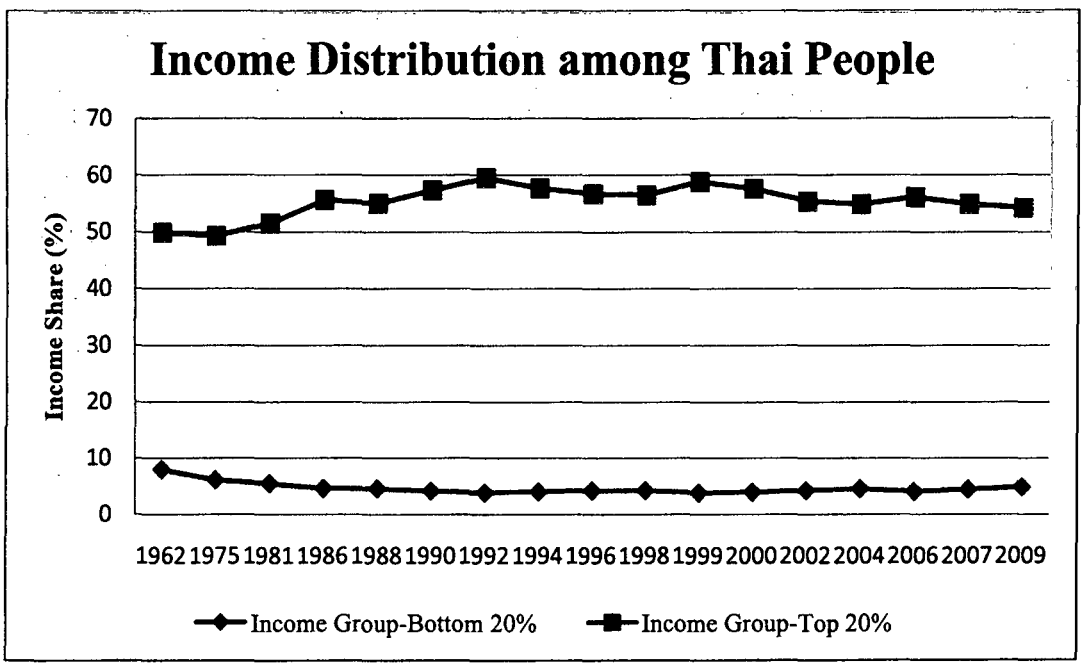


Source: Office of National Economic and Social Development Board (NESDB).

The average growth rate of the Thai economy during the 1961-1996 period was higher than 7 percent (approx. 7.44%). The growth story of Thailand changed in 1997 with the onset of the economic crisis. The economy shrank, and growth became negative for two years (-1.7% in 1997 and -10.8 % in 1998), till the economy recovered in1999. After that Thailand continued to grow at a reasonable rate with an average annual rate of growth of 4.68% until it was once again hit by the global economic recession in 2008. After registering a negative rate of growth (-2.3%) for just one year (2009), the economy recovered to a high growth rate of 7.8 percent in 2010.

Since the inception of the National Economic and Social Development Plan in 1961, Gross Domestic Product (GDP) Per Capita increased almost throughout, except, during the crisis periods in the year 1998 and in 2009 (See Appendix IV). But the pattern of income distribution was not at all fair, throughout. In the initial years (till 1981), the top 20% had less than fifty percent of the total income. But the situation changed when the economy started prospering. The following figure presents the pattern of income distribution.

Figure 3.2: Income Distribution among Thai Population, 1962-2009



Source: Economic and Social Household Survey of the National Statistical Office & Thailand Health Profile 2008-10, released by MoPH, Thailand (Table given in Appendix V)

Thai society became more unequal in terms of income distribution as market forces led economic growth. The income share of the top 20% touched 59.5 percent in 1992 leaving the bottom 20% with just 3.8 percent of total income. This implies that the Thai growth process is entirely in favour of the rich, with the peak period of growth being the peak period for income inequality too. From the Eighth Plan onwards, conscious measures were employed to let the benefits of growth reached poorer sections. Yet, even today Thailand is among the countries with very high levels of inequality.[14] The latest Gini index value calculated for Thailand is 53.6.[15]

3.3 Brief Account of the Compulsory licenses Issued

The Thai Patent Act of 11 March B.E.2522 (A.D 1979) as amended by the Patent Act (No.3) B.E. 2542 (A.D 1999) on 21 March 1999 came into force in September 1999. Part V of the Act "Licenses of Right Compulsory Licenses and Government Use" embodies the TRIPS Agreement Article 31 (b) and the Doha Ministerial Declaration on TRIPs and Public Health and incorporates broad mechanisms of using patent rights by agents other than the patent owner. Thai Patent Act sections 46 to 50 deal with non-public use of the patent right and Thai Patent Act sections 51 and 52 deal with public use of patent rights. Hence Thai Patent Act Sections 51 and 52 provide the grounds for the issuance of the government use licenses, though the government has also tried prior negotiation with the patented pharmaceutical firms.

The first set of compulsory licenses was issued in 2006 - 2007. To be exact, the first one, for a first line ARV drug – Stocrin (Efavirenz) -- on 29 November B.E.2549 (2006), the second one, for a second line ARV drug, Kaletra (Lopinavir + Ritonavir) on 26 January B.E.2550 (2007), and the third one, for an anti-platelet drug, Clopidogrel on 12 February B.E.2550 (2007).

[14] The level of inequality existing in a country is determined by the value of gini index. The countries with value between 0.200 and 0.299 are categorized as "low inequality", between 0.300 and 0.399 are categorized as "medium inequality, between 0.400 and 0.499 are categorized as "high inequality and that with 0.500 and above are categorized as "very high inequality.

[15] Value given in the CIA World Factbook.

3.3.1 Public Use of Patent for Efavirenz: Widespread use of Highly Active Antiretroviral Therapy (HAART)[16] has led to dramatic reductions in morbidity and mortality among individuals infected with the human immunodeficiency virus (HIV-1).[17] The government of Thailand produced a low-priced, combination-therapy antiretroviral drug called GPO-VIR in 2002 to give HIV patients access to antiretroviral treatment. The pill is a '3-in-1' combination, containing stavudine (Zerit) 30-40 mg, lamivudine (Epivir) 150 mg, and nevirapine (Viramune) 200 mg. Efavirenz is an effective first line Antiretroviral (ARV) Drug. It is less toxic compared to Nevirapine. In Thailand, due to the high price of Efavirenz, all new cases of AIDs have to be put on the more toxic Navirapine based ARVs as the first line of treatment. Around 20 per cent of them develop adverse reactions to the GPO-VIR. It is only then that they are switched to the Efavirenz based one, which is more than twice the price of GPO-VIR (Thailand White Paper, 2007). Hence, to increase access to Efavirenz under the universal access to antiretrovirals policy, the Department of Disease Control, Ministry of Public Health, decided to use the compulsory licensing right and authorized the Government Pharmaceutical Organization (GPO) to import or produce Efavirenz for public interest on 29th November B.E. 2549 (2006).[18]

3.3.2 Public Use of Patent for Kaletra (Lopinavir + Ritonavir): The Department of Disease Control had done a study on drug resistance among patients taking the first line ARVs. They found that around 10 per cent will develop drug resistance and will require second line ARVs, in the first few years. This depends mainly on the compliance of the patient and the virus itself. There were around 500,000 people living with HIV/AIDs in Thailand in 2006. It seemed that in the near future, at least 50,000 of them would require second line ARVs and one of the best second line drugs is the combination between Lopinavir and Ritonavir, patented by Abbott Laboratories Limited, under the trade name of Kaletra®. The monthly price for the patented product was around 6,000 Baht in 2007.

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[16] HAART is the combination of at least three drugs from the various classes of antiretroviral drugs into a 'cocktail' that typically produces a dramatic reduction in viral load and prevents further immune damage. (Definition given in paper "The Efficacy and Adverse Effects of GPO-VIR in Treatment – Naive Adult HIV Patients.")

[17] Carpenter C C et.al (2000)

[18] Letter from the Department of Disease Control, Ministry of Public Health, Thailand to Merck Sharp and Dohme.

This meant 72,000 Baht per patient per year and so a sum total of 3,600 million Baht was required for 50,000 patients. This was more than 100 per cent of the budget for ARVs in 2007. If they did not receive second line ARVs, they would have soon developed opportunistic infections and died. By resorting to the Government Use of Patent, the government expected the drug price to go down to at least 20 per cent of the prevailing price, which could save an additional 8,000 lives. Hence to increase access to Kaletra® under the universal access to antiretrovirals policy, the Department of Disease Control, Ministry of Public Health, decided to issue compulsory license on 26th January B.E. 2550 (2007) and authorized the Government Pharmaceutical Organization (GPO) to import or produce Kaletra® for public use with a royalty fee of 0.5 per cent.

3.3.3 Public Use of Patent for Clopidogrel: Clopidogrel, an anti-platelet drug, is highly effective for preventing coronary obstruction. This heart drug with the brand name Plavix was being marketed by Sanofi -Synthelabo (Thailand) Limited. It is almost the only drug that can be used when applying a coronary artery stent. However, due to the very high price of 73 Baht per day, many patients could not afford it. So, poor people who cannot afford to pay had to rely on Acetyl Salicylic Acid (Aspirin). An announcement of the Government Use of its patent was expected to reduce the price at least 10 times to less than 7 Baht and allow patients under the universal health insurance scheme to have access to the drug. Hence to make it more affordable to the government and thereby to increase access to Clopidogrel under the National Health Security Schemes, the Ministry of Public Health decided to issue compulsory license on 12th February, B.E. 2550 (2007) and authorized the Government Pharmaceutical Organization (GPO) to import or produce Clopidogrel for public use with a royalty fee of 0.5 percent.

3.3.4 Public Use of Patent for Four Anti cancer Drugs

The issuance of the second set of compulsory licenses related to four essential anti-cancer drugs. This happened when cancer had emerged as one of the top killers in Thailand for over a decade, and the leading types were lung and breast cancer. Many of the newly developed patented drugs were not included in the National List of Essential Medicines (NLEM) owing to higher prices, nor covered under the health insurance system. Hence the only option left to make them affordable was to issue compulsory licenses. But before

issuing the same, the government left the option for the pharmaceutical companies to resort to negotiations open. To come to an amicable agreement, the Committee to Negotiate the Price of Essential Patented Drugs under the auspices of the Thai government began talks with the pharmaceutical companies, who were the patent owners of the concerned drugs since mid-October, 2007. Since the offers put forward by the pharmaceutical companies were not satisfactory, the Committee to support the Implementation of the Government Use of Patents proposed that the Minister of Public Health sign the notifications of the Government Use of Patents on December 28, 2007. Though the Public Health Minister signed the four notifications, he insisted on deferring the implementation to allow a last chance for negotiation.

Table 3.1: Price and Other Details of the Anti-Cancer Drugs Considered for the Issuance of Compulsory License

Name	Brand Name	Patent Owner	ED/ NED	Presentation	Price (Baht/ Unit)		Generic Producer
					Originator	Generic	
Imatinib (tab.)	Glivec	Novartis	NED	100mg tab	917	50.2	Abil
						58.6	Natco
						70	Dabur
Docetaxel (inj.)	Taxotere	Sanofi Aventis	NED	20 mg/ 0.5ml vial	7030	1800	Dabur
				80mg/2ml vial	25000	4000	Dabur
Erlotinib (tab.)	Tarceva	Roche	NED	150 mg tab	2750	735.58	Abil
Letrozole (tab.)	Femara	Novartis	ED	2.5 mg tab	230	6.71	Abil
						6 - 7	Cipla

Source: "The 10 Burning Questions on the Government Use of Patents on the Four Anti-Cancer drugs in Thailand", released by the MoPH and NHSO, Thailand on February 2008.
Note: ED- Essential Drug, NED- Not included in the Essential Drug List, "inj" implies injection & "tab" implies tablet.

Among the four companies, only Novartis, who owned the patent right of Imatinib (marketing under the trade name, Glivec), came up with a better deal. Imatinib is used to combat Chronic Myelogenous Leukemia (CML) and Gastro-Intestinal Stromal Tumors (GISTs). The price of a 100mg tablet of the originator brand cost 917 baht, which was almost 20 times that of the generic equivalent which cost just 50- 70 baht (produced by Indian generic firms like Abil, Natco & Dabur). Novartis proposed on January 18 and finally confirmed on January 23, 2008, to allow all patients under the Universal Health

Coverage (Gold Card) scheme, whose household income was less than 1.7 million Baht per year and needed 400 mg of Imatinib per day, or whose income is less than 2.2 million Baht per year and need 600 mg of Imatinib per day, to have free access to Imatinib, if indicated by the attending physicians.[19] This was expected to ultimately put all the patients under the Universal Health Coverage scheme into the Glivec International Patient Access Program (GIPAP) operated by Max Foundation. Hence the implementation of Government Use of Patent became unwarranted. However, in order to ensure the continuity and sustainability of the commitment from Novartis, the Minister of Public Health signed a conditional Government Use of Patent on Imatinib in case GIPAP failed or was terminated. For the other three drugs mentioned in the table above the government had implemented Government Use of Patent.

3.4 Analysing the Affordability of Medicines Before and After the Issuance of Compulsory License

To analyse how far the Compulsory licensing provision can be effective in increasing the accessibility of medicines, we consider the case of the six medicines for which it has been issued and check their affordability for different quintiles of population, on the assumption that they are paying for the medicine out of their own pockets. For the first set of medicines for which compulsory licenses were issued, the income distribution of 2006 is used for the analysis since the licenses were issued by late 2006 and early 2007. For the second set of medicines, the income distribution of 2007 is used since they were issued in January 2008. Table 3.2 gives the income distribution of Thailand in the years 2006 and 2007.

Table 3.2: Income Distribution in Thailand, 2006 & 2007

Quintiles	Income Share (%)	
	2006	2007
Poorest 20%	4	4.4
Second Group	7.7	8
Third Group	12.1	12.4
Fourth Group	20	20.2
Richest 20%	56.1	54.9

Source: Thailand Socio-Economic Survey, National Statistical Office and "Education, Income Inequality and Thai Economy for the Next Generation" by San Sampattavanija.

[19] White Paper (Ministryof Public Health, Thailand, 2008).

The GNI, PPP of Thailand at current international dollars for the year 2006 was $463 billion ($463,457,801,940.3), and the population of Thailand in that year is 67.3 million (67,276,383).[20] The percentage share of income that accrued to each group was 4, 7.7, 12.1, 20 and 56.1 percent respectively from the lowest to the highest quintile.

Table 3.3: Share of Income of Each Group from Poorest to the Richest in 2006

Quintiles	Income with each group (in billion Int.$)	PCI (in Int. $)	Monthly PCI (in Int.$)
Poorest 20%	18.54	1377.77	114.81
Second Group	35.69	2652.21	221.02
Third Group	56.08	4167.76	347.07
Fourth Group	92.69	6889.86	574.07
Richest 20%	259	19323.26	1610.27

Source: GNI,PPP & Population data from World Development Indicators published by the World Bank.

Out of the total income of $ 463 billion, the richest 20 percent of the population obtained the largest share, amounting to $259 billion which was more than half of the national income. The poorest 20 percent earned only four percent of the total, or just $ 18.54 billion. The second, third and fourth group earned $ 35.69 billion, $ 56.08 billion and $ 92.69 billion respectively. The per capita income of the richest group was more than 14 times that of the poorest ones. The ability to purchase medicines is determined by the income the people earn or the wealth they possess. We will need to assess whether all the quintiles of the population could afford the life saving drugs for which compulsory licenses had been issued.

For the three medicines for which compulsory licenses were issued in the first set, the monthly expenses for the patented medicine and the generic ones were hugely different. Let us consider the cases one by one in the order in which the licences were issued.

Efavirenz : Efavirenz, with the brand name 'Stocrin' patented by Merck Sharp and Dohme (Thailand) Limited, belongs to the group of medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs) and is used as part of highly active

[20] Data Bank, World Development Indicators.

antiretroviral therapy (HAART) for the treatment of human immunodeficiency virus (HIV) type 1. It works by interrupting the formation of new HIV particles in already infected cells. When HIV is attacked by Stocrin, the virus won't able to reproduce normally. This helps to reduce the amount of virus in the blood, and thus increases the CD4 count.[21]

Table 3.4: Share of Monthly Income to be Spent by Each Group for Efavirenz

Quintiles	Share of monthly income spend before CL (%)	Share of monthly income spend after CL (%)
Poorest 20%	35.71	19.16
Second Group	18.55	9.95
Third Group	11.81	6.33
Fourth Group	7.14	3.83
Richest 20%	2.55	1.37

Note: CL means Compulsory Licensing.

The patented drug, Stocrin costs $41 (1500 Baht) per person per month.[22] Hence a person in the poorest group had to spend over 35 percent of his monthly income for the medicine. Those in the higher income groups had to spend a smaller share of their monthly income for the treatment. When the generic drug was made available as a result of compulsory licensing, the price had come down to $22 (800 Baht) per person per month, or roughly half of the initial price. As a result, except those in the poorest income quintile, who still had to pay more than 19 percent of their monthly income for the treatment, others have to spend less than ten percent of their income to purchase it.

Kaletra: The second drug for which compulsory license had been issued was Kaletra. This is a fixed dose combination between Lopinavir and Ritonavir patented by Abbott Laboratories Limited which was being used as a second line Antiretroviral (ARV) drug. Once HIV infected patients developed resistance to the first line ARV drugs, they have to shift to the second line ARV medicine.

[21] CD4 cells are a type of white blood cell that fights infection. The CD4 count measures the number of CD4 cells in a sample of your blood. Higher CD4 count reduces the complications of HIV disease and extends your life.

[22] Bridges Weekly Trade News Digest, Vol. 10, Number 42, 13th December 2006, available at http://ictsd.org/i/news/bridgesweekly/7181/

Table 3.5: Share of Monthly Income to be Spent by Each Group for Kaletra

Quintiles	Share of monthly income spend before CL (%)	Share of monthly income spend after CL (%)
Poorest 20%	157.65	104.52
Second Group	81.89	54.29
Third Group	52.11	34.55
Fourth Group	31.53	20.9
Richest 20%	11.24	7.54

Note: CL means Compulsory Licensing.

The patented medicine was priced at $ 181 for a month.[23] Hence the lowest quintile could by no means afford the treatment, since the cost was higher than their monthly per capita income. For the second quintile also, it was nearly unaffordable since it would cost more than 80 percent of their monthly income. Even for those in the third quintile, a month's treatment costs more than half of their monthly earnings. For the fourth and the richest group, the ratio was 32 percent and 11 percent of their monthly income respectively. Thus, even after the issuance of compulsory license, though the price had come down to around 66 percent of the previous price (price of the imported generic version is $120), the medicine remained out of the reach of the poorest section. The second group also has to spend around 55 percent of their monthly earning for just this medicine. The next three groups have to spend 34.5 percent, 21 percent and 7.5 percent of their monthly income respectively.

Clopidrogrel: The third medicine for which compulsory license had been issued is an anti- platelet drug, Plavix. The patent for Plavix (Clopidrogrel Bisulfate) was held by Sanofi Aventis. It is estimated that there were around 3 lakh patients needing the medicine in Thailand at the time, and was more or less the only medicine that could be used when applying a coronary artery stent.

[23] Keith Alcorn (2007), available at http://www.aidsmap.com/Abbott-announces-iKaletrai-price-cut-for-lower-middle-income-countries-makes-new-offer-to-Thailand/page/1426966/ (accessed on 11th March, 2013).

Table 3.6: Share of Monthly Income to be Spent by Each Group for Clopidogrel

Quintiles	Share of monthly income spend before CL (%)	Share of monthly income spend after CL (%)
poorest 20%	54.6	4.79
Second Group	28.37	2.49
Third Group	18.05	1.58
Fourth Group	10.92	0.96
Richest 20%	3.89	0.34

Note: CL means Compulsory Licensing.

The price of the branded medicine was $2.06 (73 Baht) per day.[24] Hence the government decided to issue a compulsory license, bringing the price down to 18 cents (less than 7 Baht). Hence those belonging to the poorest 20 percent, who had spent around 55 percent of their monthly income, now had to pay only around 5 percent of their income for a month's treatment. The second, third and fourth groups who had earlier spent nearly 30, 20 and 10 percent of their incomes, now had to spend around 3, 2, 1 percent of their income respectively. The richest group, which needed to spend less than 4 percent of their income prior to CL, had to spend a marginal fraction of their income after CL.

Table 3.7: Share of Income of Each Group from Poorest to the Richest in 2007

Quintiles	Income with each group (in billion Int.$)	PCI (in Int. $)	Monthly PCI (in Int.$)
Poorest 20%	22.13	1632.16	136.01
Second Group	40.24	2967.56	247.3
Third Group	62.37	4599.72	383.31
Fourth Group	101.6	7493.09	624.42
Richest 20%	276.13	20364.9	1697.07

Source: GNI,PPP & Population data from World Development Indicators published by the World Bank

For the three drugs in the second list of compulsory licenses issued on January 2008, the calculations are done using the income distribution in 2007. The table below presents the pattern of income distribution. The GNI, PPP of Thailand at current international dollars for the year 2007 was $502 billion ($502,975,468,628.2), and the population of Thailand in the year was 67.8 million (67,796,451). The percentage share of income accruing to

[24] White Paper (Ministry of Public Health, Thailand 2007).

the each quintile of the population was 4.4, 8, 12.4, 20.2 and 54.9 percent respectively from the lowest to the highest.

Out of the total income of $ 502 billion, the richest 20 percent received the largest share, amounting to $276 billion or more than half of the national income. The poorest 20 percent received less than five percent of the total, just $ 22.13 billion. The second, third and fourth quintiles (from the bottom) received $ 40.24 billion, $ 62.37 billion and $ 101.6 billion respectively. The per capita income in the richest group was around 12.5 times that in the poorest. The disparity ratio had slightly come down relative to 2006. These figures allow us to assess the affordability of the anti-cancer drugs for various sections of the population.

Docetaxel: Lung and breast cancer are the leading cancers among Thai males and females respectively. Docetaxel (under the trade name Taxotere in Thailand) is a clinically well-established anti-mitotic chemotherapy medication for treatment of the two cancers. Docetaxel is highly active in metastatic breast cancer, even as a third-line treatment, and can be considered as an efficient standard option in second line treatment.[25] Besides, it is also used effectively to treat gastric, head and neck cancers. The price of Docetaxel 80 mg was $ 863, and that of the generic version imported after the issuance of Compulsory License was $ 37.9 and that of the 20 mg ones were $ 237.71 and $ 9.1 respectively.[26] The dosage is 75 mg/m^2 IV (intravenous) over one hour repeated at 3 week intervals and given in four cycles.[27] So for one cycle, 120 mg of Docetaxel is

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[25] Salminen, E et. al (1999).

[26] Assessing the Implications of Thailand's Government Use Licenses, Issued in 2006-2008 (Health Intervention & Technology Assessment Program, 2009).

[27] **Calculating BSA (m^2)**
Body Surface Area (BSA in m^2) = SQRT [(weight (kg) x height (cm)) / 3600]
Or
Body Surface Area (BSA in m^2) = SQRT [(weight (lb) x height (in)) / 3131]
Ex: If you know a patient weighs 140 lb and 62 inches tall, to calculate the BSA, you can simply plug the numbers into the formula, then solve
BSA (m^2) =SQRT [(140 lb x 62 in)/3131]
140 x 62 = 8,680; 8,680 ÷ 3131 = 2.77
$\sqrt{2.77}$ = **1.66 m^2**
Then we have to multiply the BSA (m^2) with the dosage (here 75 mg/m^2). The standard requirement is 120 mg IV for a cycle.

required. Hence expenditure per patient per year was $ 5178 when the patented drug was used, which came down to $ 227.4 after the issuance of the Compulsory license.

Table 3.8: Share of Per Capita Income to be Spent by Each Group for Docetaxel

Quintiles	Share of PCI spend before CL (%)	Share of PCI spend after CL (%)
Poorest 20%	317.25	13.93
Second Group	174.49	7.66
Third Group	112.57	4.94
Fourth Group	69.1	3.03
Richest 20%	25.43	1.12

Note: CL means Compulsory Licensing.

Here the calculation is done as a fraction of yearly income since the treatment extends over a few months with three weeks intervals. The percentage share of per capita income to be spent by each group of people for purchasing the chemotherapy drug which constitutes just a part of the whole cancer treatment shows how difficult it was for an average Thai citizen to get treated for this dreadful disease. For the poorest group, the originator price was more than three times per capita income. For the second and third groups it was 1.7 and 1.1 times of per capita income. The fourth group had to allocate around 70 percent of their earnings. Only the top section could easily afford the treatment. In essence a person's *'right to life'* is determined by what he earns. The availability of generic versions at much lower prices at least made the treatment affordable to the majority of population. Though the level of burden is different on different groups ranging from 14 percent to 1 percent of their income, everybody could manage to purchase the medicine.

Erlotinib: Lung cancer has the highest incidence among Thai males. The data on Age-Standardized incidence Rates (ASR)[28] of all cancers in males, 2001-2003, collated by the National Cancer Institute and 13 Population based Cancer Registries in Thailand indicates that Trachea, Bronchus and Lung cancer incidence (cases per 100,000 per year)

[28] Age-standardisation adjusts rates to take into account how many old or young people are there in the population being looked at. This is important when looking at cancer rates because cancer is a disease that predominantly affects the elderly. So if cancer rates are not age-standardised, a higher rate in one country is likely to reflect the fact that it has a greater proportion of older people.

was 24.9. Erlotinib, sold under the trade name Tarceva in Thailand, is a chemotherapy drug in the Tyrosine kinase inhibitors group used for the treatment of lung cancer in patients with recurrence or relapse after platinum – based chemotherapy and docetaxel treatment. The Committee for the Health Care Improvement of Lung Cancer Treatment, 2006 points out that the side effects from Neutropenia and Febrile neutropenia are lower in Erlotinib than when Docetaxel and Pemetrexed are used. Despite all the advantages, it couldn't help the ill in Thailand much owing to its exorbitant price. Erlotinib 150 mg has to be taken daily (oral) for 4 months.[29] The price of Tarceva 150 mg tab marketed by Roche was $83.7. Hence the cost of the regimen was approximately $10,044. After the issuance of compulsory licensing, it came down to $22.4 bringing down the expenses for the full course to USD 2688.

Table 3.9: Share of Per Capita Income to be Spent by Each Group for Erlotinib

Quintiles	Share of PCI spend before CL (%)	Share of PCI spend after CL (%)
poorest 20%	615.38	164.69
Second Group	338.46	90.58
Third Group	218.36	58.44
Fourth Group	134.04	35.87
Richest 20%	49.32	13.2

Note: CL means Compulsory Licensing.

Here too the calculation of affordability is done as a fraction of yearly income since the regimen is for four months. Except for the richest group, the cost of the regimen (using the patented drug) was out of the reach of all others. It is more than six times the per capita income of the poorest 20 percent, more three times as that of the second group, more than two times of that of third group and about 1.3 times of the yearly earnings of the fourth ones. With the issuance of compulsory licensing, the price has fallen to nearly one-fourth. But as Table 3.9 shows, even then it is almost out of the reach of the first three groups.

Letrozole: Breast cancer has the highest incidence among Thai females. The data on Age Standardized incidence Rates (ASR) of all cancers in females, 2001-2003 by the National

[29] Refer supra note No. 26.

Cancer Institute and 13 Population based Cancer Registries in Thailand says that Breast cancer incidence (cases per 100,000 per year) was 20.9. Letrozole (trade name Femara) is an oral non-steroidal aromatase inhibitor for the treatment of hormonally-responsive breast cancer after surgery. It effectively inhibits the production of estrogen which is essential for the growth of breast cancer cells. Hence it is recommended for the treatment of local or metastatic breast cancer that is hormone receptor positive or has an unknown receptor status in postmenopausal women. The price of Letrozole 2.5mg (Femara) was $7. The generic version which was available after the issuance of compulsory license cost $ 0.2.[30]

Table 3.10: Share of Monthly Income to be Spent by Each Group for Letrozole

Quintiles	Share of monthly income spend before CL (%)	Share of monthly income spend after CL (%)
Poorest 20%	156.6	4.4
Second Group	86.13	2.43
Third Group	55.57	1.57
Fourth Group	34.11	0.96
Richest 20%	12.55	0.35

Note: CL means Compulsory Licensing.

In the case of Letrozole, the issuance of compulsory license made it accessible to almost all. This medicine has to be taken daily, and hence I have examined the share of monthly income required to be spent for its consumption. Before the issuance of the compulsory license, it was almost inaccessible for the first three groups (who have had to spend around 156, 86 and 56 percent respectively of their income). Those in the fourth quintile had to spend 34 percent and those in the fifth 12.5 percent of their earnings. After the issuance of the license, nobody had to spend more than 5 percent of their income, with the share of the income to be spared for treatment, of course, falling as you went up the income ladder.

In all the six cases, due to the implementation of compulsory licensing there resulted a drastic decline in the prices of the concerned medicines. But the extent of economic disparity that exists in Thai society makes poorer sections stay outside the realm of

[30] Refer supra note No. 26.

affordable access. Even generic versions of Kaletra & Erlotinib were unaffordable for a major chunk of population

Now let us consider how far compulsory licensing can increase medicine affordability by taking into account the various types of expenditure to which income has to be allocated and thereby define the concept of affordability of medicine. For this, we should know what portion of a person's income after spending for food can be spent for purchasing these medicines after the issuance of compulsory license. The expenditure pattern of the Thai population is reported in the Household Socio-Economic Survey conducted by the National Statistical Office, Ministry of Information & Communication Technology, Thailand.

Table 3.11: Percentage of Average Monthly Expenditure of Household by Type of Expenditure

Expenditure Type	1975-76	1981	1986	1990	1994	1998	2000	2001	2006
Food[1]	46.1	44.1	38.9	36.2	33.7	35.1	32.2	32.5	33.2
Non-food	53.9	55.9	61.1	63.8	66.3	64.9	67.8	67.5	66.8
Total	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
Consumption	96.0	93.4	92.1	90.9	89.7	86.3	86.9	87.4	88.7
Non-Consumption[2]	4.0	6.6	7.9	9.1	10.3	13.7	13.1	12.6	11.3
Total	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Sources: The 1975-1976 1981 1986, 1990 1994 1998, 2000 2001 and 2007 Household Socio-economic Surveys, National Statistical office.
Notes: 1. Excluded alcoholic beverages and tobacco products.
2. Such as taxes, gifts and contributions, insurance premiums, lottery tickets and other gambling, interest etc.

Over the years, the proportion of household spending on food had come down from 46.1 percent in 1975-76 to 33.2 percent in 2006 (the year of concern here). Though 33.2 percent is the average for the whole kingdom, the value varies among different sections of people. The data on the share of food expenditure is not available by quintiles, but is available for various socio- economic classes ranging from farm workers to professionals and the share of food expenditure to total income for the corresponding classes ranges from 38.14 percent to 15.41 percent. (See Appendix VI) As Engel's Law says, the higher

the income of the household, the lower the proportion of income it spends on food. The average of the share of spending on food to total income for all the ten socio-economic classes comes around 28 percent (See Appendix VI).

The average household size in Thailand was 3.3 (in 2004, 2005 & 2006), with the more than half of them being nuclear families with two or three members.[31] But as we have seen earlier, almost half of Thailand's wealth is in the hands of just 20 percent of the population. Hence a majority of the Thai population have to spend more than 28 percent of their income on food. All our calculations regarding the affordability of medicine are done in per capita terms, which is not available for food spending (for which only household data is available). Hence, on an average, spending on food in per capita terms can be taken as 30 percent, based on which we can check how much of a person's income that is available for non-food expenditure in each quintile has to spend to access these medicines even after the issuance of compulsory license.

Table 3.12: Share of Income for Non-Food Expenditure to be Spent for the Purchase of Medicine after the Issuance of Compulsory License (2006-07)

Quintiles	PCI in $	Monthly PCI (in $)	Income for Non-Food Expenditure (in $)	Share of 'Income for Non-food expenditure' to be spent (%)		
				Efavirenz	Kaletra	Clopidogrel
Poorest 20%	1377.77	114.81	80.367	27.37	149.32	6.84
Second Group	2652.21	221.02	154.714	14.22	77.56	3.55
Third Group	4167.76	347.07	242.949	9.06	49.39	2.26
Fourth Group	6888.86	574.07	401.849	5.47	29.86	1.37
Richest 20%	19323.26	1610.27	1127.189	1.95	10.65	0.49

Note: $ implies Current International Dollar PPP

Though food expenditure forms the single major expenditure for an individual, besides food there are a many other areas like housing, clothing, education, transportation etc to which an individual has to allocate his income to lead a normal life. For purposes of

[31] Based on Table 2.3.1 Household Structure and Sex of Household Head : 2004-2006, Household Socio-economic Survey 2007, National Statistical office, Thailand.

analysis let us postulate that if medicine constitutes more than 20 percent of the 'income available for non-food expenditure', access can be considered unaffordable.

Efavirenz, Kaletra and Clopidogrel were the medicines for which compulsory licenses were issued in the first round of such licensing by Thailand to make use of the flexibility available under Article 31 of the Agreement on Trade Related Intellectual Property Rights (TRIPs). As we have seen before, prices of these medicines came down drastically due to the implementation of this provision. The question is whether this drop in price made it accessible to the whole Thai population if they were paying for the medicines out of their own pockets. Among the three medicines, Clopidogrel is the one which could be accessed by all after the generic versions were made available. In the case of Efavirenz, the poorest 20 percent would not find it affordable, based on our maximum 20 per cent of non-food expenditure criterion. Although we have taken the share of monthly income spent on food as being 30 percent on an average, it will be much higher for the poorer groups. Hence after paying for food, it will be difficult for them to spend such a higher fraction of their income for just one medicine. Kaletra was almost unaffordable for the lower four quintile of the population if they were paying for the drug after the issuance of compulsory license.

Table 3.13: Share of Income for Non-Food Expenditure to be Spent for the Purchase of Letrozole after the Issuance of Compulsory License (Jan, 2008)

Quintiles	PCI in $	Monthly PCI (in $)	Income for Non-Food Expenditure (in $)	Share of 'Income for Non-Food Expenditure' to be spent (%)
poorest 20%	1632.16	136.01	95.207	6.3
Second Group	2967.56	247.3	173.11	3.47
Third Group	4599.72	383.31	268.317	2.24
Fourth Group	7493.09	624.42	437.094	1.37
Richest 20%	20364.9	1697.07	1187.949	0.51

Note: $ implies Current International Dollar PPP

In the case of Letrozole, the anti-cancer drug to be taken daily by breast cancer patients, treatment became affordable to all groups after the issuance of compulsory license, though the poorer sections has to allocate a larger share of income compared to the richer ones. The other two anti-cancer drugs for which compulsory licenses had been issued

along with this were Docetaxel and Erlotinib. For these two drugs, calculations are done on a yearly basis. These chemotherapy drugs have to be taken once in 21 days and the regimen requires 4 cycles to be completed. Hence the cost of the regimen is calculated and the expenses are considered as the share of per capita income available for non-food expenditure.

Table 3.14: Share of Income for Non-Food Expenditure to be Spent for the Purchase of Docetaxel & Erlotinib after the Issuance of Compulsory License (Jan, 2008)

Quintiles	PCI in $	Income for Non-Food Expenditure (in $)	Share of 'Income for Non-food Expenditure' to be spent (%)	
			Docetaxel	Erlotinib
Poorest 20%	1632.16	1142.512	19.9	235.27
Second Group	2967.56	2077.292	10.95	129.4
Third Group	4599.72	3219.804	7.06	83.48
Fourth Group	7493.09	5245.163	4.34	51.25
Richest 20%	20364.9	14255.43	1.6	18.86

Note: $ implies Current International Dollar PPP

For completing the four cycles of Docetaxel, the poorest 20 percent had to spend around 20 percent of such income. For the other groups, the price was affordable as per our criterion. But Erlotinib, even after compulsory licensing, was out of the reach for the first four groups.

From the analysis done it is clear that often the issuance of compulsory licensing alone cannot ensure medicines are affordable for the whole population, given the distribution of income is so unequal. In Thailand, out of the six drugs for which compulsory licenses had been issued, two of them (Kaletra & Erlotinib) remained unaffordable for a majority of the population and two of them (Efavirenz & Docetaxel) were out of reach for the poorest quintile. For the richest section all these medicines were easily affordable after the issuance of compulsory license, and most of them were affordable even before the issuance.

To return to the issue of the so-called success of compulsory licensing in increasing affordability, a widely cited example of such success is that of Thailand. In our discussion, we also found it effective in reducing the price of the medicines for which

they are issued. But overall success lies in the fact that it is procured by the government and provided free to all, and any resultant loss in governmental spending for some other developmental activities is not accounted anywhere. An appropriate policy may think of imposing additional taxes and using the resources thus mobilized to foster domestic generic pharmaceutical production which will help reduce prices for the long term and improve accessibility.

3.5 Thailand's Domestic Pharmaceutical Production

The World Medicine Situation Report, 2004 published by the World Health Organisation (WHO) notes that four medicine-specific factors have to be in place to ensure the accessibility: (1) Rational Medicines Selection process; (2) Prices at affordable levels; (3) Fair & Sustainable Financing for Medicines; and (4) Reliable Health & Supply Systems. Failure in any one of these will jeopardize people's access to medicines. In the case of Thailand, the government is tried its best to increase access to medicines through different policy measures including the employment of TRIPs flexibility, compulsory licensing, in 2006. For a rational selection of medicines, they issued a National List of Essential Medicines (NLEM) and provided them free of cost if prescribed by medical practitioners, with health service covered under UHC scheme. The other requirements specified by the WHO depend substantially on how the for-profit pharmaceutical companies behave and how they are being regulated. Higher prices of originator drugs and non availability of quality low-priced generic versions due to various reasons are often problems faced by developing countries such as Thailand. These problems can be rectified to a great extent by the development of local production of medical products. Some WHO reports use the term "medical products" as a collective one to cover pharmaceuticals, vaccines and diagnostics and do not include medical devices and other health services. Here too, the term is used in the same way.

Nowadays, many of the diseases can be avoided through preventive vaccination. Many epidemics like H1N1, Dengue, Avian influenza etc. are posing the need for effective immunization programmes. Hence to avoid a pandemic situation, we have to prevent the spread of these diseases through timely vaccination. Thailand officially launched its nationwide immunization programme in 1977. The National Vaccine Policy also

enshrined the '*right of basic immunization*' for the Thai people. The objectives of vaccine supply security and self-reliance were later formalized as national policy goals in the National Vaccine Policy of 2005, along with the objectives of promoting science and technology for vaccine R&D and investment in domestic vaccine production. In an interview, Yot Teerawattananon, Founder of the Health Intervention and Technology Assessment Program, pointed out that the country produces only two out of eleven vaccine antigens scheduled in Thailand's Expanded Programme of Immunization (EPI).[32] Hence it is inevitable that Thailand should improve its domestic vaccine production facility; otherwise there are chances of facing troubles in times of necessity. Now there are only three major domestic vaccine producers – the GPO, Thai Red Cross/ Queen Saovabha Memorial Institute (TRC/QSMI) and GPO-Merieux Biological Products- in Thailand. GPO and TRC/QSMI carry out both upstream and downstream production processed for the traditional vaccines they produce, i.e. Japanese Encephalitis and BCG vaccines respectively. Besides this, a small handful of private pharmaceutical companies like BioNet Asia Co., Ltd and Greater Pharma Co., Ltd are also involved in vaccine development. Of about 3 billion Baht Thailand spends each year on vaccine procurement, 80 percent is spent on high-priced imported vaccines.[33] The NVCO study pointed out the reasons for limited capacity in terms of downstream vaccine development and production such as lack of effective linkages between vaccine researchers and manufacturers, lack of essential infrastructure needed for vaccine development, inadequate facilities for pilot-scale production and industrial plants, and the lack of appropriate and qualified personnel. This gap between capabilities in basic research and that of product development and industrial production was later described as the "Valley of Death" problem in the vaccine field of Thailand.

For ensuring medical accessibility, the first requirement is that the disease should be diagnosed which in turn helps to determine the treatment to be undertaken and the medicines required. The Universal Health Care scheme helped in sorting out this problem

[32] "Thailand's New National Vaccine Strategy: Building Capacity, Accelerating Production", An Interview with Dr. Yot Teerawattananon, founder of the Health Intervention and Technology Assessment Program, June 28, 2011, accessed at http://www.nbr.org/research/activity.aspx?id=153#.UajfqNivliJ on May 20, 2013.

[33] Based on information from the Government Public Relations Department, Thailand.

to a great extent by providing free health care access. Actually that aspect of the Thailand model works well, and the government is even planning to develop Thailand into a "medical hub" in the region. Many hospitals have been recognized and approved as meeting the standards set for the Hospital Accreditation of Thailand and international standards, such as ISO. Thailand was the first country in Asia to achieve the Joint Commission International (JCI) Accreditation.[34]

After diagnosis comes the question of pharmaceutical production and medicine availability (both physical and geographical), which along with medicine prices determine accessibility.[35] All the compulsory licenses that Thailand has issued are for medicines of curative nature, not preventive ones and all these medicines are provided by importing them. Hence the matter for concern is whether this is sustainable in terms of public health policy in the long run without sufficient development of local production. The argument emphasizing the need for local production first appeared in WHO discussions in 1978 during the International Conference on Primary Health Care, while recognizing the need for continuous supply of essential drugs for primary health care. Afterwards the argument gained support and due recognition in many international forums including those of the United Nations agencies. As rightly noted in the study conducted by the World Health Organisation (WHO), it is not simply a matter of "joining the dots", but rather a systematic approach is required to make a framework to create the best environment to improve both local production and public health. Local production of medicines alone is not going to ensure absolute medicine accessibility, but the condition will be worse, if that is not realised.

3.5.1 Defining Local Production

There are two ways of understanding local production. One is with respect to the production's territorial location and the other in terms of ownership. The manufacturing taking place within a country is regarded as local production since it is within the national

[34] Based on the information from The Government Public Relations Department, Thailand.

[35] Physical availability is defined by the relationship between the type and quantity of product needed and the type and quantity of product provided, whereas geographical availability is defined by the relationship between the location of the product, and the location of the eventual user of the product.

jurisdiction as per the former criteria, but the latter one won't recognize it as 'local' if nationals do not have a majority in ownership. Hence there can be locally owned local production and production that occurs locally through a wholly owned subsidiary of a pharmaceutical multinational. Besides, there are three different stages defining the level of production of pharmaceutical products.[36]

Primary Manufacturing: the manufacturing of Active Pharmaceutical Ingredients (APIs), intermediaries and excipients. Primary manufacturing takes place mainly in industrialised countries. Some developing countries like India and China having a strong base in the chemical industry and good skills in reverse engineering also engage in production from the primary stage.

Secondary Manufacturing involves the process of mixing the raw materials and the production of dosage formulations.

Tertiary Manufacturing involves the packaging of already formulated products. Mostly, the low-income and LDCs engaged only in this stage of production, but the situation is changing now.

According to the WHO World Medicine Situation Report 2004, medicine production is highly concentrated in the industrialised countries. Five countries – the USA, Japan, Germany, France and the UK- account for the two third of the value of all medicines produced, and large volume markets of lower price medicines exist in the highly competitive markets of India and China. But just one year after the publication of the report, most of the developing countries including India became TRIPs compliant and this is becoming a hindrance in the production of low priced generic versions of the newly patented medicines. Unlike India and others, Thailand made its patent system tighter way back in 1992 without having a proper domestic pharmaceutical production sector and almost blocked the further development of domestic pharmaceutical industry by incorporating 'product patent' system along with extension of patent protection period to 20 years and narrowing the scope for issuing CL. All these together restrict the growth

[36] Local Production for the Access to Medical Products: Developing a Framework to Improve Public Health, (WHO, 2011).

of generic medicine industries. The state enterprise, Government Pharmaceutical Organisation (GPO), the largest generic producer in Thailand thanks to the protection guaranteed by the government, was founded by the GPO Act of 1966 by merging the Government Pharmaceutical Laboratory and the Department of Medical Depot to provide essential medicines to the Thai population. Public hospitals are legally obliged to use 60% of their budget to purchase NLEM-listed and GPO-produced medicines, while hospitals attached to the MoPH must use 80% of their budget to purchase drugs from GPO, even if they are priced slightly higher than the same medicines manufactured by other pharmaceutical companies. Other than GPO, the top pharmaceutical producers in Thailand are mainly the subsidiaries of MNCs like Pfizer International Corporation, Merck Sharp & Dome, Sanofi Aventis etc.[37] But with the introduction of the Universal Health Care scheme and inclusion of many medicines in the National Essential List of Medicines (NELM), the government is trying to acquire medicines at lower prices. This has led firms to invest in the production of generic versions qualifying the quality standards set by the Thai government. In an interview with Mr. Chernporn Tenganmuay, President of Thailand Pharmaceutical Manufacturers Association (TPMA) published by Focus Reports: Thailand Pharma Report 2012, he refers to the government committee that screens the drugs to decide which generics are suitable for the Essential Drugs List (EDL) and says that "there have been many government tenders and for that reason the local manufacturers have been growing very fast over the last five years as they can produce drugs cheaper. He adds that the Government Pharmaceutical Organisation has to abandon its privileges by 2015." In fact, Thailand is improving its domestic production capacities, but has to go far ahead to sustain itself with its domestic production.

Table 3.15 provides the production and import data for pharmaceutical products (for human use) in Thailand.

[37] Based on Thailand Pharma Report, (July 2012) accessed at http://www.focusreports.net /focusreports/thailand-pharmaceuticals/ on May 1st 2013.

Table 3.15: Values of Locally Produced and Imported Drugs (for human use), 1983-2008

Years	Locally Produced		Imported		Total
	Value (mn baht)	%	Value(mn baht)	%	(mn baht)
1983	3777.9	65.2	2012	34.8	5789.9
1984	5453	76.5	1673	23.5	7126
1985	6651.2	73.5	2393.1	26.5	9044.3
1986	4678	71.5	1864.5	28.5	6542.5
1987	5145.8	68.9	2325.4	31.1	7471.2
1988	6708.8	72.3	2571	27.7	9279.8
1989	8372.9	71.7	3307.6	28.3	11680.5
1990	8886	72	3449.1	28	12335.1
1991	9657.6	69.6	4216.4	30.4	13874
1992	10696.6	69.6	4682.6	30.4	15379.2
1993	11831	70	5075.3	30	16906.3
1994	12969.7	68.1	6086.6	31.9	19056.3
1995	15820.9	63	9276.4	37	25097.3
1996	18120.4	62.9	10676	37.1	28796.4
1997	19608	59.3	13467.1	40.7	33075.1
1998	16127.7	53.3	14146.5	46.7	30274.2
1999	19033.9	57.2	14232.3	42.8	33266.2
2000	20995.9	55.7	16700.4	44.3	37696.3
2001	23087.9	53.6	19967.6	46.4	43055.5
2002	24144.6	54.9	19867.9	45.1	44012.5
2003	26586.1	50.5	26024.9	49.5	52611
2004	31707.6	50.9	30545.5	49.1	62253.1
2005	29704.8	43.7	38293.4	56.3	67998.2
2006	30910	40.7	45004.6	59.3	75915.5
2007	41232.4	43.8	53000.1	56.2	94232.5
2008	35322.9	35.5	64146.1	64.5	99471

Source: Thailand Health Profile 2008-2010, MoPH Thailand
Note: The values given are wholesale values of drugs at current prices as reported.

It shows that the share of locally produced drugs has fallen from 65.2 percent in 1983 to 35.5 percent in 2008 and that of imported drugs has increased from 34.8 percent (1983) to 64.5 percent (2008). This data is no longer available online in the Drug Control Bureau website, which is mentioned as the source in the Thailand Health Profile Report. Hence it is not possible to cross check the data, or analyse which classification (HS or ISIC) is used here and which digit level data it is. This data includes only drugs meant for human

use. However, since it is difficult to get time series data for more than two decades starting with early 80s and this set has been published by the Ministry of Public Health, the discussion relies on this data. One notable aspect that the data conveys is that there was a steep increase in the share of imports in the last six years of the period (2002-08) resulting in an almost 20 percent increase in import share(from 45.1 percent to 64.5 percent). This was possibly due to the increased consumption of medicines after the implementation of the universal health care scheme. But it is not healthy to depend on imports to this extent. Thailand publishes its Health Profile Report once in every three years, and the last one published for 2008-10 has data till 2008. The latest one for the period 2011-13 is yet to be released, and hence data for years after 2008 is not available.

Pharmaceutical products can be classified into formulations (dosage forms) and bulk drugs (active pharmaceutical ingredients). In simple words, formulations means drugs ready for consumption by patients in the form of tablets, capsules, injectables or syrup. Formulations can be branded or generic. The European Medicines Agency (EMA) defines Dose Form or Formulation as "the physical manifestation ("entity") that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the Dose Form can be the state of matter, delivery method, release characteristics, and the administration site or route for which the product is formulated. A Pharmaceutical Dose Form is the form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/ manufacturer/ distributor."[38] The US FDA has defined Active Pharmaceutical Ingredient (Bulk drug) as "any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body."

[38] European Medicines Agency (2005), ICH Topic M 5 Data Elements and Standards for Drug Dictionaries, "Note for Guidance on Data Elements and Standards for Drug Dictionaries", (EMEA/CHMP/ICH/168535/2005).

"Drug substance" and "bulk pharmaceutical chemical" (BPC) are terms commonly used to mean API.[39]

Table 3.16: Composition of Import of Medicinal & Pharmaceutical Products to Thailand

Year	Bulk Drugs (SITC - 541)		Formulations (SITC -542)		Medicinal and pharmaceutical products (SITC -54)		Formulation Share in total Medicine Imports (%)
	Export	Import	Export	Import	Export	Import	
1988		86.978		69.318		156.3	44.35
1989	8.079	101.79	12.796	80.437	20.88	182.23	44.14
1990	11.76	117.64	15.3	92.642	27.06	210.29	44.06
1991	15.5	132.68	20.219	105.99	35.72	238.67	44.41
1992	26.01	183.35	31.998	130.47	58.01	313.81	41.57
1993	87.77	186.59	39.068	140.27	126.84	326.86	42.91
1994	41.27	210.05	45.732	173.83	86.99	383.88	45.28
1995	73.89	248.33	52.214	220.85	126.11	469.18	47.07
1996	46.78	248.41	58.705	256.74	105.48	505.16	50.82
1997	44.94	233.16	62.304	278.55	107.24	511.71	54.43
1998	41.89	173.43	54.532	168.05	96.42	341.48	49.21
1999	39.77	217.16	63.538	252.82	103.31	469.98	53.79
2000	48.24	214.65	68.158	267.07	116.4	481.72	55.44
2001	52.8	229.47	69.262	296.91	122.06	526.38	56.41
2002	49.86	236.08	68.127	306.96	117.98	543.05	56.53
2003	58.27	246.8	79.687	395.12	137.95	641.92	61.55
2004	47.56	226.37	97.009	441.98	144.57	668.35	66.13
2005	58.41	263.22	113.69	552.54	172.1	815.76	67.73
2006	85.38	308.52	114.77	688.14	200.15	996.66	69.04
2007	99.76	384.95	141.28	793.31	241.05	1178.26	67.33
2008	128.4	436.32	162.84	1006.1	291.25	1442.41	69.75
2009	131.2	492.92	164.49	1073	295.66	1565.89	68.52
2010	158	608.01	202.06	1191.4	360.04	1799.42	66.21
2011	165.3	674.34	215.83	1299.3	381.12	1973.65	65.83
2012	196.6	703.73	254.31	1448.5	450.9	2152.25	67.3

Source: COMTRADE
Note: Unit in Million $

[39] Taken from "Food and Drug Administration Compliance Program Guidance Manual", Chapter 56 – "Drug Quality Assurance" which deals with Active Pharmaceutical Ingredient (API) Process Inspection.

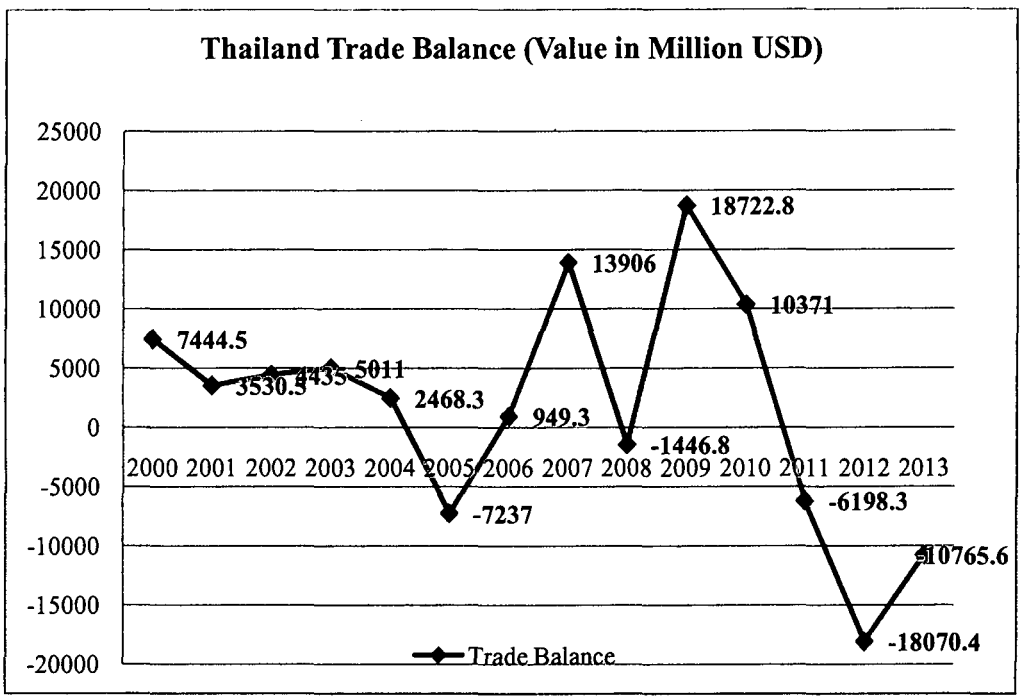
I have relied on the United Nations Commodity Trade Statistics Database for accessing Export-Import data. They provide trade statistics under different classifications like Harmonised System (HS 1992, 1996, 2002, 2007, 2012), Standard International Trade Classification (SITC Rev. 1, 2, 3, 4), and Classification by Broad Economic Categories (BEC). Here I have used the SITC Rev.3 classification. SITC has classified '*Medicinal and pharmaceutical products*' as Division 54 under Section 5: Chemicals and related products, n.e.s. Division 54 is further divided into two groups: Group: 541 – "Medicinal and pharmaceutical products, other than medicaments of group 542" and Group: 542 – "Medicaments (including veterinary medicaments)", both having their own sub-groups. Though SITC does not specifically categorise medical products using the terms- bulk drugs and formulations, Code 541 which includes selected products from chapters 26, 29 and products under chapters 3001, 3002, 3005 and 3006 in the HS classification represents bulk drugs and Code 542 which consists of selected products from HS chapter 30 (3003 and 3004) represents formulations.[40]

It is clear from the table that Thailand is still heavily dependent on imports. Over the years, export is rising- the quantity exported in 1989 was almost one-ninth of the quantity imported then and now it has risen to almost one-fifth. Since Thailand hasn't developed that much in the primary manufacturing of pharmaceuticals, the share of bulk drugs is comparatively lower in the medicinal exports all through these years. Over the period, the share of formulations in the total imports of the medicinal and pharmaceutical products has increased, and there seems to be a sharp rise in the share of formulations in imports after 2002. This was probably due to the purchase of medicines from low cost destinations to cater to the needs of the Universal Health Coverage scheme.

Thus, the analysis reveals that the success that Thailand has achieved in health care provision, especially in the supply of medical care, is to a large extent depend on its success in managing imports of the drugs its population requires. Thailand being an 'export led economy' needs to be more conscious about its trade balance which has been deteriorating recently, when they have had to depend on imports for more than fifty percent of their medical (pharmaceutical) needs.

[40] Based on Joseph, Reji K (2012).

Figure 3.3: Thailand's Trade Balance, 2000-2013



Source: Ministry of Commerce, Thailand

The trade balance of Thailand for the 2000-13 period is presented in Figure 3.3. It seems that from 2009 onwards, the trade balance is worsening. The data for the year 2013 is for the period January – April. Historically, from 1991 to 2013, Thailand's Balance of Trade averaged -118.35 USD Million. In January of 2013, the trade balance has struck a record low of -5486.84 USD Million[41]. Hence the Thai Government should prioritise the local production of pharmaceutical products since it is allocating more than 10 percent of its budget to public health. Recently Thailand has found its place among the Pharmerging countries at least as a Tier 2 country.[42] This can be considered a positive sign for future development, despite its over-dependence for its medicinal needs on imports. GPO, the

[41] See http://www.tradingeconomics.com/thailand/balance-of-trade (accessed on 23rd July 2013)

[42] The fast growing pharmaceutical markets other than the so-called major markets- the US and Canada, Britain and Western Europe and Japan- are coined by the term "Pharmerging countries" in many of documents like that of IMS Health. According to The Business Magazine of Pharma, Pharmerging Tier 1 countries include seven emerging markets such as Brazil, India, Turkey, Mexico, Russia, South Korea and China. Pharmerging Tier 2 Countries include 21 far-flung nations ranging from Venezula to Vietnam, Chile to Czech Republic.

state owned pharmaceutical firm, is the major generic producer and is supplying Lopinavir/Ritonavir 80/20mg oral solution for HIV infected patients, hard and soft artificial lenses, opioids analgesic as Morphine immediate release 10 mg tablet, Morphine oral solution 10mg/5ml oral solution and PCEC vaccine in 2011. Other compulsory license issued drugs (except Lopinavir/Ritonavir) are not yet produced domestically. So the issuance of compulsory license may not lead to development of local production, which in fact requires deliberate policy initiatives. Orphan drugs and antidotes supplied by GPO were Botalinum antitoxin injection for Antidote Project by NHSO, 1.2 MU Benzathine pencillin, Penicillamine capsule, Indomethacin 1 mg injection, Iodine tablet and Triferdine tablet.

3.6 Conclusion

The issuance of compulsory licenses brought down prices and thereby increased medicine accessibility in Thailand. But these compulsory licenses are effective only till patent expiry. Hence compulsory license can't be a permanent solution. In Thailand, local production of their generic version started even for Lopinavir/Ritonavir by the GPO only four years after the issuance of compulsory license. If there are no competitors, it is not necessary that prices must come down even after patent expiry. Hence enabling local production is inevitable to assure medicine accessibility in the long run. Adequate supply of medicines form a basic part of a public health programme. Meeting this requirement by importing most of the medicines does not seem to be healthy trend.

Chapter 4

Thailand and India: Some Comparison

4.1 Introduction

The price of medicines is the key factor determining accessibility in low and middle income countries where people mostly spend for medicines out of their own pockets. Around the world, on an average 24.9% of the total health expenditure is spent on medicines, with the figure ranging widely from 7.7% to 67.6%.[43] It is true that the compulsory licenses issued by Thailand helped them to a great extent to increase accessibility for some of the highly priced medicines for treating HIV/AIDS and some anti cancer drugs, by substantially reducing prices. But Thailand did not make any moves to issue compulsory licenses after 2008. It was not just in Thailand, but in many developing and least developed countries that the tendency to apply TRIPS flexibilities, especially by resorting to compulsory licensing, has been waning.

The implementation of Universal Health Coverage in Thailand diverted popular attention from the main issue of the cost of medicines, since government pays for most of the medicines, especially, for those belonging to the National List of Essential Medicines (NLEM). But the absence of a developed local pharmaceutical industry does have adverse implications for the prices of medicines. Thailand is now allocating more than 10 percent of its government budget to public health with an ample amount being spent on medicines. But, so far Thailand does not have a proper policy to regulate drug prices in the public and private sectors, whether they are procurement or selling prices. The result is that even various public hospitals sell the same products at different prices. Besides this the procurement of same products also takes place at different prices.[44]

[43] World Medicine Situation 2011 , WHO/EMP/MIE/2011.2.6

[44] Based on Sooksriwong, C et.al (2009).

4.2 Comparative Analysis

It would, therefore, be useful to compare the prices and availability of medicines in Thailand and India since India has employed a full-fledged drug price control policy since 1995 (though there existed one since 1963) and has been monitoring prices all through the years of liberalisation. For this purpose, I am relying on the data provided by Health Action International (HAI). Surveys and studies conducted across the world using the standardized methodology developed by WHO/HAI to calculate medicine price components, availability, affordability are made available in the HAI website. I am also relying on the methodology developed by them for doing some required calculations and for the analysis.

For India, eight studies have been undertaken since 2003. The first survey happened in Rajasthan in April 2003, second in Chennai in October 2004, third in twelve districts of Maharashtra in October 2004, fourth in Haryana in October 2004, fifth in Karnataka in November 2004, sixth in four regions of Maharashtra in January 2005, and the last one in NCT, Delhi in July 2011 and all the data are available on the HAI website. Of these surveys only the last was conducted after India made its patent system fully TRIPs compliant. Hence I am using the data from the survey done in NCT, Delhi for the Indian side of the comparison. The study in Thailand was undertaken in October 2006, and they are TRIPS compliant since 1999.

The above mentioned field study to measure the availability and prices of selected medicines was undertaken in Thailand during October - December 2006. Medicine prices and availability were measured in health facilities and pharmacies in the capital city, Bangkok, and three randomly selected districts in each part of Thailand: Phitsanulok (North), Suaratthani (South), and Nakornrachaseema (Northeast). The survey collected data on 43 medicines from 20 public sector health facilities (20 hospitals) and 21 private pharmacies selected using a validated sampling frame. Two prices were recorded – the procurement price and the price charged to patients. For each medicine, data were collected for the innovator brand, and the most sold and lowest price generic equivalents at each facility. Medicine prices were expressed as median price ratios (MPRs) relative to

a standard set of international reference prices (MSH 2005).[45] Reference prices are available only for 35 medicines surveyed. Availability was assessed and given for all the 43 medicines surveyed.

The concerned field survey in India was conducted during July and October 2011 in the National Capital Territory (NCT) of Delhi. The survey was conducted in both public and private sector units covering all the eight districts of NCT, Delhi. The three predominant public health providers in Delhi, Government of NCT, Delhi (GNCT), Municipal Corporation of Delhi (MCD) and Central Government (CG) provided data for the survey. For private sector analysis, traditional private retail pharmacies and retail chain pharmacies of one particular corporate house were chosen. In each district, five randomly selected public facilities of GNCT, Delhi and MCD, five retail pharmacies and five retail chain pharmacies located near the public facilities were sampled. For central government, three tertiary care facilities of Delhi were included. On the whole, a total of 83 public facilities and 80 private facilities were surveyed. Medicine price and availability data were collected for a basket of 50 medicines specified in dosage form and strength that included 30 core medicines and 20 supplementary medicines added according to local needs and the objectives of the survey.[46] Here too medicine prices (2011) were expressed as median price ratios (MPRs), relative to a standard set of international reference prices (but based on MSH 2010).

Since I am doing a comparative analysis, I considered only those medicines which are included in both the studies. Thus only 16 medicines are considered here (See Appendix VII). All the 16 medicines are those enlisted in the Global Core List by WHO/HAI or in the WHO-SEARO Regional Core List. At times, the same medicine is included in both the surveys, but the dosage strength may differ.[47]Such medicines are also not considered for comparison. Only the same medicines with same dosage strength are considered.

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[45] Median Price Ratio (MPR) = Median local unit price/ International reference unit price.

[46] WHO/HAI methodology has identified 30 core medicines – 14 essential medicines from global burden of diseases and 16 are specific for South East Asian region. Supplementary list of medicines (20) were mainly antimicrobial agents.

[47] Dosage strength measures the amount of drug per dosage unit. Many medications are available in different dosage strengths. For example, a medication may be produced in two versions, 75 mg per tablet and 100 mg per tablet. In both of these versions, the dosage unit is a tablet.

Another important issue is that the surveys are conducted in two different time periods and hence they need to be standardised using a base year. Here I have taken 2011 as the base year and the medicine prices in the Thailand survey are standardised to the year 2011 using MSH 2010 international reference prices. The standardization is done using the method given in the HAI manual (See Appendix VIII).

The medicine prices are compared for three sets of prices:

- Public Sector Procurement Prices
- Public Sector Patient Prices
- Private Sector Patient Prices

For the above three sets, prices of the originator brand and the lowest priced generic are being compared.

First let us have a look at the level of public procurement prices of the selected list of medicines for the two countries. To compare the level of prices, the median price ratio (MPR) standardised for the base year 2011 is being used. There are no hard and fast rules in the interpretation of MPR. Nevertheless, local prices were normally considered acceptable when:

- MPR ≤ 1 in case of public sector procurement and public sector patient prices.
- MPR ≤ 2.5 in case of retail pharmacy prices

The table 4.1 shows that public procurement prices are higher in Thailand than in India. The median MPR of India is 0.48 and that of Thailand is 2.14. Hence the procurement price in Thailand seems to be more than five times higher than that in India. The public procurement agencies are largely relying on generic versions in both the countries. Even then there exists this substantial difference in prices paid in the two countries. As per the criteria mentioned (MPR ≤ 1), the MPR of public procurement prices in India is healthy, but that is not so in the Thailand case. This in turn increases the burden on the final payer whether it is the individual consumer or the government itself.

Table 4.1: MPR of Public Procurement Prices for India and Thailand

Medicines	MPR (Public Procurement)	
	India	Thailand
Amitriptyline 25 mg cap/tab	0.59	2.39
Amlodipine 5 mg cap/tab	0.08	1.65
Amoxicillin 250 mg cap/tab	1.11	2.42
Atenolol 50 mg cap/tab	0.32	0.94
Atorvastatin 10 mg cap/tab	0.35	
Captopril 25 mg cap/tab	-	3.44, 14.39*
Ceftriaxone 1g/vial injection	0.5	0.42
Ciprofloxacin 500 mg cap/tab	0.88	2.14
Diazepam 5 mg cap/tab	0.35	5.28
Fluoxetine 20 mg cap/tab	3.44	2.31
Glibenclamide 5 mg cap/tab	0.59	2.42
Metformin 500 mg cap/tab	0.48	0.93
Omeprazole 20 mg cap/tab	0.25	0.9
Phenytoin 100 mg cap/tab	0.55	4.9, 22.64*
Ranitidine 150 mg cap/tab	0.29	0.56
Salbutamol 100 mcg/dose inhaler	0.32	2.15

Source: Calculated from the data taken from Health Action International.
Note: * implies the value given is the median price ratio for the originator brand.

Now consider the public sector and private sector prices of the same medicines in the two countries. Here, in the case of India, lowest price generics were available in the public facilities and medicines are provided for free to all patients who visit and have prescription from the facility. Due to free provision of medicines public sector prices are not recorded in any of the HAI surveys undertaken in India.

In Thailand the median MPR of public sector patient prices is 3 for the selected list of medicines, and there are two outliers like Diazepam 5 mg cap/tab and Phenytoin 100 mg cap/tab. Since medicines are provided free of cost in public sector facilities in India, a comparison in terms of prices is not possible between India and Thailand using the HAI data. While considering the availability of medicines, Thailand's situation is better than that of India. The mean availability of Lowest Priced Generic Equivalents is 70% in Thailand. The mean availability of Originator Brand in Thailand public sector is just 17% since most of the public outlets are stocked with generic drugs. In India though the

medicines are provided free of cost in public health facilities, the mean availability rate is just 43%. Moreover as per the survey, in India also all the medicines provided are generic ones. In India, government has also opened a chain of Jan Aushadi stores to provide generic medicines at discounted price since 2008. The price list of medicines in the Jan Aushadhi outlets updated in January 2011 consists of 319 medicines of various therapeutic classes. Out of the 16 medicines we have selected for the study, eight are in that list. I have calculated their MPR to assess the price at which medicines are being sold in these public retail outlets.

Table 4.2: MPR of Public Sector Patient Prices and Availability for India and Thailand

Medicines	MPR of Thai Pub. Sector Prices	Availability in Pub. Sector (%)		
		Thailand		India
		O B	LPG	LPG
Amitriptyline 25 mg cap/tab	4.79	5	100	6
Amlodipine 5 mg cap/tab	2.69	15	80	90.4
Amoxicillin 250 mg cap/tab	3.46	0	100	59
Atenolol 50 mg cap/tab	2.99	10	80	88
Atorvastatin 10 mg cap/tab	-	20	0	15.7
Captopril 25 mg cap/tab	5.19, 18.59*	20	35	0
Ceftriaxone 1g/vial injection	0.71	15	70	9.6
Ciprofloxacin 500 mg cap/tab	3.00	10	25	62.7
Diazepam 5 mg cap/tab	21.88	0	100	10.8
Fluoxetine 20 mg cap/tab	3.66	15	85	3.6
Glibenclamide 5 mg cap/tab	6.73	5	95	59
Metformin 500 mg cap/tab	2.51	10	100	66.3
Omeprazole 20 mg cap/tab	1.71	5	100	84.3
Phenytoin 100 mg cap/tab	11.75, 32.33*	55	40	39.8
Ranitidine 150 mg cap/tab	1.49	0	100	53
Salbutamol 100 mcg/dose inhaler	2.86	90	10	41

Source: Calculated from the data taken from Health Action International.
Note: * implies the value given is the median price ratio for the originator brand.
OB- Originator Brand, LPG– Lowest Priced Generic Equivalent.

Table 4.3: MPR of Jan Aushadi Medicine Prices (India)

Medicines	Unit Price (Rupees)	Unit Price (USD)	MSH_2010 Int. Reference Price (USD)	MPR
Amlodipine 5 mg cap/tab	0.38	0.0082	0.0307	0.27
Atenolol 50 mg cap/tab	0.5	0.0109	0.0095	1.14
Atorvastatin 10 mg cap/tab	0.82	0.0179	0.0376	0.47
Ceftriaxone 1g/vial injection	37.5	0.8179	0.69	1.18
Diazepam 5 mg cap/tab	0.23	0.0050	0.0061	0.82
Glibenclamide 5 mg cap/tab	0.268	0.0058	0.0034	1.72
Metformin 500 mg cap/tab	0.603	0.0132	0.0105	1.25
Ranitidine 150 mg cap/tab	0.405	0.0088	0.02	0.44

Source: Calculated from the Price List of Jan Aushadhi Medicines released on January 2011 accessed at http://janaushadhi.gov.in/

As per the price list of the Jan Aushadhi stores, for four medicines the MPR is less than one (MPR < 1), for the next three MPR is less than or equal to 1.25 (MPR $\leq$ 1.25). For Glibenclamide, the MPR is 1.72 whereas its MPR of public sector patient prices in Thailand is 6.73. The MPR of the medicines in the public sector outlets in India are much lower compared to that of Thailand. Besides, some states in India like Kerala maintain government supported retail medicine outlet chains run by primary cooperative societies where medicines are being sold at discounted prices (at prices less by 13 to 40% of the MRP).

Anyway as we have seen the public sector facilities are not able to cater the needs of the whole public in both the countries. Hence people have to depend on private sector facilities for their medical needs. So we examine the trend in private sector medicine prices and availability in the two countries.

In India, generic versions of all the 16 medicines chosen for the study are available. The mean availability of generic equivalents turned out to be 72% with more than half of them being available in more than 90% of the pharmacies surveyed. Only three medicines (Amitriptyline, Captopril and Glibenclamide) showed less than 15% availability. On the other hand, the mean availability of Originator brands was just 29%. The originator brands are not even available (0%) for seven medicines. But for Amitriptyline and Captopril, the originator brands are available at 65%.

Table 4.4: Availability of Selected Medicines in Private Sector in India & Thailand

Medicines	Availability in Private Sector (%)			
	India		Thailand	
	LPG	OB	LPG	OB
Amitriptyline 25 mg cap/tab	12.5	65	81	9.5
Amlodipine 5 mg cap/tab	95	52.5	95.2	76.2
Amoxicillin 250 mg cap/tab	92.5	0	90.5	28.6
Atenolol 50 mg cap/tab	97.5	45	95.2	61.9
Atorvastatin 10 mg cap/tab	97.5	12.5	0	85.7
Captopril 25 mg cap/tab	10	0	0	4.8
Ceftriaxone 1g/vial injection	47.5	0	33.3	4.8
Ciprofloxacin 500 mg cap/tab	100	0	95.2	23.8
Diazepam 5 mg cap/tab	37.5	35	14.3	0
Fluoxetine 20 mg cap/tab	80	0	47.6	4.8
Glibenclamide 5 mg cap/tab	5	65	100	90.5
Metformin 500 mg cap/tab	97.5	0	85.7	100
Omeprazole 20 mg cap/tab	100	0	100	14.3
Phenytoin 100 mg cap/tab	90	37.5	28.6	66.7
Ranitidine 150 mg cap/tab	97.5	95	95.2	23.8
Salbutamol 100 mcg/dose inhaler	92.5	52.5	0	100

Source: Health Action International Survey Database.
Note: OB- Originator Brand, LPG– Lowest Priced Generic Equivalent.

In Thailand the mean availability of originator brands is 60% and that of generic equivalents is 43% in the private sector for the medicines considered for the study. Among these medicines, the generic versions of three of them (Atorvastatin, Captopril and Salbutamol) are not even available in private pharmacies. Unlike the public sector in Thailand, the private sector is stocking both originator and generic medicines for sale and with notably greater stock of originator brands.

Table 4.5: MPR of Private Sector Patient Prices in India & Thailand

Medicines	India		Thailand	
	LPG	OB	LPG	OB
Amitriptyline 25 mg cap/tab	5.48	9.84	6.39	-
Amlodipine 5 mg cap/tab	1.87	6.02	6.32	24.22
Amoxicillin 250 mg cap/tab	5.5	-	4.61	14.71
Atenolol 50 mg cap/tab	7.07	8.13	5.98	27.53
Atorvastatin 10 mg cap/tab	5	5	-	-
Captopril 25 mg cap/tab	8.4	-	-	-
Ceftriaxone 1g/vial injection	2.24	-	1.4	-
Ciprofloxacin 500 mg cap/tab	3.55	-	4.51	62.7
Diazepam 5 mg cap/tab	9.73	10.1	-	-
Fluoxetine 20 mg cap/tab	6.99	-	6.71	-
Glibenclamide 5 mg cap/tab	-	7.18	6.73	20.19
Metformin 500 mg cap/tab	2.41	-	1.67	4.35
Omeprazole 20 mg cap/tab	3.11	-	5.31	-
Phenytoin 100 mg cap/tab	4.48	4.3	11.75	29.41
Ranitidine 150 mg cap/tab	0.56	0.57	2.45	29.01
Salbutamol 100 mcg/dose inhaler	1.35	1.29	-	3.23

Source: Calculated from the data taken from Health Action International.
Note: OB- Originator Brand, LPG– Lowest Priced Generic Equivalent.

As per the HAI methodology, price analysis won't be carried out for the medicines whose availability is very low. The median MPR for lowest priced generic equivalents in India is 4.48. This median MPR value is calculated here omitting the case of Glibencalmide since in the survey its availability rate is less than 10%. Among the originator drugs, the MPR of only nine is given, and the median MPR turned out to be 6.02. In the case of Thailand, MPR for medicines is noted if it is available at least in four out of the twenty private pharmacies surveyed. The median MPR for generic equivalents in Thailand is 5.65, which is calculated considering the MPRs of twelve medicines. Only nine originator brands are available in at least four outlets and the resultant median MPR is 24.22. The ratio of the MPRs, that is the originator MPR to generic MPR, seems to be very high for some medicines, which is extremely high. It ranges from 2.5 for Phenytoin 150mg to 13.9 for Ciprofloxacin 500 mg. The ratio of MPRs (MPR of OB/ MPR of LPG) in India ranges from 0.95 for Ranitidine 150 mg to 3.22 for Amlodipine 5 mg. The reason for this is that in India branded generics are more popular than the originator ones.

Originator brands if available are in the same guild as the branded products manufactured and marketed by reputed companies. For some medicines, the originator brands are slightly cheaper than popular branded generics making the ratio of MPR less than one for them. This indicates doctors are prescribing mainly the branded medicines that are pushed by the companies through their representatives. Pharmacists are stocking those branded ones for which they usually get prescriptions, though for these same medicines other generic versions are available and are comparatively cheaper.

But as a whole, the presence of such a vast generic market helped a lot in bringing down the prices of medicines in India. This is quite clear from the ratio of MPR of the originator to branded medicines in India. The achievement of India in having one of the lowest prices for pharmaceutical products in the world is the result of the policies it has formulated through the years in fostering domestic pharmaceutical production and in controlling the prices of the same through well defined drug price control policies.

4.3 Brief Account of Policies Followed by India

India introduced its drug price control policy way back in 1962 though in a very nascent form with the promulgation of the Drug (Display of Prices) Order in 1962 and the Drug (Control of Prices Order) 1963, and the prices of drugs were frozen with effect from the 1st April 1963. Thereafter, a series of drug price control orders were notified from time to time replacing the older ones based on different principles and with changes in the nature and span of control of prices from order to order. But broadly all these policies were based on the principle of effecting control over prices of essential drugs, and later bulk drugs, as well as availability of drugs while at the same time attending to the requirements of the indigenous industry for growth, cost effective production, innovation and strengthening of capacity. The Drug Policy of 1994, as implemented through the Drugs (Price Control) Order, 1995 was introduced in the context of liberalization of the economy and allowing foreign investment in the country including in the drug industry. The control over prices was done on the basis of the cost of production with allowance being given for post production expenses.

Considering the changing situation, both national and global, changes have been introduced into the pharmaceutical pricing policy recently. Like Thailand, India also maintains a National List of Essential Medicines. Though they introduced the first national list of essential medicines (1996) much later as compared to Thailand (1981), the set of policies and measures they have adopted from time to time helped to make their drug prices among the cheapest in the world. Revision of the essential medicine list happened in 2003 and further in 2011. The National List of Essential Medicines, 2011 remains the basis for the National Pharmaceutical Pricing policy (NPPP, 2012), the prevailing drug policy in India, and the Drug (Prices Control) Order, 2013. The NPPP, 2012 introduced much more specific pricing control on formulations rather than on upstream products like bulk drugs and intermediaries. The Drug Price Control Order, 2013 which includes all the medicines in its first schedule has put forward a market based approach for determining ceiling prices. The method is as follows:

Step1. First the Average Price to Retailer of the scheduled formulation[48] i.e. P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine)

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16.

[48] "scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand name.

The Ceiling Price calculated by this method is applicable to scheduled imported formulations also. But the impact of this new method of price control hasn't yet been felt properly.

And this methodology introduced recently by India has been criticised for letting the market be the determinant of ceiling prices and the impact of this policy change is yet to be felt.

The results of our analysis has applied fully to the Drug (Prices Control) Order, 1995, the cost-based pricing regulation where a list of 74 bulk drugs included in the first schedule of the order as well as formulations based on those drugs (about1577 in number in 2011) were under price control. As per this order, the retail price of a formulation shall be calculated using the following formula:

R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED. where

- "R.P." means retail price;
- "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf;
- "C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;
- "P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf;
- "P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;
- "MAPE" (Maximum Aflowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and

includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations;

- "E.D." means excise duty

This cost-based pricing system followed by India helped it to control prices through all these years. The pricing policy itself is designed in a way to balance the need of controlling prices as well as to provide sufficient profits to manufacturers. Besides this, sufficient incentives are incorporated in the industrial policies for fostering the growth of the pharmaceutical industry. The growth of the pharmaceutical industry is in fact policy-led. The pharmaceutical industry in India was in a very pathetic situation in the early years after independence. The prices in India were among the highest in the world for the broad-spectrum antibiotics, Aureomycin and Achromycin.[49]Various committees (notably the Bhatia Committee & Hathi Committee) were constituted and they had undertaken comprehensive studies of the Indian pharmaceutical scenario and made effective recommendations which were employed not only in India but also other developing countries like Sri Lanka and Bangladesh. The Patent Act of 1970 which provided for only process patents besides reduction of the period of patent protection from 14 years to 7 years gave a "big push" to the growth of the pharmaceutical sector.

4.4 Employment of TRIPS flexibilities in India

After becoming TRIPS-compliant fully in 2005 and amending its patent system, India reintroduced the product patent system with a much longer period of patent protection. Even then there was no evidence of any sudden surge in prices of pharmaceutical products till recently. Even the survey data I have used for my analysis substantiate this point. The major reasons for this seem to be the effective drug price control policy that India has employed so far and its effective and careful application of TRIPS flexibilities, not just limiting it to compulsory licensing. Specific provisions are incorporated in the Indian Patent system for avoiding the evils of patent systems like evergreening and forming patent thickets. Section 3 of the Indian Patent Act lists some more categories of

[49] Joseph, Reji K (2011).

knowledge as "not inventions within the meaning of this Act." The particularly relevant ones are the following.

- "discovery of any living thing or non-living substance occurring in nature" (section 3(c));
- "new forms of known substances which does not result in the enhancement of the known efficacy of the substance" (section 3(d));
- "mere discovery of any new property or new use of a known substance";
- "mere admixture" (section 3(e));
- "any process for the medicinal...therapeutic or other treatment of human beings" (section 3(i));
- "an invention which, in effect, is traditional knowledge" (section 3(p)).

On 1st April 2013, the Supreme Court of India gave a landmark judgment noting that Novaritis' drug Imatinib Mesylate in beta crystalline form under the brand name Glivec does not qualify the test of invention as laid down in clauses (j) and (ja) of section 2(1) of the Indian Patent Act and comes under section 3(d) of the Indian Patent Act which excludes new form of known drugs from having patent right if it is not therapeutically more effective than an earlier version of the drug.

Like Thailand, India also utilised the compulsory licensing provision very recently, but not as Government Use of Patent. A compulsory license was issued for Bayer's anti-cancer drug Sorafenib Tosylate marketed under the trade name Nexavar, granting permission to the local firm Natco to produce the generic version by paying 6% of net sales as royalty to Bayer. Thus the price of the medicine has come down from Rs. 2.8 lakhs per month to Rs. 8800 per month. Besides, Natco was also committed to donating free supplies of the medicine to 600 needy patients each year as per rule.

Thus the Indian Patent Act even after being adapted to TRIPS provides enough room to avoid unnecessary patent grants. All such provisions, especially the above mentioned ones, are essentially good if implemented effectively. But today India is also going ahead with many negotiations for various Free Trade Agreements, notably the discussions happening on the India- EU FTA. In the outcomes of these agreements much is at stake.

Besides, many of the top generic producers in India are merging or being acquired by pharmaceutical MNCs. The outcome of the new Drug Price Control policy in India is a matter of concern since often the market leaders in the pharmaceutical industry in India are the price leader firms themselves. Hence under the new drug policy proposed, there are chances for the ceiling prices to rise. This can put patients in trouble. Even Thailand imports from India when there arises the need for cheaper but quality products. The drugs supplied by the Indian pharmaceutical industry are, in fact, partly the secret of Thailand's successful compulsory licensing story.

4.5 Conclusion

After the issuance of compulsory licenses, some of the MNCs selling those highly priced drugs announced some reductions in prices both in India and Thailand. In Thailand, price reductions were mainly announced by the same companies for whom compulsory licenses have been issued. Merck Sharp & Dohme has reduced their price twice after the issuance of compulsory licensing. The price for Efavirenz was initially reduced to $21.63 per bottle of 30 tablets and then the price per tablet was reducedfrom $ 0.76 per day to $0.65. Abbott reduced the price of Kaletra and Aluvia, its new heat stabilized versions, to $1000 per year for NGOs and to the governments of some 40 countries who agreed not to issue compulsory licenses. These can be seen as a moves to retain market shares by making their products competitive with the prices of Indian generic products. In India after the issuance of compulsory license for Nexavar, the government has come up with a proposal for the issuance of three more compulsory licenses – Roche 's cancer drug for breast cancer, Trastuzumab sold under the brand name Herception, Bristol-Myers-Squibb's anti cancer drug Ixempra (Ixabepilone) for leukemia treatment, and Sprycel (Dasatinib). The Swiss company Roche has announced that it will make a cheaper version available for India through a tie-up with Emcure pharmaceuticals.[50] The production will continue at their plants in the US, Singapore and Germany. Under the deal with Emcure, they will ship the vials of the drug to Emcure for packaging and the

[50] "On Cue, Roche to Cut Cancer Prices", 24 March 2012, available at http://www.dnaindia.com/money/1666622/report-on-cue-roche-to-cut-cancer-drug-prices

cheaper products will be renamed and sold in the Indian market. These instances show that the MNCs will employ all crooked means to maintain market power. They will at times go to the extent of employing predatory pricing policies to avoid issuance of compulsory licenses. In the case of Roche, they are never planning to produce drugs in India. They themselves will make and supply cheaper versions to maintain their monopoly and for preventing technology transfer.

Moreover issuance of compulsory license is not possible for the vast majority of drugs which people rely on in their day to day life like medicines for cholesterol, hypertension, diabetes etc. and many of these drugs are among the top block-buster drugs (Ex: Lipitor) in the world. For the comparative analysis done here also, medicines for common conditions like cardiovascular, antihypertensive, antibacterial, antiepileptic, antiasthmatic, gastrointestinal diseases etc are considered. Even then there exist wide gaps in the prices of medicines between the two countries. Hence an effective national drug policy with proper price control and measures to boost domestic production especially with much emphasis on the production of generic versions with quality control is required.

Chapter 5

Conclusion

It is true that the discovery of new medicines helps in increasing life expectancy and improving the productivity of mankind. But since the major chunk of pharmaceutical production and marketing is being carried out by for-profit enterprises, the *"right to health"* or in fact the *"right to life"* itself is determined by a person's ability to pay. In this thesis, we examined how far the compulsory licensing provision of the TRIPs agreement helps in increasing medicine accessibility in the TRIPs-compliant developing world and compared that with the impact of alternative policies on medicine prices.

For analysing the effectiveness of compulsory licensing, the case of Thailand was considered. Thailand, which is often acclaimed as the symbol of successful implementation of compulsory licensing, issued all its licenses in the form of government use of patents. Hence to assess the real contribution of compulsory licensing, the dissertation analysed its impact on the affordability of medicines from the perspective of Thai citizens, given the economic situation and income distribution of the country. The study was done by dividing the whole population into quintiles and checking what percentage of her/his per capita income a person in each quintile had to spend for each of these medicines before and after the issuance of compulsory license. Affordability was also assessed in terms of the percentage income diverted to non-food expenditure that had to be spent for purchasing each of these medicines.

The analysis revealed that the level of affordability has, indeed, improved after the issuance of compulsory licenses. But even then, except for the case of Letrozole and Clopidogrel, all the other four medicines remained out of the reach of the poorest quintile. Among them, Kaletra and Erlotinib remained unaffordable for a majority of the population, including all others except the ones in the richest quintile. Hence the issuance of compulsory licenses alone cannot ensure the affordability of medicines for the whole population, since the distribution of income is very unequal. The perceived success of the compulsory licensing regime in Thailand results from the fact that the medicines are

procured by the government and provided free to all, and any consequential loss in governmental spending for some other developmental activities is not highlighted.

Further, the CL regime is mostly employed for a handful of diseases which are 'catastrophic'. But there exist many other diseases, chronic ones like heart disease, asthma, diabetes etc and high-impact diseases with patented treatments such as malaria, multi-drug-resistant tuberculosis, sepsis which have not been issued with a compulsory license (Beall, 2012).

One of the important factors which determine medicine availability and affordability is domestic production and supply. Hence, the trends in Thailand's domestic production and dependence on imports of the medicines it needs have been assessed. Though Thailand officially launched its nationwide immunization programme in 1977 and the National Vaccine Policy recognized the 'right of basic immunization' for the Thai people, domestic vaccine production is inadequate and the country is likely to face difficulties in times of increased demand. There are only three major domestic vaccine producers and of the 3 billion Baht Thailand spends each year on vaccine procurement, 80 percent is spent on high-priced imported vaccines.

If we analyse the trend of local production and dependence on imports of all pharmaceutical products (for human use) in Thailand during the last 25 years, we can see that the share of imports has been increasing. The share of locally produced drugs has fallen from 65.2 percent in 1983 to 35.5 percent in 2008 and that of imported drugs has increased from 34.8 percent (1983) to 64.5 percent (2008). There has also been a steep rise in the share of imports in the last six years (2002-08) resulting in an almost 20 percentage points increase in import share (from 45.1 percent to 64.5 percent). This was possibly due to the increased consumption of medicines after the implementation of the universal health care scheme. This shows that the rising demand for medicines is being met by imports which is not a healthy trend.

The composition of bulk drugs and formulations in the imports of the medicinal and pharmaceutical products shows that over the years (1988-2012), the share of formulations has increased, and there seems to be a sharp rise in the share of formulations in imports

after 2002. This was probably due to the purchase of medicines from low cost destinations to cater to the needs of the Universal Health Coverage scheme. Exports are improving, but the share of bulk drugs is comparatively low in medicinal exports since Thailand hasn't developed much capability in the primary manufacture of pharmaceuticals.

The GPO Annual Report 2011 mentioned about its production of Lopinavir/Ritonavir. But expcet for this one, other medicines issued with compulsory licenses are not yet produced domestically. So the issuance of compulsory license may not lead to development of local production. Though local production of medicines alone is not going to ensure adequate medicine accessibility, the condition will be worse if that is not realised. Hence a systematic approach is required to make a framework to create the best environment to improve both local production and public health.

Beall R et.al (2012) in their study find that compulsory license issuance has diminished markedly since 2006. They point out that Upper Middle Income Countries which were engaged in heightened compulsory license activity and had strong incentives to use compulsory licenses are experiencing considerable countervailing pressures against their use. A major countervailing force is the rising number of Regional Free Trade Agreements which are mostly concluded with TRIPS-plus provisions being incorporated in them.

Hence, the last part of this study dealt with other policy measures which can be employed to control drug prices. India has so far maintained an effective drug price control policy and a favourable industrial policy which contributed to the growth of a well-performing pharmaceutical industry. A comparison of Thailand's experience with India's is made to see how far such policies can help in maintaining prices within an affordable range. An analysis of medicine prices is done using the standardised methodology developed by HAI and the HAI survey data on medicine prices with the set of international reference prices (MSH 2010) as the base for comparison. The median MPR for public procurement prices in India is 0.48 and that in Thailand is 2.14. That means the procurement price in Thailand is more than five times higher than that in India. Procurement prices are generally considered acceptable if MPR $\leq$ 1 and by that criterion the MPR of public

procurement prices in India shows a healthy trend, but that is not the case in Thailand. Similarly the MPR for patient prices are also much lower in India compared to that in Thailand.

The presence of a vast generic market along with policies to monitor medicine prices helped a lot in bringing down the prices of medicines in India. Even after making its patent system TRIPs compliant, India tried to interpret the TRIPs provisions appropriately and incorporate proper clauses in the Indian Patent system to avoid the evils of the patent system such as evergreening and forming patent thickets. So far there is no evidence of any sudden surge in prices of pharmaceutical products after the country became TRIPs compliant. Even the survey data used for the analysis substantiate this point. Recently India also employed the compulsory licensing provision too to avoid exorbitant pricing for life saving drugs.

Very recently India has introduced new drug price control policy based on market-based pricing (MBP) replacing its cost-plus based pricing (CPB) principle, the impact which is yet to be felt. As a result prices may rise. For example, the price ceiling for Metformin 500 mg (diabetes), which is Rs. 4.75 as per the CPB pricing principle will go up to Rs.11.70 under the MBP pricing regime. This happens because often the market leader is also the price leader in the India pharmaceutical industry. Moreover, today India is also going ahead with negotiations on various Free Trade Agreements. All these can have far reaching consequences for medicine prices. Overall, therefore it is clear from the analysis that an effective and prudent drug price control policy must create space for the growth of domestic production along with timely application of compulsory licenses, so as to make medicines available at affordable prices. Compulsory licensing is just one of the pillars and not the edifice of the price regulation system.

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APPENDICES

Appendix I

Growth of Real - term Expenditure on Drugs, Health and GDP, 1993-2002 (1993 price =100)

Year	GDP	Health Expenditure	Drug Expenses
1993	100	100	100
1994	108.9	107.8	118.6
1995	118.6	116.4	144.9
1996	125.1	123.8	165.8
1997	119.9	127	178
1998	118.4	114.7	148.2
1999	108.8	118.2	162.6
2000	113.4	119.8	179.8
2001	117.7	126.8	200.2
2002	124.1	130.9	204.9
Avg. Annual Rate of Growth (10 yr period)	**2.43**	**3.03**	**8.29**

Source: Thailand Health Profile 1998-2000, released by Ministry of Public Health, Thailand
Note: For comparison health expenditure of 1993 were set at 100

Appendix II

Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[51] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial 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;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

[51] "Other use" refers to use other than that allowed under Article 30.

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

i. the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

ii. the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

iii. the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Appendix III

Article 31*bis*

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory license is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the provisions of Article 31(f).

Appendix IV

Gross Domestic Product Per Capita, 1960-2009 (market prices)

Year	GDP Per Capita (in Baht)	Growth rate (%)
1960	2238.7	
1962	2509.9	12.1
1964	2779.4	10.7
1966	3525.7	26.9
1968	3588.1	1.77
1970	4077	13.6
1972	4456.2	9.3
1974	6929.8	55.5
1976	8160.6	17.8
1978	11044.5	35.3
1980	14260.7	29.1
1982	17355.5	21.7
1984	19606.1	13
1986	21528.4	9.8
1988	28602.4	32.9
1990	38786.3	35.6
1992	48987.1	26.3
1994	61414.9	25.4
1996	76702.2	24.9
1998	75268.2	-1.87
2000	79702.8	5.89
2002	87134.3	9.32
2004	103793.2	19.1
2006	125355.5	20.8
2007	135537.2	8.12
2008	143567.7	5.92
2009	142626.5	-0.66

Source: Office of National Economic and Social Development Board (NESDB).

Appendix V

Income Distribution among Thai Population, 1962-2009

Years	Income Group -Bottom 20%	Income Group -Top 20%	Income Disparities (times)
1962	7.9	49.8	6.3
1975	6.05	49.26	8.1
1981	5.41	51.47	9.5
1986	4.55	55.63	12.2
1988	4.51	55	12.2
1990	4.1	57.3	14
1992	3.8	59.5	15.6
1994	4	57.7	14.4
1996	4.2	56.7	13.5
1998	4.2	56.5	13.5
1999	3.8	58.8	15.4
2000	3.9	57.6	14.8
2002	4.2	55.4	13.2
2004	4.5	54.9	12.2
2006	4.03	56.1	13.9
2007	4.4	54.9	12.5
2009	4.8	54.2	11.3

Source: Economic and Social Household Survey of the National Statistical Office & Thailand Health Profile 2008-10, released by Ministry of Public Health, Thailand

Appendix VI

Share of Income Monthly spent on Food by various Socio-economic Classes

Socio-economic Classes	Monthly Income (in Baht)	Monthly Food Exp. (in Baht)	Share of Income on Food Exp. (%)
Total Households	17787	4221	23.73
Mainly Owning Land	12837	3305	25.75
Mainly Renting Land	12092	3477	28.75
Fishing, Forestry, Agri: Services	10291	2940	28.57
Own Account Workers, non-farm	23932	4949	20.68
Professional, Tech. & Adm. Workers	42215	6504	15.41
Farm Workers	9037	3447	38.14
General Workers	9432	3583	37.99
Clerical, Sales & Service Workers	18696	5061	27.07
Production Workers	13039	4314	33.09
Economically Inactive	11377	3051	26.82
Average (for the ten classes)			**28.23**

Source: Report of the 2006 Household Socio - Economic Survey, Whole kingdom, National Statistical Office, Ministry of Information & Communication Technology

Appendix VII

Details of the Medicines Employed in the Analysis

Medicines	Dosage strength	Dosage Unit	Treatment	Global /Regional List
Amitriptyline	25 mg	cap/tab	Antidepressant	Global
Amlodipine	5 mg	cap/tab	Hypertension	Regional
Amoxicillin	250 mg	cap/tab	Adult Respiratory Infection	Global
Atenolol	50 mg	cap/tab	Hypertension	Global
Atorvastatin	10 mg	cap/tab	Cardiovascular diseases	Regional
Captopril	25 mg	cap/tab	Hypertension	Global
Ceftriaxone	1 g/vial	vial	Adult Respiratory Infection	Global
Ciprofloxacin	500 mg	cap/tab	Gonorrhea	Global
Diazepam	5 mg	cap/tab	Anxiolytic	Global
Fluoxetine	20 mg	cap/tab	Antidepressant	Regional
Glibenclamide	5 mg	cap/tab	Diabetes	Global
Metformin	500 mg	cap/tab	Diabetes	Regional
Omeprazole	20 mg	cap/tab	Peptic Ulcer	Global
Phenytoin	100 mg	cap/tab	Anticonvulsant	Regional
Ranitidine	150 mg	cap/tab	Peptic Ulcer	Regional
Salbutamol inhaler	100 mcg/dose	dose	Asthma	Global

Appendix VIII

Method to Standardize Prices to a Common Base Year for International Comparison

(Taken from the HAI manual 2008)

1. Pick a base year for comparison

It is suggested that you use the same year as your survey using the same MSH reference prices e.g. if a survey was conducted in 2008 using 2007 MSH reference prices, 2008 should be chosen as the base year. However, if the bulk of the studies were done in one particular year, it is best to pick that year as the base year and adjust other results to that year. Note: this will result in some changes to MPRs calculated in your survey.

2. Convert MPR back to country-specific prices

a. Multiply the MPR by the appropriate MSH reference price to get the price in USD
b. Multiply (2a) times the relevant currency exchange rate used in the survey to obtain the local currency unit price.

3. Convert local currency to US dollars

Divide the local currency value from (2b) by the relevant country specific official exchange rate for US dollars in the year the country survey was conducted. The period average exchange rate for the relevant survey year should be used, when available. If unavailable, use the end of period exchange rate.

4. Adjust for inflation/deflation

This is only for studies NOT conducted in the base year to adjust the country specific prices to account for deflation or inflation using the GDP deflator for the time difference between when the study was conducted to the base year chosen.

If the country CPI in the survey year is INFLATED (higher) compared to that of the base year, then the medicine prices need to be DEFLATED to base year prices (use a1 below). If the country CPI in the survey year is DEFLATED (lower) compared to that of the base

year, then the medicine prices need to be INFLATED to base year prices (use a2 below).

a1. Deflation factor $= \left[1 - \left(\frac{SurveyYearUSCPI - BaseYearUSCPI}{BaseYearUSCPI}\right)\right]$

a2. Inflation factor $= \left[1 + \left(\frac{BaseYearUSCPI - SurveyyearUSCPI}{BaseYearUSCPI}\right)\right]$

b. Multiply (4a1 or 4a2) times the price from (3) above

5. Recalculate MPR

Divide adjusted country prices from (3) or (4) above by the MSH reference price from the year prior to the base year.