SOCIAL COST OF MARKET EXCLUSIVITY EXTENSION FOR PATENTED MEDICINES IN THAILAND: ANALYSIS OF THE EFFECT OF TRIPS-PLUS PROVISIONS

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ABSTRACT

Title of Dissertation	Social Cost of Market Exclusivity Extension for Patented Medicines in Thailand: Analysis of the Effect of TRIPS-Plus Provisions
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Under the bilateral trade and investment negotiations with the United States, several developing countries were required to enforce the TRIPS-Plus provisions. The dramatic expansion of these U.S. intellectual property policies through the free trade agreement negotiations has precipitated the intense debate about the merits of these requirements between the United States and its trade partners in the developing world. On one hand, most low-income countries claim that very stringent intellectual property protection for pharmaceuticals will result in considerably higher prices for medicines, with adverse consequences for the health and well-being of their citizens. On the other hand, the United States and its research-based global pharmaceutical companies argue that prices are unlikely to rise significantly as most patented medicines have therapeutic substitutes. Under the free trade agreement negotiation with the United States, Thailand has come under policy scrutiny regarding its pharmaceutical patent regime, as drug spending is a major component of the overall national health expenditure. For a technology-importing country like Thailand, while long-run (dynamic) gains from enforcing TRIPS-Plus remain poorly understood and controversial, the shift to stronger and broader intellectual property protection in regard to these provisions unquestionably incurs substantial short-run costs arising in the form of static inefficiency including: legal and administrative costs, cost of rent transfers, and incremental cost due to higher prices of patented medicines. Among these costs, the social cost due to monopolistic prices of patented medicines is the

most noteworthy one; this study empirically assessed this cost with the objective to contribute to the ongoing controversy regarding the merits of TRIPS-Plus in the Third World countries. Central to the ongoing debate is the structure of demand for pharmaceuticals in poor developing economies, where access to medicines is predominantly sensitive to price for the reason that a large number of people, particularly the poor and the deprived, pay out of their own pockets due to a lack of health insurance coverage. Using a detailed product-level data set from Thailand, we estimated demand-side parameters together with key price and expenditure elasticities for the modern generation sub-segment, which consists of three main therapeutic categories, namely beta blocking agents, calcium channel blockers and agents acting on the renin-angiotensin system, of the oral antihypertensive drugs segment of the Thai pharmaceuticals market. We then used these estimates to carry out counterfactual simulations of what consumer welfare would have been, if Thailand had enforced TRIPS-Plus. Our results suggested that concerns about the potential adverse effects of TRIPS-Plus in developing economies may have some basis. More specifically, we estimated that in the modern generation sub-segment of the oral antihypertensive drugs segment alone, the enforcement of TRIPS-Plus would result in a substantial accumulated consumer welfare loss to the Thai economy, ranging between ฿ 30 billion and ฿ 206 billion, within a ten-year period from 2012 to 2021. The magnitudes and significance of consumer welfare loss we estimated have suggested that without clear inclusive evidence as regards the merits of TRIPS-Plus in every aspect, Thailand along with other technology-importing developing countries not accept any further intellectual property protection beyond the WTO TRIPS mandates.

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ABBREVIATIONS

Abbreviations	Equivalence
ACTN	Advisory Committee on Trade Negotiations
AIDS	Acquired Immune Deficiency Syndrome
AIDS	Almost Ideal Demand System
APEC	Asian-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
ATC Classification System	Anatomical Therapeutic Chemical Classification System
BIO	Biotechnological Industry Organization
BSA	Business Software Alliance
CBS Demand System	Central Bureau of Statistics Demand System
CES Model	Constant Elasticity of Substitution Model
CIPR	Commission on Intellectual Property Rights
CSMBS	Civil Servant Medical Benefit Scheme
CV	Compensating Variation
DDD	Defined Daily Dose
DRGs	Diagnosis-Related Groups
EAI	Enterprise for ASEAN Initiative
EDs	Essential Drugs
EMEA	European Agency for the Evaluation of Medical Products
FDA	Food and Drug Administration
FDLAIDS	First-Differenced Linear Almost Ideal Demand System

FFF	Fourier Flexible Form
FFS	Fee-For-Service
FTA	Free Trade Agreement
GARP	Generalized Axiom of Revealed Preference
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GL	Generalized Linear
GMP	Good Manufacturing Practice
GSP	Generalized System of Preferences
GTL Demand System	Generalized Translog Demand System
HIV	Human Immunodeficiency Virus
IFAC-3	Industry Functional Advisory Committee
IIPA	International Intellectual Property Alliance
IP	Intellectual Property
IPR	Intellectual Property Rights
ISUR	Iterative Seemingly Unrelated Regression
ITAC15	Industry Trade Advisory Committee on Intellectual Property Rights
ITL Demand System	Indirect Translog Demand System
LA-AIDS	Linear Approximate Almost Ideal Demand System
LDCs	Less-Developed Countries
LES	Linear Expenditure System
MFN	Most Favored Nation
MNEs	Multinational Enterprises
MoPH	Ministry of Public Health
MRI	Magnetic Resonance Imaging
NBR Demand System	National Bureau of Research Demand System
NEDs	Nonessential Drugs
NESDB	National Economic and Social Development Board

NGO	Non-Governmental Organization
NIH	National Institutes of Health
NTBs	Non-Tariff Barriers
OECD	Organisation for Economic Co-operation and Development
PhRMA	Pharmaceutical Research and Manufacturers of America
PIGL	Price Independent Generalized Linear
PIGLOG	Price Independent Generalized Logarithmic
QUAIDS	Quadratic Almost Ideal Demand System
R&D	Research and Development
SARP	Strong Axiom of Revealed Preference
SARS	Severe Acute Respiratory Syndrome
SUR	Seemingly Unrelated Regression
TIFA	Trade and Investment Framework Agreement
TNCs	Transnational Corporations
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TUSFTA	Thailand-U.S. Free Trade Agreement
UC Healthcare Scheme	Universal Coverage of Health Care Scheme
USSFTA	U.S.-Singapore Free Trade Agreement
USTR	United States Trade Representative
WARP	Weak Axiom of Revealed Preference
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

CHAPTER 1

GENERALITIES OF THE STUDY

Fuchs (1974: 105) ". . . without drugs the effectiveness of hospitals and physicians would be enormously diminished . . ."

1.1 Introduction to the Study

It is generally accepted that medicine is one of the most basic factors for human well-being as well as for national public health service system. Medicine is essential to the immediate welfare of everyone and cannot be replaced by other products. In addition, the most common treatment practiced by a physician is to prescribe medicines. In most countries the use of medicines has been progressively increasing. One reason for this increase has been the expansion in the range of effective medicines and the second is the fact that prescribing medicines is a most comfortable way for a busy doctor to end a consultation (Abel-Smith, 1976: 77).

Not only has there been an increase in the use of medicines over time, but the effectiveness of medicines has also increased. Consequently, the cost of other health care services such as the cost of doctor care, hospital care are significantly lower than they otherwise would have been without the progress in medicines (Egan, Higinbotham and Weston, 1982: 3). This is because the effective medicines could reduce the duration of therapy, the frequency of outpatient visit and inpatient day, etc. Medicine is, therefore, the key to modern medication and, thereby, the pharmaceutical industry is fundamental to the provision of health care and to the long-term improvement of standard of living.

Unlike other goods, patients and consumers cannot determine which medicine to prescribe for themselves; besides, ones cannot tell its efficacy and quality from the appearance. In socio-economic aspect, medicine is the public goods incorporating extensively rapid, innovative technological development; at the same time, it is the

moral goods (Chulalongkorn University, 2008: 3). More specifically, medicine is, in economic theory, non-rivalrous in consumption. Therefore, it should be made available to the general public at low cost. However, in global context, pharmaceutical industry is an immense multinational business with market exclusivity, endowed by patent system. This exclusive essence creates a very long period of monopoly market. As a result, a large number of people, particularly in developing and least developed countries, cannot get access to the essential patented medicines due to unaffordable high price. In Thailand, the total spent for drugs is around one-third of national health care expenditures, costing nearly 190 billion baht in fiscal year 2005 (Table A.2 and Figure A.3 in Appendix A).

The causes of public health problems are intricate. In global context, according to Bailey, Mayne and Smith (2001: 2), one in five of the world's population does not have access to health services. While the success of public health goals relies fundamentally upon equitable economic development and proper social policies, as well as upon intensified interventions in the health field, one of the essence policies is to ensure the supply of effective, reasonably-priced medicines. Access to medicines is predominantly sensitive to price for the reason that most of the poor in developing nations pay out of their own pockets. And the price is related to the presence of monopoly, or market exclusivity, in pharmaceutical market, now greatly extended by the Agreement on Trade-Related Aspects of the Intellectual Property Rights (TRIPS).

At national level, in the context of a growing health crisis, access to an affordable, quality medicine is also critical for Thai citizens, especially the poor patients suffering a disproportionately high burden of disease. In Thailand, during 1980-2005, around two-thirds of the health expenses came from household out-of-pocket payment (Figure A.2 and Table A.3 in Appendix A). In other words, most people in Thailand paid for medicines by their own money. Therefore, even slight price increases mean that life-saving medicines are unaffordable.

It is necessary to have an adequate amount of essential medicines available for public use on an equitable basis and at affordable prices. Access to health care is a constitutional right of Thai people, as declared in Chapter 3 Part 9 Section 51 of the Constitution of the Kingdom of Thailand B.E. 2550 (Constitution of the Kingdom of Thailand B.E. 2550, 2007: 22).

> A person shall enjoy an equal right to receive public health services which are appropriate and up to the quality, and the indigent shall have the right to receive free medical treatment from public health centres of the State.
>
> A person has the right to receive public health services from the State, which shall be provided thoroughly and efficiently.
>
> A person has the right to be appropriately protected by the State against harmful contagious diseases, and to have such diseases eradicated, without charge and in a timely manner.

Hence, it is the State responsibility to ensure that all Thais, wherever they may be in the Kingdom of Thailand, are able to obtain the essential drugs they need at a price that they and the country can afford, that these drugs are safe, effective, and of good quality, and that they are prescribed and used rationally.

To respond to health problems, in 2002 under the Constitution of the Kingdom of Thailand B.E. 2540 National Health Security Act B.E. 2545 was promulgated and came into force since November 19, 2002. In accordance with the Act, the Royal Thai Government carried out universal coverage policy to provide health care coverage for all Thai populace. Nonetheless, given the universal coverage scheme and other interventions, a large number of people still cannot get access to essential medicines (Chulalongkorn University, 2008: 6-7). This is attributable to the fact that lots of medicines are prohibitively expensive for most people. As a result of extremely high prices, the governmental health budget is often not enough to serve all Thais. The heart of the problem is these medicines are patented, despite the fact that access to medicine is a fundamental human right and that medicine is one of the four basic necessities of life.

Chapter 1 is comprised of eight sections offering an overview of this research. The remainder of this chapter is structured as follows. Section 1.2 briefly outlines the central issues regarding the U.S. TRIPS-plus proposal and its adverse consequences on drug prices and access to medicines. Section 1.3 provides the justification for this research. Next, research questions and objectives are clearly identified in Section 1.4 and Section 1.5, respectively. Section 1.6 in turn presents the concise structure of this

research. Attention then shifts to research benefits in Section 1.7. Chapter 1 ends with Section 1.8, discussing about the study's scope and limitation. Section 1.8 also contains some suggestions for further research issues.

1.2 Issues and Significance of the Problem

Medicines have a major impact on health, government and household spending, and health systems. Despite the fundamental role of medicines, there remains a profound gap between the benefit which medicines have to offer and the reality that for millions of people, particularly poor and disadvantaged people, essential medicines are unavailable, unaffordable, unsafe or improperly used.

Medicines prices have risen in the context of a growing health crisis. Although there have been incessantly significant improvement in health indicators in many developing countries, eleven million people around the world, the great majority of them poor, die every year from infectious diseases. Acquired Immune Deficiency Syndrome (AIDS) claims three million of these lives, tuberculosis two million, and malaria one million. This human catastrophe as a result of ill health has destroyed opportunities for poverty reduction; for instance, if malaria had been eradicated thirty five years ago, Africa's gross domestic product (GDP) would be at least one-third higher (Bailey et al.,2001: 2). Drug-resistant strains of many common diseases such as pneumonia and, recently, Escherichia coli O104:H4, are spreading fast, making existing medicines redundant and posing a threat to global public health. Besides, developing countries face a rising incidence of First World illnesses; for example, heart conditions, diabetes, and cancer. The pandemic outbreak of the Swine flu 2009 and the 2011 E. coli O104:H4 demonstrates a huge risk posed by previously unknown diseases. According to the TRIPS agreement, all new advanced medicines developed to face these challenges will be under patent for no less than twenty years and, unless something is done, will be too expensive for people living in poverty.

In Thailand, disease and ill health continue to ravage Thai population. According to the Ministry of Public Health and the Office of the National Economic and Social Development Board (NESDB), in 2020 cumulatively there will be 1,250,000 HIV-infected individuals in Thailand and of them all 1,100,000 will have

died and only 157,000 will remain alive (Suwit Wibulpolprasert, ed., 2007: 193). Pandemics of emerging infectious diseases such as hemorrhagic diarrhea caused by E. coli O104:H4, swine flu, avian influenza, Severe Acute Respiratory Syndrome (SARS) and hand-foot-mouth diseases are also the serious threat to Thai people. In addition to communicable diseases, non-communicable diseases such as heart diseases, hypertension[1], diabetes, and cancer have unleashed an epidemic of suffering across the country. Presently, these non-communicable diseases have become the leading causes of morbidity and mortality among Thai people, as evidently shown by the following hospital admission rates: firstly, the admission rate per 100,000 population of heart diseases has risen from 56.5 in 1985 to 109.4 in 1994 and to 618.5 in 2006; secondly, the admission rate per 100,000 population of diabetes has increased from 33.3 in 1985 to 91.0 in 1994 and to 586.8 in 2006; lastly, for the case of cancer, the admission rate has also risen from 34.7 per 100,000 population in 1994 to 124.4 in 2006. Moreover, the 2003-2004 health examination survey on Thai citizens exposed that the prevalence of hypertension had a propensity to increase from 5.4 percent in 1991 to 11.0 percent in 1996 and to 22.0 percent or 10.1 million individuals in 2004. Likewise, the prevalence of diabetes rose from 2.3 percent in 1991 to 4.6 percent in 1996 and to 6.9 percent or 3.2 million persons in 2004 (Suwit Wibulpolprasert, ed., 2007: 207-208). Such a rising trend results from unhealthy consumption behaviors plus physical inactivity.

In these circumstances of growing in health problems, medicine prices in Thailand have increased drastically and continuously during past decade. Lower access to essential medicines is mainly attributable to their exorbitant prices and the World Trade Organization (WTO) TRIPS Agreement was partly responsible for this increase. The stringent level of intellectual property (IP) protection under TRIPS has prevented poor people from accessing inexpensive, generic medicines. Moreover, Thailand has been required under its free trade agreement (FTA) with the United States (U.S.) to introduce TRIPS-Plus clauses, demanding Thailand to impose intellectual property right (IPR) standards that far exceed those contained in the WTO TRIPS. Under TRIPS-Plus, medicine prices will continue to rise sharply, but the

[1] The World Health Report estimated that in 2000 hypertension was the cause of 7.1 million deaths or around 13 percent of all deaths worldwide and it was also the cause of loss in non-fatal health status or loss of healthy life years.

country will be unable to use TRIPS safeguards to reduce the cost. Several studies forecast that the imposition of TRIPS-Plus clauses to developing countries will result in increases in medicine prices over time, putting a strain on national health budgets and leaving poor people with catastrophic out-of-pocket expenses for life-saving medicines.

Unlike Western countries, Thailand has not had a long period of legal development in the intellectual property field. Right over innovations were lawfully recognized when the Patent Act B.E. 2522 was promulgated and came into force in 1979. In 1992 and 1999, under the pressure from the United States, Thailand amended its Patent Act to conform to the key obligations of TRIPS[2] in order to avoid trade sanctions, in disregard of the strong opposition to the amendment (Jakkrit Kuanpoth, 2007: 2-3; Vichai Chokevivat, 2007: 10-12). The amendment significantly expanded the level of patent protection, including an increase in the scope of patentable subject-matters, a patent term extension, restricting conditions for the application of compulsory licensing, etc. The Patent Act B.E. 2522, as amended in 1992 and 1999, provides patent protection for inventions in almost all fields of technology for up to twenty years from the date of filing of the application in Thailand (Patent Act B.E. 2522, 1979: 14). Patent protection can be obtained either as a product or a process patent (Patent Act B.E. 2522, 1979: 1). The current Thai patent law, hence, has a very strong form of monopoly rights since its level of protection is as high as the minimum standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Bilateral trade and investment agreements have been strategically employed by the U.S. as an important tool to incorporate TRIPS-Plus clauses which were politically difficult to accomplish in the WTO multilateral setting. The United States, who has been bitterly disappointed with the multinational forum, has resorted to bilateral agreements as a way to better accomplish its own interests, regardless of a more balanced approach to IP Protection. The United States aims at attaining higher

[2] Under TRIPS, nations must, as a condition of membership in the WTO, recognize and enforce product patents in all fields of technology, including medicines. At the time the TRIPS agreement entered into effect, most of low and middle income countries made an exception for medicines, even though they recognized product patent in other areas, because low-cost access to life-saving, essential medicines was deemed to be an overriding public policy priority. To meet the obligations under TRIPS, all WTO member nations must however introduce or amend their patent legislation to incorporate pharmaceutical product patents.

level of IP protection, beyond the minimum standards under TRIPS Agreement. Over the decade, the U.S. has hotly continued to impose TRIPS-Plus rules on developing countries through several bilateral FTAs. The tightening of other countries' domestic IP legislation through bilateral trade negotiations plus the use of trade leverage under the U.S. trade laws unquestionably would facilitate the U.S. to make the establishment of an acceptable framework of the U.S.'s new IP regime, so-called TRIPS-Plus" provisions, within the multilateral trade negotiations. This strategy was successfully used by the U.S. in the Uruguay Round leading to the execution of the TRIPS Agreement.

Thailand has negotiated a FTA with the U.S. since 2003. During the sixth round negotiation, the United States Trade Representative (USTR) demanded Thailand to introduce the TRIPS-Plus provisions. This U.S. new IPR regime may have an adverse impact on Thailand, particularly on its attempt to build technological capacity in the pharmaceutical sector and on the access to essential medicines. On the one hand, the TRIPS Agreement was designed to promote and reward innovations by giving exclusivity of the sale in market with patent while simultaneously to ensure the disclosure of innovative processes and products. As a result of the Agreement, apart from the patent holder or its authorization, no one can exploit the patented invention during the granted period, twenty years from the filing date, in such country. On the other hand, flexibility mechanisms to limit the monopolistic power of the patent holders in specified circumstances are also indicated in the TRIPS Agreement and, of course, the Thai Patent Act. Under TRIPS-Plus, the technological development in our local pharmaceutical industry would be restrained. Moreover, the use of TRIPS flexibilities, the public health safeguards allowed under TRIPS, would be entirely destroyed.

It is obvious that TRIPS-Plus contributes to an increase in medicine prices and, at the same time, postpones or prevents the use of public health safeguards to enable price reduction through generic competition. In particular, the prolongation of market exclusivity, provided by TRIP-Plus, delays generic competition.[3] Because savings of health expenditure on medicines by price reduction from generic

[3] Three causes of market exclusivity extension, due to TRIPS-Plus, include 1) extension of patent term due to granting delay or marketing approval delay, 2) protection for data exclusivity, and 3) linkage of drug registration and the patent status of a drug.

competition are made both by replacing innovative medicines with low-priced generic equivalents and by possible price decrease of the innovative medicines per se, delaying the introduction of generic medicines to market definitely causes a large extra financial burden to both individuals and the whole country.

According to economic theory, in market characterized by informational asymmetry and low price elasticity of demand like pharmaceutical market, the ability to limit the rate of increase in medicine price is very important. Unaffordable high price due to an absence of price competition has led to inaccessibility to essential medicines especially among the underprivileged groups and certainly creates an unnecessary additional burden for the State which has to provide more budgets to serve its people. Higher medicine price, thus, without doubt undermines the financial sustainability of governmental public health programs and threatens Thai citizens' health status.

1.3 Rationale of the Study and Problem Statement

Over decade, the U.S. has continued seeking higher levels of IP protection across the Middle East and the developing world through bilateral trade and investment agreements. The growing burden of non-communicable diseases such as hypertension, diabetes mellitus, and other cardiovascular diseases makes developing countries across Asia, the Middle East, and Latin America a commercially attractive market for multinational pharmaceutical enterprises.

For Thailand, the introduction of TRIPS-Plus provisions not only adversely affects the viability of the national pharmaceutical industry but also exacerbates the problem of inaccessibility to essential medicines. Longer period of monopolistic market, endowed by TRIPS-Plus, could delay an appearance of the low cost, generic-equivalent medicines that traditionally supply the country's needs, only the unnecessarily expensive, patented version of a new medicine would be available. Consequently, numerous Thai citizens, especially the poor, cannot get access to essential medicines due to unaffordable high price. Apparently, the TRIPS-Plus clauses will incur a significant adverse impact on public health and the future well-being of all Thais. Especially, the extension of market exclusivity for patented medicines will generate a

substantial welfare loss to the whole society. The recent history of bilateral FTAs shows that several developing countries ended up accepting to some extent of the U.S.'s demand for stronger IPR due to pressures from the U.S.'s measures, trade sanctions in particular. Thereby, it is necessary for Thailand to consider what impact the U.S. new IP regime is likely to have, before decision-making.

In determining the country's position in negotiations, clear information regarding possible effects of the Thailand-U.S. FTA (TUSFTA) in every aspect is needed to support the authorities' decision. However, until present there have been very few of systemic, comprehensive studies pertaining to an important impact of the U.S. new IP rules on the National Health Service. This research was conducted from the public health perspective to provide more specific information concerning the potential impact of TRIPS-Plus on pharmaceutical prices and welfare of Thai citizens.

Given the natural setting of Thailand for the analysis of the welfare effects of the very stringent pharmaceutical patent protection associated with the U.S. TRIPS-Plus provisions, in this study we used a detailed product-level data from Thailand on annual prices and quantities consumed over a thirteen year period (1996-2008) to estimate key price and expenditure elasticities as well as demand-side parameters for the particular sub-segment, which comprises three main categories of antihypertensive drugs, namely, beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system, of the antihypertensive drugs segment of the Thai pharmaceuticals market.

Initially, using a time-series of data on a cross-section of chemical entities within the three aforementioned antihypertensive categories, we adopted the linear approximation version of an Almost Ideal Demand System (AIDS) to represent the characteristics of demand for antihypertensive drugs in Thailand. The method to estimate the parameters was Iterative Seemingly Unrelated Regression (ISUR), where the restrictions of adding up, homogenous of degree zero in prices, and symmetry were imposed. With these estimated parameters in hand, key price and expenditure elasticities were then systematically calculated.

Subsequently, in assessing the potential adverse impact of market exclusivity extension endowed by the TRIPS-Plus provisions, the counterfactual simulations of the Thai pharmaceuticals market under two policy options, with and without the

enforcement of TRIPS-Plus, were performed to measure the changes in consumer welfare. Without the enforcement of TRIPS-Plus, price of patented medicines would follow the current trend. In contrast, with the enforcement of TRIPS-Plus, ceteris paribus, three possible scenarios of 10%, 30%, and 50 % increase in price of patented medicines above the current trend were simulated.[4]

Alternatively, it is more than likely that in the nonexistence of TRIPS-Plus, generic competition would lead to more competitive pharmaceutical market. Earlier studies indicate that generic competition causes the prices of brand-name medicines to fall substantially. Correspondingly, for present purpose it is assumed that in the nonappearance of TRIPS-Plus, prices of patented medicines will reduce on average by 20 percent due to generic competition. Consequently, another three counterfactual scenarios were simulated. On one hand, price of patented medicines would decrease by 20 percent from the trend line in the absence of TRIPS-Plus. On the other hand, in the presence of TRIPS-Plus the plausible scenarios of 10%, 30%, and 50 % increase in price of patented medicines above the trend line were simulated, given that all other things being equal.

Via computing the compensating variation (CV), the social costs of the Thai society, the magnitudes of the consumer welfare loss[5] due to market exclusivity extension for patented medicines, were numerically quantified in terms of the additional drug expenditures that consumers need to incur to maintain the same level of access to medicines as before the enforcement of the provisions. Put differently, through substituting the estimated parameters into the expenditure function, we were able to calculate the welfare loss, resulting from the additional drug expenditures that the representative Thai consumer would need to incur to maintain her pre-TRIPS-Plus utility level in the face of the market exclusivity prolongation and higher drug prices in the original patentable market, under various counterfactual scenarios. Lastly, the public policy options were recommended for policy makers in order to avoid or address the negative consequences attributable to the provisions.

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[4] In this context, imagine a scenario that the imposition of TRIPS-Plus leads to the extension of market exclusivity for patented medicines and, hence, upward price adjustments in the original patentable market, as producers of patented products re-optimize and set new prices in response to the market exclusivity prolongation.

[5] The welfare loss estimated in this study represents only the static costs arising from pricing distortions due to TRIPS-Plus provisions.

1.4 Research Questions

Two main questions in the study were as follows:

1.4.1 How to measure or quantify social cost of the Thai society incurred by TRIPS-Plus provisions?[6];

1.4.2 If the TRIPS-Plus provisions were adopted, what would be the welfare loss to Thai consumers and by how much?

1.5 Research Objectives

This study was aimed at

1.5.1 Estimating consumers' welfare change, if the TRIPS-Plus provisions were imposed; and

1.5.2 Quantifying, in Thai baht, consumers' welfare loss (social cost of Thai citizens), resulting from market exclusivity extension for patented medicines, endowed by TRIPS-Plus provisions.[7]

1.6 Organization of the Study

This study is organized in six chapters offering a comprehensive analysis of the welfare effects of the new trend of IPR protection so-called TRIPS-Plus clauses in the Thailand-U.S. bilateral trade and investment negotiation. It begins with Chapter 1 addressing issues and significance of research problem. Chapter 2 holds a discourse on the central issues of worldwide patent protection harmonization and its effects on drug prices and access to affordable medicines in poor countries. Chapter 2 also

[6] Here consider only the three major issues in TRIPS-Plus that result in market exclusivity extension of patented medicines: (1) patent term compensation due to unreasonable delays, (2) protection for data exclusivity, and (3) linkage of drug registration and the patent status of a drug.

[7] Generally, social welfare is defined as the sum of producers' surplus and consumers' surplus. Consumers' surplus measures the total net benefit to consumers, we can measure the gain or loss to consumers from a government policy (in this research enforcing TRIPS-Plus) by measuring the result change in consumers' surplus. Producers' surplus measures the total profits of (domestic) producers, plus rents to factor inputs. Together, consumers' surplus and producers' surplus measure the net welfare benefit of the whole society. In this research, the scope to be measured was only the change in consumers' welfare incurred by TRIPS-Plus. More specifically, the objective of this research is to quantify (in baht) the loss to Thai consumers (Thai people) attributable to enforcing TRIPS-Plus.

includes an overview of the Thai patent system as well as the outline of the legal landscape regarding the TRIPS-Plus provisions. Attention then shifts to the welfare effects of global patent protection in Chapter 3. Particularly, Chapter 3 provides a survey of only the most select theoretical and empirical literature pertaining to the impact of international patent protection on national and global welfare. In Chapter 4, the theoretical underpinning is carefully elaborated, together with the method of analysis. Especially, the formal microeconomic theories including consumer theory, applied demand analysis as well as the theory of welfare economics are applied in order to construct the research framework. With this essence, the social cost of introducing TRIPS-Plus can be simulated and numerically quantified in pecuniary term. Afterwards, the study results, the central point of the study, are displayed in Chapter 5. Finally, the report ends with Chapter 6, which all findings are concluded and turned into policy options.

1.7 Contribution of the Study

During the sixth round of the TUSFTA negotiation, the U.S. demanded Thailand to enforce more stringent IPR protection for pharmaceuticals beyond the minimum standards required by the WTO TRIPS Agreement. The debate over the merits of these requirements has been and continues to be extremely contentious. On one hand, Thailand, similar to several other developing countries, claims that higher level of patent protection for pharmaceuticals will result in substantially higher prices for medicines, with adverse consequences for the health and well-being of the Thai people. On the other hand, the U.S. argues that prices are unlikely to rise significantly because most patented medicines have available therapeutic substitutes, and that the higher level of patent protection has served as an incentive to engage in research on diseases that extremely afflict the world's poor. This study empirically investigated the basis of these claims.

On a global plane, given the scope of the TRIPS-Plus and the intensity of the accompanying debate, it is remarkable how sparse the evidence is, on which these divergent claims are based. In addition, little is known about the extent to which pharmaceutical prices in less-developed economies might increase with the enforcement

of the TRIPS-plus mandates, and the magnitude of the associated welfare losses. Past empirical studies on the impact of patents on pharmaceutical prices and welfare in developing countries have focused almost exclusively on the WTO TRIPS Agreement. As a result, the conclusions from these studies are not directly pertinent to the TRIPS-Plus debate. In this vein, this study empirically investigated the effects of the enforcement of more stringent IPR protection for pharmaceuticals associated with TRIPS-Plus clauses, as stipulated in the TUSFTA negotiation, on drug prices and welfare in Thailand with the objective to contribute to the ongoing controversy and debate regarding its potential adverse effects in the Third World country. As there are very few studies considering these issues, this study may serve as a reference point for other developing countries that are currently in the process of trade and investment negotiation with the United States.

Besides, the ongoing debate regarding the welfare effects associated with the execution of the TRIPS-Plus provisions in developing countries mostly emphasizes the issue of affordability of medicines (i.e., access to medicines) in developing countries. This study provides further proposition that the availability of new advanced medicines (i.e., progress in pharmaceutical technology) is also important from a consumer welfare perspective. For this reason, the present study suggests that policymakers should assess policies that are related to TRIPS-Plus not only in terms of their effects on drug prices, but in terms of their effects on the availability of new medicines as well.

At national level, the major contribution of this study is that it improves upon the earlier studies in three substantive, and (it turns out) empirically important, ways. First, it is the first study employing explicit model of consumer behavior and standard analytical methodology to derive estimates of the key price and expenditure elasticities as well as demand-side parameters of the Thai pharmaceuticals market in order to be able to examine the impact of TRIPS-Plus provisions on drug prices and national welfare. Second, the study bases its findings on actual estimates of the relevant parameters of demand and structure of the Thai pharmaceuticals market whereas the findings in prior literature by Chutima Akaleephan et al. (2009) and Nusaraporn Kessomboon et al. (2010) are simply based on assumptions about market structure and demand characteristics. Lastly, apart from the fact that the counterfactual

simulations in this study are based on estimated rather than assumed parameter values, this study allows for and flexibly estimates a range of cross-product-group substitution effects. By contrast, cross-price effects are ignored in previous studies.

1.8 Limitation of the Study and Recommendations for Further Research

Normally, to get more precise idea of how the general well-being of individuals and the society as a whole will be ultimately affected by TRIPS-Plus rules, an analysis of the welfare effects of the policy change is certainly needed. In general, social welfare is defined as the sum of domestic firms' profits and consumers' welfare. However, the scope of this research was limited to quantifying only consumers' welfare loss (social cost of Thai consumers). To obtain total welfare loss of the Thai society incurred by TRIPS-Plus provisions, further research issues regarding the change in producers' welfare of domestic drug firms or producers' welfare loss of national pharmaceutical industry are highly recommended.

Besides, it is important to note that the welfare analysis in this study was the static one, focusing only on estimating the monopoly misallocation costs of strengthening patent protection in Thailand due to TRIPS-plus provisions. The study did not, however, address the question of whether the imposition of the higher level of patent protection attributable to TRIPS-Plus may spur global R&D resulting in potential dynamic benefits of innovation. More precisely, this study did not elaborate on the link between patent protection and its impact on R&D. Hence, the benefits of any increase in R&D and thus innovation in response to the enforcement of the TRIPS-Plus provisions have not been included. However, dynamic efficiency gains from increased innovation may go some way to offsetting the negative impact of these provisions, which is an essential issue for future research. Put differently, it is strongly recommended for further studies to take the stimulating effect of patent protection on R&D into consideration in order to shed further light on the ongoing debate regarding the welfare effects associated with the enforcement of the TRIPS-Plus provisions in developing economies.

Further, it is widely argued, in Thailand, that the liberalization of economic activities through bilateral and regional trade negotiations in general and the TUSFTA

in particular does not suit the need of the country and entails significant economic and social costs to all Thais. Despite the fact that a great deal of effort has already been expended in attempt to shed light on the debates over IPR, there is still a lack of official information about the potential implications of the TUSFTA. Moreover, the existing public information on the TUSFTA is very one-sided, coming mainly from the government and a group of large-scale industrialists who are poised to benefit. Hence, there are a large number of crucial aspects that require a more detailed theoretical and empirical investigation, in particular the formal literature on the prospective social costs of all treaties associated with the TUSFTA that relate to monopolization, public health, education, food security, environment, labor rights, technology transfer, and biodiversity management.

Above all, it is apparent that existing empirical studies in Thailand focus on industries at fairly high levels of aggregation. Thus, more empirical work is needed at the level of disaggregated industries or even the firm level. To date, in what is now a globalizing market economy, knowledge of the performance of firms and industries has been increasingly important to policy makers as the amount of intellectual property embodied in numerous products increases due to the potential for widespread application of technology. As the existing theoretical and empirical studies in Thailand do not provide unambiguous predictions related to more stringent IPR protection, reliable normative policy recommendations remain elusive.

CHAPTER 2

GLOBAL INTELLECTUAL PROPERTY PROTECTION AND ACCESS TO AFFORDABLE MEDICINES

Pécoul quoted in Boulet et al. (2003: 2) "[Pharmaceutical] patents are not God-given rights. They are tools invented to benefit society as a whole, not to line the pockets of a handful of multinational pharmaceutical companies."

The battle between rich and poor countries over access to essential medicines has revolved around the greater harmonization and higher protection of intellectual property rights (IPR). Every attempt of the rich economies to change IPR regime has been drowned in a sea of argument and special pleading. In particular, the debate upon the merits of the very restrictive TRIPS-Plus provisions has been and continues to be extremely contentious. Global brand name U.S. pharmaceutical firms have sought to restrict the ability of generic manufacturers to produce and distribute essential medicines and have used their economic and political clout to shape United States trade policy. They have succeeded in incorporating extremely restrictive TRIPS-Plus intellectual property (IP) provisions into U.S. regional and bilateral free trade agreements. Until present, asymmetrical power relations continue to shape intellectual property policy, reducing the amount of leeway that poorer or weaker states have in devising regulatory approaches that are most suitable for their individual needs and stages of development.

Over past decade, the United States (U.S.), who was bitterly disappointed with the WTO multinational forum, has resorted to bilateral and regional agreements as a strategic means to attain higher level of IP protection beyond the WTO TRIPS Agreement. The inclusion of the U.S. IPR chapter, so-called TRIPS-Plus provisions, in bilateral and regional free trade agreement(FTA) negotiations with less-developed economies has created a growing concern that developing countries were blackmailed by the U.S. to adopt IP laws that are not in the best interest of their people. Several

poor developing countries argue that the imposition of stricter IP protection associated with the U.S. IPR proposal will result in substantially higher prices for medicines, with adverse consequences for the health and well-being of their citizens. Especially, the inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede of technology; pharmaceutical patents will continue to be used by foreign drug companies as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements. TRIPS-Plus provisions, in the eyes of developing countries, obviously shift the international legal framework to favor U.S. innovating firms at the expense of the technology-importing developing countries. However, the United States Trade Representative (USTR) and the global brand name pharmaceutical firms claim that a stringent protection of pharmaceutical patents is a necessary condition for guaranteeing a continuing steam of new drugs that save lives and raise human health standards and that in the end these new pharmaceutical inventions will also benefit developing economies; besides prices are unlikely to rise significantly because patented drugs have therapeutic substitutes.

Chapter 2 begins with Section 2.1, reviewing a political economy background of why industrialized countries have reached a consensus in favor of introducing the patent protection for pharmaceuticals. Attention then shifts to the effect of international patent agreements on drug prices and access to medicines, presenting in Section 2.2. Consecutively, Section 2.3 provides a historical overview of the patent system in Thailand. Lastly, the chapter ends with Section 2.4 by highlighting the U.S. draft IP proposal submitted to Thailand in Thailand-U.S. Free Trade Agreement (TUSFTA) negotiation.

2.1 Political Economy Background of Patent Protection for Medicines

Few economic institutions have stirred as much controversy for such a long time as the patent system. Argument over the granting of patent monopolies on inventions has proceeded ever since the practice was formalized by the Republic of Venice in 1474 (Machlup, 1958: 2, 20-24). Particularly, the debate between developing and developed countries over whether or to what extent pharmaceutical inventions should receive patent protection has always been a classic controversial policy

question. For legal and economic reasons, patents allow drugs-inventive companies to appropriate the returns from their inventions. Pharmaceutical patents sustain high monopoly prices that provide rents to undertake further research and development (R&D) and allow the invention of new drugs.

Empirical work by several economists over nearly fifty years reveals that patents play a significant role in stimulating innovation in only few manufacturing industries. The research-oriented pharmaceutical industry is one of few for which patents are a major instrument for protecting the returns from inventions (Cohen and Merrill, eds, 2003: 3). In the innovating pharmaceutical industry, investment in R&D is comparatively high, and drugs are easily copied (Scherer, 2000: 2246-2247, 2008: 16, 2010: 541-542). Under these circumstances, the legal protection of patents is of crucial importance in determining the market performance of the R&D-intensive drug industry. Additionally, stringent drug safety regulations, introduced in the 1960s, to protect consumers from risky drugs, raised the costs of R&D in the U.S. pharmaceutical industry and lessened effective patent life. This decreased the profit per dollar invested in R&D. Also during the 1980s, a number of institutional changes in search of reducing pharmaceutical costs facilitated competition from generic drugs and squeezed the sales of the R&D-oriented drug industry. Finally, the potential market for patented drugs in developing countries has been no longer trivial. Lengthen effective patent protection in industrialized countries and press developing countries to enforce more stringent patent protection. These two tactics have become the most important parts of the R&D-intensive pharmaceutical industry's strategy to regain losses in market share associated with increased competition from generic drug companies and stricter drug safety regulations.

During the 1980s, a handful of powerful industries strongly dependent upon patent and copyright protection began intensive lobbying efforts to stimulate Third-World countries to follow the most industrialized countries in the extent of protection they provided to so-called intellectual property. These powerful industries were led by the pharmaceutical industry, where patents offer predominantly strong and effective protection (Scherer, 2000: 2248-2249). Urged by the industrial lobbies, the governments of the United States, European Union member nations, and Japan insisted that the global standard of intellectual property protection be included as a

key agenda item in the Uruguay Round of international trade negotiations. Accordingly, at the Uruguay Round, began in 1986, these powerful countries had their tabled proposals for significantly greater harmonization and higher protection of intellectual property rights (IPR). The proposals were directed at developing countries, which so far had resisted. This effort pitted the leading industrialized countries working en bloc against the less-developed countries. Probably the most contentious case in every round of negotiations was that of the pharmaceutical drugs. During that time, almost all countries in the developing world, with very poor innovative capabilities, provided weak or no patent protection for medicines. Besides, some did not sign international patent agreements, and they provided no enforcement or dispute settlement mechanisms. To confront this situation, these industrialized countries resorted to bilateral and multilateral pressures.

At the Uruguay Round, industrialized countries demanded that patents on invention be offered in all fields of industry including pharmaceuticals, that the protection period last for 20 years from the date of application, that compulsory licenses be applied only in specified circumstances, and that a strong dispute settlement mechanism be created to enforce compliance. Developing countries were diametrically opposed to these reforms. Some of them, such as Brazil and India, did so explicitly as granting stronger IPR seemed so clearly against their national interests. If patents on pharmaceutical products were permitted, the pharmaceutical transnational corporations (TNCs) would have stronger monopoly positions in selling their products; thus, prices would be elevated and monopolies for medicines would be extended. Higher prices mean smaller quantities demanded and hence lower health benefits from the newest therapies. Moreover, longer patent period will delay the appearance of the low-cost generic medicines that usually supply developing-country needs, only the expensive, patented version of a new medicine will be available. Clearly, these IP rules proposed by the rich countries will reduce access to modern medicines for poor people and lead to unnecessary death and suffering.

It is probably correct to assert that in the Uruguay Round, IPR was the one area where industrialized countries found the highest degree of agreement. It is probably also the case that this was the area where developing countries showed the biggest consensus in opposing the proposals of industrialized countries. However, in

the early 1990s, the efforts of the powerful industrialized countries culminated in an agreement that for countries to join the newly-constructed World Trade Organization (WTO), they had to provide a high level of patent protection, inter alia, for pharmaceutical products, which many less-developed countries had excluded from patentability. This agreement is widely known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[8]

2.2 Intellectual Property Protection and Access to Essential Medicines

As part of the global trade agreement negotiated in the Uruguay Round, the World Trade Organization (WTO) member nations signed up to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994. This far-reaching TRIPS Agreement sets forth minimum standards of intellectual property (IP) protection that WTO member nations must include in their domestic laws. Henceforth, TRIPS Agreement has led to a worldwide upwards harmonization of the regimes of intellectual property rights (IPR).

For most countries, TRIPS meant that in order to gain access to international markets for their exports and to the assumed benefits of free trade, they must introduce or reinforce their legislations on patents and other IPR. To conform to the Agreement, all member countries have to ensure that patent protection is available in all fields of technology, for both process and product inventions. Thus, it is no longer possible for countries to exempt medicines from patent protection, as a number of countries did before TRIPS came into force. Nor can countries like India continue to limit pharmaceutical patents to process patents only. The imposition of a higher level of IP protection is likely to benefit developed countries, which finance most research

[8] The TRIPS Agreement is one of 28 agreements that make up the Final Act of the Uruguay Round of Multilateral Trade Negotiations, the negotiations that had begun in Punta del Este in 1986 and culminated in 1994 with the signing of the Final Act and the creation of the World Trade Organization (WTO). The TRIPS Agreement is to date the broadest multilateral agreement on intellectual property (IP). Before TRIPS, the main international IPR covenants were the Paris Convention and the Berne Convention. The last revision on substance of both conventions took place at the Stockholm Conference on July 14, 1967 that established the World Intellectual Property Organization (WIPO). In the eyes of industrialized countries, a perceived weakness of the international IPR system prior to the TRIPS Agreement was that membership was far from universal as developing countries were reluctant to ratify the Paris Convention. Moreover, the IPR system lacked a harmonization of national patent laws as well as a binding enforcement and settlement mechanism. Before 1995, national IP laws were mainly unregulated within the GATT system and the details of patent protection were for the most part left to national discretion. The TRIPS Agreement addresses these perceived weaknesses.

and development (R&D) and generate most of the new knowledge and innovations, but harms developing and least developed countries, which previously could access easily to new inventions with lower cost. Medicine, together with agriculture and software, was the major area where this process has created a great controversy, as the introduction of product patent[9] has increased the exclusive position and the market power of multinational pharmaceutical innovators, with negative effects on access to medicine and the viability of the national pharmaceutical industries. Multinational pharmaceutical companies and representatives of developed countries claimed that a strong protection of IPR is an essential condition for ensuring the continuity of innovation and that in the long run it will also benefit less-developed countries (LDCs), as strong IPR will generate innovations in medicinal therapy for tropical and neglected diseases. Moreover, strong IPR will also promote technology transfer, research, and foreign investment in LDCs. Even so, there was growing concern over medicine accessibility. Most developing countries and international agencies opposed the reinforcing of IPR, because they feared that the stronger IP protection might raise the prices of drugs and restrict the access to essential medicines.

There were expectations at first time when the TRIPS agreement was introduced. The agreement has promised three main benefits to the nation members to reap: foreign direct investment, transfer of technology, and research & development. While the TRIPS agreement has yet to deliver those promises, its negative impact on human rights, in particular access to medicines, has already started to be felt. Three major criticisms about the WTO intellectual property regime are: firstly, it is naturally inequitable for developing countries; secondly, it enlarges the monopoly power of the economically strong; and lastly, it has not protected developing countries from bilateral pressure to accept stricter IP protection, such as TRIPS-Plus, than the minimum indicated in the TRIPS Agreement (Dommen, 2002: 26). Though the least-developed countries were permitted a longer time to implement the TRIPS agreement, which has recently extended until 2016, a number of studies have raised questions as

[9] The distinction between product and process patents is very worth mentioning, since if a product is patented, only the patent holder may produce or sell that product; nobody else may do so, unless the patent holder has given permission (a license). In the case of a process patent, nobody may produce that product by using the process that is protected. Nevertheless, if someone can make the same product in a different way, he/she may do so. Since for most medicines multiple methods of synthesis can be devised, process patents offer very much less protection than product patents.

to whether the protection required under TRIPS are appropriate for countries at lower level of development, and whether the poorest countries will be ready by 2016 to institute such protections.

The purpose of adopting a patent system is usually aimed at promoting investment of resources in creating inventions. In theory, the better IP protection would encourage more R&D and, hence, innovation. R&D for new advanced Western medicines was frequently given as a good example. In fact, R&D into medicines in several diseases was a good example of exactly the opposite. In the case of neglected diseases; for instance, sleeping sickness, Chagas diseases, and leishmaniasis, which only affect the poor, a patent holder will never be capable of making a profit by charging high prices. Accordingly, little R&D was conducted on these neglected diseases (Médecins Sans Frontières and the Drugs for Neglected Diseases Working Group, 2002: 10-12).

In summing up, one of the main arguments brought forward during the TRIPS negotiations in support of extending patent protection to the developing world was that raising the intellectual property standards in those countries would give pharmaceutical companies an incentive to invest in R&D for medicines of specific importance to consumers in the developing world (Diwan and Rodrik, 1991: 28; Lanjouw and Cockburn, 2001: 266). Besides, prior empirical evidence suggests that patent protection plays a vital role in providing R&D incentives for pharmaceutical companies. (Appendix B, Section B.2). Thus, one could expect the TRIPS-related reforms in the developing world to have an impact on the amount of R&D targeted at poor country markets. In this respect, Lanjouw and Cockburn (2001) and the follow-up study by Lanjouw and MacLeod (2005) examined the question of whether the change in IPR in the developing world has led to more R&D on medicines for neglected infections and tropical diseases that are rampant in the developing world.

Lanjouw and Cockburn (2001) used survey data from India, the results of interviews, and measures of research and development (R&D) constructed from a variety of statistical sources to determine trends in the allocation of research to products specific to developing country markets. Their analytical results suggest a moderate increase in inventive activities relating to medicines for malaria beginning in the mid-1980s. However, the upward trend seems to have disappeared in the late

90s (Lanjouw and Cockburn, 2001: 287). Besides, there appears to be significantly less research activity directed toward other diseases specific to least-developed countries such as Chagas' disease or leprosy. Furthermore, a recent follow-up study by Lanjouw and MacLeod (2005) revisited and updated the statistical series of Lanjouw and Cockburn (2001). Lanjouw and MacLeod (2005: 4242) discovered that the level of pharmaceutical inventive activities, more than a decade after the TRIPS Agreement was signed, related to neglected diseases specific to low-income countries still remains extremely low relative to overall pharmaceutical R&D.

Moreover, Trouiller (2002), adopting a somewhat different approach compiling data by searches of the U.S. Food and Drug Administration(FDA) and the European Agency for the Evaluation of Medical Products(EMEA), came to almost the same conclusion as Lanjouw and Cockburn (2001) and Lanjouw and MacLeod (2005) that diseases occurring mostly in the developing countries remain largely unaddressed. In their analysis, Trouiller, et al (2002: 2188) found that only one percent of the 1,393 new pharmaceuticals marketed during 1975-1999 were registered for tropical diseases, though these diseases account for roughly one third of the worldwide disease burden. The argument for a patent system promoting R&D for medical needs in the poor countries, thus, falls far short. All mentioned empirical evidence reflects the controversy that whether or not the patent system delivers the right R&D.

In addition, the report of the World Bank (1998: 34) revealed that there are a few empirical evidences of a positive relationship between IP protection and R&D. The claims of massive investment in R&D in many cases are exaggerated, mostly disregarding the important role of public funds. Even in the United States, the industrialized country with long histories of strong IP protection, during 1981-1991, around 70 percent of therapeutically essential medicines introduced, including HIV/AIDS medicines such as AZT, ddI, and D4t, were created with government involvement (Mitsuya, Weinhold, Yarchoan, Bolognesi and Broder, 1989: A26). Many anti-AIDS medicines had been originally discovered, developed, and invented by the United States National Institute of Health (NIH) and afterwards they were licensed to pharmaceutical companies for commercialization.

Besides, patentees often fail to produce their patented drugs in developing and least developed countries in which those drugs being registered; therefore, the

technology transfer hardly occurs. Almost in all cases, strong patent protection does permit patentees to have exclusive monopoly rights over the manufacturing, using, marketing, and importing of such medicines; hence, preventing competition from generic-equivalent medicines. The World Health Organization (WHO) estimated that implementing patent protection where it did not already exist would cause the rise in average price of medicines, with estimated increases varying from 12 to 200 percent (Foreman, 2002: 2). The absence of generic equivalent due to patent usually brings about the patentee having a free hand to set the price, normally away from affordability of numerous patients in the poor countries.

The imposition of a higher level of intellectual property protection has created new large burdens for developing countries. According to the World Bank (2002: 136-137), the transition to stronger protection has involved considerable short-run costs including: legal and administrative costs, cost of rent transfers, and incremental cost due to higher prices of patented drugs. Likewise, report of the Commission on Intellectual Property Rights (CIPR)[10] had a great international impact, because it originated in a country with a long tradition of protection of IPR. The report (CIPR, 2002) indicated that although the evidence is still inconclusive, there is an increasing consensus that reinforcing IPR favors developed and maybe some emerging countries, but probably not developing countries, which should be allowed to adjust the level and timing of IP protection to their development needs and conditions, as developed countries were able to do in the past. The expansion of IPR is unlikely to help most developing countries. Instead, it will increase their costs by making them pay more for essential medicines and agricultural inputs, such as seeds, hitting poor people and farmers particularly hard. The report also said the same arguments apply to the real benefits the internet can bring to the developing world. It said rich and poor countries have differing interests, and expanding IP rights makes poverty reduction more difficult. The commission urged developed countries, the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) to take poor countries' circumstances and needs into account when developing IP systems.

[10] The Commission on Intellectual Property Rights (CIPR) was set up by the UK Government but independent of it. The members are from the US, UK, Argentina and India.

All these mentioned studies are of difference in many aspects, but lead to the same conclusion that the IPR regime which a developing country needs is different from the one which can be optimal for a developed country. Too long period of IP protection have been regarded as food for the rich countries and poison for the poor. In brief, studies from various international agencies suggest that the appropriate IPR regime for each developing country needs to be decided on the basis of what is best for its development, and that the international community and governments in all countries should take decisions with that in mind.

The debate over drug product patent extension into developing and least developed countries has been a classic problem of federalism, questioning whether economic policy options should be made locally or by a supervening government entity. Generally, the possibilities of redistributive equity pull toward centralized policy, whereas allocating efficiency grounds are reinforced by decentralized policies. But, in the TRIPS dispute, the opposite is true. While the elimination of free-riding on affluent nations' innovations under centralized patent policy may improve the allocation of world R&D resources, decentralized patent policies permit poor nations to address their specified health problems by free-riding those newest pharmaceutical inventions (Scherer, 2005: 64-65). To balance the enhanced protection given to innovators, TRIPS contains carve-outs for protection of the public interest; for example, it includes public health safeguards that any country can use to encourage access to affordable medicines. In 2001, WTO members unanimously confirmed the right of all nations to use the TRIPS safeguards to promote public health, when they agreed to the Doha Declaration on the TRIPS Agreement and Public Health. The declaration asserted that IP rules should not prevent countries from protecting public health. Developing countries could enforce public health safeguards to enable price reductions through generic competition. The declaration also directed member nations to facilitate access to generic-equivalent medicines of poor countries with insufficient drug manufacturing capacity, a measure known as the 'Paragraph 6 Public Health Solution'(Malpani and Kamal-Yanni, 2006: 2).

Although the Doha declaration seemed to have established the priority of the objectives of public health over commercial interests and to have put a halt to the extension and intensification of IPR in the field of medicines, in fact over the past

decade the process has been continued through the negotiation in regional and bilateral commercial agreements, so-called Free Trade Agreement (FTA), where industrialized countries, specifically the United States, have habitually been able to introduce the issue of IPR, usually known as TRIPS-Plus provisions, forcing developing countries to accept more restrictive clauses than the minimum standards required by TRIPS.[11] Under TRIPS-Plus rules, the public health safeguards assented under TRIPS will be undermined or destroyed and the availability of low-priced, generic-equivalent medicines will be postponed. In addition to bilateral or regional FTA negotiations, the U.S. has pressured some developing countries to admit TRIPS-Plus provisions as part of the concessions required of countries newly acceding to the WTO. Besides, the U.S. continually uses a variety of unilateral pressures to push for higher IP protections including: trade sanctions, decrease in foreign assistance, withdrawal of trade preferences, and the use of technical assistance programs. Although other rich countries, especially the members of the European Union, have not pursued the TRIPS-Plus provisions, their inertia has left the U.S. liberated to enforce ever-higher levels of IP protection on developing countries. This unconcern is not consistent with the EU's commitments under the Declaration. It is, however, not astounding because the EU pharmaceutical companies also benefit from TRIP-Plus, which the developing countries are required to enact through their national legislations to be consistent with TRIPS-Plus provisions in their agreements with the U.S. (Malpani and Kamal-Yanni, 2006: 2).

It is widely agreed that high levels of IP protection is leading to public health damage since the WTO TRIPS Agreement tends to increase medicine prices by limiting generic production of medicines, and by preventing poor countries from using safeguards to provide affordable medicines to their citizens. The U.S. TRIPS-Plus provisions aggravate this problem by imposing additional restrictions to both generic competition and government action. Competition from generic drug producers

[11] Under the Bush Administration, the U.S. has pursued bilateral and regional FTA negotiations with many countries. Some have already been signed and entered into force; for example, the agreements with Israel, Singapore, Chile, Jordan, Australia, Morocco, Bahrain, Central America Countries, the North America Countries (NAFTA), the Dominican Republic(CAFTA-DR), and others. Some are in the negotiation process; for instance, the agreements with Colombia, Panama, South Africa, Namibia, Swaziland, Thailand, Malaysia, the republic of Korea, Peru and Oman. For the agreements with Panama, Colombia, and Republic of Korea, they are pending by Congressional Approval. While the agreements with Peru and Oman are pending on implementation, the agreements with Thailand, Malaysia, South African Custom Union (SACU), and United Arab Emirates are still not concluded.

is the key proven means to bring the medicine prices down in a sustainable manner. Generic competition is therefore very important to model pharmaceutical price regulations, especially those pertaining to some form of reference pricing.[12] Several studies predict that the imposition of the TRIPS-Plus provisions to developing countries will result in increase in prices of medicines over time, placing a strain on national health budgets and leaving the deprived people with disastrous out-of-pocket expenses for life-saving medicines.

2.3 Patent System in Thailand

Rights over innovations in Thailand were recognized when the Patent Act B.E. 2522 was promulgated and entered into force in 1979. Presently, in Thailand there are seven statute laws protecting IPR. These include the Patent Act B.E. 2522, the Trademarks Act B.E. 2534, the Copyright Act B.E. 2537, the Plant Variety Protection Act B.E.2542, the Protection of Layout-Designs of Integrated Circuits Act B.E.2543, the Trade Secret Act B.E. 2545, and the Protection of Geographical Indications Act B.E.2546 (Jakkrit Kuanpoth, 2007: 2). Like other developing countries, Thailand has not had a stringent IPR system. The level of IP protection has not been as high as the Western countries because in Thailand there are a large number of industries, particularly its infant pharmaceutical and chemical industries, relying upon imitating other countries' technologies. The legal development in IP field in Thailand has been based heavily upon the level of development of the Country and the Country's interest. For every developing country, too high level of IP protection as well as too long period of monopoly rights would certainly result in an impediment of its technological advancement. Additionally, if the Thai patent law provides more protection than is necessary, the patentee can extract larger price-cost margins, imposing considerable dead weight losses to the society. To enhance the Country's capability, the Thai patent law, hence, has a common aim of granting a temporary monopoly right to patent holder in order to foster the development of a required technological base, and to support an acquirement of foreign technologies.

[12] Reference pricing is being used widely in European countries; for instance, Germany, Canada, Denmark, Germany, Netherlands, Sweden, and elsewhere in attempt to control spending on prescription drugs. It refers to the process by which insurers cover only the low-cost, benchmark drugs in a therapeutic class. Patients have to pay the difference in price if they want higher-cost alternatives. Generic competition drives down the benchmark price and hence helps to reduce overall health care expenditures.

Patent system in Thailand has a long interesting history. In fact, we have been pressured from rich countries for a long time. During 1984-1985, the United States Trade Representative (USTR) requested the Royal Thai Government to amend its Patent Act, although Thai Patent Act B.E. 2522 (1979) was actually valid and consistent with international rules. As a developing country, Thailand, hence, protected only the process patent, not the product patent. According to the law, we could produce any drug for our use as long as the production process was different from that of the patentee. The process patent protection term lasted 15 years according to international rules of that time, which accepted the differences in capabilities between developing and developed countries. This can be compared to the weaken golfers getting a handicap. However, this advantage was restricted by the WTO's agenda requiring developing member nations to develop and amend their laws to protect product patent and extend protection term to 20 years by the year 2000. The deadline (the year 2000) could be extended for another five years (until 2005) for underdeveloped countries (Vichai Chokevivat, 2007: 10-11).

Until 1989, the United States employed unilateral trade sanctions against Thailand to the tune of 165 million dollars to force the Royal Thai Government to amend and expand the coverage of its patent law even before the TRIPS Agreement was concluded in the WTO (FTA Watch Thailand, 2005: 3). The USTR intimidated to cut Thailand's Generalized System of Preferences (GSP) and to employ strict Special 301 measures on Thailand. Upon 1992, despite the strong opposition to the amendment, Thailand amended its Patent Act to conform to the key obligations of TRIPS in order to avoid trade sanctions. It is memorable as the matter of history that Thailand amended its Patent Act eight years in advance of the WTO deadline while India did so in 2005, thirteen years after Thailand (Vichai Chokevivat, 2007: 10-12). Afterwards, in 1999 the Thai patent law was compelled by the USTR to revise again. In addition, the Trade Secret Act was enacted on April 12, 2002 (Trade Secrets Act B.E. 2545, 2002:1-2).[13]

[13] Thai Patent Act (no.2) B.E. 2535 (A.D. 1992) provides the legal means of product and process patents, 20 years patent protection term, Bolar provision, compulsory licensing and government use while Act (no.3) B.E. 2543 (A.D. 1999) added parallel importation and confer the patent since the filing date. Trade Secret Act B.E.2545 (A.D.2002) compels data protection against unfair competition.

The Patent Act B.E. 2522, as amended in 1992 and 1999, has expanded the level of protection significantly. The amendments included an increase in the scope of patentable subject-matters, a patent-term extension, formulating conditions for the application of compulsory licensing, abolition of the pharmaceutical price review committee, etc. As a result of amendments, the current Thai patent law stipulates patent protection for innovations in almost all fields of technology for up to twenty years from the date of filing of the application in Thailand. The protection covers either a product or a process patent. The term of patent rights is six years for a petty patent and ten years for a design patent. A petty patent term can be renewed two times, two years each. The Patent Act B.E. 2522 grants the product patent holder a very strong form of exclusive rights to exploit the patented products. The patentee may file a criminal or a civil prosecution, or both, against everyone who commits an encroachment upon his patent rights. An intended infringer subjects himself to imprisonment up to two years and a fine up to 400,000 baht or both (Jakkrit Kuanpoth, 2007: 3).

2.4 Protection of Pharmaceuticals under the Proposed Thailand-U.S. Free Trade Agreement (TUSFTA)

Nowadays bilateral trade and investment agreements are increasingly used as a strategic tool by powerful nations to incorporate TRIPS-Plus provisions that have been politically difficult to accomplish in multilateral setting, remarkably at the WTO forums. The United States, who has been frustrated with the multinational forum, has recurred to bilateral and regional agreements as a way of forum shopping to better reach its own interests, ignoring a more balanced approach to IPR protection. In addition to the use of trade leverage under U.S. trade laws, tightening other countries' IP laws through bilateral trade negotiations clearly would assist the U.S. to create the establishment of an acceptable framework of higher IP protection standards within the multilateral trade negotiations (Jakkrit Kuanpoth, 2006: 8, 2007: 4).

In general, countries that form FTAs agree at a minimum to phase out tariff and non-tariff barriers (NTBs) on mutual trade in goods in order to enhance market access between trading partners. Likewise, the U.S. regularly demands an increase of

access for U.S. exports by lessening or eliminating duties and other non-tariff barriers in its trade partner countries. Besides, the bilateral and regional trade treaties that the U.S. has signed with its trade partners usually contain chapters with IPR commitments, under which the trade partners must give preferential treatment to U.S. right owners. The U.S. intends to achieve higher levels of IP protection, beyond the minimum standards under the WTO TRIPS Agreement (this has been referred to as the "TRIPS Plus" provisions).

The insertion of the TRIP-Plus provisions in IP chapter of the FTA negotiating texts that the U.S. proposed to its trade partners resulted from intense lobbying of certain powerful industries. In Jakkrit Kuanpoth (2007: 4), the U.S. intellectual property policy has been influenced by many interest groups, including Pharmaceutical Research and Manufacturers of America (PhRMA),[14] International Intellectual Property Alliance (IIPA),[15] the Biotechnological Industry Organization (BIO),[16] the Business Software Alliance (BSA),[17] etc. The Industry Trade Advisory Committee on Intellectual Property Rights (ITAC15) consists of the members from IIPA, PhRMA, BIO, etc.

Similarly, the Industry Functional Advisory Committee (IFAC-3) on Intellectual Property Rights for Trade Policy Matters (2004: 21), which plays vital role in directing and advising the U.S. trade policy, is comprised of industry representatives from large multinational pharmaceutical companies like Eli Lilly, Merck, and Pfizer.

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[14] Pharmaceutical Research and Manufacturers of America (PhRMA), founded in 1958, is one of the largest and most influential lobbying organizations in Washington. It is a trade group, representing 48 pharmaceutical and biotechnological companies. PhRMA has 20 registered lobbyists on staff and has contracted with dozens of lobby and public relations firms to promote its members' interests. Every year, PhRMA makes substantial efforts with regard to Special 301 Report issued by the Office of the USTR on the enforcement of IP laws abroad. PhRMA's recommendations for the Special 301 Report in 2009 were especially critical of the Philippines for breaking patents and failing to abide by the TRIPS Agreement. PhRMA has also worked to minimize the effect of the November 2001 Doha Declaration.

[15] The International Intellectual Property Alliance (IIPA), formed in 1984, is a private sector coalition of seven trade associations representing U.S. producers of content and materials protected by copyright laws, including computer software, films, television programs, music, books and journals (in both electronic and print media), with the aim of strengthening international protection and enforcement of copyright by working with U.S. government, foreign government and private sector representatives.

[16] Biotechnology Industry Organization (BIO) is an industry lobby group founded 1993 in Washington, D.C. by the merger of two Washington-based biotechnology trade organizations.

[17] The Business Software Alliance (BSA), established in 1988, is a trade group representing a number of the world's largest software makers. Its principal activity is trying to stop copyright infringement of software produced by its members. It is a member of the IIPA.

Although the proposed FTAs are in principle open to negotiation, the FTAs between the U.S. and each member of ASEAN countries are basically built on the provisions of the Singapore-U.S. FTA and the basic rules embodied in United States intellectual property and trade laws. According to the White House's fact sheet (White House, Office of the Press Secretary, 2002), released on October 26, 2002, the U.S. planned to negotiate the bilateral FTAs with individual ASEAN countries through the Enterprise for ASEAN Initiative (EAI) process.[18] The fact sheet stated further that the FTAs with ASEAN countries (including Thailand) will be based on the high standards set in the U.S.-Singapore FTA (USSFTA). Thereby, there is every reason to believe that the U.S. will try its best to extract from Thailand further commitments beyond what is stipulated in the WTO TRIPS agreement, as the U.S. has already achieved this in FTAs with many countries such as Morocco, Singapore and Chile.

Thailand has involved in bilateral negotiations with the U.S. since 2003. During the summit of the Asian-Pacific Economic Cooperation (APEC) forum in Bangkok, on October19, 2003, former U.S. President Bush and former Thai Prime Minister Thaksin agreed to negotiate a bilateral free trade agreement. The Bush Administration notified Congress on February 12, 2004 that it intended to begin the negotiations, starting a 90-day period for consultations with Congress and the private before negotiations can actually commence. Upon March 30, 2004, the two sides announced that the negotiations would begin on June 28, 2004 (Ahearn and Morrison, 2004: 3). So far, Thailand-U.S. FTA has been negotiated for six times; the latest talk was the sixth round negotiation, organized in Chiang Mai, Thailand. However, the negotiation was on hold in 2006 due to the dissolution of the Thai Parliament and the subsequent military-led coup. Until present, the Agreement is still inconclusive.

As a result of the Bush's EAI, before commencing a negotiation the potential ASEAN partner must have already concluded a Trade and Investment Framework Agreement (TIFA) with the U.S. (White House. Office of the Press Secretary, 2002). In the case of Thailand-U.S. Free Trade Agreement (TUSFTA), the TIFA was

[18] The Enterprise for ASEAN Initiative (EAI) is the U.S. new trade initiative, set up by former U.S. President Bush, engaging with the Association of Southeast Asian Nations (ASEAN). The EAI offers the prospect of bilateral FTAs between the United States and ASEAN countries. Under the EAI, the United States and individual ASEAN countries will jointly determine if and when they are ready to launch FTA negotiations.

completely agreed by the two sides. According to TUSFTA Task Force, Ministry of Foreign Affairs, there are twenty-three issues to be negotiated in TUSFTA covering trade in goods and services, agriculture, investment, and intellectual property rights, as well as other issues such as government procurement, competition policy, and customs procedures.

In Thailand, it is widely argued that the liberalization of economic activities through bilateral trade and investment negotiation with the U.S. does not suit the country's need and would create substantial economic and social costs to the country. The negotiation with the U.S. also makes Thai trade policy unbalanced leading to inequalities among different interest groups. In accordance with the Thai Senate Committees' report on FTA (2004), although Thailand's exports to the U.S. could increase significantly if the Agreement is signed, it is highly probable a range of U.S. agricultural goods will have an advantage over Thai products including meat, milk, daily products, vegetable, fruit, maize and soybean. The report stated further that Thailand could also risk losing out its sovereign control over key sectors of its economy such as energy, transport, finance and education. The most apprehension is regarding the IPR chapter that would open the door for U.S. business to seek corporate monopoly on products in particular seeds and drugs.

It is compulsory to consider what impact the TUSFTA is likely to have. In determining the country's position in negotiations, an enough number of systemic, comprehensive studies in all relevant sectors and perspectives regarding the costs and benefits of the FTA are inevitably needed to support the authorities' decision making. However, there has been a lack of official information about what the legal effect of the FTA will be. The actual implications of the FTA for farmers, local communities, local drug companies, labor organization, consumers and general public are yet to be fully understood. The Royal Thai Government conducted the negotiation with the U.S. in a hasty manner without any clear information concerning the long-term impact of the Agreement. Besides, it has not provided the public an access to the draft negotiating texts since the U.S. has demanded the Thai government to keep the process of negotiations secret. This has created difficulties for Thai citizens and all stakeholders to appraise the potential impacts from the FTA. Available information of the TUSFTA is extremely one-sided, coming mostly from the government and a

group of large-scale industrialists who are supposed to benefit. There were also no adequate avenues for consultation and participation of relevant interest groups or civil society groups that would be highly affected by the FTA. Negotiating positions were determined on the basis of an appraisal of levels of competitiveness in some particular private sectors in disregard of the overall social, cultural and environmental impacts. Consultations were restricted to some business sectors. The non-transparency of the negotiations has been heavily criticized by FTA watch because the huge majority of the public are not capable of fully comprehending or participating in the content of the negotiations (FTA Watch Thailand, 2005: 1-8).

Of greatest concern in the TUSFTA negotiations are the IP rules. The largest threats are regarding patent protection extension and protection of undisclosed information pertaining to medicines since these rules will increase the monopoly rights of patent holders that renders medicines unaffordable for the poorest and most vulnerable groups. In January 2006, during the sixth round negotiation, the USTR submitted the draft IPR text to Thailand. IPR rules proposed by the U.S. are very comprehensive covering almost all areas of IPR. Chapter 14 of the U.S. draft proposal (2006),[19] which is comparable to chapter 16 of the USSFTA, applies to IP protection. The draft IP text imposes the certain obligations to Parties; for instance, the article 14.1, general provisions, requires each Party to ratify or accede to the requisite agreements such as the Patent Cooperation Treaty (1970), the WIPO Copyright Treaty (1996), etc. The proposed IP text also contains specific provisions in each area of IP protection including trademarks and geographical indications, domain names on the internet, copyright and related rights, patents, measures related to certain regulated products, and intensification for intellectual property law enforcement.

According to the draft IP text, the following TRIPS-Plus provisions as related to pharmaceutical products were included: 1) limiting the grounds for exclusion of patentability, 2) patentability for any new uses or methods of a known product, 3) prohibition of pre-grant opposition and revocation of patents, 4) restrictions on the issuing of compulsory licenses, 5) patent term extension, 6) protection for data

[19] The U.S. draft proposal (regarding IPR) submitted to Thai Trade Representative was leaked and posted on: http://www.bilaterals.org/spip.php?article3677 and http://www.bilaterals.org/spip.php?article3723

exclusivity,[20] 7) linkage between drug registration and the patent status of a drug, 8) trademarks, and 9) linkage between IPR and investment.

The details of the new IPR rules, so-called TRIPS-Plus, are now elaborated. First, the U.S. draft IP proposal demands that an effective and adequate protection must be given to inventions in all fields of technology. The products presently ruled out from patentability under Thai patent law such as plants, animals, biological processes, genes and gene sequences, medical treatment methods, business methods, and computer programs (Patent Act B.E. 2522, 1979: 4) must be protected by both product and process patents. This takes away the TRIPS safeguards that prevent foreign interests from exerting monopolistic power over these important subjects and knowledge.

The USTR text requires further that Thailand must also protect second uses (new uses) of a product already known or marketed in Thailand. According to this rule, given that an old existing drug can have several therapeutic indications, the claims to new therapeutic indications (new medical uses or new medical applications) of that drug must be patentable. Patentability for subsequent uses or new dosage forms of known products would permit 'evergreening' of patents (Savina, 1995: 32-35; Thomas, 2009: 3-4). The ultimate consequence could be the low-priced generic equivalents of the drug will be prohibited from entering the market so the price of the drug of Innovator Company will be higher even after the patent expiry in absence of competition from generic drug makers. Providing patents for such trivial inventions unnecessarily prolongs the monopolistic market and deprives all Thai citizens of the right to affordable medicines.

In addition, the USTR text demands Thailand to abrogate the pre-granting opposition. Currently under article 5 (A.3) of the Paris Convention for the Protection of Industrial Property (1883: 5), revocation of patents can be undertaken in the cases of abuses of patent rights or non-working of patents. Conversely, the abolishment of pre-granting opposition would prevent Thailand from revoking patents despite the fact that there has been an abuse of patent rights or non-working of patents, which are typically the cause of unusual high drug prices.

[20] Data exclusivity is a TRIPS-Plus rule that creates a new system of monopoly power, separating from patent, by blocking the registration and marketing approval of generic medicines for at least five years, even when no patent exists.

The text also imposes more restrictive standards on compulsory licensing than those under TRIPS and the Paris Convention, namely more stringent conditions for issuing a non-voluntary license. In complying with TRIPS-Plus, Thailand can issue compulsory licenses in the following three circumstances only: (i) to remedy a practice determined after judicial or administrative process to be anticompetitive under the Thai competition laws, (ii) in the case of public non-commercial use, and (iii) in the case of national emergency or other circumstances of extreme urgency.

The USTR proposal has obliged Thailand to extend the patent term to compensate for unreasonable delays that occur during either granting process or marketing approval process. According to the USTR's definition, granting delay occurs when there is a delay in the issuance of a patent of more than four years from the filing date or two years after a request for examination of the application has been made, whichever is later. In addition, Thailand must make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process pertaining to the first commercial use of a new pharmaceutical product.

Furthermore, to conform to the USTR's requisition, Thailand must enforce data exclusivity. According to this obligation, a period of data exclusivity, commencing from the date of marketing approval of the original product, has to be granted (at least five years for pharmaceutical products and ten years for agricultural chemical products). During an exclusive period, the national drug regulatory authority cannot use the originator's clinical test data submitted to obtain marketing approval. Consequently, the drug regulatory authority is prevented from granting a marketing approval to generic drugs on the basis of bio-equivalence or based on marketing approval of the original product in a foreign country. The obligation, hence, results in the delay of an introduction of the affordable generic equivalents for at least five years, even when pharmaceutical patent has already expired.

Another provision in the draft FTA treaty is about the linkage of marketing approval process and the patent status of a drug. With reference to the provision, during the term of a patent, the drug regulatory authority of Thailand is obligated to notify the patent owner regarding any attempt to register a generic-equivalent medicine. Unless it is assured that the manufacturing, importing and selling of the

generic equivalent will not encroach upon patent rights of the others, the authority is prohibited from approving registration for a generic medicine; therefore, the provision would hinder the entry of the low-priced generic equivalent and would impose an unnecessary burden on the Thai drug authority.

The draft treaty of the USTR also contains a provision obligating Thailand to enforce a high level of trade mark protection. The definition of 'Trade mark' under the USTR proposal is very inclusive, covering non-visually perceptible trademarks; for instance, scent marks. According to the provision, sound, texture and smell could be registered as trademarks. In addition, Thailand is demanded to give effect to Articles 1-6 of the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks (1999). This requisite provides broader protection for unregistered well-known marks since the definition of well-known marks under the Joint Recommendation obviously discriminates against local trademarks in favor of foreign well-known marks.

The USTR also proposes a further rule incorporating IP rights in the definition of investment. Referring to the requirement, Thailand is barred from imposing performance requirements. Neither expropriation nor any other equivalent measures are allowed except when those measures are taken in the public interest, on a non-discriminatory basis, against payment of prompt, sufficient and effective compensation, and in line with due process of law. The USTR also demands provisions for investor-to-state dispute settlement allowing private investors to file a lawsuit against the host state in international dispute tribunals for monetary compensation for government policies or actions judged by the court to corrode an investor's future revenues.

Because of the very restrictive TRIPS-Plus provisions, Thailand was presented with hard choices. The tradeoff becomes a must for Thailand. On one side, Thailand could comply with the U.S. IP mandates by strengthening its intellectual property laws and accept all negative consequences. In particular, the imposition of higher and wider IP protection would set the stronger monopoly positions in selling drugs to the powerful multinational corporations; as a result, pharmaceutical price, relative to those charged by local manufacturers able to imitate the most advanced medicines formulated elsewhere and sell them at more competitive prices, would be lifted up

against the limited array of domestic consumer able and willing to pay. On the other side, it could opt out and lose the benefits of free trade. Until present, the debate over the U.S. TRIP-Plus mandates in Thailand has proceeded and indeed intensified.

Next chapter shall provide a survey of the formal microeconomic literature on the introduction of intellectual property protection in the developing world. Particularly, the chapter offers the review of previous literature and research, emphasizing the impact of the international patent protection harmonization on national welfare of developing countries.

CHAPTER 3

THE WELFARE EFFECTS OF GLOBAL PATENT PROTECTION

The extension of higher level of IPR protection to Third World nations under international agreement mandates has precipitated vigorous policy debates between developing and developed countries for such a long time. Particularly, the attempt of the U.S. to impose the very restrictive TRIPS-Plus rules to developing economies through bilateral trade and investment agreement negotiations has been criticized that developing countries were blackmailed by the U.S. to adopt IP laws that are not in the best interest of their people. Less-developed countries (LDCs) have been opposed to granting stronger and broader IPR since such grants are definitely against their national interests. However, until now asymmetrical power relations continue to shape intellectual property policy, reducing the freedom that poorer or weaker states have in formulating regulatory approaches that are most appropriate for their individual needs and stages of development. Hence, it is important to raise a warning flag regarding the apparent rapid march of national public policies in the direction of stronger, broader IPR because such direction may lay a lot of future trouble on developing nations.

The growing importance of the issue of IPR has resulted in a proliferation of theoretical and empirical research analyzing the effect of protecting IPR on national welfare, technological transfers, trade volumes and economic growth. Chapter 3 provides a survey of the formal microeconomic literature pertaining to the impact of introducing more stringent IPR protection into developing economies. It begins with Section 3.1, offering the historical experience of introducing pharmaceutical patents in several countries. Section 3.2 then presents a survey of the theoretical literature, reviewing the rationale for IP protection in a closed economy (see Subsection 3.2.1) as well as the impact of strengthening IPR on national welfare in a world economy (see Subsection 3.2.2). Finally, in Section 3.3, a selection of the empirical literature on the impact of more stringent patent protection in developing countries is examined to determine if the theoretical conclusions are supported by the empirical evidence.

3.1 Historical Experience of Introducing Pharmaceutical Patents

Lall (2003: 1661) “Many rich countries used weak IPR protection in their early stages of industrialization to develop local technological bases, increasing protection as they approached the leaders.”

The continuing debate over the role of IPR in trade, growth and development has resulted in numerous initiatives through international organizations to harmonize, strengthen and broaden the level of protection for IPR all over the world. In particular, the international IPR agreement so-called TRIPS, requiring the extension of first-world patent protection standards to third-world nations including especially the mandate that patents be granted on pharmaceutical products, has been tremendously controversial.

Above all, the question as to whether extending patent protection to the developing world has positive or negative welfare effects is of great interest. In this respect, normative analysis of the effect of IPR on the development process can gain insight from examination of the historical and cross-sectional patterns of nation’s choices regarding their own IPR regimes. An important finding of this literature is a U-shaped cross-section relationship between the rigor of a country’s IPR regime and the country’s GDP per capita (Maskus, 2000; Chen and Thitima Puttitanun, 2005). The notion that the strength of a country’s IPR regime is endogenous to its level of economic development finds further support in economic history. Studies of the early American IPR regime (Khan and Sokoloff, 2001; Khan, 2004) show a weaker and more liberal patent and copyright systems than those in Europe and Britain at the time. This early U.S. IPR regime both encouraged more incremental innovation and constrained the market power of IPR holders. In addition, East Asian Economies such as Japan, Korea, and Taiwan also adopted the lax IPR regimes during their process of graduating from imitation to innovation. This available historical and cross-section evidence supports the presumption that the need for IPR varies with the level of development.

For medicines, social welfare gain for a country might be possible if the introduction of pharmaceutical patents led to emergence of a local drug industry skilled at inventing or developing a major breakthrough in pharmaceutical inventions.

Nonetheless, Italy's experience in granting drug product patent, which undermined a foundation of its strong "knockoff" industry, suggests that making the shift from imitative to innovative industry is at least time-consuming and maybe even improbable (Scherer and Weisburst, 1995: 1023). The experience of Canada after strengthening its patent regime was more favorable as it was capable of extracting from the multinational corporations an assurance to make the investment in R&D activities in Canada. In addition, Canada had a surplus of well-trained scientists upon which that shift could build (McFetridge, 1997).

In the case of developing countries, they generally tend to have relatively little domestic inventive activities; most patents registered in a poor developing economy come from rich developed countries. In theory, the grant of patents to such outsiders by a developing country may help to attract transfers of technology, augmented perhaps by direct investment in resident subsidiaries by multinational corporations.[21] To accomplish such technology transfers, patents and patent licenses alone are surely insufficient; training and know-how transfers must occur (Kaufer, 1989).

However, most of developing economies have scientific infrastructures less conducive to state-of-the-art pharmaceutical research and development than Italy's. In reality, except India, thus far transfer of technology has hardly occurred; as a result, the transition from knockoff to innovative industry cannot be true in most less-developed economies, with very poor innovative capabilities. An example is given by the case of Thailand. According to Jakkrit Kuanpoth (2006: 50), a stringent patent regime under TUSFTA will have no impact in promotion of pharmaceutical R&D in Thailand because the Thai pharmaceutical sector is industrially and technologically dependent on foreign interests due to lack of functional technological base. Contrarily, the inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede inflow of technology. Jakkrit Kuanpoth (2006: 5) sheds further light on the impact of the U.S. TRIPS-Plus provisions on drug prices as follows:

[21] In reality, direct investment in developing economies is scarcely occurred. The multinational pharmaceutical companies, by reason of the economy of scale, usually make their direct plant investment in only rich and consuming countries; for LDCs, imports have been the main vehicle through which the MNEs have supplied their products.

> The rules on data exclusivity, extension of patent term, and extension of the scope of patentability will increase the ability of the patent holders to maintain high prices. The rules will reduce generic competition, prohibit the use of a compulsory license to make the patented drug available, and allow the patent holder to maintain a longer monopoly position, charging a high price for its medicines. The TRIPS-Plus provisions that link drug registration and the patent status of a drug will unnecessarily restrain the entry of generic medicines, threaten the existence of the Thai generic companies, and inhibit the capacity of the Thai generic industry to expand its market. The prohibition of the pre-grant opposition will allow multinational companies to use invalid or spurious patents to increase prices and prevent the local manufacturers from producing the medicine.

Furthermore, the historical experience in Holland, Germany, and Switzerland suggests that it may at first be beneficial not to have a patent law. The nation does introduce a national patent law to guide its domestic inventive activity away from imitation and toward more inventive work only after industrialization has progressed further and technical skills have developed to a higher level.

In a case study of the Dutch and Swiss experience, Schiff (1971) found no evidence that industrialization was hampered by the absence of patent protection. Yet this does not prove that patents are unimportant. It only shows that it may be advantageous for a less-developed nation to use inventions, stimulated perhaps by a patent system, from other nations. The French and British patent systems may have supplied important external benefits to neighbors like Holland, Germany, and Switzerland without patent laws. In this respect, it is worth recalling that Switzerland, currently home to three of the world's top pharmaceutical companies, began by allowing patents in areas where it had an established industrial base but refrained until 1977 from granting product patents in chemical and pharmaceutical fields, where it was attempting to lay the basis for industrial development.[22]

[22] In the early days, Switzerland introduced mechanical invention patents to protect its watch industry, but initially withheld patent protection on chemical and pharmaceutical substances as its infant chemical and pharmaceutical industry relied greatly upon imitating others' technology.

3.2 Theoretical Literature on Patent Protection in the Developing World

In some areas, IPR in general and patents in particular certainly are economically and socially productive in generating invention, spreading technological knowledge, inducing innovation and commercialization, and providing some degree of order in the development of broad technological prospects (Mazzoleni and Nelson, 1998b: 1033; Langinier and Moschini, 2002: 33, 35). However, in many areas of technology this is not the case. In a number of these, strong broad patent rights entail major economic costs while generating insufficient additional social benefits. (Appendix B, B.1.3) Besides, in some strong broad patents are merely counterproductive. One needs to be discriminating and cautious on this front. (Appendix B, B.1.4) The first part of Section 3.2 concisely sums up the two seminal works of the economic theory of the patent system, demonstrating the basic intuition, the monopoly/innovation tradeoff, behind the system in a closed economy. Attention then shifts to the impact of patent protection on national welfare in a world open economy in the second part.

3.2.1 Protecting Intellectual Property Rights in a Closed Economy

A number of studies of the economic theory of the patent system have emerged since the 1960s. A seminal work in this category is Arrow (1962), who presents a basic model of invention, R&D, and imitation in a closed economy. Arrow argues that there is a tendency in industry to under-invest in R&D from society's viewpoint due to problems for a firm to appropriate the economic benefits of its R&D. Patent protection would be one way of coping with this through its effect on the rate of imitation. According to Arrow's model, the innovator's profits decrease significantly by competition when imitation occurs; hence, a delay in imitation through patent protection would be a stimulus for firms to invest in R&D, at the expense to society of the possible overpricing of products by a monopolistic patentee. (Appendix B, B.1.1)

Nordhaus (1969), which is another truly seminal work on the economic theory of patents, has presented the most thorough theoretical analysis of the costs and benefits to the firms and to society of the patent system in the Arrow type of framework. Nordhaus (1969) makes a distinction between different types of

inventions and assumes the optimal length of protection period from society's viewpoint. By increasing the length of patent protection, incentives for generating innovations are increased (that is, dynamic efficiency is increased), while a longer period of monopolistic inefficiencies is produced (that is, static efficiency is decreased). According to Nordhaus's model, optimal patent life is finite because of decreasing returns to investment in innovation; the model shows how patents are an inferior policy for promoting innovation and suggests that the degree of patent protection vary by industry.

In summary, the normative theory of Nordhaus implies that in a closed economy where a country acts in isolation, in choosing its IPR policy a country will look for the optimal balance between the benefits from enhancing the incentive to innovate, on one hand, and costs of monopoly distortions and lower diffusion of new technology and innovation, on the other. The final policy choice will be some intermediate level of patent strength. A voluminous theoretical literature[23] followed to extend the normative theory of Nordhaus and the basic question is how to optimally balance the benefits and costs of innovation.

On a broader plane, with national economies becoming increasingly affected by the forces of globalization and the resulting increase in the cross-border trade, investment and the transfer of information, there is a growing recognition of the importance of technology and knowledge spillovers for economic growth. Consequently, IPR have become an issue of international concern. Particularly, the protection of IPR is one of the most controversial issues in today's global economy. Section 3.2.2 briefly reviews the theoretical literature, conducted to answer the controversial policy question as to whether the adoption of more stringent IPR makes economic sense for developing countries and for the world as a whole. This answer is of primary importance if countries want to introduce welfare enhancing policies.

3.2.2 Global Intellectual Property Protection and National Welfare

As concluded previously, if each country acts in isolation, when establishing its system IPR, they will search for the optimal level of protection suiting their own

[23] For instance, the literature by Gilbert and Shapiro (1990), Gallini (1992), Maurer and Scotchmer (2002), and Grossman and Lai (2004).

conditions. However, as opposed to the case of a closed economy, where the country's patent strength affects only domestic economic agents, in a global market, patent protection in one country affects welfare in other countries. Thus, a country's choice of its level for IPR protection is currently reliant on the choices of other countries and its choice also affects other national markets.

Further considerations enter into the optimum choice of IP protection in a multi-country setting where the optimal degree of IP protection by one country is dependent on the protection afforded by other countries. Falvey, Martinez and Reed (2002) examine the role of patent policy in the open economy and note that the way patents are applied tends to push countries towards extreme patent strengths. This may partially describe the pressure for some degree of international harmonization that led to minimum standards specified in the TRIPS Agreement. However, despite these minimum standards, countries still retain discretion over key aspects of their patent systems. Even for two identical countries, it is not individually rational to choose patent systems of identical strength; theoretically, in a Nash equilibrium, one country will have a strong patent system and the other one will have weaker patent protection.[24]

In accordance with Gaisford and Richardson (2000: 139), in a global context, the resultant Nash equilibrium is sub-optimal as IP Protection is under-provided. The explanation for this is that each country ignores the benefits that its tighter protection produces for other countries. In the absence of an institutional framework to achieve international cooperation, as neither side takes into account these positive spillovers, less than the efficient incentives for innovative activity are provided on a worldwide basis. Furthermore, whenever two countries are not symmetric with respect to their individualities, there are further reasons why it is optimal for them to choose patent systems of different strength. That is why it comes as no surprise to notice that the

[24] To provide an insight for this statement, consider a world of two identical countries A and B. If the countries had identical patent systems, firms from A would have half the sales in country B and vice versa, assuming no transportation and transaction costs associated with the international transfer of goods. If country A has a lax patent system, it may make eminently good sense for country B to choose tighter patent procedures. By doing so, B will completely control the sales in its domestic market plus half of the sales in A. Moreover, by choosing stronger patent protection, country A provides global incentives for innovation that would not otherwise exist. Alternatively, if country A has a stringent patent system, it is reasonable for country B to choose weaker patent protection. In this case, B will not bear the costs of monopoly distortions, will reap the benefits of free riding, and will enjoy the higher level of average product improvement. Therefore, in a Nash equilibrium, where each country adopts an individually rational strategy and does not want to deviate from this, one country will have a strong patent system and the other one will have weaker patent protection.

strength of IPR protection varied across the world prior to the TRIPS which standardized patent length internationally. These differences resulted in a dispute between developed and developing countries about the increase in IPR protection during negotiations to establish common worldwide standards.

Historically, the extension of IPR to the developing world became the center of attention in trade policy arena since the 1980s. A long-lasting argument over the across-the-board strengthening of IPR raises the interesting policy question regarding whether the long run net effect on enforcing of such IPR is positive or negative. Poor developing countries, supporters of less stringent IPR protection, argue that strengthening global IPR will bestow market power on innovating firms, thus enhancing the profits of the monopolistic foreign firms at the expense of domestic welfare. In addition, further restrictions on IPR would hurt local firms' learning-by-imitating strategies, would reduce legal trade in imitative products, and lower consumers' welfare. By contrast, rich developed countries, proponents of more stringent protection, claim that less IPR protection represents blatant free-riding, which distorts natural trading patterns and reduces firms' incentives for innovations (Taylor, 1994; Gaisford and Richardson, 2000).

This acrimonious debate over the across-the-board strengthening of IPR resulted in a considerable research effort concerning its impact on the distribution of welfare, trade flows, technology transfer and growth across countries. In particular, studies regarding the likely welfare effects of the international harmonization of patent protection largely rely on a North-South trade framework models that pitch an imitative or less innovative South against an innovative North and investigate the welfare implications for both the South (that is the developing countries) and the North (the developed countries) of extending the North's IPR regime to the South. The major view in this theoretical literature is that technological-importing developing countries in the Southern Hemisphere are likely to lose from the introduction of patent protection. The intuition behind this is that extending patent protection to developing world offers the innovating firms, mostly situated in the Northern Hemisphere, with a temporary monopoly throughout the duration of patent. Besides, losses in consumer surplus from monopoly pricing are, under plausible environments, found to be higher than the extra surplus from additional innovations stimulated by strengthened patent protection in the South.

One prominent theoretical study, which analyzes the impact of extending patent protection, from an innovating country to a technology-importing country, on national and global welfare, is the Welfare Effects of Global Patent Protection, undertaken by Deardorff (1992). In a two-country model, Deardorff (1992) showed that, under plausible parameterization, the extension of patent protection from the North, where the bulk of innovations are made, to the South, which only consumes innovative products, clearly increases the welfare of the inventing North but may decrease the welfare of the developing countries. Furthermore, the decline in the South's welfare may far exceed the increase in the North's welfare. In this case, there will be adverse effects for the world as a whole resulting from tighter patent protection. More specifically, in Deardorff (1992), the optimal level of world patent protection is determined by weighing the higher level of inventive activity in the North against the consumption distortion of monopoly pricing in the South. If all innovations are made in the Northern Hemisphere, extending patent protection to more and more countries has the positive effect that an inventor can earn monopoly profit in a larger group of countries and hence, has higher incentive to innovate. There are, however, diminishing returns to this effect for the following reason. As more and more countries adopt patent protection, the extra market that can be covered becomes smaller as well as the extra invention that can be stimulated by extending patent protection. As a result, after a certain threshold, the costs resulting from an extension of patent protection associated with monopoly pricing to existing innovations come to outweigh the benefits of making new innovations resulting from extending patent protection.

Deardorff (1992) concluded that as the coverage of patent protection is extended to more and more countries in the world, there will be a definite loss in the world welfare since the number of additional innovations, stimulated by extending patent protection, diminishes with an increase in the number of markets covered. Just as Nordhaus (1969) showed that optimal patent life is not infinite. Deardorff (1992) found that optimal patent coverage is not global. In other words, the world welfare is not maximized by extending patent protection to all countries in the South. This study implies that it may be optimal to limit patent protection geographically.

Deardorff (1992) demonstrated further that even if the world's efficiency does initially improve from extending stricter patent regimes, it is due to the North's relatively high gains at the expense of the rest of the world. Moreover, for the developing countries, the benefits from new inventions and increase in inventive activity are not strong enough to outweigh the losses from monopoly power and lower dispersion of new technology. This argument provides an official rationale for developing countries to oppose the proposals for more stringent patent protection.

Deardorff 's finding is underpinned by Scherer (2004). The study by Scherer (2004) revisits the question of whether global welfare is higher under a uniform worldwide system of pharmaceutical product patents or with international accepted rules allowing low-income nations to free-ride on the discoveries of firms in rich nations. In his analytical model, which was based partly upon an analysis by Deardorff (1990, 1992). Scherer considered various key variables including the extent to which free-riding reduces the discovery of new drugs, the rent potential of rich as compared to poor nations, the ratio of the marginal utility of income in poor as compared to rich nations, and the competitive environment within which R&D decisions are made. Given that the marginal utility of income is considerably higher in poor nations than in rich ones, global welfare was found to be higher with free-riding across plausible discovery impairment and income utility combinations. This finding leads him to conclude that global welfare is maximized by permitting third-world nations free-ride on the patented medicines of first-world nations over a wide range of negative new product development impacts. Thereby, the Doha round of negotiations seems to have inclined toward a proper solution, delaying implementation of the TRIPS provisions on pharmaceuticals in the least-developed nations for a decade.

Another pioneering study by Chin and Grossman (1990) adopts a North-South Cournot duopoly model to evaluate the impact of international IP protection harmonization on global welfare. Assuming that all innovation takes place in the North and all imitation takes place in the South, the study reveals a significant role played by the size of the South's market. It also shows that interests of the North and South are generally opposed such that it may be in the South's interest to evade rather than enforce IP protection. Their partial equilibrium analysis leads to the conclusion that more stringent IP protection may or may not enhance global welfare.

Additionally, within a dynamic general equilibrium framework in which the North invents new products and the South imitates them, Helpman (1993) provided the theoretical evaluation of the welfare effect of international IPR protection harmonization by decomposing the welfare changes into four following items: 1) terms of trade; 2) production composition; 3) available products; and 4) inter-temporal allocation of consumption, and analyzed the impact of extending IPR protection on each one of these items. In Helpman (1993: 1249) , tightening IPR in the South shifts some product lines from the less developed South to the more developed North; thus, demand for factors of production decreases in the South and increases in the North. The average price level rises in the North relative to the South. Terms of trade are hence worsened for the South and improved for the North. With some manufacturing relocated from the low cost South to the high cost North, both countries lose from production inefficiency. The rate of innovation in the North responds to the tightening of IPR in the South by initially increasing and then reducing over time. The result is driven by lower cost of capital in the North due to lower risk of imitation in the South and rising cost of innovation over time. According to the model, this inter-temporal pattern of innovation hurts both the welfare of the North and the South. The bottom line of this study is that the poor technology-importing country in the South no doubt loses from enforcing tighter IPR. The welfare impact of the technology-developing industrialized country is, however, more intricate and depends upon the initial rate of imitation in the South and whether foreign direct investment is permitted in the South, among other factors.

Lai and Qiu (2003) introduced a multi-sectorial trade model allowing for innovation in both the South and the North to evaluate the effect of the enforcement of global minimum IPR standard indicated in the TRIPS Agreement. In their study, strengthening IPR in the South generates a positive externality in the sense that the availability of more product variety enhances consumers' welfare in both regions. In addition, a game-theoretic model is applied to show that in the pre-TRIPS regime, the North and the South adopt their respective Nash equilibrium IPR standards and the South equilibrium IPR standard is naturally weaker than that of the North. This study found that it is globally welfare-improving to increase the South's IPR protection standard above its Nash equilibrium level. However, an agreement that requires the

South to raise its IPR standard without compensation benefits the North at the expense of the South, and would not be compatible with the South's incentive. In order to make the incentive compatible for the South to adopt the North's IPR standard, Lai and Qiu (2003: 203) suggested that the North liberalize its traditional goods sector (e.g. by lowering its import tariffs against South's exports) to the South so that both countries reap mutual welfare gain from IPR harmonization.

The analytical framework of the previously discussed work is based on the assumption of identical demand for newly invented goods in both countries. However, in reality the developed and developing countries can have different technological needs, and, therefore, the inventions demanded by different countries can be different. For instance, the case for medicines for neglected infectious and tropical diseases such as malaria, dengue fever or the hookworm disease that are almost non-existence in the Northern Hemisphere but rampant in the developing world. If it were assumed that demand for medicines for these diseases in an industrialized country (let's say country A) tends toward zero, almost no R&D incentives for manufacturers would initiate from demand in country A. In this case, the previous models may not adequately incorporate the potential benefit to residents in a developing country (country B) of extending patent protection to country B. More specifically, patent protection in country B would be likely to increase the incentives of the original manufacturers located in country A to invest in R&D for medicines that are particularly important for resident in country B.

Diwan and Rodrik (1991) originally developed a model for addressing this issue, emphasizing the dimension of technological choice. Unlike the formerly mentioned work, in their North-South trade model, the authors assumed that the North and the South have differences in distributions of preferences over the range of potential innovations. This, in turn, implies a greater incentive for the South to protect IPR, as more stringent patent protection in the South now implies a larger part of scarce R&D resources will be allocated to the invention of goods that are of particular importance to its population. In other words, tighter IPR protection in the South leads to a better fit between innovated technologies and the preferences of its people. This additional incentive can at least partly offset the strong free-riding motivation the South would have in case of identical technological needs.

In accordance with Diwan and Rodrik (1991), the restrictiveness of the patent laws in the South has noteworthy implications for the welfare of both regions. Stricter patent protection in the South affects the welfare of the North and the South in two following ways: firstly, through the magnitude of profit transfers from the South to the North; and secondly, through the change in the range of innovated technologies. The second impact is of particular interest as it implies that Southern patents might promote the development of technologies appropriate to the South that might not have been developed if there were no patents. In this case, lower patent protection in the South would not benefit the South and increased patent protection in the South can hurt the North when the resources to go into R&D are limited.

In short, according to Diwan and Rodrik (1991), global R&D resources are limited so that the South and the North have to complete for them in order to develop their preferred technologies. Extending IPR to the South enhances the likelihood that the South's preferred technologies will be developed and, thus, may skew the range of innovations away from the Northern preferences. In this vein, Gaisford, Tarvydas, Hobbs and Kerr (2005) formulated a model of the enforcement game between a developing country's government and a foreign biotechnology firm to inspect the efficacy of the WTO TRIPS Agreement for the protection of intellectual property in agricultural biotechnology. The conclusion is that the TRIPS is unlikely to provide sufficient protection and, thus, will lead to suboptimal levels of investment. The authors also note that there exists considerable potential for the innovations appropriate to the local needs of developing countries that are left unexplored. One reason for this is the low levels of income and resulting low demand in developing countries. Hence, the degree to which the extension of patent protection in the South will change the range of innovated products remains doubtful. Merely suggesting that the South could reap larger benefits by protecting IPR more vigorously as it might encourage the invention of more 'local' technologies, leaves the important question of affordability (as to whether the developing countries are able to pay monopolistic prices for more 'appropriate' innovative products, such as drugs to combat tropical diseases, and to reap the benefits of extended protection) unanswered.

In this context, the theoretical findings of the welfare analysis by Diwan and Rodrik (1991) imply that a benevolent global planner would assign identical rates of

patent protection to the North and the South only if their welfare levels are weighed equally, that is when the global welfare function is strictly utilitarian. The results of their numerical simulations also suggest that in the case of an egalitarian global welfare function, which the poor South's welfare is given priority, the North be required to provide a greater level of patent protection.[25]

The results of the preceding models gravely depend upon the assumption of how the information concerning the innovative product is disseminated. If one assumes that information is spread without cost from the North to the South and the South's level of imitation is high, then the same product may be produced in the South with no patent protection whatsoever. But, in fact, innovative ideas do not diffuse without cost. As indicated by Deardorff (1992), the developing countries may get benefit from patent protection only if it stimulates technology transfer. In this respect, Taylor (1993) introduced a partial equilibrium static North-South model to examine how the level of unintentional technology transfer is affected by the stringency of southern patent protection.

In Taylor (1993: 626), a leader-follower framework of Stackelberg competition is adopted where the northern firm is the first to move and to set its output and 'market-made' barriers to imitation. More precisely, the southern firm is assumed to typically invest in imitative activities whereas the innovating northern firm may respond in kind by 'masking' product technology in order to deter local imitators. The influence of IPR is captured by assuming imitation costs rise as the stringency of southern patent requirements increase. In the study, Southern costs of production are supposedly affected by both institutional and market-made barriers to imitation. In this respect, southern production costs are increasing in the strength of the South's patent protection and in the level of the North's efforts at masking product technology. The results of the model show that watchful IP protection by the South

[25] A utilitarian welfare function (also called a Benthamite welfare function) sums the utility of each individual in order to obtain society's overall welfare. All people are treated the same, regardless of their initial level of utility. One extra unit of utility for a starving person is not seen to be of any greater value than an extra unit of utility for a millionaire. Utilitarianism treats all improvements equally, i.e. gives them the same weight - independent of how well off the persons are to whom the improvements go. Utilitarianism in this respect does not care for distributive justice. There are three main lines of correcting utilitarianism for considerations of distributional justice: Rawls' maximin criterion, prioritarianism and egalitarianism (seeking to equalize utilities). In particular, egalitarianism seeks to diminish (or eliminate) interpersonal differences in personal goods, especially individual utilities, as an intrinsic aim. Egalitarians are concerned with relativities, i.e. how each person's level compares with the level of other people.

lessens the need of firms in the North to invest in masking their product's features and, hence, leads to higher flow of unintended technology transfer.

Taylor (1993) concluded that an increase in the transfer of technology to the South due to vigilant IP protection would improve the productivity of resources employed in the South and, accordingly, increases its output. By contrast, laxly enforced IP laws in the South would arouse defensive reactions from the side of innovative firms by restraining technology transfer to the South. This results in a Pareto-inferior position for the world economy in that the North is diverting resources into strategies to prevent imitation while the South, in its turn, is using resources to disclose the 'embodied technology.' The author also suggested that moving away from this Pareto-inferior status quo by protecting IPR more vigorously will be beneficial for both the developed and the developing countries and the world welfare is maximized at some intermediate level of patent strength.

Taylor (1994) shed further light on the role of IPR by extending his model carried out in 1993 to investigate how the regime for IPR protection affects the firms' ability to transfer technologies aboard and go 'transnational.' In Taylor (1994), a two-country dynamic model of endogenous-growth is employed to assess the impact of IPR on world trade, growth, and technology transfer. His analytical result leads to conclusion that slackly enforced patent laws in the South reduce the incentive for innovators to perform best practice research technologies, decrease global R&D activities, lessen the enthusiasm of inventors to transfer technology across countries, and slow worldwide economic growth.

To elaborate more, the study hypothesizes that if innovative technologies are transmitted across borders, then technology transfer will generate an area of factor price equalization, an improvement in the allocation of the world's resources, and, in many circumstances, an increase in global economic growth. These benefits, however, will fail to accrue if countries provide only partial IP protection by disregarding protection for foreign-made innovations. In accordance with Taylor (1994: 372), the blunt move from a symmetric protection regime to an asymmetric one brings a loss in export opportunities for the developed countries, where most innovating firms are located, and, hence, distorts the patterns of trade in both goods and R&D. Besides, a move to asymmetric protection also eliminates technology transfer between countries

and, as a result, decelerates the rate of technological progress in all industries in the developing world. The welfare of both regions may fall in the move to asymmetric IPR regime. Perversely, if the levels of protection are equalized across countries, innovative firms will have an incentive to transfer their technologies abroad, the allocation of the world resources will enhance and, consequently, world economic growth will rise. Hence, according to the study by Taylor (1994), there is an important matter to the claims of the developed countries.

In contrast to Taylor (1994), Grossman and Lai (2004) investigated an optimal government policy for IPR protection in a world economy through a two-country, partial-equilibrium, game-theoretic model of endogenous innovation and found that the worldwide harmonization of national patent protection, as stipulated in the TRIPS Agreement, is likely to benefit rich countries at the expense of poor developing countries. Therefore, the harmonization of patent system is neither necessary nor sufficient for the efficiency of the global patent regime. This result is in line with that of Gaisford and Richardson (2000). The authors also demonstrated that an efficient global IPR regime can be attained through different combinations of national IPR policies.

In their study, Grossman and Lai (2004) considered a world economy with ongoing innovation in two heterogeneous countries[26] and analyzed determinants of a country's incentive to protect intellectual property when countries interact with each other in setting their strategic IPR policies. To put it into game-theoretic parlance, the authors (2004: 1641) derived the Nash equilibriums of a game in which two countries choose their patent policies simultaneously and non-cooperatively.

In any case, analyzing the global welfare question requires a more complex model. Generally, the major difference between the closed economy model and the world economy model is that the benefits of innovation can spread beyond national boundaries in the latter model. More specifically, the decision of countries in setting their IPR regimes in a world economy is not as straightforward as in a closed economy model for two main reasons. First, the heterogeneity of the countries in terms of market size and capacity to innovate leads to national differences in optimal patent protection. Second, a country's optimal patent protection also depends on the

[26] Two countries are different in terms of market size and innovative capability.

patent protection afforded by its trading partner. Put differently, the strength of patent rights afforded in one country affects the responsiveness of global innovation to a change in the other country's patent policies. To deal with this global aspect, Grossman and Lai (2004: 1643) derived the best response functions for the two governments.[27] Then, a country's optimal strength of patent protection was obtained by equating the benefits and costs of strengthening patent protection.[28]

The main findings of the study are as follows. Firstly, in non-cooperative setting, countries have weaker incentives to protect IPR when they are engaged in international trade than when they are not (Grossman and Lai, 2004: 1644). Secondly, a country that has a larger market for innovative products and a greater capacity to innovate, i.e. a developed country in the Northern Hemisphere, has a higher incentive to grant stronger patent protection than its counterpart in the Southern Hemisphere (Grossman and Lai, 2004: 1645). Lastly, Grossman and Lai (2004: 1647) analyzed international patent agreements with respect to the question as to which combinations of patent policies maximize aggregate global welfare and found that, with the dissimilarity in innovative capacity across countries, the common international standards for IP protection under TRIPS are not likely to be mutually beneficial. Any move from non-cooperative Nash equilibrium national IPR policy to uniform worldwide standards of IPR protection worsens the positions of developing countries both absolutely and relative to the developed countries. According to the simulation results, the developing countries potentially suffer significant losses in their national welfare and would abide by TRIPS requirements only under the threat of WTO trade sanctions. Alternatively, a mutually beneficial efficient solution can be accomplished with asymmetric IPR protection where lower levels are permitted for developing countries and higher are required for developed countries.

In summary, the theoretical literature mentioned previously largely concludes that developing countries suffer an appreciable welfare loss from adopting the same IPR standards as in developed countries. In addition, the most likely globally efficient IPR policy is not harmonization, but rather selective and gradual IPR reform, in which

[27] In the study, the best response of the government in country A expresses the strength of patent protection that maximizes aggregate welfare in country A as a function of the given patent policy of the government in country B.
[28] It is assumed in the study that the countries consider their own IPR regimes through the trade-off between the static costs of strengthening patent protection in terms of increased deadweight losses and the dynamic benefits of strong patent protection associated with increased innovation.

each country is allowed to devise policies that are appropriate for its particular technological situation and stage of development. For countries in the early stages of catch-up to the world technological frontier, this will mean policies that facilitate technology transfer and even a certain amount of imitation. At some point, however, countries need to recognize that movement toward fuller IPR protection will facilitate foreign FDI and licensing. Eventually, as a domestic innovation sector emerges, countries will find it in their interests to provide greater protection in order to protect their own inventions. Thus, an honest overall appraisal of harmonization, defined as universal adoption of U.S.-like IPR policies, is as a policy initiative that hurts developing countries for the benefit of rich countries, with the possibility but no certainty that the global benefits exceed the global costs. Next section shall provide the empirical evidence regarding the welfare implications of the international harmonization of IPR which supports this theoretical conclusion.

3.3 Empirical Literature on Patent Protection in the Developing World

Despite the fact that a great deal of effort has already been expended in the theoretical attempt to shed light on the debate over IPR and the major result from theoretical work largely suggests that the extension of patent protection from innovating country to the second country which imports but does not invent new products is likely to decrease welfare in the importing country, there are some aspects that require a more detailed empirical investigation. For this matter, Section 3.3 shall offer the empirical studies undertaken by Chaudhuri, Goldberg and Jia (2006) and McCalman (2001). Section 3.3 begins with Subsection 3.3.1, briefly outlining the paper by Chaudhuri et al. (2006) who assess the impact of the enforcement of patents for pharmaceutical on prices and welfare in India. Focus then moves to another appealing empirical work carried out by McCalman (2001), examining the potentially negative redistributive consequences of international patent harmonization for technology- importing countries, in Subsection 3.3.2.

3.3.1 Short-Term Welfare Effects of Worldwide Patent Protection in Pharmaceuticals

Although there is a considerable theoretical literature on the welfare effects of patent protection in developing countries (see Section 3.2), the empirical work in this area is still in its infancy. Among a few empirical studies, the literature by Chaudhuri et al. (2006) is the significant one on this topic.

Chaudhuri et al. (2006) empirically investigated the possible negative effects of the enforcement of product patents for pharmaceuticals, as stipulated in the TRIPS Agreement, on prices and welfare in India. Using an aggregate data set from the Indian pharmaceutical market, Chaudhuri et al. (2006: 1481) derived key price and expenditure elasticities as well as supply-side parameters for a particular sub-segment of the systemic antibiotics segment, namely fluoroquinolone. The authors, through the use of the estimated parameters, then performed several counterfactual scenarios involving the withdrawal of one or more of the domestic pharmaceutical product groups of the fluoroquinolone sub-segment and, subsequently, obtained simulated prices and market shares. Further, the authors calculated the welfare loss under various counterfactual scenarios in the face of the withdrawal of domestic products and upward price adjustments for the foreign patented products.

Consistent with their estimated results, Chaudhuri et al. (2006: 1506) found that the enforcement of patent protection in the fluoroquinolone sub-segment alone would result in a large welfare loss for the Indian economy with a lower bound of US$ 144 million and an upper bound of US$ 450 million annually. The range of the estimated welfare loss, however, depends on several factors such as the degree to which foreign pharmaceutical producers respond to stronger patent protection, the way patent policies are implemented, and the extent of national price regulation. The authors also discovered that the overwhelming portion of this amount accounts for welfare losses to Indian consumers whereas only a small fraction of this amount accounts for forgone profits of Indian pharmaceutical firms (Chaudhuri et al., 2006: 1507). In short, the authors found that the major part of the total welfare loss derives from the loss of consumer welfare.

3.3.2 International Redistribution of Income Associated with the Execution of the TRIPS Agreement

As already mentioned, the international harmonization of patent protection has been fiercely debated in the global trading system. One main concern raised by most developing countries was related to the potentially negative redistributive consequences that the international patent protection harmonization, as required in the TRIPS Agreement, might have for them (Maskus, 2000: 171). To put it differently, the technology-importing developing countries raised concerns that they are likely to be exploited by the technology-exporting industrialized countries after the adoption of the TRIPS Agreement (McCalman, 2001: 162). For this substance, the notable work by McCalman (2001) provides interesting insights with respect to the transfer of income between countries associated with the execution of the TRIPS Agreement.

With the objective to empirically quantify the welfare implications of international patent protection harmonization, McCalman (2001) adopted a structural model of innovation, originally developed by Eaton and Kortum (1996), in an international setting in order to impute the value of patent rights in 29 countries. To infer the value of patent rights in each country, the author related local parameters to the decision to patent. Particularly, these parameters include the strength of patent protection and the availability of enforcement institutions that permit the appropriation of the rents to an innovation (McCalman, 2001: 164). For instance, the value of a patent taken out in country j that belongs to an inventor from country k depends on market size of country j, the inventive step of the patented invention, and the likelihood that the patent will be imitated and/or become obsolete. The hazard rate of imitation is in turn assumed to depend on the IPR regime of country j, which is measured by several indicators such as whether certain industries are excluded from patent protection, whether the patent holder is required to undertake production in the patent granting country. The structural parameters are recovered by estimating a bilateral patent equation that determines the number of country j patents taken out by inventors from country k, along with a labor productivity equation. With the structural coefficients estimated, the author then performed a counterfactual analysis assuming those features of a country's IPR regime, that are at variance with TRIPS, are rectified. In this manner, the author was able to estimate the hypothetical value of country k's patents taken out in country j in a TRIPS-harmonized world.

In other words, the study's analytical framework relates the value of patent rights to both the sectorial coverage of patent protection, by providing information as to whether sectors such as pharmaceutical, foods, or chemicals are excluded from patent protection, and the availability of enforcement institutions in a country such as the availability of injunctions and burden of proof procedures (McCalman, 2001: 162, 164). By incorporating this relationship in the model, the author can estimate the relationship between patent institutions in a particular country and the rents associated with patent protection in that country. In particular, this estimation enables him to conduct the counterfactual experiment in which all countries adopt patent protection consistent with the TRIPS Agreement and thus provides a basis to investigate the effect of international harmonization of patent protection on the value of patent rights.

This counterfactual experiment approach allows the author to draw several following conclusions with respect to the redistributive consequences due to the TRIPS Agreement and the importance of patent protection.

Firstly, patent protection is an important, though not the only, means for appropriating the rents of an invention (McCalman, 2001: 182). Especially, McCalman (2001: 176,177) found that Switzerland recoups around 25 percent of its R&D expenditures through patent protection.[29] However, all other countries recoup less than one quarter of R&D expenditures from patent protection, with a ratio of 0.15 for the U.S. and Germany as well as 0.07 for Japan.

Secondly, patent protection harmonization is likely to generate large transfers of income between countries, with the U.S. being the major beneficiary, gaining almost six times more than Germany, the second largest beneficiary (McCalman, 2001: 178).[30] By contrast, virtually all developing countries in the sample group incur a net transfer loss from patent protection harmonization. For instance, developing countries such as Brazil (with a value of -US$ 0.93 billion net transfers induced by patent protection harmonization) and India (-US$ 0.53 billion) are main contributors to the transfer of income between countries. However, transfers made by industrialized

[29] This is mainly due to the fact that almost 50 percent of Swiss R&D expenditures are devoted to pharmaceuticals and chemicals and that the chemical and the pharmaceutical industries' reliance on patents to appropriate rents is significantly above average (McCalman, 2001: 177). See also section B.2 in appendix B.

[30] McCalman (2001: 179) defined the net transfers associated with the TRIPS Agreement as the "difference between the increase in the value of patent rights held by residents of a country and the increased value of rights granted by that country."

countries such as Canada (-US$ 1.02 billion), the U.K. (-US$ 0.54 billion), and Japan (-US$ 0.44 billion) to the U.S. and other beneficiaries would also be large (McCalman, 2001: 179).[31]

Lastly, McCalman (2001) came to conclusion that global harmonization of patent protection associated with the TRIPS Agreement clearly shifts the international legal framework to favor the U.S. innovating firms at the expense of the technological-importing developing countries.

Incidentally, in Thailand there are a few studies quantifying the potential impact of international patent protection. Besides, none of these studies has used explicit models of consumer and firm behavior to simulate its effects on the Thai social welfare. Above all, these studies are eventually limited by the fact that the simulations that are used to evaluate the potential impact of patent protection are in each case based on assumptions about demand characteristics and market structure, rather than on actual estimates of the relevant parameters. This study takes an important step towards filling this gap in the prior literature with the objective to contribute to the ongoing controversy regarding the merits of the U.S. TRIPS-Plus provisions in developing countries. In particular, the study provides the first rigorously derived estimates of the possible impact of the TRIPS-Plus provisions on pharmaceutical prices and welfare in Thailand. Next chapter shall elaborate on the theoretical framework and the method of analysis employed in this study.

[31] It is remarkable that Canada is the biggest loser—over US$ 1 billion—but this is in line with Canada's alignment with developing countries in the negotiation of the TRIPs agreement (McCalman, 2001: 178). Put differently, the huge estimated net loss for Canada resulting from global patent protection harmonization may also serve as an explanation for Canada's willingness to align with developing countries regarding their main concern that the harmonization of patents due to TRIPS has negative consequences for them.

CHAPTER 4

THEORETICAL UNDERPINNING AND METHOD OF ANALYSIS

In recent years developing countries, non-governmental organization (NGO) activists, multinational corporations and their home governments increasingly have clashed over intellectual property policies. Particularly, under the bilateral and regional trade and investment negotiations several developing countries were required by the U.S. to enforce the TRIPS-Plus provisions. The dramatic expansion of these U.S. intellectual property policies through the FTA negotiations has precipitated the intense debate between the U.S. and its trade partners in the developing world. Though many years have passed since the provisions were launched, there continues to be heated arguments for and against the merits of these provisions. On one side, most developing countries claim that unqualified intellectual property protection for pharmaceuticals due to the provisions will result in considerably higher prices for medicines, with negative consequences for their national health budgets and the wellness of their citizens. Especially, they suspect that the loss of consumers' and producers' surpluses from having to import high-priced medicines will outweigh the benefits from an increase in the number of new drugs expected to be available as a result of stronger and broader IPR protection. On the other side, the U.S. and its global pharmaceutical companies argues that the imposition of the TRIPS-Plus mandates is unlikely to significantly raise prices because most patented medicines have several therapeutic substitutes. In addition, more stringent IPR protection has served as an incentive to engage in research on diseases that disproportionately afflict the world's poor, implying that broader and stricter patent protection for pharmaceuticals will ultimately benefit developing countries by stimulating pharmaceutical innovation and transfer of technology.

Given the scope of the TRIPS-Plus provisions together with the intensity of the accompanying debate, it is somewhat surprising how sparse the evidence is, on

which these divergent claims are based. Besides, little is known about the extent to which pharmaceutical prices in developing countries might increase with the introduction of the TRIPS-Plus provisions, and the magnitude of the related welfare losses. Past empirical studies on the impact of patents on prices and innovative activity in several sectors, including pharmaceuticals, have focused almost entirely on developed economies. Aside from the fact that none of these studies estimates welfare effects, their conclusions are not directly related to the TRIPS-Plus debate. Moreover, the structure of demand for pharmaceuticals in less-developed economies differs from that in developed economies in various important respects.[32]

Any assessment of the potential price and welfare effects of the TRIPS-Plus provisions needs therefore to be based on a better empirically-grounded understanding of the characteristics of demand and the structure of markets for pharmaceuticals in poor developing economies. To what extent are consumers willing to tradeoff lower prices for older, possibly less effective therapies? How does this vary across different therapeutic classes? Are consumers willing to pay a premium for the pedigree and brand reputation of pharmaceutical products marketed by subsidiaries of foreign multinationals? How competitive are pharmaceutical markets? On the one hand, consumers' welfare is dependent upon the pricing strategies and decisions of pharmaceutical firms, which in turn derive from the firms' appraisal of the structure of market demand for pharmaceuticals. On the other hand, if consumers are unwilling to pay substantially more for newer patented medicines for which exist older, possibly slightly less effective generic substitutes, the ability of patent holders to charge a premium will be limited.

[32] The differences in the structure of demand for pharmaceuticals between the rich and poor economies can be observed from the differences in various important health indicators, such as per-capita health expenditures, health insurance coverage and causes of the burden of disease. More specifically, per-capita health expenditures in less-developed economies are in general several orders of magnitude lower than in developed economies due to the fact that households are much poorer in less-developed economies. Likewise, health insurance coverage is much rarer in less developed economies; consequently, the bulk of a household's medical expenditures are met out-of-pocket. For this matter, Cleanthous (2003) reported a very low price elasticity of demand for the U.S. market of antidepressants. This can be explained by economic intuition that in developed rich economies, like the U.S., a substantial number of consumers are covered by insurance and hence moral hazard (caused by the existence of pharmaceutical insurance coverage). Breaking down the results by insurance status, he found that the low price elasticity of demand is primarily driven by the price insensitivity of consumers who are insured. In contrast, consumers without insurance have significantly higher price elasticity of demand. Similarly, consumers in poor countries tend to have higher price elasticity of demand for medicines than those in rich countries because a large number of people are uninsured and most pharmaceutical expenses are met out-of-pocket. Additionally, the burden of disease in low-income countries is quite different from that in the rich countries. There are certain diseases that are almost exclusively suffered by Third World populations. For further details of global health indicators, see the World Health Statistics 2011 (World Health Organization, 2011).

In this respect, Thailand provides a natural setting for the analysis of the welfare effect of TRIPS-Plus for several reasons. First, it is a leading example of a developing country that has still been in the FTA negotiation process with the U.S. and has not afforded TRIPS-Plus yet. Though six years have passed since Thailand was required by the USTR to enforce TRIPS-Plus, the negotiating issue pertains to the adoption of the U.S. new IPR regime remains inconclusive.

In terms of the structure of demand for healthcare, Thailand appears to be a prototypical example of a low-income country which a large number of poor households have to cover all medical expenses out-of-pocket due to the nonexistence of health insurance coverage.[33] Moreover, the disease profile of the Thai population reflects that of several other low-income countries and is significantly dissimilar to that of most industrialized countries.

Finally, concerning the drug supply, Thailand is an ideal representative of a technology-importing developing country which cannot be self-reliant in medicine (Appendix A, A.2). For Thailand, its infant drug industry is basically composed of non-research based manufacturers. Most Thai-owned private firms are small in size and rely greatly upon imitating others' technology. Because of not having a functional technological base, for new advanced medicines the country has to be industrially and technologically dependent on foreign interests. As a result, Thailand consistently loses trade balance in the pharmaceutical sector to its trading partners.

To date, there have been some prior empirical studies considering these issues. Their emphases are however very much on the price and welfare effects implied by TRIPS. Only a few consider the issues relevant to TRIPS-Plus. In addition, their results are ultimately limited by the fact that the models that are used to assess the possible effects of IP protection are in each instance reliant on assumptions regarding demand characteristics and market structure, rather than on actual estimates of the related parameters obtained from derived demand. This present study seeks to bridge this gap in the literature and contributes to better understanding of the potential adverse effects of TRIPS-Plus in the Third World countries. Especially, it provides

[33] In Thailand, during 1980-2005, around two-thirds of total health expenditure came from household out-of-pocket payments (see Table A.3 in Appendix A). However, after the launch of the Universal Coverage (UC) of Health Care Scheme, the health expenditure structure was radically restructured. In 2008, the UC scheme became a major financing agent, contributed nearly one-fourth of total health expenditure whereas the household out-of-pocket had its share around one-fifth of total health expenditure. For more details, see Section A.2 in Appendix A.

the first thoroughly derived estimates of the possible impact of the U.S. TRIPS-Plus mandates on consumer welfare in Thailand.

In the study, the demand for antihypertensive drugs in the Thai pharmaceuticals market was modeled through the Linear Approximation of an Almost Ideal Demand System (LA-AIDS) specification so as to capture the specific features of this market. The antihypertensive segment was chosen because it contains several products that were still under patent in Thailand during the sample period. Using detailed product-level data on annual prices and quantities consumed over a thirteen year period from 1996 to 2008, key price and expenditure elasticities together with market structure parameters for the specific sub-segment, which is comprised of three major kinds of antihypertensive drugs, namely, beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system, of the antihypertensive segment were estimated. The method to estimate the parameters was Iterative Seemingly Unrelated Regression (ISUR), where the restrictions of adding up, homogenous of degree zero in prices, and symmetry were imposed. With these demand parameters in place, the counterfactual simulations of what consumer welfare would have been if Thailand had enforced TRIPS-Plus were then carried out.

The basic counterfactual scenarios we considered here involve only the static loss of consumer surplus that arises from the enforcement of TRIPS-Plus. More precisely, we focused in this paper on estimating the static (short-run) resource misallocation cost due to an increase in price of branded medicines in the original patentable market. We however did not account for the consumer welfare loss arising from the dynamic (long-run) pricing distortion.[34] In the short run, to see why the TRIPS-Plus provisions are likely to affect the patented medicine prices, imagine a scenario where the introduction of TRIPS-Plus leads to the prolongation of monopoly pricing in the market for the original patentable molecules and, hence, upward price adjustment in this market, as producers of patented products re-optimize and set new prices in response to the market exclusivity prolongation. However, the magnitude of

[34] In this context, think about the situation where the enforcement of TRIPS-Plus results in monopoly pricing extension in the market for a particular patented medicine. If the markets for potential substitutes are imperfectly competitive, then in the long run the increase in price in the original patentable market will lead to corresponding upward price adjustments in the related markets as producers of substitute products re-optimize and set new prices in the face of the increased demand for their products.

any upward adjustments will naturally vary with the degree of competition in the related markets, and with the strength of the cross-price effects.

Turning to the counterfactuals, with the demand parameters in hand we were ready to conduct counterfactual simulations. To measure the changes in consumer welfare, we considered the Thai antihypertensive market under two conditions, with and without the enforcement of TRIPS-Plus. Without the enforcement of TRIPS-Plus, medicine prices in the original patentable market would follow the current trend. On the contrary, with the enforcement of TRIPS-Plus, given that all other things being equal, three possible scenarios of 10%, 30%, and 50 % increase in price of patented medicines above the current trend were simulated.

However, prior literature by Frank and Salkever (1997) and Malpani (2007) has revealed that generic competition can reduce the prices of brand-name medicines significantly. For the purpose of this study, we assume that in the absence of TRIPS-Plus, on average, prices of brand-name medicines decrease by 20 % owing to generic competition. Subsequently, we simulated another three counterfactual scenarios: without the enforcement of TRIPS-Plus, prices of patented medicines would decrease by 20% from the trend line as a consequence of generic competition; perversely, with the enforcement of TRIPS-Plus, the additional plausible scenarios of 10%, 30%, and 50 % increase in price of patented medicines above the trend line were carried out.

Using the expenditure function associated with the LA-AIDS specification, we were able to calculate the welfare loss, measured in terms of compensating variation, i.e., the additional expenditure that the representative Thai consumer would need to incur to maintain her pre-TRIPS-Plus utility level (i.e., the same level of access to medicines as before enforcing TRIPS-Plus) in the face of the market exclusivity extension for the patented foreign medicines and the accompanying price increases.

Apart from the fact that the counterfactual simulations in this study are based on estimated rather than assumed demand parameter values, this study builds upon the former literature in that it allows for and flexibly estimates a range of cross-product-group substitution effects. By contrast, cross-price effects are mostly ignored in previous literature.

Chapter 4 is organized as follows. Section 4.1 briefly reviews the existing evidence on the immediate (static) effect of pharmaceutical patents in the Third World

nations. Section 4.2 provides some details about the specific therapeutic categories of antihypertensive drugs the study focuses on in the empirical analysis and shortly describes the data used in the study. Section 4.3 concisely summarizes the basic economic theory regarding the impact of pharmaceutical patents on drug prices and consumer welfare. Section 4.4 is the core methodological section of the study. There the analytical framework and the econometric strategy we use to estimate the relevant parameters and construct the counterfactual scenarios are thoroughly elaborated.

4.1 The Existing Evidence

As mentioned in chapter 3, empirical work on the possible impact of patent protection in developing countries is in its infancy. Thus far there have been a small number of prior relevant studies considering this issue. And most of them employed explicit models of consumer and firm behavior to simulate the static price and welfare effects implied by patent protection. For instance, Nogués (1993), Maskus and Konan (1994), and Subramanian (1995) are the pioneering studies to throw light on the short-term welfare effects of international patent protection for pharmaceuticals in developing countries. These studies depended upon aggregate data on the patent protected segment of the pharmaceutical market and simulated the transition toward a patent-induced monopoly by making several assumptions on the pre-patent market structure and market demand. However, they can only give rough estimates of the impact of patent protection as they did not take into account the independence of different therapeutic groups and the different market structures that might exist in these therapeutic groups. Put differently, not all market participants directly compete with each other. The market for anti-infective agents, for instance, can be considered as being independent of the market for, say, drugs used in cardiovascular system. Competition is therefore limited to a group of drugs that are therapeutic substitutes for each other.

Watal (2000) improved upon these studies by using more detailed (brand-level) data for all on-patent chemical entities on the pre-patent market structures and simulating the transition toward a patent-induced monopoly for each on-patent chemical entity. Brands of the same entity were assumed to be perfect substitutes and,

in the absence of patent protection, market participants engaged in Cournot-Nash competition. Watal (2000) considered both a linear and a constant elasticity demand function and linked the assumed demand elasticity to the level of therapeutic competition expressed by the market share of the chemical entity in the overall therapeutic group. However, there is a twofold criticism on his methodology. First, the assumption that brands of the same chemical entity are perfect substitutes seems at odds with the observed pattern of product differentiation through trademarks and advertising. Second, the market share of a chemical entity in the overall therapeutic group may not be a good indicator of the level of therapeutic competition faced by this entity. The degree to which one drug can be substituted by another is likely to depend on their therapeutic properties rather than on the revealed market share.

To address the shortcomings in Watal (2000), Fink (2000) developed the model that accounts for the complex demand structure for pharmaceuticals in India. In Fink (2000), consumers can choose among therapeutic substitutes that are available to treat a particular disease. In addition, for each drug, they have the choice among various brands that are chemically equivalent, but differentiated through the promotional activities of pharmaceutical manufacturers. His analytical approach builds around the calibration of a theoretical model to actual data from the Indian pharmaceutical market, to answer the hypothetical question of what the market structure would look like, if India allowed product patent protection on pharmaceuticals. However, his simulated results depend on the values of assumed elasticities instead of those estimated from derived demand.

While several past studies mentioned earlier have evaluated the potential price and welfare effects of the WTO TRIPS, the two other studies by Chutima Akaleephan et al. (2009) and Nusaraporn Kessomboon et al. (2010) have attempted to estimate the possible impact of broader and stricter IPR protection relevant to the U.S.TRIPS-Plus in Thailand. However, neither Chutima Akaleephan et al. (2009) nor Nusaraporn Kessomboon et al. (2010) employed explicit model of consumer behavior as their analytical framework. Specifically, while the first study by Chutima Akaleephan et al. (2009) has examined the potential impact of TRIPS-Plus on drug spending through simple calculation of the average price differential between innovative drugs and their generics in competitive market, the latter by Nusaraporn Kessomboon et al. (2010)

has adopted the model developed by Joan Rovira to measure the effects of stricter IPR protection. Although both studies are able to isolate the likely impact of TRIPS-Plus on drug prices, they are ultimately limited by the fact that they do not (and cannot) provide any sense of the magnitude of the welfare loss that consumers are likely to suffer, as they are not grounded in any explicit model of consumer behavior.

Particularly, the study by Nusaraporn Kessomboon et al. (2010) can be criticized on two grounds. First, the Rovira's model itself has been questioned in terms of its construct validity due to a lack of theoretical consistency. Specifically, the model fails to facilitate the quantification of consumer demand based on the well-established theoretical axioms of optimal consumer behavior (in other words, the model cannot link actual data to pure theory, i.e., the maintained hypothesis of consumer behavior). Consequently, the mutual interdependence of a variety of pharmaceutical goods depending on relative prices, household/governmental budgets, and preferences were neglected. For this reason, the results obtained by using this model tend to invalidate due to no linkage between standard consumer theory and the estimation technique.

Second, the assumption about unrealistically low price elasticity of demand is still problematic. In Nusaraporn Kessomboon et al. (2010), price elasticity of demand for pharmaceuticals in Thailand was assumed to be constant and equal to -0.01, which is almost perfectly inelastic, implying that there are almost no close therapeutic substitutes available in the Thai pharmaceuticals market. This assumption seems conflicting with the fact that, even within narrowly specified therapeutic segments, consumers often have a choice of several alternative drugs, of varying vintages and levels of therapeutic efficacy, produced by companies with varying reputations for quality. The use of such price elasticity tends to overstate the impact of TRIPS-Plus.

Most importantly, these past studies, while they provide some useful indicative figures, are mostly limited by the fact that the simulations employed to assess the potential impact of patents are in each instance based on assumptions about demand characteristics and market structure, rather than on actual estimates of the relevant parameters. This study takes an advanced step towards filling this gap in the aforementioned prior literature with the objective to contribute to the ongoing acrimonious debate regarding the potential negative effects of the U.S. TRIPS-Plus provisions, as it pertains to the pharmaceutical industry in developing countries.

Particularly, the study improves upon the bygone literature related to the likely adverse impacts of TRIPS-Plus in Thailand in three substantive ways. First, other studies that were carried out in the recent past only used empirical models, which are not fully consistent with economic theory. We add to this literature by using a theory-consistent demand system approach in our analysis. In addition, owing to the fact that we base our counterfactual simulations on estimated (instead of assumed) parameter values, this study offers the first rigorously derived estimates of the magnitude of the welfare loss that the citizens of Thailand are likely to suffer from the enforcement of the TRIPS-Plus provisions. A Third and perhaps even more important methodological difference between this paper and prior studies is that we take into account and flexibly assesses a range of cross-product-group substitution effects. By contrast, the cross-price effects are disregarded in earlier studies.

4.2 The Setting and the Data

To understand the negative consequences of the enforcement of TRIPS-Plus for access to medicines in Thailand, it is important first to fully understand the Thai pharmaceuticals market structure. Of particular interest in this study are the degree of price sensitivity of demand for pharmaceuticals and the magnitude of the welfare loss.

To shed light on these matters, we decided to put emphasis on the antihypertensive therapeutic segment of the Thai pharmaceuticals market. The market for antihypertensive drugs was chosen because hypertension is a worldwide major health problem of the elderly that has a rising trend and is closely correlated with the economic and social development of the society.[35] In Thailand, hypertension afflicts more than 10 million individuals, resulting in a huge economic burden.[36] Estimate indicates that in 2008 the costs incurred for antihypertensive drug therapy amounted to around 11 billion baht in consumer prices (see Table C.2 in Appendix C).

[35] According to the World Health Report (World Health Organization, 2006), it was estimated that in 2000 hypertension was the cause of 7.1 million deaths or approximately 13 % of all deaths worldwide and it was also one of the three major causes of loss in non-fatal health status or loss of healthy life years.

[36] The 2003-2004 health examination survey on Thai people revealed that the prevalence of hypertension had a tendency to rise from 5.4% in 1991 to 11.0% in 1996 and to 22% or 10.1 million individuals in 2004 (Department of Disease Control. Bureau of Epidemiology, 2006).

In the present study, market demand for the specific sub-segment, which consists of three therapeutic categories of antihypertensive agents, viz. beta blocking agents, calcium channel blockers and agents acting on the renin-angiotensin system, of the antihypertensive drugs segment was modeled using detailed product-level data on annual prices (baht) and quantities consumed [37] (milligram) over a thirteen year period from 1996 to 2008. In all, 422 oral antihypertensive drugs were included in the sample.[38] A complete list of the drugs used in the study, their therapeutic category, their dosage form and strength, their Defined Daily Dose, and their number of producers is displayed in Table C.1 (Appendix C). The sample comprises all types of drugs, including on-patent branded foreign products, off-patent branded foreign products, and generic versions,[39] in the Thai antihypertensive drug market. Some (antihypertensive) drugs that are usually used for other indications besides hypertension were excluded to avoid problems of product heterogeneity.[40]

More specifically, in this study the sample includes only pharmaceutical products that were indicated for antihypertensive use according to the Guidelines for Anatomical Therapeutic Chemical (ATC) classification and Defined Daily Dose (DDD) assignment 2009.[41] Some drugs that were defined as antihypertensive agents according to the ATC classification system but were commonly prescribed for the treatment of indications other than hypertension were excluded from the sample in

[37] In this study, quantity consumed of a particular drug in Thailand was obtained from the following formula.
Quantity consumed in the country = quantity imported + quantity produced domestically- quantity exported

[38] Drugs having the same chemical structure that were produced by different companies were included as separate products. Likewise, drugs having the same chemical substance with different strengths (in terms of milligram) were classified as separate products.

[39] In the study, generic versions were separated into two groups, i.e., local products (generics that were produced domestically) and imported products (generic drugs that were imported from foreign countries).

[40] With this approach, we believe that the sample collected in the study is highly representative of the market for antihypertensive drug products.

[41] The Anatomical Therapeutic Chemical (ATC) classification system and the Defined Daily Dose (DDD) as a measuring unit are recommended by the WHO for drug utilization studies. The system is now widely used globally. In the ATC classification system, the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. Drugs are classified in groups at five different levels. The drugs are primarily divided into fourteen main groups (1st level), with pharmacological/therapeutic subgroups (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. In order to measure drug use, it is however important to have both a classification system and a unit of measurement. To deal with the objections against traditional units of measurement, a technical unit of measurement called the Defined Daily Dose to be used in drug utilization studies was developed. The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. For the class of antihypertensive agents (which is categorized from the drugs that use in cardiovascular system at the 2nd level), it is mainly classified into sub-classes at the 3rd level according to the mechanism of action. In the present study, we adapted this classification (at the 2nd and 3rd levels) and used the adapted version for establishing the multistage demand system. For further information, see the Guidelines for ATC classification and DDD assignment 2009 (WHO Collaborating Centre for Drug Statistics Methodology, 2009).

order to prevent product heterogeneity problems. For instance, verapamil, a member of the class of drugs known as calcium channel blockers, was excluded from the sample because it did not have a main indication for treating hypertension.[42] Additionally, the data are yearly aggregates and include only oral preparations (oral dosage forms), which are the major fraction of the total consumption of antihypertensive medicines.[43]

Among antihypertensive drugs, beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system are the latest generation molecules available in Thailand. We considered focusing our analysis on these three therapeutic categories for several reasons. First, with a share of 90% in the sales of antihypertensive drugs, (Appendix C., Table C.2) they are truly representative of the market for antihypertensive drugs. Second, they are the drug of choice that can be prescribed for many of the hypertensive conditions, some of which are also treated by alternative drugs. Hence, if there were product groups for which we would expect to have many substitutes readily available, these would be beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system. Especially, they themselves are close therapeutic substitutes. The presence of many therapeutic substitutes within these aforementioned categories makes them ideal for investigating the claim that the presence of close therapeutic substitutes will prevent drug prices from rising once TRIPS-Plus is enforced. Third, they are the leading costs[44] entailing a large financial burden to both individuals and the country as a whole. As shown in Table C.2 (Appendix C), in 2008 the spending on these drugs amounted to nearly 10 billion baht in consumer prices. Finally, several molecules within these three antihypertensive categories were still under patent in Thailand at the time of investigation. And at the same time there were also many substitute products for these molecules being produced and/or distributed in Thailand by both a number of domestic firms and a number of local subsidiaries of foreign multinationals. To put it differently, these three antihypertensive categories contain all types of drugs needed to observe including on-patent branded foreign drugs, off-patent branded foreign

[42] Verapamil is an L-type calcium channel blocker. It has been used in the treatment of hypertension, angina pectoris, and cardiac arrhythmia. However, its main indication is for the treatment of cardiac arrhythmia. Therefore, we excluded it from the study. Diltiazem (another calcium channel blocker) as well as some alpha blocking agents (such as prazosin and doxazosin) were also excluded for the same reason.

[43] We excluded other dosage forms as their values and quantities consumed are insignificant.

[44] The costs incurred by antihypertensive drug therapy are massive because hypertension is a chronic disease and, accordingly, patients have to take medicines every day for whole life.

drugs, and generic substitutes. Hence, they enable us to be able to observe patterns of substitution among various types of antihypertensive drugs (particularly between branded and generic versions). By the way, all data used for empirical investigation were taken from Bureau of Drug Control, Food and Drug Administration (FDA), Ministry of Public Health, Thailand.

As data on drug prices were missing, we had to rely on the utilization of unit values[45] as proxies for unobserved market prices. This approach is however subject to potential measurement bias, as it does not account for quality variation, i.e. the differences in therapeutic efficacy among various drug items used to treat the same medical condition.[46] In response to this problem, we adopted the WHO Defined Daily Dose (DDD) to standardize and transform the unit value of a drug to its daily cost of treatment (expenditure for a particular drug per day).[47] With these virtual prices in hand, market structure parameters can be estimated. Thereby, in this study we decided to rely on the use of daily cost of treatment of a medicine as a proxy for price information in order to keep the measurement error problem at reasonable levels. Incidentally, missing values of a particular drug due to zero consumption were replaced by its average expenditure.

4.3 Conceptual Preliminaries: The Monopoly/Innovation Tradeoff

The basic economic theory regarding the impact of pharmaceutical patent protection on drug prices and consumer welfare is straightforward. Pharmaceutical patent, by conferring monopoly power, i.e. exclusive rights to produce and sell the patented medicine, to the patent-holder, enables the patent-holder to raise the price of

[45] Ratios of nominal expenditure on a drug to the quantity purchased.

[46] For instance, consider the average dosages for the treatment of hypertension of the two different chemical molecules—namely, captopril and ramipril—in the same therapeutic class so called ACE inhibitors. While the average maintenance dose per day for captopril is 50 milligrams orally, the daily dose for ramipril is 2.5 milligrams orally. Hence their potencies (therapeutic efficacies) are different (because one milligram of ramipril is not equivalent to one milligram of captopril). This will lead to the units-of-measurement problem.

[47] The Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a drug used for its main indication in adults. It should be emphasized that the defined daily dose is a unit of measurement and does not necessarily reflect the recommended or Prescribed Daily Dose. Doses for individual patients and patient groups will often differ from the DDD and will necessarily have to be based on individual characteristics (e.g. age and weight) and pharmacokinetic considerations. Drug consumption data presented in DDDs only give a rough estimate of consumption and not an exact picture of actual use. The DDD as a measuring unit is recommended by the WHO for drug utilization studies. DDDs provide a fixed unit of measurement independent of price and formulation enabling the researcher to assess trends in drug consumption and to perform comparisons between population groups. The system is now widely used internationally with a large number of academic users. For more details regarding the DDD, see Guidelines for ATC Classification and DDD Assignment 2009 (WHO Collaborating Centre for Drug Statistics Methodology, 2009).

the patented medicine above the level that would have prevailed in a competitive market. Put differently, pharmaceutical patents allow the patent-holders to charge prices in excess of full production and distribution costs to earn handsome profits; these profits (price-cost margins) are the extra expenses that consumers have to pay under power over prices the patents confer. That is the immediate (static) effect of pharmaceutical patents. On the other hand, a longer-term, more dynamic viewpoint suggests that the promise of these monopoly profits is exactly what is needed to spur research and innovative activities that will lead to the introduction of newer and better medicines, which will over time displace the older medicines and raise consumer welfare. Hence, for a closed economy case, a country faces a trade-off between the static costs of strengthening patent protection in terms of increased deadweight losses and the dynamic benefits of stronger patent protection in terms of increased pharmaceutical innovation. In choosing its patent policy, a country will look for the optimal balance between the benefits from enhancing the incentive to innovate, on one hand, and costs of monopoly distortions and lower diffusion of new pharmaceutical technology and innovation, on the other. The optimal policy choice will be some intermediate level of patent strength.

Matters become even more complicated when considering a world economy model, which the benefits of innovation can spread beyond national boundaries. Within a multi-country setting, the tradeoffs are no longer so simple for the following reasons. First, the heterogeneity of the countries in terms of market size and capacity to innovate leads to national differences in optimal patent protection. Second, a country's optimal patent protection also depends on the patent protection afforded by its trading partners. From an individual country's perspective, the welfare consequences of patent protection depend on whether the patent-holders are foreign or domestic firms, and on the extent to which patent protection serves to stimulate appropriate research and innovation. This, in turn, will depend on what other nations are doing, and on the importance of the country in question in influencing the priority areas of research. Also, the pricing decisions of patent holders may be adapted. Specifically, foreign patent holders may have a range of reasons to engage in international reference pricing, i.e. set prices not to maximize profits in the particular national market but to maximize global profits. For the Third World countries this

may mean prices that are higher than domestic monopoly prices, magnifying the static pricing distortions that originate from patents.

We focused in this paper on estimating the possible welfare effect of introducing TRIPS-Plus in Thailand. However, the welfare loss we estimated represents only consumers' cost in the form of static inefficiency arising from pricing distortions attributable to TRIPS-Plus. We do not consider the impact of TRIPS-Plus on the dynamic loss of consumer surplus. Similarly, the approach in this paper does not address the potential dynamic benefits of innovations that may results from more stringent IPR protection.

4.4 The Analytical Framework and Estimation Approach

4.4.1 The Analytical Framework

For a technology-importing country like Thailand, while long-run gains from enforcing TRIPS-Plus remain poorly understood and controversial, the shift to stronger and broader intellectual property protection in regard to these provisions absolutely incurs substantial short-run costs arising in the form of static inefficiency including: legal and administrative costs,[48] cost of rent transfers,[49] and incremental cost due to higher prices of patented medicines.[50] Among these costs, the social cost due to monopolistic prices of patented medicines is the most noteworthy one. This study focuses on quantifying this cost.

In this respect, TRIPS-Plus contributes to an increase in drug prices through preventing generic competition. Longer period of monopolistic market endowed by TRIPS-Plus[51] could delay the introduction of the low-cost, generic equivalent. As a

[48] The country's costs of complying with TRIPS-Plus include upgrading offices for registering and examining patents and trademarks; training examiners, judges, and lawyers; improving courts to manage intellectual property litigation; and training customs officers and undertaking border and domestic enforcement actions.

[49] As TRIPS-Plus permits patent-holder to extend monopoly period for innovative medicines, this will cause a substantial contraction of the potential supply of domestic generic copies, whose introduction would be delayed for many years. Thus, one impact of TRIPS-Plus is to transfer economic rents from domestic pharmaceutical producers to foreign multinationals.

[50] The resource misallocation cost in the form of static inefficient.

[51] TRIPS-Plus does permit a patent-holder to have longer monopoly period for their patented medicines through three main mechanisms including: extension of patent term due to granting delay or market approval delay, protection for data exclusivity, and linkage of drug registration and the patent status.

result, only the high-priced, patented version of a new drug would be available. Because savings of health expenditure on drugs by price reduction from generic competition are made both by replacing innovative drugs with low-priced generic substitutes and by possible price reduction of the innovative drugs per se., delaying the introduction of generic drugs to the market will result in a huge additional financial burden for both households and the country. Particularly, the absence of the generic equivalent usually leads to the patent-holder having free hand to set a price, usually away from affordability of people in the poor countries. In market characterized by informational asymmetry and low price elasticity of demand like pharmaceutical market, the ability to limit the rate of increase in price is crucial. Unaffordable high price due to the absence of price competition will result in lower access to essential medicines, especially among the underprivileged groups and conclusively generates an additional burden for the country which has to provide more budgets to serve its people.

Under the FTA negotiation with the United State, Thailand has come under policy scrutiny regarding its IPR regime, pharmaceutical patent regime in particular, as drug spending is a major component of the overall national health expenditure with an increasing trend. (Appendix A., Table A.2 and Figure A.3) In order to empirically assess the potential welfare effects of TRIPS-Plus, it is important first to fully understand the specific characteristics of the Thai pharmaceutical demand structure as understanding demand pattern is an essential prerequisite for designing the optimal intellectual property policies and for predicting and analyzing policy impacts. Of particular interest is the degree of price sensitivity of demand for pharmaceuticals.

Because estimation of price elasticities requires estimation of the demand function, we start our analysis by estimating demand. Particularly, the demand parameters allow us to estimate the price elasticities of demand and substitution patterns across products in the antihypertensive market, which are needed in the computation of subsequent welfare analysis. Given the significance of the demand estimation in the analysis, it is important to adopt a relatively general and flexible demand specification, which has a number of desirable properties.

Demand estimation on pharmaceuticals is rather a complex task. Standard economic theory assumes that the decision to purchase a good, to make the payment,

and then to consume it are undertaken by one person. For pharmaceuticals, however, this is hardly ever the case. Indeed, this decision may involve as many as four different people: the doctor, who chooses and prescribes the drug; the pharmacist, who may choose among branded or generic substitutes; the insurer, who may pay in full or for a portion of the spending on drug; and the patient, who consumes the drug and may also influence the choice of drug and make partial or full payment. The details of this decision-making process vary from country to country and depend on various institutional and economic circumstances; for instance, freedom of the doctor to prescribe the drug he finds most suitable for the patient, policies which may encourage generic substitution, the availability and design of health insurance plans, and the patient's income.

Next subsection offers the discussion of the available modeling alternatives for the estimation of demand in differentiated products markets. It also sketches the application of the Multistage Almost Ideal Demand System model (our specification choice) to the demand for antihypertensive drugs in Thailand.

4.4.2 Modeling the Demand for Pharmaceuticals: An Overview

In this study, we are interested in estimating empirical model of consumer behavior for two main reasons: to infer firm conduct and to measure change in consumer welfare. An important part of evaluating the possible impact of TRIPS-Plus involves trying to understand pharmaceutical firm conduct. Unfortunately, we have little data to study firm conduct directly. Therefore, the basic exercise is to first estimate consumer behavior, then use the demand estimates to "reverse engineer" firm behavior and use a particular theory to simulate a counterfactual. Especially, we could estimate how consumers choose among different types of medicines, that is, on-patent branded drugs, off-patent branded drugs, domestic generics, and imported generics, and use the estimates to compute the consumer's price sensitivity. Given this price sensitivity, we can compute how the firms change their pricing behavior as a result of change in environment, say due to a change in IPR regime. Another reason in estimating consumers' demand pattern is to measure change in consumer welfare. In particular, the main objective of this paper is to evaluate the consumer welfare loss from the introduction of TRIPS-plus.

Modeling the demand for pharmaceutical products in Thailand has usually faced two challenges. The first one is that because in Thailand many drugs can be bought only with prescription and, due mainly to the introduction of the Universal Coverage (UC) of Health Care Scheme in 2002, a large number of Thai consumers are covered by health insurance,[52] agency and moral hazard issues can have significant implications for the estimated demand patterns and their interpretation.

A second challenge is that the pharmaceutical market is a classic differentiated product market. Even with narrowly specified therapeutic segments, consumers often have a choice among products containing different active ingredients, of varying vintages and levels of therapeutic efficacy, produced by companies with varying reputations of quality. Besides, such products are available in multiple presentations, i.e., combinations of dosage forms (tablet, capsule, suspension, etc.), strength (10 milligrams, 20 milligrams, etc.), and package sizes (10 capsule blister pack, 100 tablet bottle, etc.). Even if we define products by aggregating across the multiple presentations, where drugs containing the same active ingredient are marketed by a particular manufacturer, the number of products in the segment of interest is large. The multiplicity of differentiated product poses problems for the standard techniques of demand estimation.

However, over the last couple of decades, new approaches and techniques have been proposed for the estimation of demand parameters in differentiated products markets. Among them, the two approaches that have been used most frequently in empirical work are the multistage budgeting approach and the discrete-choice framework. (Appendix D., D.12)

In the case of pharmaceuticals, the discrete-choice approach presents some difficulties, both conceptual and practical. At a conceptual level, the basic assumption of unit demand by individual consumer that underlies the discrete choice framework seems untenable. Moreover, it is well known that computationally tractable versions

[52] In terms of health security coverage in Thailand, in early stage the non-government sector played the major role. Particularly, around two-thirds of the healthcare costs came from household out-of-pocket payments. However, after the launch of the Universal Coverage (UC) of Health Care Scheme in 2002, the ratio of government and non-government expenditure on health has thoroughly reversed. The impact of the UC healthcare scheme absolutely changed the structure of health expenditure. In 2008, the UC scheme became a major financing agent, having the biggest number of members, contributed nearly one-fourth of total health expenditure whereas the Civil Servant Medical Benefit Scheme (CSMBS) and the household out-of-pocket had their share around one-fifth of total health expenditure. See Section A.2 in Appendix A for more details.

of discrete choice models tend to exaggerate the welfare effects of product entry and exit, as the implied demand functions never intersect the vertical exit, i.e., product demand can never become zero (put differently, the implied virtual prices are infinity). This feature arises because the presence of an idiosyncratic error term in the underlying utility function implies a taste for variety; consequently, each additional product generates an increment in utility, and the product space can never become too crowded. In practice, the consequences of this aspect of discrete choice models for welfare analysis can be mitigated through the adoption of relatively general functional form (e.g., random coefficient model) and/or the use of micro data (Petrin, 2002; Berry and Pakes, 2007). Unfortunately, we do not have micro data in the current application. Besides, it is not a good strategy for us to adopt an approach that would, by its nature, tend to overstate the welfare effects of product entry and exit because such approach can mislead us (and, eventually, the policy makers) about the optimal intellectual property policy choice.

In practical terms, the discrete choice approach requires data on physical sales shares (as opposed to revenue shares). If the analysis were limited to sales of pharmaceutical products containing a single molecule of active ingredient, this would not pose a problem as the data on the quantity of the relevant active ingredient (e.g., 20 milligrams of enalapril) are available in the database. But if the analysis were to be extended to include pharmaceutical products containing other molecules that represent close therapeutic substitutes, it is not clear that physical sales shares are very meaningful. For instance, 20 milligrams of enalapril are not directly comparable with 20 milligrams of ramipril. In this context, the discrete choice approach would be unappealing as the therapeutic efficacy of a drug is not completely captured by its observed characteristics but vary by patient (consumer). When working with data, one quickly learns that product attributes can explain some of the differentiation among products, but far from all of it.

For all reasons, we base our estimation strategy on a multistage budgeting approach. The basic idea of this approach is to use the therapeutic classification of a product, that is, the therapeutic segment and sub-segment the product belongs to, to organize all products in the antihypertensive segment into a hierarchical taxonomy, consisting of two levels. At the higher level are various sub-segments of antihypertensive

drugs segment. The first stage of budgeting then corresponds to the allocation of expenditures across sub-segments in the upper level of the taxonomy.

In the second stage of the budgeting process, corresponding to the lower level of the taxonomy, a flexible functional form is adopted to model how the expenditures allocated to each sub-segment are distributed across the product groups within a sub-segment. Especially, to model demand at the second stage we employ a relatively general and flexible demand specification, namely the linear approximation version of an Almost Ideal Demand System (AIDS) specification, widely known as the Linear Approximate Almost Ideal Demand System (LA-AIDS).

The two-stage demand estimation approach we propose presents many advantages; functional form flexibility is one of them. While the a-priori segmentation of the product space at the higher level imposes some restrictions on the demand patterns, the substitution patterns implied by the AIDS specification at the lower level are very general, as they permit in theory an unconstrained pattern of conditional cross-price elasticities across product groups within a sub-segment. Given that competition among differentiated products tends to be highest within sub-segments, this lack of restrictions at the lower stage is a significant advantage of AIDS over alternative approaches. An additional advantage is that the AIDS model, though developed with micro data in mind, aggregates perfectly over consumers without requiring linear Engel curves; consequently, it is commonly used to estimate price and income elasticities of the demand for goods when expenditure share data are available. This is important here, because in this paper we work with aggregate data. Lastly, the implied demand curves intersect the price axis, so that the virtual price is not infinity. Subsection 4.4.3 shall describe in detail the Multistage Expenditure Allocation Models together with an Almost Ideal Demand System (AIDS), the theoretical model and empirical specification of demand we employ in this study.

4.4.3 Demand for Pharmaceuticals in Thailand: A Multistage Almost Ideal Demand System Approach

4.4.3.1 Multistage Budgeting as an Economic Decision-Making Process : A Way to Construct a Multilevel Demand System

An economist who wishes to investigate patterns of consumption is always faced with the problem caused by the immense number of commodities and

services available to the consumer. An analysis of a complete demand system, consisting of thousands of equations, would require huge quantities of data and computer memory. Within the basis of a time-series analysis, such an exercise is well-nigh impossible.

The usual way to address this problem is to assume a priori some sort of structure in the consumers' preferences, the most common assumption being that of weak separability. This approach implies that commodities can be partitioned into a number of separate groups, where a change in price of a commodity in one group affects the demand for all commodities in another group in the same manner. In addition, the practitioner will often also assume (at least implicitly) a multistage decision process, where expenditure is allocated between groups using price indices, and where within-group allocation is performed independently. (Appendix C., C.2.2)

Multistage budgeting is very common in economics literature. The idea was originally developed by Strotz (1957, 1959) and Gorman (1959) as a two-stage budgeting process for the estimation of broad categories of products such as food, clothing and shelter. This method postulates that consumers allocate total expenditure first to broad groups of goods, based on a price index for each group, and then further allocate expenditure within each of these groups, based on group individual prices and group expenditures. An idea of two-stage budgeting is thoroughly described in Subsection C.2.3, Section C.2, Appendix C.

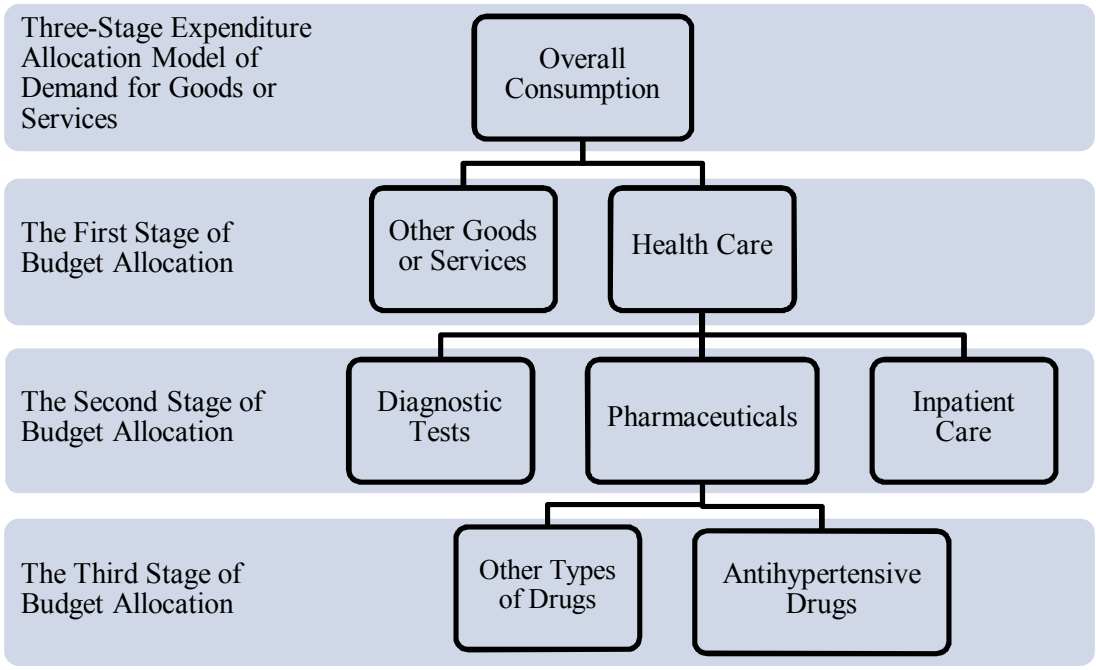

Figure 4.1 Utility Tree of Individual Demand for Goods or Services

To deal with the complexity on the decision process of human consumption, we utilize the idea of multistage budgeting to construct a multilevel demand system for differentiated pharmaceutical products. Specifically, we adopt in this study a separable demand model using the concept of multistage budgeting as an economic decision-making process to estimate the demand for oral antihypertensive drugs that are regularly used in outpatient care. In particular, the empirical demand specification is based on an Almost Ideal Demand System (AIDS), which offers several desirable properties. We hypothesize that the individual utility derived from the use of antihypertensive drugs is weakly separable from quantities of all other types of goods consumed. Consequently, consumers follow a multistage process to allocate their budget to antihypertensive products. The multistage expenditure allocation model is illustrated in Figure 4.1. Initially, the total spending is allocated to broad categories of goods or services, such as health care versus other types of good or services. The health care spending is then separated in subgroups, such as pharmaceuticals, diagnostic tests and inpatient care. Given the prevalence of the hypertension, the budget share for pharmaceuticals is assigned to antihypertensive

drugs and other types of drugs. Finally, the choice is among different categories of antihypertensive drugs according to their therapeutic attributes, their efficacy and safety, the patients' conditions and the cost of treatment.

4.4.3.2 Two-Stage Expenditure Allocation Model of Demand for Drugs Used in the Treatment of Hypertension

The demand for pharmaceuticals has been investigated in studies by Ellison et al. (1997) and Chaudhuri et al. (2006). Their focuses are on the structure of the demand for two therapeutic categories of antibiotics, i.e., cephalosporins and quinolones, respectively. Demands are modeled in two stages. Firstly, a particular substance is singled out from a set of substances; then, a brand/generic version of the product is chosen. This approach is suitable for the analysis of products within a specific therapeutic category since the substances, which are the members of the same category, constitute close therapeutic substitutes and may be similar in terms of their therapeutic efficacy. The model relies on the hypothesis that decisions of physicians within a given therapeutic category do not depend on the availability of alternative therapeutic categories but are based on the specific names of substances.

We argue however that this scenario may not reflect the doctors' view correctly. Indeed, doctors tend to be concerned with the efficacy and safety of broad categories of pharmaceuticals, each including a set of active ingredients with similar characteristics. Doctors may then choose from among a limited set of therapeutic categories classified according to common practice, standard treatment regimen, patients' underlying diseases, and shared beliefs regarding their efficacy and safety. More precisely, at the first stage a decision has to be made on a particular chemical entity chosen from among a limited set of therapeutic categories to fight the patient's disease. This choice usually rests with the doctor who prescribes the substance. Although no two different chemical entities (within a selected category) have exactly the same effect, they are intimate therapeutic substitutes which fight the same disease. Unless the doctor makes his decision for a particular drug on a purely medical basis, the prices of different close substitutes may influence the doctor's choice of which chemical entity to prescribe. Once a particular substance has been selected, a second decision has to be made on the particular brand supplying this chemical entity. This decision is either made by the doctor, the pharmacist, and/or the patient. It is primarily

influenced by the patient's budget and brand loyalty induced by marketing and advertising, as well as by past experience.

The present study intends to investigate the structure of the demand for antihypertensive drugs in Thailand by modeling the decision process of rational patients.[53] We are interested specifically in the price and income sensibility of the modern generation of antihypertensive therapeutic categories, i.e., beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system. Similar to previous work, we model the demand for antihypertensive drugs as a two-stage budgeting problem but do not separate all specific substances. Instead, we consider a wider set of substances (i.e., therapeutic categories), those that can be prescribed for common treatment of hypertension. In the first stage, antihypertensive drugs are aggregated into three main groups according to what are plausible alternatives in the treatment of hypertension, one of which is a group of the modern generation of antihypertensive medicines (henceforth modern generation). In the second stage, modern generation is divided into four sub-groups: on-patent branded drugs (original drugs that were still under patent protection during the period of investigation), off-patent branded drugs (original drugs that patents have already expired), domestic generics (generic drugs produced domestically), and imported generics (generic drugs imported from abroad). The allocation of drug expenditure across sub-groups within modern generation is analyzed using the linear approximation of an Almost Ideal Demand System (AIDS) specification. The AIDS model is chosen here because the expenditure share data are available. We then compute conditional own- and cross-price elasticities between sub-groups within modern generation group. We also estimate conditional expenditure elasticities for each sub-group belonging to the modern generation.[54] The method to estimate parameters is the Zellner (1962)'s Iterative Seemingly Unrelated Regression (ISUR) with parameters restrictions of adding up, homogeneous of degree zero in prices and symmetry. For a more complete discussion as to the SUR model, see Appendix E.

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[53] We are aware that patients take decisions about the use of antihypertensive drug(s) under doctor's advice. However, as suggested by several studies, e.g. Cockburn and Pit (1997), doctors' decisions are also influenced by their patients' preferences. Hence we can plausibly assume that the final decision about consumption is made by patients.

[54] Because we are interested only in the price and income sensibility of the *modern generation* group, this model is thus estimated only at the second stage of the two-stage budgeting process.

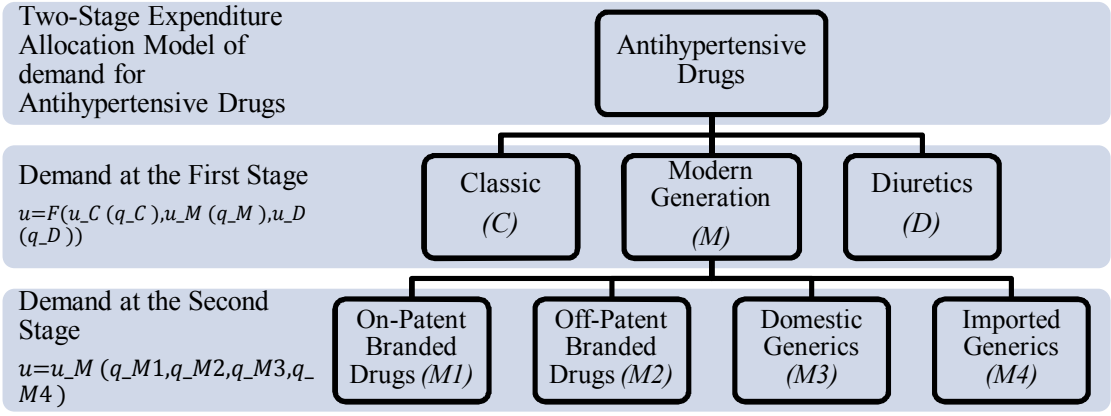

Figure 4.2 Utility Tree of Individual Demand for Antihypertensive Drugs

Note: We divide expenditures on antihypertensive drugs into 3 main groups:

1) Modern generation. Expenditure on beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system.
2) Diuretics. Expenditure on low-ceiling diuretics, high-ceiling diuretics, potassium-sparing agents, and other diuretics.
3) Classic. Expenditure on therapeutic categories of antihypertensive drugs other than modern generation and diuretics. For instance, antiadrenergic agents, agents acting on arteriolar smooth muscle, and so on.

More specifically, this study applies the two-stage, weakly separable budgeting method (Strotz, 1957; Gorman, 1959) as a patient's decision-making process to estimate the demand for antihypertensive drugs in Thailand. Using Thai annual time-series of pharmaceutical expenditures and prices for the period 1996 to 2008, we then choose, as demand model for the parametric analysis, a static version of the Linear Approximate Almost Ideal Demand System (LA-AIDS), proposed by Deaton and Muellbauer (1980a). We assume that the individual utility derived from the use of antihypertensive drugs is weakly separable from quantities of all other types of pharmaceutical products consumed (Figure 4.1).[55] Consequently, a rational

[55] The weak separability of preference hypothesis is both necessary and sufficient for the estimation of demand function in a second stage of a two-stage budgeting structure. To be more exact, Gorman (1959) proposed that if the sub-utility functions of the second stage are homothetic then price indexes are independent of utility. In this respect, Deaton and Muellbauer (1980b) proved that if the sub-utility functions are homothetic, then the cost

patient follows a two-stage process to allocate his/her budget to antihypertensive products. A two-stage budgeting model with preference structure is assumed as given in Figure 4.2.

As illustrated in Figure 4.2, a patient first decides with respect to the purchase of three major groups of antihypertensive drugs, namely, classic (C), diuretics (D), and modern generation (M)[56]; and, second, with respect to the four sub-groups that are included in the modern generation group, that is, the purchase of on-patent branded drugs (M1), off-patent branded (M2), domestic generics (M3), and imported generics (M4). In what follows q_i denotes the quantity demanded of i^{th} good, p_i represents the corresponding nominal price and y denotes total expenditure (or income) on the three aggregate groups of antihypertensive drugs. Thus, the utility function corresponding to the two-stage budgeting process of the patient can be written as

$$u = F\big(u_C\,(q_C), u_D(q_D), u_M(q_{M1}, q_{M2}, q_{M3}, q_{M4})\big)\,,$$

where $u_g(\cdot)$ are homothetic sub-utility functions that depend on a subset q_g of one or more goods. $F(\cdot)$ and the sub-utility functions $u_g(\cdot)$ satisfy the classical conditions of monotonicity and quasi-concavity.

As can be seen from Figure 4.2, the patient first maximizes the utility function $u = F\big(u_C\,(q_C), u_D(q_D), u_M(q_M)\big)$, subject to the budget constraint and, second, once he or she has determined the quantity (q_M) and expenditure (y_M) destined to a particular aggregate good, in this case, *modern generation*, he should then allocate this expenditure among the specific goods which are included in the aggregate, thus maximizing $u = u_M(q_{M1}, q_{M2}, q_{M3}, q_{M4})$.[57]

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function is proportional to utility. Consequently, the price index is independent of utility. Appendix C, Section C.2, Subsection C.2.3, shows in more detail for this matter.

[56] The classification of antihypertensive drugs in the first stage of the expenditure allocation process in this study is adapted from the ATC classification system. For the detailed classification of antihypertensive drugs, see the classification of drugs used in cardiovascular system (C02-Antihypertensives, C03-Diuretics, C07-Beta blocking agents, C08-Calcium channel blockers and C09-Agents acting on the renin-angiotensin system) in the Guidelines for ATC classification and DDD assignment 2009 (WHO Collaborating Centre for Drug Statistics Methodology, 2009: 102).

[57] Gorman's theory of two-stage budgeting suggests two alternative approaches to modeling consumer behavior. The first is based on a utility function for each consuming unit that is additive in sub-utility functions for all

In sum, we assume in our model of consumer behavior that individual expenditures on antihypertensive drugs are allocated so as to maximize an individual utility function. We require that both of the two systems of individual demand functions that result from the two-stage allocation process are integrable. These demand functions can be generated by Shepard's lemma from expenditure (cost) functions for each individual consumer. This model of the two-stage allocation process results in two systems of individual demand functions. The first stage of the process generates a system for the allocation of antihypertensive drugs expenditure among three main groups, i.e., classic (C), diuretics (D), and modern generation (M). The second stage of the process produces a system for the allocation of modern generation group expenditure among its four subgroups, i.e., M1, M2, M3 and M4. The system of individual demand functions for the allocation of modern generation group expenditure corresponds to homothetic preferences so that demand functions for all subgroups within group M are proportional to modern generation group expenditure.

By the way, the analysis of consumer allocation of personal consumption expenditures among antihypertensive products is of interest in this study. The study of expenditure patterns over time provides insights about important factors such as relative prices and income that will affect future consumption patterns. In general, economists can analyze the extent of competition between products in a differentiated product industry using measures called the 'own and cross price elasticities of demand.' The own price elasticity of demand measures the responsiveness of a product's demand to its own price. The own price elasticity is formally defined as the percentage change in demand for the product that would result from a 1 % increase in the product's price. The cross price elasticity of demand measures the responsiveness

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commodities groups. Under this restriction the group utility functions must correspond to indirect utility functions having the generalized Gorman polar form. An important advantage of this approach is the possibility of exact aggregation over consumers at the second stage of the budgeting process. A significant disadvantage is the imposition of the restriction on elasticities of demand implied by additivity at the first stage of the process. The second approach to consumer demand modeling suggested by the theory of two-stage budgeting is based on homothetic separability. The utility function of each consuming unit is not required to be additive, but sub-utility functions for all commodity groups must be homothetic. In this study, our model of consumer demand treats individual subgroups of *Modern Generation* group as homothetically separable from *Classic* and *Diuretics* groups. In modeling consumer demand for antihypertensive drugs we permit price and income elasticities to be determined empirically. As discussed beforehand, the cost of this flexibility at the first stage is that consumer demands for individual subgroups of *Modern Generation* group at the second stage are required to be proportional to total expenditure of *Modern Generation* group. For a detailed and comprehensive discussion on this topic, see Section C.2, Subsection C.2.3 in Appendix C.

of demand for one product, say product A, with respect to the price of a second product, say product B. The cross elasticity of demand for product A with respect to product B's price is formally defined as the percentage change in the demand for product A that would result from a 1% change in product B's price. The larger the cross elasticity of demand between two products, the closer the two products are as substitutes in the eyes of consumers. These elasticities can be calculated if the demand functions for the products in the industry are known or have been econometrically estimated.

In this study, we address econometric methods for analyzing competition between antihypertensive drugs in the Thai pharmaceutical market using 'aggregate-level' data that provides information on price and expenditure aggregated over individual consumers. In order to estimate a demand system for antihypertensive drugs, obtaining the necessary aggregate-level data of drug prices and expenditures is only the first step. A particular specification, or functional form, for the demand system must also be chosen. Particularly, we suggest that a flexible functional form be used for the demand specification. A flexible functional form leaves the own and cross price elasticities of demand free to be estimated from the data. A non-flexible functional form, on the other hand, may impose restrictions on the demand elasticities, which can lead to biased results.

Subsection 4.4.3.3 sums up concisely different approaches to the derivation of theoretically plausible demand systems. The choice of functional form for demand estimation and some of the considerations that go into choosing a demand system specification are also discussed in this subsection. More accurately, a brief theoretical discussion of demand systems together with their properties is presented first. Separability conditions that allow for aggregation across commodities and specific classes of preferences that allow for consistent aggregation across consumer are then discussed. After dealing with some of the considerations that go into choosing a demand system specification, a description of the AIDS, i.e., the flexible functional adopted in this study, is given in Subsection 4.4.3.4, together with a detailed discussion of its strengths and weaknesses in comparison with other demand system specifications.

4.4.3.3 Demand System Specification and Estimation

1) Approaches to Estimating Models Consistent with Demand Theory: The Models of Individual Consumer Case

Essentially there are two different approaches to the derivation of theoretically plausible demand systems. One approach starts with a well-behaved utility function that satisfied certain axioms of choice. Maximization of the utility function subject to the budget constraint yields a set of simultaneous demand functions. By specifying a particular utility function, a demand system is obtained from this optimization process. For instance, the linear expenditure system (LES) is derived from the Klein-Rubin utility function. See, e.g., Powell (1974). An alternative approach starts with an arbitrary demand system and then imposes restrictions on the system of demand functions. Restrictions include the homogeneity conditions, Slutsky symmetry constraints, etc. Examples of this approach are given in Court (1967); Byron (1970); and Heien (1982, 1983).

There are four properties that all theoretically plausible demand systems should satisfy. They are 1) adding up, 2) homogeneity, 3) symmetry, and 4) negativity. For completeness, a brief description of each will be given. For a more detailed discussion, see Section C.3 in Appendix C.

The adding-up restriction states that the budget shares of both ordinary and compensated demand functions sum to one; equivalently, the total value of ordinary and compensated demands sums to total expenditure. The homogeneity condition is that the quantity demanded remains unchanged if all prices and income increase by the same proportion. Restated, this says that there exists no money illusion. Slutsky's symmetry condition is that the compensated cross-price derivatives or elasticities are equal. The negativity restriction relates to the matrix of compensated price derivatives. It states that the matrix of substitution terms must be negative semi-definite. This, in turn, implies that the diagonal elements, compensated own-price derivatives, are non-positive. This can alternatively be expressed by saying that the compensated demand curve is downward sloping, i.e., the "law of demand" holds. Some of the theoretically plausible demand systems automatically satisfy these conditions while the more flexible forms allow the demand analyst to test them. Adding-up, homogeneity, and Slutsky symmetry are usually invoked a priori or tested in empirical demand system models.

With the development and increased popularity of duality concepts, currently there are four equivalent ways of representing consumer preferences, namely, 1) specifying a utility function and solving the maximization problem, 2) specifying an indirect utility function and applying Roy's identity, 3) specifying an expenditure function and applying Shephard's lemma, and 4) taking a differential approximation to the demand system. For a detailed and inclusive discussion regarding alternative approaches to modeling demand, see Appendix D.

The primary advantage of these duality relationships is that theoretically plausible demand systems can be obtained by relatively simple differentiation rather than by direct optimization techniques. In addition, desirable properties of the underlying preferences (and resultant demand systems) oftentimes can be obtained more easily by employing different representations other than the traditional direct utility function. More will be said about these issues when we discuss the derivation of the almost ideal demand system (AIDS). However before we deal with the derivation of the AIDS (that is, the empirical specification of demand for antihypertensive drugs in this study), some important theoretical and applied properties of demand systems will be discussed.

2) Aggregation across Commodities

The theory of consumer behavior is based on an individual consumer's preferences. However, data are usually only available for aggregate commodity groups and aggregate groups of consumers. What are the conditions that will allow us to consistently treat aggregate groups of commodities and consumers given that our theory is based on micro relationship? The first of these problems, aggregation across commodities, has been solved by using separability concepts. The latter problem will be discussed in the next subsection.

A direct utility function is weakly separable if and only if the marginal rate of substitution between any two commodities belonging to the same group is independent of the level of consumption of a third commodity in any other group, i.e.,

$$\frac{\partial\left(\mathrm{U}_i/\mathrm{U}_j\right)}{\partial q_k} = 0 \quad \text{for } i, j \in I \text{ and } k \notin I, \tag{4.1}$$

where U_i, U_j are marginal utilities associated with commodities i and j, respectively, belonging to group I, and q_k is the quantity of the k^{th}good, which does not belong to group I. Strong separability implies that the marginal rate of substitution between two commodities is unaffected by the consumption of a third commodity which may belong to the same group of commodities as i and j. See Appendix C, Section C.2, Subsection C.2.2, for a more comprehensive discussion of separability concepts. See also Phlips (1974), and Deaton and Muellbauer (1980b).

Closely related to the concept of strong separability is additive preferences (e.g., Phlips (1974)). Preferences are additive if the direct utility function, U, except for a monotonic transformation, can be written as the sum of different functions that can be expressed only in terms of the quantities of commodities appearing in that particular group. That is,

$$U(q_1, q_2 \dots, q_n) = \sum_{i=1}^{n} f_i(q_i), \tag{4.2}$$

where $f_i(\cdot)$ is a function whose arguments are the quantities of commodities appearing in the i^{th}group. The LES is an example of a demand system derived from additive preferences.

What are the theoretical and empirical implications of assuming different forms of separability? First, separability assumptions usually result in the reduction of the number of unknown parameters to be estimated. The demand analyst can concentrate on aggregate commodity groups. Weak separability is a necessary and sufficient condition for the second stage of two-stage budgeting (Deaton and Muellbauer, 1980b: 124). This allows, for example, one to focus on the demand for pharmaceutical items. The quantity or expenditures on pharmaceuticals can be expressed as a function of the prices of pharmaceutical items and total pharmaceutical expenditure. Price changes in other groups only affect the quantities demanded of pharmaceutical items through their impact on total pharmaceutical expenditure. However, separability restrictions are not imposed without some costs. Strong separability (additivity) implies, among other things, that there exists an approximate linear relationship between price and income elasticities (Deaton, 1975). This is a very serious limitation that runs counter to most empirical results.

Thus for highly disaggregate commodities such as pharmaceutical items, more flexible forms that do not impose additivity should be employed. The AIDS will be used in this study to analyze the demand for antihypertensive drugs. Some of the justifications will become more apparent later, but for now the AIDS does not imply additive preferences and the limitations that are associated with this class of preferences.

3) Aggregation across Consumers

So much has been done concerning aggregation across commodities that it led Muellbauer (1975: 525) to conjecture that, probably no really new results remain to be discovered. However, the same cannot be said about the problem of aggregation across consumers. The usually approach has been to assume identical preferences across consumers, express variables in the demand function in per capita terms, and summarily invoke the representative consumer argument. More specifically, it is assumed that by expressing aggregate demand functions in per capita terms, the theoretically micro or individual results approximately carry over to the aggregate or market demand functions. But this line of argument has little theoretical foundation.

Muellbauer (1975, 1976) has obtained conditions under which consistent aggregation across consumers is permitted. If preferences belong to a price independent generalized linear (PIGL) class, then market demands can be represented as if they were the outcomes of decisions by a rational representative consumer (Deaton and Muellbauer, 1980a: 313). Necessary and sufficient conditions that permit consistent aggregation across consumers can be stated in terms of the budget shares or expenditure (cost) functions. In terms of budget shares, $w_i = p_i q_i / y$, where p_i represents price, $q_i$represents the quantity demanded, and y is total expenditure, the individual budget share equations must have the "generalized linear" (GL) form:

$$w_{ih} = \mathrm{v}_h(y_h, \mathbf{p})\mathrm{A}_i(\mathbf{p}) + \mathrm{B}_i(\mathbf{p}) + \mathrm{C}_{ih}(\mathbf{p}), \tag{4.3}$$

where h represents the h^{th} family, $\mathbf{p}$ denotes a price vector, and $\mathrm{v}_h, \mathrm{A}_i, \mathrm{B}_i,$ and C_i are functions satisfying $\sum_i \mathrm{A}_i = \sum_i \mathrm{C}_{ih} = \sum_h \mathrm{C}_{ih} = 0$, and $\sum_i \mathrm{B}_i = 1$ (Deaton and Muellbauer, 1980a: 323). With respect to the expenditure or cost function, in order for individual behavior to be preference consistent it must take the form

$$\{c(u_h, \mathbf{p})/\mathrm{k}_h\}^{\alpha} = (1 - u_h)\{a(\mathbf{p})\}^{\alpha} + u_h\{b(\mathbf{p})\}^{\alpha}, \tag{4.4}$$

where c represents the cost function, u the utility level of the h^{th}family, k_h represents family composition effects, and $a(\mathbf{p})$ and $b(\mathbf{p})$ are functions of the price vector $\mathbf{p}$. When α approaches zero, we obtain the price independent generalized logarithmic (PIGLOG) form

$$\log\{c(u_h, \mathbf{p})/\mathrm{k}_h\} = (1 - u_h)\log\{a(\mathbf{p})\} + u_h\log\{b(\mathbf{p})\}, \tag{4.5}$$

where $a(\mathbf{p})$ and $b(\mathbf{p})$ are linear homogeneous concave functions. For particular forms for $a(\mathbf{p})$ and $b(\mathbf{p})$ and with $\mathrm{k}_h$taken to be unity (because lack of data on individual family compositions), the AIDS can be derived from this expenditure function. It can also be shown that the LES, the quadratic utility function, a weakly restricted form of the indirect translog and the AIDS are members of the PIGL class. Thus, these demand systems are derived from preferences that allow consistent aggregation across consumers. See Deaton and Muellbauer (1980a: 324-325).

4) Functional Forms and Hypothesis Testing

Traditional functional forms such as the double-log or LES have frequently been used to empirically analyze consumer expenditure patterns. However, they have some serious limitations. For example, the double log form implies constant price and income elasticities over time. See Appendix D, Section D.2, Subsection D.2.1. Additionally, these functional forms imply a rigid relationship between quantities demanded, and prices and income. To circumvent some of these problems, more flexible functional forms have been developed. Examples include: the direct and indirect translog, quadratic expenditure system, S-branch, Laurent, generalized Leontief, AIDS, and Fourier transformation equations. The first seven models are sometimes interpreted as providing (local) second-order approximations to arbitrary twice differentiable demand systems while the Fourier transformation has the capability in principle of providing global approximations to arbitrary demand systems (Gallant, 1981).

One major advantage of these flexible functional forms is that they allow for the testing of some of theoretical restrictions such as symmetry,

homogeneity, and negativity. Oftentimes, nonflexible forms automatically impose these restrictions. Another advantage of flexible functional demand equations is that they allow price and income elasticities to vary over time, thereby letting the data determine the empirical values. Also, flexible forms take on constant elasticities as special cases. For an example of the Box-Cox flexible form, see Pope, Green and Eales (1980).

While these so-called flexible forms have some distinct advantages over their more inflexible counterparts, there are some disadvantages. As an illustration consider the Box-Cox flexible form. A Box-Cox transformed demand equation has the form:

$$q_{it}^{(\lambda)} = \beta_0 + \beta_1 p_{1t}^{(\lambda)} + \cdots + \beta_n p_{nt}^{(\lambda)} + \beta_{n+1} y_t^{(\lambda)} + u_{it} \quad , i = 1, \ldots, n; t = 1, \ldots, T \,, \quad (4.6)$$

where q_{it} is the per capita quantity demanded of the i^{th}commodity in time period t, p_{jt} is the corresponding price of the j^{th} commodity, y_t is per capita disposable income, and λ is the transformation parameter and u_{it} is a disturbance term.

Estimation of this function may yield the maximum value of the likelihood function, give the best fit, and provide more flexible patterns for elasticity movements over time, but yet not make much sense from an economic viewpoint. What is the economic interpretation of a likelihood estimate of, say, $\hat{\lambda}$ = -3? Such an estimate is not ruled out on a priori grounds and a value of this size may occur rather frequently.

How does the Fourier approximation compare with the AIDS and other flexible and nonflexible forms? The Fourier flexible form introduced in Gallant (1981) is given by:

$$\frac{p_i q_i}{y} = \frac{x_i b_i - \sum_{\alpha=1}^{A} \left\{ u_{0\alpha} x' k_\alpha + 2 \sum_{j=1}^{J} j \left[u_{j\alpha} \sin(j k'_\alpha x) + v_{j\alpha} \cos(j k'_\alpha x) \right] \right\} k_{i\alpha} x_i}{b' x - \sum_{\alpha=1}^{A} \left\{ u_{0\alpha} x' k_\alpha + 2 \sum_{j=1}^{J} j \left[u_{j\alpha} \sin(j k'_\alpha x) + v_{j\alpha} \cos(j k'_\alpha x) \right] \right\} k_\alpha x}, \quad (4.7)$$

where $p_i q_i / y$ is the i^{th} expenditure share, x the income normalized prices, i.e., $x = p/y$ where p is price and y is income, the k's are multi-indexes and $\sin(\cdot)$

and cos (·) are trigonometric functions. This system obviously has desirable flexibility properties, but it may introduce artificial cyclical effects due to the sine and cosine terms. However, statistical partial F-tests should indicate non-significant results in the absence of cyclical effects. Even if partial F-tests are statistically significant, the question still remains: What are the economic factors associated with this type of change (King, 1984)? Another disadvantage of this form is that it does not permit consistent aggregation across consumers.[58]

We think the choice of the preferred system remains an empirical issue since there are advantages and disadvantages for each system. The LES, quadratic system, a weak form of the translog, and the AIDS all permit consistent aggregation across consumers whereas the "Fourier" demand system does not. The Fourier series approximation on the other hand allows for global approximation properties and more general relationships for the patterns of elasticities over time.

The bottom line of this discussion on flexible functional forms appears to be one of a tradeoff between imposing plausible economic restrictions versus possibly better data fitting with less economically plausible forms. This tradeoff will be made more explicit in the next subsection. Concerning hypothesis testing and functional forms, it is well known that the test for the validity of restrictions also implicitly tests for the functional form. That is, the specific model chosen and the particular constraint being tested are confounded. Thus, it is important to allow for as much generality or flexibility in the underlying model as possible, *ceteris paribus*, in which to carry out the proposed tests. Some of the demand systems, as mentioned previously, do not allow for testing of some of the particular demand properties. They are automatically satisfied from the system's specification.

5) Considerations in Choice of Demand System Specification

The need to understand the competitive interactions among a group of products arises in a number of regulatory settings and litigation. For example, in the case of TRIPS-Plus enforcement, the extent to which Thai consumers

[58] To prove that the Fourier flexible form is not derived from the PIGL class of preferences, it is necessary and sufficient to demonstrate that the budget share can be expressed in the form $w_i = v(y,p)\mathrm{A}_i(p) + \mathrm{B}_i(p)$; see Muellbauer (1975, 1976). After several manipulations of the Fourier budget share form, it can be shown that it cannot be expressed in the form given by Muellbauer. Thus the Fourier form does not belong to the PIGL class of preferences.

would suffer the welfare loss depends upon how closely the generic medicine competes with the original branded product in the eyes of consumers. The closer the competition, the greater the consumer welfare loss would be expected to be. Similarly, in a patent infringement case, the extent to which the patent-owner has suffered lost sales is subject to how closely the infringer's product competes with the patent-owner's product. The closer the competition, the larger the lost sales would be likely to be.

As mentioned previously, economists often summarize the extent of competition between products in a differentiated products industry using the own and cross price elasticities of demand. These elasticities can be calculated if the demand functions for the products in the industry are known or have been economically estimated. In estimating a demand system, a particular specification, or functional form, for the demand system must be chosen. However, misspecification of the consumer demand system can result in biased econometric results and misleading conclusions. In this respect, we suggest that a 'flexible functional form' be used for the demand system specification. While, a flexible functional form leaves the own and cross price elasticities of demand free to be estimated from data, a non-flexible form may impose restrictions on the demand elasticities, which can lead to biased results.

A reliable competitive analysis in turn requires reliable estimates of the own and cross price elasticities of demand (or, more generally, the demand functions for the set of products at issue). Reliable elasticity estimates in turn require an appropriate choice of demand system specification. There are two types of considerations in the choice of specification: econometric considerations and theoretical considerations.

(1) Econometric Considerations

In general, when choosing an econometric specification, a tradeoff exists between the flexibility of the specification to reflect the characteristics of the observed data and the statistical precision of the elasticity estimates. A less flexible specification generally has fewer parameters to estimate and thus may lead to more precise elasticity estimates. On the other hand, being less flexible, the specification may fail to fit the data well, which could induce bias into the elasticity estimates. In other words, the specification may fail to capture important characteristics

of the data. During 1980's econometricians realized the importance of using 'flexible functional forms' that place a minimal (or no) restrictions on the estimated values of the demand elasticities.[59]

Classical statistical testing procedures may not be useful for helping to choose between alternative specifications where one alternative demand system specification is not nested within one another, a situation that often arises. While non-nested testing procedures could be used to choose between specifications, another approach is to use the more flexible specification as long as it produces acceptable levels of precision in the elasticity estimates.

(2) Theoretical Considerations

Under the economic theory of consumer choice a demand system must satisfy three properties: Slutsky symmetry, homogeneity of degree zero in price and total expenditure, and adding up. Section C.3 in Appendix C shows an inclusive discussion on these properties. Some demand specifications allow these properties to be easily imposed and tested, while other specifications do not. Generally, one would want to impose the restrictions implied by these properties because certain calculations of interest (e.g., consumer welfare calculations) would not be valid if the demand system did not satisfy the properties of consumer demand. On the other hand, empirical demand studies have often found that the properties of consumer demand are rejected by statistical tests. Thus, the ability to both impose and test the properties of consumer demand is valuable property for a demand system specification.

A second theoretical consideration relates to whether the demand system specification can be obtained by aggregation over individual consumers. A demand system and its associated properties are derived at the level of the individual utility-maximizing consumer. The question is whether the demand system and its properties transfer over to the aggregate-level data that is obtained by aggregating over individual consumers. In that case, the aggregate level demand can be treated as the demand of a 'representative consumer' and the estimated demand

[59] Pollak and Wales (1992: 60) defined a flexible functional form as being "capable of providing a second order approximation to the behavior of any theoretically plausible demand system at a point in the price-expenditure space. More precisely, a flexible functional form can mimic not only the quantities demanded, the income derivatives and the own-price derivatives, but also the cross-price derivatives at a particular point." See also Diewert (1971: 481) and Deaton (1986), for a definition of flexible functional forms.

system should exhibit the appropriate properties. In particular, the welfare of the representative consumer (i.e., from the estimated demand system) is equal to the true consumer welfare, i.e., the aggregation of welfare over individual consumers. If the demand system cannot be obtained by aggregating over consumers, there is no guarantee that the demand system estimated on aggregate-level data will exhibit the appropriate properties and that the consumer welfare calculated from the demand system will be equal to the true consumer welfare. See Deaton and Muellbauer (1980b: 148-159).

In the following subsection, we shall focus on the Almost Ideal Demand System (AIDS), a flexible functional form demand system adopted in this study. We first discuss its strengths and weaknesses in comparison with other demand system specifications and then describe the AIDS specification.

4.4.3.4 Empirical Specification of Demand for Antihypertensive Drugs: A Linear Approximate Almost Ideal Demand System (LA-AIDS)

1) Attributes of the AIDS specification

Deaton and Muellbauer (1980a) first developed the Almost Ideal Demand System (AIDS). They listed the advantages of their system as follows: it gives an arbitrary first-order approximation to any demand system; it satisfies the axioms of choice exactly; it aggregates perfectly over consumers without invoking parallel linear Engel curves; it has a functional form which is consistent with known household-budget data; it is simple to estimate in its linear approximate form; and it can be used to test the restrictions of homogeneity and symmetry through linear restrictions on fixed parameters. They also noted that although many of these desirable properties are possessed by one or other of the Rotterdam or translog models, neither possesses all of them simultaneously. See Deaton and Muellbauer (1980a: 312).

Blanciforti and Green (1983) noted an additional desirable property that the AIDS is indirectly non-additive, allowing consumption of one good to affect the marginal utility of another good, whereas the linear expenditure system (LES) is directly additive, implying independent marginal utilities. Therefore, the AIDS does not require the strict substitution limitations implied by the additive models such as LES. While the AIDS has many desirable properties, it is difficult to

estimate as it is non-linear in parameters. To simplify this problem, Deaton and Muellbauer suggested using a linear approximation for the reason that the estimated coefficients in a Linear Approximate Almost Ideal Demand System (LA-AIDS) models are easier to estimate and interpret. Several studies have shown that the AIDS and LA-AIDS models are equivalent or superior to other common demand specifications such as translog (Lewbel, 1989), Rotterdam (Gao, Wailes and Cramer, 1994), and LES (Green, Hassan and Johnson, 1995). Because of its desirable advantages, the AIDS model along with LA-AIDS has been extensively employed in empirical work as regards both macro- and micro-demand analysis. See, e.g., Chalfant (1987) and Green and Alston (1990). The AIDS model has a number of desirable properties as we now discuss.

(1) Flexibility

AIDS has a high degree of flexibility in the econometric sense described previously. It is derived from an expenditure function that is a second order approximation to any expenditure function; thus, it is a flexible functional form demand system. Consequently, the AIDS demand specification is a first order approximation to any demand system (Deaton and Muellbauer, 1980a: 312). This result implies that even if the true underlying demand system is not AIDS, AIDS will nevertheless provide a reasonably accurate approximation at any set of prices not too far from the point of approximation. For this reason, a flexible demand system has considerable advantages over an inflexible demand system in terms of reliably estimating the cross price elasticities of demand.

The downside to flexibility is the large number of parameters that need to be estimated. Even after imposing Slutsky symmetry and homogeneity of degree zero (as described in the following issue), estimation of the most parsimonious flexible functional form demand system (e.g., AIDS) with N products, will generally require the estimation of at least $(N^2 + 3N - 4)/2$ parameters. For example, a system with 10 products would have at least 63 parameters.

(2) Imposing and Testing Consumer Demand Properties

AIDS allows for easy imposition and testing of the properties of consumer demand. Slutsky symmetry can be imposed through setting$\gamma_{ij} = \gamma_{ji}$ for $i = 1, \dots, N$ and j $= 1, \dots, N$. Then, the cross price derivatives of

compensated demand for products i and j will be equal as required by Slutsky symmetry. This condition is generally required to do valid consumer welfare calculations. Similarly, homogeneity of degree zero can be imposed by setting $\sum_{j=1}^{N} \gamma_{ij} = 0$ for $i = 1, \ldots, N$. Then, the share for each product i will not change if total expenditure Y and all prices p_j are increased by the same percentage. Adding-up requires, in addition to the other restrictions, $\sum_{i=1}^{N} \alpha_i = 1$ and $\sum_{i=1}^{N} \beta_i = 0$ since the revenue shares must sum to one across products.

The above-mentioned parameter restrictions can be imposed during estimation. Alternatively, the restrictions can be tested using standard statistical methods after estimation of the AIDS model.

(3) Aggregation

AIDS at the aggregation level can be obtained through aggregation over individual consumers (Deaton and Muellbauer, 1980a: 312). Thus, AIDS estimated on aggregation-level data can be treated as the demand system for a representative (typical) consumer. The demands and welfare calculations for this representative consumer will appropriately reflect the aggregated demands and welfare of the individual consumers.

2) Comparison with Other Demand Systems

As already described, the AIDS has several desired features. We now compare the AIDS with other widely used demand systems and show that these other systems generally do not possess as many desirable attributes as the AIDS.

(1) Logit

The logit model of consumer demand has been proposed for use in merger analysis and other situations under certain conditions. See, e.g., Werden and Froeb (1994), Werden, Froeb and Tardiff (1996) and Werden, Froeb and Beavers (1999). The logit model has the advantages that it is easy to estimate, that it satisfies the restrictions of consumer demand, and that it aggregates across individual consumers.

However, logit is not very flexible. As is well-known, logit exhibits the independence of irrelevant alternatives (IIA) property (McFadden, 1981: 222-223). This property constrains the cross price elasticity of product *i* with respect to product *j*'s price to be equal for all *i*. In other words, cross elasticities of demand

with respect to a particular product's price are all equal. See, for instance, Hausman (1975: 517), McFadden (1981: 222) and Hausman and Leonard (1997: 322). To derive this result, start with the equation for the quantity share of product *i* under the logit model:[60]

$$\pi_i = \frac{\exp(\alpha p_i + Z_i\gamma)}{\sum_{j=1}^{N} \exp(\alpha p_j + Z_j\gamma)} \ . \tag{4.8}$$

The cross elasticity of product *i* with respect to product *j*'s price is derived by differentiating (4.8) with respect to p_j and multiplying by p_j/π_i, which yields

$$\frac{p_j}{\pi_i}\frac{\partial \pi_i}{\partial p_j} = -\frac{p_j}{\pi_i}\frac{\exp(\alpha p_i + Z_i\gamma)}{[\sum_{k=1}^{N} \exp(\alpha p_k + Z_k\gamma)]^2} \exp(\alpha p_j + Z_j\gamma)\,\alpha = -\alpha p_j \pi_j \ . \tag{4.9}$$

As equation (4.9) demonstrates, the cross elasticities for all products *i* ($i \neq j$) with respect to the price of product *j* are equal to the same value, $-\alpha p_j \pi_j$. Note that this cross price elasticity value is driven by π_j, the quantity share of product *j*. If product *j* has a large quantity share, its cross price elasticities will be large for all other products.

It is easy to think of examples where this property will fail to hold. Consider a case of an industry consisting of several branded 'premium' products with large industry shares and several 'economy' products with smaller shares. One would expect that the economy brands would compete more closely with each other than they do with the branded premium products. That is the cross price elasticities between the economy products are larger than the cross price elasticities between the economy products and the branded premium products. Logit cannot capture this situation because it would force the cross elasticity of branded premium product A with respect to the price of economy product B to be the same as the cross elasticity of economy product C with respect to the price of economy product B.

[60] For ease of exposition, equation (4.8) assumes that each consumer inflexibly purchases one unit from the category. The logit model can be generalized to allow for an "outside alternative," i.e., a choice for consumers not to purchase any product in the category. However, the conclusion regarding equal cross price elasticities continue to hold in the logit model with an outside alternative.

This property of logit is highly undesirable when the goal of a given analysis is to determine how closely two or more products compete with each other. A demand specification that severely limits the values that the cross price elasticities can take could result in badly biased cross price elasticity estimates and, hence, incorrect conclusions concerning the extent of competition between products.

(2) Nested Logit

Nested logit models improve upon the basic logit model by grouping products into 'nests.' See, e.g., Berry (1994). Products within a nest are allows to compete more closely with each other than they do with products outside the nest, thus reducing the problem of equal cross price elasticities. The problem is not entirely eliminated, however, since the cross price elasticities within a nest are still constrained to be equal.

In addition, the nested logit is somewhat more difficult to estimate than the basic logit. Moreover, the econometrician must decide how to group products into nests. While external information (e.g., market research) and statistical testing procedures can aid in these decisions, an element of judgment is still involved.

(3) Random Effects Logit

A relatively new extension to the logit model is 'random effects' logit or 'mixed' logit. See, for example, Berry et al. (1995). This model can be thought of as assuming that each consumer has logit demand, but that consumers differ in the value weights they place on price and other product attributes. As a result, aggregate demand does not exhibit the equal cross price elasticity property although the property continues to hold for each individual. For example, people who bought a Toyota station wagon and place a good deal of weight on having a station wagon would be more likely to switch to a Honda station wagon than to a sports car if the Toyota station wagon price were to increase. In aggregating over individuals, the people who choose station wagons largely determine the cross price elasticities among station wagons, while the people who choose sports car largely determine the cross price elasticity of sports cars with respect to station wagons. Therefore, in the aggregate, the cross price elasticities among station wagons are large and the cross price elasticities of sports cars with respect to station wagons are small.

The random effects logit has the advantage that it requires that substantially fewer parameters be estimated than a typical flexible functional form such as AIDS. However, this benefit comes at the cost that the random effects logit is substantially more difficult to estimate than AIDS in a typical application. In addition, although it is less restrictive than the basic logit model, the random effects logit may not have the flexibility to perform as well as AIDS in many situations.

In the one direct comparison of which we are aware, the results for AIDS and the random effects logit were similar in some respects, but different in others (Nevo, 2000). A topic for future research is determining the conditions under which the random effects logit or, alternatively, a flexible functional form would be preferred.

(4) Log-Log Demand

A log-log demand system takes its name from the fact that the log of a product's quantity is related to the logs of the prices of all the products as well as the log of category expenditure. Specifically, under the log-log specification, the demand equation for product *i* is

$$\log q_i = \alpha + \beta \log Y + \sum_{j=1}^{N} \gamma_{ij} \log p_j \qquad (4.10)$$

where q_i is the quantity of product i, Y is category expenditure, p_j is the price of product j, and α, β, and γ_{ij}'s are parameters to be estimated.

The log-log demand system is flexible in that it can approximate any demand system at a given set of prices. It is also relatively easy to estimate in an unrestricted fashion. Imposing the restrictions of consumer theory is however not straightforward. More accurately, imposition of the adding-up restriction is problematic. See Deaton and Muellbauer (1980b: 17) for a detailed discussion on this point. Besides, the log-log system as applied to aggregate-level data cannot be obtained through aggregation over individuals. Finally, the log-log system has the undesirable attribute that the elasticities of demand are constant for all prices. Thus, although the log-log system might approximate a general demand system at the point of approximation, it may fail to approximate it well as one moves away from the point of approximation.

(5) Other Flexible Demand Systems

A wide variety of other flexible demand systems exists such as the various translog forms. See, e.g., Pollak and Wales (1992: 53-59) and Deaton (1986: 1788-1793). These systems share many of the properties of the AIDS. However, they are generally not as easy to estimate as the AIDS because of non-linearity in the share equations. A topic for future research is the comparison between the AIDS and translog forms in terms of how well they perform moving away from the point of approximation.

3) Empirical Implementation of the AIDS Expenditure Share Equation

To determine the functional form of the demand equations resulting from the constrained maximization of the utility function for the second stage of an individual decision-making process, we use a static version of the Almost Ideal Demand System (AIDS), following Deaton and Muellbauer (1980a).[61] We assume that an individual consumer allocates his/her total modern generation group expenditure among subgroups of group *M* in accord with the homothetic preference (i.e., the homothetic expenditure function). Demand functions in budget share form are derived from a natural logarithmic differentiation of the expenditure function with respect to prices. Put another way, the approach to deriving demand equations is to specify the form of the cost function and then apply the Shephard's (1953, 1970) lemma. In this respect, the consumer cost function is dual to the utility function in that it gives the minimum expenditure needed to reach a specified level of utility, when given the prices. The cost function is also referred to as the expenditure function.

More precisely, in our model of consumer behavior the individual expenditure function derived from the consumer theory is aggregated across individuals to obtain the expenditure on antihypertensive drugs in the local

[61] The AIDS developed by Deaton and Muellbauer (1980a) builds on a model by Working (1943) and Leser (1963). Their model expresses the i^{th} budget share (w_i) as a function of log Y (where Y is total per capita expenditure), i.e., $w_i = \alpha_i + \beta_i \log Y$. The Working-Leser model was extended by Deaton and Muellbauer to include the effect of prices. The resultant demand system was derived, by use of duality concepts, from a particular cost or expenditure function, i.e., equation (4.11). Deaton and Muellbauer chose this cost function because it was flexible, it represented preferences that permit exact non-linear aggregation over consumers, and it resulted in demand functions with desirable properties. See Deaton and Muellbauer (1980a: 313).

market area.[62] Muellbauer (1975, 1976) showed that exact aggregation is possible within a specific family of preferences. These preferences are known as the price independent generalized logarithmic (PIGLOG) class of preferences. The PIGLOG class can be denoted by the following expenditure function, which is the minimum expenditure necessary to attain a certain utility level at any given price:

$$\log c(u, \mathbf{p}) = (1-u) log\{a(\mathbf{p})\} + u log\{b(\mathbf{p})\}, \tag{4.11}$$

where u is the level of utility ranging from 0 to 1, $a(\mathbf{p})$ and $b(\mathbf{p})$ represent the positive linearly homogeneous functions of a price vector $(\mathbf{p})$ to be specified. The expenditure function in equation (4.11) includes two components. While the expenditure $\log a(\mathbf{p})$ is interpreted as necessary expenditure, the expenditure $\log b(\mathbf{p})$ is interpreted as luxury expenditure. It is shown that the expenditure function is increasing in utility and non-decreasing in prices.

Next we take specific functional forms for $\log a(\mathbf{p})$ and $\log b(\mathbf{p})$. For the resulting cost function to be a flexible functional form, it must possess enough parameters so that at any single point its derivatives $\partial c/\partial p_i$, $\partial c/\partial u$, $\partial^2 c/\partial p_i \partial p_j$, $\partial^2 c/\partial u \partial p_i$, and $\partial^2 c/\partial u^2$ can be set equal to those of an arbitrary cost function. Following Deaton and Muellbauer (1980a), we assume

$$\log a(\mathbf{p}) = \alpha_0 + \sum_i \alpha_i \log p_i + \frac{1}{2}\sum_i \sum_j \gamma_{ij}^* \log p_i \log p_j \tag{4.12}$$

and

$$\log b(\mathbf{p}) = \log a(\mathbf{p}) + \beta_0 \prod_i p_i^{\beta_i}, \tag{4.13}$$

[62] Aggregation theory provides the necessary conditions under which the aggregate demand, i.e. the representation of market demand, can be treated as if it was the outcome of the decisions of a rational representative consumer (Muellbauer, 1975). More specifically, the AIDS model was originally developed with micro data in mind, so that Y_M and w_i^M in (4.20) refer to an individual expenditure and expenditure share respectively. However, Muellbauer (1975, 1976) and Deaton and Muellbauer (1980a) show that exact aggregation over individuals is possible so that equation (4.20) can be applied in nearly identical form to aggregate data, with w_i^M denoting the aggregate conditional expenditure share of product (sub) group *I*, and Y_M denoting the average expenditure of a representative consumer. Thus interpreted, equation (4.20) can be estimated with aggregate product level data on expenditure (revenue) shares, prices, and average individual expenditure.

where $\alpha_0, \alpha_i, \beta_0, \beta_i,$ and γ_{ij}^* are parameters, and i and j are indexes representing different subgroups within *modern generation (M)* group. Substituting for $\log a(\mathbf{p})$ and $\log b(\mathbf{p})$ in (4.11) we can write the cost function as

$$\log c(u, \mathbf{p}) = \alpha_0 + \sum_i \alpha_i \log p_i + \frac{1}{2}\sum_i \sum_j \gamma_{ij}^* \log p_i \log p_j + u\beta_0 \prod_i p_i^{\beta_i}, \quad (4.14)$$

which is linearly homogeneous in prices, given that the following restrictions on the parameters hold

$$\sum_i \alpha_i = 1, \sum_i \gamma_{ij}^* = \sum_j \gamma_{ij}^* = 0, \sum_i \beta_i = 0. \quad (4.15)$$

By differentiating equation (4.11) with respect to prices and applying Shepard's lemma, we then obtain the compensated or Hicksian demand functions.[63] That is,

$$\frac{\partial c(u, \mathbf{p})}{\partial \mathbf{p}_i} = q_i(u, \mathbf{p}) = q_i \ . \quad (4.16)$$

Multiplying both sides by $p_i / c(u, \mathbf{p})$, equation (4.16) becomes:

$$\frac{\partial \log c(u, \mathbf{p})}{\partial \log p_i} = \frac{\partial c(u, \mathbf{p})}{\partial p_i} \times \frac{p_i}{c(u, \mathbf{p})} = \frac{p_i q_i(u, \mathbf{p})}{c(u, \mathbf{p})} = w_i^M(u, \mathbf{p}) , \quad (4.17)$$

where $w_i^M(u, \mathbf{p})$ is the expenditure share of the i^{th} subgroup[64] within *modern generation (M)* group.

According to the cost function from equation (4.14), equation (4.17) becomes

$$w_i^M = \phi_i + \sum_j \gamma_{ij} \log p_j + \beta_i u \beta_0 \prod_i p_i^{\beta_i} \ , \quad (4.18)$$

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[63] The demand functions can be derived directly from cost function, i.e., equation (4.11) and (4.14). It is a fundamental property of the cost function that its prices derivatives are the quantities demanded, as illustrated by equation (4.16). See Shephard (1953, 1970), or Diewert (1971, 1974).

[64] i^{th} Subgroup = subgroup *M1, M2, M3, M4* within group *M*.

where $\gamma_{ij} = \frac{1}{2}(\gamma_{ij}^{*} + \gamma_{ji}^{*})$. (4.19)

Since total expenditure for antihypertensive drugs in *modern generation (M)* group, Y_M[65], is equal to $c(u, \mathbf{p})$ in equilibrium for a utility-maximizing consumer, by solving for u (indirect utility) in terms of $\mathbf{p}$ and Y_M from equation (4.14)[66], and substituting the result into equation (4.18), we obtain the AIDS in budget share form as:

$$w_i^M = \phi_i + \sum_j \gamma_{ij} \log p_j + \beta_i \log \frac{Y_M}{P} \ , \tag{4.20}$$

where P is a price index defined by

$$\log P = \alpha_0 + \sum_i \alpha_i \, log \, p_i + \frac{1}{2} \sum_i \sum_j \gamma_{ij} \, log \, p_i \, log \, p_j . \tag{4.21}$$

The following restrictions are implied by equation (4.15) and (4.19)

$$\sum_i \gamma_{ij} = \sum_j \gamma_{ij} = 0 , \gamma_{ij} = \gamma_{ji} \quad , \forall \, i, j \ (i \neq j) \tag{4.22}$$

Provided that (4.15), (4.19) and (4.22) hold[67], the equation (4.20) defines a system of demand functions. These are homogeneous of degree zero in prices and total expenditure and satisfy the Slutsky symmetry. The total expenditure is then given by $\sum w_i^M = 1$.

The interpretation of the demand share summarized by (4.20) is straightforward. Without any change in relative prices and expenditures, i.e., the second and the third terms of the right-hand side of the equation, the budget shares of different subgroups within group *M* are constant. Changes in relative prices affect the

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[65] We define $Y_M = \sum_i p_i q_i$ as the total expenditure on antihypertensive drugs within group *M*, where p_i and q_i represent the price and the quantity for the i^{th}subgroup by the representative consumer.

[66] More specifically, total expenditure Y_M is equal to $c(u, \mathbf{p})$ in equilibrium for a utility maximizing consumer. Hence, $c(u, \mathbf{p})$ can be inverted to give $u(\mathbf{p}, Y_M)$, which is the indirect utility function.

[67] Restated, this says that the basic demand is restricted by the three conditions: (i) adding-up, (ii) homogeneity and (iii) symmetry.

demand share through the term γ_{ij}. These capture the effect on the i^{th} budget share from a one percent increase in price of the j^{th} subgroup within group *M*, with Y_M/P held constant. Changes in real expenditure are taken into account by parameter β_i, which is assumed equal to zero.

Put differently, the static AIDS model, i.e. equation (4.20), expresses the budget share for a particular group of antihypertensive drugs as a function of prices and real antihypertensive expenditure. The coefficients have the following interpretation:

ϕ_i = intercept: average budget share when all logarithmic prices and real expenditures are equal to one.

β_i = expenditure coefficient: change in the i^{th} budget share with respect to a percentage change in real antihypertensive expenditure with prices held constant.

γ_{ij} = price coefficient: change in the i^{th} budget share with respect to a percentage change in the j^{th} price with antihypertensive expenditure held constant.

The share equation also underlines some basic properties of the demand function. Other things being equal, the expenditure share of each group of commodities is inversely associated with its own price and is positively related to the price of other goods. The expected sign of γ_{ii} is then negative. On the other side, γ_{ij} should exhibit a positive sign for any $i \neq j$ if goods are close substitutes.

The demand for antihypertensive drugs may also be affected by variables other than prices that account for expenditure shifts. For instance, socioeconomic characteristics of the population and aspects of health care supply may also affect the use of antihypertensive drugs. However, these aspects may be of little relevance in the demand share of different classes of antihypertensive drugs, unless they shape preferences for specific antihypertensive categories.

4.4.4 Estimation Procedure

The initial specification of model (4.20) generates equations that are non-linear in their parameters. Specifically, in practice the translog price index in equation (4.21) causes some empirical problems. First, its specification makes the AIDS a non-linear econometric model; consequently, it is difficult to estimate the model (Deaton and Muellbauer, 1980a). Second, the prices in equation (4.21) are likely to be highly correlated, and the high correlation among prices can cause collinearity problems. However, Buse (1994) used the AIDS model to estimate meat consumption in the U.S. and concluded that the collinearity among prices in the AIDS model was not a serious problem as was presumed in the literature.

Nevertheless, several studies have replaced the translog price index, log *P*, by the Stone's (1954a) index, log P^*, where $\log P^* = \sum w_i \log p_i$, and P^* is assumed to be approximately proportional to *P*, such that $P^* = \alpha_0 P + e$, and w_i is the expenditure (revenue) share of the i^{th} good. See, e.g., Deaton and Muellbauer (1980a), Chalfant (1987), Cotterill (1994) and Vickner and Davies (1999).

Consequently, by using the Stone's (1954a) index the AIDS has been termed the "Linear Approximate Almost Ideal Demand System" (LA-AIDS). Thus, equation (4.20) becomes

$$w_i^M = \alpha_i + \sum_j \gamma_{ij} \log p_j + \beta_i \log \frac{Y_M}{P^*} \ , \tag{4.23}$$

where $\alpha_i = \phi_i + \beta_i \alpha_0$. Using the Stone's index makes the LA-AIDS in equation (4.23) a much simpler estimation problem. This can be done by calculating the Stone's index directly and then treating the total expenditure, $\log(Y_M/P^*)$ in equation (4.23), as a predetermined variable before estimating equation (4.23) using OLS regressions (Deaton and Muellbauer, 1980a). Deaton and Muellbauer (1980a) suggest that by using the Stone's index, the model becomes linear in parameters, and the estimation can be done equation by equation by OLS, which is equivalent to maximum likelihood estimation for the system as a whole. What is more, treating the Stone's index as exogenous can reduce the collinearity problem (Chen, 1998). Deaton and Muellbauer estimated an eight-commodity demand system using aggregate

annual UK data from 1954 to 1974 and concluded that there was no significant difference between the parameters obtained from the AIDS and the LA-AIDS. Alston, Foster and Green (1994) conducted the Monte Carlo experiments in which data were generated by the LA-AIDS to investigate whether the Stone's index is a good approximation. They concluded that demand analysts can consequently have a certain degree of confidence when estimating the LA-AIDS. As a result, the LA-AIDS model has been a popular tool for researchers in the analysis of both macro- and micro-demand system. See, for instance, Deaton and Muellbauer (1980a), Blanciforti and Green (1983), Chalfant (1987), Cotterill (1994), Asche, Bjørndal and Salvanes (1998), Henneberry, Piewthongngam and Qiang (1999) and Vickner and Davies (1999).

Chalfant (1987), Green and Alston (1990) and Alston et al. (1994) suggested elasticity formulas that can be used with the parameters obtained from the LA-AIDS and the Stone's index. The formula of the (conditional) uncompensated partial own- and cross-price elasticities of demand (ε_{ij}) suggested by Chalfant (1987), Green and Alston (1990), and Alston et al. (1994) is:

$$\varepsilon_{ij} = \frac{d\ln Q_i}{d\ln P_j} = -\delta_{ij}^K + \frac{\gamma_{ij}}{w_i} - \beta_i \frac{w_j}{w_i} \ , \qquad (4.24)$$

where δ_{ij}^K is the Kronecker delta ($\delta_{ij}^K = 1$ for $i = j$ and $\delta_{ij}^K = 0$ for $i \neq j$), w_i and w_j are average budget shares of good i and j, and γ_{ij} and β_i are parameters estimated from the LA-AIDS. Several studies used this elasticity formula in their work. Alston et al. (1994) conducted the Monte Carlo experiments to examine the appropriate formula to compute elasticities. They found that the results calculated from equation (4.24) are preferably accurate relative to alternatives as it is a reasonably good approximation to those calculated from the true AIDS.

The formula of the (conditional) expenditure elasticity for the i^{th} subgroup of group M (η_i) can be derived from either the Slusky equation or a computational approach (i.e., differentiating equation (4.23) with respect to $\log Y_M$ and doing some transformation). The computational procedure is now shown as follows:

$$\frac{\partial w_i^M}{\partial \log Y_M} = \beta_i \implies \frac{\partial w_i^M}{\partial Y_M} = \frac{\beta_i}{Y_M} \Rightarrow \frac{p_i}{Y_M^2}\frac{Y_M \partial q_i - q_i \partial Y_M}{\partial Y_M} = \frac{\beta_i}{Y_M} \Longrightarrow$$

$$\frac{Y_M \partial q_i}{\partial Y_M} = \frac{\beta_i Y_M}{p_i} + q_i \Longrightarrow \frac{Y_M}{q_i}\frac{\partial q_i}{\partial Y_M} = \frac{\beta_i}{w_i^M} + 1 \text{ , i. e. , } \eta_i = \frac{\beta_i}{w_i^M} + 1 \qquad (4.25)$$

The studies of Cotterill (1994), Vickner and Davies (1999), and Cotterill, Putsis and Dhar (2000) estimated the demand system using the LA-AIDS simultaneously with the supply system using price-reaction functions. In particular, they estimated the LA-AIDS employing the Stone's index. It has been found that the Stone's index can cause econometric problems. In this respect, Pashardes (1993) examined the effect of using the Stone's index by comparing analytical expressions and empirical findings obtained from the AIDS model with and without the Stone's index approximation. Pashardes found that the Stone's index causes the parameters estimated to be biased. Similarly, Buse (1994) examined the LA-AIDS using the Stone's index and concluded that the seemingly unrelated estimator of the LA-AIDS was inconsistent.

Another problem of using the Stone's index is the units-of-measurement problem. According to the study of Cotterill et al. (2000), one assumption made in their price-reaction functions was that, so as to observe a manufacturer's wholesale price (P_i^W), the retailer's price (P_i^R) is used as a proxy and assumed to be proportional to its wholesale price. In other words, the wholesale price is scaled by a constant number (m) to represent a proportional markup rule of the retailer's price decision, i.e., $P_i^R = mP_i^W$. Moschini (1995) suggested caution in using the Stone's price index in the LA-AIDS due to the units-of-measurement problem, such as when prices are scaled up. Owing to Moschini's work, the LA-AIDS model with scaled prices could be shown to be different from the original AIDS model, and thus the estimated parameters would generally be biased. Moschini (1995) concluded that for the purpose of estimating the LA-AIDS model, "the standard Stone index should be avoided." Moschini suggested that a price index should meet a desirable property in which an appropriate price index should be invariant to the units of measurement of prices. This desirable property is called the commensurability property (Diewert, 1987; Moschini, 1995). Moschini also suggested that the units-of-measurement problem

may be solved by using a price index that satisfies this property. Moschini recommended several price indices that may be used to maintain the specification of the AIDS linear and that satisfy the commensurability property. The indices recommended by Moschini were the Tornqvist index, the corrected Stone index, and the Laspeyres price index.

The Tornqvist index is written as:

$$\log P_t^T = \frac{1}{2}\sum_{i=1}^{n}(w_{it} + w_i^0)\log\left(\frac{p_{it}}{p_i^0}\right). \tag{4.26}$$

The corrected Stone index is written as:

$$\log P_t = \sum_{i=1}^{n} w_{it}\log\left(\frac{p_{it}}{p_i^0}\right). \tag{4.27}$$

The Laspeyres price index is written as:

$$\log P_t^L = \sum_{i=1}^{n} w_i^0 \log p_{it}\,, \tag{4.28}$$

where the zero superscript denotes base period values, such as mean values. In a Monte Carlo experiment, Moschini found that the LA-AIDS could approximate the AIDS well when the recommended price indices were used.

To put it in a nutshell, the initial specification of model (4.20) generates equations that are non-linear in their parameters; as a result, it is difficult to estimate the model. To solve this problem, many studies follow Deaton and Muellbauer (1980a) and use the Stone's (1954a) index. However, it is widely cited that applying the Stone's index causes the units-of-measurement error as prices will never be perfectly collinear. The Stone's index does not satisfy the commensurability property of index numbers because it is not invariant to changes in the units of measurement for prices. One of the solutions to correct the units-of- measurement error is that prices are scaled by their sample mean.

So as to avoid the non-linear estimation and overcome the measurement error, in this study we follow Moschini (1995)'s suggestion and use the Laspeyres price index, i.e., equation (4.28). Likewise, to avoid simultaneity problems we use the mean values of the expenditure shares to calculate the Laspeyres price index. With this transformation, and adding an error term, ω_i[68], that captures taste shifts and the effects of omitted variables, the stochastic version of the static linear AIDS becomes:

$$w_i^M = \alpha_i + \sum_j \gamma_{ij} \log p_j + \beta_i \log \frac{Y_M}{P_t^L} + \omega_i \,, \tag{4.29}$$

The linear version of the AIDS model defined by (4.29) is adopted in our study to investigate the expenditure shares of the four subgroups of the modern generation of antihypertensive drugs at the lower stage of the two-stage demand system. The LA-AIDS model in equation (4.29) is technically a simultaneous equation system. Therefore, we estimate the model through the Zellner (1962)'s Iterative Seemingly Unrelated Regression (SUR) procedure with the software STATA. During the estimation process, we impose parameter restrictions of adding-up, homogeneous of degree zero in prices, and symmetry. The set of restrictions, specifically the adding-up conditions, leads to a singular residual variance/covariance matrix and, hence, the undefined likelihood function. Consequently, we drop one share equation from the system, i.e., the imported generics (M4) equation, which represents the smallest budget share on average across the four subgroups. Using the estimated parameters of the share equations of the other three groups and the restrictions applied in (4.15) and (4.22), we then obtain the parameters for the dropped equation. See Appendix E, for a more detailed discussion on the SUR estimation approach.

The variances of the estimated parameters for the dropped equation can be obtained by the following equations:

$$var(\hat{\alpha}_{M4}) = \sum_{i=M1}^{M3} var(\hat{\alpha}_i) + 2 \sum_{i=M1}^{M3} \sum_{j=M1}^{M3} cov\left(\hat{\alpha}_i, \hat{\alpha}_j\right), i \neq j \,, \tag{4.30}$$

[68] The random term, ω_i , is normally and identically distributed with variance σ_ε^2.

$$var(\hat{\gamma}_{(M4)(j)}) = \sum_{i=M1}^{M3} var(\hat{\gamma}_{ij}) + 2\sum_{i=M1}^{M3}\sum_{k=M1}^{M3} cov(\hat{\gamma}_{ij}, \hat{\gamma}_{kj}), i \neq k, \quad (4.31)$$

$$var(\hat{\beta}_{M4}) = \sum_{i=M1}^{M3} var\hat{\beta}_i + 2\sum_{i=M1}^{M3}\sum_{j=M1}^{M3} cov(\hat{\beta}_i, \hat{\beta}_j), i \neq j, \quad (4.32)$$

where i =*M1*, *M2*, *M3*, *M4*; j =*M1*, *M2*, *M3*, *M4*; and k =*M1*, *M2*, *M3*, *M4*.

4.4.5 Conditional Expenditure and Conditional Price Elasticities

Since we are interested in studying the response of the demand for different antihypertensive types to changes in price and expenditure, we calculated elasticities at the sample mean of expenditure shares. Following equation (4.24), we derive the conditional uncompensated (Marshallian) own-price elasticity (ε_{ii}) and conditional uncompensated cross-price elasticities (ε_{ij}) as

$$\varepsilon_{ii} = \frac{\gamma_{ii}}{w_i^M} - \beta_i - 1 , \quad (4.33)$$

$$\varepsilon_{ij} = \frac{\gamma_{ij}}{w_i^M} - \beta_i \frac{w_j^M}{w_i^M} , \qquad i \neq j . \quad (4.34)$$

We then use equation (4.25), i.e., $\eta_i = (\beta_i / w_i^M) + 1$, to compute the conditional expenditure elasticity for the i^{th} subgroup of group *M*. A positive value of the expenditure elasticity(η_i) suggests that good i is normal.

The conditional income compensated or net (Hicksian) own-price elasticities (δ_{ii}) and cross-price elasticities (δ_{ij}) are obtained by applying the Slutsky decomposition to equation (4.25) and using the Laspeyres price index in equation (4.28). These can be written as

$$\delta_{ii} = \frac{\gamma_{ii}}{w_i^M} + w_i^M - 1 , \quad (4.35)$$

$$\delta_{ij} = \frac{\gamma_{ij}}{w_i^M} + w_j^M \,, \qquad i \neq j \,. \tag{4.36}$$

Consumer theory suggests that own-price elasticities, i.e. equations (4.33) and (4.35), are negative for ordinary goods. Moreover, if equations (4.34) and (4.36) are positive, the two subgroups within group *M* are cross substitutes, otherwise they are complements.

Using again the Slutsky equation, it is possible to derive a relationship between the compensated cross-price elasticities and expenditure elasticities, that is,

$$\varepsilon_{ij} = w_j^M \sigma_{ij} - w_j^M \eta_i \,, \tag{4.37}$$

where σ_{ij} are the partial elasticities of substitution, also known as the Allen elasticities of substitution, defined as

$$\sigma_{ij} = 1 + \frac{\gamma_{ij}}{w_i^M w_j^M} \quad i \neq j \,. \tag{4.38}$$

The sign of σ_{ij} determines whether the goods *i* and *j* are complements or substitutes. If σ_{ij} is positive (negative), the two goods are substitutes (complements).

4.4.6 Counterfactual Scenarios and Welfare Assessment

4.4.6.1 The Counterfactual Scenarios

Now we turn to the counterfactual simulations of what consumer welfare would have been if Thailand had enforced TRIPS-Plus. The basic counterfactual scenarios we consider here involve only the static loss of consumer surplus that arises from the enforcement of TRIPS-Plus. More precisely, the intention of this paper is to estimate the static (short-run) resource misallocation cost due to an increase in price of branded medicines in the original patentable market. In the short run, to see why the TRIPS-Plus provisions are likely to affect the patented medicine prices, imagine a scenario where the introduction of TRIPS-Plus leads to the prolongation of monopoly pricing in the market for the original patentable molecules

and, hence, upward price adjustment in this market, as producers of patented products re-optimize and set new prices in response to the market exclusivity prolongation. However, the magnitude of any upward adjustments will naturally vary with the degree of competition in the related markets, and with the strength of the cross-price effects.

Turning to the counterfactuals, with the estimated demand parameters in hand we are ready to conduct counterfactual simulations. To measure the changes in consumer welfare, we consider the Thai antihypertensive market under two conditions, with and without the enforcement of TRIPS-Plus. Without the enforcement of TRIPS-Plus (in other words, without market exclusivity extension), medicine prices in the original patentable market would follow the current trend. On the contrary, with the enforcement of TRIPS-Plus, given that all other things being equal, three possible scenarios of 10%, 30%, and 50% increase in price of patented medicines above the current trend are simulated.

More specifically, indeed the range of the estimated welfare loss depends on several factors such as the degree to which foreign pharmaceutical producers respond to stronger IPR (patent) protection, the way IPR (patent) policies are implemented, the extent of national price regulation and the existence of therapeutic substitutes. Accordingly, we simulate in this paper the three possible counterfactual scenarios. The first scenario is the circumstance that the foreign pharmaceutical firms respond weakly to the market exclusivity extension. In this case, the situation of 10% increase in price of medicines in the original patentable market above the current trend is simulated. The second scenario is the situation that drug firms respond moderately; in this case scenario of 30% increase in price level of patented medicines above the current trend is carried out. Lastly, in the situation that firms respond strongly to market exclusivity extension, scenario of 50% increase in price of patented medicines above the current level is performed.

Nevertheless, it is more than likely that in the absence of TRIPS-Plus, generic competition (along with some governmental healthcare policies such as generic use promotion) may lead to more competitive market. Especially, previous studies have found that generic competition causes the prices of brand-name medicines to fall sizably between 30 and 80 percent. See, e.g., Frank and Salkever

(1997) and Malpani (2007). When considering this finding in combination with the historical context of the variation in medicine prices in Thailand, we conclude that the minimum range of price decrease seems to be most likely to occur in the Thai pharmaceutical market. Correspondingly, we assume for the purpose of this study that in the absence of TRIPS-Plus, on average, prices of patented medicines decrease by 20 percent as a result of generic competition. Consequently, we simulate another three counterfactual scenarios. That is, in the absence of TRIPS-Plus, prices of patented brand-name medicines would decrease by 20 % from the trend line due to generic competition; contrarily, in the presence of TRIPS-Plus, the additional plausible scenarios of 10%, 30%, and 50% increase in price of patented medicines above the trend line are carried out, ceteris paribus.

4.4.6.2 Welfare Assessment

By substituting the estimated parameters into equation (4.14), i.e., the expenditure function equation, we are able to calculate the welfare loss, measured in terms of compensating variation (CV), i.e., the additional expenditure that the representative Thai consumer would need to incur to maintain his pre-TRIPS-Plus utility level (i.e., the same level of access to medicines as before enforcing TRIPS-Plus) in the face of the market exclusivity extension for the patented foreign medicines and the accompanying price increases.

Formally, let $\mathbf{P^0}$ denote the price vector before enforcing TRIPS-Plus, $\mathbf{P^1}$ the simulated price vector post TRIPS-Plus, u^0 the utility attained by consumers before TRIPS-Plus, and *E (u,* **P***)* the expenditure (cost) function given by equation (4.14). Then the compensating variation is given by:

$$CV = E(u^0, \mathbf{P^1}) - E(u^0, \mathbf{P^0}) \tag{4.39}$$

where $E(u^0, \mathbf{P^1})$ and $E(u^0, \mathbf{P^0})$ are computed according to (4.14). Note that in this calculation the utility u refers to the utility that the typical Thai consumer derives from the consumption of oral antihypertensive drugs. This is the utility that we keep constant at u^0. We thus ignore potential substitution away from antihypertensive drugs altogether as a result of enforcing TRIPS-Plus. However, we believe that such substitution effects are likely to be very small in practice as hypertension is a chronic disease that patients have to take medicines for their whole life.

In words, equation (4.39) can be explained by the following situation. Initially, the representative Thai consumer (put another way, Thai citizens) consumes the combination $q_{M1}^0, q_{M2}^0, q_{M3}^0, q_{M4}^0$ and obtains utility of $u_M^0 = u_M(q_{M1}^0, q_{M2}^0, q_{M3}^0, q_{M4}^0)$. When the price of *on-patent branded drugs (M1)* rises due to enforcing TRIPS-Plus, the typical Thai consumer would be forced to move to another combination, say $q_{M1}^1, q_{M2}^1, q_{M3}^1, q_{M4}^1$, and obtains utility of $u_M^1 = u_M(q_{M1}^1, q_{M2}^1, q_{M3}^1, q_{M4}^1)$, where $u_M^0 > u_M^1$. As a result, the consumer suffers a loss in utility. However, if the consumer were compensated with extra purchasing power of amount *CV*, the consumer could afford to remain on the u_M^0 indifference curve despite the price rise by choosing combination $q_{M1}^2, q_{M2}^2, q_{M3}^2, q_{M4}^2$ and obtaining $u_M^2 = u_M(q_{M1}^2, q_{M2}^2, q_{M3}^2, q_{M4}^2)$, where $u_M^0 = u_M^2$. The *CV*, therefore, provides a monetary measure of how much the consumer needs if the consumer is to be compensated for the price rise.

Unfortunately, individuals' utility functions and their associated indifference curve maps are not directly observable. However, in practice we can make some headway on empirical measurement by determining how the *CV* amount can be shown on the compensated demand curve. As mentioned earlier, by applying Shephard's lemma, the compensated demand function for *Modern Generation* group, $\mathrm{h}_M(\cdot)$, can be found directly from the expenditure function, i.e. Equation(4.14), by differentiation:

$$\mathrm{h}_M(\mathbf{P}, u) = \frac{\partial E(\mathbf{P}, u)}{\partial p_{M1}}, \tag{4.40}$$

where **P** denotes a price vector of group *M*, i.e., $\mathbf{P} = \{p_{M1}, p_{M2}, p_{M3}, p_{M4}\}$.

Hence, the compensation described in Equation (4.39) can be found by integrating across a sequence of small increments to price from p_{M1}^0 to p_{M1}^1, where $p_{M1}^0 < p_{M1}^1$:

$$CV = \int_{p_{M1}^0}^{p_{M1}^1} dE = \int_{p_{M1}^0}^{p_{M1}^1} h_M(\boldsymbol{P}, u^0) dp_{M1}, \tag{4.41}$$

while p_{M2}, p_{M3}, p_{M4} and utility are held constant.

CHAPTER 5

EMPIRICAL RESULTS

In Chapter 5, the empirical results are prudently presented and discussed. The chapter is structured as follows. Section 5.1 offers the estimated results together with their interpretation. All elasticities calculated from the estimated parameters are also displayed and discoursed in this section. Then, the counterfactual estimates of the potential impact of TRIPS-Plus on consumer welfare and their connotation are reported and described in Section 5.2.

5.1 The Structure of Demand

5.1.1 Estimation Results and Their Interpretation

The LA-AIDS model defined by equation (4.29) is used to inspect the expenditure shares of the four subgroups of group M. Independent variables include the prices of different antihypertensive types and consumer expenditure. All explanatory variables are presented in natural logarithms. Due to the adding-up restriction, the variance/covariance matrix is singular and the likelihood function undefined. The usual procedure followed in this study has been to omit one of the equations in the second stage of the system, to estimate the remaining system and to calculate the parameters in the omitted equation via the adding-up condition. In our case, the omitted equation is the imported generics (M4). Due to the simultaneous equation system, the model (4.29) has been estimated by using the Iterative SUR estimation method of Zellner (1962) with parameter restrictions of adding-up, homogeneous of degree zero in prices, and symmetry.

Table 5.1 displays the results from estimation of the lower-level AIDS system characterizing demand patterns within the modern generation (M) group. Our data

cover three observed units[69], i.e., beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system. As data for these three units of observation were annually available for thirteen years from 1996 to 2008; hence, each equation has been estimated with 39 observations. The coefficient of determination (R^2) suggests that all explanatory variables in this LA-AIDS model explain approximately 83%, 59% and 74% of variations (or variability) in the use of antihypertensive drugs, respectively for subgroupM1(on-patent branded drugs), subgroupM2 (off-patent branded drugs) and subgroupM3 (domestic generics).

As illustrated in Table 1, the price coefficient of independent variable $\log P_{M1}$ in the expenditure share equation w_{M1} is equal to 0.206. The interpretation is that an increase in price of on-patent branded drugs (M1) by 1% will result in a significant increase in expenditure share of on-patent branded drugs(w_{M1}) by 0.206 %, ceteris paribus. Note that this price coefficient is significant at less than 1%. In the case of the expenditure coefficient of independent variable $\log Y_M/P^L$ in the share equation w_{M1}, its meaning can be interpreted as follows. If the real expenditure for antihypertensive drugs in modern generation group (Y_M/P^L) increases by 1%, expenditure share of on-patent branded drugs(w_{M1}) will significantly increase by 0.044%, ceteris paribus; this expenditure coefficient is significant at less than 5%. Likewise, all other coefficients of explanatory variables $\log p_i$ and $\log Y_M/P^L$ in every share equation can be interpreted in the same way as these two instances.

The last line of Table 1 reports the estimated expenditure coefficients, which are, in all but one case, positive and highly significant. The exception is the domestic generics (subgroup M3) for which we estimate a significantly-negative expenditure coefficient. The interpretation is that the impact of consumer expenditure on the demand share of subgroup M1, M2 and M4 is positive and negative for subgroup M3.

[69] In contrast to earlier work, our units of observation are wider sets of substances (i.e., therapeutic categories) rather than specific chemical substances. More specifically, our observed units are three modern antihypertensive categories mostly prescribed for the treatment of hypertension in outpatient care, namely, beta blocking agents, calcium channel blockers, and agents acting on the renin-angiotensin system. Average prices of each modern antihypertensive category have been imputed using expenditure data and quantities. Quantities are measured in days of treatment (DOT) and prices are consequently defined in currency units per one day of treatment (baht per day). A daily dose is standardized by the WHO Defined Daily Dose (DDD) so that all chemical substances within the same category are comparable.

Table 5.1 Parameter Estimates for the Restricted Linear Approximate AIDS Model of Modern Generation Group

	On-Patent Branded Drugs (*M1*)		Off-Patent Branded Drugs (*M2*)		Domestic Generics (*M3*)		Imported Generics (*M4*)	
Mean Budget Share	0.174		0.606		0.169		0.051	
Mean log p_i	2.643		2.865		0.284		0.908	
Observations	39		39		39		39	
R^2	0.826		0.587		0.738		N.A. (Dropped Eq.)	
	Coeff.	S.E.	Coeff.	S.E.	Coeff.	S.E.	Coeff.	S.E.
Constant	-0.832**	0.345	0.250	0.317	1.813***	0.363	-0.231*	0.141
log p_{M1}	0.206***	0.020	-0.016	0.018	-0.188***	0.021	-0.001	0.008
log p_{M2}	-0.109***	0.024	-0.081***	0.022	0.224***	0.026	-0.034***	0.010
log p_{M3}	-0.105***	0.031	0.151***	0.028	-0.036	0.033	-0.010	0.013
log p_{M4}	0.008	0.022	-0.054***	0.020	0.000	0.023	0.045***	0.009
log Y_M/P^L	0.044**	0.021	0.035*	0.019	-0.099***	0.022	0.020**	0.009

Source: Estimated Based on Data from the Thai FDA.

Note: 1) Asterisks (*, **, ***) denote significance at the 10%, 5% and 1% level, respectively.

2) Coefficients of imported generics (M4) is calculated from the adding-up restrictions.

Note, however, that all values are close to zero, implying its low effect on the demand share. Restated, the expenditure coefficients suggest that the influence of consumer expenditure on the demand share of all antihypertensive types is negligible. Moreover, for subgroup M3 the negative sign of its expenditure coefficient cannot be a proof of inferior type of goods, since the dependent variable is the budget share rather than quantity. As reported in Table 5.2, the estimated expenditure elasticities are all positive and statistically significant, indicating that the demand for all types of

antihypertensive drugs within group M is normal. More precisely, different oral antihypertensive types, i.e., on-patent branded drugs, off-patent branded drugs, domestic generics, and imported generics, are normal goods.

Most price coefficients are highly significant with some exceptions[70], but surprisingly the demand for on-patent branded drugs (subgroup M1) and imported generics (subgroup M4) seems to be positively related to their own price and negatively related to the price of other antihypertensive types. However, price coefficients are not very informative at this stage and the results cannot be interpreted as a sign of complementarity rather than substitution with other antihypertensive types. For ease of interpretation, the price elasticities will be analyzed later on in Subsection 5.1.2. Particularly, we investigate in this subsection complementary and substitution effects between antihypertensive types.

5.1.2 Elasticities and Their Inference

Using the estimation results from Table 5.1 and applying the definitions derived in Subsection 4.4.5, we calculate the conditional (i.e., constant expenditure)[71] own-price, cross-price and expenditure elasticities of the demand for different antihypertensive types.[72] The figures are summarized in Table 5.2 and Table 5.3. Some important implications can be straightforwardly derived.[73]

In Table 2, the estimated expenditure elasticities appear in the last column. As expected, these are positive and statistically significant for all types of antihypertensive drugs within modern generation (M) group. The result may suggest that antihypertensive drugs are normal goods and is in accordance with those of Baye, Maness and Wiggins (1997), who estimated that cardiovascular drugs (including antihypertensive drugs) have positive income elasticity (around 0.91). On-patent

[70] Specifically, out of a total of 16 price coefficients we estimate, ten are significant at less than 1% while the rest are insignificant.

[71] As mentioned earlier, the demand system is estimated by assuming weak separability between the consumption of the specific antihypertensive drugs and other goods. The implication of this assumption is that the elasticities are partial elasticities; for instance, they are conditional upon allocation of total expenditure between these particular antihypertensive drugs and other goods.

[72] Elasticities are calculated at the average expenditure shares (mean budget shares) for each of the antihypertensive types, based on the formulas provided by Chalfant (1987), Green and Alston (1990) and Alston et al. (1994).

[73] The elasticities we calculate can provide important insights into how patients (doctors) will respond to the price (income) change (for example, which drug types consumers will substitute towards).

branded drugs (M1), off-patent branded drugs (M2), and imported generics (M4) appear to be "luxuries", or more formally "superiors", with expenditure elasticities greater than unity. This suggests that these product types capture a disproportionate share of incremental sales when consumers choose to spend more in the modern generation (M) antihypertensive segment. The evidence also indicates that domestic generics (M3) can be denoted as "necessities", with expenditure elasticity less than unity. As total spending on modern generation antihypertensive drugs rises, the need for additional consumption of domestic generic medicines is negligible, ceteris paribus.

Table 5.2 Conditional Price Elasticities and Conditional Expenditure Elasticities Evaluated at Sample Mean

	Mean Budget Share	Mean $log\ p_i$	Uncompensated Own-Price Elasticities	Compensated Own-Price Elasticities	Expenditure Elasticities
On-Patent Branded Drugs (*M1*)	17.4%	2.643	0.140***	0.358***	1.253**
Off-Patent Branded Drugs (*M2*)	60.6%	2.865	-1.169***	-0.528***	1.058*
Domestic Generics (*M3*)	16.9%	0.284	-1.114	-1.044	0.414***
Imported Generics (*M4*)	5.1%	0.908	-0.138***	-0.067***	1.392**

Source: Calculated from System Estimates (Reported in Table 5.1) Based on Data from the Thai FDA.

Note: 1) Elasticities calculated at average expenditure shares.

2) Asterisks (*, **, ***) denote significance at the 10%, 5% and 1% level, respectively.

The fourth column of Table 5.2 reports the uncompensated own-price elasticities we estimate, which are all statistically significant at the 1% level, except for the statistical insignificance of the domestic generics (M3) type. The values below unity, in absolute terms, of uncompensated own-price elasticities indicate that, out of the four cases, the two demands are price inelastic, with imported generics (M4) in common with on-patent branded drugs (M1) appearing as the categories which are most insensitive to their own price, -0.138 and 0.140, respectively. By contrast, demand appears to be highly elastic, with the estimated elasticities (in absolute terms), being greater than unity in the remaining product types. More specifically, off-patent branded drugs (M2) together with domestic generics (M3), whose their budget share is 77.5%, is the goods which are the most sensitive to their own price, i.e., -1.169 and -1.114, respectively; the magnitude of these own-price elasticities matches the features of the Thai pharmaceutical market mentioned earlier, which would suggest that most of the Thai consumers are likely to be quite price-sensitive.[74] This might be because in Thailand, during our investigation period, health insurance coverage was so rare and almost all of household health expenses were fundamentally met out-of-pocket.[75] Our result is in line with Cleanthous (2011: 43), who found that poor American patients who are uninsured have a relatively high own-price elasticity, that is, -1.108, of demand for pharmaceuticals. Accordingly, we argue in accordance with our findings that millions of people in developing economies, particularly poor and underprivileged groups, tend to be more price-sensitive than those in developed economies.

Furthermore, it is worth noting that the highest own-price elasticities, in absolute terms, are found for the most expensive antihypertensive type, namely off-patent branded drugs (M2), and the low-cost domestic generic equivalents (M3). The rationale may be that doctors and patients are more likely to increase or reduce the

[74] In developed economies, elasticities of this magnitude have typically only been found for generic drugs or among consumers who lack health insurance.

[75] In Thailand, during 1980-2005, the share of health expenditure from private sector was around 70 percent of total health expenditure. The main source of private health expenditure was the households and employers rather than private health insurance. The portion of private health insurance slightly increased from 2.2 percent of total health expenditure in 1995 to 3.2 percent in 2005. This was no meaning, compared with the part from the households and employers (around 64% of total health expenditure in 2005). Household out-of-pocket spending was not only the largest source of funds for health care in private sector, but in the overall health expenditure as well. During this period, around two-thirds of total health expenses came from household out-of-pocket payments.

consumption of these antihypertensive drugs when their price changes, as these antihypertensive drugs are at least partially used in the treatment of hypertension and have a large number of identical or close therapeutic substitutes (due to an absence of patent protection). Put another way, since the demand for off-patent branded drugs (M2) and domestic generics (M3) is very responsive to variations in relative prices due to the presence of many alternative products in local market area; consequently, drug firms employ price competition (penetration) strategy in order to expand (or at least retain) their market share.

On the other hand, doctors and patients are less likely to substitute away from relatively high-priced, on-patent branded drugs (M1), owing to the absence of identical substitute products. A single source of supply with no short-term alternatives leads to price inelasticity of pharmaceutical demand. In other words, the nonexistence of generic equivalent due to patent protection usually brings about the patent holder, i.e., drug firms, having a free hand to set monopolistic price. Similarly, the demand for imported generics (M4), whose market share is relatively very small (5.1%), exhibits the low responsiveness to changes in their own price despite the fact that there exist several identical or close therapeutic substitutes in local market area. This might be the case of a niche market, which firm aims at satisfying a small, specific market segment; in this case the particular segment could be the prospective patients who wish to consume foreign branded products but not at such high price as products within subgroup M1 and M2. Basically, to maximize revenues and obtain desired profit margin from a particular market segment, firms targeting the niche market segment commonly use the price skimming strategy. That is a firm charges the highest initial price (that buyers are willing to pay) for a time period. As the demand of the first market segment (i.e., high-end buyers) is satisfied, the firm lowers the price to attract another, more price-sensitive segment. Therefore, the skimming strategy gets its name from skimming successive layers of "cream," or buyer segments, as prices are lowered over time. However, this pricing strategy usually results in price inelasticity of demand for a period of time.

For the expected sign, apart from the on-patent branded foreign drugs (M1) for which we estimate positive own-price elasticity, the remaining product types have negative own-price elasticities as the theory predicts. The negative own-price

elasticities of demand, as shown in the fourth and the fifth columns of Table 5.2, suggest that off-patent branded drugs (M2), domestic generics (M3), and imported generics (*M4*) are ordinaries. That is, all else being equal, quantity demanded decreases as the price for the good increases, and vice versa.

Somewhat surprisingly, the estimated own-price elasticity of demand for the on-patent branded foreign drugs (M1) exhibits positive and highly significant value, indicating that they are the distinct group of antihypertensive drugs that will experience an increase in their quantity demanded in response to an increase in their price. In this case, the demand curve exhibits a positive slope rather than the typical, negatively-sloped demand curve of ordinary goods. Normally, the usual law of demand states that the quantity demanded and the price of a commodity are inversely related, other things remaining constant. That is, if the income of the consumer, prices of the related goods, and preferences of the consumer remain unchanged, then the change in quantity of good demanded by the consumer will be negatively correlated to the change in the price of the good. Goods that follow the law of demand are known as "ordinary goods." Indeed, most goods are ordinary. However, in some cases this may not be true. There are two exceptions: one is the case of a Giffen good; another is a Veblen good.

A Giffen good is one which people paradoxically consume more of as the price rises, violating the law of demand. In normal situations, as the price of a good rises, the substitution effect causes consumers to purchase less of it and more of substitute goods. In the Giffen good situation, the income effect dominates, leading people to buy more of the good, even as its price rises. More completely, Giffen good is a special case of inferior good that the income effect may theoretically be large enough (to dominate over and reverse the substitution effect) to cause the demand curve for a good to slope upward. Essentially, there are three necessary preconditions for the Giffen phenomenon to arise. First, the good in question must be an inferior good.[76] Second, there must be a lack of close substitute goods, and lastly the good must constitute a substantial percentage of the buyer's income. The classic example given by Marshall (1895) is of inferior quality staple foods, whose demand is driven by poverty that makes their purchasers unable to afford superior foodstuffs. As the

[76] It is worth noticing that all Giffen goods are inferior goods but not all inferior goods are Giffen goods.

price of the cheap staple rises, they can no longer afford to supplement their diet with better foods, and must consume more of the staple food. Some type of premium goods, such as premium wines or celebrity-endorsed perfumes, are sometimes claimed to be Giffen goods. It is claimed that lowering the price of these high status goods can decrease demand because they are no longer perceived as exclusive or high status products. However, since the perceived nature of the high status goods changes significantly with a substantial price drop, these goods are not considered to be Giffen goods, but rather to be Veblen goods. Aside from the Giffen paradox, the Veblen effect is another one of a family of theoretically possible anomalies in the general theory of demand in microeconomics. The distinction is maintained by the assumption that a change in the price of non-Veblen goods will not significantly change the perceived nature of the good itself.

More specifically, Veblen goods (a.k.a. ostentatious or positional goods), often confused with Giffen goods, are goods for which increased prices will increase quantity demanded. However, this is not because the consumers are forced into buying more of the good due to budgetary constraints (as in Giffen goods). Rather, Veblen goods are high-status goods such as expensive wines, automobiles, watches, perfumes, or jewelry (particularly at the high end, like the Rolls-Royce Phantom and the Rolex). The utility of such goods is associated with their ability to denote status. Decreasing their price decreases the quantity demanded because their status-denoting utility becomes compromised. In short, Veblen goods are a group of commodities for which consumers' preferences for buying them increases as their price increases, as greater price confers greater status, instead of decreasing according to the law of demand.[77]

[77] This "anomaly," however, is mitigated when one understands that the demand curve does not necessarily have only one peak. In fact, the goods generally thought to be Veblen goods are still subject to the curve since demand does not increase with price infinitely. Demand may go up with price within a certain price range, but at the top of that range the demand will cease to increase before it begins to fall again with further price increases. At the other end of the spectrum, where luxury items priced equal to non-luxury items of lower quality, all else being equal more people would buy the luxury items, although a few Veblen-seekers would not. Thus, even a Veblen good is subject to the dictum that demand moves conversely to price, even though the response of demand to price is not consistent at all points on the demand curve. A Veblen effect is named after economist Thorstein Veblen, who first identified the concepts of conspicuous consumption and status-seeking in 1899. See more in a classic article by Leibenstein (1950).

In summary, price elasticity of demand is typically negative for most products; however, Giffen and Veblen goods are two exceptions with positive own-price elasticity of demand. Any good where the income effect more than compensates for the substitution effect is a Giffen good. Unlike Giffen goods, certain goods are meant for conspicuous consumption: they are subject to the Veblen effect in that the higher the price paid, the greater the satisfaction derived. While Giffen good may cause an upward sloping demand curve for an individual at a low price band, Veblen effect also may cause an upward sloping market demand curve but at a high price band (where good is considered worthy of conspicuous consumption).

In our case, the Veblen goods seem to give us the most appropriate explanation for several reasons. First, as mentioned earlier to be a Giffen good it is required that a good must be inferior. However, rather than inferiors the on-patent branded antihypertensive drugs in subgroup M1 appear to be superiors with income elasticity greater than one (1.253), as shown in Table 5.2. Moreover, there still remain various products in the local market area that can be prescribed as the alternatives for the on-patent foreign products, even though at our investigation period there were no identical substitutes as these brand-name drugs were protected by patent. Besides, the Giffen good should demonstrate a relatively low price that the poor and deprived people are forced to curtail their consumption of the more expensive goods and buy more of this low-priced good due to budgetary constraints. But the relative price of a group of the brand-name drugs type M1 is pretty high ($log\ p_{M1}$=2.643), indicating that this incident should be the Veblen effect rather than the Giffen paradox.

For all reasons, we come to the conclusion that positive own-price elasticity of demand for the on-patent branded drugs (M1) reveals the Veblen effect; restated, this say that the positive value of the own- price elasticity of demand for on-patent branded drugs suggests that they are Veblen goods. The rationale is that some patients, particularly high income patients, will purchase brand-name drugs which cost more money for the sole believe that they are of higher quality due to their higher price. Put another way, the patients do get more satisfaction from receiving high-priced, brand-name products as they think higher price signifies higher quality. As a result, they equate price to quantity (in other words, quantity demanded of these brand-name drugs is a direct function of their price) and the market demand curve for

the on-patent branded drugs (M1) would slope the opposite way. A positive low price elasticity of demand for patented branded drugs type M1 (in comparison with a negative high price elasticity of demand for unpatented branded drugs type M2) infers that in the Thai market, medicines are sold under monopolistic competition condition, and patents and product differentiation lead to inelastic high prices.

Another two possible explanations for positive own-price elasticity of demand for antihypertensive drugs type M1 and its price insensitivity are physician agency and moral hazard issues. For the first issue, the rationale adopted here is based on the framework of physician-induced demand.[78] The plausible explanation is that most pharmaceutical products in Thailand including antihypertensive drugs must be prescribed by a physician (i.e., physician-determined demand), implying that a third party makes the product choice most of the time.[79] And because physicians exert a strong influence over the quantity and pattern of pharmaceuticals demanded, consequently, it is possible that physicians may have an incentive to (over) prescribe the new, expensive, brand-name drugs; restated, this says that because of asymmetric information physicians may influence a patient's demand for high-priced, branded products in their own interests (rather than in the best interest of a patient).

As to the latter issue, the justification for this estimation result is that a number of Thai people have some sort of health insurance that may include drug-reimbursement, and may cover almost all drugs in the choice set[80]; this creates the moral hazard, i.e., an increase in the demand for high-priced branded drugs. The emphasis of our explanation lies on consumer incentives and hence moral hazard

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[78] In this study, inducement is defined as "prescription of drugs that a well-informed consumer would not want to use."

[79] In most industries consumers choose the product, the quantity and the method of payment. In the case of prescription drugs the decision is shared by the patient, the physician and sometimes the prescription drug coverage provider. If a patient were left alone to make a decision, he or she would base that decision on the expected health outcome of a treatment and the cost of the treatment, net of any insurance co-payment. A patient's expectation on a health outcome depends on his/her information about the treatment, which in turn depends on factors like health awareness, direct-to-consumer advertising, word-of-mouth, personal experience with antihypertensive products or medication for symptomatically similar diseases. However, legislation prevents and protects the patient from making an uninformed decision by requiring that a prescribing physician makes the treatment choice. The patient, therefore, can only participate in the optimization of his/her utility by trying to affect the physician's preferences. In this study, we plausibly assume that drug-prescribing physicians care about their patients and, thus, try to maximize their patients' utility—i.e., the physician assists the patient to demand "exactly those quantities of medicines that the patient would have chosen if he/she had the same information and knowledge the physician has."

[80] For instance, the Civil Servant Medical Benefit Scheme (CSMBS).

effects on the insured patient.[81] A typical theoretical background of moral hazard in health care is that health insurance reduces the net money price of medical care and such a reduction may lead to increased use of health care. In the case of prescription drugs, there often is a choice between existing and new pharmaceutical technology (i.e., the innovative, high-priced, brand-name drugs). To the extent that insurance gives access to the new technology on the same conditions as the old, it creates an incentive for the insured to ask for the latest, high-priced, brand-name drug, giving rise to moral hazard. That is, patients insured against prescription drug expenditures are willing to pay higher prices for new medications than they would be willing to pay when uninsured. Interviews with physicians have revealed that in most cases a physician would prescribe a molecule (generic name), not a specific drug (brand name), especially when the generic is available. A physician would consider choosing the branded drug if the patient asks him to. The decision to buy brand over generic is influenced by the patient's perception of quality and the price difference between two drugs as already explained.

What is more appealing is the implication of the price insensitivity of demand for drugs type M1. In this respect, the implication of the result is that wealthier patients and patients with prescription drug insurance tend to be less price-sensitive.[82] Indeed, the demand for on-patent branded drugs is more likely to be highly price-insensitive, and the more acute the illness the higher the insensitivity. The insensitivity is exacerbated by higher income and by insurance coverage.

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[81] Apart from its effect on the behavior of insured patients, insurance also affects the behavior of agents acting on behalf of the patient, in particular the physician.

[82] In Thailand, during 1980-2005, the share of health expenditure from private sector was around 70 percent of total health expenditure. The main source of private health expenditure was the households and employers rather than private health insurance. The portion of private health insurance slightly increased from 2.2 percent of total health expenditure in 1995 to 3.2 percent in 2005. This was no meaning, compared with the part from the households and employers (around 64% of total health expenditure in 2005). Household out-of-pocket spending was not only the largest source of funds for health care in private sector, but in the overall health expenditure as well. During this period, around two-thirds of total health expenses came from household out-of-pocket payments. Accordingly, during this period, when taking a look at the big picture, agency and moral hazard issues were not of great importance in the Thai pharmaceuticals market as all private health expenses were fundamentally met out-of-pocket and health insurance coverage was so rare. However, our empirical result has uncovered the importance of the agency and moral hazard issues when focusing on more details. Our result suggests that agency and moral hazard issues might be large and of significance in some certain market segments, namely, civil servants and high-income consumers. According to the data base, during our investigation period the on-patent branded drugs type *M1* were mostly prescribed for civil servants (who can receive reimbursement for their drug expenses from the CSMBS) and high-income patients (who were willing to pay higher prices for their medications).

Akin to the result of Marshallian price elasticities, all but one resulting Hicksian own-price elasticities are statistically significant at less than 1% level. The insignificant one is the domestic generic category (M3). As displayed in the fifth column of Table 5.2, the Hicksian own-price elasticities of demand for ordinary drugs within category M2, M3, and M4 are smaller in magnitude compared with the Marshallian elasticities as the theory predicts, indicating that the pure effect of substitution is only partially compensated by the income effect. By contrast, the one exception is the on-patent branded drug category (M1), whose compensated own-price elasticity is relatively larger in magnitude in comparison with those of uncompensated elasticity. Again, this proves that the antihypertensive category M1 exhibits the Veblen effect, contradicting basic law of demand.

Substitution and complementary relationships among antihypertensive types are captured by the Allen elasticities summarized in Table 5.3. Positive value denotes that the two types are cross substitutes. More precisely, positive value with the large magnitude between the two products suggests that such products are close substitutes to one another. The larger the Allen elasticity of substitution between two products, the closer they are as substitutes in the eyes of consumers. As one might perhaps expect for products within a therapeutic sub-segment, these are positive in three cases: (i) on-patent branded and off-patent branded drugs (M1 and M2), (ii) off-patent branded and domestic generic products (M2 and M3), and (iii) on-patent branded drugs and imported generics (M1 and M4). And the rest are negative. What is striking, however, is how large, positive and significant the Allen elasticities of substitution between different types of antihypertensive drug are.

Table 5.3 Allen Elasticities of Substitution between Two Types of Antihypertensive Drugs

	On-Patent Branded Drugs (*M1*)	Off-Patent Branded Drugs (*M2*)	Domestic Generics (*M3*)	Imported Generics (*M4*)
On-Patent Branded Drugs *(M1)*	-	0.848	-5.393***	0.887

Table 5.3 (Continued)

	On-Patent Branded Drugs (*M1*)	Off-Patent Branded Drugs (*M2*)	Domestic Generics (*M3*)	Imported Generics (*M4*)
Off-Patent Branded Drugs *(M2)*	-	-	3.187***	-0.100***
Domestic Generics *(M3)*	-	-	-	-0.160

Source: Calculated from System Estimates (Reported in Table 5.1) Based on Data from the Thai FDA.

Note: 1) Elasticities calculated at average expenditure shares.

2) Asterisks (*, **, ***) denote significance at the 10%, 5% and 1% level, respectively.

Historical evidence indicates that no one antihypertensive drug within the sample is clearly more effective than another in bringing high blood pressure down to the desired level. A major source of differentiation, therefore, is the mechanism of action of an antihypertensive drug as this is identified by a drug's category. Another major source of differentiation is an antihypertensive drug's side effect profile that is common to drugs of the same active ingredient (molecule). In the case of hypertension, patients are highly heterogeneous in their response to treatment; hence, experience with other patients should only influence a physician's decision initially. For the same reason, existing protocols and guidelines for the treatment of hypertension are merely suggestive in nature. The initial choice of an antihypertensive class and molecule is based on the patient's own or his/her family's medical history; for example, the patient's underlying diseases. In the absence of a medical history, physicians start an experimentation phase; often, a physician will begin with antihypertensive drug with the least overall side effects. Therapeutic effects appear shortly (it may vary from a few weeks to a month depending on severity of hypertension). This implies that a patient's initial experimentation phase is short-lived and will not affect the long-term market shares in antihypertensive products. The

brevity of the experimentation phase as compared to total treatment time (i.e., a person's life span) justifies that annual data captures all learning.

Scientists do not currently have definitive biological tests that can be administered to humans to predict exact response to a particular treatment. Prescribing physicians have to rely on their patients to find out whether or not a certain pharmacological treatment is working out. As a result, in the case of hypertension, patients influence the physician's choice in antihypertensive drugs. What is more, it is highly unlikely that a physician would change types of antihypertensive drugs during the continuation phase of a treatment for price considerations due to the difference in the way different-type drugs are believed to fight hypertension.

The major effect of price in the case of antihypertensive drugs is in the choice between (off-patent) branded drugs (namely, drugs type M2) and the generic equivalents (namely, drugs type M3 and M4), where the difference in price is more pronounced. Interviews with physicians have disclosed that in most cases a physician would prescribe a molecule (generic name), not a specific brand (brand name), especially when the generic is available. As mentioned earlier, a physician would consider selecting the branded product if the patient demands him to. With a molecule prescription, a hospital pharmacist would typically choose to dispense the generic rather than the branded version due to lower cost. In the case that a physician chooses to prescribe the brand (instead of the molecule) when a generic exists, in order to pay less a patient can alter this prescription for the generic via a pharmacist in most hospitals. Since all antihypertensive drugs of the same molecule are bioequivalent[83], they should be ideally perfect substitutes in demand. Our empirical result shows likewise. According to our estimation result, imported generic drug (M4) does not appear to be good substitute for off-patent, brand-name drug (M2). By contrast, the

[83] The pharmaceutical industry is characterized by an impressive stream of new products due to rigorous R&D. The quality of its products has been subjected to especially close regulation by the FTA, which regulates entry and maintains high product quality standards. In order to be approved by the FDA for marketing to the public, a drug must go through difficult and lengthy pre-clinical and clinical trials. Accordingly, the patent system is in place to ensure that there is sufficient incentive for innovation to take place, and that the high costs of R&D can be recouped. During the life of the patent, the innovator firm has a monopoly on the sale of a particular drug. Following the expiration of a patent, generic competitors may enter the market following FDA approval. To obtain this approval, a generic manufacturer must demonstrate that its product is biologically equivalent to the innovator drug. Biological or therapeutic equivalence means a drug acts on the body with the same strength and similar bioavailability as the same dosage of a sample of another drug of the same active ingredient when the route of administration is the same.

low-cost domestic generic equivalent (M3) looks as if it is almost perfect substitute for the high-priced off-patent foreign drug (M2) in the eyes of patients (physicians). As the price of the off-patent branded drug increases, the quantity demanded for the domestic generic equivalent increases drastically, ceteris paribus, indicating that when the price of the high-priced off-patent branded product increases, most patients (physicians) may prefers to switch towards the affordable domestic generic version rather than the more expensive foreign generic equivalent. This interpretation is in line with the positive sign plus the large magnitude of the partial elasticity of substitution between antihypertensive type M2 and M3 (3.187), as well as the negative sign plus the small value of the Allen elasticity of substitution between antihypertensive type M2 and M4 (-0.100). The result also supports that most Thai consumers seem to be quite price-sensitive. This may be because during our period of investigation health insurance coverage was so rare and almost all of private health expenses were basically met out-of-pocket.

Also, the Allen elasticities of substitution confirm that the relatively high-priced drugs type M2 and M4 seem to be pretty good substitutes for high-end, brand-name drugs type M1. Unlike antihypertensive type M2 and M4, domestic generic products (M3) do not appear to be substitutes for innovative products within type M1. The rationale may be that, in the eyes of high-end patients (physicians), the low-priced domestic products are not perceived to be effective against severe hypertension. Moreover, newer generation drugs within category M1 are usually taken into account to overcome specific problems in the treatment of complicated hypertension. As a result, given that all else being equal, when the price of a high-end, brand-name product type M1 rises, instead of choosing less costly alternative (namely, domestic generic), high-end patients (physicians) may prefer to substitute away from an on-patent, branded, foreign product and towards a relatively high-priced, off-patent, branded drug or an imported generic, which are perceived to be more effective and of higher quality than those produced domestically.

The basic claim made by proponents of TRIPS-Plus is that any adverse impacts on consumer welfare from the introduction of very stringent IPR protection for pharmaceuticals associated with TRIPS-Plus in a certain market will be mitigated

by the availability of close therapeutic substitutes. The cross-subgroup expenditure switching effects,[84] implied by the Allen elasticities of substitution between antihypertensive subgroup M1 and M3 (i.e., the very low degree of substitutability), and antihypertensive subgroup M2 and M3 (i.e., the high degree of substitutability), suggest that for this claim, to be valid, there need to be unpatented (i.e., patent-expired) substitutes available within fairly narrowly defined therapeutic categories. As the extent to which this is true will vary across therapeutic segments, the impact of TRIPS-Plus clauses is likely to be correspondingly variegated. It is worth noting that, in the case of different therapeutic segments, the relative magnitudes of consumer welfare loss due to the enforcement of TRIPS-Plus vary with the initial market shares of the on-patent branded drugs, if the initial market share for particular therapeutic segment is large, the consumer welfare loss that is attributable to market exclusivity extension endowed by TRIPS-Plus is also large. Estimates of the impact of TRIPS-Plus on consumer welfare loss under different counterfactual scenarios are demonstrated later in Section 5.2.

As already mentioned, the low-priced, domestic generics type M3 appear to be rather inappropriate alternates for high-end, brand-name drugs type M1. Instead, the large, negative and significant value of the Allen elasticity of substitution between antihypertensive type M1 and M3 (-5.393) suggests that they are actually good complements. The possible explanation is that in the case of a severe hypertension in which only one drug cannot control blood pressure level, doctors may prefer to prescribe a more effective, expensive product type M1 in combination with a low-cost, traditional, domestic generic type M3 in order to be able to bring such high blood pressure level down as well as to optimize the cost of treatment.

Likewise, the small, negative and insignificant value of the Allen elasticity of substitution between antihypertensive type M3 and M4 (-0.160) implies that they are neither right substitutes nor good complements. The justification may be that different groups of patients have different preferences. For instance, low-income patients with no health insurance are normally more price-sensitive and may prefer to take the low-

[84] The expenditure switching effect is the effect arising from substitution away from one subgroup and towards other subgroups (of group *M*) due to price increase.

priced medicines (M3). In contrast, some patients may prefer to consume somewhat higher-priced counterparts (M4) because they think if a drug is more expensive it must be better quality. Hence, for the producers, a specific pricing strategy is usually employed to attract a certain buyer segment. Put differently, pharmaceutical firms use different pricing strategies for capturing and exploiting different buyer segments.

5.2 Counterfactual Estimates of the Impact on Consumer Welfare and Their Connotation

To get more precise idea of how consumers' well-being will be immediately affected by TRIPS-Plus, we computed as last step in our analysis the effect of the policy change on consumer welfare. In this respect, to measure the changes in consumer welfare, the Thai antihypertensive market was considered under the two simulated conditions, with and without the enforcement of TRIPS-Plus. Without the enforcement of TRIPS-Plus, medicine prices in the original patentable market would follow the current trend. On the other hand, with the enforcement of TRIPS-Plus (i.e., with market exclusivity extension), three possible scenarios of 10%, 30%, and 50% increase in price of patented medicines (type M1) above the current trend were simulated, ceteris paribus. The first scenario is the situation that the subsidiaries of multinational pharmaceutical firms (i.e., the patent holders of patented molecules) respond weakly to the market exclusivity extension due to the presence of various close substitutes. In this case, the situation of 10% increase in price of patented medicines (type M1) in the original patentable market above the current trend was simulated, given that all other things being equal to the without-TRIPS-plus situation. Additionally, in the case of moderate responsiveness due to the existence of some alternatives, the scenario of 30% increase in price level of patented medicines above the current trend was carried out, ceteris paribus. Finally, in the circumstance that patent holders respond strongly to market exclusivity prolongation due to the absence of close substitutes, assuming that all else being equal, we simulated the worst-case scenario of 50% increase in price of patented medicines above the current trend.

Alternatively, it sounds perfectly plausible that in the nonappearance of TRIPS-Plus, generic competition would lead to more competitive pharmaceutical

market and, hence, price reduction. Especially, preceding literature, e.g., Frank and Salkever (1997) and Malpani (2007), has revealed that generic competition emphatically causes the prices of brand-name medicines to fall substantially between 30 and 80 percent. Correspondingly, for present purpose we have assumed that in the nonexistence of TRIPS-Plus, prices of patented medicines in the original patentable market decrease, on average, by 20 percent attributable to generic competition. Accordingly, another three counterfactual scenarios were simulated. Similar to the first three scenarios, on one side, price of patented medicines would decline by 20 percent from the trend line in the absence of TRIPS-Plus. On the other side, in the presence of TRIPS-Plus the plausible scenarios of 10%, 30%, and 50 % increase in price of patented medicines above the trend line were simulated, all else being equal.

Consumer welfare losses were measured by the compensating variation (CV), defined as the additional expenditure that all Thai consumers need to incur to maintain the same utility level as before enforcing TRIPS-Plus. As stated previously, we have considered six possible scenarios listed in the two preceding paragraphs. For this matter, it should be noted that all of scenarios we simulated involve only the static (immediate) effect of TRIPS-Plus (i.e., upward price adjustment in the original patentable market) on consumer welfare. More precisely, we estimated in this study the static welfare effects (i.e., short-run loss) in the context where the introduction of TRIPS-Plus leads to the prolongation of monopoly pricing period in the market for particular patentable molecules and, hence, the increase in price in the original patentable market. We did not, however, consider a dynamic effect [85] (i.e., long-term loss) where the increase in price in the original patentable market might lead to corresponding upward price adjustments in the market for generic substitutes. In short, rather than emphasizing dynamic loss, in this study we considered estimating only the static loss to consumers. Regarding the dynamic impact of TRIPS-plus, we leave it for further research issue. Table 5.4 and Table 5.5 display our estimates of the rates of change in consumer welfare and the magnitudes of the loss to the whole

[85] To see why cross-molecule/cross-group substitution effects are likely to significantly worsen the consumer welfare loss in the long-run, in this context imagine a scenario where the introduction of TRIPS-Plus leads to the increase in prices of the original, patented medicines. If the markets for potential substitutes (e.g., the market for generic products) are imperfectly competitive, then the increase in price in the original patentable market may lead to corresponding upward price adjustments in the related markets as producers of substitute products re-optimize in the face of the increased demand for their products.

society resulting under the first three scenarios (i.e., scenarios 1 to 3), severally. Likewise, Table 5.6 and Table 5.7 exhibit our estimates of the rates of change in consumer welfare and the magnitudes of consumer welfare loss arising out of another three scenarios (i.e., scenarios 4 to 6), respectively.

Table 5.4 Counterfactual Estimates of Consumer Welfare Changes from Market Exclusivity Extension and Static Upward Price Adjustments due to the Introduction of TRIPS-Plus Provisions (Scenarios 1 to 3)

Counterfactual Scenarios	The Rate of Change in Consumer Welfare after Upward Price Adjustments of Patented Medicines in the Original Patentable Market (%)									
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Scenario 1: 10% increase in price over price trend	5.82	5.92	6.03	6.13	6.21	6.28	6.36	6.41	6.46	6.52
Scenario 2: 30% increase in price over price trend	16.56	16.84	17.13	17.42	17.63	17.84	18.06	18.20	18.34	18.49
Scenario 3: 50% increase in price over price trend	26.31	26.75	27.19	27.64	27.96	28.29	28.63	28.85	29.07	29.31

Source: Calculated from Expenditure Function Displayed in Equation (4.14) with the Use of the Estimated Parameters Reported in Table 5.1.

Note: 1) The rates of change in consumer welfare were measured in terms of the growth rates of total expenditure of antihypertensive group *M*, which are needed to incur to sustain the pre-TRIPS-Plus utility level.

2) The price trend in an absence of TRIPS-Plus situation is used as a baseline for welfare calculation.

Table 5.5 Counterfactual Estimates of Consumer Welfare Losses from Market Exclusivity Extension and Immediate Upward Price Adjustments due to the Introduction of TRIPS-Plus Provisions (Scenarios 1 to 3)

Counterfactual Scenarios	Static Losses to Consumers due to an Increase in Price of Patented Medicines in the Original Patentable Market in Response to Monopoly Pricing Prolongation Conferred by TRIPS-Plus (Billion Baht)										
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Accumulated Losses (2012-2021)
Scenario1: 10% increase in price over price trend	1.03	1.26	1.53	1.87	2.29	2.81	3.46	4.26	5.26	6.53	30.30
Scenario2: 30% increase in price over price trend	2.94	3.57	4.35	5.32	6.51	7.98	9.81	12.08	14.93	18.52	86.01
Scenario3: 50% increase in price over price trend	4.67	5.67	6.91	8.44	10.32	12.65	15.55	19.16	23.67	29.35	136.39

Source: Calculated From Counterfactual Estimates of the Rates of Change in Consumer Welfare, Demonstrated in Table 5.4, Together With the Use of Overall Antihypertensive Expenditure from the Baseline (i.e., without the Enforcement of TRIPS-Plus).

Note: 1) Consumer welfare losses were estimated in terms of the compensating variation (CV) defined as the additional expenditure that consumers need in order to achieve the same utility level as before TRIPS-Plus enforcement at the new prices.

2) The values of the welfare loss were evaluated at consumer prices and the consumer prices were averagely marked up by 80% over producer prices. It is noticing that the average markup of 80% is in accordance with the figure estimated by the Ministry of Public Health. See Suwit Wibulpolprasert, ed. (2007).

3) The price trend in an absence of TRIPS-Plus situation is used as a baseline for welfare calculation.

Table 5.6 Counterfactual Estimates of Consumer Welfare Changes from Market Exclusivity Extension and Static Upward Price Adjustments due to the Introduction of TRIPS-Plus Provisions (Scenarios 4 to 6)

Counterfactual Scenarios	The Rate of Change in Consumer Welfare after Upward Price Adjustments of Patented Medicines in the Original Patentable Market (%)									
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Scenario 4: 10% increase in price over price trend	18.86	19.20	19.55	19.90	20.15	20.41	20.68	20.85	21.02	21.21
Scenario 5: 30% increase in price over price trend	29.76	30.28	30.81	31.35	31.74	32.13	32.54	32.80	33.07	33.35
Scenario 6: 50% increase in price over price trend	39.64	40.32	41.01	41.70	42.21	42.73	43.25	43.59	43.94	44.31

Source: Calculated from Expenditure Function Displayed in Equation (4.14) with the Use of the Estimated Parameters Reported in Table 5.1.

Note: 1) The rates of change in consumer welfare were measured in terms of the growth rates of total expenditure of antihypertensive group *M*, which are needed to incur to sustain the pre-TRIPS-Plus utility level.

2) The reduction in prices of patented medicines by 20 percent below the price trend in an absence of TRIPS-Plus situation is used as a baseline for welfare calculation.

Table 5.7 Counterfactual Estimates of Consumer Welfare Losses from Market Exclusivity Extension and Immediate Upward Price Adjustments due to the Introduction of TRIPS-Plus Provisions (Scenarios 4 to 6)

Counterfactual Scenarios	Static Losses to Consumers due to an Increase in Price of Patented Medicines in the Original Patentable Market in Response to Monopoly Pricing Prolongation Conferred by TRIPS-Plus (Billion Baht)										
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Accumulated Losses (2012-2021)
Scenario4: 10% increase in price over price trend	3.34	4.07	4.97	6.08	7.44	9.13	11.23	13.84	17.12	21.24	98.46
Scenario5: 30% increase in price over price trend	5.28	6.42	7.83	9.58	11.72	14.37	17.68	21.78	26.93	33.4	154.99
Scenario6: 50% increase in price over price trend	7.03	8.55	10.43	12.74	15.58	19.11	23.5	28.95	35.78	44.37	206.04

Source: Calculated From Counterfactual Estimates of the Rates of Change in Consumer Welfare, Demonstrated in Table 5.6, Together With the Use of Overall Antihypertensive Expenditure from the Baseline (i.e., without the Enforcement of TRIPS-Plus).

Note: 1) Consumer welfare losses were estimated in terms of the compensating variation (CV) defined as the additional expenditure that consumers need in order to achieve the same utility level as before TRIPS-Plus enforcement at the new prices.

2) The values of the welfare loss were evaluated at consumer prices and the consumer prices were averagely marked up by 80% over producer prices. It is noticing that the average markup of 80% is in accordance with the figure estimated by the Ministry of Public Health. See Suwit Wibulpolprasert, ed. (2007).

3) The reduction in prices of patented medicines by 20 percent below the price trend in an absence of TRIPS-Plus situation is used as a baseline for welfare calculation.

Table 5.4 and Table 5.6 present our estimates of the rate of change in consumer welfare (%) after upward price adjustments of patented medicines allied with TRIPS-Plus under the aforementioned simulated situations. The estimates of percentage change in consumer welfare were then turned into the sizes of potential loss that the Thai society may incur. All the estimates of magnitude of loss to the Thai people are reported in Table 5.5 and Table 5.7 in terms of monetary value, or more specifically, in Thai baht currency. By our calculations, within a ten-year period from 2012 to 2021, in the presence of TRIPS-plus the accumulated damage to the Thai consumers, resulting from market exclusivity extension for proprietary drugs in the modern generation (type M) sub-segment of the antihypertensive drugs segment, was estimated to be worth in the range of around 30 to 136 billion baht under the first three simulated situations (Table 5.5) or around 98 to 206 billion baht (Table 5.7) under another three simulated situations. It is noted that indeed the range of the estimated welfare loss varies depending on several factors such as the degree to which drug originators respond to monopoly period prolongation, the way intellectual property rights policies are implemented, the extent of national price regulation, and, especially, the availability of therapeutic substitutes.

The more comprehensive interpretation of our estimated results can be exemplified through the following instance. Let's consider the first scenario where the patent holders respond weakly to the market exclusivity extension; in our estimation, in fiscal year 2012 the Royal Thai Government would need to provide an extra budget for the spending on antihypertensive drugs type M for the Thai citizens equal to ฿ 1.032 billion (i.e., 5.82 % of the estimate of the annual expenditure on antihypertensive drugs type *M* in the absence of TRIPS-Plus)[86] in order to maintain the same level of access to medicines (in other words, in order to retain the pre-TRIPS-Plus utility level) as before the enforcement of TRIPS-Plus. Similarly, the additional expenditure on antihypertensive drugs type M that the Thai people would need to incur to maintain their pre-TRIPS-Plus utility level in the face of the market exclusivity extension for

[86] More specifically, we predicted that, in the absence of TRIPS-Plus, the overall expenditure on antihypertensive type *M* would amount to ฿ 17.73 billion in consumer price in 2012. We also estimated that the loss to the Thai society related to the imposition of TRIPS-Plus would be worth around ฿ 1.032 billion that is equivalent to 5.82% of ฿ 17.73 billion.

brand-name drugs and the accompanying price increases is said to amount to ฿ 1.255 billion (i.e., 5.92% of the annual spending on antihypertensive drugs type M) in 2013, ฿ 1.531 billion (i.e., 6.03% of the annual spending on antihypertensive drugs type M) in 2014, ฿ 1.872 billion (i.e., 6.13% of the annual spending on antihypertensive drugs type M) in 2015, and so on. Put differently, we estimated that in the modern generation (type M) sub-segment of the antihypertensive drugs segment alone, the Thai society would carry the burden of lack of access to medicines attributable to the enforcement of TRIPS-plus in terms of mortality, morbidity, socio-economic devastation, and caring for the sick, which is said to amount to ฿ 1.032 billion in 2012, ฿ 1.255 billion in 2013, ฿ 1.531 billion in 2014, ฿ 1.872 billion in 2015, etc. Likewise, all other results in another five scenarios (i.e., scenarios 2 to 6) can be interpreted in the same way as the first scenario.

Of particular interest from a policy perspective are the magnitudes of the welfare loss attributable to the prolongation of monopoly market. As shown in Table 5.5 and 5.7, within a time period of ten years from 2012 to 2021, the enforcement of TRIPS-Plus would result in a sizable accumulated loss of consumer welfare, which is as high as about 30 billion baht in the first scenario, 86 billion baht in the second scenario, 136 billion baht in the third scenario, 98 billion baht in the fourth scenario, 155 billion baht in the fifth scenario, and 206 billion baht in the last scenario, for the Thai society. Additionally, if we compare the results across these six scenarios, despite the fact that the absolute levels of the welfare loss vary considerably all the counterfactual scenarios produce qualitative similar patterns, patterns that are consistent with what we would expect when the subsidiaries of foreign multinationals re-optimize the prices of proprietary drugs in response to the reduced competition.

In general, a patent for a particular medicine reduces competition as it blocks the entry of competitive products supplied by companies other than the patent holder. To be exact, a patent may even protect the patent holder from any competition for a continual period of time, i.e. twenty years, and allow the patent holder to exercise some market power and therefore to charge a price that exceeds the marginal cost of production during the life of the patent. Nevertheless, the extent of protection from competition and thus the ability to charge a non-competitive price depends on various

factors. First, it depends on the availability of therapeutic substitutes and consumers' knowledge of their availability. Furthermore, it depends on the extent to which the medicine is unique and desired by consumers and on the extent to which consumers are able to shift their demand to alternative non-patented medicines. For instance, generic drug prices are significantly lower than brand-name prices, and a considerable share of the market is taken by generic drugs. What is more, the optimal price of a medicine that patent holder sets is likely to vary across countries with different levels of income and different structures of market demand (which can be observed by different price elasticities of demand) despite the fact that pharmaceutical patent allows a patent holder to charge a non-competitive price for a medicine. Accordingly, we should note that the range of the estimated welfare loss in fact varies depending on several determining factors; for example, the degree to which patent holders (i.e., subsidiaries of foreign multinationals) respond to the extension of monopoly period, the way patent and other IPR policies are implemented, the extent of national price regulation, and especially the availableness of therapeutic substitutes. We should note further that the magnitude of the consumer welfare loss under a certain therapeutic segment vary with the initial market share of the proprietary drugs in the segment as well, if the initial market share for a particular therapeutic segment is large, the consumer welfare loss is also large.

For all reasons, we computed the likely welfare losses under several plausible counterfactual scenarios by altering the virtual (simulated) price of proprietary drugs, all else equal. More accurately, because the estimates in this study were generated assuming that the prices of the products that remain in the market are not adjusted upwards, they provide a sense of what consumer losses would be if the introduction of TRIPS-Plus leaded to upward price adjustments of brand-name medicines (i.e., antihypertensive type M1) in the original patentable market. Of course, virtual prices are never observed in any market. For this reason, it is difficult to estimate how far medicine prices would have increased in Thailand, if the TRIPS-Plus mandates had come into force. We should note however that all of the virtual price numbers we employed in simulated situations seem a priori plausible. In our simulations, we estimated price increases between 10% and 50%. This range is in line with the estimates reported in Frank and Salkever (1997) and Malpani (2007). While these

numbers are again based on simulations, and hence not observed, we can obtain a rough idea about their plausibility by exploring the probable rates of change in medicine prices in some developing countries that have already enforced TRIPS-Plus and then applying them to our simulations through making some adjustments to them to match the historical context of the change in medicine prices in Thailand. In this regard, Jordan seems to be a natural candidate and makes a very useful case study to examine the costs and benefits of these US measures as it was effectively the first country to agree to TRIPS-Plus rules. In order to assess the public health consequences of the US-Jordan FTA, Malpani (2007) measured the burden of TRIPS-Plus on access to affordable medicines in Jordan in terms of expenditure on drugs that the Jordanians and its government could have saved in an absence of TRIPS-Plus using the rates of decrease in price of original products due to generic competition varying from 30% to 80%. For the present purpose of this study, we assume that brand-name drug prices increase between 10 % and 50% in the consequence of enforcing TRIPS-Plus measures in Thailand.

CHAPTER 6

POLICY OPTIONS AND CONCLUSION

In Chapter 6, all findings are concluded and turned into recommendations for national health policy. Specifically, Chapter 6 is composed of two main sections. We provide discussions on various TRIPS-Plus-related policy options in Section 6.1. Section 6.2 concludes.

6.1 Policy Implications, Discussions and Recommendations

Now we turn to the policy perspective on our appraised results. Given the sizes of the estimated welfare loss due to upward price adjustments of the original branded medicines due to the enforcement of TRIPS-Plus, policymakers may be tempted to execute or adopt the use of price controls, and other regulations. However, such policies would put a limit not only on prices, but also on the incentives of innovating pharmaceutical producers to expand their operations and speed the launch of the very latest breakthrough drugs into the Thai market so that the welfare loss due to the delay or even lack of superior new pharmaceutical inventions to fight diseases could become problematic and may turn out to be a permanent effect. Therefore, accomplishing the correct tradeoff between availability of new superior drugs and affordability is extremely vital to Thailand and every technology-importing country.

Pharmaceuticals are sold under classic monopolistic competition conditions. Patents and product differentiation lead to prices that are well above production costs. But companies strive for partial monopoly positions and high margins by introducing new drugs. To do so, they incur substantial R&D costs and marketing costs, reducing bottom-line profits. When superior new products emerge from drug R&D, both consumers and producers alike benefit. In the United States, the pharmaceutical industry has for decades appeared at or near the top of industry rankings by after-tax profit returns on stockholders' equity (Scherer, 1996: 342). However, profit reports

prepared following conventional accounting practices, including current-year write-off of research and development expenditures, tend to overstate true economic profitability, given the growth rates experienced by pharmaceutical firms. When drug makers' R&D outlays were capitalized and amortized at plausible rates, the industry's overall rate of return on invested capital in the 1970s and 1980s was found to exceed all-industry averages by only two to three percentage points (U.S. Office of Technology Assessment, 1993).

The perception, correct or incorrect, that pharmaceutical prices and profits have been excessive, taxpayer burdens from rising public health care costs, and the belief, especially in small developing nations, that reducing drug prices and profits will at best have a minor impact on R&D expenditures by companies oriented toward serving worldwide markets, have led many governments in the industrialized and less-developed world to impose more or less thoroughgoing price controls on pharmaceutical products.[87] In this respect, there are countless variations in the ways governments regulate drug prices. These can be compacted into five broad groupings, i.e., reference pricing, item-by-item negotiation and control, formula pricing, profit or rate of return regulation, and capping or budgetary constraint controls. See U.S. Office of Technology Assessment (1993: 250-262), Shulman and Lasagna, eds. (1994), and Danzon (1997), on which a following brief description of each is based. Many nations' policies entail a mix of the various methods, with the mix changing over time, so what follows can provide only selective snapshots.

Under reference pricing, more-or-less comparable drugs are placed into a reference group, and reimbursement is provided under national or regional health insurance plans only at the lowest price within the reference group. The U.S. maximum allowable cost approach to Medicaid drug reimbursement is a relatively innocuous version, placing generics and branded drugs with identical active ingredients in the same group. A more drastic approach was taken by Germany beginning in 1989 and Sweden beginning in 1993. Different chemical entities treating the same illness are placed in the same reference group. The broader the reference

[87] Among 56 nations whose governmental policies toward the pharmaceutical industry were surveyed by Ballance, Pogany and Forstner (1992: 140-145 and 166-171) , 30 nations (12 industrialized and 18 developing) were characterized as having "substantial" price controls and 20 (11 industrialized and nine developing) as having "limited" controls. Only six (all in the developing category) were said to have no controls.

group and the more it includes new formulations along with older drugs, the more likely it is to discourage investments in discovering and developing superior new drugs.

In France and (until 1993) Italy, the prices of individual outpatient drugs seeking reimbursement under national health insurance plans were set in administrative proceedings taking into account a wide array of criteria, including therapeutic novelty and contribution to the economy. Drugs produced and developed locally tended to receive higher prices than imported drugs, which created incentives for local firms to develop and introduce numerous new drugs of insufficient therapeutic novelty to achieve significant sales outside the home market. This, along with the low standards imposed by the agencies regulating new drug introductions, helps to explain the relatively modest external sales of French and Italian drug manufacturers.

Under the health care reforms proposed in 1993 by U.S. President Clinton but rejected by the Congress, a different form of ad hoc regulation was contemplated. An Advisory Council on Breakthrough Drugs was to be charged with reviewing the prices of new drugs and, in case where they were considered excessive, implementing measures ranging from public suasion or "jawboning" to making the drugs ineligible for health insurance reimbursement. The drugs most likely to be singled out for this regulation were the "blockbusters." The difficulty with this approach is that curbing significantly the prices and profits of blockbuster drugs could make it difficult for companies to cover their research and development investments on less successful drugs. Severe impairment of R&D incentives could result.

Many nations, including Italy since 1993 (Fattore, 1996) and Canada since 1987, relate the reimbursable prices of relatively new drugs to the prices of the same drugs in other nations. When nation (such as Spain) characterized by generally low prices are included in the comparison group, this creates incentives for multinational drug manufacturers to set prices higher in the comparison group jurisdiction than those they would otherwise be included to charge. What is more, in Japan, the huge majority of drugs are dispensed directly by physicians, who are then reimbursed by government health authorities on a formula basis for the drugs. New drugs receive relatively high prices, and after that, their prices are reduced downward systematically

with the drug's age. This system has two important incentive effects. For one, to encourage the use of their drugs, manufacturers set prices that allow a physician generous profit margins between the physician's acquisition costs and the reimbursed prices, leading to the extraordinarily high prescribing rates observed in Japan. Second, because new drugs command the highest prices, manufacturers have strong incentives, as in France and Italy, to introduce many new drugs, whether or not they make significant therapeutic contributions. This in turn is partly responsible for the poor external market performance of Japanese drug manufacturers. For this matter, Thomas (1996) and Ikegami, Ikeda and Kawai (1998) show in more detail.

The United Kingdom is the only nation known to have a rate of return regulation system analogous to the way electrical and telephone utilities were regulated in the United States for many decades. In an annual determination, the assets of individual companies, including the capitalized value of research and development outlays, are measured. Each company negotiates with the regulatory authority an allowed before-tax rate of return on its assets, usually in the range of 17 to 21 percent. Prescription drug sales revenues are set (or adjusted after-the-fact) so that, after operating, R&D, and sales promotion costs are deducted, the company is left with profit sufficient to yield the agreed-upon rate of return on assets. In the cost calculations, promotional expenditures can be deducted only up to a limit of approximately 9 percent of sales. The U.K. Price Regulation Scheme would appear to reward investments in research and development and hence to avoid the negative incentive problems in many other nations' regulatory approaches. However, there is a paradox. If the scheme is executed mechanically, large companies with R&D portfolios containing many projects tend to realize substantially higher returns on investment than small companies with few projects. See Scherer (1995: 36-38). Given the high lopsidedness of drug development project outcomes, companies with many projects can include the substantial R&D investment from numerous "losers" as well from (the few) blockbusters in their R&D asset base, and the large investment base will allow the companies to realize most, if not all, of the profit potential from blockbusters. If a small company is lucky enough to develop a blockbuster, it will by its very smallness have few losers in its investment base, so the revenues it is allowed to realize on the blockbuster will be severely limited by regulation. If on the other

hand (with appreciable probability) it achieves no blockbuster, its returns will be severely limited by market competition.

Germany exemplifies the use of aggregate budget constraints and rollbacks. In an attempt to control escalating health care costs, the Federal Health Ministry beginning in 1993 set a tight overall drug budget, requiring inter alia a rollback from previous spending levels. The first DM 280 million of spending above that target was to be deducted from the incomes of physicians. If the budget was exceeded by DM 281-360 million, the excess was to be deducted from reimbursements to drug manufacturers. Between 1995 and 1997, German drug budgets were decentralized regionally out to the level of individual physicians (as is also done in the United Kingdom). An apparent consequence of individual physician spending constraints was that primary care physicians referred increased numbers of patients to specialists and hospitals, who were subject to different individual constraints. In 1998, cost containment emphasis in Germany shifted away from drug budget constraints toward increased individual patient copayments.

In a nutshell, the pharmaceutical industry has made vast contributions to health care across countries for many decades as the drug research and development revolution gained momentum. Progress in biological science and molecular engineering is likely to provide the basis for further dramatic therapeutic advances in the future. But the conditions that create strong incentives for investment in pharmaceutical R&D, including the TRIPS Agreement, and, more recently, the TRIPS-Plus provisions and the like, also arouse public concern over monopoly positions, high prices, and the introduction of products of uncertain efficacy or safety. From that concern flow regulatory interventions into clinical testing protocols and pricing that could retard future technological progress. The problem is complicated by the fact that individual nation states can rationally behave as free riders or more accurately, cheap riders, ignoring the consequences of their policies on drug R&D decisions in other parts of a complex multinational industry. On a global plane, achieving the correct tradeoff between progress, affordability, and optimal provision of test information remains an elusive goal.

In Thailand, although the quality of domestically produced medicines has much improved due partly to the promotion of Good Manufacturing Practice (GMP),

the Thai pharmaceutical industry is composed mainly of non-research based manufacturers. In 2005, there were only 162 firms involving in manufacturing modern medicines in the country (Thailand Development Research Institute, 2006). Almost all the local Thai-owned private firms are small in size, involved in packaging or formulating drugs, and primarily characterized by low production capacity and simple technology. Due to not having own technology to produce active ingredients, most local drug firms generally acquire chemical ingredients and technologies from foreign sources.[88] In the case of affiliates of foreign multinationals, they have played dominant roles in the Thai pharmaceutical market in terms of production, importation, and distribution for a long time. Foreign investment in Thailand appears in the forms of joint ventures and wholly-owned subsidiaries. Most affiliates of foreign drug companies supply the Thai market by importing finished products from aboard. Some foreign companies have formulation and packaging factories, but they have not established local plants for the production of basic active ingredients in Thailand (UNCTAD. International Trade Centre, 1999).[89]

No firms, whether foreign or local, are engaged in R&D activity in the search for new drugs in Thailand. Some basic and applied research programs have been carried out in state universities, but the achievement of these programs still remains uncertain. Besides, researchers in the public sector usually lack financial resources and management skill to convert their research outcomes into large scale commercial ventures. Successful research outcomes are normally sold to foreign companies. What is more, foreign multinationals view Thailand as an inappropriate location of research unit due to several factors, including the scarcity of well-trained personnel, equipment and resources, the lack of a chemical industrial base, the low level of technological capability, and the deficiencies of the registration system for new medicines. See Siripen Supakankunti et al (1999) for further details.

[88] Less than ten companies in Thailand are involved in the production of raw materials that can be used as inputs for the production of medicines. Almost all the raw materials produced by those companies are confined to intermediate ingredients such as alcohol, solvent, and sodium chloride. Only a few active ingredients that possess therapeutic effects (e.g., chloramphenicol and ferrous sulfate) are manufactured in Thailand (P. Hutangkura and C. Sepulveda, 1979; Petsri Bumrungcheep, 1981).

[89] Like R&D, the absence of the production of active ingredients in Thailand can be explained by two factors: (i) the lack of capacity of domestic companies, and (ii) the limited size of the market, making it unappealing to the multinationals. Since the domestic production of active ingredients is almost non-existent, most chemical compounds required for transformation into finished drugs are imported, mainly from the U.S., the U.K., Germany, Switzerland, France, Japan, Italy, Eastern Europe countries and China.

On the whole, Thailand is unable to achieve self-reliant pharmaceutical production. The lack of a functional technological base and production capacity of its domestic firms leads to high dependency on other countries as to technology, medicinal active ingredients and finished drugs (new advanced drugs in particular). This means that the healthcare service in Thailand will face difficulties, especially when situations of crisis occur, such as during conflict or war, in case of epidemic, or the natural disasters. In a few words, because of not possessing a functional technological base, the country has to be industrially and technologically dependent on foreign interests for the supply of drugs. As a result, the country consistently loses trade balance in the pharmaceutical sector to its trading partners. See Appendix A, Section A.4.

From a perspective of the technology-importing developing country like Thailand, the perceived role of patents and other IPR in industrial and economic development should be significantly different from that portrayed in technologically advanced countries like the United States. It would be illogical for Thailand to adopt the very high standards of TRIPS-Plus IPR protection. While a stringent patent regime as enshrined under TUSFTA may be desired to foster research, the high degree of patent protection in Thailand would promote R&D and protect research results developed elsewhere. The inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede inflow of technology. Patents will continued to be used by foreign drug firms as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements, resulting in serious damage to the health and well-being of the whole society.

In regard to medicines prices, Thailand was well aware of its problems of access to essential medicines. As a response to high prices, in 2001 it jointly proposed a draft text for a ministerial declaration on IPR and public health. The collective effort of Thailand and other developing countries led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, which buttresses the importance of access to medicines and reaffirms the right of WTO Members to use the flexibilities available under TRIPS to increase the affordability of medicines. Accordingly, it would be a sad irony then for Thailand to adopt the TRIPS-Plus rules that may further restrain its accessibility to essential medicines.

The very high level of intellectual property protection required by TRIPS-Plus will have a ginormous effect on prices. In this respect, the TRIPS-Plus rules that are designed to expand the scope and lengthen the period of monopoly, i.e., data exclusivity, patent-term extension, linkage between drug registration and the patent status, broadening the scope of patentability, and so on, enhance the ability of the patent holders to maintain high prices and, hence, a huge welfare loss to every Thai consumer, as evidently shown by our empirical results. For a comprehensive analysis, see Jakkrit Kuanpoth (2007), on which the five following paragraphs are based.

Granting exclusive rights over test data will impede generic competition. Thai generic producers would have to conduct their own clinical trials, which they do not have the ability to do. Since the trial process is not only very costly but also time consuming, the only option for the local Thai firms would be to wait until the exclusivity period expired, which would delay the entry of generic drugs into the market. Consumers would then be forced to pay monopoly prices for the original drugs for an extra ten years. Furthermore, data exclusivity will let multinational drug firms dominate the market even if there is no patent on the drugs they sell. When a patent is granted for the medicines, Thailand would have little or no chance to grant a compulsory license or allow government use to make the patented drugs available. This is because the medicines produced under the government license would remain unable to obtain market approval during the exclusivity period due to the lack of the clinical test data required for registration.

In principle, patents are granted on condition that the holder must work the patented invention or license it within a certain period of time from the date of granting the patent. Thailand integrates several measures into its law so as to reinforce the local working of patents. The current patent law comprises not only compulsory licensing but a system of forfeiture and revocation of patents as well. The TRIPS-plus on compulsory licensing will restrict flexibleness that Thailand can issue, such as non-voluntary licenses to assure the health of its citizens and to facilitate development of local industries. Also, the Thai government will not be able to force the patent holder to reveal the know-how needed to produce the medicine. In that way, TRIPS-Plus rules will extremely limit the ability of the Royal Thai government to enforce technology transfer, lessen the effectiveness of compulsory licensing as a means of

ensuring access to medicines, and impede the ability of the Thai generic drug industry to expand its market.

The USTR text disallows Thailand from adopting pre-grant oppositions. This straightforward administrative procedure is necessary for Thailand because it allows local generic companies to challenge the validity of a patent at relatively low cost, prior to an infringement action. Generic producers that work in the same field are often in a position to challenge patents before they are granted. This system reduces excessive burdens on the courts and contributes to speedy proceedings of patent invalidation. The exclusion of the pre-grant opposition will allow multinational companies to block challenges on invalid patents, increase prices and preclude local medicine manufacture.

The TRIPS-Plus provisions that require an extension of patent term would threaten the existence of the Thai generic firms by preventing them from exploiting patented technology for the duration of the extended period. This would effectively increase the patent life for proprietary drugs, thus preventing the launch of generic products. The patent holder can then maintain a longer monopoly period position and charge high prices for its medicines. Especially, the extended term of pharmaceutical patents proposed by the United States is too long. No matter how much investment involving drug development is claimed by the pharmaceutical companies, it would still be imprudent for Thailand and every technology-importing developing country to offer protection periods for longer than twenty years. The logic is that pharmaceuticals generate a high rate of turnover, and therefore maximum profits need to be recouped to their owners by selling drugs at high prices around the world. Due to the urgent need for technological acquisition, the developing country will be denying itself the benefits from newly developed modern technology by granting an unnecessarily lengthy protection period which will discourage competitive innovation. Modern scientific innovation has continued to yield evermore rapid technological change, and hence new products are developed and launched rapidly. No technology, no matter how beneficial it is, should be bestowed more than a twenty-year term for protection as required by TRIPS.

The TRIPS-Plus provisions that link drug registration and the patent status of a drug will unnecessarily restrict the entry of generic medicines. The provisions require

the national drug regulatory body, before approving registration for a generic version, to ensure that the manufacturing, importing and selling of the generic medicine will not infringe the original company's patent rights. The practice of linking patent status to registration is not easy to implement in view of the fact that the national drug regulatory body in Thailand has no patent expertise to determine whether the generic medicine sought for registration is the same or different from the medicine that another company has patented. This would cause considerable delays to the introduction of the generic product. Moreover, the provisions requiring Thailand to extend the scope of patentability to new uses and new formulations of the known drugs will allow multinational companies to claim exclusive rights over formulations that do not generate a truly new and inventive product. A great many drugs, although therapeutically effective, have other far from perfect properties and potential side-effects. Drug patentee can come up with secondary improvements that can then also be patented. This would protect the original patent holder against generic competition, even in situations where a generic company is prepared to challenge what it perceives as bad patents. Costly and time-consuming litigation can keep the matter locked up in the courts for several years, thereby unnecessarily restraining the entry of generic medicines.

To sum up, this study has found that the enforcement of the very stringent intellectual property protection for pharmaceuticals as stipulated in the TUSFTA negotiation seems likely to generate severe damage to the Thai economy in terms of high drug prices and, hence, balance-of-payment difficulties. To be exact, while long-run gains from enforcing TRIPS-Plus (i.e., availability of a stream of new breakthrough drugs that suit developing countries' needs) remain poorly understood and contentious, the move towards stronger and broader intellectual property protection with respect to TRIPS-plus clauses may incur a huge welfare loss to the Thai society. In our estimation, considering the modern generation sub-segment of the antihypertensive drugs segment alone, the enactment of TRIPS-Plus provisions would result in an enormous accumulated loss of consumer welfare, which is as high as around 30 to 206 billion baht within a ten-year period as illustrated in Table 5.5 and 5.7; restated, this says that as a result of the execution of TRIPS-plus, the Thai citizens would carry the burden of lack of access to medicines in terms of

morbidity(i.e., pain and suffering from the illness), mortality, socio-economic devastation, and caring for the sick, which is said to amount to ฿ 30-206 billion for the duration of ten years from 2012 to 2021. This result calls for a reexamination of the merits of the TRIPS-Plus rules being negotiated under the TUSFTA in every aspect. Without the clear comprehensive evidence that the benefits of enforcing TRIPS-Plus will outweigh the costs, Thailand should not accept any further intellectual property rights protection beyond the WTO TRIPS mandates.

The existing system for the international protection of industrial property rights under the framework of the Paris Convention, WTO/TRIPS, and recently FTA/TRIPS-Plus, have failed to accommodate and protect the interests of developing countries. The present norms and standards clearly do not assist developing countries in their attempt to achieve self-reliance in the field of science and technology. It seems as if it were inevitable that developing countries would submit to some of the developed countries' demands as reflected in the successful conclusion of the Uruguay Round and the adoption of the TRIPS Agreement. However, in the near future concerted efforts in the multilateral forums must be made by the developing countries with the aim of eliminating the use of regional or bilateral coercion through trade sanctions such as the extension of domestic trade law and TRIPS-Plus rules under FTAs. Multilateral talks are more appropriate in dealing with the problems of conflicting interests between the North and the South, when compared with bilateralism. Concerning an appropriate strategy on international trade negotiations, developing countries should increase their role in the negotiations at the relevant international forums such as WTO and WIPO so as to influence the world trade agenda. Concerted multilateralism will help to reduce bilateral pressure from the more powerful countries.

Thus far, the trade policy of some developing countries including Thailand has yielded too much to the developed countries' demands, especially in bilateral negotiations. As an international trading institution, the WTO has played a central role in global business transactions. It has also played a significant role in dispute settlement among Contracting Parties. Developing countries, therefore, should take full advantage of the current round of WTO trade talks. Strategic alignment and closer economic cooperation among developing countries need to be set up in negotiations at

the WTO, WIPO, and smaller regional trade talks like AEC forum into the bargain. A more united stand will help Thailand and its counterparts by strengthening their bargaining power.

For the fulfillment of the goal of industrial and economic development, self-sufficiency in pharmaceutical production is crucial in facilitating a strong and healthy labor-force that is not reliant upon foreign interests. However, in practice self-sufficiency is rare. Few developing countries (e.g. China, India, and Brazil) can claim to be self-sufficient in drug supply. Most developing countries including those that provide the final formulations or packaging require significant imports of pharmaceuticals and intermediates. So as to achieve the goal of accessibility to medicines, a developing country must adopt and implement appropriate policies relating to technology, health, and IPR to ensure effective, safe and affordable medicines. The details of those policies are now highlighted.

First, on the technology policy, the developing countries should aim at increasing national technological capabilities including: monitoring technological change in international markets; obtaining technical assistance from other countries and relevant international organizations; increasing financial support for industrial R&D to public research institutes and private enterprises; supporting research activities in the private sector by providing soft loans for industrial research and tax credit on R&D expenditure; providing an effective service in technological consultancy to private firms; fostering production and commercialization of research results; developing the personal skill of scientists and engineers; encouraging efficient co-operation among researchers in universities and the industries, supporting technological co-operation among domestic firms, etc. In order to achieve key policy goals of self-sufficiency in drug supply, the developing countries have to come up with rational and coherent national pharmaceutical policies as part of their overall development strategies. The pharmaceutical industry is vital to a nation’s well-being and therefore it should not be left solely in the hands of free enterprise or foreign interests. It is the stark reality that no country, no matter how developed it is, does not subsidize national pharmaceutical sector. The locally-owned drug firms in developing countries should benefit from the government’s supported subsidy for raw material procurements and R&D activities.

Second, with regards to health policy, a developing country's government should establish a scheme for cooperative health action with other developing countries, especially those with a higher technological level. International cooperation among developing countries may include: R&D projects of drug development, production of medical substances, procurement of drugs suitable to the needs of the developing countries, and clinical testing for the quality and efficacy of drugs.

For centuries, developing countries like Thailand have also used traditional medical practices and indigenous medicines for preventive and curative treatment of ailments before turning to Western drugs. Many developing countries possess extensive tropical natural resources such as herbs and other botanical products which have great potential for use as raw materials in industrial pharmaceutical production. Most of these natural resources have not been fully explored or appreciated in modern, science-based therapy. The government of developing countries should initiate research projects aimed at discovering the therapeutic value of these indigenous resources and developing these materials into medically useful compounds. In addition, the government must give value to customary knowledge and the traditional methods of treatment must be incorporated into the national health-care plan. In essence, there should be a co-existence between research in traditional and modern medicine.

Third, on IPR policy, a developing country's government should take measures to facilitate the availability of patented products. While it is advisable to adopt the system of compulsory licensing, it has to be borne in mind that the compulsory licensing alone cannot help a country to address all the problems related to public health. This is because limiting access to pharmaceuticals can result from several structural problems. A country can be well advised to use other public policy measures, within and outside IPR law to address these problems. For instance, a developing country's government should apply all other possible means in addition to compulsory licensing, including parallel import, broad exceptions to patent rights (e.g., research exemptions), private use (i.e., the use for private and non-commercial purposes), and Bolar provision (i.e., the use of patented information for registration of drugs which facilitates prompt marketing of generic drugs), etc.

Now let us turn to another policy implication. Given the sizes of the estimated welfare loss due to upward price adjustments of the patented medicines, policymakers

may be tempted to enforce or carry out the use of direct price or profit controls, and other regulations. According to economic theory, it is undeniable that in market characterized by informational asymmetry and low price elasticity of demand like pharmaceutical market, welfare loss due to high monopoly prices could potentially be mitigated by price controls or other price regulations. However in this case, the incentives of multinationals to hasten the introduction of new superior drugs onto the Thai market would become questionable, and the welfare loss attributable to the lack of new pharmaceutical inventions to fight diseases could become momentous and may turn out to be a permanent phenomenon. A good example is the case of India, where both low incomes and especially its rigorous price regulations limit sustainable prices. Foreign multinationals are said sometimes not to market new drugs at all until late in their life cycle. Emphatically, a patent owner may simply refuse to supply a drug placed under what it views as too stringent price control. As discussed earlier, efforts by national authorities to control pharmaceutical costs by imposing drug price controls are found throughout the industrialized and less-developed world. These sometimes succeed in their proximate goal, but cause bulges in other parts of the health care balloon. Although one may share the underlying cost control goals, a review of the consequences suggest that the aversion of most economists to direct price and profit controls is well-founded.

In the case of Thailand, we suggest that rather than adopting the use of stringent direct price or profit controls, more flexible price regulation policies, namely some form of reference pricing, in combination with generic use promotion be implemented so as to effectively restrain an increasing burden of prescription drug expenditures on national public health budget. As mentioned previously, under reference pricing, more or less comparable drugs are placed into a reference group, and reimbursement is provided under national health insurance plans only at the lowest price within the reference group. Regarding generic substitution stimulation, national health organizations and other health institutions together with governmental hospitals should begin establishing formularies, guidelines, or treatment regimens listing the drugs those deemed most cost-effective and suitable for use against particular illnesses. When appropriate generic drugs exist, formularies strongly encourage affiliated health institution and hospital staff to use them in place of higher-priced branded drugs.

In addition to the magnitudes of the estimated welfare loss, our calculated results of price sensitivities of demand as reported in Table 5.2 also produce some interesting implications for national health insurance policy. Among other results, the most interesting result is a very low price elasticity of demand for original branded drugs type *M1* (uncompensated own-price elasticity = 0.140). Breaking down the result by insurance status, we find that the low price elasticity of demand is primarily driven by the price insensitivity of consumers who are insured, namely the civil servants. This finding implies that patients with prescription drug insurance tend to be less price-sensitive. In fact, demand for original proprietary drugs is usually more likely to be highly price-insensitive because original brand-name drugs are protected by patents. The insensitivity is intensified by insurance coverage. With some third party, i.e., the Royal Thai Government, or, more precisely, the Civil Servant Medical Benefit Scheme (CSMBS), paying the bill, this caused the problem of moral hazard in company with agency issue, due to no economic incentive to contain medical costs. As a result, the medical expenditure grew larger and larger, resulting in the spiraling medical inflation.

In an attempt to curb the rising costs of prescription drugs and offset the demand-increasing effects of generous health care insurance, this study recommends that all governmental health security schemes be operated on a prepaid insurance basis. Especially, prospective reimbursement systems (i.e., bundled payment) together with capping or budgetary constraint controls should be carried out. On the contrary, retrospective reimbursement system, namely fee-for-service, should be avoided or discontinued. The following paragraph provides the rationale behind our recommendation.

In Thailand, fee-for-service (FFS) is currently the dominant reimbursement method for the Civil Servant Medical Benefit Scheme (CSMBS). According to the FFS, medical services are unbundled and paid for separately. The payment is retrospectively determined by the total bill at discharge. A hospital will send the final charge for a CSMBS patient to the CSMBS and the CSMBS will reimburse the hospital the total charge or some reasonable percent of it. The disadvantage of this system is that it gives an incentive for physicians to provide more treatments (including unnecessary ones) because payment is dependent on the quantity of care,

rather than quality of care. Similarly, when patients are shielded from paying (cost-sharing) by health insurance coverage, they are incentivized to welcome any medical service that might do some good. FFS is thus a payment system that raises costs and discourages the efficiencies of integrated care. On the other hand, according to the bundled payment (a.k.a. Diagnosis-Related Groups or DRGs), hospitals are paid a predetermined price for their services. A price based on the average cost of treating patient with a particular diagnosis. They can no longer charge what they want. They are reimbursed only for what the DRGs allow.[90] For this reason, governmental health security schemes should move away from FFS and towards the bundled payment. For better understanding, next two paragraphs draw a concise comparison of the retrospective FFS to another two prospective payment methods, namely capitation and bundled payment.

In the health insurance and the health care industries, FFS occurs when doctors, hospitals and other health care providers receive a fee for each service such as an office visit, test, procedure, or other health care services. Payments are issued retrospectively, after the services are provided. FFS is inflationary, raising health care costs. It creates a potential financial conflict of interest with patients, as it incentivizes overutilization, treatments with either an inappropriately excessive volume or cost. FFS does not incentivize physicians to withhold services. When bills are paid under FFS by a third party, patients (along with doctors) have no incentive to consider the cost of treatment. Patients can welcome services under third-party payers, because when people are insulated from the cost of a desirable product or service, they use more. Similarly, primary care physicians who are paid under a FFS model tend to treat patients with more procedures than those paid under capitation. While in a capitation allowance, physicians are discouraged from performing procedures (including necessary ones) because they are not paid anything extra for performing them, FFS incentivizes primary care physicians to invest in radiology clinics and perform physician self-referral in order to generate income.

[90] In the mid-1980s, it was believed that Medicare's then-new hospital prospective payment system using diagnosis-related groups may have led to hospitals' discharging patients to post-hospital care more quickly than appropriate in order to save money. It was therefore suggested that Medicare bundle payments for hospital and post-hospital care; however, despite favorable analyses of the idea, it had not been implemented as of 2009.

Bundled payment, also known as episode-based payment, episode payment, episode-of-care payment, case rate, evidence-based case rate, global bundled payment, global payment, package pricing, or packaged pricing, is defined as the reimbursement of health care providers (such as hospitals and physicians) on the basis of expected costs for clinically-defined episodes of care. It has been described as “a middle ground” between fee-for-service reimbursement (in which providers are paid for each service rendered to a patient) and capitation (in which providers are paid a “lump sum” per patient regardless of how many services the patient receives). Unlike fee-for-service, bundled payment discourages unnecessary care, encourages coordination across providers, and potentially improves quality. Unlike capitation, bundled payment does not penalize providers for caring for sicker patients. Considering the advantages and disadvantages of fee-for-service, bundled payment for episodes of care, and global payment such as capitation, we conclude that episode payments are the most immediately viable approach.

Other proper cost containment policies, namely, individual patient co-payment, direct quantity control (e.g., a certain drug can be used only in specific indications), and indirect quantity control (e.g., National Essential Drugs List) should be seriously considered and implemented into the bargain, so as to limit escalating health care costs and deal with agency and moral hazard issues. In the case of National Essential Drugs List policy, the National Drug Committee is to be charged with reviewing the cost-effectiveness (and also the risks-benefits) of all chemical entities, and selecting from the menu of alternative drugs (in terms of molecule or generic name) those deemed most cost-effective to be listed in the National Essential Drugs List. Under this policy, only expenditure on essential drugs (EDs) can be fully or partially reimbursed from the governmental health insurance schemes. In other words, this approach makes the nonessential drugs (NEDs) ineligible for health insurance reimbursement.

To put it in a nutshell, for a technology-importing country like Thailand achieving the right tradeoff between availability of new advanced drugs (i.e., progress in medication) and affordability (i.e., access to medicines) is a matter of the greatest importance to the health and well-being of everyone in a country. Specifically, in choosing a set of appropriate policies a technology-importing developing economy

should look for the optimal balance between the benefits of regulating drug prices in terms of affordability, on one hand, and costs of lower diffusion of the most modern pharmaceutical technologies, on the other. The optimal policy choice should be some intermediate level of regulatory strength. In this vein, we suggest that, with the aim of curbing pharmaceutical costs and alleviating consumer welfare loss owing to high prices of patented medicines, a technology-importing developing country keep away from employing such rigid direct price and profit controls. Instead, it should have considered a proper mix of more flexible price policy choices, namely, reference pricing, formula pricing, and capping or budgetary constraint controls, together with some other cost containment policies such as generic use promotion, and some form of cost-sharing (i.e., individual patient co-payments).[91] We should note that an optimal set of these policies can vary across countries and over time, depending on a particular context of individual countries. We also suggest that as regards the reimbursement methods and policies, governmental health insurers, or more accurately, governmental health security (insurance) schemes, move away from a system that reimburses retrospectively (i.e., Fee-For-Service) towards prospective payment systems, namely bundled payment (alias Diagnosis-Related Groups).

Concerning a country's negotiating position on the IPR, thus far we have found that the existing system for the international protection of industrial property rights under the framework of the Paris Convention, WTO/TRIPS, and more recently FTA/TRIPS-Plus, have failed to accommodate and protect the interests of poor developing nations. The current norms and standards explicitly do not assist developing countries in their attempt to attain self-reliance in drug supply. In this case, while the benefits from imposing TRIPS-Plus are still peculiarly silent and controversial, the flow of evidence has shown that the introduction of stringent patent protection for pharmaceuticals in developing nations will result in substantially higher prices for medicines, with serious adverse consequences for the health and well-being of their people. Particularly, the result of this study discovers that the TRIPS-Plus provisions apparently shift the international legal framework to favor U.S. innovating pharmaceutical firms at the expense of the technology-importing developing

[91] In health care, cost sharing occurs when patients pay for a portion of health care costs not covered by health insurance. Examples include copays, deductibles and coinsurance.

countries. Put differently, the extension of the tighter pharmaceutical patent protection to the developing South clearly increases the welfare of the inventing North but may decrease the welfare of the developing countries. Accordingly, we strongly recommend that Thailand, along with other developing nations, not consent to any additional IPR protection beyond the WTO TRIPS obligations, if there is no clear inclusive evidence about the merits of the TRIPS-Plus requirements.

Incidentally, price regulation and compulsory licensing are two of the most widely mentioned policy options available to governments of developing countries. There is an ongoing debate about how much leeway governments should have to introduce these options and about the relative efficacy of the two options in limiting price increases. The magnitude and significance of the welfare losses we estimate from the loss due to the imposition of stringent IPR protection for pharmaceuticals suggest that there may be an independent role for compulsory licensing in addition to or in lieu of price regulation for the sole purpose of mitigating the welfare loss stemming from the exclusivity period for original branded medicines and the associated high prices. There is no reason why a technology-importing developing country should not continue to use these mechanisms in order to meet public interest objectives. Indeed, every technology-importing developing country would benefit by adopting compulsory licensing and other provisions for compulsory working in its law. Especially, in market characterized by informational asymmetry and low price elasticity of demand like pharmaceutical market, the ability to limit the rate of increase in medicine price is primarily essential. In view of that, the welfare loss due to high prices of patented medicines could potentially be mitigated by either appropriate price regulation scheme or compulsory licensing. These two mechanisms when appropriately implemented would ensure optimal control over effective working of patented inventions.

6.2 Concluding Remark

The results of our analysis suggest that concerns about the potentially adverse welfare effects of TRIPS-Plus in developing countries may have some basis. More specifically, we estimate that in the modern generation sub-segment of the oral

antihypertensive drugs segment alone, the enforcement of the U.S. TRIPS-Plus provisions would result in a substantial accumulated consumer welfare loss for the Thai economy, ranging between ฿ 30 billion and ฿ 206 billion, within the ten years' duration (2012-2021). Otherwise stated for a ten-year period from 2012 to 2021, the citizens of Thailand would carry the strain of lack of access to medicines in terms of physical and mental suffering from unhealthiness which is said to amount to ฿ 30-206 billion as a result of TRIPS-Plus enforcement. On the whole pharmaceutical market, as a matter of fact the losses increase in the number of patented products that are affected by TRIPS-Plus. This pattern is driven by the empirical finding that domestic generic products are viewed by Thai consumers as close substitutes for original branded medicines. The existence of some degree of domestic competition irrefutably has a big impact on consumer well-being.

The huge magnitude of the estimated consumer welfare losses has interesting policy implications. It suggests a potentially independent role of compulsory licensing in addition to, or in lieu of price regulation, for the sole purpose of mitigating the loss of consumer welfare arising from the market exclusivity extension for patented medicines and the accompanying price increases. Applying compulsory licensing under certain circumstances permitted by TRIPS will make life-saving medicines more accessible to the underprivileged living in poverty. Even if one considers the adverse effect of TRIPS-Plus to be only a transitional phenomenon that will diminish in importance as foreign drug firms respond to TRIPS-Plus enforcement by expanding their product portfolios (which will generate welfare gain originating from the availability of new breakthrough drugs to fight diseases), the welfare loss due to upward price adjustment remains substantial. This welfare loss could potentially be alleviated through appropriate price controls or other price regulations. However in this case, the incentives of foreign multinationals to speed the entry of new superior drugs into the Thai market would become questionable, and the welfare loss deriving from the delay or even lack of the introduction of the newest pharmaceutical inventions could become a permanent effect.

Therefore, attaining the correct tradeoff between availability of new advanced drugs (i.e., progress in medication) and affordability (i.e., access to medicines) is a

matter of the highest importance to every technology-importing developing country. More precisely, the present study points out that from a consumer welfare perspective, the issue of (new) product availability is as important as the issue of affordability. In this sense, our suggestion is that policy makers should assess TRIPS-Plus related policies not only in terms of their effects on drug prices, but also in terms of their impact on (new) product availability. However, such tradeoff may lead to tension between policies designed towards addressing these two sets of effects. Intellectual property rights enforcement without price regulation is likely to bolster foreign firms' incentives to market their products in developing countries and use licensing more extensively than in the past, but it brings with it the potential of substantial price increases of patented products. Accompanying price regulation can prevent patent holders from exploiting their market power but not without diminishing the incentives of such innovating firms to expand their operations in the developing world. A mix of policies that would completely neutralize adverse effects on consumer welfare is hence unlikely.

Although a combination of policies that would absolutely offset adverse effects on consumer welfare is still dubious, the tradeoff is a must for policymakers. This study suggests that the optimal policy choice in regulating drug prices should be some intermediate level of regulatory strength. Specifically, this study suggests that rather than employing the stringent direct price and profit controls, a technology-importing developing country consider a proper set of more flexible price regulations (i.e., reference pricing, formula pricing, and capping controls), together with other cost containment policies (namely, generic use promotion, and individual patient co-payments). This study also suggests that as regards the reimbursement system, the national health insurance scheme move away from a retrospective payment system (namely, Fee-For-Service) and towards prospective payment systems (i.e., bundled payment).

Further, we find that expenditure (product) switching across sub-segments has a limited role in containing consumer welfare loss. The claim of TRIPS-Plus proponents that any adverse effects resulting from the introduction of very stringent IPR protection for pharmaceuticals in a particular market would be mitigated by the availability of close therapeutic substitutes is thus only valid if there are patent-expired substitutes available within fairly narrowly defined therapeutic categories.

Lastly, the magnitudes and importance of consumer welfare loss we estimate from the loss attributable to the enforcement of TRIPS-Plus suggest that without clear comprehensive evidence as to the merits of TRIPS-Plus in every aspect, Thailand along with other technology-importing developing countries should not accept any further IPR protection beyond the WTO TRIPS mandates.

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APPENDICES

APPENDIX A

HEALTH AND DRUG EXPENDITURES IN THAILAND

A.1 National Health Expenditure Trends

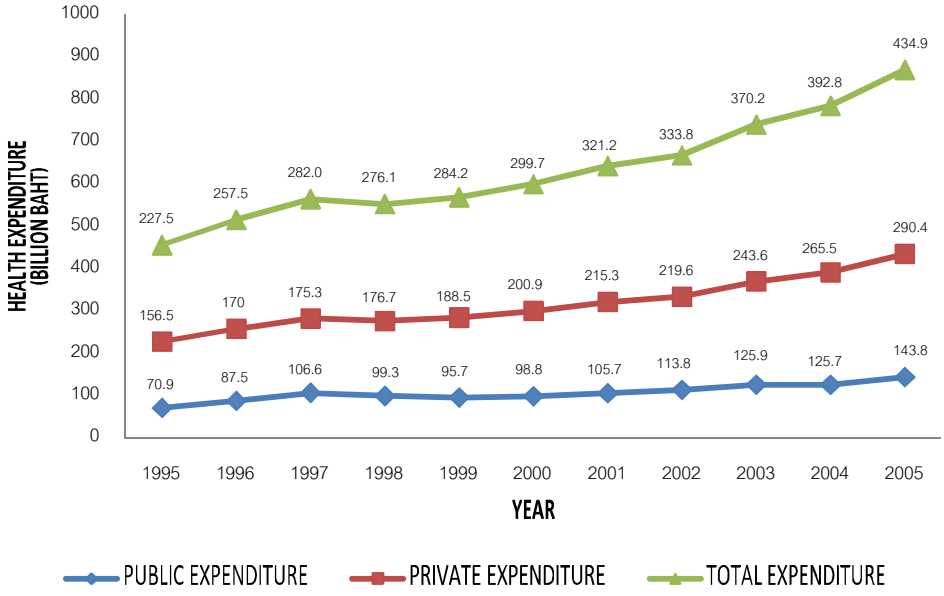

Figure A.1 Total, Public, and Private Health Expenditures, 1995-2005

Source: 1) Office of the National Economic and Social Development Board, 2005.
2) Viroj Tangcharoensathien, 1996.
3) Myers, 1988.

During the past decades, Thailand has faced the escalating burden in health care expenditure. Total health expenditures, as shown in Figure A.1 and Table A.2, were on a rapid upward trend, increasing from 25,315 million baht in 1980 to 434,974 million baht in 2005, a seventeen-fold increase. Per-capita health spending enlarged from 545 baht in 1980 to 6,994 baht in 2005(Suwit Wibulpolprasert, ed., 2007: 316), a nearly thirteen-fold increase in current prices. The national health expenditure, as a

percentage of GDP, increased from 3.8 percent in 1980 to 6.1 percent in 2005, the growth increasing at the rate faster than that of GDP, i.e. an average at 7.7 percent in real terms in comparison with an annually average 5.7 percent of GDP. The majority of health spending was on curative care, in particular spending on drugs, as evidently illustrated by the fact that the ratio of spending on drugs rose to 42.8 percent of total health spending in 2005 (Table A.2).

Table A.1 Comparison of Health Expenditures among Some Asian Countries

Country	Health Expenditure		
	Per capita(USD)	As percentage of GDP	Proportion (Government : Household)
Indonesia	113	3.1	35.8 : 64.1
The Philippines	174	3.2	43.7 : 56.3
Sri Lanka	121	3.5	45.0 : 55.0
Malaysia	374	3.8	58.2 : 41.8
Thailand(2004)	145	6.1	32.0 : 67.6
Singapore	1,156	4.5	36.1 : 63.9
South Korea	1,074	5.6	49.4 : 50.6

Source: World Health Organization, 2006.

Note: For 2004, the exchange rate of 40 baht to a US dollar is used.

As can be seen from Table A.1, though Thailand's per capita health expenditure is not so high, its spending as a percentage of GDP is higher than those of other Asian countries. Besides, a higher portion of the spending, during 1980-2005, was from the private sector (Figure A.1 and Figure A.2), in particular household out-of-pocket payments. In 2005, the share of health spending in private sector was 66.8 percent, whereas 33.2 percent belonged to public sector. These figures indicate that Thai people bear a great part of healthcare expenditures for themselves. Accordingly, an increase in prices of medicines means a considerable additional burden to Thai citizens; especially for the underprivileged, even slight price rises mean that life-saving medicines are unaffordable.

A.2 Sources of Health Expenditures in Thailand

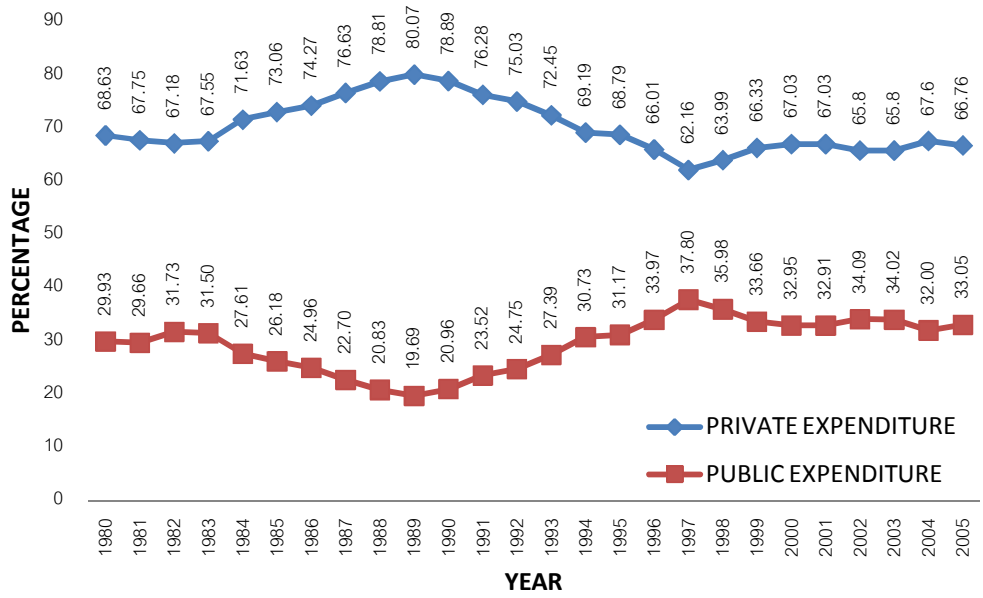

Figure A.2 Portions of Public and Private Health Expenditures, 1980-2005
Source: Table A.3.

According to Table A.3, there are three main categories of health spending sources: public sector, private sector, and financial aid. For the part of financial aid, it was very small and insignificant (Table A.3). The two major sources of spending are from public and private sectors. Over twenty-three years (1980-2005), the share of health expenditure from public sector was only 29.4 percent (on average) of total health expenditure, compared with 70.2 percent (on average) of those from private sector (Table A.3 and Figure A.2). The most important source of public spending was from government budget, particularly the Ministry of Public Health, a central administration agency. In analyzing the sources of private health expenditure, Table A.3 reveals that the main source was the households and employers rather than private health insurance. The portion of private health insurance slightly increased from 2.2 percent in 1995 to 3.2 percent in 2005. This was no meaning, compared with the part from the households and employers (Table A.3). In addition, household out-of-pocket spending was not only the largest source of funds for health care in private sector, but

in the overall health expenditure as well. Around two-thirds of total health expenses came from household out-of-pocket payments (Table A.3). Since the households bore the greatest share of healthcare costs, increase in prices of healthcare services, including medicines, did affect drastically to Thai populace. Every additional payment, resulting from increase in price of healthcare services, has posed a significant financial burden to most households.

In terms of health security coverage, in early stage, Thailand had a tendency to expand health security or insurance to cover all Thai citizens under the following major schemes: medical benefits for civil servants and state enterprise employees, social security, medical services for the poor and society-supported groups, voluntary health insurance project, private health insurance, and vehicle accident victim protection. At this stage, the non-government sector played the major role and around two-thirds of the healthcare costs came from household out-of-pocket payments. However, after the occurrence of economic crisis in 1997, the government sector switched its role to dominate in terms of expenditure. Since 2002, after the launch of the Universal Coverage (UC) of Health Care Scheme, the health expenditure structure has been radically restructured. The ratio of government and non-government[92] expenditure on health has thoroughly reversed as a result of the introduction of the Universal Health Care Coverage, which reflected to health care consumers who used to be uninsured. The impact of the UC healthcare scheme absolutely changed the structure of health expenditure. In 2008, the UC scheme became a major financing agent, having the biggest number of members, contributed nearly one-fourth of total health expenditure whereas the Civil Servant Medical Benefit Scheme (CSMBS)[93] and the household out-of-pocket had their share around one-fifth of total health expenditure (International Health Policy Program.The National Health Accounts 2006-2008 Working Group, 2010: 45).

In 2008, Thailand national health expenditure was 364 billion baht at current prices, increased from 224 billion baht in 2005 and the proportion of total health expenditure to gross domestic product (GDP) was 4.0 percent. Total health expenditure per capita in 1988 was 1,650 baht (at 1988 prices) and increased over

[92] The non-government sources are household and others private sectors (such as voluntary health insurance, traffic accidence insurance, non-profit institutions and private corporations).
[93] This included the State enterprises and the Public Independent Organization.

twenty years to 5,739 baht (at 2008 prices) in 2008. The share of public financing sources was 74.8 percent of total health expenditure in 2008, of which the central government accountable for 63.0 percent, local government 5.1 percent, and the Social Security Scheme 6.7 percent respectively. The non-government sources shared 24.9 percent of total health expenditure, of which household out-of-pocket payments contributed the major share of 17.7 percent(International Health Policy Program.The National Health Accounts 2006-2008 Working Group, 2010: 45-46), compared with more than sixty percent in early stage before the launch of the UC healthcare scheme.

Since 2001, under the universal health care policy, the coverage of health security of Thai population rose to 96.0 percent by 2006, that is, 74.3 percent of populace under the universal coverage of health care schemes, leaving only 4.0 percent without any health insurance coverage (Suwit Wibulpolprasert, ed., 2007: 327). Clearly, with the universal health care policy the accessibility to health care was enormously improved. Moreover, this policy has lessened the direct financial burden of household in terms of health care expenses. However, when considering the amount of governmental health budget, it was found that the hospital budget were on the rising trend, consistent with the Ministry of Public Health (MoPH) budget. According to Bureau of the Budget (2007), the MoPH budget, specially the budget for other health activities which comprise the universal healthcare fund, enlarged notably from 30,113 million baht in 2002 to 82,741 million baht in 2007.

Table A.2 Health and Drug Expenditures in Relation to GDP, 1980-2005 (Million Baht)

Year	GDP			Health Expenditure				Drug Expenditure				
	Actual Values	Value in 1988 Prices	Increase (percent)	Actual Values	Value in 1988 Prices	Increase (percent)	As Percentage of GDP	Actual Values	Value in 1988 Prices	Increase (percent)	As Percentage of GDP	As Percentage of Health Expenditure
1980	662,482	913,733	4.61	25,315	34,916	-	3.82	-	-	-	-	-
1981	760,356	967,706	5.91	31,755	40,415	15.75	4.18	-	-	-	-	-
1982	841,569	1,019,501	5.35	34,873	42,246	4.53	4.14	-	-	-	-	-
1983	920,989	1,076,432	5.58	41,181	48,131	13.93	4.47	16,686	19,502	-	1.81	40.52
1984	988,070	1,138,353	5.75	52,241	60,187	25.05	5.29	20,629	23,767	21.87	2.09	39.49
1985	1,056,496	1,191,255	4.65	59,265	66,824	11.03	5.61	26,317	29,674	24.85	2.49	44.41
1986	1,133,397	1,257,177	5.53	66,060	73,275	9.65	5.83	18,669	20,708	-30.21	1.65	28.26
1987	1,299,913	1,376,847	9.52	75,704	80,184	9.43	5.82	21,352	22,616	9.21	1.67	28.73
1988	1,558,804	1,559,804	13.29	89,968	89,968	12.20	5.77	26,674	26,674	17.94	1.71	29.65
1989	1,856,992	1,749,952	12.19	105,091	99,033	10.08	5.66	33,763	31,817	19.28	1.82	32.13
1990	2,183,545	1,945,372	11.23	125,302	111,635	12.72	5.74	35,369	31,511	-0.96	1.62	28.23
1991	2,506,635	2,111,862	8.56	138,818	116,955	4.77	5.54	39,464	33,249	5.51	1.57	28.43
1992	2,830,914	2,282,572	8.08	157,965	127,368	8.90	5.58	42,770	34,486	3.72	1.51	27.08
1993	3,170,258	2,473,937	8.38	184,062	143,634	12.77	5.81	42,364	33,059	-4.14	1.34	23.02
1994	3,629,341	2,722,006	10.03	199,949	149,962	4.41	5.51	52,823	39,617	19.83	1.45	26.41
1995	4,186,212	2,967,542	9.02	227,477	161,255	7.53	5.43	68,437	48,514	22.46	1.63	30.08
1996	4,611,041	3,087,751	4.05	257,507	172,438	6.93	5.58	81,440	54,536	12.41	1.77	31.63
1997	4,732,610	3,002,925	-2.75	282,001	178,935	3.77	5.96	92,728	58,838	7.89	1.98	32.88
1998	4,626,447	2,715,051	-9.59	276,090	162,025	-9.45	5.97	82,888	48,643	-17.33	1.82	30.02
1999	4,637,079	2,712,800	-0.08	284,235	166,284	2.63	6.13	91,208	53,359	9.70	1.98	32.09
2000	4,923,263	2,835,981	4.54	299,757	172,671	3.84	6.09	102,400	58,986	10.55	2.08	34.16
2001	5,133,836	2,910,338	2.62	321,239	182,108	5.47	6.26	116,767	66,194	12.22	2.27	36.35
2002	5,451,854	3,069,738	5.48	333,798	187,949	3.21	6.12	120,290	67,731	2.32	2.21	36.04
2003	5,917,368	3,272,881	6.62	370,206	204,760	8.94	6.24	144,085	79,693	17.66	2.43	38.92
2004	6,489,847	3,494,175	6.76	392,829	211,502	3.29	6.05	172,734	93,001	16.70	2.66	43.97
2005	7,087,660	3,653,433	4.56	434,974	224,213	6.01	6.14	186,331	96,047	3.28	2.63	42.84
		Average	5.70		Average	7.72			Average	7.52	Average	33.28

Source: Suwit Wibulpolprasert, ed., 2007, 316.

Though the universal health care policy did improve the accessibility to health care services of Thai inhabitants and simultaneously alleviated the financial suffering of individuals attributable to health care expenditure, the UC and other governmental health security schemes just help to transfer an individual healthcare cost to public or national cost. Increase in prices of health services, especially medicines, still hurts Thai society due to considerable additional social cost. In addition, there are a number of people who are currently uninsured; most of them are the deprived people living in poverty. Thereby, increase in prices of health services including medicines has posed an inevitably substantial cost to not only individuals but the whole country.

A.3 Drug Expenditure Trends and Drug Consumption Pattern

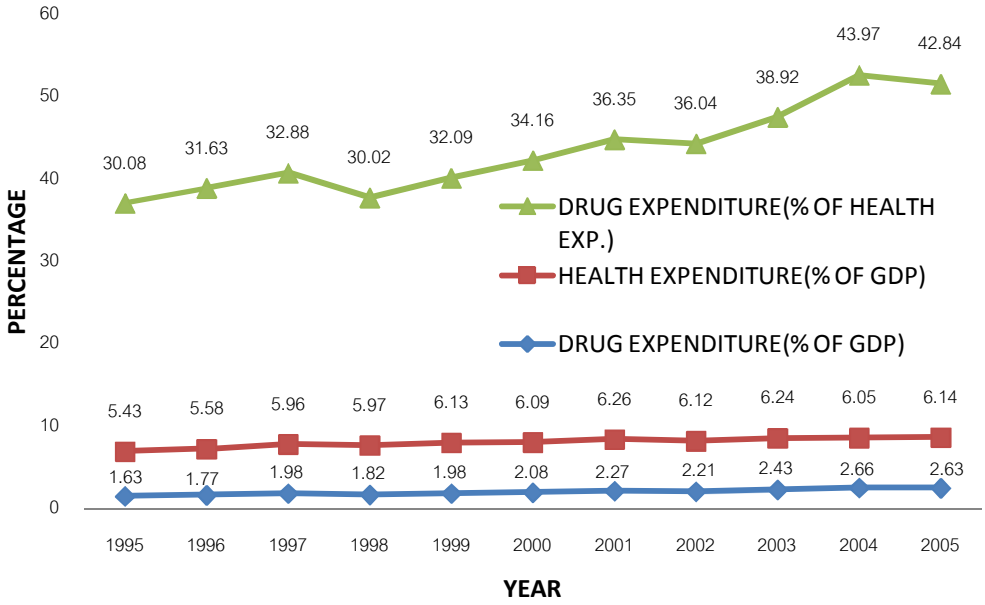

Figure A.3 Overall Health and Drug Expenditures in Relation to GDP and Proportion of Drug Expenditure to Health Expenditure, 1995-2005

Source: Table A.2.

In Thailand, since 1988 the rate of increase in drug expenditure was greater than that of overall health expenditure and that of economic growth (Table A.2). During the period 1983-2005, on average, the drug spending accounted for 33.3

percent (around one-third) of national health expenditure (Table A.2 and Figure A.3). In 2005, drug consumption accounted for approximately 103,517 million baht in wholesale prices (Suwit Wibulpolprasert, ed.,2007: 119) or 186, 331 million baht in retail prices (Table A.2), or 42.8 percent of the overall national health expenditure (Table A.2 and Figure A.3). This figure was very high, compared with other developed countries such as the Organization for Economic Co-operation and Development (OECD) countries where drug expenditure was only about 10-20 percent of total health expenditure (Figure A.4). An analysis of drug consumption patterns of Thai populace indicated that around two-thirds of total spending was done in accordance with the decision or guidance of professionals; for example, physicians, pharmacists, and other health professions. The rest was done as advised by families, friends, or advertisements. Nonetheless, medication use under the advice of health professionals has incessantly increased.

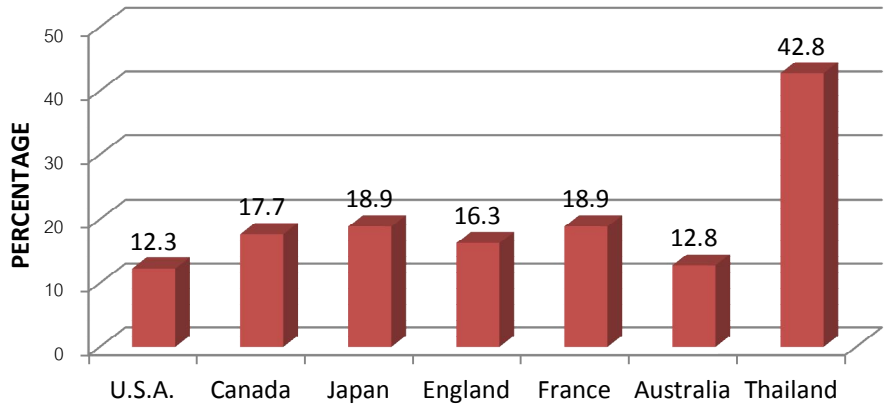

Figure A.4 Drug Expenditure as a Percentage of Total Health Expenditure

Source: Organisation for Economic Co-operation and Development(OECD), 2006.

Note: Data from OECD are on OTC drug dispensary and outpatients, but for Thailand data cover outpatient, inpatient, and OTC drug use.

Table A.3 Portions of Sources of Health Expenditure in Thailand, 1980-2005 (1988 prices)

Source of spending	1980	1982	1984	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
1.Public sector																							
Ministry of Public Health	17.76	19.07	16.50	14.04	12.58	11.53	11.16	12.95	14.82	15.58	17.87	19.67	20.15	21.69	24.44	23.57	22.10	21.02	19.16	21.25	20.03	19.78	19.75
Other ministries	8.73	8.14	6.64	6.00	5.39	4.82	4.23	3.64	3.39	3.06	2.68	2.78	2.94	3.02	2.55	2.08	2.14	2.07	2.22	2.06	2.32	1.80	1.40
Civil servants benefit scheme	2.61	3.50	3.43	3.93	3.74	3.51	3.35	3.44	3.69	3.71	4.30	4.98	4.91	5.28	5.50	5.95	5.34	5.69	5.97	6.13	6.13	5.04	6.66
State enterprise benefit scheme	0.44	0.58	0.57	0.66	0.63	0.59	0.56	0.58	0.62	0.62	0.70	0.83	0.82	0.94	0.98	1.02	0.89	0.54	0.94	0.92	1.07	1.04	0.86
Workers' compensation fund	0.40	0.44	0.48	0.33	0.36	0.39	0.38	0.35	0.45	0.48	0.50	0.58	0.60	0.62	0.70	0.59	0.49	0.42	0.40	0.37	0.40	0.38	0.35
Social security	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.56	1.30	1.34	1.89	1.75	2.42	3.63	2.77	2.70	3.21	4.22	3.36	4.08	3.96	4.04
Total	29.93	31.73	27.61	24.96	22.70	20.83	19.69	20.96	23.52	24.75	27.39	30.73	31.17	33.97	37.80	35.98	33.66	32.95	32.91	34.09	34.02	32.00	33.05
2. Private sector																							
Private health insurance	0.88	0.91	0.90	0.95	1.00	1.06	1.11	1.12	1.11	1.12	1.12	1.15	2.19	2.44	2.66	2.82	2.88	2.43	2.61	2.92	3.01	3.20	3.19
Households and employers	67.75	66.7	70.73	73.32	75.63	77.76	78.97	77.77	75.17	73.91	71.33	68.04	66.60	63.57	59.50	61.17	63.45	64.60	64.42	62.88	62.79	64.39	63.57
Total	68.63	67.18	71.63	74.27	76.63	78.81	80.07	78.89	76.28	75.03	72.45	69.19	68.79	66.01	62.16	63.99	66.33	67.03	67.03	65.80	65.80	67.60	66.76
3. Other																							
International financial aid	1.44	1.09	0.76	0.77	0.67	0.35	0.24	0.15	0.19	0.23	0.15	0.08	0.04	0.01	0.03	0.03	0.01	0.02	0.06	0.11	0.18	0.40	0.18
Grand total (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Total health expenditure (Billion baht)	34.9	42.3	60.2	73.2	80.2	90.0	99.0	111.6	112.0	127.4	143.6	150.0	161.3	172.4	178.9	162.0	166.3	172.7	182.1	188.0	204.8	211.5	224.2
Increase rate (%)	-	4.53	25.05	9.65	9.43	12.20	10.08	12.72	4.77	8.90	12.77	4.41	7.53	6.93	3.77	-9.45	2.63	3.84	5.47	3.21	8.94	3.29	6.02
As percentage of GDP	3.82	4.14	5.29	5.83	5.82	5.77	5.66	5.74	5.54	5.58	5.81	5.51	5.43	5.58	5.96	5.97	6.13	6.09	6.26	6.12	6.24	6.05	6.14
Population(million)	46.45	48.49	50.40	52.65	52.61	54.54	55.45	56.34	56.66	57.37	58.58	58.72	59.28	59.79	60.46	61.15	61.58	61.77	62.09	62.55	62.94	62.53	62.20
Per capita expenditure(baht)	752	871	1,194	1,392	1,524	1,650	1,786	1,981	2,064	2,220	2,452	2,554	2,720	2,884	2,959	2,649	2,700	2,795	2,933	3,005	3,253	3,382	3,605
Increase (%)	-	15.82	37.08	16.58	9.51	8.23	8.27	10.94	4.17	7.56	10.44	4.16	6.50	6.03	2.60	-10.5	1.93	3.52	4.94	2.45	8.27	3.97	6.57

Source: Suwit Wibulpolprasert, ed., 2007: 319.

A.4 Drug Supply

In national public health system, major health technologies are drugs and medical supplies including medical and health technologies for use in treatment of illnesses; for instance, CT scanners, ultrasound, lithotripters, and magnetic resonance imaging (MRI). In Thailand, concerning the drug supply, the subsidiaries of multinational pharmaceutical companies have played vital roles in terms of importation and distribution. Foreign investment in the Thai pharmaceutical industry appears mostly in the forms of wholly-owned subsidiary companies and a few joint ventures, most of which come from Switzerland, Germany, the United States, the United Kingdom, Japan, and Italy(P. Hutangkura and C. Sepulveda, 1979: 211). Most affiliates of foreign firms have supplied the Thai market by importing finished products from aboard. There are only ten drug companies engaged in local drug formulation (UNCTAD. International Trade Centre, 1999). Foreign companies have not established local factories for the medicine production in Thailand, even if they have many formulation and packaging plants around the world. Besides, no firms in Thailand, whether foreign or local, are engaged in research and development (R&D) activity in the search for new innovative medicines (Jakkrit Kuanpoth, 2006: 29). Hence, the country cannot be self-reliant in terms of innovative drug supply.

During the economic booming period 1988-1996, with the monopolies of new advanced drugs, endowed by international patent agreements, the percentage of imported drugs grew up rapidly. Even after the Asian financial crisis in 1997, the import trend was steadily increasing, up to 56.3 percent in 2005 (Figure A.5). Regarding the values of domestic consumption, both local production and imported drugs had the progressively increasing trends (Figure A.6). In addition, since 2002 the values of imported drugs had their increasing rates higher than those of local production. Consequently, in 2005 the imported values rose and exceeded the local production values for the same year; the difference in values was around nine billion baht as shown by Figure A.6.

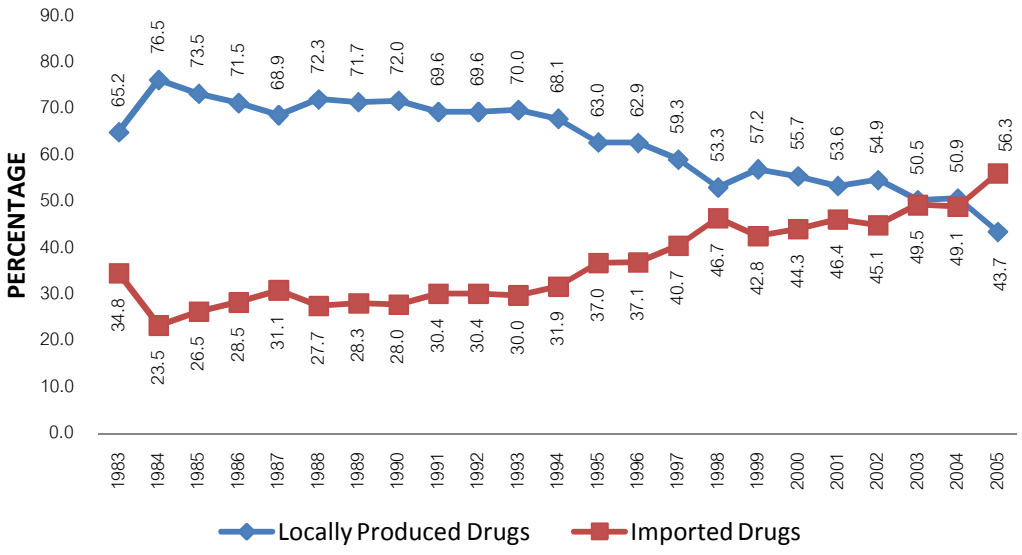

Figure A.5 Ratio of Locally Produced and Imported Drugs for Human Use, 1983-2005

Source: Food and Drug Administration. Bureau of Drug Control, 2007.

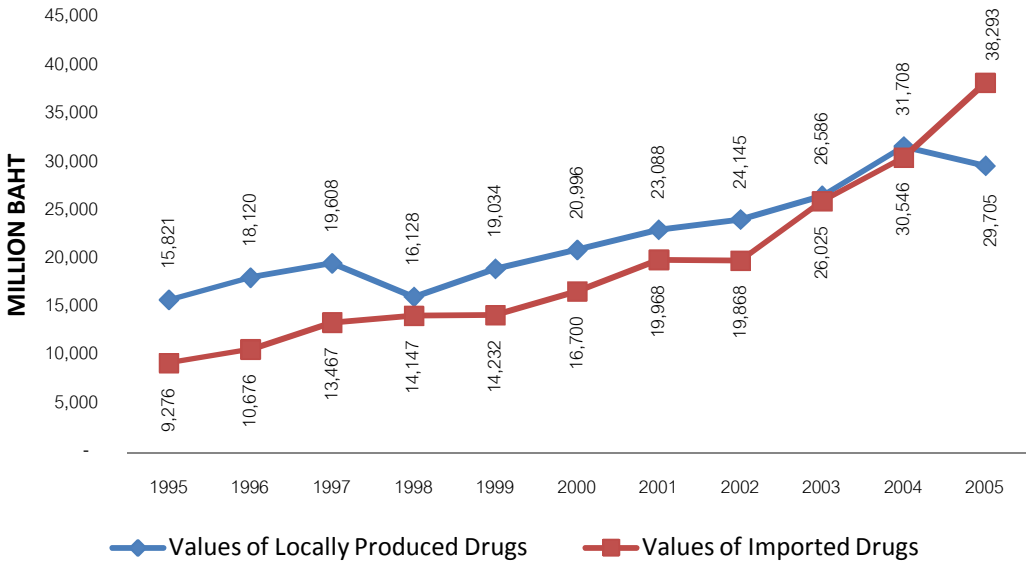

Figure A.6 Values of Locally Produced and Imported Drugs, 1995-2005

Source: Food and Drug Administration. Bureau of Drug Control, 2007.

Although the quality of domestically produced medicine has much improved partly owing to the promotion of Good Manufacturing Practice (GMP), Thailand pharmaceutical industry is primarily composed of non-research based manufacturers. In 2005, there were 162 firms involving in producing modern medicines in Thailand and nearly ninety percent of these manufacturers are private firms (Thailand Development Research Institute, 2006). Most of Thai-owned private firms are small in size, characterized by low production capacity and simple technology. These domestic producers generally involve in packaging or formulating drugs. Most companies do not have their own technology to produce active ingredients. They, therefore, acquire chemical ingredients and technologies from foreign sources. Because of not having a functional technological base, for new advanced medicines the country has to be industrially and technologically dependent on foreign interests. As a result, the country consistently loses trade balance in the pharmaceutical sector to its trading partners. See Jakkrit Kuanpoth (2006).

APPENDIX B

PATENTS AND THE PHARMACEUTICAL INDUSTRY

In Appendix B, Section B.1 briefly reviews the underlying economic theory as to patent protection and R&D incentives. Section B.2 provides previous empirical studies, explaining why patents are so important to the pharmaceutical industry. Section B.2 also includes the historical overview of the pharmaceutical patent controversy and the emergence of the international IP agreement, widely known as the WTO TRIPS Agreement.

B.1 Patent System

For more than a century the patent system has been studied with notable care by economists. Over the years, the economic theory of how patent protection affects inventor behavior and how those responses in turn can affect the choices of patent policy-makers has seen rich theoretical development. Section B.1 begins with Subsection B.1.1 providing some underlying background on the patent system. At first, the logic and paradoxes of the system are explored. Then, the pro and contra of patent protection are discussed in Subsections B.1.2 and B.1.3. SectionB.1 ends with Subsection B.1.4, presenting a tradeoff between costs and benefits of the patent system, namely the monopoly/innovation tradeoff.

B.1.1 Rationale for Patents

A patent by definition is a monopoly granted by the State to the original inventor for a certain number of years for the commercial exploitation of a clearly identified, scientific or technological invention (Langinier and Moschini, 2002: 31).

Before a patent is issued, the application is examined in the Patent Office to ensure that required standards of patentability are maintained. However, there are several differences in detail among diverse national systems. One significant difference is the determination of who the originator of an invention is. In practice, according to Kaufer (1989: 11) and Silbertson (1998: 815-816), there are two main approaches to grant an inventor a patent; that is, the American approach and the continental European approach. Both approaches are based on the principle of priority. For the United States, patent is assigned to the first person to invent; nevertheless, the U.S. approach is not popular. Most other countries follow the European approach by granting a patent to the first person who files an application for a patent on a particular invention. Patents are normally classed with laws or measures for the protection of so-called "intellectual property" or "industrial property" (Machlup, 1958: 1).[94] To be patentable, an invention must be accurately described and published to allow the skilled person in the particular field of the invention to carry it out. Also, a patentable invention must satisfy exacting requirements; for instance, they must be new, must involve an inventive step, and must be useful for industrial application (Langinier and Moschini, 2002: 31). However, determining whether an invention is genuinely inventive and useful is still quite problematic and ambiguous.

The basic idea behind the patent grant is to fight what would otherwise be a tendency toward under-investment in research and development (R&D). Under-investment can take place in that innovations are in central respects similar to public goods, making it hard for the inventors to appropriate their benefits, and because of the uncertainties encompassing inventive activity(Arrow, 1959: 11, 15). Innovative products or processes that naturally embody new scientific knowledge are non-excludable and non-rival—attributes which are specific to public good (Langinier and Moschini, 2002: 32). [95] Without intellectual property rights (IPR), once the information inherent in the innovations is public, competitors of the original inventor are free to make use of it. Besides, the use of knowledge by a person does not reduce

[94] This class includes the protection of exclusivity for copyrights, trademarks, trade names, artistic designs, and industrial designs, besides technical invention.

[95] Pure public goods have two basic attributes. First, they are non-rival in consumption, meaning that a person's use of a public good does not affect its amount available for other people. Second, they are non-excludable, meaning that it is not possible to prevent individuals from utilizing the public good once it is available.

the availability of the knowledge to others. It is clear that in a lack of IPR, most innovations and discoveries would illustrate public goods attributes.

Particularly, Arrow (1962: 615) suggests that, with no appropriate legal measures, the market system will not handle new knowledge properly and will cause a market failure. The intuition behind this is that imitators have the incentive to free-ride on the efforts of the original inventor who incurs all R&D costs. The original inventor, however, foresees that once the R&D costs are sunk and the innovations are produced, he will not gain sufficient profit to recover his costs. Thus, if the market for innovations is perfectly competitive and information inherent in the innovation is publicly available, the potential inventor will not be willing to incur the risks and costs associated with the inventive process. As a result, given that innovations are socially desirable, the level of innovations will be sub-optimal if innovations remain unprotected (Arrow, 1959: 11-12; Langinier and Moschini, 2002: 32-33).

To address this market failure, for activities as intricate and uncertain as research, invention, and development, a patent system is one of the practical, legal alternatives to motivate the investment in R&D (Bailey et al., 2001: 12; Langinier and Moschini, 2002: 33). Patents work by affecting the excludability attributes of an otherwise pure public good. By preventing others from imitating an inventor's innovation or by putting the inventor in a position to license imitators only in exchange for compensation, patents allow inventors to "appropriate" the economic benefits flowing from their inventive contributions. The expectation of such rewards is what provides a sufficient incentive to invent. In an absence of patent protection, imitation might occur so swiftly that an inventor could appropriate at best a small fraction of his innovation's benefits, and if the expected amount were too small, an incentive failure would occur and desirable inventions would not be forthcoming.

In summing up, in a competitive market with the nonexistence of IPR, most discoveries and innovations exhibit public goods attribute, non-excludable and non-rival in consumption. The problems occur since an initial inventor has to bear the whole costs of an innovation, R&D cost in particular, whereas everyone benefits from an innovation by free riding on the innovative efforts of the original inventor. The inherent externalities of an innovation, associated with the attributes of public goods, create a market failure and lead to an inefficiently low level of innovations available

in a market. IPR in general and patents in particular can tackle this problem by endowing inventors with property rights on their discoveries and innovations. However, the patent system is far from perfection because it is just a second-best solution, leaving prices in excess of costs throughout the monopoly period. Strong patent rights may be conducive to new technological inventions but concurrently it often entails significant economic costs. Thereby, the underlying economic theory of patents usually focuses on the monopoly-innovation tradeoff. Generally, the main economic benefits and costs of the patent system are closely related to nature of market failure that it addresses, and to the second-best character of the solution it provides. Next issues provide the discussion of the costs and benefits of the patent system.

B.1.2 Social Benefits of Patent System

Patent is one component of a broader system of intellectual property (IP) protection including copyright, trademarks, geographical indications, and protection of trade secrets. It is perhaps the most important legal means to encourage innovation. Patents are of benefit to the society because they can promote discoveries, assist the dissemination of knowledge, avoid wasteful innovation efforts, facilitate technology transfer, and induce the development and commercialization of innovations (Mazzoleni and Nelson, 1998b: 1033; Langinier and Moschini, 2002: 33, 35). By conferring on discoverers the sole rights to exploit the fruits of their efforts for a limited time, patents have an effect on the incentive to innovate and are likely to increase the flow of useful innovations.

A further benefit of patent is that it requires disclosure of inventions. In most countries, information of a newly-patented product is legally obliged under patent law to publicly disclose within 18 months after the filing date (Langinier and Moschini, 2002: 35). This requirement, as a vehicle for knowledge disclosure, helps to generate quick and wide diffusion of the scientific and technical information underlying new inventions. By providing an incentive for disclosure, patents allows other inventors to avoid copying existing inventions and makes it easier to develop further inventions building on a current technological knowledge.

Granting patent rights is also important for avoiding wasteful innovation races. This rationale is articulated in the so-called "prospect theory of the patent system", originated by Kitch (1977). The prospect theory hinges upon the idea that broad, early patent on a prospect opening innovation permits an orderly pursuit of follow-up innovations and reduces the social costs associated with racing towards a common innovation.[96] Under the articulation of Kitch (1977), unless there is a controlling patent, several inventors will see the same opportunity and know that their competitors also see it, and the consequence will be races for identical innovation. Innovation races result in a situation where the social return of an innovation is not maximized.[97] To tackle this commercialization concern, Kitch (1977) proposes that by granting broad patent rights early in the inventive process, a single patent holder could effectively coordinate post-invention development and commercialization efforts undertaken by others. This approach reduces potential costs of duplication in the R&D process, and prevents third parties' use of un-patentable information generated during the development and commercialization process. Under the prospect theory, the holding of a broad patent on a prospect invention would optimally insure against commercialization risk and costs, promoting the investment needed to make and sell products in the marketplace. Furthermore, Langinier and Moschini (2002: 35-36) argues that patent can facilitate technology transfer by reducing transaction costs of licensing innovation. To put a value on information, suppose a prospective buyer needs to obtain the specific information, but if the seller does not have property rights on it, the prospective buyer has no motive to pay for it. Under this situation, knowledge cannot be disseminated; in other words, technology transfer does not occur. While the difficulty of licensing reduces demand for information, patent can play an important role in licensing and hence help to transfer technological information.

Apart from stimulating innovations, an additional distinct role for patents is as instruments for inducing the development and commercialization of innovations (Mazzoleni and Nelson, 1998a: 276; Langinier and Moschini, 2002: 35). In 1775,

[96] In prospect theory, an original discovery or invention is seen as opening up a whole range of follow-on developments or inventions (Kitch, 1977). It is noted that discoveries from basic research and a lot of university inventions are often of this sort.
[97] The social return is the difference between the expected profits of an innovation and its cost.

more than two centuries ago, this distinct role of patents had been articulated by the Parliament of the Kingdom of Great Britain to justify the extension of Watt's steam engine patent (Mazzoleni and Nelson, 1998a: 276; Boldrin and Levine, 2008: 1; Spear, 2008). More recently, in 1980, the same distinction was argued and led to the passage of the Patent and Trademark Laws Amendments, widely known as the Bayh-Dole Act. The major amendments of this Act were to permit the universities and other entities to patent, maintain title to and commercialize federally funded inventions as well as to allow federal agencies to grant monopoly licensing for their inventions. Langinier and Moschini (2002: 36) argues that with no exclusive license supported by patent rights, several inventions generated by publicly funded R&D may not be employed in technological developments as firms would not be invested in high-priced development work demanding an invention be transformed into a new product. But, if patent is granted early in the innovation process before the crude invention is ready for actual use, a patent owner is assured that if development is successful, his economic rewards can be appropriated. Accordingly, patents can encourage firms to commit large amounts of money and resources in the development of inventions.

In brief, as a public policy tool, patent was designed to promote and reward innovations, together with ensuring disclosure of innovations so as to make them commonly known and available (Bailey et al., 2001: 9; World Health Organization. Regional Office for the Western Pacific, 2006: 1). If meeting the criteria of novelty, inventiveness, and capacity for industrial application, new inventions can be filed on either a product or a process patent. Patent systems were developed initially either by encouraging the importation of new technologies into a country or by building new inventions. Rather than keep the invention secret, countries learned that one efficient way of obtaining inventor to publicly reveal his invention was to offer him a certain period of monopoly rights for making a commercial use of his invention in exchange for doing so. After an exclusive period, the monopoly rights were lifted; hence, the invention could be freely used by everyone. Theoretically, when the Patent Office published the patent application explaining the invention, the public learned quickly about the new invention, and finally got free access to exploit it. Meanwhile, the patent holders benefited from the patent by selling their new inventions at a higher price than would have been the case without patent as the patent monopoly precludes

rivalry. Ideally, both public and patent holder benefit from the patent deal (Boulet et al., 2003: 5).

B.1.3 Social Costs of Patent System

While encouraging some new inventions that would not otherwise be made and accelerating the launching of others, the patent system simultaneously extracts social costs. According to Kaufer (1989: 42-43), granting of patent monopolies produces two main kinds of social costs. The first one is administrative costs incurred by the government and patent recipients, but the most noteworthy one is the resource misallocation costs in the form of static and dynamic inefficiencies caused by patents on inventions that would have been widely available without patent protection, or with less protection. Kaufer (1989: 41) notes that "even if patent protection proves to be highly effective in appropriating social benefits, it is a second-best solution, leaving prices in excess of costs during the patent's life and hence causing a misallocation of resources relative to the 'first best' of inventions financed by minimally distorting taxes." Kaufer (1989: 43) states further that "if a patent provides more protection than is necessary to induce the desired invention or innovation, the patentee can extract larger price-cost margins, imposing dead-weight losses, and those may persist for too long a period."[98]

How much power over price a patent confers differs broadly from case to case, depending upon the availability of substitutes and consumers' knowledge of their availability. The most extreme cases pertain to the pricing of patented drugs, for which demand is characteristically rather inelastic over an extensive price range. In the United States, from 1956 through the mid of 1960s, the Pfizer Company and its four licensees sold the antibiotic pills, tetracycline, to drugstores at a wholesale price of $30.60 per bottle of 100 capsules, while the production costs ranged only between $1.60-3.80 per bottle. Total sales to drugstores during the monopolistic period surpassed $ 1 billion. After patent had expired, many unlicensed firms started

[98] According to standard economic theory, a monopoly generates a deadweight loss to society as the monopolist charges a price for the patented product which is in general higher than the price that would prevail under perfect competition. Also, the total quantity demanded in the monopoly market is typically lower than the quantity demanded under perfect competition because some consumers are not willing to pay the full monopoly price. This normally causes a loss of consumer surplus which is higher than the additional producer surplus created by the monopolist. In economic parlance, this net welfare loss is referred to as deadweight loss.

producing and selling tetracycline at wholesale price only around $ 2.50 per bottle (Scherer, 2005: 14). By this means, it is normal to question what effect in practice the patent system has.

Aside from the first-order costs,[99] Kaufer(1989: 43) points out that the patent system also generates other important costs, the second- and third-order costs. These costs occur when the patent induces inefficient rent-seeking, inhibits the creative efforts of others, or cooperates with other entry barriers to strengthen monopolistic market positions. It is the case that one firm's patents block another firm from inventing. Patents may also stimulate over-investment in R&D because firms imitate each other's innovative programs and hasten them until inventions arise untimely leading to extensive "inventing around" existing patents and finally resulting in unqualified inventions. Imperfections of the patent system, therefore, can cause not only under-investment but also over-investment in R&D (Kaufer, 1989: 41).

B.1.4 Costs and Benefits on Balance: The Monopoly/Innovation Tradeoff

The fundamental tradeoff of patent protection is to strike a balance between the benefits of patent protection due to higher R&D incentives and a higher level of innovation on the one hand and the deadweight loss to society resulting from patent protection on the other (Langinier and Moschini, 2002: 34; Kremer and Glennerster, 2004: 33). In addition to encouragement of new innovations, another crucial benefit of patents is that they make the technological information inherent in the patented innovation available to the public because the patent document is generally published by the patent office (Langinier and Moschini, 2002: 35); without patent protection, the innovators could alternatively recur to trade secrets to protect their innovation (Friedman, Landes and Posner, 1991). Moreover, there are several additional benefits and costs of patent protection, i.e. positive effects on follow-up innovations, on the one hand, and wasteful duplication of costs in "patent races"[100] (Leveque and

[99] The first-order costs comprise the resource misallocation cost and the administrative costs.

[100] The prospects of monopoly rents associated with patent protection may encourage too many potential innovators to invest in R&D in order to make the innovation and to obtain the patent. Finally, in this so-called patent race, the sum of R&D investments of all potential innovators will be higher than the optimal investment effort that would be sufficient to create the innovation. In other words, patent races cause a situation where the social return of an innovation is not maximized (Leveque and Meniere, 2004:24).

Meniere, 2004: 24) and the anticommons problem[101] (Heller, 1998: 668; Heller and Eisenberg, 1998: 698) in the biochemical industry, on the other hand.

It is very difficult to assess the efficiency and the social welfare effects of the patent system. Improving the protection of intellectual property is not necessarily socially beneficial. Empirical work has so far indicated a positive cross-sectional relationship between strong appropriability of return from innovation and innovative performance.[102] But the social cost-benefit calculation is not straightforward. Strong appropriability will not yield more innovation in all contexts and innovation may come at excessive cost. Put differently, although the prospect of monopoly rents should induce inventive effort, the costs of disclosure can in some circumstances more than offset the prospective gains to patenting (Horstmann, MacDonald and Slivinski, 1985; Levin et al., 1987: 787).

Apart from the direct costs of administering a patent system, the monopolistic constraints resulting from the patent system attach several costs that are no doubt considerably high but immeasurable to the society. On the opposite side of the balance, the society benefits from the system as there exists innovations that would not otherwise be made or that would become available at a later date without the patent incentive. Scherer (1980: 454) has roughly classified these innovations into two categories: those that have modest economic impact, and those that have exceptional high economic value. According to Scherer (1980: 454), without patent protection, the social gain forgone due to losing innovations in the first category would be immaterial. However, innovations in the second category represent a horse of a different color. Breakthrough innovations are normally few and far between, but even a few can make a radical change in human well-being. For instance, the appearance of xerographic copying processes allowed the American economy to realize savings of at least a quarter billion dollars a year (at 1967 level of utilization). In the absence of patent protection, the American society would probably have to wait for several years

[101] In essence, the tragedy of the anticommons occurs when rationally and separately acting individuals collectively under-utilize and thus partly waste a given scarce resource (Heller and Eisenberg, 1998:698). In theory, individuals under-utilize a scarce resource when too many individuals hold effective rights of exclusion in the given scarce resource (Heller, 1998:668).

[102] The term "appropriability" means that to have the incentive to undertake R&D, a firm must be able to appropriate returns sufficient to make the investment worthwhile. A patent confers, in theory, perfect appropriability (due to monopoly of the invention) for a limited time in return for a public disclosure that ensures, again in theory, widespread diffusion of benefits from innovation when the patent expires.

longer for xerography. Because of the existence of such breakthroughs, altogether governments choose to retain the patent system rather than scrap it.

B.2 Importance of Patents to Pharmaceutical Industry

". . . pharmaceutical industry stands alone in the extent of its involvement with the patent system . . ." Silberston (1973: 231)

Section B.2 provides three main points. First, patents are important, but only to a few industries, one of which is innovative pharmaceutical industry. Second, the importance of patent protection for these industries is attributable to the strength that patents provide in litigations. Finally, Section B.2 offers political economy discussion of why industrialized countries have reached a consensus in favor of introducing the patent protection for pharmaceuticals and also highlights the pressure put by industrialized countries for reforming patent policies in less-developed countries.

B.2.1 The Inter-Industry Importance of Patents

Although there is a general supposition that patents are a vital instrument for allowing innovators to appropriate the returns from innovations, there are theoretical as well as empirical reasons to question whether patent rights advance innovation in a substantial way in most industries. For example, Nordhaus (1969) has proposed one of the most thorough economic analyses of patent. His model shows how patents are an inferior policy for promoting innovation; it also advises that the degree of patent protection should vary by industry. Additionally, empirical work by many economists over nearly fifty years suggests that patents play a major role in stimulating invention in only a few manufacturing industries (Scherer et al., 1959; Taylor and Silberston, 1973; Mansfield, 1986). Likewise, surveys of R&D managers by Levin and et al. (1987) and, more recently, Cohen and et al. (2000) found that in most industries patents are judged to be less important means of protecting innovations than, for example, being first to market or retaining know-how as trade secrets.

Although we should therefore not assume that patents invariably induce innovation, neither should we assume the contrary. Firms may rely more heavily on other means of protecting innovations, but patents may still yield a return. Arora and

colleagues (2003: 35) recently showed that patents do appear to stimulate R&D across the manufacturing sector, although the magnitude of the stimulus varies greatly from industry to industry. Mansfield (1986), Levin and et al. (1987), and Cohen and et al. (2000) all find that pharmaceutical and medical equipment R&D benefits the most from patenting.

In short, economic research has made a convincing case that, in most industries, the impact of patent protection on innovative effort as well as on prices and profits is on the whole marginal. The most important exception is pharmaceutical which as an industry is greatly reliant on patents. Perhaps the pioneering study to throw light on this issue was undertaken by Mansfield (1986). His figures are reproduced in Table B.1; they show by industry during the early 1980s the percent of inventions that would not be developed nor introduced into the market without patent protection.

As shown by Table B.1, a large number of pharmaceutical products generated by the pharmaceutical manufacturers would neither have been developed nor introduced, if there had been no patent protection. More specifically, 60 percent of pharmaceutical products that had already been introduced during 1981-1983 would not have been developed and 65 percent of pharmaceutical drugs that had been developed in this period would not have been introduced in the absence of patent protection. Mansfield (1986: 180) concluded that patent protection may not be an essential stimulus for innovation in most industries except a few industries, particularly pharmaceuticals and chemicals, which the effect of the patent system were reported to be very substantial.

Table B.1 Percent of Developed or Commercially Introduced Inventions That Would Not Have Been Developed or Commercially Introduced if Patent Protection Could Not Have Been Obtained

Industry	Percent that would not have been introduced	Percent that would not have been developed
Pharmaceuticals	65	60
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Fabricated metal products	12	12
Primary metals	8	1
Electrical equipment	4	11
Instruments	1	1
Office equipment	0	0
Motor vehicles	0	0
Rubber	0	0
Textiles	0	0

Source: Mansfield, 1986: 175.

Note: Some inventions that were developed in this time period (1981-1983) were not introduced then, and some inventions that were introduced then were not developed then. Thus, the left-hand column of the table refers to somewhat different inventions than does the right-hand column.

Mansfield's conclusion is in line with early empirical studies on patents undertaken by Scherer and et al. (1959), and Taylor and Silberston (1973). His conclusion is also obtained strong support from studies carried out by Levin et al. (1987) and more recently Cohen et al. (2000). The comprehensive study of Levin et al. (1987) explored the relative importance of various approaches of protecting the inventors' returns on their inventions. The authors prepared an inclusive questionnaire and interviewed research managers from 130 U.S. industries. One set of questions included the managers' opinions concerning the significance of alternative instruments of

appropriating the returns from innovations produced by their companies.[103] The authors differentiated between process and product innovations. In addition, the answers were rated on a scale of one to seven. The study showed that on average the most significant instruments of appropriating the returns from process and product innovations are lead time and sales/service efforts. On the contrary, patents to secure royalty income in process and product innovations were only 65 percent and 67 percent as important as lead time and sales/service efforts respectively.

Levin et al. (1987: 795-797) also revealed the inter-industry importance of patents for appropriating the returns from innovation. Again, the answers in their fundamental survey were rated on a scale of one to seven. The study result has led to conclusion that patents are the most important means for the research-intensive drug companies to protect their process and product innovations; these patents were rated 40 percent and 51 percent higher than the industrial average for processes and products respectively. Moreover, there were only 5 of 130 industries that rated product patents to prevent imitation higher than six (out of seven) points; the drug industry was one of the five. The conclusion of Levin et al. was consistent with a classic study of the British patent system conducted by Taylor and Silberston (1973). Evidently then, patents are an effective policy instrument in determining the returns to innovative efforts in a handful of industries, particularly research-intensive pharmaceutical industry.

B.2.2 The Inter-industry Strength of Legal Protection

Patent is one mechanism among other alternatives to appropriate the returns from innovation; the importance of patents differs so distinctly among industries. Additionally, evidence gathering in recent years indicates that patents are effective in only a few industries. The ineffective of patents in most industries raises the question of why it plays a major role in specific industries like chemicals and pharmaceuticals. Levin et al. (1987: 799) suggests that means of appropriating the returns from R&D can be grouped into patents and non-patent mechanisms (secrecy, lead time, learning curve advantages, and sale/service efforts). For instance, lead times are the most

[103] Alternative instruments of appropriating the returns from innovations included patents to prevent duplication, patents to secure royalties, industrial secrets, lead time, learning advantages, and sales and /or service efforts.

crucial instrument of appropriating the returns from innovation for some industries (such as consumer electronics) that the rate of innovation and product differentiation is very fast. Many inventions may not be patentable because they cannot satisfy the requirements for a patent; for instance, the invention has to be novel. However, even if an invention were patentable, it could be that the owners would prefer to keep it as a secret since a patent discloses valuable information.[104]

Obviously, the legal aspect is a key factor explaining the importance of patents to the pharmaceutical industry. Levin et al. (1987: 798) in their study so-called Appropriating the Returns from Industrial Research and Development gave the reason of why patents are particularly effective in chemical industries. Their explanation was . . . the comparatively clear standards can be applied to assess a chemical patent's validity and to defend against infringement. The uniqueness of a specific molecule is more easily demonstrated than the novelty of, for example, a new component of a complex electrical or mechanical system. Similarly, it is easy to determine whether an allegedly infringing molecule is physically identical to a patented molecule; it is more difficult to determine whether comparable component of two complex systems do the same work in substantially the same way. This explanation could also be extended to pharmaceutical industry for which patents are the most effective instrument of appropriating the returns from R&D.

In conclusion, patents appear to be a major instrument for fostering technological innovation and diffusion in only a few industries. One of the few industries is pharmaceuticals; because pharmaceutical drugs are easily copied, the legal protection provided by patent litigation is clearly in favor of R&D-intensive drug firms.

B.2.3 Pharmaceutical Industry and Worldwide Patent Protection for Pharmaceutical Products

Pharmaceutical industry is one of the world's most R&D-intensive industries, generating for nearly a century a continuing steam of new drugs that save lives and raise human health standards materially. In affluent nations, pharmaceutical

[104] This could be mostly significant when the inventor is afraid that the courts will not protect his patent rights.

companies have the highest company-financed research and development-to-sales proportions of any industries for which data have been reported (Scherer, 2008: 16, 2010: 541-542). Pharmaceutical firms typically invest around 10-16 percent of their sales in R&D contrasting with around 2.5 percent of the nation-wide average R&D investment as a proportion of GDP of industrial countries (Evenson and Ranis, 1990; Nogués, 1990: 15). Almost all of the research-oriented pharmaceutical firms, accountable for innovations in drug therapy, have their home bases in highly industrialized countries such as the United States, the European Union countries, or Japan, where demand of most highly competent scientists is at hand. In general, these pharmaceutical firms operate internationally as multinational enterprises. Nowadays, the extent of multinational operation has globally increased, in part due to several cross-border mergers.

Inventing an innovative medicine and bringing it through the tests needed to get approval from regulatory agencies in the economically advanced countries costs more than 100 million dollars per successful new drug entity. The Pharmaceutical Research and Manufacturers of America claimed that in 2001 its members spent over 30 billion dollars in discovering and developing new drugs (Johnson and Walworth, 2003: 2). Since the pharmaceutical products under development are not assured success, investment in this business is very risky. Only a small percentage of new drugs become financially successful to their investors. The highest expenditure by far in carrying the newly effective and safe medicines to market is in development rather than manufacture or duplication. While the costs and risks concerned in new drug development are high, the costs of product imitation are generally low. Once a successful drug is marketed, it may be replicated with little effort. A drug developed and approved by the government for marketing after extensive research and development and clinical testing by the developer can often be duplicated with relatively inexpensive chemical ingredients and processes.

Because of such a huge investment, there are influential incentives to obtain required regulatory approvals in other countries in order to sell this drug as broadly as possible. Foreign markets are generally supplied both by exporting and through direct plant investment in consuming rich economies. As stated early, most of the research and development (R&D) outlays are invested to find therapeutically attractive

molecules and assure their efficacy and safety. In a lack of legal barriers to copying, once a newly safe and effective medicine has been found and marketed, another firm might come up with a generic equivalent by investing only about a million dollars on production cost and start completing with the original research firm, resulting in a huge reduction of surplus revenues that repay original firm's initial investments and hence undermining incentives to invest in research and product testing (Scherer, 2000: 2246-2247). As a consequence of the large gap between R&D and imitation costs, research-oriented pharmaceutical companies attach exceptionally high importance to the patent system, which in practice grants them twenty years of sole rights to exploit their innovations, as a means of recouping their investment (Mansfield, Schwartz and Wagner, 1981: 913; Levin et al., 1987: 811).[105] To sum up, patent protection on marketed new pharmaceutical entities is a major component of their profit-earning expectations; according to Kitch (1973) without patent or some equivalent barrier [106], emulators could free-ride on the information generated by the innovator's hundred-million-dollar R&D and testing spending, invest only a few hundred thousand dollars on process engineering and begin to compete with the original inventor, lessening its quasi-rents.

The involvement of worldwide business expansion through multinational operations along with serious tension on patent protection set the stage for a conflict between the drug makers and the world's developing countries. Before TRIPS, under the Paris Convention, many countries ruled out pharmaceutical products from patentability since pharmaceuticals were regarded to be of such huge significance to the national welfare. Within the context of the Paris Convention, countries could-and did- freely design a patent regime that was in line with their level of development and their overall, national priorities, as long as they did not discriminate between local and foreign investors. Even Switzerland, home to three of the world's top pharmaceutical companies, refrained until 1977 from granting product patents in pharmaceutical field.

[105] Levin et al. (1987:811) found that patents raise imitation costs by 40 percentage points for both major and typical new drugs, and by 25 points for typical chemical products. Their findings were consistent with those of Mansfield and others, who studied the effect of patents on imitation costs in three industries. In Mansfield and others' study (1981:913), it was concluded that patents generally raised imitation costs by 30 percentage points in drugs, 10 points in chemicals, and 7 points in electronics and machinery. According to these two studies, it comes to conclusion that an impact of patent on imitation costs in the ethical drug industry was bigger than those in the other industries. Therefore, patents are regarded as more important in ethical drugs than elsewhere.

[106] Such as a regulatory on new drug approval as a barrier to copying

Most developing and least-developed countries followed this pattern and had a tendency to endow their countries with weaker patent protection than the rich economies did (Scherer, 2000: 2247-2248). Accordingly, during that period the level of patent protection, the Member States had adopted, varied towards countries' interests. While some used to grant patents for pharmaceutical product and process inventions, some others allowed patent protection only for process inventions, thus not preventing local companies from developing different manufacturing processes for drugs that were not patent protected as a product. Other countries, in particular least-developed countries, did not grant any form of protection for inventions in the pharmaceutical sector. In addition, the term of protection conferred by a patent varied greatly among countries. These patent policies of the less-developed countries (LDCs), which usually denied patent protection to medical and food products, were viewed as a thorn in the eyes of research-based multinational pharmaceutical manufacturers.

Patent and other forms of intellectual property rights such as trademark, trade secrets and copyright were seriously important to highly research & knowledge-intensive industries; for instance, computer & its technology, electronics, scientific equipment, and particularly pharmaceuticals & chemicals (Mansfield et al., 1981; Levin et al., 1987). As these industries took more interest in the design of intellectual property rights, their business strategies came to be more and more based on the use of intellectual property rights. This in turn meant that these giant companies had a greater and greater incentive to influence their design (Drahos and Braithwaite, 2004: 2-3). Their business model paradigm took it as axiomatic that there had to be strong intellectual property rights–the stronger the better. Normally, among major U.S. corporations in these industries had a strong and powerful business network. One important reason for the well-built relationship was to strengthen their bargaining power for mutual benefit. Since these influential U.S. companies wanted intellectual property rights, they took a common interest in lobbying the U.S. government on their design. A cycle of regulatory growth was thus created.

Almost all of multinational pharmaceutical corporations had invested in developing countries and thus perceived the threat to their international markets that generic manufacturers, in countries like India, posed for the R&D pharmaceutical

industry (Drahos and Braithwaite, 2002: 59). The failure to acquire universal patent protection for their new pharmaceutical innovations was noticed as a major constraint on their global turnovers and profits. An effort to change the circumstance at a World Intellectual Property Organization (WIPO) conference in Kenya during the 1970s demonstrated this failure. Under the context of the WIPO, countries had moved carefully in ceding sovereignty over intellectual property rights. The pharmaceutical manufacturers afterward searched for other forums to pursue their quest (Scherer, 2000: 2248).

In the 1980s, the international IP protection rules experienced something of a quantum leap. During the early 1980s, a small group of Washington-based policy entrepreneurs conceived of the radical idea of linking the intellectual property regime to the trade regime. Among the proponents, the Pfizer's chief executive officer (CEO), Edmund Pratt, was the leader of this idea. Basically, their policy idea was to get an agreement on intellectual property into the General Agreement on Tariffs and Trade (GATT). Beyond other things, such an agreement would be enforceable under GATT dispute resolution procedures (Drahos, 2003: 3). The U.S. pharmaceutical companies, led by Edward Pratt and a member of President Reagan's business advisory committee on international trade, started their campaign to bring the U.S. government into the dispute (Ryan, 1998: 67-69). The far-reaching idea of a trade-based approach to intellectual property was fanned out to enlist the help of movie, music recording, and software industry leaders who were similarly distressed about the copyright protection in some countries outside the United States. Pratt together with other Pfizer senior executives began delivering speeches outlining the linkage between trade, intellectual property and investment at various business forums; for example, the National Foreign Trade Council and the Business Round Table. Their intent was to push the newly concept of intellectual property issue through national and international trade associations (Paine and Santoro, 1992; Scherer, 2000: 2248-2249; Drahos, 2003: 3-4). Besides, they in turn persuaded the European and Japanese pharmaceutical companies to join the campaign through the so-called Dolder Group.[107] Because of such intensive campaign, the message about a trade-based approach to intellectual property went out along the business networks to chambers of

[107] Dolder Group named after a Swiss hotel, the Dolder Grand, at which pharmaceutical executives met regularly.

commerce, business councils, business committees, trade associations, and top business bodies. In addition, their shrewd public relations campaign was highly successful in building the term "piracy" to be accepted as the definition of the imitation of intellectual property products in countries with permissive intellectual property laws. Lobbying efforts at the U.S. Congress led to amendments in Section 301 of the U.S. international trade code, identifying other countries' failure to grant full patent or copyright protection for U.S. products as an unfair trade practice.[108] Prodded by a lobby arranged by pharmaceutical executives, in the 1980s the U.S. government commenced pressuring other countries with international trade sanction under Section 301 of the U.S. trade law, unless they complied with U.S. intellectual property standards (Paine and Santoro, 1992; Ryan, 1998: 67-69). Under the force from the United States, several countries such as Thailand, Korea, Brazil, and Canada amended their patent and copyright laws to conform to the U.S. intellectual property code and started enforcing them industriously.

The U.S industry leaders together with their European and Japanese business counterparts widened their lobbying movement to enforce the idea of a trade-based approach to IP protection standard globally.[109] Urged by industrial lobbies, the governments of the United States, European Union member nations, and Japan persisted strongly that harmonization of national intellectual property laws was a key agenda item in the Uruguay Round of international trade negotiation (Scherer, 2000: 2249; Drahos and Braithwaite, 2004: 25).[110] Afterwards, in 1994, at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), the

[108] Section 301 of the U.S. trade code defines other countries' failure to grant full patent and copyright protection for U.S. products as an unfair trade practice. To comply with the law, the President's Trade Representative Office has been responsible for monitoring foreign intellectual property practices as well as identifying for unilaterally imposed trade sanctions the most outrageous perceived offenders.

[109] Linking intellectual property to trade had been the task of a few key persons. Pfizer, led by Edmund Pratt, had played a vital role in urging this linkage. Under Pratt's leadership, the Advisory Committee on Trade Negotiations (ACTN) had pushed that the US government should develop an integrated multilateral and bilateral intellectual property strategy based on trade linkages. Jacques Gorlin, adviser to ACTN, headed the Intellectual Property Committee, the key lobbying body on the industrial side of intellectual property. Eric Smith, the Executive Director of the International Intellectual Property Alliance, had assisted to put the pertinent language into the Generalised System of Preferences programme. Smith and another copyright lawyer, John Baumgarten, had an important influence on the framed work of the language of Section 301.

[110] In the early 1930s, ravaging protectionism policies of many nations led to the collapse of the world economy. This became the impetus for twenty-three nations to sign a treaty in 1974, known as General Agreement on Tariffs and Trade (GATT). The goals of GATT were aimed at promoting and regulating the liberalization of international trade through round of trade negotiations. The Eighth Round of Multilateral Trade Negotiations, held in Uruguay in 1986 and concluded in April 1994, known as the Uruguay Round of Multilateral Trade Negotiations, produced the Marrakesh Agreements, which established the World Trade Organization (WTO).

negotiation was formally ratified. The effort of industrialized nation coalition, demanding patent law unification, was completely successful. The Treaty of Marrakech produced an agreement, widely known as the agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS),[111] requiring inter alia that all member countries provide full patent protection for pharmaceutical products—for industrialized countries, by the year 1999; for less-developed countries, by the year 2004 ; and for least-developed countries, by the year 2016 (Culyer and Newhouse, eds., 2007: 1319).

[111] The TRIPS Agreement is an Annex 1C of the Marrakesh Agreement, signed in Marrakesh, Morocco, on 15 April 1994.

APPENDIX C

DATA ON DRUGS WITHIN THE SAMPLE, STRUCTURE OF PREFERENCES AND PROPERTIES OF DEMAND

Appendix C starts with Section C.1, offering information on drugs used in this study. Section C.2 discusses specific assumptions (e.g., separability conditions) that allow for aggregation across commodities. Appendix C ends with Section C.3. There the theoretical properties of demand functions are presented in detail.

C.1 Summary Information on the Drugs within the Sample

Oral antihypertensive drugs marketed in Thailand during 1996-2008 were included in the study so as to capture the market for antihypertensive drugs. The sample pools data from the three major therapeutic categories, identified using the Anatomical Therapeutic Chemical (ATC) codes, [112] of antihypertensive drugs, including Beta Blocking Agents, Calcium Channel Blockers and Agents Acting on the Renin-Angiotensin System.[113] In all, 422 oral antihypertensive drugs were included in the study.[114] The data are annual aggregates of values and quantities consumed in Thailand over a thirteen year period from 1996 to 2008.[115] All data were drawn from the Thai Food and Drug Administration (FDA). A complete list of the drugs—classified by the mechanism of action, used for empirical analysis, their dosage form and strength, their defined daily dose (DDD) and their number of producers is presented in Table C.1.

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[112] See the Guidelines for ATC classification and DDD assignment 2009 (WHO Collaborating Centre for Drug Statistics Methodology, 2009).

[113] Agents acting on the renin-angiotensin system include Angiotensin Converting Enzyme Inhibitors (ACE inhibitors), Angiotensin II Antagonists (AIIA or ARB), and Renin-Inhibitors.

[114] Drugs having the same chemical structure that were produced by different companies were included as separate products. Likewise, drugs having the same chemical substance with different strengths (in terms of milligram) were classified as separate products.

[115] In this study, value and quantity consumed of a drug in Thailand can be calculated by the following formula. Value (or quantity) consumed in the country = value (quantity) imported + value (quantity) produced domestically-value (quantity) exported

Table C.1 Names and Descriptions of Antihypertensive Drugs within the Sample Sub-Segment

Generic Name	Dosage Form and Strength	Number of Producers	DDD (mg)
Beta Blocking Agents			
betaxolol	tab 20 mg	1	20
nebivolol	tab 5 mg	1	5
propranolol	SR cap 160 mg	1	160
atenolol+chlortalidone	tab 50+12.5 mg	1	1
atenolol+chlortalidone	tab 100+25 mg	1	1
bisoprolol+HCTZ	tab 2.5+6.25 mg	1	1
bisoprolol+HCTZ	tab 5+6.25 mg	1	1
pindolol+clopamide	tab 10+5 mg	1	1
atenolol	tab(25,50,100 mg)	24	100
bisoprolol	tab(2.5,5,10 mg)	2	10
carvedilol	tab(6.25,12.5,25 mg)	2	37.5
metoprolol	tab 100 mg	14	150
metoprolol	SR tab(200 mg)	2	200
propanolol	tab(10,20,40 mg)	26	160
propranolol	SR cap/tab 80 mg	2	80
pindolol	tab(5,10,15 mg)	1	15
timolol+amiloride+HCTZ	tab 10+2.5+25 mg	1	1
Calcium Channel Blockers			
barnidipine	cap 10 mg	1	10
barnidipine	cap 15 mg	1	15
isradipine	tab/cap(2.5,5 mg)	1	5
lacidipine	tab(2,4 mg)	1	4
lercanidipine	tab(10,20 mg)	1	10
manidipine	tab 10 mg	1	10
manidipine	tab 20 mg	1	20
nicardipine	SR cap 40 mg	1	80
nifedipine	SR tab 60 mg	1	60
amlodipine	tab(5,10 mg)	8	5
felodipine	SR tab(2.5,5 mg)	6	5
felodipine	SR tab 10 mg	5	10
nicardipine	tab(10,20 mg)	2	60
nifedipine	cap/tab(5,10 mg)	7	30
nifedipine	SR tab 10 mg	1	20
nifedipine	SR tab/cap 20 mg	7	40
nifedipine	SR tab 30 mg	3	30
nitrendipine	tab(10,20 mg)	2	20

Table C.1 (Continued)

Generic Name	Dosage Form and Strength	Number of Producers	DDD (mg)
Agents Acting on the Renin-Angiotensin System			
cilazapril	tab(1,2.5,5 mg)	1	2.5
delapril	tab 15 mg	1	30
fosinopril	tab 10 mg	1	20
imidapril	tab 5 mg	1	5
imidapril	tab 10 mg	1	10
candesartan	tab(4,8 mg)	1	8
candesartan	tab 16 mg	1	16
irbesartan	tab 150 mg	1	150
irbesartan	tab 300 mg	1	300
olmesartan	tab(20,40 mg)	1	20
telmisartan	tab 40 mg	1	40
telmisartan	tab 80 mg	1	80
valsartan	tab 320 mg	1	320
irbesartan+HCTZ	tab 150+12.5 mg	1	1
irbesartan+HCTZ	tab 300+12.5 mg	1	1
candesartan+HCTZ	tab 8+12.5 mg	1	1
valsartan+HCTZ	tab 80+12.5 mg	1	1
valsartan+HCTZ	tab 160+12.5 mg	1	1
valsartan+HCTZ	tab 160+25 mg	1	1
losartan+HCTZ	tab 100+25 mg	1	1
losartan+HCTZ	tab 50+12.5 mg	1	1
telmisartan+HCTZ	tab 40+12.5 mg	1	1
telmisartan+HCTZ	tab 80+12.5 mg	1	1
bosentan	tab(62.5,125 mg)	1	250
captopril	tab(12.5,25,50 mg)	7	50
enalapril	tab(5,10 mg)	19	10
enalapril	tab 20 mg	15	20
lisinopril	tab(5,10,20 mg)	4	10
perindopril	tab(2,4,8 mg)	2	4
quinapril	tab(5,10 mg)	3	10
quinapril	tab 20 mg	3	20
quinapril	tab 40 mg	1	40
ramipril	tab 2.5 mg	7	2.5
ramipril	tab 5 mg	5	5
ramipril	tab 10 mg	2	10
losartan	tab 50 mg	4	50
losartan	tab 100 mg	2	100
valsartan	tab 80 mg	2	80
valsartan	tab 160 mg	2	160

Source: Food and Drug Administration. Bureau of Drug Control, 2010.

Table C.2 Market Share of and Expenditures on Various Therapeutic Categories within the Antihypertensive Drugs Market, 2008

Therapeutic Category	Market Share (%)	Estimated Value in Consumer Prices (Million Baht)
Beta blocking agents	9.7	1,069.77
Calcium channel blockers	31.0	3,431.07
Agents acting on the renin-angiotensin system	49.1	5,427.44
Diuretics	3.8	418.70
Other antihypertensive drugs	6.4	708.88
Total	100	11,055.86

Source: Food and Drug Administration. Bureau of Drug Control, 2010.

Note: The values in consumer prices were estimated by the author from the actual values of consumption in producer prices.

C.2 Structure of Preferences

Given the large number of goods available to the consumer, estimating consumer demand is difficult because of limited data and a relatively large number of parameters to estimate. Therefore, assumptions are made on how goods can be aggregated and separated into groups as a means of conserving degrees of freedom for estimation.

C.2.1 Composite Commodity Theorem

One way to reduce the number of parameters to be estimated in a demand system is by combining n goods into a set of $S < n$ commodity aggregates. The existence of consistent commodity aggregates for demand can be justified by making use of the Hicks-Leontief composite commodity theorem. The composite commodity theorem asserts that if a group of prices move proportionately then the corresponding

groups of commodities can be treated as a single good. Formally, let $\phi_i = \log(p_i/P_I)$ where p_i is the price of good i and P_I is the composite price index for group I, $i \in I$. Denoting $\boldsymbol{\phi}$ as a vector of ϕ_i, the Hicks-Leontief composite goods theorem states that $\mathbf{q}^*$ maximizes a utility function given **P** if $\boldsymbol{\phi}$ is constant (Deaton, 1986).

While prices of related goods do tend to be strongly correlated over time, the Hicks-Leontief theorem requires that prices of goods within the same group are perfectly correlated, which typically does not hold. Lewbel (1996) relaxes the assumption of perfect collinearity of prices, by allowing $\boldsymbol{\phi}$ to move over time, and instead assumes that the distribution of $\boldsymbol{\phi}$ is independent of **P.**

C.2.2 Separability

An alternative to applying the composite goods theorem is to assume a group of closely related commodities is separable from other goods.[116] Separability assumptions imply restrictions on the nature of substitutability between goods in different groups, which, in turn, limits the number of parameters needed to estimate demand functions. For example, preferences are typically assumed to be separable between consumption in one time period and another time period, and between leisure and goods. Such restrictions can be thought of in terms of two-stage budgeting, the idea that a consumer can allocate total expenditure in two stages: in the first stage, expenditure is allocated to broad groups of goods (e.g., food, housing, and entertainment), while in the second stage, group expenditures are allocated among elementary goods (e.g., meats, eggs, cereals, and so on). Substitution between goods in different groups is limited in different ways by different separability assumptions. Several types of separability have been defined that differ in the degree of restrictions on the substitution effects of price changes between goods in different groups. For the purpose of this study, only weak and strong separability are described because they are the most commonly invoked.

Suppose a vector of goods, $\mathbf{q}$, can be partitioned into S sub-vectors, $\mathbf{q}^1, \ldots, \mathbf{q}^S$, where $\mathbf{q}^I$ contains n^I goods, and the preference ordering of goods in each sub-vector

[116] This subsection is based on Deaton and Muellbauer (1980b) and Pollak and Wales (1992: 35-53).

can be represented by a utility function, $u^I(\mathbf{q}^I), \forall\, I = 1,..., S$. The utility function is said to be weakly separable with respect to this partition if and only if u ($\mathbf{q}$) is of the form:

$$u(\mathbf{q}) = f\left(u^1(\mathbf{q}^1),..., u^S(\mathbf{q}^S)\right) \tag{C.1}$$

where f (·) is a monotonically increasing function. A utility function of this form implies subgroup (conditional) demand functions of the form:

$$q_i = q_i\left(M^I(\mathbf{p}^1,...,\mathbf{p}^S, M), \mathbf{p}^I\right) \forall I = 1,..., S; i = 1,..., n^I \tag{C.2}$$

where M^I (·) is expenditure on group I, and q_i is a function of prices for group I, $\mathbf{p}^I$ and group expenditure, M^I (the subscript denotes the elementary good and the superscript denotes the group). By differentiating (C.2) with respect to p_j and holding utility constant, the Slutsky substitution term[117] can be written as

$$s_{ij} = \delta_{IJ} \frac{\partial q_i}{\partial p_j}\bigg|_{u=\bar{u}} + \frac{\partial q_i}{\partial M_I} \frac{\partial M_I}{\partial p_j}\bigg|_{u=\bar{u}}, i \in I, j \in J, \delta_{IJ} = \begin{cases} 1, \text{if } I = J \\ 0, \text{if } I \neq J \end{cases}. \tag{C.3}$$

By symmetry of the Slutsky matrix, we know

$$\delta_{IJ} \frac{\partial q_i}{\partial p_j}\bigg|_{u=\bar{u}} + \frac{\partial q_i}{\partial M_I} \frac{\partial M_I}{\partial p_j}\bigg|_{u=\bar{u}} = s_{ij} = s_{ji} = \delta_{JI} \frac{\partial q_j}{\partial p_i}\bigg|_{u=\bar{u}} + \frac{\partial q_j}{\partial M_J} \frac{\partial M_J}{\partial p_i}\bigg|_{u=\bar{u}}.$$

Solving for $\partial M^I / \partial p_j$,

$$\frac{\partial M^J}{\partial p_j} = \delta_{IJ}\left[\frac{\partial q_j / \partial p_i}{\partial q_i / \partial M^J} - \frac{\partial q_i / \partial p_j}{\partial q_i / \partial M^J}\right] + \left(\frac{\partial M^I / \partial p_i}{\partial q_i / \partial M^J}\right) \frac{\partial q_j}{\partial M^I}.$$

[117] The Slutsky equation shows that the unobservable Hicksian demand response to prices (a pure substitution effect) can be represented as a combination of observable Marshallian income and price effects:

$$s_{ik} = \frac{\partial h_i(\mathbf{p}, u)}{\partial p_k} = \frac{\partial q_i(\mathbf{p}, M)}{\partial p_k} + \frac{\partial q_i(\mathbf{p}, M)}{\partial M} q_k(\mathbf{p}, M).$$

Notice that the term on the right hand side (RHS) in round brackets is independent of *j*. Letting $(\partial M^I / \partial p_i)/(\partial q_i / \partial M^J) = \lambda_{IJ}$, a proportionality factor that is specific to the I and J groups, then

$$\frac{\partial M^I}{\partial p_j} = \delta_{IJ}\left[\frac{\partial q_j / \partial p_i}{\partial q_i / \partial M^J} - \frac{\partial q_i / \partial p_j}{\partial q_i / \partial M^J}\right] + \lambda_{IJ}\frac{\partial q_j}{\partial M^I}. \tag{C.4}$$

Substituting (C.4) into (C.3), we can rewrite the Slutsky substitution term as[118]

$$s_{ij} = \delta_{IJ}\frac{\partial q_j}{\partial p_i} + \lambda_{IJ}\frac{\partial q_i}{\partial M^I}\frac{\partial q_j}{\partial M^J}, \forall i \in I, j \in J, \delta_{IJ} = \begin{cases} 1, \text{if } I = J \\ 0, \text{if } I \neq J \end{cases}. \tag{C.5}$$

If good *i* is in the same group as good *j*, then s_{ij} is composed of both price and expenditure effects. However, if good *i* and good *j* are in different groups, then substitution between goods in different groups is composed only of group expenditure effects.

Alternatively, strong separability places more severe restrictions on group preference ordering and hence intra-group substitution. The utility function is said to be strongly separable with respect to the partition $\{N_1, \ldots, N_S\}$ if and only if u ($\mathbf{q}$) is of the form

$$\mathrm{u}(\mathbf{q}) = \mathrm{f}\left(\mathrm{u}^1(\mathbf{q}^1) + \ldots + \mathrm{u}^S(\mathbf{q}^S)\right). \tag{C.6}$$

where f $(\cdot)$ is a monotonically increasing function.

Since a strongly separable utility function is certainly weakly separable, then (C.5) holds. However, additivity of the utility function implies that any new group can be formed from a combination of any two or more groups, which prevents any particular relationships between pairs of group (i.e., λ is the same for all groups).[119]

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[118] By homogeneity, $\sum_{i=1}^{n} p_i s_{ik} = 0$. Using the homogeneity condition, the own-price Slutsky substitution term can be recovered as follows:

$$s_{ii} = -\frac{1}{p_i}\left[\sum_{i \neq i'}^{n} p_{i'} s_{ii'} + \frac{\partial q_i}{\partial M^I}\sum_{J \neq I}^{S}\lambda_{IJ}\sum_{J=1}^{S}\frac{\partial q_j}{\partial M^J}\right], i, i' \in I, I \neq J.$$

[119] To see this, denote three goods, *i*, *j*, and *k,* each belonging to a different group, *I*, *J*, and *K*. Combining groups *J* and *k* into a new group *L*, by(C.5), the Slutsky substitution terms for *i* and *j* , and *i* and *k* are:

Hence, the assumption of additive preferences holds if and only if the Slutsky substitution terms are

$$s_{ij} = \lambda \frac{\partial q_i}{\partial M^I} \frac{\partial q_j}{\partial M^J}, \forall i \in I, j \in J, I \neq J \tag{C.7}$$

where λ is the same for all expenditure groups.

Strong separability has several empirical consequences. First, for the law of compensated demand[120] to be satisfied,

$$s_{ii} = -\frac{\lambda}{p_i} \frac{\partial q_i}{\partial M} \left(1 - p_i \frac{\partial q_i}{\partial M} \right) < 0, \tag{C.7.1}$$

At which point $\lambda > 0$ and all elasticities with respect to aggregate expenditure must be positive.[121] Under these assumptions, goods can only be normal $(\partial q_i / \partial M > 0)$ and substitutes $(s_{ij} > 0)$. Second, if the number of goods is large, then

$$\eta_{ii} \approx -(\lambda / M)\eta_{iM}, \tag{C.7.2}$$

which is referred to as Pigou's Law (Deaton, 1974).

Strong separability is sometimes called block additivity and the subsets are referred to as blocks, whereas the weakly separable utility function is called a utility tree and the subsets are called branches. This terminology arises from the nature of substitution between groups under the two assumptions. For example, if the utility

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$$s_{ij} = \lambda_{IJ} \frac{\partial q_i}{\partial M_I} \frac{\partial q_j}{\partial M_J} = \lambda_{IL} \frac{\partial q_i}{\partial M_I} \frac{\partial q_j}{\partial M_J}, \text{ and } s_{ik} = \lambda_{IK} \frac{\partial q_i}{\partial M_I} \frac{\partial q_k}{\partial M_K} = \lambda_{IL} \frac{\partial q_i}{\partial M_I} \frac{\partial q_k}{\partial M_K}.$$

By dividing s_{ij} by s_{ik}, $\lambda_{IJ} = \lambda_{IK}$, which means λ_{IJ} is dependent only on J. By symmetry, $\lambda_{IJ} = \lambda_{JI}$, which means λ_{IJ} is independent of I and J, or that $\lambda_{IJ} = \lambda$ (Deaton and Muellbauer, 1980b: 141-142).

[120] There are four properties of demand, regularly referred to in empirical literature of demand system models, one of which is negativity property. Negativity Property is derived from properties of the expenditure function. Specifically, the concavity of expenditure function implies that the matrix of own-and cross-price effects in Hicksian demands is negative semi-definite (and symmetric). Formally, the n-by-n matrix formed by the elements $\partial h_i / \partial p_j$ is negative semi-definite, that is, for any n vector ξ, the quadratic form $\sum_i \sum_j \xi_i \xi_j \partial h_i / \partial p_j \leq 0$. If $i=j$, then $\partial h_i(\mathbf{p}, u) / \partial p_i < 0$; in other words, the compensated own-price effects are negative. Apart from negativity property, adding-up (Engel and Cournot aggregation), homogeneity, and Slutsky symmetry are properties of demand, usually invoked a priori or tested in empirical demand system models.

[121] Equation (C.7) defines the off-diagonal terms of the Slutsky matrix. The diagonal terms can be filled in using the relationship $\sum_{i=1}^{n} s_{ik} p_k = 0$.

function is a tree with S branches, in general, we cannot combine two branches into a single branch and treat the new utility function as a tree with S-1 branches. However, with block additivity, it is always permissible to combine blocks into a single block because λ is independent of groups.

Separability restrictions limit the number of parameters to be estimated by restricting inter-group substitution. Specifically, under weak and strong separability (equations (C.5) and (C.7), respectively), the unconditional Slutsky substitution term between two goods i and j in groups I and J, $J \neq I$ is proportional to their expenditure effects. The restrictions placed on the Slutsky substitution term allow for the estimation of demand functions based solely on group expenditure and prices (conditional demand). Indeed, weak separability is both necessary and sufficient for the second stage of two-stage budgeting. The estimation of unconditional demand functions using two-stage budgeting is made complicated by the requirement to use price and quantity indexes to allocate total expenditure among groups at the first stage.

C.2.3 Two-Stage Budgeting

Strotz (1957, 1959) and Gorman (1959) pioneered the concept of two-stage budgeting. They assumed that in the first stage a consumer allocates total expenditure among broad groups of goods I, $I = 1,\ldots,S$ containing $n_1,\ldots,n_S$ goods, and then, given group expenditure in the second stage, the consumer chooses among elementary goods within each group. Formally, the budget allocation problem of the consumer at the first stage can be defined as

$$\max_{u^1,\ldots,u^S} F\left(u^1(\mathbf{q}^1),\ldots,u^S(\mathbf{q}^S)\right) \text{s.t. } M = \sum_{I=1}^{S} M^I = \sum_{I=1}^{S} c^I(\mathbf{p}^I, u^I) \qquad \text{(C.8)}$$

where the cost of achieving group I at the price vector $\mathbf{p}^I$, $c^I(\mathbf{p}^I, u^I)$, is equivalent to the expenditure on group I, M^I, and F(·) is an aggregator utility function, consisting of sub-utility functions, $u^I(\cdot)$, $I = 1, \ldots, S$ associated with the quantity vector for group I, $\mathbf{q}^I$. To solve the first-stage allocation problem, knowledge of all prices and quantities of elementary goods is required, which provides no useful restrictions for estimation.

For separability to provide meaningful restrictions for estimation of demand equations, it must be possible to summarize the price vectors for each subgroup by a single price index. However, an exact solution to the two-stage budgeting problem holds only under stringent restrictions on the utility and sub-utility functions. To show this, let $c^I(\bar{\mathbf{p}}^I, u^I)$ denote the cost of consuming sub-utility u^I at base-period group prices, $\bar{\mathbf{p}}^I$. The cost of achieving group I at price vector $\mathbf{p}^I$ can be rewritten as

$$c^I(\mathbf{p}^I, u^I) = c^I(\bar{\mathbf{p}}^I, u^I)\frac{c^I(\mathbf{p}^I, u^I)}{c(\bar{\mathbf{p}}^I, u^I)} = c^I(\bar{\mathbf{p}}^I, u^I)P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u^I), \forall I = 1,...,S \qquad \text{(C.9)}$$

where $P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u^I)$ is the true cost-of-living price index, and $c^I(\bar{\mathbf{p}}^I, u^I)$ can be thought of as a quantity index (Carpentier and Guyomard, 2001).

The problem with the true cost-of-living price index is that it is dependent on utility. Gorman (1959) derived conditions under which a single price index and a single quantity index can be used in the first-stage allocation.[122] One possibility is that the aggregator utility function is additive among groups (equation (C.6)) and the indirect utility function of each group is of the Gorman generalized polar form.[123] As discussed above, strong separability is unrealistic for use in estimating demand. Alternatively, Gorman proposed that if the sub-utility functions of the second stage are homothetic then price indexes are independent of utility.[124] However, this assumption implies that all of the conditional expenditure elasticities in the second stage are one, which is also unrealistic.

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[122] Bieri and de Janvry (1972: 22) note that if the aggregator utility function is weakly separable, then local price indices exist that are specific to each expenditure equation. This implies knowledge of S^2 price indices, which is not useful for estimation.

[123] Suppose the indirect utility function for group I, $\Psi^I(\cdot)$ is of the Gorman generalized polar form,

$$\Psi^I(M^I, \mathbf{p}^I) = F^I[M^I / b^I(\mathbf{p}^I)] + a^I(\mathbf{p}^I),$$

for some increasing function $F^I(\cdot)$, while the first-stage (aggregator) utility function is additive

$$u = \Psi^1(M^1, \mathbf{p}^1) + ... + \Psi^S(M^S, \mathbf{p}^S).$$

Interpreting $b^I(\mathbf{p}^I)$ as a price index and $v^I = M^I / b^I(\mathbf{p}^I)$ as a quantity index, the consumer maximization problem becomes

$$\max u = \sum_{I=1}^{S} F^I(\mathbf{v}^I) + \sum_{I=1}^{S} a^I \mathbf{p}^I \text{ s.t. } M = \sum_{I=1}^{S} M^I = \sum_{I=1}^{S} b^I(\mathbf{p}^I) v^I.$$

where the price index is independent of u (Deaton and Muellbauer, 1980b: 130-131).

[124] Deaton and Muellbauer (1980b) show that if the sub-utility functions are homothetic, then the cost function is proportional to utility, i.e., $c(\mathbf{p}^I, u^I) = u^I b^I(\mathbf{p}^I)$. Hence, the true cost-of-living index is independent of utility:

$$P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u^I) = \frac{c^I(\mathbf{p}^I, u^I)}{c(\bar{\mathbf{p}}^I, u^I)} = \frac{u^I b^I \mathbf{p}^I}{u^I b^I \bar{\mathbf{p}}^I} = \frac{b^I \mathbf{p}^I}{b^I \bar{\mathbf{p}}^I}.$$

In practice, it is usually assumed that the true cost-of-living price index can be approximated by a conventional price index (e.g., a Paasche or Laspeyres price index) that might not hold utility constant,

$$\mathrm{P}^I(\mathbf{p}^I, \overline{\mathbf{p}}^I, u^I) \cong \mathrm{P}^I(\mathbf{p}^I, \overline{\mathbf{p}}^I). \tag{C.10}$$

Under assumption of equation (C.10), the utility maximization problem of equation (C.8) can be approximated as

$$\max_{c^1,\ldots,c^S} \phi(\mathrm{c}^1(\overline{\mathbf{p}}^1, u^1), \ldots, \mathrm{c}^S(\overline{\mathbf{p}}^S, u^S), \overline{\mathbf{p}}^1, \ldots, \overline{\mathbf{p}}^S)$$
$$\text{s.t. } M = \sum_{i=1}^{S} \mathrm{c}^I(\overline{\mathbf{p}}^I, u^I)\mathrm{P}^I(\mathbf{p}^I\overline{\mathbf{p}}^I)$$

where $\mathrm{c}^I(\overline{\mathbf{p}}^I, u^I)$ can be approximated by a quantity index and $\mathrm{P}^I(\mathbf{p}^I, \overline{\mathbf{p}}^I)$ by an implicit price deflator.

Carpentier and Guyomard (2001) approximate unconditional elasticities of demand using an approximation to the Slutsky substitution term assuming weak separability (equation (C.5)).[125] Denoting the superscript as representing the composite group and the subscript as representing the elementary good, Carpentier and

[125] Suppose $j \in J$, $i \in I$, $J \neq I$ and Marshallian and Hicksian demand for composite good I is $Q^I(P^1,\ldots,P^S, M)$ and $H^I(P^1,\ldots,P^S, u)$, respectively. At an optimum, we know

$$\left.\frac{\partial M^I}{\partial p_j}\right|_{u=\bar{u}} = \left.\frac{\partial\left(\mathrm{P}^I(\mathbf{p}^I, \overline{\mathbf{p}}^I, u^I)\mathrm{H}^I(\cdot)\right)}{\partial p_j}\right|_{u=\bar{u}} \cong P^I \frac{\partial \mathrm{H}^I(\cdot)}{\partial P^J}\left.\frac{\partial P^J}{\partial p_j}\right|_{u=\bar{u}}$$

where the approximation results from the assumption that each price index, $\mathrm{P}^I(\mathbf{p}^I, \overline{\mathbf{p}}^I, u^I)$ can be approximated by (C.10). From the definition of $\mathrm{P}^I(\mathbf{p}^I, \overline{\mathbf{p}}^I, u^I)$ in (C.9) and using Shephard's lemma, we know

$$\left.\frac{\partial P^J}{\partial P_j}\right|_{u=\bar{u}} = \left.\frac{\partial \mathrm{c}^J(\mathbf{p}^J, u^J)}{\partial p_j}\frac{1}{\mathrm{c}^I(\overline{\mathbf{p}}^J, u^J)}\right|_{u=\bar{u}} = \frac{h_j(\mathbf{p}^J, u^J)}{\mathrm{c}^J(\overline{\mathbf{p}}^J, u^J)},$$

where $h_j(\cdot)$ is Hicksian demand for good j in group J. By multiplying (C.4) by p_j and summing over all j in J, we get

$$\sum_{j\in J}^{n} p_j \left.\frac{\partial M^J}{\partial p_j}\right|_{u=\bar{u}} = \lambda_{IJ}\sum_{j\in J} p_j \frac{\partial q_j}{\partial M^J} = \lambda_{IJ},$$

Which after substitution is

$$\lambda_{IJ} = \sum_{j\in J}^{n} p_j \left.\frac{\partial M^J}{\partial p_j}\right|_{u=\bar{u}} = P^I P^J \frac{\partial \mathrm{H}^I(\cdot)}{\partial P^I}.$$

Using (C.5) and the above, the Slutsky substitution term can be written as

$$s_{ij} = P^I P^J \frac{\partial \mathrm{H}^I(P^1, \ldots, P^S, u)}{\partial P^I}\frac{\partial \mathrm{q}_i(\mathbf{p}^I, M^I)}{\partial M^I}\frac{\partial \mathrm{q}_j(\mathbf{p}^J, M^J)}{\partial M^J}, j \in J, i \in I, J \neq I$$

which in elasticity form is the unconditional Hicksian elasticity of demand in (C.13). Using the Slutsky equation, the unconditional Marshallian elasticity demand in (C.12) can be derived (Carpentier and Guyomard, 2001).

Guyomard (2001) approximated the unconditional Marshallian expenditure (η_{iM}) and price (η_{ij}) elasticities of demand and the Hicksian (η_{ij}^{*}) elasticities of demand as

$$\eta_{iM} = \eta_{iM}^{I}\eta^{IM}, \tag{C.11}$$

$$\eta_{ij} = \delta_{IJ}\eta_{ij}^{I} + w_j^J\eta_{iM}^{I}\eta_{iM}^{J}\left(\frac{\delta_{IJ}}{\eta_{jM}^{J}} + \eta^{IJ}\right) + w_j^J w^J \eta^{IM}\eta_{iM}^{I}\left(\eta_{jM}^{J} - 1\right), \tag{C.12}$$

$$\eta_{ij}^{*} = \delta_{IJ}\eta_{ij}^{I*} + w_j^J\eta^{IJ*}\eta_{iM}^{I}\eta_{jM}^{J}, \tag{C.13}$$

Where

η_{iM}^{I}= expenditure elasticity for good $i \in I$ conditional on expenditure for group *I,*

η^{IM}= expenditure elasticity for composite group *I* with respect to total expenditure, *M,*

η_{ij}^{I} = Marshallian elasticity of demand for good $i \in I$ with respect to price $j \in J$ conditional on $J = I$,

η^{IJ} = Marshallian elasticity of demand for composite group *I* with respect to composite price *J,*

w_j^J= budget share for good $j \in J$ conditional on *J*,

w^J= budget share for composite group *J*,

η_{ij}^{I*}= Hicksian elasticity of demand for good $i \in I$ with respect to price $j \in J$ conditional on $J=I$,

η^{IJ*}= Hicksian elasticity of demand for composite group *I* with respect to composite price *J*,

δ_{IJ}= $\begin{cases} 1, \text{if } I = J \\ 0, \text{otherwise} \end{cases}$.

Under the assumption that sub-utility functions are homothetic, the price index is a true cost-of living index, and (C.11) and (C.13) reduce to

$$\eta_{ij} = \delta_{IJ}\eta_{ij}^{I} + w_j^J\left(\delta_{IJ} + \eta^{IJ}\right),$$

$$\eta_{ij}^{*} = \delta_{IJ}\eta_{ij}^{I*} + w_j^J\eta^{IJ*},$$

$$\eta_{iM} = \eta^{IM},$$

Because $\eta_{iM}^{I} = \eta_{jM}^{J} = 1$.

It can be seen from (C.11)–(C.13) that the unconditional Marshallian price elasticities of demand for goods within the same group (*I*=*J*) consist of two parts: (a) the effect of price *j* on quantity *i* that arise from estimation of conditional demand (η_{ij}^{I}), and (b) the effect of the first stage budget allocation process (second and third terms on the RHS). The conditional Marshallian price elasticity of demand is equal to its unconditional counterpart if any of the following conditions holds:

$$w_j^J = 0$$

$$\eta_{iM}^{I} = 0$$

$$w^J = \frac{1 + \eta^{IJ}\eta_{jM}^{J}}{1 - \eta_{jM}^{J}}$$

The unconditional expenditure elasticity is proportional to the product of the conditional expenditure elasticity and the first stage expenditure elasticity. Hence, conditional elasticities of demand can be substantially different from unconditional elasticities.

Two-stage budgeting can be used two ways in pharmaceutical demand analysis. One can specify the first and second stages to obtain unconditional demand elasticities. Because the number of observations in many time-series data sets is small, two-stage budgeting allows for estimation of disaggregated elasticities of demand. For instance, let consider the drugs used in diabetes. The first-stage estimates of elasticities of demand could be based on aggregate groups like insulins and analogues, blood glucose lowering drugs (excluding insulins), and other drugs used in diabetes. Assuming that each drug group is weakly separable, then the second-stage estimates could be based on detailed drugs within each group. Homogeneity and symmetry restrictions can be applied at either the first or second stage or both stages of estimation. Using (C.11) and (C.12), the unconditional elasticities of demand can be obtained from the first- and second-stage estimates. Alternatively, similar to the present study one can model only the second stage of the two-stage budgeting process. This use of two-stage budgeting has been common in economics literature, especially in demand estimation studies.

C.3 Properties of Demand Functions

Standard demand theory analyzes the choice behavior of an individual who maximizes his utility or satisfaction from consuming goods or services given a limited budget set. The assumptions that a consumer faces a linear budget constraint and has preferences that are rational, non-satiated, continuous and strictly convex lead to certain desirable and testable properties of demand functions. Essentially, there are four properties that all theoretically plausible demand systems should satisfy. They are homogeneity, adding up, symmetry, and negativity. A description of each is given as follows.

Property 1: Homogeneity. In consumer demand theory, the budget constraint is assumed to be linear and satisfied with equality, $\sum_{i=1}^{n} p_i q_i = M$, implying that the Marshallian demand functions, $\mathrm{q}_i(\mathbf{p}, M), \forall i = 1, \ldots, n$, are homogeneous of degree zero in prices and expenditure, and satisfy the adding-up conditions. Similarly, given the indifference curve, relative prices are all that is required to determine demand, the Hicksian demands, $\mathrm{h}_i(\mathbf{p}, u)$, are the derivatives of a function homogeneous of degree one and hence are homogeneous of degree zero. Put formally, the homogeneity restriction requires that, for scalar $\theta > 0$,

$$\mathrm{h}_i(\theta\mathbf{p}, u) = \mathrm{h}_i(\mathbf{p}, u) = \mathrm{q}_i(\theta\mathbf{p}, \theta M) = \mathrm{q}_i(\mathbf{p}, M).$$

According to the homogeneity condition, the quantity demanded remains unchanged if all prices and expenditure increase by the same proportion (θ); restated, this says that there exists no money illusion. Applying Euler's theorem[126] to the Marshallian demand functions implies that:

$$\sum_{j=1}^{n} p_j \frac{\partial \mathrm{q}_i(\mathbf{p}, M)}{\partial p_j} + M \frac{\partial \mathrm{q}_i(\mathbf{p}, M)}{\partial M} = 0,$$

which can be expressed in elasticity form as

$$\sum_{i=1}^{n} \eta_{ij} + \eta_{iM} = 0.$$

[126] Euler's theorem states that if the function f(x) is homogeneous of degree zero, then $\sum_{i=1}^{n} (\partial f(\mathbf{x})/\partial x_i) x_i = 0$.

This equation states that the sum of all own-and cross-price elasticities (η_{ij}) for good i is equal to negative of its expenditure elasticities (η_{iM}).

Property 2: Adding up. The assumption of the linear budget constraint also implies the adding-up conditions, i.e., Cournot and Engel aggregation. The partial derivatives of the budget constraint with respect to p_k and M are:

$$\sum_{j=1}^{n} \frac{\partial \mathrm{q}_j(\mathbf{p}, M)}{\partial p_k} p_j + \mathrm{q}_k(\mathbf{p}, M) = 0, \text{and}$$

$$\sum_{j=1}^{n} \frac{\partial \mathrm{q}_j(\mathbf{p}, M)}{\partial M} p_j = 1.$$

Converting to elasticities, the Cournot and Engel aggregation conditions are:

$$\sum_{j=1}^{n} \eta_{ik} w_j + w_k = 0,$$

$$\sum_{j=1}^{n} w_j \eta_{iM} = 1.$$

Cournot and Engel aggregation imply that changes in total expenditure and prices cause rearrangements in purchases that do not violate Walras's law.[127]

In short, the adding-up restriction says that the budget shares of both compensated and ordinary demand functions sum to one; equivalently, the total value of compensated and ordinary demands sums to total expenditure, that is,

$$\sum p_k \mathrm{h}_k(\mathbf{p}, u) = \sum p_k \mathrm{q}_k(\mathbf{p}, M) = M\,.$$

The next two properties of demand, namely symmetry and negativity, are derived from properties of the expenditure function. Specifically, the concavity of expenditure function implies that the matrix of own-and cross-price effects in Hicksian demands is negative semi-definite and symmetric.

[127] Walras's law states that if the first n-1 markets are in equilibrium then the last market is also in equilibrium. This is so because the aggregate demand for goods must equal their aggregate supply.

Property 3: Symmetry. Slutsky's symmetry condition requires that the compensated cross-prices derivatives or elasticities are equal, that is, for all $i \neq j$,

$$\frac{\partial \mathrm{h}_i(\mathbf{p}, u)}{\partial p_j} = \frac{\partial \mathrm{h}_j(\mathbf{p}, u)}{\partial p_i}.$$

For convenience, $\partial \mathrm{h}_i / \partial p_j$ is denoted by s_{ij} ; likewise s_{ji} represents $\partial \mathrm{h}_j / \partial p_i$. Hence, $s_{ij} = s_{ji}$, i.e., the Slutsky substitution terms are equal.

Property 4: Negativity. The negativity restriction relates to the matrix of compensated price derivatives. It states that the matrix of the Slutsky substitution terms must be negative semi-definite. Expressed mathematically, the *n*-by-*n* matrix formed by the elements s_{ij} is negative semi-definite, that is, for any *n* vector ξ, the quadratic form

$$\sum_i \sum_j \xi_i \xi_j s_{ij} \leq 0 .$$

This in turn implies that the diagonal elements, compensated own-price derivatives, are non-positive; for all *i*,

$$s_{ii} \leq 0.$$

This can alternatively be expressed by saying that the compensated demand curve is downward sloping, i.e., the "law of demand" holds. Thus, an increase in price with utility held constant must cause demand for that good to fall or at least remain unchanged. Adding-up (Engel and Cournot aggregation), homogeneity, and Slutsky symmetry are usually invoked a priori or tested in empirical demand system models.

APPENDIX D

MODELS OF PHARMACEUTICAL DEMAND

D.1 Empirical Analysis of Consumer Behavior

D.1.1 Parametric and Nonparametric Methods

The neoclassical model of consumer behavior postulates that a consumer's choice behavior can be described as deriving from utility maximization subject to a budget constraint.[128] One is then naturally led to ask what this traditional model implies about observed behavior. This question has been addressed from two distinct approaches, which have turned out to be amazing rich in empirical work for decades.

The first approach, known as parametric methods, originating in the work of Slutsky (1915) and Antonelli (1886), derives necessary and sufficient conditions involving the derivatives of the demand functions. Typically, this approach proceeds by postulating parametric forms for the underlying utilities or demand functions and fitting them to observed data. The estimated demand functions can then be tested for consistency with the maximization hypothesis, used to make welfare judgments, or used to forecast demand for other price configurations. However, this procedure will be satisfactory only when the postulated parametric forms are good approximations to the "true" demand functions.

The second approach so-called nonparametric techniques of revealed preference analysis, originating in the work of Samuelson (1938, 1947, 1948), derives algebraic conditions on the demand functions implied by maximizing behavior. These conditions, known as revealed preference conditions, provide a complete list of the

[128] Specifically, standard demand model analyzes the choice behavior of an individual who gains utility or satisfaction from consuming goods or services given a limited budget set that is determined by exogenous prices and expenditure. It assumes that consumers have complete information about the choices available and that they use this information to catalog and evaluate their choices prior to selecting goods or services to consume. The consumer chooses a utility-maximizing bundle of goods that can be observed in the market.

restrictions imposed by maximizing behavior in the sense that every maximizing consumer's demand behavior must satisfy these conditions and all behavior that satisfies these conditions can be viewed as maximizing behavior. Shortly, this approach attempts to base the theory on a minimal set of axioms: the Samuelson's idea is to deduce properties of demand from a simple and direct axiom on behavior.[129]

The distinction between these two approaches is not trivial. While the calculus approach assumes the entire demand function is available for analysis, the algebraic approach assumes only a finite number of observations on consumer behavior are available. For this matter, the latter assumption is rather realistic as all available data on consumer behavior does comprise a finite number of observations. Indeed, the calculus approach is parametric in the sense that demand behavior is assumed to be adequately described by some parametric family of functional forms; one can then estimate the parameters that best describe the data by various statistical techniques and test for the restrictions imposed by the particular hypothesis one has in mind. This procedure suffers from the drawback that one is always testing a joint hypothesis: whatever restrictions one wants to test plus the maintained hypothesis of functional form. The revealed preference approach on the other hand is non-parametric: the approach provides a complete test of the hypothesis in question alone with no further assumptions regarding functional form.[130] Required hypothesis tests include testing whether data are consistent with axioms of revealed preference such as the generalized axiom of revealed preference (GARP), the strong axiom of revealed preference (SARP), and the weak axiom of revealed preference (WARP).[131] However, this approach does present a number of defects (Varian, 1983). In many cases the tests

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[129] For a more detailed discussion of the revealed preference approach, see, e.g., Samuelson (1938, 1948) , Afriat (1967, 1973) , Diewert (1973), and Varian (1982, 1983, 1984).

[130] More precisely, the revealed preference approach is non-parametric in that it requires no ad hoc specifications of functional forms for demand equations. For this matter, a strong version of the axiom of revealed preference asserts that if $\mathbf{q}_1(\mathbf{p}, M)$ is indirectly revealed preferred to $\mathbf{q}_n(\mathbf{p}, M)$ through some transitive chain of comparisons through intermediate bundles, then $\mathbf{q}_n(\mathbf{p}, M)$ cannot be revealed preferred to $\mathbf{q}_1(\mathbf{p}, M)$. Samuelson conjectured, and Houthakker (1950) showed the validity of the conjecture, that this strong axiom implies the existence of a utility function. Their results show that some restrictions on demand functions can be obtained without going as far as assuming the existence of a utility function.

[131] According to WARP, if a vector of goods, $\mathbf{q}_1(\mathbf{p}, M)$, at price $\mathbf{p}$ and expenditure M is revealed to be preferred (R) to another bundle at the same prices and expenditure, $\mathbf{q}_2(\mathbf{p}, M)$, and $\mathbf{q}_1(\mathbf{p}, M) \neq \mathbf{q}_2(\mathbf{p}, M)$, then $\mathbf{q}_2(\mathbf{p}, M)$cannot be revealed to be preferred to $\mathbf{q}_1(\mathbf{p}, M)$. Alternatively, $\mathbf{q}_1(\mathbf{p}, M)\mathrm{R}\,\mathbf{q}_2(\mathbf{p}, M) \leftrightarrow \mathbf{q}_1(\mathbf{p}, M) \cdot \mathbf{p}_1 \geq \mathbf{q}_2(\mathbf{p}, M) \cdot \mathbf{p}_1$. Under SARP, if $\mathbf{q}_1(\mathbf{p}, M)\mathrm{R}\,\mathbf{q}_2(\mathbf{p}, M)$ and $\mathbf{q}_2(\mathbf{p}, M)\mathrm{R}\,\mathbf{q}_1(\mathbf{p}, M)$ and so on until $\mathbf{q}_{n-1}(\mathbf{p}, M)\mathrm{R}\,\mathbf{q}_n(\mathbf{p}, M)$, then $\mathbf{q}_1(\mathbf{p}, M)$ is revealed to be preferred to $\mathbf{q}_n(\mathbf{p}, M)$. To conform to GARP, if $\mathbf{q}_1(\mathbf{p}, M)$ is strictly revealed to be preferred (RS) to another bundle,$\mathbf{q}_2(\mathbf{p}, M)$, and $\mathbf{q}_1(\mathbf{p}, M) \neq \mathbf{q}_2(\mathbf{p}, M)$, then $\mathbf{q}_2(\mathbf{p}, M)$ cannot be strictly revealed to be preferred to $\mathbf{q}_1(\mathbf{p}, M)$. Alternatively, $\mathbf{q}_1(\mathbf{p}, M)\mathrm{R}\,\mathbf{q}_2(\mathbf{p}, M) \leftrightarrow \mathbf{q}_1(\mathbf{p}, M) \cdot \mathbf{p}_1 > \mathbf{q}_2(\mathbf{p}, M) \cdot \mathbf{p}_1$.

cannot be carried out due partly to large data sets. Also, the methods do not naturally recap the data in a beneficial way. Moreover, it is problematic to include stochastic considerations in a good manner. Above all, several studies such as Alston and Chalfant (1991a) have suggested that these nonparametric tests tend to have low power (i.e., low odds of finding violations of WARP or GARP even when structural change is present) when applied to aggregate time-series data; in other words, with this approach the practitioner tends to under-reject the hypothesis of stable preferences.[132] This study does pursue the first approach as we prefer the simplicity of working with utility functions.

D.1.2 Parametric Approach to Empirical Demand Models: Demand in Product Space versus Demand in Characteristics Space

Essentially, according to empirical literature concerning parametric analysis of consumer behavior there are two prominent different approaches to the derivation of theoretically plausible demand system: demand in product space and demand in characteristics space. This part shall briefly present these two leading ideas of demand estimation, which are commonly used in applied demand analysis.

The empirical analysis of consumer behavior has a long and rich history in economics and econometrics. The first statistical estimation of demand dates back at least to Moore (1914).[133] Early work treated estimation as merely a way of summarizing data, and had little connection with economic theory. Since the pioneering work of Stone (1954b), econometricians estimating demand systems have struggled with the need for flexible functional forms, which do not impose a prior the data cannot overcome, while keeping a connection to economic theory (either by imposing it, or finding ways to test it). Examples of resulting demand systems include the Linear Expenditure model (Stone, 1954b) , the Rotterdam model (Barten, 1964;

[132] In the demand analysis literature, structural change refers to changes in parameters of a model. In some cases, individual utility functions of a stable population of consumers may change in response to changes in health concerns or other information. In other cases, changes in the demographic composition of a heterogeneous collection of consumers could result in different preferences for a representative consumer. Alternatively, preferences may be affected by strategies of firms such as advertising and product innovation. In previous studies, parametric and nonparametric methods have been used to detect structural change. Nonparametric methods include testing if data are consistent with axioms of revealed preferences. Consistency of the data with these axioms may be interpreted as an indication of the absence of structural change in demand.

[133] Moore's work was pre-dated by attempts to summarize relations between quantities and prices. See Schultz (1938) and Stigler (1954) for a survey of the early work and a discussion of Moore's contributions.

Theil, 1965), the Translog model (Christensen, Jorgensen and Lau, 1975), and the Almost Ideal Demand System (Deaton and Muellbauer, 1980a). All these demand models can be classified as models in product space. The main modeling concern of this approach was to specify demand in a way that was both flexible and consistent with standard demand theory.[134]

A parallel line of research treats goods as bundles of attributes, rather than qualitatively different products (Lancaster, 1966, 1971; Rosen, 1974). Within this class of characteristics-based models especially prevalent is the study of discrete choice (McFadden, 1974), which likes the work on demand model, also emphasizes the direct and close connection between economic theory, econometrics, and empirical work.[135]

The distinction between product-based approach and characteristics-based approach to modeling demand is very important in empirical work. On one side, the demand systems in product space solve the dimensionality problem[136] (due to the large number of parameters to be estimated) by assuming the utility is separable and thus we can split the products into groups and estimate a flexible demand system within a group and between groups. The demand systems in characteristics space on the other side solve the dimensionality problem by projecting the products onto a characteristics space. This approach is to view a product as a collection of characteristics. The basic idea is somewhat similar to the product-based approach: some products are better substitutes to each other than others; therefore, we can separate the products into distinct groups. However, rather than separating the products into discrete segments we use the attributes of products to derive their relative substitutability. The dimensionality problem is solved by making the relevant dimension, i.e., the dimension of the characteristics (not the number of products). A main issue to deal with is how to specify unobserved product attributes, which are key to explaining the data. Indeed, there are several ways to operationalize this approach, but the most popular one is based on the discrete choice model. However, as

[134] See Deaton (1986) and Theil and Clements (1987) for a comprehensive review of this literature.
[135] See McFadden (1981, 1984) and Train (2009) for survey of this line of research.
[136] The large number of coefficients in complete demand systems is the ubiquitous issue in estimation. A relatively large sample size is required. Theoretical restrictions, such as symmetry, homogeneity, and Engel aggregation help to reduce the number of parameters to be estimated. However, for complete demand systems derived from the maximization of a constrained utility function, these restrictions are automatically satisfied.

discussed in Chapter 4 (Subsection 4.4.2), in the case of pharmaceutical products the characteristics-based approach presents some difficulties; besides, pharmaceuticals are final products. Therefore, in this study we utilize the idea of demand in product space and look for restrictions through aggregation, symmetry and separability to reduce the dimension of the problem.

Incidentally, Section D.2 shall comprehensively present different ways of modeling demand. Particularly, some parametric families of functional forms having been used regularly in the demand estimation literature are discussed in this section.

D.2 Approaches to Estimating Demand Models

The choice of functional form for demand is limitless but several models have become staples in the literature on estimation of demand. Linear and logarithmic (or double-log) single-equation models of demand have been popular since the inception of empirical estimation of demand because they are comparatively easy to estimate and interpret. However, some properties of demand, as discussed in Appendix C (Section C.3), cannot be satisfied using such models. In Subsection D.2.1, we describe popular single-equation models and discuss their strengths and weaknesses.

Alternatively, with the development and increased popularity of duality concepts demand can be specified as a system of demand equations derived from one of the following approaches: 1) specifying a utility function and solving the maximization problem, 2) specifying an indirect utility function and applying Roy's identity, 3) specifying an expenditure function and applying Shephard's lemma, and 4) taking a differential approximation to the demand system. The parameter estimated using any model of these approaches can be restricted to make the system satisfy the properties of demand implied by the theory (i.e., homogeneity, Slutsky's symmetry, and Cournot and Engel aggregation conditions). In Subsection D.2.2, we discuss several popular demand systems derived using each of the four approaches and the corresponding sets of restrictions that can be imposed on the parameters. We also discuss the tradeoffs between parsimony and flexibility among the alternative demand models.

D.2.1 Demand Estimation without Utility Theory: The Single-Equation Models of Demand

Presently, the major approach to demand analysis is utility-based or some variant thereof. This approach, to be explained in Subsection D.2.2, derives demand equations by postulating that the consumer behaves as if he chooses the consumption basket to maximize a utility function subject to budget constraint. This approach gives rise to elegant and intuitive interpretations of the coefficients of the demand equations in terms of the utility function.

But this is not the only way of proceeding in demand analysis. There is an older tradition that uses demand equations directly, without any reference to the utility function. According to this approach, ad hoc single-equation models of demand are directly specified. In this pragmatic approach, the demand for particular good is specified as a simple function of income and prices. This procedure, which goes back to Cassel (1932), has been used extensively by Stone (1954a) and others. The most popular functional forms used in the single-equation approach include linear, semi-log, double-log[137], and Box-Cox[138] models (Chern, Huang and Lee, 1993). These models are still used today because the parameters are easy to estimate and interpret. For example, the parameters resulting from the double-log model are the elasticities of demand with respect to expenditure and prices.

However, such models are inconsistent with standard utility maximization. For the double-log model to satisfy the adding-up restrictions (Engel aggregation in particular) all of the expenditure elasticities must be unit elastic (Deaton and Muellbauer, 1980b: 17; Johnson et al., 1984: 75).[139] Thus, the expenditure shares will add to one only if the elasticities of demand with respect to expenditure are restricted to implausible values. Estimates from such models may have limited use in pharmaceutical demand analysis because they violate the adding-up condition.

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[137] The double-log system is defined as $\log q_i = \alpha_i + \eta_i \log M + \sum_{j=1}^{n} \eta_{ij} \log p_j \ , \ i = 1, \ldots, n$, where q_i is the quantity demanded of good *i*; p_j is the price of good *j*; and *M* is total expenditure.

[138] The Box-Cox functional form—which nests the linear ($\sigma_q = \sigma_M = \sigma_p = 1$), double-log ($\sigma_q = \sigma_M = \sigma_p = 0$), and semi-log $(\sigma_q = 1, \sigma_M = \sigma_p = 0)$models—takes the form of $q_n^{(\sigma_q)} = c_{0n} + c_{nM} M^{(\sigma_M)} + \sum_{j=1}^{N} c_{nj} p_j^{(\sigma_p)}, \forall n =$ *1,...,N,* where *qn* is the quantity of good *n*, *M* is total expenditure, and *pj* is the price of good *j*.

[139] Pollak and Wales (1992: 24) noted that a demand system is said to exhibit expenditure proportionality if the demand for each good is proportional to expenditure, $q_i(P, M) = b_i(P)M$, or, equivalently, if all expenditure elasticities are equal to one.

D.2.2 Approaches to Estimating Models Consistent with Demand Theory

Four approaches that are consistent with demand theory have also been used to estimate demand relationships. In the first approach the utility function is specified and Marshallian demand functions are derived by maximizing the utility function subject to a budget constraint. In the second approach, Roy's identity is used to recover Marshallian demand functions from a specified indirect utility function. Similarly, in the third approach Shephard's lemma is used to recover the Hicksian demand functions from a specified expenditure function and the Hicksian demand functions are then transformed to obtain Marshallian demands. In the fourth approach, a differential approximation is applied directly to the demand function. These approaches include functional forms that range in restrictiveness. All four approaches include models known as flexible functional forms.[140]

A theme throughout the literature on demand estimation is the tradeoff between flexibility of the demand system and parsimony with respect to the number of parameters required to estimate the demand system. A related issue is the degree to which a demand system imposes theoretical restrictions from demand theory a priori or can be used to test such restrictions.

In this subsection, we discuss the four approaches to derivation of the demand systems that are consistent with utility maximization and give examples of models based on these approaches that are frequently used in empirical investigations of demand. We highlight the tradeoffs of each approach in terms of parsimony and flexibility.

D.2.2.1 Maximization of the Utility Function

One way to derive Marshallian demand functions that are consistent with utility maximization is to specify a utility function and solve for the demand equations that maximize the utility function subject to the budget constraint, as in the primal approach. For example, the linear expenditure system (LES) is based on the utility function suggested by Klein and Rubin (1947):

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[140] Pollak and Wales (1992: 60) defined a flexible functional form as being "capable of providing a second order approximation to the behavior of any theoretically plausible demand system at a point in the price-expenditure space. More precisely, a flexible functional form can mimic not only the quantities demanded, the income derivatives and the own-price derivatives, but also the cross-price derivatives at a particular point."

$$\mathrm{u}(\mathbf{q}) = \sum_{n=1}^{N} \beta_n \log(q_n - \gamma_n), \tag{D.1}$$

where q_n is quantity of good *n*, β_n is the marginal budget share for good *n*, and γ_n is the minimum quantity of good *n* consumed. Maximizing (D.1) subject to the budget constraint, $\sum_{n=1}^{N} p_n q_n = M$, yields Marshallian demand functions of the form

$$q_n = \gamma_n + \frac{\beta_n\left(M - \sum_{j=1}^{N} p_j \gamma_j\right)}{p_n}, \forall n = 1, \ldots, N.$$

The resulting expenditure function for good *n* is

$$p_n q_n = p_n \gamma_n + \beta_n\left(M - \sum_{j=1}^{N} p_j \gamma_j\right), \forall n = 1, \ldots, N. \tag{D.2}$$

Because preferences are additive, the demand system reflects the consumer's budget allocation process under strong separability. First, the consumer allocates expenditures to achieve the minimum quantity of each good ($p_n \gamma_n$). Second, the consumer distributes the remainder of the available expenditure ($M - \sum_{n=1}^{N} p_n \gamma_n$) over all goods in fixed proportions, β_n for good *n*. The price and expenditure elasticities are defined respectively in (D.3) and (D.4) as follows:

$$\eta_{ik} = -\frac{\beta_i}{p_i q_i}\left[\delta_{ik}\left(M - \sum_{j=1}^{n} p_j \gamma_j\right) + p_k \gamma_k\right], \text{ and} \tag{D.3}$$

$$\eta_{iM} = \frac{\beta_i}{w_i}. \tag{D.4}$$

The adding-up, homogeneity, and symmetry conditions hold when

$$\sum_{n=1}^{N} \beta_n = 1. \tag{D.5}$$

The number of structural parameters required for estimation of the LES is small (Johnson et al., 1984: 64; Deaton, 1986: 1788). To estimate the LES, one needs to estimate only 2*N* parameters, which is considerably less than the potential number of

independent shares and elasticities in a theoretically plausible demand system, $N(N-1)/2+2N-2$ (Pollak and Wales, 1992: 60).[141]

However, the LES utility function is typically too restrictive for demand analysis in that it provides a poor approximation of the actual process that generated the data. Note that the indirect utility function associated with (D.2) is

$$\mathrm{v}(\mathbf{p},M)=(M-\textstyle\sum_{n=1}^{N}p_n\gamma_n)/\prod_{n=1}^{N}p_n^{\beta_n}.$$

By inversion, the cost function is

$$\mathrm{c}(\mathbf{p},\mathrm{u})=\textstyle\sum_{n=1}^{N}p_n\gamma_n+u\prod_{n=1}^{N}p_n^{\beta_n}.$$

For the cost function to be concave and the compensated law of demand to hold, β_n must be greater than zero, which implies that all goods must be normal and must be substitutes for each other. In addition, the cost function is of the Gorman polar form, which further restricts behavior by allowing only for linear Engel curves. This is contrary to the well-known household budget studies that find a nonlinear relationship between expenditure and food budget shares. However, cost functions that are of the Gorman polar form do allow for exact linear aggregation across consumers such that aggregate demand can be treated as coming from a "representative" consumer (Deaton, 1974). Another restrictive property of the LES is that it represents an additive utility function, so the own-price elasticity of demand for good *n* is approximately proportional to the elasticity of demand for good *n* with respect to total expenditure(i.e., Pigou's Law, equation (C.7.2)) (Deaton and Muellbauer, 1980b: 66).

Alternative popular functional forms derived from the utility function approach include the S-Branch system (Brown and Heien, 1972) and the constant elasticity of substitution (CES) model. The generalized CES utility function nests a translation of the Cobb-Douglas ($\sigma = 1$), the Leontief ($\sigma = 0$), and the linear ($\sigma = \infty$) forms of the utility function:

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[141] At a point, a demand system has *N* expenditure shares, *N* expenditure elasticities, *N* own-price elasticities, and $N(N-1)$ cross-price elasticities. However, not all of these N^2+2N values are independent. By Walras' law, the expenditure shares must add up to one, so only *N*–1 shares are independent. This implies that *N*–1 expenditure elasticities will be independent. By symmetry, only $N(N-1)/2$ of the cross-price elasticities are independent. Given the expenditure shares, expenditure, elasticities of demand, and cross-price elasticities of demand, the own-price elasticities of demand can be inferred from these values using Cournot aggregation. Hence, adding up these values, a theoretically plausible demand system entails at most $N(N-1)/2+2N-2$ independent shares and elasticities.

$$\mathrm{u}(\mathbf{q}) = \sum_{n=1}^{N} \gamma_n (q_n - \alpha_n)^{\sigma-1/\sigma}.$$

This form of utility yields demand functions that are just as restrictive as those from the LES in that the Engel curves are linear and substitution between goods is constant across all pairs. The S-Branch system assumes a strongly separable utility function in which the block sub-utility functions for S groups, $\mathrm{u}(\mathbf{q}^1, \ldots, \mathrm{u}(\mathbf{q}^S)$, are of the generalized CES form and the aggregator utility function, u[•], is a CES (superscript denotes group and subscript denotes individual good):

$$\mathrm{u}[\mathrm{u}^1(\mathbf{q}^1), \ldots, \mathrm{u}^S(\mathbf{q}^S)] = \left[\sum_{I=1}^{S} \alpha^I \left(\mathrm{u}^I(\mathbf{q}^I)\right)^{(\sigma-1)/\sigma}\right]^{\sigma/(\sigma-1)}$$

$$\text{where } \mathrm{u}^I(\mathbf{q}^Y) = \left(\sum_{i \in I}^{N^I} \gamma_i (q_i - \alpha_i)^{(\sigma^I-1)/\sigma^I}\right)^{\sigma^I/(\sigma^I-1)}.$$

The S-Branch nests the LES utility function and is less restrictive than the LES in that it allows goods to be complements, but it does not allow inferior goods and the Engel curves are still linear. Deaton noted that applications of utility-derived demand systems with such strict restrictions on parameters should "be seen for what they are, i.e., untested theory with 'sensible' parameters, and not as fully-tested data-consistent models" (Deaton, 1986: 1788).

D.2.2.2 Application of Roy's Identity to the Indirect Utility Function

Let $\mathbf{p} = [p_n]$ and $\mathbf{q} = [q_n]$ be vectors of the N prices and quantities and let $\mathbf{q} = \mathbf{q}(\mathbf{p}, M)$ be the systems of N demand equation. If we substitute the demand equations into the utility function, $\mathrm{u} = \mathrm{u}(q_1, \ldots, q_N)$, utility becomes a function of income and prices,

$$\mathrm{u} = \mathrm{u}\big(\mathbf{q}(\mathbf{p}, M)\big) = \mathrm{v}(\mathbf{p}, M). \qquad \text{(D.6)}$$

The function $\mathrm{v}(\cdot)$ is called the indirect utility function; it gives the maximum utility attainable corresponding to given values of income and prices. It can be shown (Theil, 1980: App. B) that (D.6) has the following derivatives:

$$\frac{\partial \mathrm{v}(\cdot)}{\partial M} = \lambda\,, \qquad \frac{\partial \mathrm{v}(\cdot)}{\partial p_n} = -\lambda q_n\,, \qquad \forall n = 1, \ldots, N, \qquad \text{(D.7)}$$

where λ is the marginal utility of income. Taking the negative of the ratio of the price derivative to the income derivative, we obtain from (D.7)

$$q_n = -\frac{\partial \mathrm{v}/\partial p_n}{\partial \mathrm{v}/\partial M}, \qquad \forall n = 1, \ldots, N, \tag{D.8}$$

which is known as Roy's (1942) identity.

Roy's identity gives a second way of generating a system of Marshallian demand functions consistent with demand theory, namely, specifying an algebraic form of the indirect utility function and then applying Roy's identity. One of the earliest applications of this approach was by Houthakker (1960), who derived the indirect addilog demand system. The indirect utility function for the indirect addilog demand system is

$$\mathrm{v}(\mathbf{p}, M) = \sum_{n=1}^{N} a_n (M/p_n)^{b_n}. \tag{D.9}$$

Application of Roy's identity to (D.9) yields a system of demand functions that are homogenous of degree zero and satisfy Engel aggregation and Slutsky symmetry a priori (Johnson et al., 1984: 66).[142] The complete set of demand parameters in the indirect addilog system can be estimated with $2N - 1$ independent coefficients (i.e., $N \times b_n$ and $(N-1) \times a_n$). The addilog demand system enforces a priori restrictions on the elasticities of demand and is not a flexible functional form. In fact, the indirect utility function is indirectly additive, which generates several of the implications of direct additivity discussed in Subsection C.2.2, including the own-price elasticity of demand for good *n* being approximately proportional to the expenditure elasticity of demand for good *n* (Deaton, 1974).

Alternatively, Christensen et al. (1975) specified a quadratic approximation to the indirect utility function, v(**p**, *M*), where

$$\mathrm{v}(\mathbf{p}, M) = -\sum_{n=1}^{N} \alpha_n \log(p_n/M) - \frac{1}{2}\sum_{n=1}^{N}\sum_{j=1}^{N} \gamma_{nj} \log(p_n/M)\log\left(p_j/M\right). \tag{D.10}$$

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[142] This resulting demand system is the "Indirect Addilog" defined as $q_i = \frac{a_i b_i (M/p_i)^{b_i+1}}{\sum_{i=1}^{n} a_i b_i (M/p_i)^{b_i+1}}$.

When Roy's identity is applied to (D.10), the demand for good *n* is

$$\mathrm{q}_n(\mathbf{p}, M) = \frac{M}{p_n}\left[\frac{\alpha_n + \frac{1}{2}\sum_{j=1}^{N}\gamma_{nj}\log(p_j/M)}{\sum_{j=1}^{N}\alpha_j + \frac{1}{2}\sum_{k=1}^{N}\sum_{j=1}^{N}\gamma_{kj}\log(p_j/M)\log(p_k/M)}\right].$$

Therefore, the expenditure share equations, with the conventional normalization that $\sum_{n=1}^{N}\alpha_n = -1$, are

$$\mathrm{w}_n(\mathbf{p}, M) = \frac{\alpha_n + \frac{1}{2}\sum_{j=1}^{N}\gamma_{nj}\log(p_j/M)}{-1 + \frac{1}{2}\sum_{k=1}^{N}\sum_{j=1}^{N}\gamma_{kj}\log(p_j/M)\log(p_k/M)}, \forall n = 1, \ldots, N.^{143} \quad (\mathrm{D}.11)$$

This system is known as the indirect translog (ITL) demand system, for which adding-up and symmetry conditions hold when

$$\sum_{i=1}^{n}\gamma_{ij} = 0, \sum_{i=1}^{n}\alpha_i = 1, \text{and } \gamma_{ij} = \gamma_{ji}. \quad (\mathrm{D}.12)$$

The price and expenditure elasticities arising from the ITL demand system are listed severally as follows:

$$\eta_{ij} = \frac{\frac{\gamma_{ij}}{w_i} - \sum_{k=1}^{n}\gamma_{ki} - \delta_{ij}}{1 + \sum_{k=1}^{n}\sum_{l=1}^{n}\gamma_{kl}\log\left(\frac{p_l}{M}\right)}, \text{and} \quad (\mathrm{D}.13)$$

$$\eta_{iM} = 1 + \frac{-\sum_{j=1}^{n}\frac{\gamma_{ij}}{w_i} + \sum_{i=1}^{n}\sum_{j=1}^{n}\gamma_{ij}}{1 + \sum_{i=1}^{n}\sum_{j=1}^{n}\gamma_{ij}\log\left(\frac{p_j}{M}\right)}. \quad (\mathrm{D}.14)$$

The ITL indirect utility function is a generalization of the Cobb-Douglas form and reduces to the Cobb-Douglas form when all of the γ's are equal to zero.

An extension of the ITL is the generalized translog (GTL) demand system with an indirect utility function of the form

$$\log \mathrm{v}(\mathbf{p}, M) = -\sum_{n=1}^{N}\alpha_n \log\left(\frac{p_n}{M^*}\right) - \frac{1}{2}\sum_{n=1}^{N}\sum_{j=1}^{N}\gamma_{nj}\log\left(\frac{p_n}{M^*}\right)\log\left(\frac{p_j}{M^*}\right), \quad (\mathrm{D}.15)$$

[143] Since the share equations are homogenous of degree zero in the parameters, α_n cannot be identified and a normalization is needed.

where $M^* = M - \sum_{n=1}^{N} p_n b_n$ (Pollak and Wales, 1980).

Similar to the LES, a portion of total expenditure M in the GTL is allocated to pre-committed quantities; i.e., $M - \sum_{n=1}^{N} p_n\, b_n$, implying a commitment of "subsistence" expenditure and leaving a remainder for discretionary expenditure. Therefore, the GTL nests the ITL system when $b_1 = \cdots = b_n = 0$ and the LES system when $\sum_{n=1}^{N}\sum_{k=1}^{N} \gamma_{nk} = 0$.[144] The GTL and its nested counterparts belong to the price-independent generalized logarithmic preferences (PIGLOG) class of demand systems. This class of preferences has the desirable property of permitting exact nonlinear aggregation over consumers. Cost functions that are PIGLOG are popular because they allow Engel curves to be log-linear, and always give rise to demands of a form consistent with Working and Leser's Engel model (Deaton and Muellbauer, 1980b: 75).[145] On the other hand, preferences that can be represented by an indirect utility function of the Gorman polar form (e.g., LES, Cobb-Douglas, and CES) allow for exact linear aggregation but yield linear Engel curves.

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[144] Pollak and Wales (1992) provided a detailed description of other members of the translog family, including the linear translog ($\sum_{n=1}^{N}\gamma_{ni} = 0$), the homothetic translog ($b_1 = \cdots = b_n = 0, \sum_{n=1}^{N}\gamma_{in} = 0$), and the log translog.

[145] The PIGLOG class of preferences is a special case of generalized linearity, in which the representative cost function is of the form

$$\mathrm{c}(\mathbf{p}, \mathrm{u}) = \theta[\mathrm{u}, \mathrm{a}(\mathbf{p}), \mathrm{b}(\mathbf{p})],$$

where $\mathrm{a}(\mathbf{p})$ and $\mathrm{b}(\mathbf{p})$ are linearly homogenous functions of prices and the function $\theta[\cdot]$ is linearly homogenous in $\mathrm{a}(\cdot)$ and $\mathrm{b}(\cdot)$. When the representative expenditure function is independent of prices and depends only on the distribution of expenditures, then the representative cost function is of the price-independent generalized linearity (PIGL) form:

$$\mathrm{c}(\mathbf{p}, \mathrm{u}) = [\mathrm{a}(\mathbf{p})\}^{\alpha} + \mathrm{ub}(\mathbf{p})^{\alpha}]^{1/\alpha}.$$

The limit of this representative cost function as α approaches zero yields the PIGLOG cost function:

$$\log \mathrm{c}(\mathbf{p}, \mathrm{u}) = \log \mathrm{a}(\mathbf{p}) + \mathrm{ulog}\, \mathrm{b}(\mathbf{p}).$$

Inverting the PIGLOG cost function yields an indirect utility function of the form

$$\mathrm{v}(\mathbf{p}, M) = \frac{\log M - \log \mathrm{a}(\mathbf{p})}{\log \mathrm{b}(\mathbf{p})}$$

The demand function for good n can be recovered using Roy's identity and is

$$\mathrm{q}_n(\mathbf{p}, M) = M\left[\frac{\partial \mathrm{a}(\mathbf{p})/\partial p_n}{\mathrm{a}(\mathbf{p})} - \frac{\partial \mathrm{b}(\mathbf{p})/\partial p_n}{\mathrm{b}(\mathbf{p})\log \mathrm{b}(\mathbf{p})}(\log M - \log \mathrm{a}(\mathbf{p}))\right],$$

and the equations for expenditure shares($w_n = p_n q_n / M$) are

$$w_n = p_n\left[\frac{\partial \mathrm{a}(\mathbf{p})/\partial p_n}{\mathrm{a}(\mathbf{p})} - \frac{\partial \mathrm{b}(\mathbf{p})/\partial p_n}{\mathrm{b}(\mathbf{p})\log \mathrm{b}(\mathbf{p})}(\log M - \log \mathrm{a}(\mathbf{p}))\right],$$

which is exactly the form of the ITL and GTL expenditure share equations. The PIGLOG cost function yields Engel curves that are consistent with the model proposed by Working and Leser: $w_n = \alpha_n + \beta_n log M$, where α_n and β_n are functions of prices.

D.2.2.3 Application of Shephard's Lemma to the Expenditure function

The consumer's cost function is dual to the (direct) utility function in that it gives the minimum expenditure needed to reach a specified level of utility, given the prices. The cost function is also referred to as the expenditure function. We write the cost function as $\mathrm{c}(\mathbf{p}, \mathrm{u})$, which can be derived by substituting $\mathrm{c}(\cdot)$ for M in the indirect utility function. This cost function has the property that

$$\frac{\partial \mathrm{c}(\mathbf{p}, \mathrm{u})}{\partial p_n} = q_n\,, \qquad \forall\, n = 1, \ldots, N, \tag{D.16}$$

which is referred to as Shephard's lemma. Accordingly, a third approach to estimating demand systems is to specify the form of the expenditure (cost) function and recover the Hicksian demand functions using Shephard's lemma. One popular demand system that uses this approach is the almost ideal demand system (AIDS). Deaton and Muellbauer (1980b: 75) suggested approximating a cost function consistent with PIGLOG preferences,

$$\log \mathrm{c}(\mathbf{p}, \mathrm{u}) = \mathrm{a}(\mathbf{p}) + \mathrm{ub}(\mathbf{p}), \tag{D.17}$$

with $\mathrm{a}(\mathbf{p})$ and $\mathrm{b}(\mathbf{p})$ as

$$\mathrm{a}(\mathbf{p}) = \alpha_0 + \textstyle\sum_{n=1}^{N} \alpha_n \log p_n + \frac{1}{2} \sum_{n=1}^{N} \sum_{l=1}^{N} \gamma_{nl}^{*} \log p_n \log p_l, \tag{D.18}$$

$$\mathrm{b}(\mathbf{p}) = \beta_0 \textstyle\prod_{n=1}^{N} p_n^{\beta_n}, \tag{D.19}$$

$$\text{where} \quad \gamma_{nl}^{*} = \frac{1}{2}(\gamma_{nl} + \gamma_{ln}).$$

By applying Shephard's lemma and noting that $w_n = \partial \log \mathrm{c}(\mathbf{p}, \mathrm{u}) / \partial \log p_n$, the expenditure share for good n is [146]

$$w_n = \frac{\partial \log \mathrm{c}(\mathbf{p}, \mathrm{u})}{\partial \log p_n} = \mathrm{u}\, \beta_n \beta_0 \prod\nolimits_{k=1}^{N} p_k^{\beta_k} + \alpha_n + \sum\nolimits_{k=1}^{N} \gamma_{nk} \log p_k. \tag{D.20}$$

Inverting the cost function yields the equation for u,

[146] By Shephard's lemma, $\partial \mathrm{c}(\mathbf{p}, \mathrm{u}) / \partial p_n = q_n$. Multiplying both sides by $p_n / \mathrm{c}(\mathbf{p}, \mathrm{u})$, then

$$\frac{\partial \log \mathrm{c}(\mathbf{p}, \mathrm{u})}{\partial \log p_n} = \frac{p_n q_n}{\mathrm{c}(\mathbf{p}, \mathrm{u})} = w_n\,.$$

$$\mathrm{u} = \frac{\log M - \mathrm{a}(\mathbf{p})}{\mathrm{b}(\mathbf{p})}, \tag{D.21}$$

and u can be substituted back into (D.20) to yield expenditure share equations as functions of only the observable prices and expenditure:

$$w_n = \alpha_n + \sum_{j=1}^{N} \gamma_{nj} \log p_j + \beta_n \log\left(\frac{M}{P}\right), \quad \forall n = 1, \ldots, N, \tag{D.22}$$

where

$$\log P = \alpha_0 + \sum_{k=1}^{N} \alpha_k \log p_k + \frac{1}{2} \sum_{k=1}^{N} \sum_{l=1}^{N} \gamma_{kl} \log p_k \log p_l.$$

The adding-up conditions imply the following parametric restrictions:

$$\sum_{n=1}^{N} \gamma_{nj} = 0, \sum_{n=1}^{N} \beta_n = 0, \sum_{n=1}^{N} \alpha_n = 1.$$

Symmetry requires that $\gamma_{ij} = \gamma_{ji}$, and c(**p**, u) must be homogenous of degree 1 and increasing in **p**, which implies that

$$\sum_{n=1}^{N} \gamma_{jn} = 0.$$

Since the cost function is PIGLOG, the Engel curves are log-linear, allowing exact nonlinear aggregation of consumers into a representative consumer. Deaton and Muellbauer refer to (D.22) as the almost ideal demand system, or AIDS for short.

One drawback to estimating the AIDS is that it is nonlinear in the parameters because the price index used to deflate total expenditure, P, is a function of parameters to be estimated. To circumvent the associated problems, Deaton and Muellbauer (1980a) suggested approximating P with Stone's price index:

$$\log P = \sum_{n=1}^{N} w_n \log p_n. \tag{D.23}$$

This system is referred to as the linearized AIDS (LAIDS) or the linear approximate AIDS (LA-AIDS). While very convenient and hence popular, this approximation has some drawbacks. First, while the LAIDS is an approximation to a well-behaved demand system, the model does not satisfy the requirements for integrability. Second, Stone's price index (which does not satisfy the requirements for a price index

discussed by Moschini (1995)) contains the dependent variables as elements in the share equation system with potential implications for estimation bias.

Banks, Blundell and Lewbel (1997) argued that consumption data yield Engel curves that are more nonlinear (rank > 2) than what is permitted by the AIDS and ITL models. They extended the AIDS to allow for quadratic Engel curves and called it quadratic AIDS (QUAIDS). They derived the QUAIDS from an indirect utility function of the form

$$\log \mathrm{v}(\mathbf{p}, M) = \left(\left[\frac{\log M - \log \mathrm{a}(\mathbf{p})}{\mathrm{b}(\mathbf{p})} \right]^{-1} + \lambda(\mathbf{p}) \right)^{-1}, \qquad (\mathrm{D}.24)$$

where a(**p**) and b(**p**) are as defined in (D.18) and (D.19) and $\lambda(\mathbf{p}) = \sum_{n=1}^{N} \lambda_n \log p_n$. By Roy's identity, the expenditure shares of the QUAIDS model are

$$w_n = \alpha_n + \sum_{j=1}^{N} \gamma_{nj} \log p_n + \beta_n \log\left(\frac{M}{\mathrm{a}(\mathbf{p})}\right) + \frac{\lambda_n}{\mathrm{b}(\mathbf{p})} \left[\log\left(\frac{M}{\mathrm{b}(\mathbf{p})}\right) \right]^2. \qquad (\mathrm{D}.25)$$

The QUAIDS is rank three and has quadratic logarithmic expenditure shares.

The AIDS cost function and ITL indirect utility functions are only locally concave and convex, respectively (Deaton, 1986). Gallant (1984) proposed using a Fourier-series rather than a Taylor-series expansion to approximate indirect utility, making the indirect utility function approximation globally convex.

Gallant (1984) argued that the Fourier flexible form (FFF) is a semi-nonparametric model that avoids model misspecification errors induced by parametric models like the AIDS and ITL, which may generate biased and inconsistent estimators. Indeed, Gallant (1984) argued that desirable statistical properties of elasticities also may not hold at any particular data point (e.g., the mean of the data) chosen arbitrarily as a point at which to evaluate elasticities when a locally flexible model is estimated. The FFF has been combined with the AIDS and ITL models to create globally flexible versions of these models (Chalfant, 1987; Piggott, 2003). Several studies have also generalized the AIDS and ITL functional forms to create other demand systems (e.g., Pollak and Wales, 1980; Bollino, 1987; Lewbel, 1989; Moschini, 2001).

D.2.2.4 Differential Approximation to the Demand function

A final approach is based on a direct approximation of the Marshallian demands. Transforming the differentials of the Marshallian demands yields a set of equations that are local first-order approximations to the underlying relationship between quantities, prices, and income. The most common differential demand system is the Rotterdam model (Theil, 1965; Barten, 1966). More-recent alternatives include the first-differenced linear AIDS (FDLAIDS) (Deaton and Muellbauer, 1980a), the National Bureau of Research (NBR) demand system (Neves, 1987), and the Central Bureau of Statistics (CBS) demand system (Keller and Van Driel, 1985). Barten (1993) showed that these four differential demand systems can be nested into a model referred to as Barten's synthetic model.

Consider the Rotterdam model of Theil (1965) and Barten (1966). Theil derived the Rotterdam model, beginning with the logarithmic differential of the Marshallian demand for good n, $q_n(p_1, \dots, p_N, M)$, such that

$$d \log q_n = \sum_{i=1}^{N} \eta_{nj} d \log p_j + \eta_{nM} d \log M, \qquad (D.26)$$

where q_n is quantity of good n, p is price, M is total expenditure, and η_{nj} and η_{nM} are Marshallian elasticities of demand for good n with respect to the price of good j and total expenditure. Using the Slutsky equation, i.e., $\eta_{nj}^{*} = \eta_{nj} + \eta_{nM} w_j$, (D.26) becomes

$$d \log q_n = \sum_{j=1}^{N} \eta_{nj}^{*} d \log p_j + \eta_{nM} \left(d \log M - \sum_{j=1}^{N} w_j \, d \log p_j \right), \qquad (D.27)$$

where η_{nj}^{*} is the Hicksian price elasticity, and w_j is the expenditure share for good j. Multiplying both sides of (D.27) by the expenditure share for good n, w_n, results in the Rotterdam demand system:

$$w_n d \log q_n = \sum_{j=1}^{N} \pi_{nj} d \log p_j + \theta_n d \log Q, \qquad (D.28)$$

where $d \log Q$ is a Divisia volume index; that is

$$d\log Q = d\log M - \sum_{n=1}^{N} w_n d\log p_n \qquad (D.29)$$

or

$$d\log Q = \sum_{n=1}^{N} w_n d\log q_n ,$$

the parameters of the system are defined as

$$\pi_{nj} = \frac{p_n p_j}{M} s_{nj}, \qquad (D.30)$$

$$\theta_n = \frac{\partial q_n}{\partial M} p_n , \qquad (D.31)$$

and s_{nj} is the Slutsky substitution term.[147]

To sum up, the choice of model for a demand system is difficult. Ad hoc single-equation models might be found to fit the data better than other functional forms, but such models do not generally conform to demand theory. On the other hand, demand systems derived directly from a utility function are consistent with demand theory but require the use of restrictively simple functional forms that may not well represent the true data-generating process. Flexible functional forms may be flexible enough to approximate the data-generating process while allowing the imposition of restrictions from demand theory like Cournot and Engel aggregation, homogeneity, and symmetry. However, a difficulty with flexible functional forms is that the number of structural parameters required to maintain generality is large (Johnson et al., 1984: 76).

In addition, flexible functional forms may be too flexible in the sense that they allow elasticities of demand to take values that are implausible or inconsistent with priors. As discussed by (Alston and Chalfant, 1991a, 1991b), the choice of functional form is whimsical in that theory offers little or no guidance to the

[147] The Slutsky equation shows that the unobservable Hicksian demand response to prices (a pure substitution effect) can be represented as a combination of observable Marshallian price and income effects:

$$s_{nj} = \frac{\partial \mathrm{h}_n(\mathbf{p},u)}{\partial p_j} = \frac{\partial \mathrm{q}_n(\mathbf{p},M)}{\partial p_j} + \frac{\partial \mathrm{q}_n(\mathbf{p},M)}{\partial M}\mathrm{q}_j(\mathbf{p},M).$$

The following equation represents the elasticity form of the Slutsky equation (s_{nj}), which is regularly used in empirical applications:

$$\eta^*_{nj} = \eta_{nj} + \eta_{nM} w_j .$$

choice and the results from a particular choice may be fragile, i.e., sensitive to the choice even when a flexible functional form is employed. For instance, choosing an incorrect functional form could induce autocorrelation or other patterns that could be mistaken for structural change in data generated by a known, stable data-generating process with no autocorrelation in the sampling errors (Alston and Chalfant, 1991a, 1991b).

APPENDIX E

ESTIMATING THE PARAMETERS OF A SET OF ERROR RELATED ECONOMIC RELATIONS

Estimation of economic relationships by using data on a set of economic units (a cross section) that are observed at more than one point in time (a time series) is a problem frequently encountered in econometrics. For example, if we are studying the economic behavior of pharmaceutical manufacturers, we may observe costs, inputs, and outputs for a number of firms across Thailand every year for a number of years. On the aggregate level, if we are studying the international pharmaceutical consumption, we may observe spending on drugs, drug prices, and the corresponding explanatory variables, for a number of countries every quarter or every year for a number of years. In these examples, an investigator will possess a time-series of data on a cross section of economic units. The problem is how to specify a statistical model that will capture individual differences in behavior so that we may combine or pool all the data (information) for estimation and inference purposes.

In Appendix E, we consider one statistical model that may be used to combine time series and cross-sectional data. Let's consider the investment behavior of *N* firms, over the *T* years. We let y_{it} = investment by the i^{th} firm in year t, X_{2it} = profit measure for the i^{th} firm in year t, X_{3it} = capital stock measure for the i^{th} firm in year t, e_{it} = error term for the i^{th} firm in year t, and specifying the following flexible statistical model

$$y_{it} = \beta_{1it} + \beta_{2it}X_{2it} + \beta_{3it}X_{3it} + e_{it} \ , i = 1, \dots, M; t = 1, \dots, T. \quad (E.1)$$

In the general model, the intercepts and response parameters are permitted to differ for each firm in every time period. This model is intractable in its current form, as there are more unknown parameters than data points. There are many types of

simplifying assumptions that can be made to make the model operational. The challenge is to specify a statistical model that is consistent with the data-generation process.

As one possibility the Seemingly Unrelated Regression (SUR) equation model is obtained if we assume the error e_{it} are contemporaneously correlated (in other words, correlated across equation errors in the same time period). Under the SUR specification

$$\begin{aligned} \beta_{1it} &= \beta_{1i} \\ \beta_{2it} &= \beta_{2i} \\ \beta_{3it} &= \beta_{3i} \,. \end{aligned} \qquad \text{(E. 2)}$$

That is, the parameters of the investment function differ across firms (note that the "i" subscript remains) but are constant across time.

More generally, in many applications y_i and X_i, for $i = 1, 2, \ldots, M$, will contain observations on variables for T different times period, where the subscript i corresponds to a particular economic or geographic unit, such as a household, a firm, a region within a country, or, in this research, a chemical ingredient of a particular drug. Consequently, a Seemingly Unrelated Regressions (SUR) model for a set of equations provides a framework for specifying a statistical model reflecting how time-series and cross-sectional data can be combined. In Appendix E, we shall consider sets of regression equations that are error related. When we write the set of equations as a single linear statistical model, the new error vector may be both heteroskedastic and correlated. To take account of this information, we demonstrate a variant of the generalized least squares estimation rule.

Relative to using the least squares rule on each equation individually, we note that under many conditions normally fulfilled in practice, when the equations are combined and the equation error information is used, we have an improvement in terms of the precision with which the unknown parameters are estimated. Given the estimated coefficients and the estimated covariance matrix, it is possible to test individual and cross-equations hypotheses regarding the unknown coefficients. The significant idea in Appendix E revolves around (i) writing two or more linear

statistical models as a single linear statistical model, and (ii) recognizing that if the cross-equation errors are correlated, making use of this information in a generalized least squares estimator context results in an increase in estimation precision.

This is a two-stage estimation procedure. The first stage involves least squares estimates of the individual equation coefficients ($\hat{\beta}_i$) and equation errors ($\hat{\mathrm{e}}_i$). The estimated equation errors ($\hat{\mathrm{e}}_i$) are then used to construct an estimated error covariance matrix for the single linear statistical model representing the set of equations. The second stage consists of using the estimated covariance matrix and the generalized least squares rule to estimate the unknown parameters and to conduct relevant tests of hypotheses.

The statistical inference machine runs on information and in this seemingly unrelated regressions (SUR) section we focus on how to make use of the additional information concerning cross correlations among equation errors. When equations are estimated individually, this potential information is omitted. To improve precision, it is useful to investigate whether it is possible to reformulate the statistical model to make use of additional sample information that may be at our disposal. As economic units may have many things in common, Zellner (1962) first proposed ways of pooling the sample information and modeling them as a set of relations so as to take account of this information explicitly. Zellner (1962) has given this type of statistical model the name of "Seemingly Unrelated Regressions" (SUR) or error related regression equations. The SUR model is another form of the general error covariance statistical model involving a special form of heteroskedasticity and autocorrelation that appears jointly. Thus, if we want to use all of the information at our disposal, the SUR is the appropriate model.

Appendix E provides a general framework for specifying and carrying through a range of economic problems within a context of the seemingly unrelated regressions statistical model. Appendix E is organized as follows. In Section E.1, the general formulation involving a set of *M* relations is specified and analyzed. Estimation with a known and unknown covariance matrix is then given in Section E.2. Finally, Section E.3 presents the hypothesis testing.

E.1 A General SUR Formulation

Let's consider a general formulation for the SUR statistical model. In a general specification of M seemingly unrelated regression equations, the i^{th} equation is given by

$$\mathrm{y}_i = X_i\beta_i + \mathrm{e}_i \qquad i = 1, 2, \ldots, M, \tag{E.3}$$

where y_i and e_i are of dimension$(T \times 1)$, X_i is $(T \times K_i)$, and β_i is $(K_i \times 1)$. Note that each equation does not have to have the same number of explanatory variables. Combining all equations into one big model yields

$$\begin{bmatrix} \mathrm{y}_1 \\ \vdots \\ \mathrm{y}_M \end{bmatrix} = \begin{bmatrix} X_1 & & \\ & \ddots & \\ & & X_M \end{bmatrix} \begin{bmatrix} \beta_1 \\ \vdots \\ \beta_M \end{bmatrix} + \begin{bmatrix} \mathrm{e}_1 \\ \vdots \\ \mathrm{e}_M \end{bmatrix}, \tag{E.4}$$

or, alternatively,

$$\mathbf{y} = \boldsymbol{X}\boldsymbol{\beta} + \mathbf{e}\,, \tag{E.5}$$

where the definitions of y, X, β and e are obvious from equation (E.4) and their dimensions are, respectively, $(MT \times 1)$, $(MT \times K)$, $(K \times 1)$, and $(MT \times 1)$, with $K = \sum_{i=1}^{M} K_i$. Thus, the specification (E.5) has precisely the form of the linear statistical model.

Given that e_{it} is the error for the i^{th} equation in the t^{th} time period, the assumption of contemporaneous disturbance correlation, but not correlation over time, implies that the covariance matrix for the complete error vector can be written as

$$\boldsymbol{W} = E[\mathbf{e}\mathbf{e}'] = \begin{bmatrix} \sigma_{11}I_T & \cdots & \sigma_{1M}I_T \\ \vdots & \ddots & \vdots \\ \sigma_{M1}I_T & \cdots & \sigma_{MM}I_T \end{bmatrix} = \Sigma \otimes I_T\,, \tag{E.6}$$

where

$$\Sigma = \begin{bmatrix} \sigma_{11} & \cdots & \sigma_{1M} \\ \vdots & \ddots & \vdots \\ \sigma_{M1} & \cdots & \sigma_{MM} \end{bmatrix},$$

and $\otimes$ indicates each element of Σ is multiplied by an identity matrix.

The matrix Σ is symmetric, so that $\sigma_{ij} = \sigma_{ji}$, and it is nonsingular and thus has an inverse.

E.2 Estimation with a Known and Unknown Covariance Matrix

When the system of equation (E.4) is view as the single equation (E.5), we can estimate $\boldsymbol{\beta}$ and hence all the β_i by the generalized least squares procedures. Thus, the generalized least squares estimator, i.e., equation (E.7), is best linear unbiased.

$$\widehat{\boldsymbol{\beta}} = (\boldsymbol{X}'\boldsymbol{W}^{-1}\boldsymbol{X})^{-1}\boldsymbol{X}'\boldsymbol{W}^{-1}\mathbf{y} = [\boldsymbol{X}'(\Sigma^{-1} \otimes \boldsymbol{I})\boldsymbol{X}]^{-\mathbf{1}}\boldsymbol{X}'(\Sigma^{-1} \otimes \boldsymbol{I})\mathbf{y} \qquad \text{(E.7)}$$

The covariance matrix for $\widehat{\boldsymbol{\beta}}$ is given by $(\boldsymbol{X}'\boldsymbol{W}^{-1}\boldsymbol{X})^{-1} = [\boldsymbol{X}'(\Sigma^{-1} \otimes \boldsymbol{I})\boldsymbol{X}]^{-\mathbf{1}}$. In these expressions, we have used the result $\boldsymbol{W}^{-1} = \Sigma \otimes \boldsymbol{I}^{-1} = \Sigma^{-1} \otimes \boldsymbol{I}$.

In practice, the variances and covariances (σ_{ij}s) are unknown and must be estimated with their estimates being used in equation (E.3) to form an estimated generalized least squares estimator. To estimate the σ_{ij}, we first estimate each equation by least squares $\hat{\beta}_i = \mathrm{b}_i = (X_i'X_i)^{-1}X_i'\mathrm{y}_i$ and obtain the least squares residuals $\hat{\mathrm{e}}_i = \mathrm{y}_i - X_i\,\mathrm{b}_i$. Consistent estimates of the variances and covariances are then given by

$$\hat{\sigma}_{ij} = \frac{1}{T}\hat{\mathbf{e}}_i'\hat{\mathbf{e}}_j = \frac{1}{T}\sum_{t=1}^{T}\hat{e}_{it}\,\hat{e}_{jt} \qquad \text{(E.8)}$$

If we define $\hat{\Sigma}$ as the matrix Σ with the unknown σ_{ij} replaced by $\hat{\sigma}_{ij}$, then the estimated generalized least squares estimator for β corresponding to equation (E.7) can be written as

$$\widehat{\widehat{\boldsymbol{\beta}}} = \left[\boldsymbol{X}'\left(\hat{\Sigma}^{-1} \otimes \boldsymbol{I}\right)\boldsymbol{X}\right]^{-\mathbf{1}}\boldsymbol{X}'\left(\hat{\Sigma}^{-1} \otimes \boldsymbol{I}\right)\mathbf{y} \qquad \text{(E.9)}$$

This estimator is the one that is generally used in practice and is the general version of Zellner (1962)'s Seemingly Unrelated Regression (SUR) estimator.[148]

[148] For a more complete discussion of the generalized least squares framework and seemingly unrelated regression, refer to Judge et al. (1988: Chapters 8, 9 and 11) and the references it contains, such as Srivastava and Giles (1987).

E.3 Hypothesis Testing

E.3.1 Testing for Contemporaneous Correlation

If contemporaneous correlation does not exist, least squares procedure applied separately to each equation is fully efficient and there is no need to employ the seemingly unrelated regression estimator. Thus, it is useful to test whether

H_o: The contemporaneous covariances σ_{ij} are zero, for $i \neq j$

H_1: At least one covariance is nonzero

For the general case of *M* equations, an appropriate test statistic, under the normal linear model, is given by

$$\lambda = T \sum_{i=2}^{M} \sum_{j=1}^{i-1} r_{ij}^2 \ , \qquad \text{(E. 10)}$$

where r_{ij}^2 is the squared correlation, i.e., $r_{ij}^2 = \hat{\sigma}_{ij}{}^2 / \hat{\sigma}_{ii}\,\hat{\sigma}_{jj}$, and $\hat{\sigma}_{ij}$ is signified by (E.8). Under H_o, λ has an asymptotic χ^2 distribution with $M(M-1)/2$ degrees of freedom, where *M* is the number of equations and the estimated error correlations are used in the computation of λ. The null hypothesis is rejected if λ is greater than the critical value for a $\chi^2_{d.o.f.}$ distribution at a pre-specified significance level.

E.3.2 Linear Restrictions on the Coefficients

Consider a set of linear restrictions of the form $\boldsymbol{R\beta} = \mathbf{r}$, where $\boldsymbol{R}$ and $\mathbf{r}$ are known matrices of dimension $(J \times K)$ and $(J \times 1)$, respectively. It is possible to construct a test statistic for testing the null hypothesis $H_o = \boldsymbol{R\beta} = \mathbf{r}$. There are two main differences between the procedures for testing general linear hypotheses and those adopted in this section. First, the relevant test statistic will now depend on Σ which, because it is unknown, needs to be replaced by the estimator $\hat{\Sigma}$. This replacement means that estimator properties and test statistics are based on asymptotic

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For a more complete write-up of combining cross section and time-series data, see Hsiao (2003) and Judge et al. (1988: Chapter 10 and Sections 11.14 to 11.16 of Chapter 11). See also Sections 10.2 to 10.3 of Chapter 10 of Greene (2008: 254-272).

rather than finite sample distributions. Second, it is now possible to test and impose restrictions that relate the coefficients in one equation with the coefficients in other equations. This possibility is of particular interest in economics. For example, if the coefficient vectors for each equation are all equal, $\beta_1 = \beta_2 = \cdots = \beta_M$, the use of data aggregated over micro-units does not lead to aggregation bias. Also, some aspects of economic theory often suggest symmetric and other linear relationships between coefficients in different equations. For this purpose, a generalized version of the *F*-test for a set of linear restrictions may be used.

Turning to the question of testing $H_o = \boldsymbol{R\beta} = \mathbf{r}$ against the alternative $\boldsymbol{R\beta} \neq \mathbf{r}$, we note that, when H_o is true,

$$\boldsymbol{R\hat{\beta}} \sim N(\mathbf{r}, \boldsymbol{RCR'}) , \tag{E.11}$$

where $\boldsymbol{C} = [\boldsymbol{X'}(\Sigma^{-1} \otimes \boldsymbol{I})\boldsymbol{X}]^{-1}$. Thus,

$$\mathrm{g} = \left(\boldsymbol{R\hat{\beta}} - \mathbf{r}\right)'(\boldsymbol{RCR'})^{-1}\left(\boldsymbol{R\hat{\beta}} - \mathbf{r}\right) \sim \boldsymbol{\chi}^2_{(J)} . \tag{E.12}$$

This result is a finite sample one (providing the errors are normally distributed), but it is not operational because it depends on the unknown covariance matrix Σ. When Σ is replaced by $\hat{\Sigma}$, we have the asymptotic result

$$\hat{\mathrm{g}} = \left(\boldsymbol{R\hat{\hat{\beta}}} - \mathbf{r}\right)' \left(\boldsymbol{R\hat{C}R'}\right)^{-1} \left(\boldsymbol{R\hat{\hat{\beta}}} - \mathbf{r}\right) \xrightarrow{d} \boldsymbol{\chi}^2_{(J)} . \tag{E.13}$$

Since equation (E.13) holds only when H_o is true, we reject H_o if a calculated value for $\hat{\mathrm{g}}$ exceeds the appropriate critical value from a $\boldsymbol{\chi}^2_{(J)}$ distribution.

BIOGRAPHY

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EXPERIENCES	2007-Present: Independent Researcher 2004-2006: Business Development Director, Pan Rajdhevee Group Public Co., Ltd. 2003-2004: National Sales Manager, Roche Thailand Co., Ltd. 2000-2003: Sales Manager, Aventis Pharma Co., Ltd.