PARALLEL IMPORTATION IN THE PHARMACEUTICAL SECTOR: A KEY STRATEGY IN ATTAINING DRUG AFFORDABILITY*

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I. INTRODUCTION

Parallel imports (PI) are goods produced genuinely under intellectual property right (IPR) protection, placed into circulation in one market, and then imported into a second market without the authorization of the local IPR owner. The underlying principle that drives parallel importation is that prices of goods vary across markets. Several factors cause this phenomenon, such as the differences in costs of raw materials and labor, tax rates, and even government subsidies. Yet what is important is the effect of this price differential when the cheaper products find their way into the markets wherein the same products are priced higher but covered by IPR. Obviously, consumers would rather purchase the more affordable of the identical goods, to the detriment of the local manufacturer. Parallel importation can be described as an arbitrage business, that is, the practice of taking advantage of a state of price imbalance between two or more national market, regardless of the source of the price imbalance. Aside from being beneficial to consumers in the domestic level, a crucial consequence in the international scale is that it arbitrages away price discrimination widely observed for certain products, thus leading to price convergence.

In no other industry has the impact of parallel trade been greater than in the pharmaceutical industry. For one, there are widely documented price differentials of pharmaceutical products across national markets. For another, these products are inelastic given their nature as indispensable to health care. Accordingly, prices are largely dictated by licensed drug

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manufacturers within a market. Parallel importation thus offers another option to consumers. Countries with high drug prices import the same drugs from countries with relative prices low enough to sufficiently cover costs of transportation, registration, repackaging, compliance with national requirements, and other incidental costs. The parallel imports then provide a more reasonable alternative to institutional buyers and end-users within the importing market.

> The controversy surrounding parallel importation concerns the polarized interests of pharmaceutical companies that own product patents and the end users or drug consumers that are inherent given the nature of the pharmaceutical industry. On one hand, the manufacture of drugs is research-intensive, involving huge sums of money to discover, synthesize, test, develop and market new drugs. Drug manufacturers therefore protect their investments by means of IPR, particularly patents. They are vehemently against parallel importation, since this significantly reduces their profits and makes it more difficult for them to recoup their investment. In the long run, this faction argues that parallel importation would result in the curtailment of innovation in the industry. On the other hand, consumers and public health authorities, especially in developing countries, are mainly concerned about the affordability of drugs, in order to be accessible to a larger market base. Price controls of local manufacturers can be achieved not only by actual parallel imports but also by the mere threat of it in a more liberal market.
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> This conflict persists not only because of the natural tendencies of the key actors involved to advance their personal interests, but because despite studies having been conducted on the actual impacts of PI, there seems to be no conclusive empirical data as to its exact effect on research and development. The trade-off has never been clearly proven. What has happened instead is that this conflict has been adopted by developed and developing nations, who have taken sides that are at par with their own welfare. The Philippines is a developing nation that is most vulnerable to the phenomenon of parallel trade because of the extremely high prices of patented drugs in the country, reportedly the second highest in Asia. At present, it has not yet availed of any of the flexibilities the international agreements on IPR it is party to have granted. Consequently, a substantial percentage of its almost 90 million population is deprived of adequate health care and medication. As if to highlight the problem within the Philippine setting, Pfizer, the largest drug manufacturer in the market has filed a case of patent infringement against the government for importing

and using 80 tablets of its patented drug, Norvasc, for the purpose of early registration, in preparation of the expiry of the patent in 2007. This case coincides with a resurgence of interest in improving government policy and legislation on PI in pharmaceuticals. For instance, there are two pending bills in Congress that have passed the third readings in the respective houses they have been filed and are now awaiting consolidation in a bicameral level.

With all these developments, I find it an opportune time to put together and review available materials and existing studies on PI in pharmaceuticals to gain a deeper understanding of the concept. This enlightened comprehension can then be used to formulate a workable and practical solution for the Philippine situation. This legal research paper aims to achieve just that. It seeks to be not only an academic exercise, but more so a relevant and useful reference given the present state of affairs.

In this paper, I explore the concept of parallel importation – its theoretical and empirical underpinnings. In the next section, I present the economic angle of the phenomenon, by discussing the findings of three major studies on the impact of PI of pharmaceuticals on direct and indirect savings, and the net welfare on a per country basis. These studies also try to identify who are the winners and losers in parallel trade. I then proceed to the perceived and actual conflicts brought about by PI. It is at this point I introduce the international legal framework regulating IPR and PI. The conclusions from both the economic and the legal angles were then used to come up with general recommendations on policies to follow with respect to parallel trade in pharmaceuticals.

I next delve into the specific Philippine situation: the local market for pharmaceuticals, the importunate problem regarding unaffordable drugs, the relevant government policies, and the state of domestic legislation on the matter. Thereafter, I thresh out the pending Pfizer case, even setting forth portions of the actual pleadings of the parties, and summarizing the primary legal issues involved. Based on these, I come up with a personal analysis and a recommendation as to how the case should be resolved. Finally, I provide the current developments in terms of better legislation on IPR and PI in the Philippines that may serve as the solution to the persistent problem of lack of access to health care. I end with courses of action the Philippines should definitely take, considering all the research and discussion on the subject matter that have been presented throughout the paper.

II. PARALLEL IMPORTATION – A WORLD VIEW

A. GENERAL BACKGROUND ON THE CONCEPT

1. Parallel Imports and the Underlying Principle/ Controversy

Parallel imports (PI) are goods produced genuinely under intellectual property right (IPR) protection, placed into circulation in one market, and then imported into a second market without the authorization of the local IPR owner.[1] They are also known as gray-market imports. In practice, this means a situation, where a wholesaler in one country makes available to a purchaser in a second country a product patented in both countries, at a lower price than it is available in the second country. If the latter allows parallel imports, then the purchaser could import the product at a lower price than the product is available locally.[2] For example, the European Union allows parallel trade among member countries in virtually all goods. Thus, it is permissible for a trading firm to purchase quantities of prescription drugs in Spain and import them into Sweden or Germany without the local distributor owning licensed patent rights.[3] It must be emphasized at this juncture that parallel imports are therefore goods authorized for original sale, albeit in a different market. They are not counterfeited or pirated merchandise. Hence, they are identical to legitimate or authorized products, except that they may be differently packaged and may not carry the original manufacturer's warranty.

Parallel trade arises because of profitable opportunities for arbitrage between national markets with different prices for identical goods. Specifically, parallel imports emerge where international price differences, if expressed in a common currency, exceed the costs of transporting and selling goods across borders.[4] Hence, if permitted, PI may be expected to equalize customer prices of identical goods in various markets, though differences would persist because of transport charges, tariffs, the costs of meeting distribution regulations and taxes. What really drives parallel importation is that prices of goods vary across markets. Several factors

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[1] Ulrika Enemark et al, The Economic Impact of Parallel Imports, at 10 (2006, Center for Applied Health Services Research and Technology Assessment, University of Southern Denmark).

[2] World Health Organization CIPIH Report, *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[3] Keith Maskus, Parallel Importation in Pharmaceuticals: Implications for Competition and Prices in Developing Countries, at 2 (2001, University of Colorado).

[4] *Id.* at 11.

cause this phenomenon, such as the differences in costs of raw materials and labor, tax rates, and even government subsidies. Economic theory identifies four reasons that such price differences exist: retail price discrimination, vertical pricing inefficiencies, free riding on fixed distribution costs, and differential price controls.[5]

• Retail Price Discrimination

The most obvious determinant of PI is retail price discrimination by manufacturers in different markets. In the textbook model of price discrimination, a manufacturer maximizes profit by setting price in segmented markets according to local demand elasticity.[6] Other things equal, the larger the market and the more inelastic is demand, the higher the price. Small markets with elastic demand curves receive the product at a lower price. The basic notion that manufacturers exercise price discrimination at the retail level is somewhat misleading, however. Firms typically sell to local wholesale distributors, which then deal with retailers.

• Vertical Pricing Inefficiencies

A second explanation for PI is that such trade may flow between international distributors or between distributors and retailers. In many circumstances efficient distribution would require permitting the right-holder a significant degree of vertical control over the operations of its licensees. For instance, multinational enterprises build markets through establishing exclusive dealership rights in various territories.[7] Exclusive rights make it easier to monitor marketing efforts and enforce product quality. However, it may be difficult or legally impossible in foreign markets to implement private contractual provisions prohibiting sales outside the authorized distribution chain. Seen this way, restrictions against PI are a necessary complement to exclusive territorial rights.[8] The primary difficulty with this argument is that a combination of exclusive territories and barriers to parallel trade could invite collusive behavior among exclusive dealers in products bearing IPR. This problem seems particularly prevalent in developing countries, where distribution systems are poorly developed and

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[5] *Id.* at 12.

[6] *Id.*

[7] *Id.* at 20.

[8] J. S. Chard & C. J. Mellor, *Intellectual Property Rights and Parallel Imports*, THE WORLD ECONOMY 12: 69-83 (1989).

concentrated among a few firms and consequently, certain local prices tend to be higher.

- **Free Riding on Distribution Costs**

Still, a third explanation for parallel trade related to price discrimination, is that it is possible to free ride on the investment, marketing and service costs of authorized distributors. These distributors incur costs of building their territorial markets through advertising, discounting, and post- sale service maintenance. In the area of prescription pharmaceuticals, these costs are likely to be quite significant. For example, distributors must maintain detailed records about the production and disposition of particular batches of their products and accept returns of products with expired shelf lives.[9] In order to earn a return on those investments, they must charge a markup over these costs. Naturally, such enterprises would prefer protection from competition by parallel importers who can simply buy the goods abroad without incurring similar costs.[10] Indeed, this is the primary motivation for permitting privately contracted exclusive territories in the first place. In line with this, the World Intellectual Property Organization (WIPO) advocates the principle that restrictions against PI are a natural extension of the right of IPR holders to control vertical markets. These restrictions may stimulate competition by encouraging investment in inter-brand competition and also by providing incentives to build markets and provide services. A failure to provide adequate protection for these investments by allowing PI freely might result in slower rates of introduction of new drugs. Another potential problem is the greater propensity toward resource waste, when authorized dealers, in an attempt to differentiate their versions of the otherwise identical drugs in competition from PI, engage in excessive packaging, advertising, and promotional efforts, leading to resource waste relative to the true costs of informing consumers and medical providers.

- **Differential Price Controls**

A fourth source of PI is that international price differences may stem from national price regulations established to achieve particular social

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[9] Richard Rozek & Richard Rapp, *Parallel Trade in Pharmaceuticals: The Impact on Welfare and Innovation*, JOURNAL OF ECONOMIC INTEGRATION 7, 181-203 (1992).

[10] Claude Barfield & Mark A. Groombridge, *The Economic Case for Copyright Owner Control over Parallel Imports*, THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 1: 903-939 (1998).

objectives. This is very common in the pharmaceutical sector, in which virtually all nations regulate prices in order to limit consumer costs or public health budgets. Evidence shows that such regulations vary considerably across countries and account for significant price variability.[11] Allowing parallel trade could defeat the purposes of regulation as distributors in more regulated (lower-price) markets ship medicines to less regulated (higher-price) markets. These exports could exacerbate any shortages in the export market of medicines arising from the regulatory standards, as distributors in the more regulated markets would rather choose to supply to the less regulated ones, than within their own countries. In this context, one argument for banning or controlling parallel exports is the need to defend regulations. A second argument is that parallel imports coming from regulated markets could be restricted on the theory that such regulations amount to a sector-specific export subsidy.[12] This interpretation however has not been tested at the World Trade Organization.

Whether or not the variances in price result from one or a combination of these reasons, what is important is the effect of this price differential when the cheaper products find their way into the markets wherein the same products are priced higher but covered by IPR. Obviously, consumers would rather purchase the more affordable of the identical goods, to the detriment of the local manufacturer. As put by Professor Keith E. Maskus of the University of Colorado in his Final Report to the World Intellectual Property Organization, PI is essentially an arbitrage business, that is, the practice of taking advantage of a state of price imbalance between two or more national market, regardless of the source of the price imbalance. Aside from being beneficial to consumers in the domestic level, a crucial consequence in the international scale is that it arbitrages away price discrimination widely observed for certain products, thus leading to price convergence.

In no other industry has the impact of PI been greater than the pharmaceutical industry. For one, there are widely documented price differentials of pharmaceutical products across national markets. For another, these products are inelastic given their nature as indispensable to

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[11] PATRICIA DANZON, PHARMACEUTICAL PRICE REGULATION: NATIONAL POLICIES VERSUS GLOBAL INTERESTS (1997).

[12] Frederick Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, JOURNAL OF INTERNATIONAL ECONOMIC LAW 1: 607-636 (1998).

health care. Accordingly, prices are largely dictated by licensed drug manufacturers within a market. Parallel importation thus offers another option to consumers. Countries with high drug prices import the same drugs from countries with relative prices low enough to sufficiently cover costs of transportation, registration, repackaging, compliance with national requirements, and other incidental costs. The parallel imports then provide a more reasonable alternative to institutional buyers (e.g. hospitals) and end-users within the importing market.

However, the nature of the pharmaceutical industry has increased the controversy shrouding PI. On one hand, the manufacture of drugs is research-intensive, involving huge sums of money to discover, synthesize, test, develop and market new drugs. Drug manufacturers therefore protect their investments by means of IPR, particularly patents. They are vehemently against PI, since this significantly reduces their profits and makes it more difficult for them to recoup their investment. In the long run, this faction argues that PI would result in the curtailment of innovation in the industry. On the other hand, consumers and public health authorities, especially in developing countries, are mainly concerned about the affordability of drugs, to be accessible to a larger market base. Price controls of local manufacturers can be achieved not only by actual PI, but also by the mere threat of it in a more liberal market. These polarized interests have caused the regulation of PI in the pharmaceutical sector to be a critical issue in the global trading system.[13]

2. Development of Parallel Importation

PI in pharmaceuticals has existed in Europe since the beginning of the 1970's, particularly in Germany, Netherlands, and the United Kingdom. Later, it was introduced in the Scandinavian countries.[14] The establishment of a single European market provided a breakthrough in parallel trade since the European Union followed the regional exhaustion principle, meaning goods once purchased may be freely resold within the union. Furthermore, the European Court of Justice has declared that the free circulation of goods takes precedence over IPR. Parallel trade in Europe is also recognized under Articles 30 and 36 of the Treaty of Rome. These

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[13] Maskus, *supra* note 3, at 23.
[14] Encmark, *supra* note 1, at 7.

provisions allow the free movement of goods and bestow the right to control the import of goods by national governments.[15]

Although the European legal framework supports parallel trade, the main impetus is still economic viability. The wider the price differential for the same product between two countries, the more attractive parallel trade is, as this results in higher profit margins. In this manner, despite the policy of regional exhaustion, the regulation or deregulation of pricing, which is controlled by governments or manufacturers or both, permits these sectors to maintain an influential role in PI. For instance, Spain, Portugal and France, recognized as low-priced countries, are prime targets for parallel export, while Denmark, the Netherlands, and the UK, with their relatively high prices, are seen as parallel import destinations.[16]

Growth of parallel trade in Europe is driven by increasing trends towards cost-containment, as shown by Germany's stance on parallel trade in 2000 when it introduced parallel import substitution to curb escalating drug spending - this marked a political U-turn on the issue. Moreover, other factors such as the increased number of parallel import licenses granted, EU enlargement, and litigation victories for parallel traders have contributed and continue to contribute to the expansion of PI. It has been entirely beneficial to proponents of parallel trade that no evidence could be found that parallel imports caused patients to suffer from ingesting sub-standard or wrongly used medicines. Thus, the regulatory system for PI was completely safe. Also beneficial for consumers was the fact that the threat of making PI purchases seemed to raise the bargaining power of public- health services and insurance firms in negotiating price concessions from manufacturers. Indeed, this seemed to be the more important source of profit transfers from manufacturers to purchasers. This observation is also significant for health authorities in developing nations.

Today, parallel trade has also expanded globally. It has taken a foothold in non-EU countries such as Russia, South Africa, India, Israel, and the Philippines, according to a new report published by Reuters Business Insight. Specifically in India, parallel export trade continues to grow based on the low price of raw materials and low manufacturing costs. This is further bolstered by the demand for cheaper drugs from developing

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[15] Tim Atkinson, *Global Parallel Trade – A Growing Concern*, *available at* http://www.samedanltd.com/members/archives/EPC/Spring2002/TimAtkinson.htm

[16] *Id.*

countries within Asia and Africa, since savings of up to 70 percent can be achieved compared with prices in the importing countries.

The development of PI in these regions was reinforced by the landmark victory in April 2001 of South Africa against 40 pharmaceutical manufacturers over Section 15C of the Medicines and Related Substances Control Amendment Act, which enabled the country to parallel import HIV/AIDS drugs from India and Brazil. This victory recognized the utility of parallel trade for humanitarian reasons.[17]

Even the United States has provided another frontier for parallel traders in the pharmaceutical sector. This is mostly brought about by the very large market and high drug prices present in this economic power. However, since the US has a more conservative policy on parallel trade, given that most of the major drug companies in the world are American corporations, the developing countries of Asia and South Africa combined still provide potentially the most lucrative markets for PI.

Still, the growth of PI has been stunted by certain impediments to which primarily come from four sources.[18] First, manufacturers and some hospitals, and pharmacists resented PI, believing it to be solely entrepreneurial and not to add any value or technology to the drugs market. Second, manufacturers engaged in considerable differentiation of products across countries through differences in packaging, labeling, information inserts, and so on. These practices considerably raised the cost of PI and seemed to limit its growth. Third, in those countries with concentrated wholesale distribution systems, distributors often implicitly colluded in refusing to supply parallel traders. These two factors are of particular relevance for developing nations considering relaxing restraints on parallel imports. Fourth, government regulations at times were aimed at reducing PI. Such regulations included licensing and approval delays and price "claw-backs" from pharmacists that discouraged the use of PI. At the same time, some countries provided financial incentives to encourage substitution of PI for purchases from original manufacturers. Though they had no substantive data to support these claims, survey results pointed to the following difficulties with PI from the standpoint of economic welfare. First, PI firms perform no R&D and undertake little capital investment.

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[17] *Id.*

[18] Maskus, *supra* note 3, at 35.

Thus, they engage in free riding on original R&D without taking a long-term view of the future of the pharmaceutical sector. Second, to the extent that PI is undertaken the activity incurs wasteful transportation costs and re-packaging costs. Third, parallel imports reduce profit margins for original manufacturers, perhaps significantly in drugs with large markets. These reduced margins are transferred to PI firms, distributors, and pharmacists and hospitals. The extent to which ultimate patients, insurance firms, or public health services benefit from lower prices was unclear in their study, though they found little evidence of significant savings.

For obvious reasons, the EU is the natural location in which to study the potential for PI in pharmaceuticals because of the essentially free movement of such goods, subject to any informal impediments and trade costs. What is even more useful for purposes of study is that despite this free movement, there remains considerable variability in identical, branded drug products across the European Union.

B. THE ECONOMICS OF PARALLEL IMPORTATION

Since parallel importation is largely price driven, it is important in the study of this phenomenon to understand its true economic repercussions. As mentioned earlier, the controversy surrounding it revolves around the conflicting interests of drug manufacturers and the consumers. While this debate may be presented as a humanitarian struggle, the basic issue is really economic in nature. The question of whether the savings and welfare benefits to consumers can compensate for the loss of profits must first be resolved in an empirical level, even before other considerations such as long-term implications on research and development vis-à-vis greater access to healthcare may be delved into.

To facilitate the analysis of the economic aspect of parallel trade in pharmaceuticals, three recent studies on the net benefits of PI conducted by independent research organizations will be looked into in this section of this legal research paper. The first study was conducted in 2003 by the York Health Consortium at the University of York. This was sponsored by the European Association of Euro-Pharmaceutical Companies. The second study, sponsored by Johnson & Johnson was conducted in 2004 by LSE Health and Social Care at the London School of Economics. These two studies produced contradictory results. The York study concluded that parallel trading gives significant direct savings with signs of indirect competitive effects, while the LSE study found only very modest savings

and no signs of competitive effects. Broadly, the York study found in favor of the consumers of drugs, pointing to benefits to patients directly as well as indirectly through savings to the national health system. It reached the conclusion that direct and indirect savings from the parallel trade of pharmaceuticals have helped contain the mounting public health care expenditure in many European countries, and that users of health services would benefit from such savings. In contrast, the LSE study found that direct benefits to patients and health care systems are negligible and that the main beneficiaries are the parallel traders.

This disparity in findings between the two studies prompted a third study to undertake a critical review of the theoretical arguments and empirical evidence concerning parallel imports. This was also commissioned by the European Association of Euro-Pharmaceutical Companies in 2005, and conducted by the Centre for Applied Health Services Research and Technology Assessment at the University of Southern Denmark. The study first assessed the methodologies applied by the two and determined that the methodology applied for estimating direct savings on drug expenditures by the York study is the most appropriate. Using a similar methodology, it concluded that parallel trade generates considerable savings.[19]

The findings culled from these three significant reports are utilized in this present section on the economics of parallel imports.

1. Impact on Savings

Analysis of the LSE vs. the York Studies on PI and Direct Savings

Direct savings provide the quantitative measure of the benefits of the importing country in parallel trade. As previously stated, the main proponents of PI are the consumers who benefit from lower drug prices. The query however is how much of this perceived benefit is based on empirical evidence and how much is merely theoretical. The studies conducted attempt to answer this.

At the onset though, it must be emphasized that the intent and methodology of the York and the LSE studies differ. The York study was

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[19] Enemark, *supra* note 1, at 7.

aimed at estimating the financial benefits related to parallel trade of medicine in terms of savings to national health insurance systems. It focused on the financial benefits available through savings from products included under some form of public health insurance. On the other hand, the LSE study had a wider scope, intending as well to compare prices across countries with a view to analyzing price convergence and assessing possible profits to parallel traders.

As to methodology, the York study covered the year 2002, and attempted to measure the direct savings in five countries, namely UK, Germany, Sweden, Netherlands, and Denmark. It focused on the top-selling products for each country, plus a random sample of 150 products to arrive at the price effect estimation. For Denmark, Germany, and Sweden, savings estimates were based on detailed calculations for all parallel-imported products. Savings were estimated by multiplication at individual product level of the quantity sold and the price differential between the selected parallel import price and the originator price using the actual fortnightly price differential and quantity sold. For the UK and the Netherlands, the estimates were based on average price differences between parallel and originator products and total pharmaceutical data. The LSE study meanwhile covered the period 1997-2002, and involved the same five countries, plus Norway. A selection of six product categories, covering 21% of the brand market provided the basis for the study. Since one of the objectives was studying price convergence between countries, the between-country comparison of prices required that information for the same products were collected in all countries. The problem however, is that some of these products were not subject to parallel import in all countries and not during the entire period. For instance, for 2002, savings were estimated for the same 19 products in each of the countries. In Denmark however, estimated savings were based on 14 products only, as there were no parallel imports in the Danish market in 2002 for 5 of the 19 products. Moreover, unlike the York study that utilized actual values, direct savings under the LSE study were estimated using the intra-country price spread in pharmacy purchase price (originator price – parallel import price) and the quantity sold, assuming inelastic demand and using a hypothetical average price for parallel imports, which does not really give an accurate picture of the savings to the end-users.

Given these differences in methodology, the results turned out to be conflicting. The York study reported total direct savings from the parallel trade of pharmaceutical products in 2002 to be 635 million euros.

The LSE results showed comparatively modest direct savings of only 45 million euros. It must be taken to mind though that this figure is only based on 21% of the market. Extrapolating from this figure covering 21%, then the direct savings can be estimated at around 225 million, substantially higher than the published 45 million in savings, but still significantly lower than the amount determined by the York study. A breakdown of the results of both studies is presented in the following table:[20]

STUDY	YEAR (data)	COUNTRY	DIRECT SAVINGS	INDIRECT SAVINGS/ PRICE EFFECTS	COMMENT
York Study	2002	UK	342	Limited price effect. Decreasing price for on-patent drugs with competition. Increasing price for on-patent drugs without competition.	Top-selling products + random sample of 150 products.
		Germany	194		
		Sweden	47		
		Netherlands	32		
		Denmark	16		
		Total	635 million euros		
LSE Study	2002	UK	6.9	No price effects	6 product categories, 19 products covering 21% of brand market
	(1997-2002)	Germany	17.7		
		Sweden	3.8		
		Netherlands	12.8		
		Denmark	3		
		Norway	0.6		
		Total	44.8 million euros		

The remaining difference in the absolute figures of direct savings, after extrapolating from the sample utilized by the LSE study can be mostly attributed to the selection of products for analysis. Hence, noting these differences in methodologies, and adjusting for the fact that the LSE study due to its other objectives was based on a sample of varying

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[20] *Id.* at 20.

representativeness in the countries studied, the savings estimates would be much less different than may seem at first glance.[21]

Beyond arriving at absolute figures for direct savings, both the LSE study and the York study analyzed the distribution of the savings and the competitive effects of parallel trade. The two studies differed in that the York study reported a 60/40 government to patient split of savings, while the LSE study reported that all savings fell on the government side.[22] This finding must be understood though in the context of the pharmaceutical industry, in which even if savings primarily accrued to the government, the benefit would ultimately redound to the patient or consumer, if greater value for money can be achieved.

Finally, the two studies also tried to analyze the competitive effects of parallel trade in the market. This would reveal the effect of parallel imports on the movement of prices of pharmaceutical products. The York study used time series data where it was available, particularly for Denmark, Germany, and Sweden. The method used was visual inspection as well as statistical analysis to isolate competition effects by studying average price changes and price variance over time with and without parallel importing. The inspection of the time plot suggests limited price competition. For on-patent drugs without competition prices have increased over the period 1997-2002, while for on-patent drugs with parallel imports in the market prices have decreased. In this area, the LSE study used a methodology similar to the York study, with a time series for a five-year period. The method also included graphic inspection, and in addition tested the null hypothesis of co-movement of prices (equal price changes over time), against a hypothesis of no co-movement. The hypothesis that the mean change in price is the same was tested for each of the 19 products using a t-test with unequal variance. Based on this, it was concluded that there are very limited competitive effects. The caveat though is that only a very small sample of products was utilized in the test from which to generalize.[23]

It must be noted however that acceptance that there is co-movement of prices of originator and parallel-imported products does not necessarily imply that there is no price effect. Co-movement of prices may be reflective of either competition or the lack of it. It is indicative of

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[21] *Id.* at 19.
[22] *Id.* at 21.
[23] *Id.* at 23.

competition when either the originator price or the PI price is reduced in order to increase the market share and other manufacturers follow immediately to preserve their market share. Of course, in the case in which one stakeholder with monopoly power can dominate the market and constrain market supply, co-movement shows a lack of competition. The LSE study concluded that the small average price spread was a problem. If the PI share however is low because the supply of parallel imports is low, then the parallel importer would have an incentive to set prices higher as increased demand could not be translated anyway into sales. On the other hand, a small price spread could also reflect that competition is working.

From the results of these two major studies, it can be deduced that the empirical literature is still insufficient to provide convincing basis for the economic theory behind parallel importation. It is even characterized by some disagreement about the magnitude of the savings as well as about the existence of price competition. The theory suggests that the short-term effects of allowing parallel trade of drugs would stimulate direct savings to purchasers of pharmaceuticals in importing countries, as parallel imports would be sold at a lower price than the originator price. Yet the theory is unclear as to what extent any competitive pressure will be sufficient to result in lower originator prices, especially in the face of supply restrictions and monopolies within the local market, that parallel traders invariably experience. With all the surrounding ambiguity in both theory and evidence and the disparity in findings, more empirical analysis was needed. Thus, a third major study was conducted: the CAST study.

The CAST Study

The CAST study followed the York study in terms of methodology, considering the shortcomings of that LSE applied. This study went beyond the scope of the first two by undertaking to provide an estimate for the direct savings and to analyze the likely contribution to savings from competitive effects, the so-called indirect savings. Indirect savings may arise either because competition results in price decreases or reduces the price increases below the level expected without competition on one hand, or because the potential competition leads to limited pricing on the other. In the latter reason, the manufacturer chooses to reduce the domestic price to a level at which it is less profitable for parallel importers to enter the market. In theory, indirect savings are calculated from the quantity sold of the original product multiplied by the price differential between the original manufacturers' product as it would have developed in

the absence of competition from parallel imports and the actual development after introduction of parallel imports in the market.

The research was conducted over Denmark, Germany, Sweden, and the United Kingdom, all with large and mature markets for parallel importing of drugs. The time frame for the estimation of direct savings was 2004. For indirect savings, a five-year time frame from 2000 to 2004 was used for the time series analysis of prices and competitive parameters.[24]

Variables included for each specific product, which was part of the dataset of the 50 products that were the highest selling in 2004, were quarterly prices of domestically produced or directly imported drugs and prices of parallel imports for the same products. Pharmaceutical retail prices were used, since it represents all the price elements included at the point of consumption by the end-user, including distribution costs and taxation.

For Denmark, Germany and Sweden, the direct savings were calculated by multiplying the quantities of parallel-imported products sold by the retail price difference between domestic or directly imported products, and parallel imports of the same products. This procedure was based on an implicit premise that there is no quantity effect of the reduction in prices, or that the consumption of a drug does not increase as cheaper PI products become more available. This assumption is quite reasonable, since price is not likely to be a main determinant of either prescription or consumption. Another assumption made is that the cheapest product is made available to consumers -- otherwise savings would not materialize. This method however, could not be applied to the UK market because the pharmacies in that market are reimbursed the same amount for the same products irrespective of whether they are direct or parallel imports. Savings are instead realized through a claw-back system, in which the NHS retains a percentage corresponding to the estimated savings. Thus, for purposes of the study, savings were estimated on the basis of total sales and the realized claw-back percentage for 2004.[25]

Indirect savings on the other hand, may occur as originator prices are decreased or as the growth rate in originator prices is decreased as a result of competitive pressure by parallel imports. To assess the

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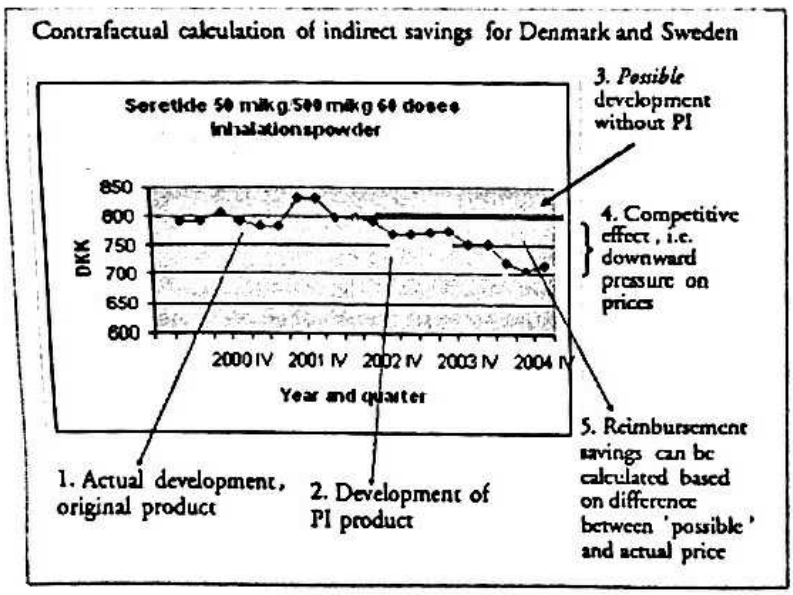
[24] *Id.* at 25.
[25] *Id.*.

competitiveness and the existence of indirect savings, two methods were employed. One method analyzed the price series for the 50 products taking into account the development in prices over time, while the other, which was used for Denmark and Sweden only, produced an estimate for the full market using specific assumptions about the development of thee originator price with and without competition from PI. A regression analysis was conducted based on the time series data, to test whether the entry of parallel imports to the market affected the originator price. The rest of the methodology is quite technical and rather than go into the specifics and details, what is important is that what ultimately resulted were not actual amounts of indirect savings, but the presence of a competitive effect of PI. The following figure[26] illustrates the second analytical method for calculation of indirect savings.



Applying the methodology just discussed, the results of direct and indirect savings summarized in the table[27] below were arrived at.

	Direct	Indirect
Denmark	14.2	8.3
Sweden	45.3	16.4
Germany	145.0	n.a.
UK	237.0	n.a.
Total	441.5	24.7

[26] *Id.* at 27.
[27] *Id.* at 48.

These show that there are considerable direct savings in the four countries. The figure for the UK would even be larger if savings made by pharmacies were included. Likewise, the estimated German savings would also increase if savings by sickness funds on pharmacy bills to pharmacies that do not meet the PI quota were included. Hence, the total direct savings figure of 441.5 million euros can be regarded as a fair but conservative estimate.

As for indirect savings, while there were some signs of such downward competitive pressure on prices for some products, and also on average prices, the picture for many products is that such pressure is remarkably absent. Contributing factors could be an increasingly supply-restricted market or restrictive price regulation. Such an interpretation could be supported by the seemingly modest competitive price effect observed across countries. This cannot be determined decisively on the basis of the currently available data, however. Estimates of the indirect savings have been made for Denmark and Sweden, based on assumptions about the likely originator price in the absence of parallel importing. These estimates suggest that such indirect savings are not insignificant.

More importantly, the CAST study allows a reanalysis and reconciliation of the earlier York and LSE studies. The following table[28] contains a comparison with previous results from the York study (based on 2001 data).

	Direct	Indirect	York study: Direct savings
Denmark	14.2	8.3	16
Sweden	45.3	16.4	47
Germany	145.0	n.a.	194
England	237.0	n.a.	342
Total	441.5	24.7	599

This table shows decreasing savings over time, most notably in Germany and UK. In Germany direct savings declined by 32%, while in the UK the estimated direct savings were reduced by approximately 20%. This decline in savings can be partly attributed to regulatory changes that have taken place in recent years. For instance, there is the strict price control in Sweden and the change in PI quotas and mandatory rebates to sickness funds in Germany. For Germany, the savings are exceptionally low in 2004

[28] *Id.*

due to the temporary but significant increase in the mandatory discounts to sickness funds, which led to withdrawal of about one-third of the PI products. Other explanations for the apparent decrease in savings could be that prices have converged so that the savings per quantity sold are lower, or that supplies have been increasingly restricted and therefore sales have gone down.

No direct comparison with the LSE Study can be made due to differences in the methods used. What is notable however is that the LSE Study found no competitive or indirect effects. Two approaches were used. The first method involved a review of the competitive patterns for five of the highest selling PI products in Germany, the Netherlands, and the UK. Based on this material, it was concluded that there may be little competition in products subjected to intensive parallel distribution.[29] It is added, however, that this is by no means conclusive evidence and that it may suggest that arbitrage is keeping prices and price increases within a certain range. Furthermore, no explanation was given for including only three of the study's six countries, or for limiting the method to 5 products rather than all nineteen. The second method was used to answer the question: Does parallel trade promote price competition in destination countries? Panel data for all products for 1997-2002 were used in a random effects model. No evidence of price competition was found in the four different models estimated. Finally, in the LSE study much is made of the fact that parallel importers make a profit out of their activities. It is also claimed that the parallel importers are the main beneficiaries of the PI activities.

In summary, despite some conflicting results in the three studies presented, the fundamental issue of whether or not there are direct savings was resolved. There definitely are, and in quite a large figure. There are indirect savings and competitive effects as well, though results are more varied in this area. What is worthy of emphasis though is that when looking at the gains from parallel trade, one must remember that ultimately, notwithstanding controversy as to the actual distribution, a significant portion of all savings generated by parallel trade redounds to the benefit of end-users of pharmaceuticals. All patients pay for health services in one form or another, through contributions, taxes, and direct fees. Since all countries have some form of co-payment, price reductions due to PI result in direct gains to patients, but citizens also experience indirect gains

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[29] *Id.* at 50.

through savings accruing to the national health or insurance system that in principle enable the purchase of more or better health services to the benefit of patients. This would bring us to the next section of this paper that discusses the perceived benefit of all advocates of parallel trade in the pharmaceutical sector: the increase in welfare.

2. Impact on Welfare

Total welfare is defined as the sum of consumers' surpluses net of the public expenses, and the profits of both the drug manufacturer and the parallel importer(s).[30] Price competition has a direct positive effect on welfare, since reduced prices result in lower total drug expenditure. The availability of cheaper PI of the same brand products found in a certain market will translate into direct savings as part of the current volume of consumption is shifted to PI's. The magnitude of the resulting savings depends on the volume of consumption shifted, and the difference between the prices of the PI and the original product. Over and above this basic savings, additional savings may occur to the extent that the manufacturer responds to potential or actual competition from PI by changes in pricing strategy. The increased competitiveness of the market may for instance result in a decrease in originator price or a reduction in any planned growth in price.[31] Thus, savings will not only be limited to the consumption of PI, but will also occur in relation to consumption of products at the originator price. The magnitude of such indirect savings depends on the total volume of products in the market as well as the degree to which manufacturers respond to increased competitiveness. These savings may directly benefit the user, when co-payment is related to price, or indirectly benefit the user, as when there is a reduction in third party drug expenditure, thus allowing resources to be used for other purposes.

Another theory is one that relates parallel imports to vertical price control.[32] A manufacturer protected by IPR in both a home and foreign market sets wholesale prices to distributors at sufficiently low rates to induce profit-maximizing retail prices, which vary according to demand elasticity. This enables distributors in the foreign market to sell the product

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[30] *Id.* at 14.

[31] *Id.*

[32] Keith Maskus, and Yongmin Chen, Vertical Price Control and Parallel Imports: Theory and Evidence, 2000. Paper presented at the International Seminar on International Trade. Cambridge, MA: National Bureau of Economic Research (5 June, 1999).

profitably outside the authorized channels in the home country and in other markets. Banning parallel imports always benefits the manufacturer, but has ambiguous impacts on social welfare in the two countries. Parallel imports expand competition facing the original manufacturers in the home country and other high-priced markets and benefits consumers there through lower prices. However, permitting PI reduces the supply available on the foreign (wholesaler) market, which in turn raises prices to consumers in that country. Again, therefore, there is a tendency toward retail price convergence in this vertical-pricing model, with consumers in low-price countries (perhaps developing nations) being harmed and those in high-priced nations benefiting.[33] Moreover, parallel trade wastes resources through transportation of goods between countries, whether in both directions or only from high retail price countries to low retail price countries. One significant policy conclusion is that parallel imports are likely to be beneficial in terms of total surplus generated among nations when trade costs (including tariffs) are low but harmful when trade costs are high. An implication of this is that it is parallel importation permitted through regional trade agreements that may have the effect of raising welfare.

The welfare effects from parallel trade will depend on the drug regulations, efforts of originators to exert vertical price control, the level of demand dispersion across markets and the need for manufacturers to achieve payback on their global research and development costs. For equal levels of income between countries, PI decreases total welfare when the only difference between the two markets is in terms of the level of patient co-payment, i.e. where price differences are due to regulation only.[34] However, when the countries differ in the utility patients obtain from consumption then PI increases total welfare as resources are allocated from those with low needs (exporters) to those with high needs. This conclusion is, however, only relevant when comparing countries with similar income.

In sum, what makes parallel importing of pharmaceuticals controversial is that as a whole, the net welfare effects are generally ambiguous. The most persistent argument is that parallel importing could on balance have negative welfare effects in the long term due to a negative

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[33] Yongmin Chen, and Keith Maskus, Vertical Pricing and Parallel Imports, Manuscript, University of Colorado (2001).

[34] Bordoy Jelovac I, *Pricing and Welfare Implications of Parallel Imports in the Pharmaceutical Industry*, INTERNATIONAL JOURNAL OF HEALTH CARE FINANCE AND ECONOMICS 2005; 5(1):5-21.

impact on research and development. This argument rests on a number of critical assumptions though. One of these is that marginally declining profits in the pharmaceutical industry translate into reductions in research and development rather in other areas within the respective companies. The perceived trade-off between short-term savings and long-term lack of innovation is explored further in the following section.

3. Opportunity Costs and the Ongoing Debates

a. R&D vs. Greater Access to Health Care

A key health-policy objective of any country is to give patients access to existing pharmaceutical drugs at a reasonable cost. From a welfare point of view, effective medicines have a value both to the individual and to society as a whole. Pharmaceutical drugs have private value to the individual both as treatments of symptoms and as cures. But they also have additional value to society because their use protects the rest of society from disease, in that it limits the risk that ill people can contaminate healthy individuals. This positive externality is one important reason for subsidizing broad access to drugs and could also be used to justify subsidies to research and development (R&D) in new drugs. Total welfare is maximized in the short-run if existing drugs are provided at a price equal to, or in some cases below, the marginal cost of production. The problem, however, is that developing new drugs typically involves substantial investments in R&D. The average cost in the United States and the EU to develop a new pharmaceutical drug is estimated to be between approximately $300 million and $500 million and in some cases substantially higher.[35] These costs are mainly fixed and sunk once the drug is developed. When all costs are expressed in net present values at the time of product launch, R&D accounts for perhaps 30% of total costs for U.S. pharmaceutical firms.[36]

If prices were set equal to, or even below, marginal cost of production the pharmaceutical companies would not be able to recoup their investments and the economic incentives for research and development would disappear. The long-run result of marginal-cost-pricing is, therefore,

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[35] Linnosmaa I. et al, Parallel importation of pharmaceuticals in Finland: effects on markets and expenditures. Pharmaceutical Development and Regulation, 2003; 1:67-74.

[36] *Id.*

that too little investment in research and development takes place and too few drugs are developed. To correct for this market imperfection, patents exist to reduce competition and allow pharmaceutical companies to exercise some market power in order to recover their investments in R&D. Thus, without considering tradeoffs across countries, the welfare optimization problem in a particular economy involves a compromise between giving patients access to existing drugs at reasonable costs versus ensuring profits for pharmaceutical companies. These anticipated profits serve as incentives for researching and developing new drugs in the future. Unfortunately, monopoly pricing of existing drugs causes static problems of insufficient market access for patients.

Given parallel importation, drug manufacturers holding original rights may find their profits diminished by its ability to interfere with discriminatory price setting, maintaining vertical control, and limiting licensing revenues. This reduction in profits would definitely limit incentives for further innovation, slowing down the pace of technical change and product development. Thus, the regulation of PI, like that of IPR generally, involves a tension between short-run static costs of market power and long-run dynamic benefits of faster product introduction. This situation of reduced profits is further exacerbated by the fact that the pharmaceutical industry is characterized by a peculiar structure with extremely high upfront investments, a very high product failure rate and high product liability. In comparison, the variable costs of production are relatively low. Thus, the payback period is relatively long and is one good reason for the patent protection of such highly research and development intensive goods. Given this kind of structure, Ramsey pricing can be an efficient strategy for paying for research and development. This concept uses price discrimination to generate higher profits in market segments with higher willingness and ability to pay and lower profits in market segments with low ability to pay. This depends however on an effective segmentation of distinct markets with limited leakage and arbitrage. The problem is that with parallel trade, it is difficult for the pharmaceutical industry to uphold such market segmentation. It has been pointed out that the conclusion that price differences increase welfare depends on an assumption that price

discrimination is based on a segmentation of markets according to true individual demand elasticity.[37]

It has been argued that reduced revenues to manufacturers and transfer of profits to parallel importers who do not invest in research and development may result in lower investment in research and development. Thus, despite sufficient willingness to pay (through higher prices) among some consumers, the development of new medicines will suffer in the long run.[38] As such parallel trade, while targeting static efficiency (to keep costs low), is in conflict with the objective of promoting dynamic efficiency because of the disincentives for research and development as opposed to a situation without parallel trade but with Ramsey pricing. This argument, however, depends on an assumption that reduced profits necessarily translate into reductions in research and development. As research and development is the core value driver, such a response strategy by the manufacturer would not necessarily be profit maximizing in the long term.

While increased price competition is likely to reduce investments in research and development this prediction is not sufficient to determine the net effect on social welfare.[39] The net effect will depend on the shape of the innovation production function over the research and development cost levels before and after increased price competition. Assuming diminishing returns to scale, there will be cost levels at which the marginal productivity is low and at which the effect of reduced research and development costs on innovation will only be moderate. Obviously, there will also be cost levels at which this effect is substantial. The starting point, i.e. the current level of research and development costs and the shape of the production curve, will determine how the gains in static efficiency (through the reduction of prices towards marginal costs) and the loss in dynamic efficiency (long-term reduction in innovation) balance out. Indeed, it is possible that at low marginal innovation productivity, increased price competition will improve welfare, as long as the price competition does not shift profit margins below the margins associated with minimum total social costs.

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[37] Juhl Gyldmark, The Economics of Parallel Trade Revisited: Possible Implications for the Social Welfare in Europe, Draft (2000).

[38] Patricia Danzon, *The Economics of Parallel Trade*, PHARMACOECONOMICS 1998; 13(3):293-304.

[39] JA Vernon, Examining the Link Between Price Regulation and Pharmaceutical R&D Investment, HEALTH ECONOMICS 2005; 14(1):1-16.

Taking on a different perspective, one may realize also that parallel trade may also adversely affect short-term access to healthcare, via new, innovation drugs. This happens when manufacturers set higher launch prices for new products because the development of parallel trade has reduced the period during which high profits can be gained. Manufacturers may use higher launch prices to gain profits in high-price markets before parallel importers can mobilize and may also launch in fewer countries in order to reduce the scope for parallel trade.[40] As low prices in one market may spill over to other markets due to parallel trade and/or reference pricing, manufacturers may prefer longer launch delays in some countries. Since price-sensitive market segments will have a greater reduction in demand relative to a hypothetical demand curve this would imply that low-income consumer countries with significant co-payment will have slower access to innovation drugs. This is argued to be welfare decreasing. This argument is based, however, on an assumption that the point of departure was optimal to begin with.

Empirical Evidence as to Long-term Effects on R&D

The studies that have been discussed earlier all focused on the impact of PI on savings, price, and ultimately on net welfare. Many more smaller scale studies with similar purposes and objectives exist. Yet despite all these, the consensus is still that there is no conclusive empirical evidence on the magnitude of the economic impact of PI, and the net welfare effect remains largely ambiguous. Thus, with respect to the actual correlation of PI and research and development, even less precision must be expected, since no study has focused on the possible effects of PI on research and development. The empirical evidence is thus at best circumstantial, i.e. the effects of relative price differences on new drug launches. This is partly due to inherent differences in time span: PI has particularly increased in the new millennium, whilst any effects on research and development will only show up after a considerable time lag. The effects of PI on profits in the research-based pharmaceutical industry may not necessarily translate into cuts in research and development, but might equally likely affect other cost areas, e.g. marketing or administration.[41]

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[40] Danzon, *supra* note 38.
[41] Maskus, *supra* note 3.

One study covering 25 countries and 85 new chemical entities launched over the period 1994-98 analyzed the effect of pharmaceutical price regulation on delays in new drug launches (21).[42] Low price in one market may spill over to others through parallel trade and price referencing. Manufacturers may thus prefer longer delay or non-launch rather than accepting a low price. The hypotheses were: (1) in markets that can be separated, differential pricing will be used and new drugs launched promptly, while (2) in non-separable markets, prices will converge and delays in the launch of new products will occur in low-price countries. The data analysis suggested that within the EU, the likely parallel-exporting countries in Southern Europe have fewer launches of new chemical entities and a longer average delay in the launch of new products. Furthermore, launch delay appeared to decrease with increased market size and expected price. When controlling for national income the effects were smaller but still significant.

It must be stressed however that these results are merely indicative and do not address the issue of the effects of parallel importing on research and development. The most appropriate statement about empirical evidence of the effect of PI on research and development would seem to be that there is really no convincing evidence available.

It can however be said that even if there were data it is conceptually hard to answer the question on the impact of PI on R&D for four reasons.[43] First, the precise effects of profits on original manufacturers would depend on the particular structure of competition, though they are surely negative. Second, a small volume of PI does not imply small price and profit effects. Third, even if it is possible to calculate the impacts on expected profits ex ante, there is still not much information about the long-run sensitivity of R&D spending to declines in profitability. For example, it could be linear, in which case any threat of PI would reduce R&D. However, if the relationship were non-linear and/or characterized by threshold effects, R&D could be insensitive to exposure to PI until there is a marked reduction in expected profits. Fourth, an important observation is that because incentives for PI emerge primarily on economically successful, or "blockbuster" drugs, the effects of PI might be concentrated or even

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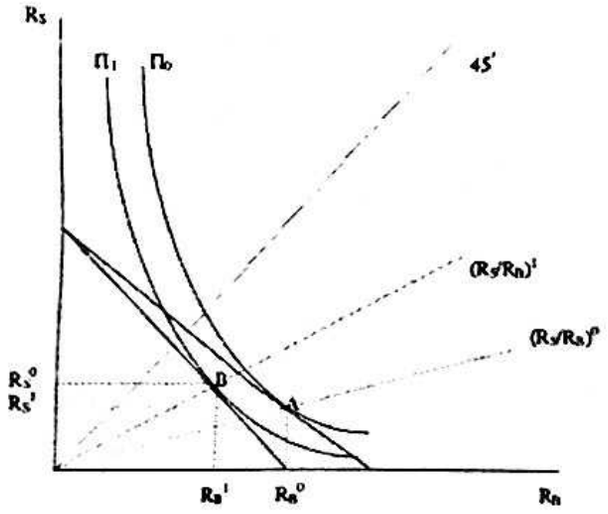
[42] Patricia Danzon et al, *The Impact of Price Regulation on the Launch Delay of New Drugs–Evidence From Twenty-five Major Markets in the 1990s*, HEALTH ECONOMICS 2005; 14(3):269-292.

[43] Maskus, *supra* note 3, at 26.

confined in such drugs.[44] Because they typically make up a significant share of the profits earned by research-intensive pharmaceutical firms, the impact on overall profitability could be substantial even if a small number of drugs in the overall portfolio were targeted. Indeed, in a dynamic sense this feature of PI has especially perverse consequences. PI firms do not have to undertake the significant R&D costs of developing new drugs and therefore contribute little to dynamic drug introduction. Moreover, by focusing their competitive efforts on the price markups in blockbuster drugs, they do not have to worry about the substantial uncertainty implicit in attempting to develop a successful new drug. Rather, their form of competition aims squarely at drugs that are already revealed to be successful.

Based on all these, it is evident that PI has at least two certain deleterious effects on R&D programs. First, by reducing the returns to all original R&D in drugs, there would be a scale effect reducing the total of R&D spending. Second, by reducing the relative profitability of blockbuster drugs, it would induce pharmaceutical firms to devote relatively more resources to smaller drugs with lower average profit margins and market sizes. This tradeoff is illustrated in the following figure:[45]



Suppose that there is free entry in the long run into R&D in the pharmaceutical sector.[46] This means that R&D costs in the first period

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[44] *Id.*

[45] *Id.* at 50.

[46] Patricia Danzon, PHARMACEUTICAL PRICE REGULATION: NATIONAL POLICIES VERSUS GLOBAL INTERESTS (1997).

must be just covered by profits (quasi-rents) made in later periods of competition. Only firms for which this condition is true would survive in the long run. Firms in the industry must decide in the initial period of competition how much R&D to undertake and how to allocate it between "small" drugs (with R&D level RS) and "blockbuster" drugs (with R&D level RB). The curve labeled P0 depicts the tradeoff between R&D choices that would procure zero long-run profits in the sector for a given international structure of taxes and regulations, and without the possibility of parallel trade. Professor Maskus has drawn it to be convex, reflecting the notion that as RB gets lower, further small reductions in RB would require larger marginal increases in RS to maintain zero profits.[47] Equilibrium without PI is depicted at point A, where the zero-profit tradeoff is tangent to a straight line giving the ratio of the additional costs of one more unit of RS to the resources saved from undertaking one less unit of RB. The ratio of small-drug research to blockbuster research is given by (RS/ RB)0. Suppose that a regime of PI were not permitted within an important market segment. As discussed above, this change necessarily would reduce the quasi-rents in the competition periods, shifting the zero-profit locus in toward the origin to P1. In this case, the scale effect could be read at the intersection of the ray (RS/RB)0 and the new profit locus, with both types of research reduced. However, an additional impact to consider is that because PI target blockbuster drugs the relative cost line would pivot in as well. The reason is that the relative return to blockbuster research must increase in order to compensate for the higher cost of dealing with PI. Accordingly, the research decision would be further distorted along the new profit locus toward more small-drug research and less blockbuster research at point B. Overall, blockbuster R&D must fall while small-drug R&D could fall or rise, with an increase shown in this diagram.[48]

Possible Options

The seeming incongruence of consumer accessibility via more affordable prices and innovation via research and development, can be solved by separating the short-term from the long-term objectives. Professor Maskus proposes that the best solution from a welfare perspective is to reward new innovations with a fixed lump-sum transfer to the innovating firm and to distribute existing drugs at competitive prices or

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[47] This may be demonstrated by linear demand curves for the two drug types assuming a larger market for the blockbuster drug.

[48] Maskus, *supra* note 3, at 26.

even below competitive prices given their additional social value. While a policy to separate fixed and variable costs of pharmaceutical drug production might be impractical or even impossible to implement in most cases, it can be useful in particular situations. More precisely, cost-based pricing and lump sum payments for innovations could be the only way to achieve both the current and future health objectives in the poorest countries of the world.

b. Conflicting Interests of Developed and Developing Countries

Regulation of PI in the pharmaceuticals area has become a critical issue in the global trading system. Advocates of strong international patent rights for new medicines support a global policy of banning PI, arguing that if such trade were widely allowed it would reduce profits in the research-intensive pharmaceutical sector and ultimately slow down innovation of new drugs. Moreover, PI could make it difficult for health authorities in different countries to sustain differential price controls and regulatory regimes. However, public-health authorities in many countries argue that it is important to be able to purchase drugs from the cheapest sources possible, requiring an open regime of PI. Whether or not such imports actually occur, the threat that they might come in could force distributors to charge lower prices.

At this point, it is best to contextualize the problems of static distortions and dynamic efficiency. First of all, the trade-off between different objectives is not identical in all countries and, consequently, the optimal policy differs across nations. Moreover, in a global economy with trade in pharmaceutical products, a health-care policy in one country may have important implications for policies in other countries. Starting with the issue of different objectives in industrialized and developing countries,[1] it is crucial to note that the weights put on short-run and long-run objectives depend on several factors and the optimum is likely to vary across countries with different levels of income. National policies and priorities are largely influenced on the status of one's economy, on the level of influence the country wields in the international scene, and on what among the divergent objectives is more favored by the majority of the constituency. Countries with high average income are likely to put more weight on new and improved drugs relative to countries with medium or low average income. As long as future drugs are normal goods, rich countries can be expected to have a higher willingness to pay for research and development. Lower rates of time preference in developed countries could also affect the trade-off in

the same direction. Governments in industrialized countries are therefore more willing to accept high profits in the pharmaceutical industry to promote future innovations and improved drugs, while governments in developing countries prefer to give patients access to existing drugs at low costs. The latter approach typically involves weak or absent patent rights and reliance on generic imitation to keep prices down. One unfortunate result of this difference in interests is that R&D expenditures are rarely aimed at developing treatments for the endemic diseases of impoverished nations, such as tuberculosis and malaria.[49] For example, The World Health Organization (1996) estimated that of the $56 billion spent globally on medical R&D in 1994, less than 0.2 percent was spent on TB, diarrheal maladies, and pneumonia. Virtually all of the latter research was performed by public agencies and military authorities. Further, there is insufficient R&D in anti-malarial vaccines or drugs. A Wellcome Trust study found that public and non-profit malaria research amounted to $84 million in 1993, with vaccine research amounting to a small portion of that spending.[50] Private sector spending was lower still. Additional research into vaccines and anti- malarial drugs is underway under the auspices of the Multilateral Initiative on Malaria, involving the UNDP, the World Bank, and the WHO, and the Medicines for Malaria Venture, a public-private sector cooperative initiative. However, funding for the former comes to perhaps $3 million per year and the latter group is soliciting support from foundations in the hopes of achieving $30 million per year. These amounts seem inadequate for the job, given the underlying costs of developing and testing new drugs.[51]

It is evident that policymakers in developing countries especially would place a higher weight on affordability of medicines than on promoting R&D abroad. The cost of medicine represents the greatest share of health-care expenditures for people in poor countries. Expenditure on pharmaceuticals ranges from 10–20 per cent of expenditure on health in the richest countries and 20–60 per cent in poorer countries. Unlike many rich countries, most developing countries lack universal health insurance. Across Asia, medicines comprise between 20 to 80 per cent of out-of-pocket health-care costs. In Peru, where 70 per cent of expenditures on medicines

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[49] Enemark, *supra* note 1.

[50] Jeffrey Sachs, Michael Kremer and Amar Hamoudi, Center for International Development, Harvard University, *The Case for a Vaccine Fund, available at* www.cid.harvard.edu/cidsocialpolicy/policypapers.htm.

[51] Maskus, *supra* note 3.

are paid for out-of-pocket, only 52 per cent of the population has health insurance, and coverage mostly excludes those living under the poverty line.[52]

This controversy is well illustrated by the lawsuit filed by 39 South African licensed pharmaceutical distributors to overturn South Africa's 1997 Medicines Law. This legislation would permit South Africa's health minister to resort to PI in cases where a drug protected by a patent is priced at excessive levels in South Africa. Further, pharmaceutical firms in industrialized nations that recently agreed to provide many of their HIV/AIDS drugs at low cost in Sub-Saharan African nations remain concerned that these drugs might come into higher priced markets through parallel exports to Korea, Japan, Brazil, and other countries.

Higher Drug Prices in Developing Countries

The greater priority accorded by developing countries to affordability is really rooted in the phenomenon that manufacturers' prices for identical drugs tend to be higher in lower-income nations. This is quite baffling since if national pharmaceutical markets are largely segmented, as they seem to be outside the European Union, the finding that prices are elevated in such countries as South Africa, Mexico and Brazil relative to those in Canada, Spain and Italy seems anomalous. Three explanations seem capable of explaining this trend. Perhaps the most significant is that the notion that markets are externally segmented but internally integrated may be misleading. In particular, domestic markets could be bifurcated between high-income consumers, with a low degree of price sensitivity and a high ability and willingness to pay for new drugs, and low-income consumers who are more price-sensitive and less able to pay. In such cases the market demand curve can be "kinked" between a low-volume, inelastic segment and a high-volume, elastic segment.[53] Then it is highly possible that a pharmaceutical firm with market power would find it more profitable to supply the inelastic segment of the

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[52] PATENTS VERSUS PATIENTS: FIVE YEARS AFTER THE DOHA DECLARATION, *available at* http://www.oxfam.org/en/policy/briefingpapers/bp95_patentsvspatients_061114.

[53] F. M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, paper prepared for Working Group 4 of the Commission for Macroeconomics and Health of the World Health Organization (2001).

market at a high markup and avoid supplying the elastic segment altogether. Indeed, the firm would prefer not to sell to low-income consumers at a low price for fear that the drugs would be resold to higher-income consumers via "internal parallel imports". This is a classic case in which an inability to price discriminate among consumers within a country discourages firms from selling to poorer consumers, with a lower net supply offered as a result. As such, it is possible that higher prices in developing countries for particular products reflect a decision to sell low volumes at high markups. This situation is common in other areas of products protected by IPRs and brand names. For example, legitimate copies of Microsoft Office have been observed to sell at considerably higher prices in Taiwan, Hong Kong, and China than in the United States.[54] In the former countries software licensees are willing only to provide legitimate copies to such users as foreign enterprises and government offices, which are less likely to infringe the copyright. In contrast, in the United States, segments of users are based on underlying demand elasticity. Thus, it is feasible to offer discounts to academic users and students on the expectation that they will not re-sell or copy their products.

A second and related reason that prices may be high in poor countries is that distribution systems may be concentrated or monopolistic. In countries where pharmaceutical products are largely imported, such imports may come into the market through a small number of domestic distributors. Single wholesalers would maximize profits by limiting their supply and gaining a monopolistic markup over import costs. Indeed, many developing nations regulate distribution in such a way that only one domestic firm is permitted to serve as a licensee for particular foreign brands. This combination of monopolistic distribution structure and limited intra-brand competition is heavily anti-competitive.[55]

The third reason is simply that some affluent nations may have stringent price controls in place that limit manufacturer's prices to levels

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[54] Keith Maskus, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (2000).

[55] Keith Maskus & Mohamed Lahouel, *Competition Policy and Intellectual Property Rights in Developing Countries*, THE WORLD ECONOMY 23: 595-611.

below those in poorer nations. These price controls may be based on cost markups or on reference prices, in which regulators look to prices abroad to set allowable charges. Where parallel imports originate in countries with strict price regulations they have complex potential impacts on economic well-being and R&D performance in both origin and destination countries.

Whatever the actual reason is, the end result is the same. The higher prices in developing and least-developed countries provide the core driver in their partiality for PI-friendly policies. These higher prices are often set by multinational drug manufacturers that are corporate citizens of the more developed nations that tend to adopt their interests and champion research and development. While the struggle between the polarized interests of these countries is present in almost all sectors and trading issues, what is interesting is that this particular struggle takes place with a peculiar legal order for a backdrop. This is the subject of discussion in the next section.

C. THE LEGAL FRAMEWORK

1. International Law on Intellectual Property

Intellectual property rights have always been regulated by international law through treaties such as the Berne Convention and the Paris Convention for the Protection of Industrial Property but have only been governed by the World Trade Organization and thus linked with trade issues, since 1994, by means of the Agreement on Trade Related Intellectual Property and Services or TRIPS. The TRIPS Agreement represented the single greatest expansion of intellectual property protection in history. To allay the concerns of developing countries, the Agreement established that countries could adopt measures to protect public health, promote public interest, and prevent abuse of intellectual property rules. These measures, known as public-health safeguards, enable countries to obtain cheaper patented medicines or generic equivalents of patented medicines. In addition, countries are empowered with flexibilities to determine the circumstances under which they apply safeguards. The TRIPS Agreement also provided developing countries with a 'transition period' for delayed implementation. Examples of some public health safeguards in the TRIPS Agreement are (1) Parallel importation (Article 6) that allows countries to import a patented product marketed in another country at a lower price; (2) Compulsory licensing and government use (Article 31) that allows governments to temporarily override a patent and authorize production of

generic equivalents of patented medicines in the public interest. This is broadly defined and at the discretion of each country. Another is the 'Bolar provision', which allows testing and regulatory approval of generic versions of drugs before the patent expires to ensure that generic copies can be introduced immediately upon patent expiry.[56]

At the same time as this new global intellectual property regime was being implemented, new threats to public health were emerging – most notably the HIV epidemic. Many developing countries began addressing the HIV and AIDS crisis by providing low-cost medicines for their citizens. Some of these efforts encountered opposition from pharmaceutical companies, which sought to block production of generic equivalents of patented medicines in Brazil and Thailand.

Widespread public outrage resulted, and developing-country trade representatives insisted that the public-health consequences of TRIPS should be addressed as part of a larger 'development round' negotiation of new trade rules, launched in Doha in 2001. As a result, TRIPS and public health were key issues on the agenda of the Fourth Ministerial Meeting of the WTO in Doha, Qatar in November 2001, where WTO members launched the Doha 'Development' Round of trade negotiations. These efforts produced the 'Doha Declaration on TRIPS and Public Health', which asserted that the TRIPS Agreement should not prevent member countries from protecting public health. This was unanimously approved by all WTO members. The Doha Declaration unequivocally recognized and clarified that the TRIPS Agreement should not prevent WTO member countries from taking measures to protect public health. The Declaration reaffirmed the right of developing countries to use safeguards created under the TRIPS Agreement to reduce the price of medicines, and also instructed WTO members to find a solution for countries with insufficient generic manufacturing capacity.

Article 4 of the Declaration states:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS

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[56] *Patents Versus Patients: Five Years After the Doha Declaration, available at* http://www.oxfam.org/en/policy/briefingpapers/bp95_patentsvspatients_061114

> Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and, in particular, to promote access to medicines for all. In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Specifically, the Declaration recognizes the legitimate need of countries to take measures to reduce the price of medicines, such as using TRIPS safeguards. The Declaration also acknowledges the need for WTO members to identify a mechanism that developing countries with insufficient or no drug manufacturing capacities could use to import generic versions of patented medicines under compulsory licenses. This is because TRIPS stated that compulsory licensing must be predominantly for the domestic market, which meant that poor countries without the necessary manufacturing capacity could not rely upon other countries to provide medicines. Finally, the Declaration extended the 'transition period' for least-developed countries to 2016, with each least-developed country retaining the right to apply for additional deferments.

The Doha Declaration is a subsequent legal agreement (to TRIPS) that can be relied upon to interpret the TRIPS Agreement, and can be used to lodge a complaint under the WTO Dispute Settlement Understanding. Above all, it represents a political and moral commitment by all WTO members to ensure the TRIPS Agreement does not obstruct poor individuals from gaining access to inexpensive medicines.[57]

Parallel Trade on the other hand, although considered a safeguard under TRIPS, is mainly regulated through trade agreements and the existing trade policies implemented within each national jurisdiction. The interplay of these different sources of international law is what comprises the legal framework relevant to the issue at hand.

The most pertinent kind of intellectual property to the pharmaceutical sector is the patent. The patent provides inventors of new products and technologies the exclusive legal rights of making, selling, using, distributing, and importing their inventions. A country's law concerning the territorial exhaustion of these rights is an important

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[57] *Id.*

component of how it regulates and limits their use. Exhaustion policies may cover one or all of these exclusive rights, and can fall under three types. Under national exhaustion, exclusive rights end upon first sale within a country but IPR owners may exclude parallel imports from other countries. Under international exhaustion, rights are exhausted upon first sale anywhere and parallel imports cannot be excluded. A third possibility is regional exhaustion, under which rights end upon original sale within a group of countries, thereby allowing parallel trade among them, but are not ended by first sale outside the region.

A policy of national exhaustion amounts to a government-enforced territorial restriction on international distribution. Countries following this regime choose to isolate their markets from unauthorized foreign competition in legitimate goods traded under recognized IPR protection. Thus, original manufacturers retain complete authority to distribute goods and services themselves or through dealers, including the right to exclude PI through border controls. In contrast, countries permitting PI are not territorially segmented and do not recognize any right to exclude imports of goods in circulation abroad.[58]

Note also that in principle a country could treat parallel imports and parallel exports (PE) separately. It is possible that a country might permit PI and ban PE in order to encourage low prices on its market. It is also possible that a country could ban PI and permit PE in order to sustain export opportunities for its distributors. Despite this potential segmentation in legal regimes, this is rarely if at all practiced by any country.

Because IPR are recognized on a territorial basis, each nation has established its own policy covering parallel imports. American negotiators in the Uruguay Round tried to incorporate a global standard of national exhaustion into the Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS). However, it was impossible to reach such an agreement because of divergent views on the net benefits of PI. Rather, Article 6 of TRIPS simply states that:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

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[58] Maskus, *supra* note 3.

This language implies that no violation or limitation of a TRIPS obligation beyond national treatment (Article Three) and most favored nation (Article Four) may be invoked to challenge the treatment of parallel imports. Article Six preserves the territorial prerogative to regulate parallel trade. This flexibility was important in gaining the acceptance of TRIPS by many developing countries.[59] Undoubtedly many negotiators from developing countries considered PI to be an effective antidote to concerns about the potential price impacts of pharmaceutical patents required by the agreement.

2. Overview of Policies of Major Players

Until the present though, debate still continues over the question of whether TRIPS should be extended to mandate a uniform global policy of exhaustion. Some analysts advocate a global ban against PI as a natural extension of the rights of intellectual property owners to control international distribution.[60] This position is advanced forcefully by representatives of the research-intensive pharmaceutical firms.[61] Others support a comprehensive rule of international exhaustion and would place no restrictions on parallel imports in order to integrate markets.[62] The argument is that restraints against PI constitute non-tariff barriers to trade and are inconsistent with the fundamental principles of the WTO. However, advocates of this view often modify it by recognizing the possible need for restraints in pharmaceuticals, which are subject to sharp international price differentials for regulatory purposes. Two further points should be clarified. First, opponents of PI often claim that permitting them would support consumer deception and trade in counterfeit goods and pirated goods. However, such arguments are irrelevant in the strict sense of assessing the impacts of PI. Consumer deception would occur in case lower-quality parallel imports were marketed as legitimate versions of higher-quality products. Counterfeiting and piracy are trade in unauthorized versions of products, which is a different concept than

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[59] West P. & Mahon J., Benefits to Payers and Patients From Parallel Trade (2003, York Health Economics Consortium)

[60] Claude Barfield & Mark Groombridge, *The Economic Case for Copyright Owner Control over Parallel Imports*, THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 1: 903-939(1998).

[61] Harvey Bale, Jr., *The Conflicts between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, JOURNAL OF INTERNATIONAL ECONOMIC LAW 1: 637-653(1998).

[62] Frederick Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, JOURNAL OF INTERNATIONAL ECONOMIC LAW 1: 607-636 (1998.).

parallel imports. In either case, customs authorities are empowered to act against such trade without restricting genuine PI. Nonetheless, as a practical matter there could be some difficulties with deception and product quality, raising the costs of effective monitoring at the border.[63]

Second, a ban on PI per se does not extend to preventing imports of generic drugs or imitative drugs that may be legitimately on the market in another country because the original products are not patented there. However, if domestic sale of such drugs would violate patents owned in the importing market, they may be excluded for that reason. Exhaustion policies vary widely in the area of pharmaceuticals, even among developed economies. The European Union pursues regional exhaustion but excludes PI coming from nonmembers. The European Court of Justice (ECJ) consistently has upheld the view that, under Article 30 of the Treaty of Rome, free circulation of goods takes precedence over IPR.[64] This principle extends to arbitrage possibilities created by national price controls. For example, countries may not use the existence of differential price controls in pharmaceuticals to justify restrictions on parallel trade within the EU.[65] An important exception is that if products are placed on the market under a compulsory license, they may not be parallel imported.[66]

Within its territory the United States employs the first-sale doctrine, under which rights are exhausted when purchased outside the vertical distribution chain. Thus, companies cannot prevent customers from re-selling goods anywhere within the country. This policy is seen as a useful restraint against market power arising from privately contracted exclusive territories. Indeed, there are now a number of E-commerce "pharmacies" (distributors) offering prescription, trademarked drugs to consumers at prices below retail. Under its trademark law the United States could be open to PI subject to its "common-control exception". This rule allows trademark owners to bar PI except when both the foreign and U.S. trademarks are owned by the same entity or when the foreign and U.S. trademark owners are in a parent-subsidiary relationship.[67] Furthermore, for a trademark owner to block PI it must demonstrate that the imported

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[63] Maskus, *supra* note 3.

[64] For trademarks the initial case was Consten and Grundig v Commission (C-56/64), for patents it was Merck v. Stephar (C-187/80) and for copyrights it was Deutsche Grammophon v. Metro (C-78/70).

[65] Merck v. Primetown (C-267/95 and C-268/95).

[66] Pharmon v. Hoechst (C-19/84).

[67] K Mart Corporation v. Cartier, 486 US 281 (1987).

goods are not identical in quality to the original products and could cause confusion among consumers.[68] These principles would suggest that PI in pharmaceuticals is permissible for the imports are certainly identical to original products. However, two legal restraints prevent PI in prescription drugs. First, American patent owners are protected from parallel imports by an explicit right of importation. Second, PI of trademarked, prescription drugs are explicitly excluded under terms of a 1988 law covering pharmaceuticals. An attempt to relax this restriction through new legislation was passed in 2000 but not implemented by the Clinton Administration, which cited that it could not guarantee the purity of imported drugs.

Japan allows PI in patented and trademarked goods unless the goods are explicitly barred from parallel trade by contract provisions or unless their original sale was subject to foreign price regulation. Its case law makes Japan considerably more open to PI than the United States.[69] Australia generally permits parallel imports in trademarked goods but patent owners may block them. Thus, Australian consumers cannot benefit from cheaper drugs available on foreign markets. Developing countries vary widely in their restraints on PI of pharmaceuticals.

Some nations disallow PI because their patent laws provide a strict right of importation to authorized licensees; these laws are common in countries with British or French colonial legacies. Moreover, several developing nations have laws permitting only one national distributor for products imported under trademark, effectively banning parallel imports. However, Hong Kong and Singapore prefer open regimes of parallel trade because of their nature as centers of entry-port trade. India follows a regime of international exhaustion in trademarked and patented goods. A number of developing countries, including Argentina, Thailand, and South Africa, recently have enacted laws permitting parallel imports of pharmaceutical products.

The South African case is in point in order to understand the controversies involved. In December 1997 the government of South Africa amended its Medicines Act, which would permit the Minister of Health to suspend patent rights and issue compulsory licenses in cases where it was

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[68] See "Ruling Against Unauthorized Imports Upheld," The Journal of Commerce, January 7 2000.
[69] Abbott, *supra* note 62.

deemed necessary to offset a high price of patented drugs. The law would legalize parallel imports of patented medicines in such cases. A constitutional challenge to the law was raised in South African courts by pharmaceutical companies. Under considerable pressure from the research-based pharmaceutical companies, the United States placed South Africa on its Special 301 Priority Watch list in 1998. The South African action aroused considerable sympathy among American advocates of price controls in medicines. The activism of those groups was instrumental in persuading the pharmaceutical companies to drop the issue, and the US to moderate its stance on the issue.

D. CONCLUSIONS/RECOMMENDATIONS BASED ON ECONOMIC AND LEGAL PERSPECTIVES

Parallel trade in pharmaceuticals is an important policy issue in many countries and is engulfed in controversy, in part due to the many contradictory stakeholder interests, but also because the theoretical literature shows conflicting results and the empirical data is still growing. So far, the economic and international legal frameworks of this contentious issue have been discussed. At this juncture, I will attempt to summarize what has been set forth before going into the specific context of the Philippine setting.

Parallel imports in patented and brand-name drugs arise for a variety of factors associated with price differences across markets: price discrimination by manufacturers, vertical price setting within distribution systems, and differential systems of price controls. As may be expected, PI have complex effects on markets in theory. There are many reasons to believe that price discrimination in competitive markets can be beneficial overall, so that a presumption in favor of restraining parallel trade could be supported. However, under some circumstances ensuring access to cheaper imports is warranted. To summarize, it is useful to list here the potential benefits and costs of permitting PI.

The benefits[70] of parallel imports are as follows.

1. By permitting pharmacists, hospitals, and insurance services to procure drugs from cheaper international sources, prices of brand-name

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[70] Maskus, *supra* note 3.

drugs are directly reduced. Presumably this reduction is passed on to final consumers (patients) in some degree. This price-reducing impact may be of particular benefit in developing countries where firms sell small volumes at high prices.

2. The threat of accessing PI drugs may be sufficient to provide health providers enough negotiating leverage with original manufacturers that they would accept lower prices. Thus, PI can be a complement to price control programs.

3. Parallel imports may be a source of technology transfer in that it could make products available on markets where firms could reverse engineer their compositions.

The costs[71] of parallel imports are as follows:

1. To the extent that original manufacturers set prices according to local demand elasticity and market size, integrating markets through PI could raise the prices in exporting countries by reducing available supply there. Under plausible circumstances firms could refuse to supply small markets altogether.

2. Parallel trade uses resources in transport costs and repackaging. These costs may take up a significant portion of any potential price advantages.

3. PI firms engage in no R&D and undertake little in the way of marketing investments. Thus, they are permitted to free ride on the marketing expenses of original manufacturers and their licensees, which could reduce their willingness to supply certain markets and products.

4. To the extent that PI reduces profitability of original manufacturers, and their R&D programs are sensitive to such profit reductions, the activity can slow down global drug development. Because PI firms target the most successful drugs ex post, it reduces the relative returns to engage in development of breakthrough or blockbuster drugs.

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[71] *Id.*

5. It is conceivable that extensive regimes of PI in drugs of particular interest to developing countries could offset any incentives to more R&D emerging from the TRIPS Agreement.

1. Potential welfare effects

Based on the major studies cited and analyzed earlier, short-term welfare benefits of parallel trade to importing countries are likely to occur in terms of lower drug expenditure, provided that lower costs are transferred to the consumers of pharmaceuticals. Such benefits may occur through two mechanisms: direct savings and indirect savings. The availability of cheaper PI of the same brand products as currently in the market will translate into direct savings, as parallel imports enter the market at lower than the originator price. In addition, to the extent that parallel trade puts competitive pressure on the originator price, thus resulting in price decreases or a deceleration of price increases, there will be indirect savings in drug expenditures. However, the magnitude of these savings and the actual response to parallel trade in the end is an empirical question.

In terms of long-term welfare benefits, it has been argued that research and development could suffer from reduced profits in the pharmaceutical sector. It has also been shown, however, that this is not necessarily the case under all circumstances and there is so far no convincing empirical evidence.

Another important issue is the determination of how the net welfare effects are distributed among the major stakeholders, for this will also affect the policy preference of nations, depending on the interests sought to be protected. The distribution of any savings in drug prices will depend on the regulatory environment and health care financing system. Ultimately, however, all patients pay for health services through contributions, taxes and direct fees and therefore gain either directly or indirectly, if savings materialize. The York report concluded that direct and indirect savings from the parallel trade of pharmaceuticals have helped contain public health care expenditure and that due to the nature of the national health systems, the users of health services benefit from such savings. The LSE report, on the other hand, concluded that the lack of sizeable direct benefits, the limited price competition in individual markets, the existence of reported product shortages in some member states, and the size of absolute and relative profits accruing to parallel traders may force policy-makers to re-evaluate the rationale behind parallel trade.

The disparities in the savings estimates in these two studies were mainly attributable to methodological differences. Taking these methodological differences into account and specifically adjusting for the fact that the LSE study due to its other objectives was based on a sample of varying representativeness in the countries studied and that the savings reported only pertained to this small section of the market, it appeared that the savings estimates would be much less different between the two studies than may appear at first glance.

Few studies have attempted to quantify the indirect savings and none of them very comprehensively. Increased competitiveness of the market would, however, indicate the presence of indirect savings. The LSE study found no competitive effects, but it is uncertain whether the approach of pooling data from national markets with very different regulatory frameworks may not contain a risk of washing out possible effects in individual countries. The York study also found only limited signs of competitive effects. It is the CAST Study that presents estimates of indirect savings for two countries. The analysis revealed signs of such downward competitive pressure on prices for some products, and also on average prices, but the picture for many products is that such pressure is remarkably absent. Contributory factors to this marked absence could be an increasingly restricted supply market or restrictive price regulation. This may also be consistent with attempts by pharmaceutical firms to reduce parallel trade by deliberately and strategically limiting any competitive response to threats or pressures brought by PI.

As to the enduring conflict between R&D in the pharmaceuticals sector and lower prices of drugs brought about by parallel trade, there is negligible empirical evidence supporting the contention that permission of PI would ultimately result to lower R&D and drug innovations, at least on a per country basis. A firm-level analysis focusing on basic R&D would be more appropriate if the data were available. At this simple point, however, there seems to be little reason to argue empirically that parallel imports clearly reduce R&D expenditures in pharmaceuticals.

2. Conclusions and Policy Recommendations

The theoretical literature and the empirical evidence that have been reviewed so far support the following conclusions. First, there are substantial price differences across countries in identical branded drugs. Second, these prices roughly follow Ramsey pricing but there are many

instances of prices that are higher in developing nations than in developed countries. Third, PI in drugs within the European Union reached substantial proportions in the 1990s, particularly in the more successful products. Despite that, significant price differences remain between countries and there is little evidence of price convergence caused by PI. This may be attributable to non-price strategies that manufacturers are undertaking to combat parallel trade without according unto it any welfare benefits. Finally, there is no detectable relationship between parallel imports and R&D performance within OECD nations, but the data available to check for such a relationship are crude.

The following policy recommendations seem to be supportable and sensible given the foregoing.[72]

1. In order to avoid price spillovers associated with price discrimination, high- income nations could be encouraged to prohibit parallel imports in pharmaceuticals. However, they could permit parallel exports from their markets to poor countries in essential drugs. Such a regime would require negotiating a multilateral agreement.

2. If a desirable regime of differential pricing is to be established, the richer nations cannot use prices in low-income jurisdictions as references for their own price controls. Thus, an agreement not to set reference pricing schemes on the basis of prices in low income economies would be beneficial for maintaining the integrity of the system and for sustaining R&D incentives.

3. Parallel importation by low-income nations should be permitted if they wish in order to avoid problems with high prices charged in low-volume products. These countries also should be permitted to ban parallel exports to high- income economies in order to keep supply available locally.

4. To the extent that high domestic prices in developing countries are caused by exclusive distributorship regulations, such requirements should be eliminated in order to complement the effects of parallel imports.

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[72] Scherer, *supra* note 53.

5. The fact that parallel trade incurs transport costs implies that regional exhaustion regimes among poor countries would be beneficial. In such integrated markets (say in SubSaharan Africa, Central America, the Andean nations, and ASEAN) there would be free parallel trade among the members. The threat of PI within such regions would discipline country-specific monopoly pricing. However, such regional groupings would be expected to prevent parallel exports out of their regions. Thus, having reviewed the theories and evidence available on parallel trade in pharmaceutical products, modified restraints on such trade are in the global interest.

Finally, a very precise and legal means of reconciling the clashing interests of healthcare users and pharmaceutical companies is by facilitating the entry of generic competition after the expiry of a patent. This is one means of potentially bringing down the price of health-care products. Countries can employ a number of intellectual property measures or exceptions, consistent with the TRIPS agreement, to promote rapid market entry of generic products after patents on products expire. One measure of importance is a provision that exists in most countries' legislation, commonly known as the "early working" or Bolar exception, which allows prospective generic producers to make use of a patented product within the patent period for the purposes of obtaining regulatory approval of their product as soon as the patent expires. The "early working" exception constitutes jointly, with parallel imports and compulsory licenses, one of the flexibilities that the TRIPS agreement permits, with an aim to get a balance between private and public interests, as set out in articles 7 and 8 of the agreement.

This policy has been used very successfully in the United States and other jurisdictions to facilitate generic entry as soon as the patent expires. It has recently been introduced in the European Union. In the United States the generic share of the market (by volume of prescriptions) has risen from 19% to over 50% since this legislation was introduced in 1984 as part of the Hatch–Waxman Act.[73] Evidence from the United States shows that, especially where there are several generic producers (and hence competition), this will result in very substantial price declines on patent expiry. But this outcome may depend on the size of the market. In

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[73] World Health Organization CIPIH Report *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

developing countries where markets are small, this mechanism may work less effectively to reduce prices significantly and it needs, hence, to be supplemented by other measures, including those to promote generic competition and regulate prices.

In some countries, companies (both the originator and generic producers) may differentiate their off-patent original or generic products through branding and promotion to obtain higher prices. Whereas consumers may prefer a more expensive brand-name food product to an equivalent and cheaper supermarket own-label, for rational or irrational reasons, there is no reason to purchase a medicine accordingly if both the branded and generic have been properly approved by the health authority for marketing. Several developed countries have introduced policies that allow doctors to prescribe medicines by generic names, or for pharmacists to substitute approved generics for brand-name drugs prescribed by doctors. One answer to this problem is appropriate legislation in relation to prescribing, and the education of pharmacists, doctors and patients in the availability of brand-name and generic products and their pricing.[74]

In summary, countries should provide in national legislation for measures to encourage generic entry on patent expiry, such as the "early working" exception, and more generally policies that support greater competition between generics, whether branded or not, as an effective way to enhance access by improving affordability. Restrictions should not be placed on the use of generic names. Moreover, developing countries should adopt or effectively implement competition policies in order to prevent or remedy anti-competitive practices related to the use of medicinal patents, including the use of pro-competitive measures available under intellectual property law.

III. THE PHILIPPINE EXPERIENCE

A. THE PHARMACEUTICAL INDUSTRY IN THE PHILIPPINES

The Philippines is a developing country with a population of over 90 million as of 2006,[75]making it the 12th most populous country in the world. Roughly two-thirds reside on the island of Luzon. Manila, the

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[74] *Id.*

[75] Philippine Demographics, *available at* http://en.wikipedia.org/wiki/Demographics_of_the_Philippines#statistics.

capital, is the eleventh most populous metropolitan area in the world. Life expectancy is 69.91 years, with 72.28 years for females and 66.44 years for males. Population growth per year is about 1.92%, with 26.3 births per 1,000 people. In the 100 years since the 1903 Census, the population has grown by a factor of eleven. This represents a much faster rate of growth than other countries in the region. Indonesia for instance has only grown by a factor of five.[76] In 2004, the average per capita income in the Philippines was $3.20 per day.[77] About 30 million people of this huge population lived on less than $2 per day in 2005.[78]

According to the latest Philippine Pharmaceuticals and Healthcare Report released by the Business Monitor Index (BMI), the Philippines pharmaceuticals market has posted solid growth in recent years. This was boosted by the strong economic performance in 2006, in which the Philippines recorded the lowest budget deficit in several years.

Drug prices remain a key area of contention, with pharmaceuticals prohibitively expensive for much of the population. Various studies conducted by the Department of Trade and Industry, concerned non-governmental organizations (NGOs) and pharmaceutical groups have shown that drug spending in the Philippines is astonishingly among the highest in Southeast Asia.[79]

Southeast Asia Pharmaceutical Market (in US $ Millions)					
Country	1997	1998	1999	2000	2001
Philippines	1,247	1,012	1,183	1,118	1,062

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] Explanatory Note of House Bill No. 4943: AN ACT TO MAKE THE LAWS ON PATENTS, TRADENAMES AND TRADEMARKS MORE RESPONSIVE TO THE HEALTH CARE NEEDS OF THE FILIPINO PEOPLE BY ALLOWING THE IMPORTATION, EARLY DEVELOPMENT OF PATENTED MEDICINES AND EXCEPTIONS TO THE APPLICATION OF STANDARD COMPULSORY LICENSING REQUIREMENTS FOR DRUGS OR MEDICINES TO LOWER DRUG OR MEDICINE PRICES BY AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

Indonesia	1,156	439	811	986	1,025
Thailand	923	586	743	772	780
Hong Kong	344	374	386	402	425
Malaysia	301	227	269	302	308
Singapore	208	185	217	243	241

These are startling and grossly disproportionate statistics given the weak purchasing power of a considerably large portion of the population. Unfortunately, those in the lower income brackets are the most susceptible to disease and health problems. Norvasc, a medicine for hypertension, priced at P44.75 in the Philippines, sells for the equivalent of P5.00 in India. Bactrim 400 for respiratory tract infection can be purchased at P17.75 per tablet in the Philippines, compared to P1.00 in Pakistan and 69 centavos in India. Moreover, a Ventolin inhaler priced at P406 in local pharmacies may be purchased for only P231 in Bangkok.[80] These are just a few popular drugs cited to illustrate the great disparity in prices to the disadvantage of Philippine consumers.

The government is thus making a concerted effort to bring prices down, with austerities viewed as inevitable by almost all market watchers.[81] The latest plans include expanding the low cost drug program from state procurement agency the Philippine International Trading Corp (PITC), the introduction of Bolar-style reforms to allow the early working of generics, and the possible amendment to House Bill 2139, which would impose patent expiration on the date of 'international' expiry rather than at the end of the end of the local patent's term of validity. As expected, multinational drug-makers - which dominate the market - have fiercely opposed these measures, claiming that they discourage investment by innovator companies. Also, firms argue that parallel imports both violate patent rights and put patients' lives at risk, as the safety and efficacy of these drugs cannot be guaranteed.

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[80] *A Just Cause: Quality Affordable Medicines for All*, Sponsorship Speech of Senator Mar Roxas for. SB No. 2263, August 16, 2006 [hereinafter Roxas Speech].

[81] Philippine Pharmaceuticals and Healthcare Report 2006, Business Monitor Index, *available at* http://www.businessmonitor.com/images/pdfs/pharma/SSPH03-20060101_a.pdf

Another severe problem plaguing the pharmaceutical sector is the presence of fake drugs. This is prevalent among the large low-income population. The authorities have recently pledged to strengthen regulatory and enforcement structures. Measures include giving regulators greater powers to recall product batches and increasing prison sentences for counterfeiters. This problem is basically also an offshoot of the high prices of branded medicines.

B. GOVERNMENT POLICY REGARDING LOWERING THE PRICES OF MEDICINES[82]

The Philippine government has constantly been active in fielding measures to make medicines more affordable to the large lower-income segment of the population. On September 13, 1988, Republic Act 6675, The Generics Act, was approved. This mandated that the generic name of a drug must be displayed prominently above the brand name on drug packaging, and was aimed at encouraging the substitution of generics for brand-name drugs, thereby decreasing drug expenditures. One of the results of this law and its immediate implementation was that the Philippines was placed in the Special 301 Watch List by the United States for three straight years from 1989 to 1991. On April 1992, the Philippines was listed on the Special 301 Priority Watch List. According to the US, the Philippines was remiss in its legal obligations to protect intellectual property under its patent law. The US had a large stake in this, since the major patent holders in the Philippines at that time, and even today, were huge US-based pharmaceutical firms, lead by Pfizer.

The Philippines agreed to increase protection for intellectual property under its patent law as a condition for its removal from the Priority Watch List for 1993, yet the country remained in the list in 1994 and 1995. In 1995, Undersecretary of State Jeffrey E. Garten met with John D. Negroponte, the US Ambassador to the Philippines. He expressed that the US will be monitoring the progress of patent, trademark, and copyright legislation in the Philippine Congress to ensure that legislation would meet the terms of the bilateral agreement it had with the US and TRIPS.

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[82] The facts and events in this section were taken from the report of Jennifer Ellen Mattson on the 1999 Collaboration between the US Government and Pharmaceutical Industry to Oppose Philippine Government Effort to promote expanded Use of Generics for Off-patented Drugs. University of California at Berkely, February 9, 2005, available *at* http://www.cptech.org/ip/health/c/phil/philtimeline.html.

On September 4, 1996, the Philippine Congress approved Republic Act No. 8203, the Special Law on Counterfeit Drugs. This law prohibits the sale and distribution of counterfeit drugs. The definition given for "counterfeit drug" under the law is much broader than the World Health Organization definition of a counterfeit drug as "one which is deliberately and fraudulently mislabeled with respect to identity and/or source." The RA 8203 definition of counterfeit drug includes any "unregistered imported drug product, except drugs brought into the country for personal use as confirmed and justified by accompanying medical records." This later served as a legal obstacle to efforts to import less expensive drugs. Despite these efforts, the US persisted in its concern regarding what they perceived as the lack of progress in terms of the full enforcement of IPR by the government.

The next significant milestone was on June 6, 1997 when the Congress approved Republic Act No. 8293, the Intellectual Property Code. Significant changes made under the law include the following: (1) The law establishes the Intellectual Property Office (IPO) to replace the Bureau of Patents, Trademarks and Technology Transfer. The IPO is assigned the role of approving patents and marks and settling disputes. (2) Penalties for the repetition of patent infringement change. Whereas the old law called for a fine of P10,000 and/or five years of imprisonment, the new law prescribes a payment of P100,000 to P300,000 and/or six months to three years of imprisonment. Also (3) whereas under RA 165, the old IP Law, the importation of a product was not considered to constitute the "working" of that product in the Philippines, Chapter VIII, Section 69(d) of the new code states, "importation of the patented article shall constitute working or using the patent." On January 1, 1998, RA 8293, went into effect.

A year after, Philippine Secretary of Health Alberto Romualdez proposed an administrative order in which the BFAD would accept applications to register only the following pharmaceuticals: unbranded generic products, unbranded "innovator" products of the innovator company, and branded innovator products of the innovator company. In addition, only over-the-counter products and patented innovator products would be allowed to be marketed as branded products after December 31, 2000; all other pharmaceutical products would have to be marketed as unbranded generic products. The proposed AO would in effect prohibit firms from using their trademarks on most pharmaceuticals. On February 16, 1999, the Pharmaceutical Research and Manufacturers of America (PhRMA), an association representing the largest American manufacturers

of pharmaceuticals, submitted its recommendation that the Philippines be listed as a Watch Country on the Special 301 Report. It argued that the administrative order being proposed violated Article 20 of the TRIPS, which states:

> The use of a trademark in the course of trade shall not be unjustly encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.

PhRMA also argued in its recommendation that the proposal violated the Philippine Constitution's due process clause, since the property envisioned in this clause includes all kind of property. The Department of Health tried to comply with what the US required but the State Department remained unsatisfied. This marked a long period in which the US was trying to exercise its influence and use its clout to convince Secretary Romualdez to forego with the administrative order. However, the opposing interests remained at a stalemate. When it seemed that the government had no intention of backing out, the US started applying pressure in different ways. There were even threats to retaliate against Philippine exports and to withdraw concessions under the General System of Preferences (GSP) in case the government would not relent.

The government was not to be bullied so easily this time. The Department of Health announced that the National Health Insurance Program would use the average price of generic versions of a drug for reimbursements in an effort to encourage physicians to prescribe generic drugs, on October 1999. This was followed by another administrative order (AO 42), "Creation and Establishment of the Pharmaceutical Affairs Consultative Committee". This assigned the new committee an agenda, including a review of the proposal to market drugs as generics. It was also around this time that Representative Ernesto Herrera introduced House Bill 8660 to reinforce the Generics Act of 1988, to "emphasize moral obligation of medical and paramedical practitioners" to prescribe generic drugs; and to "ensure the adequate supply of drugs with generic names at the lowest possible cost." In an explanatory note accompanying the bill, Herrera states:

> The World Health Organization identifies the determinants of drug pricing as cost of production, discovery, distribution, and dispensation. These are mostly given factors that we can do nothing about. Yet there are special measures that would lower

> the cost of medicines. These include setting stiffer penalties for non-compliance with generic prescription, multinational corporations' (MNCS) disclosure of selling prices in different countries, liberalization of trade outlets, amending the policy on granting distributorship, amending the provision on patents, and conducting congressional oversight.

Herrera's Bill, HB8660, would introduce penalties for violations of section 6(b) of the Generics Act, which mandates that "all medical, dental, and veterinary practitioners shall write prescriptions using the generic name." It would also amend Section 54 of RA 8293, the Intellectual Property Code, to modify the term of patent of pharmaceutical products to 20 years from the date of application. That section states that "the term of patents shall be 20 years from the filing date of the application." HB 8660 would add to that sentence the conditional clause, "except for pharmaceutical products which (sic) shall be 20 years from the filing date of the application, be it here in the Philippines, or outside of the Philippines. Section 5 of HB 8660 would allow parallel importation of pharmaceutical products by "more than one Philippine importer" or distributor. HB 8660 would also require multinational drug companies "to disclose their drug selling prices in the Philippines vis-à-vis in other countries," and would allow the Department of Health to establish penalties for non-disclosure. This proposed legislation really alerted the US, through the Department of State Medicine. In order to allay the fears of the US, DOH Secretary Romualdez held a briefing with US Embassy officials, in which he reported that pharmaceuticals account for at least 60% of total health care costs in the Philippines, a figure he said is "too high compared to other countries." He stressed, "prices are unreasonable, especially when compared to (those in neighboring countries)." Romualdez said the department would take a variety of actions to bring down the price of pharmaceuticals. First, he said DOH would look into the marketing practices of pharmaceutical firms and physicians' prescription patterns. Second, he disclosed that the government was in the process of discussing with some other countries proposals to source pharmaceuticals and/or raw materials for pharmaceuticals from those countries. Third, the government was also examining ways to "open the market to cheaper imports," mainly through changes to existing law of parallel importation. Fourth, the DOH would revise the insurance reimbursement scheme for pharmaceuticals in order to promote use of generics. Fifth, he noted efforts to reform DOH's procurement system. Finally Romualdez said DOH was preparing enhanced regulatory processes for the inspection and accreditation of pharmaceutical manufacturing

facilities, based on what USFDA does. Basically, the contents of this briefing comprise the extent of government action and define its policy in terms of trying to lower the prices of medicines for consumers.

It was also around this time then House Majority Leader Mar Roxas became deeply involved in the campaign to lower drug prices. This involvement has endured until today, as he is the author of the latest proposed amendments to our laws on patents, which will be discussed later. By the end of 1999, he announced that he would launch an inquiry into high prices for medicine, which he attributed to "the pharmaceutical industry's dependence on marketing, advertising and promotions as a tool to ensure steady sales." At that time he argued that the "huge budget set aside by medical companies for the purpose of luring physicians into prescribing their drugs defeats the objectives and mission of the Generic Drugs Act." He suggested a parallel importation system, floating the idea of creating a government entity to import and distribute certain pharmaceuticals, citing Thailand as an example. This was meant to achieve what the Generics Act of 1988 had failed to do – reducing the cost of pharmaceuticals and the "market dominance" of the multinational pharmaceutical companies. As of the start of the new millennium, the prices remained unreasonably high, while the industry's profits were unjustifiably high. The number of registered brand-name drugs had increased dramatically and the share of the local market held by multinational pharmaceutical companies has remained constant. Some experts blamed transfer pricing, distribution and retail mark-ups, and marketing expenses as the prime reasons behind the alleged high pharmaceutical prices. The high prices of these branded drugs led generic producers to set prices for their drugs at levels just below those of branded competitors. President Estrada was quite public of his support for this government campaign, to the chagrin of US officials who trivialized the efforts by characterizing them as merely a way to restore the recent drop in Estrada's popularity by pitting "greedy foreign companies" against the masses. The US pegged this as a politicized issue. The US Embassy was quite vocal about their opposition to the government actions and constantly tried to engage the administration in dialogues aimed at putting the pressure on.

Mar Roxas was appointed as the Secretary of the Department of Trade and Industry in 2000. Together with Secretary Romualdez, he pursued the agenda of lowering drug prices. It was around this time that public hearings were already being conducted on proposed legislation to allow parallel importation. One means of achieving this would be the

deletion of the following sentence from the Counterfeit Drug Act: "If the unregistered imported drug product has a registered counterpart brand in the Philippines, their product shall be considered counterfeit." The US then became even more aggressive in their efforts to impede the implementation of any such policy. This time, even the American Chamber of Commerce was involved, and exerted pressure on US government officials to do something.

In spite of the strong opposition, the Department of Health was still able to issue Administrative Order 85 (series 2000). The DOH, through this, determined that "(a) key strategy to lower drug prices is the importation of finished drug products from other countries where these are cheaper than in the Philippines. One component of this strategy is the parallel importation scheme where a similarly branded product that is cheaper in other countries will be imported and introduced in the local market. These imported products will be registered in the BFAD before these are sold to the public."[83] It was through this initiative that the National Government commenced parallel drug importation as early as the year 2000, as a viable and legal option to bring in lower priced drugs from other countries to counter the prohibitive effects of transfer pricing. By means of this, the importation of generic pharmaceuticals from countries such as India is now allowed in the Philippines. As a result of this from 2002 to 2004 the Philippines International Trading Corporation (PITC) succeeded in importing low-costs drugs from India to an amount of about USD 535,000 and they are now planning to import lower-cost patented drugs from China.[84]

The parallel importation program for pharmaceuticals is one of the Government's progressive initiatives in the public health sector designed to benefit the majority of our population. It gives flesh to Article XIII, Section 11 of the 1987 Constitution, which provides that: "The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health, and other social services available

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[83] Administrative Order No. 85, Series of 2000 issued by the Department of Health, entitled "Registration Requirements for a Government Agency Importing a Pharmaceutical Product with a Registered Counterpart Brand in the Philippines."

[84] *Philippine Focus: Parallel Imports and Generic Drugs in the Philippines*, January 13, 2006, *available at* http://www.mirandah.com/news/?id=122.

to all the people at affordable cost."[85] Thereafter, the parallel importation program was specifically identified in the Medium Term Philippine Development Plan for 2005-2010 as one of the schemes to reduce by half the cost of medicines. Goal 3 (Improved Accessibility and Affordability of Essential Services) of the MTPDP for 2005-2010 states that one of the main goals of the Government is to "reduce by half the cost of medicines through increased and improved distribution, importation through the Philippine International Trading Corporation (PITC) and local sourcing, partnership with the pharmaceutical industry, resolution of patent issues, increased use of generic products, community based initiatives..."[86] Through the parallel importation program, Government aims to reduce by substantial amounts the price of essential and vital medicines and drugs, thereby placing them within reach of the majority of Filipinos who cannot afford these medicines due to their prohibitive costs.

The persistent opposition from the US and from the major drug manufacturers however, has succeeded in stalling the implementation of most government measures particularly in the legislative realm. Until today, not much of what was initiated at that time has been achieved, despite the foundations having been laid down. Of course, the abrupt change in administrations and the different political, social, and economic concerns that have faced the country since have relegated the policy issue regarding pharmaceuticals to the background. Yet a resurfacing took place between 2005 and 2006. With pending bills to improve legislation and finally liberalize policies on parallel importation, and the still unresolved Norvasc case between Pfizer and the Philippine government, the problem of high drug prices has again found its way to the forefront of things. As mentioned earlier, the government now is on a renewed and pro-active campaign to lower drug prices.

C. APPLICABLE LAWS ON PATENTS AND PARALLEL IMPORTATION

The most pertinent Philippine Statute today on the issues of parallel importation and patent protection is Republic Act No. 8293, the Intellectual Property Code of the Philippines (IPC), which took effect on

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[85] Pfizer Ltd. (UK) and Pfizer, Inc. (Philippines) v. PITC, BFAD Director Leticia Barbara B.Gutierrez, BFAD LICD Officer-in-Charge Emilio L. Polig, Jr. and BFAD, Civil Case No. 06-172, ANSWER with Compulsory Counterclaim, par.29.

[86] Pfizer et al. v. PITC et al, Civil Case No. 06-172, ANSWER with Compulsory Counterclaim, par.30.

January 1, 1998. Most of the provisions of this code were lifted from the TRIPS, since this piece of legislation was passed in pursuance to it.

Under the present state of our law, patent owners oppose parallel importation citing Section 71 of the IPC, which secures to the patentee the right to exclude anyone from making, using, selling or *importing* patented products.[87] By means of this provision, the code conferred on the patent-holder the exclusive right of importation, over and above the basic rights of making, using and selling, all of which the old law conferred. Now, even with this provision, parallel importation would still be made possible if, by means of the flexibilities allowed by Article 6 of TRIPS and the Doha Declaration regarding exhaustion policies, the Philippines adopted a policy of international exhaustion. This is not the case though, since the Philippines follows a policy of national exhaustion. This effectively serves to prohibit parallel importation in the country. Section 72.1 of the IPC expresses that the owner of a patent has no right to prevent third parties from performing the rights conferred by patent, without his authorization, in the following circumstances: "Using a patented product which has been put in the market in the Philippines by the owner of the product or with his express consent, insofar as such use is performed after the product has been so put in the said market."

In addition, Section 95 of the IPC provides very restrictive rules on compulsory licensing and Section 101 of the IPC gives the patentee the power to move for the cancellation of the compulsory licenses upon showing of new facts and circumstances justifying such action. Lastly, patent owners argue that parallel importation violates the trade name and trademark protection clause in the IPC. Hence, in spite of all the flexibilities and safeguards granted by international agreements, the Philippine legal framework can be described as more protective of IPR holder rights. This is incongruous given that in the negotiations concerning TRIPS and the Doha Declaration, the developing nations were those who actively fought for

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[87] Explanatory Note of House Bill No. 4943: AN ACT TO MAKE THE LAWS ON PATENTS, TRADENAMES AND TRADEMARKS MORE RESPONSIVE TO THE HEALTH CARE NEEDS OF THE FILIPINO PEOPLE BY ALLOWING THE IMPORTATION, EARLY DEVELOPMENT OF PATENTED MEDICINES AND EXCEPTIONS TO THE APPLICATION OF STANDARD COMPULSORY LICENSING REQUIREMENTS FOR DRUGS OR MEDICINES TO LOWER DRUG OR MEDICINE PRICES BY AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

these concessions. What is even more ironic is the peculiar state of the healthcare system in the Philippines, characterized by some of the highest drug prices among developing nations.

One, however, does not even have to go beyond the legal structure to see the paradoxical situation surrounding Philippine laws and policies today. It should be noted that the exercise of the patentee's exclusive rights is subject to and must be correlated with the public interest exceptions under Section 74[88] in favor of the Government or any third person authorized by the Government in the circumstances enumerated there under. The public interest consideration under Section 74, particularly as the same relates to public health, is of primordial importance especially as this echoes the constitutional mandate for the State to protect the health of the people (Sec. 15, Art. II, 1987 Constitution) and to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost (Sec. 11, Art. XIII, 1987 Constitution). Clearly, there are gaps that have to be filled and inconsistencies that have to be corrected.

IV. THE NORVASC CASE

A. FACTS OF THE CASE

The Philippine government's attempt to expedite the registration of generic drugs in the Philippines has been challenged by the American-based pharmaceutical firm, Pfizer, Inc which has sued Philippine Government-owned company, the Philippines International Trading Corporation (PITC) and the Bureau of Food and Drugs (BFAD) for having imported and registered a patented anti-hypertensive medicine.

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[88] "Sec. 74. Use of Invention by Government—

74.1. A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:

(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires, or

(b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his license, is anti-competitive.

xxx"

The product in question is *amlodipine besylate*, which in the United States, known as Norvasc. The equivalent product in India, Amlogard is available at a much cheaper price.

In this matter Pfizer Ltd. UK and Pfizer, Inc. Philippines filed a case in the Philippines Regional Trial Court , Makati City Branch against the PITC, BFAD and two employees at the BFAD for having imported 200 Amlogard tables from India for the purposes of submitting them for BFAD registration, as registration was required even if the drugs were not intended to be sold until the expiry of the Pfizer patent.

The BFAD then approved the drug in the form of parallel import drug registration. The PITC claimed that it informed Pfizer that they do not intend to manufacture the drug, but to begin the process of registering the equivalent product, so it can promptly enter the market when Pfizer's patent expires. (The PITC is the sole entity authorized by the Department of Health to conduct parallel importation on drugs.)

The allegations of ultimate facts found in the complaint filed by Pfizer stated that:

> ***Allegations Common to All Causes of Action***
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> 7. Pfizer UK is the registered owner of the invention called *"Improvements in Pharmaceutically Acceptable Salts of Amlodipine,"* evidenced by Philippine Letters Patent No. 24348 issued on 13 June 1990 by the Intellectual Property Office (IPO). Pursuant to R.A. No. 165, the law then in force, Pfizer UK's product is valid for 17 years, or until 13 June 2007.
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> 8. Generally, the invention relates to the *besylate* salt of *amlodipine* for use in treating ischaemic heart disease, especially angina, or hypertension, in a human being. The invention arose out of a discovery that amlodipine was best administered in the form of a salt of a pharmaceutically acceptable acid, which must satisfy four physiochemical criteria: (a) good solubility; (b) good stability; (c) non-hygroscopocity; and (d) processability for tablet formulation. Based on various rigid tests, the besylate salt showed a unique combination of the foregoing, thereby making it

outstandingly suitable for the preparation of pharmaceutical formulations of *amlodipine.*

9. Amlodipine besylate is a revolutionary pharmaceutical preparation for the treatment of hypertension, which works by slowing down the flow of calcium through muscle cells found in the walls of blood vessels. Since calcium is required for muscles to contract, blood vessels dilate and relax, thereby allowing blood to flow more easily through the body.

10. Since *amlodipine besylate* first became available in 1990, plaintiffs and their worldwide affiliates have exclusively used the same generally under the brand name ***Norvasc,*** which has helped many people around the world improve their lives. Since its launch, the efficacy and safety of *amlodipine besylate* have been studied in over 800 clinical trials involving at least 400,000 patients, thereby fortifying the drug's innovative and ground-breaking effects.

11. The Philippines and the United Kingdom are parties-signatories to the Paris Convention for the Protection of Industrial Property (Paris Convention), the Patent Cooperation Treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the Word Trade Organization (WTO) and are members of the WTO and the World Intellectual Property Organization, which were all intended, *inter alia,* for the protection of industrial property.

12. Pfizer UK brings the instant action pursuant to Section 2, Article II of the Philippine Constitution, which provides that the Philippines adopts, among others, the generally accepted principles of international law as part of the law of the land and adheres to the policy of peace, equality, justice, freedom, cooperation, and unity with all nations. Furthermore, Section 3 of Republic Act No. 8293, otherwise known as the "Intellectual Property Code of the Philippines" (IPC), grants a right in favor of Pfizer UK to seek redress before Philippine courts insofar as it states that:

> *International Conventions and Reciprocity* – Any person who is a national or who is domiciled or has a real and effective industrial establishment in a country which is a party to any convention, treaty or agreement relating to intellectual property rights or the repression of unfair competition, to which the Philippines is also a party, or extend reciprocal rights to nationals of the Philippines by law, shall be entitled to benefit to the extent necessary to give effect to any provision of such convention, treaty or reciprocal law, in addition to the rights to which any owner of an intellectual property right is otherwise entitled by this act.

13. Pfizer Phils. is the exclusive licensee of Pfizer UK to import, market, distribute and sell various Pfizer products in the Philippines, particularly *amlodipine besylate,* under the brand name Norvasc. By virtue of Certificates of Product Registration (CPR) Nos. YZ-015552 and YZ-016930 issued by BFAD, Pfizer Phils.' *amlodipine besylate, (Norvasc)* is marketed and sold in the Philippines in 5 and 10 mg. tablet forms. Pfizer Phils. has been promoting *amlodipine besylate* in the Philippines since 1991, and has been distributing the same through the Zuellig Pharma Corporation.

14. On 21 September 2005, Pfizer Phils.' Medical and Regulatory Affairs Division discovered, through the BFAD website, that an application for product registration was filed by the PITC for *amlodipine besylate,* using the brand name *Norvasc.* In an attempt to forestall any infringement of Pfizer UK's patent, Pfizer Phils. immediately wrote a letter dated 21 September 2005 to PITC, informing the latter that the *amlodipine besylate* pharmaceutical compound is covered under Letters Patent No. 24348; hence, PITC's application for product registration of *amlodipine besylate* with the BFAD constitutes patent infringement.

15. PTIC replied through a letter dated 26 September 2005, denying such allegations. Through a letter dated 6 October 2005, Pfizer Phils. reiterated its demand for PITC to immediately withdraw its BFAD application for

product registration. Pfizer Phils.' letter however, went unheeded.

16. Director Gutierrez and Atty. Polig, as Officer-In-Charge of the LICD, were well apprised of the ensuing dispute between Pfizer Phils. and PTIC concerning the right to use *amlodipine besylate* under the *Norvasc* brand, inasmuch as copies of the foregoing letters were vigilantly furnished them. Director Gutierrez is the highest-ranking officer tasked to provide overall management, direction, supervision and control over BFAD. The key functions of BFAD LICD include rendering legal advice in the enforcement of relevant laws and regulations and preparing recommendations, resolutions and other administrative issuances pertaining to drug regulation. Notwithstanding such duties, Director Gutierrez and Atty. Polig did not offer any reply, comment or explanation, written or otherwise.

17. Instead, upon information, BFAD Director Gutierrez granted PITC's application for product registration, by issuing Parallel Import Drug Registration (PIDR) Nos. 2141 (for 5 mg. tablets) and 2140 (for 10 mg. tablets), effective 8 December 2005 until 30 December 2010.

18. In a meeting held on 11 January 2006, PITC assured Pfizer Phils. that a written response from the Office of the Government Corporate Counsel (OGCC) will be forthcoming by 13 January 2006, and that the same would comprise an undertaking on PITC's part not to import, sell, market or otherwise, distribute *amlodipine besylate* products until after the patent thereon has expired.

19. In a letter dated 17 January 2006, Pfizer UK and Pfizer Phils., through undersigned counsel, sent a final demand to PITC to (1) desist from utilizing the CPR's (PIDRs) for whatever purpose, including the importation and distribution of *amlodipine besylate* during the effectivity of Pfizer UK's patent; and (2) execute an undertaking to such effect and to surrender the foregoing CPRs (PIDRs) to the BFAD; otherwise, a patent infringement case will be filed against PITC. BFAD Director Gutierrez was furnished a copy of this letter.

> 20. In a letter dated 24 January 2006, PITC simply informed undersigned counsel that it has referred the matter to the OGCC "for review/study and appropriate action/reply." In a letter dated 7 February 2006, the OGCC insisted that there was no infringement of Pfizer UK's patent. Although the OGCC said that PITC would "respect" plaintiffs' intellectual property rights, it refused to have PITC execute the requested undertaking.
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> 21. In a letter dated 19 January 2006, Pfizer Phils. implored BFAD Director Gutierrez to take appropriate action in invalidating the issuance of CPRs (PIDRs) in favor of PITC, considering the far reaching legal and other implications thereof on the level of protection accorded to intellectual property rights in the Philippines. BFAD Director Gutierrez, however, merely ignored Pfizer Phils.' concerns.
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> 22. All in all, PITC, Director Gutierrez and Atty. Polig of the BFAD were all clearly apprised of the infringement of Pfizer UK's patent over *amlodipine besylate*, which plaintiffs vigilantly intend to protect. PITC, Director Gutierrez and Atty. Polig of the BFAD, however, unjustly and wantonly disregarded plaintiff's valid and lawful demands."[89]

In the Answer filed by defendants BFAD, Director Leticia Barbara B. Gutierrez, and Atty. Emilio L. Polig, Jr., they denied the allegations in paragraphs 8, 9, and 10 of the Complaint, as set forth above, for lack of knowledge or information sufficient to form a belief as to the truth thereof.[90] They also denied the allegation in paragraph 17 set forth above, insofar as it is made to appear that Director Gutierrez allowed defendant PITC to import *amlodipine* (as besylate) for 5 and 10 mg tablets effective December 8, 2005 to December 30, 2010. In truth, what defendant BFAD issued to defendant PITC were two Certificates of Product Registration (CPRs) for amlodipine (as besylate) 5 and 10 mg tablets to confirm that the products or tablets submitted for laboratory testing have "been found to conform with the requirements and standards for registration of pharmaceutical products per existing regulations in force as of date."[91] Most

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[89] Pfizer et al. v. PITC et al, Civil Case No. 06-172, COMPLAINT.
[90] *Id.*, ANSWER, par III.
[91] *Id.*, ANSWER, par X.

of all, they deny the allegations in paragraph 22 of the Complaint that there has been an infringement of plaintiff Pfizer (UK)'s patent over *amlodipine besylate* and that Director Gutierrez and Atty. Polig, Jr. unjustly and wantonly disregarded plaintiff's valid and lawful demands for being baseless, self-serving and for reasons stated under the special and affirmative defenses they raised.[92]

As for defendant Philippine International Trading Corporation (PTIC), in its Answer, it denied the allegations contained in paragraphs 8, 9, 10, 12, 13, and 21 for lack of knowledge or information sufficient to form a belief as to the truth or falsity thereof.[93] It also denied the allegations contained in paragraph 22 insofar as it stated that PTIC unjustly and wantonly disregarded the plaintiff's demand for an undertaking not to import, sell, distribute and market Norvasc before the patent expiration in 13 June 2007.[94]

B. THE PARTIES AND THEIR RESPECTIVE ARGUMENTS

The plaintiff in this pending case is Pfizer Limited or Pfizer UK, a foreign corporation duly organized and existing under the laws of the United Kingdom. It does not do business in the Philippines and does not maintain any office in this country. Pfizer Philippines, the other plaintiff, is a Philippine corporation, with its main office along Ayala Avenue, Makati City.

Defendant PTIC is a government-owned international trading corporation primarily tasked to export, import, and market a wide range of commodities, industrial products, and consumer goods. Executive Order No. 442 issued by President Gloria Macapagal-Arroyo, designated PITC as the lead coordinating agency to make quality medicines available, affordable, and accessible to the greater masses of Filipinos. Defendant BFAD is a government regulatory agency under the Department of Health, created pursuant to Executive Order No. 851. Its current director, Leticia Barbara B. Gutierrez, and its Officer-In-Charge of the Legal, Information and Compliance Division, Atty. Emilio L. Polig, Jr., are both defendants as well.

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[92] *Id.*, ANSWER, par. XIII.
[93] *Id.*, ANSWER, par. 6.
[94] *Id.*, ANSWER, par. 8.

Causes of Action

The plaintiffs' main cause of action against the defendants is patent infringement. Plaintiffs based this cause of action on Section 71.1 of the IPC, which echoing Section 28 of the TRIPS, provides:

> (a) Where the subject matter of the patent is a product, to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling, or importing that product; and
>
> (b) Where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.

As a consequence of these rights, Section 76.1 of the IPC authorizes the filing of a civil action for infringement:

> Civil Action for Infringement – The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement.

According to the plaintiffs, an individual or entity with a certificate of patent issued by the IPO has the exclusive right to make, use and sell the patented machine, article or product for the purpose of industry or commerce, throughout the territory of the Philippines for the term of the patent, and such making, using, or selling by any person without authorization of the patentee shall constitute infringement of its patent.[95]

As to respondent PTIC, the plaintiffs argue that its use of amlodipine besylate, without the knowledge, authority, or consent of the patent owner, makes it liable for patent infringement under Section 76.1. In support of this, plaintiffs cited AO No. 85, series of 2000, issued by the Department of Health that prescribes the registration requirements for a

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[95] Del Rosario v. Court of Appeals, 225 SCRA 152, 163 (1996).

government agency importing a pharmaceutical product with a registered counterpart brand in the Philippines.[96] This includes the submission of commercial samples and "full laboratory testing by BFAD of every batch/lot number of product per importation." They then went on to say that the submission of commercial samples in support of PITC's BFAD application necessitates the actual use and importation of the patented product, without sufficient authority. Furthermore, the performance of experiments for a commercial purpose constitutes the act of "using" Pfizer UK's amlodipine besylate without authority from the patent holder and is, thus, a clear act of patent infringement. A patent is infringed when the essential or substantial features of the patented invention are taken or appropriated, or the device, machine, or other subject matter alleged to infringe is substantially identical with the patented invention.[97]

Against the BFAD, the plaintiffs allege Inducement of Patent infringement. Apart from direct infringement, Section 76.6 of the IPC also proscribes the inducement of patent infringement by making such individual or entity jointly and severally liable with the infringer, thus:

> Anyone who actively induces the infringement of a patent or provides the infringer with a component of a patented product or of a product produced because of a patented process knowing it to be especially adopted for infringing the patented invention and not suitable for substantial non-infringing use shall be liable as a contributory infringer and shall be jointly and severally liable with the infringer.

According to the plaintiffs, by allowing the submission of samples of, conducting experimentation on, and issuing the PIDRs in favor of PITC for amlodipine besylate, despite having full knowledge of Pfizer UK's valid and existing patent thereon, BFAD Director Gutierrez and Atty. Polig committed ultra vires acts, outside the scope of their BFAD duties, insofar as they actually induced and facilitated PITC's infringement of the subject patent. The PIDRs do not in any way indicate that such may only be used as authority for market distribution upon the expiration of the patented compound. On the strength of the BFAD's PIDRs alone, PITC can immediately proceed to import, market, sell and distribute Pfizer UK's amlodipine besylate. By having issued the PIDRs erroneously, if not

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[96] Pfizer et al. v. PITC et al, Civil Case No. 06-172, COMPLAINT, par. 26.

[97] *Id.*, COMPLAINT, par. 27.

unlawfully, in PITC's favor, respondent BFAD officials induced the infringement of the patent.

In addition, plaintiffs also had causes of action for injunction and damages against the different respondents. The reliefs prayed for by plaintiffs include a writ of preliminary injunction enjoining PITC from making, using or offering for sale or distribution *amlodipine besylate* products to various hospitals or drugstores, or to any other individual or entity in the Philippines, or from otherwise infringing the patent; a writ of preliminary injunction enjoining BFAD and its officers from entertaining the applications for product registration for *amlodipine besylate*, covered by the patent, at least until it expires; and a writ of preliminary mandatory injunction directing BFAD and its officers to recall, cancel or otherwise invalidate Parallel Import Drug registration Nos. 2141 and 2140 issued in favor of PITC, or any other similar authority for importation, market distribution or sale of the patented medicine in the Philippines. It also prayed for nominal and exemplary damages, and the condemnation, seizure or forfeiture of PITC's infringing goods or products, wherever they may be found, including the materials and implements used in the patent infringement.[98]

Special and Affirmative Defenses

The BFAD set forth the following defenses in its answer:

1. It is the Constitutional mandate of the government to make essential and life-saving pharmaceutical products available to the people at affordable cost.
2. It has the duty to evaluate all applications for registration of pharmaceutical products with regard their safety, quality and efficacy.
3. The acceptance of the application for registration of a pharmaceutical product and the subsequent issuance of the certificate of product registration (CPR) do not bestow legal right or title over any intellectual property attached to the pharmaceutical product.
4. Republic Act No. 8293 has provided for limitations on patent rights.

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[98] *Id.*, COMPLAINT.

5. The issuance of an injunctive writ will cause far greater and irreparable injury to the government as compared to the degree of benefit to plaintiffs.

The third and fourth are the most relevant to the subject matter of this paper, thus, the discussion in support of them as found in the answers, shall be set out in full:

Third Defense

XXXIII

> A drug's patent status and its registration status are two (2) distinct matters. Its registration has nothing to do with its patent or any issue relating thereto. The registration of a pharmaceutical product is specifically concerned with the determination of the product's safety, quality and efficacy for use by the public. It does not involve any legal right or title over any intellectual property attached to the pharmaceutical product.

XXXIV

> Thus, Article III on General Guidelines of A.O. 2005-0001 explicitly provides:
>
> > The acceptance of CPR applications by BFAD shall not be interpreter, nor construed, as an approval, endorsement, or representation that the applicant has legal right or title over any intellectual property attached to the pharmaceutical product applied for. (emphasis supplied)

XXXV

> Moreover, the CPR, which is issued by the defendant BFAD after a particular pharmaceutical product subject for registration has passed an evaluation as to its purity, safety, quality and efficacy in accordance with existing rules on product registration contains a special condition indicative of the defendants' recognition of patent rights, viz:

> **Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by BFAD, that Registrant has the right or privilege to the use of the name or brand registered;** Registrant hereby agree and affirm to indemnify and/or hold BFAD free and harmless against any and all third party claims on infringement of patent, trademark or intellectual property rights arising from the registration of the product(s) listed on the other side hereof. (emphasis supplied)

XXXVI

Indeed, defendant BFAD has neither the legal authority nor competence to rule on the issue of patent infringement relative to or in connection with an application filed with it for registration. To reiterate3, defendant BFAD's mandate, as far as drugs are concerned, is specific and limited only to the determination of their quality, safety and efficacy. Other issues not germane to its mandate like patent, patent infringement or copyright are outside the ambit of its jurisdiction. To this, Article I on Rationale of A. O. 2005-001 echoes:

> x x x It is clear, however, from the 1978 Constitution and the aforementioned laws, rules and regulations that the Department, through **the Bureau of Food and Drugs (BFAD), is mandated only to ensure the safety, efficacy and good quality of pharmaceutical products applied for registration. It has no mandate at all to pass upon intellectual property matters since it does not have the legal authority, resources and competence to do so.**
>
> Meanwhile, pursuant to Republic Act No. 8293, otherwise known as the Intellectual

> Property Code of the Philippines, **issues pertaining to intellectual property rights, particularly patent rights, trademarks, trade names, copyrights, and unfair competition are properly lodged with either the Intellectual Property Office (IPO) or a court of law with competent jurisdiction on the subject matters.**[99] (emphasis supplied)

Fourth Defense

XXXVII

R. A. 8293 has provided for exemptions to the exclusive right of a patent owner. Thus:

> SEC 72. Limitations of patent rights. – The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to Section 71 hereof in the following circumstances:
>
> x x x
>
> 72.2 Where the act is done privately and on a non-commercial scale or for a non-commercial purpose; Provided, That it does not significantly prejudice the economic interest of the owner of the patent.
>
> 72.3 Where the act consists of making or using exclusively for the purpose of experiments that relate to the matter of the patent invention. (emphasis supplied)

XXXVIII

Surely, plaintiff Pfizer Ltd.(UK) is without any right to prevent defendant PITC from submitting an application for product registration of *amlodipine besylate Norvasc* 5 and 10 mg

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[99] *Id.*, ANSWER.

tablets as the same was done privately and for a non-commercial purpose. Also, the submission did not in any way prejudice, much less significantly, the economic interests of Pfizer Ltd. (UK). To stress, only 40 tablets each of *Norvasc* 5 mg tablet and *Norvasc* 10 mg tablet were submitted to the defendant BFAD. These representative samples were sourced from duly accredited distributors of *Norvasc* 5 and 10 mg tablets in Pakistan.

XXXIX

Besides, the application for the product registration and the corresponding submission of the samples was for the exclusive purpose of conducting an experiment that relate to the subject matter of patent invention. As stated above, the samples of *Norvasc* 5 and10 mg tablets were submitted to defendant BFAD to verify their quality, safety and efficacy. Again, this act falls under one of the limitations of patent rights as provided under Section 72.3 of R. A. 8293.

XL

Lastly, as decreed under Section 74 of R. A. 8293, a government agency or third person authorized by the Government may exploit the invention even without the agreement of the patent owner where public interest, in particular, national security, nutrition, health or development of other sectors, as determined by the appropriate agency of the government, so requires.[100]

PITC on the other hand, forwarded the following defenses in its separate answer:

1. It is allowed under the IPC to import few samples of patented drugs for testing/experimentation purposes, to determine whether the drugs meet the BFAD standards.
2. It is authorized to initiate steps to ascertain proper sourcing of essential but low-priced drugs.

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[100] *Id.*

3. The plaintiff Pfizer Phils. failed to state a cause of action, since it did not allege any act or omission on the part of the Defendants which could show that its rights as exclusive distributor have been violated. Neither did it allege that it is a co-owner of the patent, with Pfizer UK.
4. The issuance of TRO's and/or writs of preliminary injunction will cause far greater and irreparable harm to PITC and the government parallel importation program, as compared to the degree of benefit to Plaintiffs by the issuance thereof.

PITC then included a compulsory counterclaim for damages and attorney's fees totaling P1,500,000.00. The specific paragraphs in support of the first defense, as found in the answer, are hereunder set forth.

> 10. In September 2005, curious about the Pfizer-made Norvasc from Pakistan and delighted about the possibility of finding a solution to the woes of millions of hypertensive Filipinos who can ill afford the Norvasc sold by Pfizer, Inc. in the Philippines, PITC caused the delivery to the Philippines of forty (40) pieces of the Pfizer-made Norvasc 5mg. tablets and forty pieces of the Pfizer-made Norvasc 10 mg. tablets ultimately sourced from UDL Distribution (PVT)Ltd. (a duly authorized distributor in Pakistan of the range of products of Pfizer Laboratories Ltd. [Pakistan]).
>
> 11. Shortly thereafter, or sometime in September 2005, PITC filed an application with the BFAD for the registration on the Pfizer-made pharmaceutical products (amlodipine besylate) Norvasc 5 mg. tablet and (amlodipine besylate) Norvasc 10 mg. tablet sourced from Pakistan, for the purpose of the having the above mentioned samples tested or experimented on to determine whether the Pakistan sourced samples of Norvasc 5 mg. tablet and Norvasc 10 mg. tablet meet (or perhaps exceed)the standards of BFAD in terms of quality, safety, and efficacy.
>
> 12. It bears stressing that, for several years since the year 2000,PITC has been applying with BFAD for the registration of various other expensive drugs, medicines and pharmaceutical compounds sourced from other countries. In the course of these applications and subsequent registrations, PITC has come to learn and ascertain that the testing/or

experimentation on the submitted samples are done in an exhaustive and stringent manner within BFAD-controlled premises and the results are sent to PITC directly.

13. On 08 December 2005,BFAD, through Director Leticia Barbara Gutierrez, approved PITC's application for product registration of (amlodipine besylate) Norvasc 5 mg. tablet and (amlodipine besylate) Norvasc 10 mg. tablet, which is effective from08 December 2005 to 30 December 2010.

14. PITC is well aware that the product amlodipine besylate is covered by an existing patent registered under Pfizer UK that is to expire by 13 June 2007, but is not unmindful of the rights conferred by law on the holder of a valid and subsisting patent. As a matter of policy, all medicines and drugs actually imported by PITC for distribution in the Philippines are not covered by any existing patent. Consequently, PITC, directly and through counsel, repeatedly and consistently undertook to respect the patent rights of Pfizer UK.

15. In fact, through a letter dated 26 January 2006 and addressed to BFAD Director Leticia Barbara B. Gutierrez, PITC President Roberto M. Pagdanganan expressly manifested the said position of PITC that the latter will not "import, distribute or sell Norvasc".

16. Likewise in a letter dated 07 February 2006, the Office of the Government Counsel, PITC's statutory legal counsel, made a formal and categorical assurance to counsel Pfizer, Inc. that since the issuance of Certificate of Product Registration over the subject product ([amlodipine besylate] Norvasc 5 mg. tablet and [amlodipine besylate] Norvasc 10mg. tablet), PITC has not imported nor distributed Norvasc in the Philippines and firmly intends to respect the subsisting patent rights of Pfizer UK and Pfizer, Inc.

17. Thus, PITC at this point in time has not imported, distributed or sold Norvasc 5 mg. tablet and Norvasc 10 mg. tablet, and it has not firmed up any plan to do so until the expiration of the patent on 13 June 2007.

18. Therefore, in the light of the foregoing, PITC categorically denies that PITC's mere application for product registration and the subsequent issuance by BFAD of a Certificate of Product Registration for (amlodipine besylate) Norvasc 5 mg. tablet and (amlodipine besylate) Norvasc 10 mg. tablet in PITC's favor by itself amounts to making, using, offering for sale, selling or importing the said product and thus cannot be deemed an infringement of Pfizer's patent rights or a violation of Section 71of Republic Act No. 8293, otherwise known as the Intellectual Property Code.

19. At any rate, the owner of the patent, Pfizer UK, has no right to prevent PITC from proceeding with the application for product registration of (amlodipine besylate) Norvasc 5 mg. tablet and (amlodipine besylate) Norvasc 10 mg. tablet as the application is an act done privately and on a non-commercial scale or for a non-commercial purpose, and neither does it significantly prejudice the economic interests of Pfizer UK.

Section 72.2 of the Intellectual Property Code states that:

> Section 72.2. Limitations of patent rights. – the owner of the patent has no right to prevent third parties from performing, without his authorization, the acts referred to in section 71 hereof in the following circumstances:
>
> xxx
>
> 72.2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose; *Provided*, that it does not significantly prejudice the economic interests of the owner of the patent.
>
> xxx

20. The act of importing representative samples (amlodipine besylate) Norvasc 5 mg. tablet and (amlodipine besylate) Norvasc 10 mg. tablet by PITC from and submitting to BFAD for analysis was done privately and not on a

> commercial level. Neither were the samples intended for commercial use. To reiterate, only 40 tablets each of Norvasc 5 mg. tablet and Norvasc 10 mg. tablet were submitted to BFAD. These representative samples were ultimately sourced from duly accredited distributors of Norvasc 5 mg. and Norvasc 10 mg. tablet in Pakistan.
>
> 21. Further, the act of applying for product registration and submitting samples in the process thereof by PITC consists of making or using exclusively for the purpose of experiments that relate to the subject matter of the patented invention. As stated above, the samples of Norvasc 5 mg. tablet and Norvasc 10 mg. tablet were submitted to BFAD to verify their quality, safety and efficacy. Again, this act falls under the limitations of patent rights as provided under Section 72.3 of the Intellectual Property Code.
>
> 22. Lastly, as authorized by Section 74 of the Intellectual Property Code, a Government agency or third person authorized by the Government may exploit the invention even without the agreement of the patent owner where the public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires."[101]

C. Legal Issues

From the set of facts and allegations culled from the actual pleadings filed, the basic legal issue is really whether or not the defendants are guilty of infringing the Pfizer patent over Norvasc. It therefore has to be determined whether the elements of patent infringement are present, and given the special defenses raised, whether or not the "early working" or Bolar exception is applicable in the Philippine jurisdiction, so as to exempt the acts of the government in this instance.

Pfizer holds a Philippines patent on Norvasc, which expires in June 2007. The Pfizer prices for Norvasc vary by country. Pfizer charges different prices in the Philippines than they do in India. In the Philippines, the prices are $.87 per day for the 5 mg version, and $1.46 per day for the 10 mg dose. In India, the prices are $.12 and $.18 per day, for the same

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[101] *Id.*

doses of the same drug made by the same company.[102] For the vast majority of people who live in the Philippines, this is not affordable. The World Bank reports that the Philippines has a per capita income of $1,170 per year. This is of course an average. Many earn much less. About 20 percent of the population earns less than $400 per year. A handful of Philippine residents earn more. The top 10 percent have an average per capita income of $4,247.[103] It is obvious that given this context, Pfizer is employing the profit maximizing strategy of selling to the economic elite at high prices. Their target market is really only the wealthiest Philippine resident.

> Last year, Pfizer sold P1.2-billion worth of Norvasc, corresponding to a 34.5 percent growth.[104] "It's a monopoly often sustained by the patent rights of these companies over these medicines," said Angelito Mendoza, FTA labor convenor. Multinational companies, in fact, hold more than 90 percent — if not all — of patents granted by the Intellectual Property Office (IPO).[105] The sad reality though is that not only the wealthy are in need of this drug. Hypertension is a common disease throughout the population. With this marketing strategy however, the cure for this ailment is confined to a particular sector only.

> By virtue of Executive Order No. 442 issued by Gloria Macapagal-Arroyo in July 2005, the PITC was designated as "the lead coordinating agency to make quality medicines available, affordable and accessible to the greater masses of Filipinos." PITC's mandate allows it to engage in parallel importation of low-priced generic medicines from countries like India and Pakistan. In September 2005, the PITC brought in 40 pieces each of 5-mg and 10-mg Norvasc tablets from Pakistan and submitted these to BFAD for registration. BFAD, being the agency under the Department of Health, which regulates the registration of medicines before they are marketed in the country, in turn granted PITC's parallel import drug registration.[106] According to the PITC, it will not sell the cheaper Indian version of the Pfizer product to the public until the Pfizer patent expires in June 2007. Its only goal is to begin the process of registering the imported version, so it

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[102] Judit Rius San Juan, *Pfizer is suing Philippine's governmental officials in their personal capacity in order to stop parallel trade*, March 31, 2006, *available at* http://secondview.blogspot.com/2006/03/pfizer-is-suing-philippines.html.

[103] *Id.*

[104] Alecks Pabico, *Ensuring Access to Cheap Medicines and the Pfizer Case*, May 12, 2006 *available at* http://www.pcij.org/blog/?p=911.

[105] *Id.*

[106] *Id.*

could promptly enter the market when the Pfizer controlled patent expires. Sec. Roberto Pagdanganan, president and chairman of PITC, said that they obtained the Certificate of Product Registration (CPR) for the anti-hypertension drug only in anticipation of the patent's expiration. "We have not marketed or sold a single Norvasc. In fact, we have informed Pfizer that we have no intention of doing so until after the Pfizer patent expires," he said.[107]

Again, the World Trade Organization's (WTO) TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, which was further reinforced by the 2001 Doha Declaration on public health, also accorded governments and member-states various tools, including parallel importation and compulsory licensing, to fulfill their public health obligations and ensure access to cheaper drugs. *Parallel importation allows* patented medicines to be purchased from the cheapest source *without* having to get the consent of the patent holder. *Compulsory licensing allows* governments to order a local firm to produce a drug and pay for a negotiated royalty to the patent holder.[108]

Pfizer, however, is claiming that the case is not one of parallel importation because the product in question did not come from a source it authorized. Pfizer contends that Pfizer India found that none of the PITC's sources were their authorized distributors or sub-distributors. Pfizer's view is that the act of importing the Amlogard tablets infringed its patent on Norvasc. The complaint further states that BFAD and its officers induced the violation of Pfizer's patent rights by granting registration approval to PITC. Furthermore there was no legal assurance that their patent would not be infringed by the importation of an unauthorized *amlodipine besylate* product and the company was also concerned about product safety as it was an unknown from which manufacturing source the product would be imported to the Philippines. It has therefore asked the Makati RTC to revoke PITC's parallel import drug registration and to enjoin BFAD from entertaining applications by generic drug companies for registration of amlodipine besylate. Industry sources say the court case will effectively extend the multinational company's monopoly over amlodipine besylate by at least 18 months, which is the period it takes BFAD to evaluate an application for drug registration filed by a generic company.[109]

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[107] *Id.*
[108] *Id.*
[109] *Id.*

What is at stake legally is a new twist on the issue of "early working" of a patent. The practice of exempting from patent infringement a generic drug that is brought into a country for early registration in IP is referred to as "Bolar provision", after the change in the US patent law to allow for such use. In the United States, there was a 1983 dispute between Roche and Bolar Pharmaceuticals. Bolar was in possession of small quantities of a generic version of a sleeping pill marketed by Roche as Dalmane. The Bolar Company wanted to register a generic version, so it could promptly enter the market when the Roche patent expired. Roche successfully sued Bolar and its officers and importers, claiming the effort to register the generic product violated the Roche patent. This had the effect of delaying entry by generics for about 18 months. In 1984, the US Congress changed US patent law to allow for the early working of a patent when preparing a generic drug registration, effectively overturning this decision. This is known as the "Bolar" provision, or "Bolar amendment."[110]

Some countries have implemented similar statutory changes in their laws (early Australia, Canada, Argentina, Israel), and recently the European Union required its member states to implement similar provisions. Some countries in Europe have done this through statutory changes, while others already allow this through interpretations of other exceptions in patent laws, including domestic experimental use exceptions.

There is no express Bolar provision in the Philippines Intellectual Property Code. The exception, however, has been part of Philippine regulatory practice for several years, and it has never been challenged before. Although the Philippine patent law has not been amended yet, the Consumer Project on Technology (CPTech) says this custom has been part of Philippines regulatory practice for several years, and has never been challenged before. If this exception were applicable in the Philippines, then the importation and use by PITC of the 80 tablets despite the validity of the Pfizer patent, would not constitute infringement. It would be excused as a necessary step to ensuring the availability of the drug in the Philippine market, after the expiration of the patent.

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[110] Terrorism Pfizer Style, Judit Ruis San Juan, March 31, 2006, *available at* http://secondview.blogspot.com/2006/03/pfizer-is-suing-philippines.html.

D. A CRITICAL ANALYSIS OF THE CONFLICT AND THE SUGGESTED RESOLUTION

The recurring theme in this paper, thus far, has been the polarized interests that shape the landscape of the pharmaceutical industry in the world, and most especially in the Philippines. It is the classic battle between wealthy entities, in this case the multi-national pharmaceutical companies, and the less fortunate, who cannot afford basic needs. While this can be depicted as a long-term (innovation) versus short-term (greater access to drugs) conflict, ultimately, it is an economic issue. As discussed earlier, savings for one party translates into loss of profits for another. An economic trade-off always exists, but since the opposing parties are indispensable to each other, the best course of action is to achieve an optimum balancing of interests. This is where the law or the legal framework comes into the picture. It provides a standard of peremptory behavior and order amidst the persistent conflict.

The Norvasc case, I believe, is simply an offshoot of the current environment as I have described it. The expected parties are well represented. There is Pfizer, the largest pharmaceutical company in the Philippines on the one hand, and on the other, there is the Philippine government, at the helm of an impoverished nation. This present dispute has all the elements of a much-publicized case. In fact, much has been written about it in the news, and advocates in either side are very vocal and passionate. Although the repercussions of any decision on this case will have economic, humanitarian, and political effects, the issues to be resolved are fundamentally legal ones. The Philippines has a valid and enforceable IPR law in place that confers rights but grants exemptions. What really has to be done is juxtapose the situation with the present law, interpreted in a reasonable manner and in the light of its spirit and purpose.

Pfizer is quite confident that they have the legal arsenal in this case, since the letter of the law seems to be in their side. The IPC clearly grants patent holders the exclusive rights to import and use the products covered by the patents. The PITC did import and use samples of Norvasc currently under patent, without the authorization of Pfizer. All the elements of infringement, as provided under Section 76.1 seem to be present. Furthermore, PITC cannot hide behind its mandate under E.O. No. 442. In this respect, I would have to agree with Pfizer in its Reply, wherein it

expressed that PITC had a strained interpretation of the EO.[111] While it is true that the EO granted PITC the task of "procuring, sourcing and marketing of quality, essential and low-priced generic medicines needed by the Filipino consumers..." it is clear that the terms "quality", "essential", and "low-priced" qualify the broader term "generic".[112] In truth, E.O. 442 did not, in any way, authorize PTIC to import or distribute patented drugs. It, by clear language of the law, limited the foregoing acts to generic medicines.[113] Moreover, there is no express Bolar or early working exception provided by the IPC. Thus, based on the current state of the laws, it would seem that the government of the Philippines through its agents, is guilty of patent infringement, with no exception.

However, as I stated earlier, it is a basic principle in statutory construction, that the letter of the law should be interpreted with the spirit and intent of the law in mind. In this context, assuming arguendo the elements of infringement are indeed present, PITC and the BFAD cannot be in any way made liable, since the acts allegedly constituting the offense are covered by an exception. Section 72 of the IPC provides for limitations of patent rights. Under this provision, where the act is done privately and on a non-commercial scale, or for a non-commercial purpose, it is not considered infringement, if it does not significantly prejudice the interests of the patent owner. Also, when the act of making or using is exclusively for the purpose of experiments that relate to the subject matter of the patented invention, then there is no infringement. PITC claims that its assailed acts fall under these instances, as argued in paragraphs 19 to 21, set forth above. Pfizer, in its Reply, tries to counter this by arguing that while the importation and use of the 80 tablets may not, for the sake of argument, be considered to be of commercial scale, these acts, nonetheless, were undertaken for a commercial purpose.[114] The issuance of a certificate of product registration is a requirement imposed by BFAD before any pharmaceutical product may be manufactured, imported, sold, or otherwise distributed in the Philippine market.[115] According to Pfizer, quite clearly, PITC had no other intent in registering its imported amlodipine besylate with BFAD, but to sell and distribute the same commercially. As to the acts

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[111] Pfizer et al. v. PITC et al, Civil Case No. 06-172, REPLY, par. 21.

[112] *Id.*, REPLY, par. 20.

[113] *Id.*, REPLY, par. 23.

[114] *Id.*, REPLY, par. 12.

[115] Administrative Order No. 67, series of 1989, otherwise known as the "Revised Rules and Regulations on Registration of Pharmaceutical Products".

being done for the purpose of experimentation, Pfizer argues that the experiments conducted by PITC were necessary steps for market approval, which is not the type of experimentation contemplated by the IPC. The type of experimentation covered must relate to tests or examinations that may help ascertain whether the patented product performs in accordance with the claims set forth under the letters patent –to refine the invention and prove that it would work for its intended purpose.[116]

These counter arguments of Pfizer may seem substantial at first glance. However, a more in depth analysis will reveal that PITC was right in claiming exception under these provisions. First of all, the fact that a section limiting rights of patent owners was included shows that the code still wants to strike a balance between protecting IPR and ensuring that no absolute monopoly exists. Monopolies cause a lot of economic deadweight and wastage and must be tempered else they control the market fully and impose their interests at the expense of all the other actors. Secondly, the exemption given to acts done in a non-commercial scale or for a non-commercial purpose may very well cover the assailed acts committed by PITC. The provision uses the word "or", so as long as the act is either of the two, it must fall under the exception. Only 80 tablets were imported and used. This is clearly no commercial in scale. This is even less than what a patient needing Norvasc as regular medication can be expected to have. Even Pfizer in its Reply, seems ready to concede this. Thus, as long as the proviso that the act does not prejudice the economic interests of the patent holder is fulfilled, PITC cannot be held to have infringed the patent. Obviously, no economic prejudice was caused, since the tablets did not partake of any portion of the Pfizer market. They were used exclusively for the purposes of early registration and would only be publicly available after the expiration of the patent, at which time Pfizer would no longer enjoy any economic protection. In this light, whatever commercial purpose Pfizer is trying to attribute to the acts of PITC, will really never take place during the validity of the patent. Thus, no rights conferred by law are violated.

At this point, despite the absence of any express Bolar provision in the IPC, the limitations under Section 72 could compensate for the time being. The "early working" exception also refers to activities that are not commercial, nor profit-oriented in nature, and may cover experiments and other preparatory steps needed for the success of the product. This is very

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[116] Baxter International, Inc., et al. v. Cobe Laboratories, Inc., USCA Federal Circuit, 10 July 1986.

applicable to the situation wherein, as in this case, an existing patent is about to expire and the registration of similar products to be offered after the expiry is in the works. If this were not allowed, then the expiry date would be rendered meaningless and superfluous because the patent holder would still have a virtual monopoly of the market for several months, even years, after the expiration of the patent. This is because the registration of new distributors would only be permissible after the expiry date. The process of registration itself would take time, and there would therefore be a period between the expiration date and the date of actual registry of new distributors, in which the only available drug would still be that of the patent holder. This would be tantamount to an extension of the life of the patent. It is therefore not only logical, but in keeping with the law that applications for registration be initiated before the expiration of patents, so that by the time the actual expiry date arrives, the registration process will have been accomplished and there will already be new licensed players in the market who can sell the drug at more affordable prices.

Finally, this interpretation is in keeping with the 1987 Constitution of the Philippines and the TRIPS agreement and Doha Declaration. Article XIII, Section 11 of the Constitution provides that: "The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost." As the fundamental law of the land, other laws must be measured by the standards the constitution provides. This section unequivocably expresses the policy to ensure that drug prices be at levels that are not prohibitive, given the income levels of the Filipinos. Of course, since the Philippines is a market economy, the government despite this policy, cannot artificially restrict prices. Economic factors will come into play. Over and above this, the Philippines is party to international treaties that obligate it to respect and protect IPR, and as a result, price levels are also affected. Hence, the constitutional policy must be enforced in the most reasonable manner, dealing with all these externalities at the same time. Interpreting the IPC provisions in a manner that respects IPR but at the same time safeguarding the interests of the consumers, particularly by allowing opportunities for cheaper medicines to be made available to them, adheres to the Constitution. In addition, the Doha declaration grants several flexibilities and safeguards for developing countries, so that their citizens will not be unduly deprived of healthcare by the restrictively high prices that usually result from patent protection. Although amendments to the IPC are still underway to formally take advantage of these flexibilities, interpreting the present IPC provisions in a

manner not as narrow as the construction of Pfizer, will in no way be in violation of Philippine international law obligations. This interpretation is in fact what the law contemplates. It will serve the interests of consumers without prejudicing in the slightest the rights of the patent holder.

Pfizer must not be allowed to use the Philippine justice system to further its own profit-oriented purpose of effectively extending the validity of its patent, at the expense of the market at large. The government must not allow itself to be bullied by a mere corporate entity whose sole goal is to increase the bottom line.

V. THE FUTURE OF PHILIPPINE LEGAL POLICY ON PARALLEL IMPORTATION IN THE PHARMACEUTICAL SECTOR

After presenting the phenomenon of parallel trade in pharmaceuticals by delving into its economic and legal angles from an international perspective, I then provided an overview of the Philippine pharmaceutical industry and the problems facing it today. I next proceeded to relate the Norvasc case that unwittingly exemplifies the situation in the drug market in the Philippines today. This case lays bare the inadequacies and gaping holes in the present Philippine law that cause ambiguities giving rise to similar disputes. While the case is still pending and there is uncertainty as to how the courts will ultimately resolve it, one thing is for sure: Philippine law on IPR is in need of amendment at the soonest possible time. The Philippines thus far has not exploited the flexibilities granted by the TRIPS and the Doha Declaration and has not set definite policies on parallel importation.

In this final section of the legal research paper, I will present the current developments pertaining to this much-needed legislation. Furthermore, taking into consideration the recommendations stemming from the economic and legal analysis, and bearing in mind the problems facing the Philippines today, I will end with some comments and suggestions on what still can be done. In spite of all the conflicts and problems that have been discussed in this paper over and over again, it would be fruitful to bring it to a close in a positive and hopeful note.

A. THE PENDING BILLS

Within the last decade, Mar Roxas has been a formidable force behind government campaigns and advocacies concerning the pharmaceutical sector. As has been related earlier, he worked in close collaboration and alliance with former Health Secretary Alberto Romualdez in coming up with administrative orders that would bring the Generics Act to life, despite intense pressures from the US and drug companies. Thus it is befitting that the Senate Bill 2263 on the proposed amendments to the IPC was sponsored by him. The bill was introduced on 13 October 2005 and referred to a Senate Committee on Trade and Commerce and the Senate Committee on Health on 24 October 2005. They came up with Committee Report No. 79. This bill has recently been passed in third reading. There is also a corresponding House Bill 4943 sponsored by Representative Junie E. Cua of the lone district of Quirino, that has also been passed by the House of Representatives. These two bills cover substantially the same amendments and are at present waiting for consolidation to be done by both houses of Congress.

According to Roxas, in his sponsorship speech, the principles that guided the committees in crafting Bill 2263 are:

> (1) To promote greater competitiveness and responsiveness in the Philippine pharmaceutical industry with the least government intervention. We need to loosen the monopolistic or oligopolistic power that some multinational pharmaceutical companies have long enjoyed to the detriment of all Filipinos by broadening consumer access to the supply of medicines and by supporting the domestic generics industry.
>
> (2) To adopt internationally accepted best practices that have made medicines more affordable and accessible in so many other countries around the world. In fact, all these proposed amendments are similar, if not exactly the same, as express provisions already adopted by other countries in their own patent laws. If others have it, then there is no reason why we should not provide the same for the benefit of all Filipinos.
>
> (3) To comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the DOHA Declaration on the TRIPS Agreement and Public Health of the World Trade Organization (WTO). And,

> (4) To increase the flexibility of government to anticipate and respond to various possible challenges to Philippine public health from global pandemics like bird flu or SARS and even to biological and/or chemical terror attacks.[117]

He also summarized the salient features of SB No. 2263 as follows:

> First, we shall amend Section 72.3 of the IPC in order to expressly adopt the "early working" doctrine. This refers to the process by which generic companies are allowed to experiment and test for regulatory approval of generic versions of a drug or medicine before its patent expires. This will allow generic producers to get ready earlier so that they can start the production and sale of a generic drug shortly after its patent expires. As explained by the WHO, in the absence of such provision, generic manufacturers can only start the time-consuming process of testing and registration after the expiry of the patent. This easily delays the marketing of generic drugs for another two to three years after patent expiry. Once enacted, this proposed amendment will increase the supply of medicines by allowing the early or immediate entry of generic versions within a short period after patent expiration.
>
> This proposed amendment is known internationally as the Bolar amendments after such were entered into US Law. Many other countries have adopted similar provisions, such as, Canada, Argentina, Thailand, Malaysia and Indonesia. Moreover, this principle has been recognized by the WTO in a case involving Canada vs. the European Union member states.
>
> Second, we shall amend Section 72.1 of the IPC by adopting "the doctrine of international exhaustion of intellectual property rights" from the present domestic exhaustion principle currently applied in the Philippines. Under the international exhaustion regime, once a product has been introduced anywhere in the world by the patent owner, then anyone may buy and import the same for resale in the Philippines without risk of patent infringement. This means that the price in the Philippines will be influenced by the price it is sold in other countries. Consequently, this amendment will allow the parallel importation of medicines so that anyone, whether a trader or an individual, can shop beyond our shores for better prices. Thus

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[117] Roxas Speech, *supra* note 80.

domestic prices can be moderated through competition from imports of exactly the same medicines. This international exhaustion principle leading to parallel importation is done by numerous countries including Japan, Israel and Thailand and others.

Third, in order to more easily operationalize the foregoing, CR No. 79 and SB No. 2263 seeks to amend Section 147 of the IPC such that there will be an exception to the application of trademarks and tradename restrictions when applied to parallel imports.

Fourth, the bill amends Section 22.1 of the IPC by disallowing the issuance of another patent for new uses of an existing substance that has already been patented. This amendment limits the protection provided to the original patent of 20 years. This enables generic companies to aggressively market their own versions without threats of lawsuits arising from newly-discovered uses for previously patented products. The committee adopted this approach from the Indian Patent Act.

Fifth, the bill amends Section 74 of the IPC, "Use of Invention by Government", in order to remove the requirement for government to undergo the long and tedious compulsory licensing process so that government may avail of the medicine for public health reasons in a more timely manner.

At present, the IPC requires the government to go through the cumbersome compulsory licensing procedures before it may use any patent. A review of Supreme Court cases on compulsory licensing would show that it takes 6 to 8 years before an entity has a clear approval to do the same. The health of our people cannot be made to wait this long especially in times of emergencies. The government must have the power to do this outright without need for a lengthy process. Based on the standards set in the Senate Bill No. 2263 which is patterned after TRIPS, our government will have the ability to act decisively and immediately when confronted with debilitating illnesses like tuberculosis or public health emergencies like avian influenza and SARS - without fears of possible lawsuits from patent owners.[118]

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[118] *Id.*

I have set forth here in full the House Bill 4943, for the precise language of the amendments. The amendments here fall under the five salient features pointed out by Roxas.

> **AN ACT TO MAKE THE LAWS ON PATENTS, TRADENAMES AND TRADEMARKS MORE RESPONSIVE TO THE HEALTH CARE NEEDS OF THE FILIPINO PEOPLE BY ALLOWING THE IMPORTATION, EARLY DEVELOPMENT OF PATENTED MEDICINES AND EXCEPTIONS TO THE APPLICATION OF STANDARD COMPULSORY LICENSING REQUIREMENTS FOR DRUGS OR MEDICINES TO LOWER DRUG OR MEDICINE PRICES BY AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES**
>
> **SECTION 1.** *Sec.21 of Republic Act No. 8293 is hereby amended to* read as follows:
>
> "Sec. 21. Patentable Inventions. - Any technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable shall be patentable. It may be, or may relate to, a product, or process, or an improvement of any of the foregoing. NEW USES OR MOLECULES OR COMPOUNDS OF A PATENTED INVENTION SHALL BE DEEMED AS INCLUDED IN THE ORIGINAL PATENT AND SHALL NOT BE ALLOWED TO BE COVERED BY A NEW AND SEPARATE PATENT.
>
> **SEC. 2.** Sec. 72 of Republic Act No. 8293 is hereby amended to read as follows:
>
> "Sec. 72. Limitations of Patent Rights. - The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:
>
> 72.1, Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market; PROVIDED THAT, WITH REGARD TO DRUGS OR MEDICINES, THE LIMITATION ON PATENT RIGHTS SHALL APPLY AFTER A DRUG OR MEDICINE HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE

PATENT OWNER, OR BYANY PARTY AUTHORIZED TO USE THE INVENTION.

72.2. Where the act is done privately and on a non-commercial purpose: Provided, that it does not significantly prejudice the economic interests of the owner of the patent;

72.3. Where the act consists of making or using exclusively for EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR FOR COMMERCIAL PURPOSES THAT DO NOT UNREASONABLY CONFLICT WITH A NORMAL EXPLOITATION OF THE PATENT AND THAT DO NOT UNREASONABLY PREJUDICE THE LEGITIMATE INTERESTS OF THE PATENT OWNER, TAKING INTO ACCOUNT THE LEGITIMATE INTERESTS OF SUCH THIRD PARTIES.

72.4 WHERE THE ACT INCLUDES TESTING, USING, MAKING OR SELLING THE INVENTION INCLUDING ANY DATA RELATED THERETO, SOLELY FOR PURPOSES REASONABLY RELATED TO THE DEVELOPMENT AND SUBMISSION OF INFORMATION REQUIRED UNDER ANY LAW OF THE PHILIPPINES OR OF ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT.

72.5 [72.4]. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

72.6 [72.5]. Where the invention is used in any ship, vessel, aircraft, or land vehicles of any other country entering the territory of the Philippines temporarily or accidentally: Provided, that such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines.

SEC. 3. Sec.74 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 74. Use of Invention by Government. - 74.1. A government agency or third person authorized by the

Government may exploit the invention even without agreement of the patent owner where:

(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

(b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his license, is anti-competitive.

74.2. Unless otherwise provided herein, the use by the Government, or third person authorized by the Government shall be subject, mutatis mutandis, to the conditions set forth in Sections 95 to 97 and 100 to 102.

74.3. SUBJECT TO THE CONTROL, SUPERVISION AND DETERMINATION OF THE RESPECTIVE SECRETARIES OF THE DEPARTMENT OF HEALTH AND DEPARTMENT OF TRADE AND INDUSTRY, THE IMPORTATION, INCLUDING PARALLEL IMPORTATION, OR MANUFACTURING OR SALE OR DISTRIBUTION BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES OF DRUGS OR MEDICINES TO PROTECT PUBLIC HEALTH SHALL BE IMMEDIATELY EXECUTORY ONLY UPON FILING OF AN EX PARTE NOTICE BEFORE THE INTELLECTUAL PROPERTY OFFICE (IPO). THIS PROCEDURE SHALL BE AN EXCEPTION TO THE APPLICATION OF THE STANDARD REQUIREMENTS OF COMPULSORY LICENSING. ANY DRUG OR MEDICINE PROCURED, AS PROVIDED HEREIN, SHALL BE EVALUATED AND APPROVED FOR PUBLIC CONSUMPTION BY THE BUREAU OF FOOD AND DRUGS (BFAD) AFTER PROPER LABORATORY TESTING FOR SAFETY, EFFICACY AND QUALITY. IT IS PROVIDED FURTHER, THAT THE SALE AND DISTRIBUTION OF SUCH DRUGS OR MEDICINES SHALL ONLY BE MADE BY PERSONS WHO ARE DULY LICENSED BY BOTH THE DEPARTMENT OF HEALTH TO ENGAGE IN THE SALE AND DISTRIBUTION OF DRUGS OR MEDICINES AND AUTHORIZED BY THE DEPARTMENT OF TRADE AND INDUSTRY TO BE OFFICIAL DISTRIBUTORS OR RETAILERS OF THE DRUGS OR MEDICINES SUBJECT OF THE SAID PROCUREMENT.

ALL IMPORTATIONS, MANUFACTURING, SALE OR DISTRIBUTION OF DRUGS OR MEDICINES SHALL BE UNDERTAKEN BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENATIVES THROUGH THE COORDINATED REGULATORY EFFORTS AND SUBJECT TO THE APPROVAL OF THE DEPARTMENTS OF HEALTH AND TRADE AND INDUSTRY.

THE IMPORTATION, MANUFACTURING, SALE OR DISTRIBUTION OF DRUGS OR MEDICINES UNDER THIS PROVISION SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING ORDER OR INJUNCTION AND NO SUIT OF ANY KIND RELATED TO SUCH MAY BE FILED AGAINST THE RELEVANT PUBLIC OFFICIALS OR OTHER PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY FOR ANYTHING WHICH IS IN GOOD FAITH DONE OR INTENDED TO BE DONE IN THE EXECUTION OR PURPORTED EXECUTION OF THIS PROVISION.

THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY SHALL ACCORDINGLY INDEMNIFY ITS MEMBERS AND OTHER OFFICIALS, INCLUDING PERSONNEL OF THE DEPARTMENTS PERFORMING ANY FUNCTION OR SERVICE RELATED TO THIS PROVISION AGAINST ALL COSTS AND EXPENSES REASONABLY INCURRED BY SUCH PERSONS IN CONNECTION WITH ANY CIVIL OR CRIMINAL ACTION, SUIT OR PROCEEDINGS TO WHICH HE MAY BE, OR IS MADE A PARTY BY REASON OF THE PERFORMANCE OF HIS FUNCTIONS OR DUTIES, UNLESS HE IS FINALLY ADJUDGED IN SUCH ACTION OR PROCEEDING TO BE LIABLE FOR NEGLIGENCE OR MISCONDUCT.

THE INTELLECTUAL PROPERTY OFFICE (IPO) SHALL HAVE ORIGINAL AND EXCLUSIVE JURISDICTION OF ALL CASES FOR THE IMPORTATION OR ISSUANCE OF COMPULSORY LICENSES OF DRUGS OR MEDICINES AS DESCRIBED HEREIN. ALL CASES DECIDED UPON BY THE INTELLECTUAL PROPERTY OFFICE (IPO) WITH FINALITY SHALL BE APPEALABLE TO THE COURT OF APPEALS. THE INTELLECTUAL PROPERTY

OFFICE SHALL ALLOW ONLY ONE MOTION FOR RECONSIDERATION OF ITS DECISION.

PARALLEL IMPORTATION SHALL REFER TO THE IMPORTATION AND RESALE OF DRUGS OR MEDICINES IN THE PHILIPPINES, WHETHER PATENTED OR NOT AND WITHOUT THE CONSENT OF THE PATENT HOLDER, BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES BASED UPON THE JOINT DETERMINATION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY FOR THE PURPOSE OF PROTECTING PUBLIC HEALTH. DRUGS AND MEDICWES APPROVED AND IMPORTED FOR THIS PURPOSE SHALL NOT BE CONSIDERED AS COUNTERFEIT DRUGS AS DEFINED BY APPLICABLE LAWS.

SEC. 4. Sec.166 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 166. Goods Bearing Infringing Marks or Tradenames. - 166.1. UNLESS OTHERWISE PROVIDED, no article of imported merchandise which shall copy or simulate the name of any domestic product, or manufacturer, or dealer, or which shall copy or simulate a mark registered in accordance with the provisions of this Act, or shall bear a mark or trade name calculated to induce the public to believe that the article is manufactured in the Philippines, or that it is manufactured in any foreign country or locality other than the country or locality where it is in fact manufactured, shall be admitted to entry at any customhouse of the Philippines.

166.2. THE IMPORTATION, MANUFACTURING, SALE OR DISTRIBUTION BY THE GOVERNMENT OF DRUGS OR MEDICINES WITH TRADEMARKS AND TRADENAMES FOR THE PROTECTION OF PUBLIC HEALTH AS PROVIDED IN SECTION 74.3 OF THIS ACT SHALL BE A LIMITED EXCEPTION TO THE RIGHTS CONFERRED BY TRADEMARKS AND/OR TRADENAMES; PROVIDED FURTHER, THAT SUCH DRUGS OR MEDICINES PROCURED BY ?"E GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES UNDER THIS PROVISION SHALL NOT BE SUBJECT TO ANY TEMPORARY

RESTRAINING ORDER OR INJUNCTION AND NO SUIT OF ANY KIND RELATED TO SUCH MAY BE FILED AGAINST THE RELEVANT PUBLIC OFFICIALS OR OTHER PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY FOR ANYTHING WHICH IS IN GOOD FAITH DONE OR INTENDED TO BE DONE IN THE EXECUTION OR PURPORTED EXECUTION OF THIS PROVISION.

THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY SHALL ACCORDINGLY INDEMNIFY ITS MEMBERS AND OTHER OFFICIALS, INCLUDNG PERSONNEL OF THE DEPARTMENTS PERFORMING ANY FUNCTION OR SERVICE RELATED TO THIS PROVISION AGAINST ALL COSTS AND EXPENSES REASONABLY INCURRED BY SUCH PERSONS IN CONNECTION WITH ANY CIVIL OR CRIMINAL ACTION, SUIT OR PROCEEDINGS TO WHICH HE MAY BE, OR IS MADE A PARTY BY REASON OF THE PERFORMANCE OF HIS FUNCTIONS OR DUTIES, UNLESS HE IS FINALLY ADJUDGED IN SUCH ACTION OR PROCEEDING TO BE LIABLE FOR NEGLIGENCE OR MISCONDUCT. THE INTELLECTUAL PROPERTY OFFICE (IPO) SHALL HAVE ORIGINAL AND EXCLUSIVE JURISDICTION OF ALL TRADEMARK AND TRADENAMES CASES INVOLVING THE IMPORTATION OR ISSUANCE OF COMPULSORY LICENSES OF DRUGS OR MEDICINES AS DESCRIBED HEREIN. ALL CASES DECIDED UPON BY THE INTELLECTUAL PROPERTY OFFICE (IPO) WITH FINALITY SHALL BE APPEALABLE TO THE COURT OF APPEALS. THE INTELLECTUAL PROPERTY OFFICE SHALL ALLOW ONLY ONE MOTION FOR RECONSIDERATION OF ITS DECISION.

166.3. In order to aide the officers of the customs service in enforcing this prohibition, any person who is entitled to the benefits of this Act, may require that his name and residence, and the name of the locality in which his goods are manufactured, a copy of the certificate of registration of his mark or trade name, to be recorded in books which shall be kept for this purpose in the Bureau of Customs, under such regulations as the Collector of Customs with the approval of the

Secretary of Finance shall prescribe, and may furnish to the said Bureau facsimiles of his name, the name of the locality in which his goods are manufactured, or his registered mark or trade name, and thereupon the Collector of Customs shall cause one (1) or more copies of the same to be transmitted to each collector or to other proper officers of the Bureau of Customs.

SEC. 5. *Separability Clause.* - Any portion or provisions of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

SEC. 6. *Repealing Clause.* - All laws, decrees, executive orders, proclamations and administrative regulations, or parts or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SEC. 7. *Effectivity Clause.* -This Act shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation.

Approved.

B. COMMENTS AND RECOMMENDATIONS

Based on the theoretical and empirical analysis conducted, simple and logical conclusions were reached which can serve as guiding principles as the Philippines tries to solve the problem of high drug prices in a predominantly low-income population. The primary tool the Philippines can harness is a sound and solid law regulating the pharmaceutical market. If and when these bills are finally enacted into laws, it must be ascertained that all necessary amendments are already incorporated, and that the resulting law is ideal, unambiguous, and adapted to the peculiar experience of the Philippine market. A useful test to measure the sufficiency and effectivity of the law would be the ability to avoid disputes similar to the present Norvasc case, or at the least, to be able to settle them speedily without need for strained interpretations.

Applying the recommendations arrived at earlier, there are three imperative courses of action the Philippines must undertake at this point. The first is legalizing parallel trade in pharmaceuticals. All the major studies have reached the same conclusion that parallel importation results in direct

savings for the consumers. In a developing country like the Philippines, this is the primary issue that has to be addressed. Even the Constitution emphasizes this governmental thrust. The common argument that short-term savings would later be offset by lack of innovation has no conclusive evidence in support of it, and thus should not be much of a factor in Philippine policies especially if pitted against the very real problem of poor Filipinos prevented from availing of much-needed medicines because of extremely high prices. Moreover, even if this were actually proven, it would not be of much moment to the Philippines, since the research and development is undertaken by foreign firms. The Philippines has much to gain and little to lose if at all, by allowing parallel trade.

The TRIPS Agreement and the Doha Declaration precisely leave it up to the member country to decide on the issue of parallel trade, thus it cannot be argued that legalizing such would go against Philippine international legal obligations. All that has to be done in this respect is for the country to expressly adopt an international policy of exhaustion. This is one of the main features of the proposed bills above. Although experts have noted that a regional exhaustion policy may be the most beneficial to developing nations, this may take a longer time to implement in the Philippines, since it would entail agreements with neighboring countries, over and above those already in place. This would take more time and effort, and at the end of the day, it would be more efficient to just avail of international exhaustion. Also, I must emphasize here that although the PITC has been involved in a parallel importation program, and even if there are administrative orders in place that do allow parallel trade in order to provide cheaper medicines, these do not pertain to parallel trade in the strict sense, for in both instances, only generic drugs are imported. Parallel importation includes products also under patent. However, since the IPC confers to patent holders the exclusive right to import, mere executive issuances cannot override this. The administrative orders are limited to generic drugs or those whose patents have already expired. Incorporating a policy of international exhaustion in the IPC would solve this problem, and would take advantage of the concessions granted by the WTO agreements, that the developing countries exerted much effort for. This would also take away the need for the Philippines to negotiate and enter into separate agreements with countries like India and Pakistan, every time it is in need of drugs that are more affordable there. I must add though, that under this course of action, it is best that exhaustion should cover all the exclusive rights (except "making" of course), and not just selling or importing, lest

this lead to the incongruous situation in which products covered by patents can be imported and sold, but not used or distributed.

The second course of action is to include an express Bolar exception in the law. This would dispense with the need to argue based on other more ambiguous provisions, as is being done by PITC in the Norvasc case, just to justify measures taken for early registration. The process of registration can take up to three years, and this would effectively extend the life spans of patents that have already expired. Early registration of new drug suppliers would ensure that as soon as the patent expires, a wider range of choices is provided for consumers. The bills that are now pending final legislative action both contain this exception, in black letter law. This would also prevent a repeat of the Norvasc case. The rights and limitations of patent holders would thus become more definite and evident. This also is the best way to facilitate the entry of generic competition, which has worked successfully in other countries to lower drug prices. In line with this, the Generics Act has to be reviewed and reinforced for stricter implementation. The government has to strengthen its Generics programs, for the presence of many suppliers is the only efficient way to really pressure prices to go down. Even if some larger firms segment the market due to this or resort to non-price strategies, what is still important is that in any way, there will be cheaper and more options available to the public.

Finally, the government must fortify its defense, and even civil society must express support for a favorable decision on the part of the respondents in the Norvasc case. This is a historical case that has stirred up interest again in the pharmaceutical sector and the many problems it is facing. The decision in this case will be of invaluable worth for jurisprudence and shall be binding on subsequent disputes brought before our judicial system. A favorable decision would also set a positive environment for the enactment of the consolidated bill into law. This would also send a message to the US and the multinational pharmaceutical firms that have historically tried to influence Philippine policy on these issues and bully the government into succumbing to their own interests.

These courses of action I have mentioned are not out of this world or novel theories. They are the most logical suggestions, based on theoretical principles and empirical evidence. Many of our lawmakers and public officials have been aware of these. Yet the problem is always the actual legislation and implementation of what has to be done. For once, the Philippines has to embrace and prioritize the interests of its own nationals

over the wellbeing of profit-oriented entities that are foreign in origin, no matter how much coercion they utilize. As in many other cases far removed from the subject matter of this legal paper, the solution is the same: stronger political will and the steadfast follow-through of the foundations that have already been laid out.

VI. CONCLUSION

Notwithstanding the absence of any conclusive data as to the magnitude or consistency of savings and welfare benefits, the bottom line is that parallel importation in the pharmaceutical industry has its advantages for and an overall positive impact on health care consumers. As an economic concept, many factors and variables come into play in the actual world, such that it is hard to come up with precise and conclusive empirical evidence by means of studies. Yet the theory behind parallel trade is reflected and affirmed by the trends that are documented by these studies. Parallel importation prevents IPR over pharmaceuticals from becoming absolute monopolies, hence prices of drugs are brought down.

Since the most compromised of health care consumers are the ailing and impoverished in developing nations, they are also expected to benefit the most from adequate government policies and legislation allowing PI. Thus, it is in the best interest of developing nations to implement international exhaustion policies within their jurisdiction, and utilize the flexibilities accorded by the TRIPS and the Doha Declaration, to the fullest extent possible. The specific situation of the Philippines best illustrates the problems developing countries are facing. With a pending case against the government, and an onslaught of pressure from foreign drug firms and their host countries, there is no better time than now for the Philippine government to turn theory into practice and take action. At this point, the proper course of action has been identified, and is supported by economic and legal theory. What remains is for the government to act. It is not helpless. It can act now. It can and it should once and for all transcend political pressure and address head on the people's needs.

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