

Welfare Effect of Market Exclusivity Extension for Patented Medicines in Thailand: Analysis of the Effect of TRIPS-Plus Provisions

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Abstract

Under the free trade agreement negotiations with the United States and the European Union, Thailand, along with several developing countries, is required to enforce TRIPS-Plus provisions. Most developing countries claim that stringent intellectual property protection for pharmaceuticals would result in considerably higher prices for medicines, with adverse consequences for the health and well-being of their citizens. This paper empirically assesses the basis of these claims. Using a detailed product-level data set from Thailand, we estimate demand-side parameters together with key price and expenditure elasticities for a set of three main categories of antihypertensive drugs. We then use these estimates to carry out counterfactual simulations of what consumer welfare would have been, had Thailand enforced TRIPS-Plus. According to our estimation, the enforcement of TRIPS-Plus would result in a substantial accumulated consumer welfare loss to the Thai economy, ranging between 30 billion baht and 136 billion baht, within a 10-year period from 2012 to 2021. The magnitude of consumer welfare loss suggests that without clear and inclusive evidence regarding the merits of TRIPS-Plus in every aspect, Thailand should not accept any further intellectual property protection beyond the TRIPS mandates.

Keywords

Free Trade Agreement; TRIPS; TRIPS-Plus; intellectual property protection; patented medicines; consumer welfare

Introduction

Under trade and investment negotiations with the United States (U.S.) and the European Union (E.U.), several developing countries were required to enforce TRIPS-Plus provisions – the intellectual property rights (IPR)-related requests, which have more stringent protection of IPR than those stipulated in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In TRIPS-Plus, 10 crucial provisions as related to pharmaceuticals are included as follows: (i) patentability of animal and plants; (ii) patentability for any new uses or methods of a known product; (iii) prohibition of pre-grant opposition and revocation of patents; (iv) restrictions on the issuing of compulsory licenses; (v) patent term compensation for granting and marketing approval delay; (vi) protection for test data exclusivity; (vii) linkage between drug registration and the patent status of a drug; (viii) trademarks; (ix) parallel import limitations through contracts with the patent holders; and (x) linkage between IPR and investment. The largest threats are regarding patent protection extension and

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protection of undisclosed information pertaining to medicines since these provisions will increase the monopoly rights of patent holders, rendering medicines unaffordable for the poorest and most vulnerable groups.

The negotiations leading up to TRIPS-Plus, and in particular the provisions relating to pharmaceuticals, have been highly contentious. The main point of contention is the claim made by governments of many low-income countries that stringent IP protection for pharmaceuticals due to TRIPS-Plus will result in substantially higher prices for medicines, with adverse consequences for the health and well-being of their citizens. Especially, they suspect that the loss of consumers' surplus from having to pay for exorbitant, imported 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. Countering this claim, the governments of the U.S. and the E.U. argue that the imposition of TRIPS-Plus is unlikely to significantly raise prices because most patented medicines have many therapeutic substitutes. Moreover, the presence of TRIPS-Plus has served as an incentive to engage in research on diseases that disproportionately afflict the world's poor, implying that stringent patent protection for pharmaceuticals will ultimately benefit developing countries by stimulating innovation and transfer of technology.

Many studies have attempted to identify the impact of patents on prices. For instance, Caves, Whinston, Hurwitz, Pakes and Temin (1991) compare the prices of branded drugs to those of generic substitutes, and find that the relative price of generic substitutes decreased with the number of generic substitutes available for a particular branded drug. Lu and Comanor (1998) report that newly patented drugs that provided significant therapeutic gains over existing substitutes were launched at considerably higher relative prices than those that offered more modest therapeutic gain. In Thailand, there are a few studies attempting to estimate the potential impact of strict IPR protection for pharmaceuticals. For instance, Chutima Akaleephan et al. (2009) examine the possible impact of TRIPS-Plus on drug spending through simple calculation of the average price differential between innovative drugs and their generics. Nusaraporn Kessomboon et al. (2010) adopt the model of impact of changes in intellectual property rights to calculate the impact of TRIPS-Plus on access to medicines. Although these studies are able to isolate the likely impact of patent protection on drug prices, they are limited by the fact that they do not (and cannot) provide any sense of the magnitude of the consumer welfare loss, as they are not grounded in any model of consumer behavior.

Several studies have improved upon the aforesaid literature by using explicit models of consumer and firm behavior to simulate the welfare losses implied by patent protection; for instance, Nogués (1993), Maskus and Konan (1994), Subramanian (1995), Fink (2000) and Watal (2000). However, these past studies, while they provide some useful indicative figures, are ultimately 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 a further step towards filling this gap and contributes to better understanding of the potential effects of TRIPS-Plus in developing countries. We provide the first rigorously-derived estimates of the possible impact of TRIPS-Plus on consumer welfare in Thailand. We also allow for and flexibly estimate a range of cross-product-group substitution effects. By contrast, cross-price effects are ignored in previous literature.

Background and Data

In Thailand, drug expenditure accounts for almost half of healthcare expenses (Wibulpolprasert, 2010). The Thai pharmaceutical market has a 2013 value of more than 160 billion baht, already the second largest in Southeast Asia (Gross, 2014). While the values of imported drugs accounted for one third of drug expenditure in 1987, it became two thirds in 2010 mostly due to high-priced patented drugs (Kanchanachita, 2013).

In this study, we focus on the antihypertensive therapeutic segment of the Thai pharmaceuticals market. The market for antihypertensive drugs was chosen because hypertension is a major worldwide health problem among older adults with a rising trend. In 2000, hypertension was the cause of 7.1 million deaths or approximately 13% of all deaths worldwide (World Health Organization, 2006). In Thailand, hypertension is one of the three major causes of loss of healthy life years. Its prevalence rose from 5.4% in 1991 to 22% or 10.1 million individuals in 2004 (Department of Disease Control. Bureau of Epidemiology, 2006), resulting in a huge economic burden. Estimates indicate that in 2008, the costs incurred for antihypertensive drug therapy amounted to around 11 billion baht.²

Market demand for the specific sub-segment—which consists of three therapeutic categories of antihypertensive agents, namely 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 and quantities consumed over a 13-year period from 1996 to 2008. These three categories are not only close therapeutic substitutes, but they are also the latest generation molecules available with a 90% share in the Thai antihypertensive market. Hence, they are truly representative of the market for antihypertensive drugs. In all, 422 oral antihypertensive drugs were included in the sample³. The sample comprises all types of drugs including on-patent branded products, off-patent branded products and generic versions. The sample includes only products that were indicated for antihypertensive use according to the 2009 Guidelines for Anatomical Therapeutic Chemical (ATC) classification and Defined Daily Dose (DDD) assignment. Some drugs that were defined as antihypertensive agents but were commonly prescribed for the treatment of indications other than hypertension were excluded from the sample to prevent product heterogeneity problems. The data are yearly aggregates and include only oral dosage forms, which are the major fraction of overall antihypertensive consumption. All data were taken from Bureau of Drug Control, Food and Drug Administration, Thailand.

As data on drug prices were missing, we had to rely on the utilization of unit values 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., differences in therapeutic efficacy among various drug items used to treat the same medical condition). In response to this problem, we adopted the WHO Defined Daily Dose to standardize and transform the unit value of a drug to its daily cost of treatment (expenditure for a particular drug per day). With these virtual prices in hand, market structure parameters can be estimated. Thereby, we decided to rely on the use of daily cost of treatment of a medicine as a proxy for price information 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.

² Market share of and expenditures on various therapeutic categories within the antihypertensive drugs market is available from the author upon request.

³ The list of drugs is available from the author upon request.

Analytical Framework and Estimation Approach

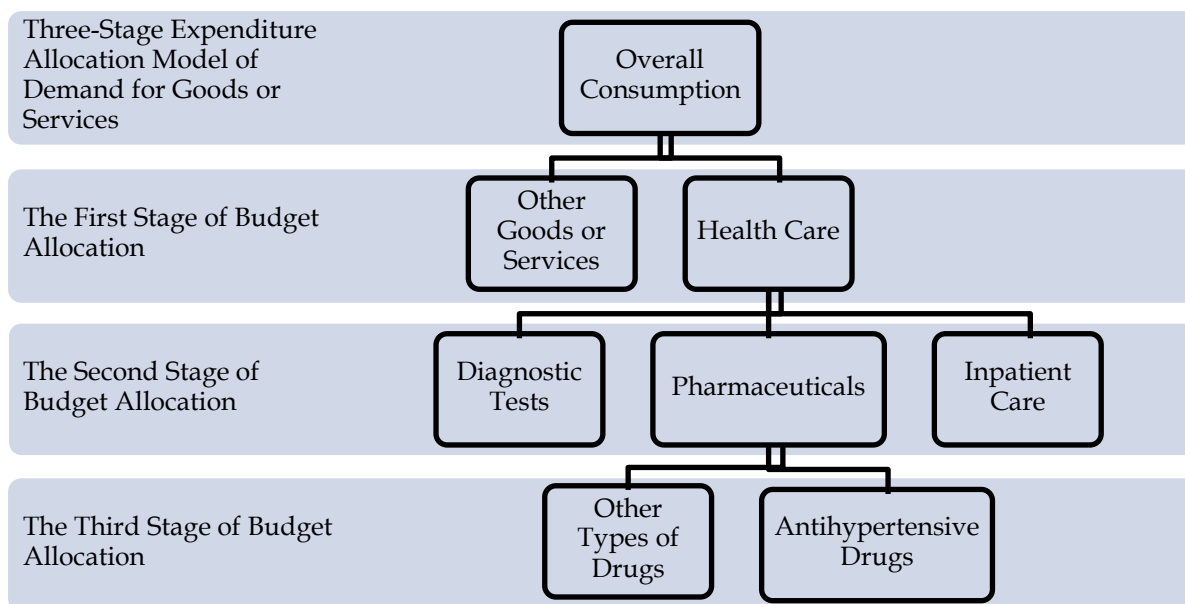
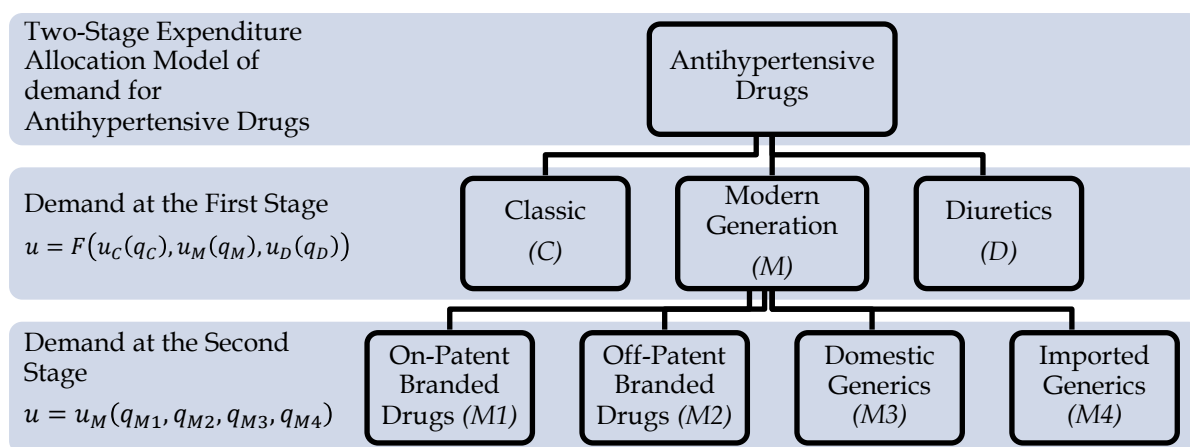
For a technology-importing country like Thailand, while long-run gains from enforcing TRIPS-Plus remain poorly understood and controversial, the shift to stringent IP protection relating to the provisions clearly incurs substantial short-run costs arising in the form of the incremental cost due to higher prices of patented medicines. This study empirically assessed this cost to contribute to the ongoing debate regarding the merits of TRIPS-Plus in developing countries.

TRIPS-Plus contributes to an increase in drug prices by preventing generic competition. A longer period of monopolistic market, endowed by TRIPS-Plus, could delay the introduction of the low-cost, generic equivalent. As a result, only the high-priced, patented version of the original drug would be available. Because savings on drug expenditure by price reduction from generic competition are made both by replacing high-priced original drugs with low-priced generic substitutes and by possible price reduction of the original drugs per se, delaying the introduction of generic drugs to the market unquestionably results in a huge additional financial burden for both households and the countries. The absence of the generic equivalent leads to the patent-holder having free hand to set a price – usually away from affordability in developing countries.

Under the FTA negotiations, Thailand has come under policy scrutiny regarding its pharmaceutical patent regime as drug spending is a major component of the overall national health expenditure. In order to assess the potential welfare effects of TRIPS-Plus, it is crucial to fully understand the structure of demand for pharmaceuticals in Thailand as understanding demand pattern is a prerequisite for designing the optimal patent policy and for predicting and analyzing policy impacts. Of particular interest is the degree of price sensitivity. Because estimation of price elasticities requires estimation of the demand function, we start our analysis by estimating demand using the Almost Ideal Demand System (AIDS) proposed by Deaton and Muellbauer (1980). The AIDS model is commonly used to estimate price elasticities of demand when expenditure share data are available. The demand parameters allow us to estimate the price elasticities and substitution patterns across products in the antihypertensive market, which are needed in the computation of subsequent welfare analysis.

Modeling the Demand for Pharmaceuticals

To deal with the complexity of human consumption, we adopt a separable demand model using the idea of multistage budgeting as the individual decision-making process. We then build on the AIDS specification to sketch the demand for oral antihypertensive drugs that are regularly used in outpatient care. The individual utility derived from the use of antihypertensive drugs is assumed to be weakly separable from quantities of all other types of goods consumed. Consequently, consumers follow a multistage process to allocate their budget to antihypertensive products. Initially, the total spending is allocated to broad categories of goods, 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 hypertension, the budget share for pharmaceuticals is assigned to antihypertensive drugs and other types of drugs (Figure 1). 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 (Figure 2).

Figure 1: Utility tree of individual demand for goods or services**Figure 2:** Utility tree of individual demand for antihypertensive drugs

The demand for pharmaceuticals was investigated in several studies, such as Ellison, Cockburn, Griliches, and Hausman (1997). Demand is modeled in two stages. First, 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 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.

Using Thai annual time-series of pharmaceutical expenditures and prices for the period from 1996 to 2008, we investigate the structure of market demand for antihypertensive drugs by modeling the decision-making process of rational patients. We are aware that a patient makes a decision about the use of an antihypertensive drug under a doctor's advice. However, a doctor's decision is also influenced in some degree by a patient's preference (Cockburn & Pit, 1997). Therefore, we can plausibly assume that the final decision about consumption is made by the patient. We are interested 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. As shown by Figure 1, the individual utility derived from the use of antihypertensive drugs is weakly separable from quantities of all other types of drugs consumed. Consequently, a rational patient follows a two-stage process to allocate their budget to antihypertensive products (Figure 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); and, second, with respect to the four subgroups that are included in the *modern generation* group, that is, the purchase of *on-patent branded drugs* (M1), *off-patent branded drugs* (M2), *domestic generics* (M3) and *imported generics* (M4).

The individual expenditure function derived from the consumer theory is aggregated across individuals to obtain the expenditure on antihypertensive drugs in the local market area. 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:

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

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. Following Deaton and Muellbauer (1980), we assume

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

$$\text{and } \log b(\mathbf{p}) = \log a(\mathbf{p}) + \beta_0 \prod_i p_i^{\beta_i}, \quad (3)$$

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 (1) we can write the cost function as

$$\log c(u, \mathbf{p}) = \alpha_0 + \sum_i \alpha_i \log p_i + \frac{1}{2} \sum_i \sum_j \gamma_{ij}^* \log p_i \log p_j + u \beta_0 \prod_i p_i^{\beta_i}, \quad (4)$$

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

$$\sum_i \alpha_i = 1, \sum_i \gamma_{ij}^* = \sum_j \gamma_{ij}^* = 0, \sum_i \beta_i = 0. \quad (5)$$

By applying Shepard's lemma and substituting afterwards the indirect utility function derived from (2), we then obtain the expenditure share of the i^{th} subgroup within *modern generation* (M) group

$$w_i^M = \alpha_i + \sum_j \gamma_{ij} \log p_j + \beta_i \log \frac{Y_M}{P} \quad (6)$$

where Y_M is the total expenditure for antihypertensive drugs in *modern generation* (M) group, P is a price index defined by

$$\log P = \alpha_0 + \sum_i \alpha_i \log p_i + \frac{1}{2} \sum_i \sum_j \gamma_{ij} \log p_i \log p_j \quad (7)$$

$$\text{and } \gamma_{ij} = \frac{1}{2} (\gamma_{ij}^* + \gamma_{ji}^*). \quad (8)$$

The following restrictions are implied by (5) and (8)

$$\sum_i \gamma_{ij} = \sum_j \gamma_{ij} = 0, \gamma_{ij} = \gamma_{ji} \quad \forall i, j (i \neq j). \quad (9)$$

Provided that (5), (8) and (9) hold, the equation (6) 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 (6) 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 demand share through the term γ_{ij} . These capture the effect on the i^{th} budget share from a 1% 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.

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.

Estimation Procedure

The initial specification of model (6) generates equations that are non-linear in their parameters. Consequently, it is difficult to estimate the model. To solve this problem, many studies follow Deaton and Muellbauer (1980) and use the Stone's index. However, the Stone's index does not satisfy the fundamental property of index numbers. Applying the Stone index causes the units-of-measurement error because it is not invariant to changes in the units of measurement for prices. One solution to correct the units-of-measurement error is that prices are scaled by their sample mean. In this study, to avoid the non-linear estimation and overcome the measurement error, we follow Moschini (1995)'s suggestion and use the Laspeyres price index. With this transformation, and adding an error term, u_i , that captures taste shifts and the effects of omitted variables, the stochastic version of the static linear AIDS is:

$$w_i^M = \alpha_i + \sum_j \gamma_{ij} \log p_j + \beta_i \log \frac{Y_M}{P^*} + u_i, \quad (10)$$

where $\log P^*$ is the Laspeyres price index defined by

$$\log P_t^* = \sum_i w_i^0 \log p_{it}, \quad (11)$$

where the zero superscript denotes base period values, such as mean values.

The linear version of the AIDS model defined by (10) is used 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 (10) is technically a simultaneous equation system; therefore, we estimated the model through the Zellner (1962)'s Iterative Seemingly Unrelated Regression (ISUR) procedure with STATA. During the estimation process, we imposed parameter restrictions of adding-up, homogeneous of degree zero in prices, and symmetry. The adding-up conditions led to a singular residual variance/covariance matrix and, hence, the undefined likelihood function. Consequently, we dropped 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 (5) and (9), we then obtained the parameters for the dropped equation. The variances of the estimated parameters for the dropped equation can be obtained by (12), (13) and (14):

$$\text{var}(\hat{\alpha}_{M4}) = \sum_{i=M1}^{M3} \text{var}(\hat{\alpha}_i) + 2 \sum_{i=M1}^{M3} \sum_{j=M1}^{M3} \text{cov}(\hat{\alpha}_i, \hat{\alpha}_j), i \neq j, \quad (12)$$

$$\text{var}(\hat{\gamma}_{(M4)(j)}) = \sum_{i=M1}^{M3} \text{var}(\hat{\gamma}_{ij}) + 2 \sum_{i=M1}^{M3} \sum_{k=M1}^{M3} \text{cov}(\hat{\gamma}_{ij}, \hat{\gamma}_{kj}), i \neq k, \text{ and } \quad (13)$$

$$\text{var}(\hat{\beta}_{M4}) = \sum_{i=M1}^{M3} \text{var}(\hat{\beta}_i) + 2 \sum_{i=M1}^{M3} \sum_{j=M1}^{M3} \text{cov}(\hat{\beta}_i, \hat{\beta}_j), i \neq j, \quad (14)$$

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

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 Chalfant (1987), Green and Alston (1990) and Alston, Foster, and Green (1994), we derive the conditional uncompensated (Marshallian) own-price elasticity (ε_{ii}) and conditional uncompensated cross-price elasticities (ε_{ij}) as

$$\varepsilon_{ii} = \frac{\gamma_{ii}}{w_i^M} - \beta_i - 1, \quad (15)$$

$$\varepsilon_{ij} = \frac{\gamma_{ij}}{w_i^M} - \beta_i \frac{w_j^M}{w_i^M}, \quad i \neq j. \quad (16)$$

Using the Slutsky equation, we then obtain the conditional expenditure elasticity for the i^{th} subgroup of group M given by

$$\eta_i = 1 + \frac{\beta_i}{w_i^M}. \quad (17)$$

For (17), a positive value suggests that a 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 (17) and using the price index in (11). These can be written as

$$\delta_{ii} = \frac{\gamma_{ii}}{w_i^M} + w_i^M - 1, \quad (18)$$

$$\delta_{ij} = \frac{\gamma_{ij}}{w_i^M} + w_j^M, \quad i \neq j. \quad (19)$$

Consumer theory suggests that own-price elasticities, i.e. (15) and (18), are negative for ordinary goods. Moreover, if (16) and (19) 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: $\varepsilon_{ij} = w_j^M \sigma_{ij} - w_j^M \eta_i$, where σ_{ij} are the partial elasticities of substitution, also known as the Allen elasticities of substitution

$$\sigma_{ij} = 1 + \frac{\gamma_{ij}}{w_i^M w_j^M} \quad i \neq j. \quad (20)$$

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).

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. Specifically, 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, 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 are equal, three possible scenarios of 10%, 30% and 50% increase in price of patented medicines above the current trend are simulated.

Welfare Assessment

By substituting the estimated parameters into (4), 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.

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 $E(u, \mathbf{P})$ the expenditure (cost) function given by equation (4). Then the compensating variation is given by:

$$CV = E(u^0, \mathbf{P}^1) - E(u^0, \mathbf{P}^0) \quad (21)$$

where $E(u^0, \mathbf{P}^1)$ and $E(u^0, \mathbf{P}^0)$ are computed according to (4).

Results and Discussion

The Structure of Demand

Table 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 (i.e., beta blocking agents, calcium channel blockers and agents acting on the renin-angiotensin system). Data were annually available for 13 years from 1996 to 2008; hence, each equation was 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 in the use of antihypertensive, respectively for subgroup *M1* (on-patent branded drugs), subgroup *M2* (off-patent branded drugs) and subgroup *M3* (domestic generics).

As illustrated in Table 1, the price coefficient of $\log P_{M1}$ in the expenditure share equation w_{M1} is equal to 0.206. The interpretation is 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*. The value 0.044 of the expenditure coefficient of $\log Y_M / P^*$ in the

share equation w_{M1} suggests that if the real expenditure for antihypertensive drugs in *modern generation* group (Y_M/P^*) increases by 1%, expenditure share of on-patent branded drugs (w_{M1}) will significantly increase by 0.044%, *ceteris paribus*. Likewise, all other coefficients of explanatory variables $\log p_i$ and $\log Y_M/P^*$ in every share equation can be interpreted in the same way as these two instances. Note that a negative sign indicates an inverse relationship.

Table 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	
Obs.	39		39		39		39	
R^2	0.826		0.587		0.738		N.A. (dropped equation)	
	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
$\log Y_M/P^*$	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. The coefficients of imported generics (M4) were calculated from the adding-up restrictions.

The last line of Table 1 reports the estimated expenditure coefficients, which are, in all but one case, positive and significant. The exception is the domestic generics (M3) for which we estimate a significantly-negative 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. Note, however, that all values are close to zero, implying its low effect on the demand share, or the influence of consumer expenditure on the demand share of all antihypertensive types is negligible. Moreover, for subgroup M3 the negative sign cannot be a proof of inferior type of goods, since the dependent variable is the budget share rather than quantity. As reported in Table 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.

Most price coefficients are highly significant with some exceptions. However, price coefficients are not very informative at this stage. The results cannot be interpreted as a sign of complementarity rather than substitution with other antihypertensive types. For ease of interpretation, the price elasticities, along with complementary and substitution effects, will be analyzed next.

Elasticities

Using the results from Table 1 and applying the definitions, we calculate the conditional own-price, cross-price and expenditure elasticities of the demand for different antihypertensive types. The figures are summarized in Table 2 and 3. Some important implications can be derived.

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 group M. The result may suggest that antihypertensive drugs are normal goods. On-patent branded drugs, off-patent branded drugs and imported generics appear to be “luxuries,” or more formally “superiors,” with expenditure elasticities greater than unity, indicating that these product types capture a disproportionate share of incremental sales when consumers choose to spend more in the modern generation antihypertensive segment. The evidence also indicates that domestic generics 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 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 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 2 reports the uncompensated own-price elasticities we estimate, which are all statistically significant at the 1% level, except for the insignificance of the domestic generics 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 in common with on-patent branded drugs 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. Specifically, off-patent branded drugs together with domestic generics – whose budget share is 77.5% – are 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, which suggests that most of the Thai consumers are likely to be quite price-sensitive. This might be because in Thailand, during our investigation period, health insurance coverage was so rare and almost all household health expenses were fundamentally met out-of-pocket. 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 expensive antihypertensive type, namely off-patent branded drugs, and the low-cost domestic generic medicines. The demand for these two types is very responsive to variations in relative prices due mainly to the presence of many alternative products in the local area. In the absence of patent protection, most antihypertensive drugs have many identical/close therapeutic substitutes so that doctors and patients can switch from expensive products to other, cheaper ones.

On the other hand, doctors and patients are less likely to substitute relatively high-priced, on-patent branded drugs, owing to the absence of identical substitute products. A single source of supply with no short-term alternatives leads to price inelasticity of demand. The nonexistence of a generic equivalent due to patent protection usually allows the patent holder to have a free hand to set the monopolistic price. Similarly, the demand for imported generics—whose market share is, relatively, very small (5.1%)—exhibits the low responsiveness to changes in their own price despite the fact that several identical/close therapeutic substitutes exist. This might be the case of a niche market, which aims to satisfy a small and 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 prices as products within subgroup *M1* and *M2*. Basically, to maximize revenues and obtain a 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 for a period of time. 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. 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 drugs 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 2, suggest that off-patent branded drugs, domestic generics and imported generics 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 drugs exhibits positive and significant value, indicating that they are the distinct group 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. There are three possible rationalizations for this phenomenon. The first is that some patients—particularly high income patients—would love to purchase brand-name drugs which cost more money for the sole belief that they are of higher quality. As a result, they equate price to quantity and the market demand curve for the on-patent branded drugs slopes 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. Patents and product differentiation lead to inelastic high prices.

Another two possible explanations for positive own-price elasticity of demand for drugs type *M1* are physician agency and moral hazard issues. For the first case, the rationale is based on

the framework of “physician-induced demand.” In Thailand, most medicines must be prescribed by physicians, implying that a third party makes the product choice most of the time. As physicians exert a strong influence over the quantity and pattern of pharmaceuticals demanded, drug companies spend their huge advertising and promotion budgets to motivate physicians to prescribe their products. Accordingly, there is an incentive for physicians to (over) prescribe expensive, brand-name products. In this case, physicians may influence a demand for high-priced medicines in their own interests rather than in the best interest of their patients.

As to the latter explanation, the justification for the phenomenon is that some groups of Thai people (e.g., civil servants) have some sort of health insurance (e.g., Civil Servant Medical Benefit Scheme) that may include drug-reimbursement and cover almost all drugs in the choice set. This creates the moral hazard, or an increase in the demand for high-priced branded drugs.

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 drugs. To the extent that insurance gives access to the new drug 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 whose insurance covers prescription drug expenditures are more willing to pay higher prices for new medications than they would be willing to pay when uninsured. Generally, a physician would prescribe a generic name of drug, not a specific brand name. 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 price difference between the two drugs.

To determine whether the three aforesaid explanations are correct, more empirical evidence is needed. Researchers may use these explanations as research questions for future studies.

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 rich or insured patients tend to be less price-sensitive. 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 intensified by higher income and by insurance coverage.

Substitution and complementary relationships among antihypertensive types are captured by the Allen elasticities, summarized in Table 3. Positive value denotes that the two types are cross substitutes. Precisely, positive value with the large magnitude between the two products suggests that such products are close substitutes for 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 drugs are.

Table 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	-	0.848	-5.393***	0.887
Off-patent branded drugs	-	-	3.187***	-0.100***
Domestic generics	-	-	-	-0.160

Source: Calculated from system estimates (reported in Table 1).

Note: 1. Elasticities calculated at average expenditure shares.

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

Among antihypertensive types, the major effect of price is in the choice between off-patent branded drugs (M2) and the generic equivalents (M3 and M4), where the difference in price is more pronounced. Interviews with physicians reveal that in most cases, a physician would prescribe a molecule (generic name), not a specific brand (brand name), especially when the generic is available. 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 name 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, they should ideally be perfect substitutes in demand. Our empirical results shows likewise. According to our results, imported generic product does not appear to be good substitute for off-patent, brand-name product. By contrast, the low-cost domestic generic equivalent looks as if it is almost a perfect substitute for the high-priced off-patent branded product in the eyes of patients and physicians. As the price of off-patent branded drugs increases, the quantity demanded for domestic generic equivalents increases drastically, *ceteris paribus*, indicating that when the price of high-priced off-patent branded products increases, most patients and physicians may prefer to switch to the affordable, domestic generic version rather than 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), and the negative sign plus the small value of the Allen elasticity of substitution between antihypertensive type M2 and M4 (-0.100). The result also demonstrates 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 private health expenses were basically met out-of-pocket.

The large and negative value of the Allen elasticity of substitution between antihypertensive type M1 and M3 (-5.393) suggests that domestic generics type M3 do not appear to be substitutes for innovative products type M1. This may be because low-priced domestic products are not perceived to be effective against severe hypertension. By contrast, innovative products type M1 are usually used to overcome specific problems in the treatment of complicated hypertension. Instead of substitute products, they are actually good therapeutic complements. In the case of a severe hypertension in which only one drug cannot control blood pressure well, doctors may prefer to prescribe a more effective antihypertensive type M1 in combination with a low-cost, traditional generic type M3 to be able to bring high blood pressure down and optimize the cost of treatment.

The basic claim made by TRIPS-Plus proponents is that the adverse impact from stringent IPRs protection for pharmaceuticals will be mitigated by the availability of close therapeutic

substitutes. The cross-subgroup expenditure switching effects—implied by the Allen elasticities of substitution between subgroup *M1* and *M3* (i.e., the very low degree of substitutability), and subgroup *M2* and *M3* (i.e., the high degree of substitutability)—suggest that for this claim to be valid, there need to be unpatented substitutes available within fairly narrowly defined therapeutic categories.

Counterfactual Estimates of the Impact on Consumer Welfare

Table 4 and 5 display our estimates of the rates of change in consumer welfare and the magnitudes of the loss to the whole society resulting under the different scenarios, respectively. 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 (*M1*) in the original patentable market above the current trend was simulated, given that all other things are equal to the without-TRIPS-plus situation. 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 extension due to the absence of close substitutes, assuming that all else is equal, we simulated the worst-case scenario of 50% increase in price of patented medicines above the current trend.

Table 4 presents our estimates of the rate of change in consumer welfare after upward price adjustments of patented medicines allied with TRIPS-Plus under the simulated situations. The estimates of percentage change in consumer welfare are then turned into the sizes of potential loss that Thai society may incur. All the estimates of magnitude of loss to Thai people are reported in Table 5 in terms of monetary value (Thai baht). As illustrated in Table 5, in the presence of TRIPS-plus, the 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—is estimated to be worth in the range of around 30 to 136 billion baht within 10 years from 2012 to 2021. 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.

Table 4: Counterfactual estimates of consumer welfare changes from market exclusivity extension and static upward price adjustments due to the introduction of TRIPS Plus provisions

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 from current 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 from current 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 from Current 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 (4) with the use of the estimated parameters reported in Table 1.

Note: 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.

A more comprehensive interpretation of our estimated results can be illustrated through the following instance. 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 spending on antihypertensive type *M* for Thai citizens equal to 1,032 million baht (i.e., 5.82 % of the estimate of the annual expenditure on antihypertensive type *M* in the absence of TRIPS-Plus) 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 type *M* that Thai people would need to incur to maintain their pre-TRIPS-Plus utility level in the face of the market exclusivity extension for brand-name drugs and the accompanying price increases is said to amount to 1,255 million baht (i.e., 5.92% of the annual spending on antihypertensive type *M*) in 2013, 1,531 million baht (i.e., 6.03% of the annual spending on antihypertensive type *M*) in 2014, 1,872 million baht (i.e., 6.13% of the annual spending on antihypertensive type *M*) in 2015, and so on. Put differently, we estimate that in the modern generation sub-segment of the antihypertensive drugs segment alone, 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 million baht in 2012, 1,255 million baht in 2013, 1,531 million baht in 2014 and 1,872 million baht in 2015. Likewise, all other results in another two scenarios can be interpreted in the same way as scenario 1.

Table 5: Counterfactual estimates of consumer welfare losses from market exclusivity extension and immediate upward price adjustments due to the introduction of TRIPS-Plus provisions

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)										Accumulated losses (2012-2021)
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	
Scenario 1: 10% increase in price from current trend	1.032	1.255	1.531	1.872	2.290	2.809	3.455	4.257	5.263	6.527	30.297
Scenario 2: 30% increase in price from current trend	2.937	3.572	4.354	5.321	6.506	7.978	9.809	12.084	14.934	18.519	86.019
Scenario 3: 50% increase in price from current trend	4.666	5.672	6.912	8.443	10.322	12.653	15.553	19.157	23.672	29.348	136.403

Source: Calculated from counterfactual estimates of the rates of change in consumer welfare demonstrated in Table 4 together with the use of overall antihypertensive expenditure from the base case (i.e., without the enforcement of TRIPS-Plus scenario).

Note: The values of the welfare loss were evaluated at consumer prices.

Of particular interest from a policy perspective are the magnitudes of the welfare loss attributable to the prolongation of the monopoly market. As shown in Table 5, within a time period of 10 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 and 136 billion baht in the last. Additionally, if we compare the results across the first, second and third scenarios, despite the fact that the absolute levels of the welfare loss vary considerably, all the counterfactual scenarios produce qualitatively 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. We should note further that the magnitude of the consumer welfare loss under a certain therapeutic segment varies 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.

Conclusion and Policy Recommendations

The results of our analysis suggest that concerns about the potentially negative welfare effects of TRIPS-Plus in developing countries may have some basis. We estimate that in the modern generation sub-segment of the oral antihypertensive segment alone, the enforcement of TRIPS-Plus would result in a substantial accumulated consumer welfare loss for the Thai economy, ranging between 30 billion baht and 136 billion baht, within a 10-year period (2012-2021). Put another way, for a 10-year period from 2012 to 2021, Thai citizens would carry the strain of lack of access to medicines in terms of physical and mental suffering from unhealthiness, said to amount to 30-136 billion baht as a result of TRIPS-Plus enforcement. Within the whole pharmaceutical market, the losses increase in the number of patented products that are affected by TRIPS-Plus. This pattern is driven by our finding that domestic generic products are viewed 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 magnitude of the estimated consumer welfare loss has interesting policy implications. It suggests a potentially independent role of compulsory licensing in addition to 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 essential medicines more accessible to poor and vulnerable groups. 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 drugs to fight diseases), the welfare loss due to upward price adjustment remains substantial. This welfare loss could potentially be mitigated through appropriate price controls or price regulations together with an optimal set of cost containment policies.

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 stringent IPRs protection for pharmaceuticals 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 significant magnitudes of consumer welfare loss suggest that without clear and inclusive evidence as to the merits of TRIPS-Plus, Thailand, along with other technology-importing developing countries, should not accept any further IPRs protection beyond the WTO TRIPS Agreement.

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