PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES

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1. Introduction

Parallel imports (PI), also called gray-market imports, are goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right. This owner is typically a licensed local dealer. For example, it is permissible for a trading firm to purchase quantities of prescription drugs in Spain and import them into Sweden or Germany without the approval of the local distributor owning licensed patent rights. Indeed, rules of the internal market in the European Union permit parallel trade among those countries in virtually all goods. Note that these goods are authorized for original sale, not counterfeited or pirated merchandise. Thus, parallel imports are identical to legitimate products except that they may be packaged differently and may not carry the original manufacturer's warranty.

The ability of a right-holder to exclude PI legally from a particular market depends on the importing nation's treatment of exhaustion of intellectual property rights (IPR). As discussed further below, a regime of national exhaustion awards the right to prevent parallel imports, while one of international exhaustion makes such imports legal.

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. It is evident that policymakers in developing countries especially would place a higher weight on affordability of medicines than on promoting R&D abroad.

This controversy is currently 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.

In this report I discuss these issues and present available theory and evidence on the extent and effects of PI in drugs. In the next section I consider the legal treatment of PI in pharmaceuticals, including provisions within international trade agreements. In Section Three I discuss available evidence on the extent to which stronger patent regimes may be expected to raise prices of new patentable drugs in poor nations. In Section Four

I present and assess several theoretical claims about determinants of PI and their potential impacts on pricing and innovation. In Section Five I analyze available empirical evidence on differential prices of trademarked medicines across countries at varying levels of economic development. I also discuss recent work on the impacts of PI in medicines within the EU, which has an open internal regime. In Section 6 I put forward some conclusions about the benefits and costs of PI in developing countries and make a series of policy recommendations. In that regard, my essential conclusion is that there is an important rationale for restricting parallel exports of medicines from low-income countries to high-income countries, though the former group could remain open to PI. This idea could be supplemented by regimes of regional exhaustion among poor countries in order to increase market size within which prices are integrated.

2. The Legal Status of Parallel Trade in Pharmaceuticals[1]

Patents provide inventors of new products and technologies the legal right to exclude rivals from making, selling, and distributing those inventions. Trademarks provide their owners the right to prevent rivals from using identical or confusingly similar identifying marks and trade names on their goods. A country's law concerning the territorial exhaustion of these rights is an important component of how it regulates and limits their use. 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.

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, I am unaware of any governments that make such distinctions and it is surely rare in any event.

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

[1] This section draws from Maskus (2000a).

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 Six 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.*

I believe that 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. However, there is legal debate about this interpretation.[2] Overall, it seems that Article Six preserves the territorial prerogative to regulate parallel trade. This flexibility was important in gaining the acceptance of TRIPS by many developing countries.[3] 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.

Debate continues over the question of whether TRIPS should be extended to mandate a uniform global policy. Some analysts advocate a global ban against PI as a natural extension of the rights of intellectual property owners to control international distribution (Barfield and Groombridge, 1998). This position is advanced forcefully by representatives of the research-intensive pharmaceutical firms (Bale, 1998). Others support a comprehensive rule of international exhaustion and would place no restrictions on parallel imports in order to integrate markets (Abbott, 1998). 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 if 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 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.

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

[2] See Abbott (1998), Cottier (1998), and Bronckers (1998).
[3] See Watal (2001).

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.[4] 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.[5] An important exception is that if products are placed on the market under a compulsory license, they may not be parallel imported.[6]

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.[7] Furthermore, for a trademark owner to block PI it must demonstrate that the imported goods are not identical in quality to the original products and could cause confusion among consumers.[8] These principles would suggest that PI in pharmaceuticals are permissible for they 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 (Abbott, 1998). Australia generally permits parallel imports in

[4] 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).
[5] *Merck v Primetown* (C-267/95 and C-268/95).
[6] *Pharmon v Hoechst* (C-19/84).
[7] *K Mart Corporation v Cartier*, 486 US 281 (1987).
[8] See "Ruling Against Unauthorized Imports Upheld," *The Journal of Commerce*, January 7 2000.

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 entrepot 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.

In order to understand the controversies involved, consider the South African case. In December 1997 the government of South Africa amended its Medicines Act, which now, *inter alia*, would permit the Minister of Health to suspend patent rights and issue compulsory licenses in cases where it was 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 and its implementation is still pending. 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 Clinton Administration to moderate its stance on the issue.

3. Competitive Aspects of Product Patents

The TRIPS Agreement requires that all member countries provide patents for new pharmaceutical products by the year 2005. In the intervening period they must provide exclusive marketing rights that operate in a fashion similar to patents. Thus, there is great concern that the provision of product patents in pharmaceutical products could confer considerably greater market power on rights-holders. If so, such firms might be expected to reduce sales or output in particular markets, supporting higher monopolistic prices in key medical therapies.

3.1 Potential Impacts on Prices

This basic fear has some grounding in fact but may be overstated. The extent to which prices will rise in response to exercise of stronger market power is a function of several variables. First, *market structure* before and after the new patent regime matters crucially. In this area are included such elements as the number of firms (home and foreign) competing with rights holders, the nature of that competition, the ease of market entry and exit, quality differentiation among products, openness to trade, and wholesale

and retail distribution mechanisms. Second, *demand elasticity* is a key variable determining market power and this may vary markedly across countries and over time. Third, *pricing regulations*, particularly with respect to pharmaceuticals, may blunt tendencies toward monopoly pricing, albeit at some potential cost in terms of reduced willingness of firms to supply markets with such controls. Fourth, *competition policies* may also limit monopoly practices. Particular examples include whether parallel imports are allowed and whether sole distributorship laws support market power.

It is remarkable how little is confidently known about the potential impacts of this fundamental policy change, despite the fact that the pharmaceutical sector is the most extensively studied of all IPR-sensitive industries. This information gap results from a scarcity of data that would support estimation of key elasticities and market-structure parameters, and uncertainty about the potential price and profitability impacts of patents and effects on innovation. However, several articles may be reviewed in order to understand the issues and to get a sense of the (tentative) conclusions they reach. It is fair to say that the preponderance of conclusions is pessimistic about net effects of drug patents on economic welfare in developing countries (or, more accurately, net importers of patentable drugs).

An excellent overview is provided by Nogues (1993), who lists a series of interrelated factors on which pharmaceutical pricing decisions depend. A key determinant is the structure of market competition before and after the introduction of patents for medicinal preparations.[9] Roughly stated, the more competitive is the local drugs market before patents are awarded, the larger is the pre-patent share of drug production that consists of copies of patentable drugs, and the more inelastic is demand for medicines, the higher will be the increases in prices associated with patents. Each of these factors depends on the strength of patent protection and collateral determinants of market structure, including trade protection, investment regulations, and marketing and entry restrictions.

The absence of product patents and the relative ease of entry into imitative production means that there are significant numbers of small and medium-sized firms producing generics, "me-too" drugs, and copied drugs in countries without product patents. This (pre-patent) structure characterizes (or did characterize) a wide range of countries that have been studied, including Argentina, Brazil, Chile, India, Italy, Turkey, Korea, Egypt, and Lebanon.[10] The Chilean study shows clearly that drug prices fall markedly in the presence of competing products (Coloma, et al, 1987). The real price of Glaxo's aerolin fell by some 52% over the period 1983-1986 as two competing copies came on the market; in the prior five years when aerolin was a monopoly its real price rose by 45%. Moreover, Schut and Van Bergeijk (1986) present evidence that, across a sample of 32 countries in 1975, a standardized pharmaceutical price index is much lower

[9] See also Subramanian (1995) and Maskus and Eby-Konan (1994) who develop numerous interesting extensions.

[10] See also Coloma, et al (1987), Katz and Groisman (1988), Kirim (1985), Lanjouw (1998), Maskus (1997), and Scherer and Weisburst (1995).

on average in countries without patents than in countries with patents. To isolate the impact of patents they compute the following regression:

$$P = 38.5^{*} + 1.4^{*}GDPPC - 0.6^{*}CONSPC + 7.1DPAT - 15.7^{**}CDP - 11.1IPC$$

where *P* indicates pharmaceutical price index; *GDPPC* is GDP per capita; *CONSPC* is drug consumption per capita; *DPAT* is a dummy for existence patent protection (either process or products or both); *CDP* is a dummy for pharmaceutical price controls, and *IPC* is a dummy for indirect price controlling measures. The asterisks indicate significant coefficients. Thus, drug prices rise with per-capita income, fall with per-capita consumption volume, fall with price controls, and rise with patent protection. The patent coefficient is insignificant, but this is likely due to the inclusion of process patents and the inability to distinguish between enforced and unenforced product patents (that is, the strength of the legal regime).

Thus, the preponderance of evidence suggests that pre-protection market structures are relatively competitive in middle-income countries with significant imitative capabilities and that prices are sensitive to demand variables and patent protection. Further, there is likely to be a considerable element of oligopoly in the pharmaceutical industries in many developing countries after patents are recognized by virtue of the ability of drug firms to differentiate their products through brand loyalty and marketing.

In this context, it seems likely that the introduction of patents could place pronounced upward pressure on drug prices. Casual evidence compiled by this author in Taiwan and China is consistent with this concern. For example, it appears that uncontrolled prices of protected drugs at small pharmacies in Beijing and Shanghai have risen by a factor of three or four on average since the introduction of exclusive marketing rights in 1991 and patents in 1993.[11] Given the regression results reported above, such impacts could be expected to be even larger in higher-income developing economies, though smaller in poorer nations.

The most extensive study I have come across is by Lanjouw (1998) for India. Her research indicates that India currently has a highly competitive pharmaceutical sector. There are some 250 large pharmaceutical firms (12 of the 20 largest are Indian) and another 16,000 small producing units. These firms are quite capable at product adaptation. For example, within seven years of its introduction in India, 48 firms were producing a version of Ciprofloxacin, which is a patented drug in Europe and the United States. When Glaxo Corporation marketed a version of Zantac, it was quickly met with several local competitors who had already copied the drug. Interestingly, many of the companies competing with these on-patent drugs are foreign-owned multinational enterprises (MNEs). Thus, competition is based essentially on product differentiation and brand recognition. In India such brand advantages are important (reflecting quality control, reputation effects, and physician prescription practices) but seem to capture only perhaps a 10% price premium on uncontrolled products.

[11] Based on interviews conducted in December, 1997.

In such a context, the introduction of pharmaceutical product patents could be expected to raise prices considerably if they are uncontrolled. Lanjouw provided a comparison of the relative prices in 1995 of four on-patent drugs in India and Pakistan, the United Kingdom, and the United States. [12] For example, the price of Ranitidine was 14.1 times higher in Pakistan, and 56.7 times higher in the United States, than in India.

As noted earlier, some of these differences are attributable to higher per-capita incomes in the developed economies, though Pakistan's incomes are not much higher than India's. Another distinction is that only about 4% of India's population is covered by medical insurance that bears prescription benefits, so that most consumers must directly buy drugs, making them more price-sensitive. It seems that pharmacists, on a widespread scale, are willing to substitute cheaper alternatives for prescription pharmaceuticals. Moreover, the Indian government subjects a large part of the pharmaceutical market to price controls. Finally, an important distinction between India and Pakistan is that the latter country provides product patents. For these reasons, India has drug prices that are quite low on a world scale.

Assessing these factors, it is likely that the most significant price-restraining difference is that India has not patented drugs since 1970, a fact that itself supports partially the competitive structure of the Indian market. Thus, as Indian patents are introduced in the next decade, one would expect to see substantial price increases on newly patented drugs relative to what those prices would be otherwise. Again, how much such prices would increase depends on numerous collateral factors. With regard to particular drugs, much will depend on whether new products dominate a therapeutic application or whether (and how quickly) alternative treatments (both on-patent and off-patent) become available. Put more simply, the larger is the share of the drugs market that is patented, the higher will be the price impacts, which would vary also across therapeutic classes. In 1993 a maximum of 8.4% of registered drug sales in India were of products containing substances patented in Europe (Redwood, 1994), suggesting that the impending price impacts could be relatively slight. However, as patents are introduced and strengthened, it is likely that this share will rise to a higher equilibrium level, albeit a lower level than that in developed countries.

More generally, as incomes rise and more consumers are covered by insurance programs the demand for patented (and branded) drugs will become less elastic, supporting greater price hikes.

The Indian government could attempt to control the prices of patented drugs through administrative price ceilings. This is a common strategy in many countries, including developed countries (at least for that portion of the drug market that is procured by public budgets), and is allowable under TRIPS. In doing so, however, three interesting complications arise. First, companies that are awarded patents may choose not to supply the Indian market at the regulated prices, suggesting that a balance must be struck between public-health needs and access. Second, price regulations are often stated on a "cost-plus" formula, which encourages firms to set high transfer prices on imported

[12] See also Danzon and Kim (1998).

ingredients (Lanjouw, 1997) and could actually raise prices unless transfer prices are otherwise controlled. Third, it seems that price ceilings set in key developed countries, such as the United States, Canada, and France, are increasingly tied to reference indexes of prices in other markets (Danzon, 1997). Accordingly, firms have an incentive to bargain for the highest possible prices in the low-price economies, such as India, in order to gain a higher set of global reference prices. This issue, which is becoming increasingly important in the international pharmaceutical markets, promises to be fairly controversial in low-cost countries as patents are adopted. Rather than having firms set country-specific prices given local demand and market-structure characteristics (price discrimination supported by international proscriptions against parallel imports), markups could be a function of public-health concerns in developed economies, imparting an upward bias to prices in the larger poor economies.

This review suggests that the preponderance of forces will support markedly higher drug prices in economies such as India as patents are introduced. Accounting only for static price impacts under elasticities assumed to vary by therapeutic class, Watal (2000) computes that patents would result in an average price increase in the price of drugs of perhaps 50 percent if patents had been available, from a 1994 base. In the most extreme scenarios they could rise by 200 percent, a finding consistent with that in Fink (2000). Considering the other qualifications mentioned earlier, this is probably a conservative benchmark from which other influences will raise prices further.

Given this possibility, the role of parallel imports in dealing with price impacts is an important question. As will be discussed in the ensuing sections, this issue is complex. On the one hand, it is possible to argue that market segmentation (that is, a restriction on PI) would be more beneficial in poor countries for it would permit patent holders to set lower prices in developing nations as part of a global price-discrimination strategy. On the other hand, it seems from available price evidence that prices are often higher than in developing nations than would be expected under a simple price-discrimination equilibrium and, indeed, are at times higher than in the rich nations. Under such circumstances PI can provide a welcome source of lower-cost drugs.

3.2 Potential Impact on Local Pharmaceutical R&D

Offsetting these costs is the possibility of some dynamic benefits, however, which should not be ignored. First, it is possible that a higher proportion of new drugs will be made available to countries as they protect patents, though evidence in India suggests that product introduction in India is not much less frequent or slower than that in protected markets. Second, as originally noted by Diwan and Rodrik (1991), it is likely that additional global research will be devoted to the diseases of poor nations, which currently attract a small portion of global R&D funds. For example, the World Health Organization (1996) claims that of the $56 billion spent globally on medical R&D in 1994, only 0.2% was on pneumonia, diarrheal maladies, and tuberculosis, which account for 18% of global illness. Virtually all of this research was undertaken by public agencies or military authorities. The aggregate market size for pharmaceuticals of the

countries that will upgrade their patents over the next eight years is sufficiently large that, even at current shares of drugs patented elsewhere, the rise in demand could be as much as 25% of global spending (Lanjouw, 1998). While this is a crude calculation, it suggests that international pharmaceutical firms could enjoy marked increases in profits in developing countries, some portion of which would be devoted to research on tropical diseases.

Third, it is likely that some of this additional R&D would take place in MNE research facilities in developing economies, depending on local skill endowments, infrastructure, and demand characteristics. Market development activities could particularly be enhanced. Stronger patents (and trade secrets and brand protection) should have the effect of lowering contracting costs and facilitating know-how transfers (Arora, 1996). While the extent of these impacts on technology transfers from stronger patents remains an understudied empirical issue, survey results from Contractor (1981) indicate that licensing in high-technology sectors can be sensitive to patent protection.

Finally, some observers argue that stronger drug patents will encourage local firms to devote additional R&D spending toward developing patentable substances. In truth, the preponderance of evidence clearly suggests that domestic pharmaceutical companies in developing countries are unlikely to marshal the considerable resources required to compete successfully at this end of the business. The introduction of patents was not accompanied by any increase in the inflation-adjusted trend of R&D expenditures or on the introduction of new chemical entities in Italy (Scherer and Weisburst, 1995). Evaluations of pharmaceutical stock prices in Japan and Korea after patents were adopted suggest that investors anticipated drug firms to lose business and profits (Kawaura and LaCroix, 1995; LaCroix and Kawaura, 1996). Nogues (1990) found no reason to anticipate increases in R&D by local pharmaceutical firms in Argentina. Survey results in Lebanon found no intention on the part of local drug firms to compete through product research (Maskus, 1997).

4. Economics of Parallel Imports

The significant differences in policies reviewed above suggest that no clear case may be made that PI are beneficial or harmful in welfare terms, although they do harm the interests of IPR owners. The economic literature on the subject is limited but provides important insights that are useful for framing policy.

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 (expressed in a common currency) exceed the costs of transporting and selling goods across borders. Thus, 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.

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. In this section I discuss these basic theories and consider the welfare tradeoffs implicit in each. All of them could be important in pharmaceuticals, though price controls clearly loom large in this sector.

4.1 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. 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 effects of price discrimination in segmented markets are illustrated simply in Figure 1.[13] The line D_a is the demand curve for a pharmaceutical product in country A, which is assumed to be the high-income country. The line D_b is the demand curve in the low-income economy. One way to think about this model is that market A is the aggregation of high-income economies and market B is the aggregation of low-income economies and a single price exists in each. For simplicity I assume that demand in both markets would equal 500,000 units per month at a zero price. However, the maximum willingness to pay in country B is \$35 per treatment and that in country A is \$80 per treatment. In this structure, even though demand elasticity varies along these linear demand curves, for any common price in the two countries, market A displays the less elastic demand curve. Thus, the demand curves may be written as $P_a = \$80 - 0.16Q_a$ and $P_b = \$35 - 0.07Q_b$, where quantities are in thousands. Make the simplifying assumption that the manufacturer of this drug is able to supply both markets at a constant marginal cost of \$10 per treatment.

Initially suppose that the markets are segmented by a restraint on parallel exports. Then the manufacturer would maximize profits (actually quasi-rents from production, not counting its fixed R&D costs) by setting marginal cost equal to marginal revenue in each market. Performing this calculation with these demand curves, I find that price in market A is \$45 and quantity purchased is 219,000 units per month, with equilibrium shown at point A. Equilibrium price in market B is \$22.50 and quantity purchased is 179,000 units. Thus, in the segmented equilibrium the price in the high-income market is two times higher than the equilibrium price in the low-income market.

In market A, consumer benefits (measured in the usual way as consumer surplus under the demand curve) is triangle γ, or \$3.8 million. Quasi-rents earned in market A are the area above MC and below price, or area ($\eta + \varepsilon + \delta + \nu + \rho + \mu + \theta + \sigma$), which amounts to \$7.7 million per month. In market B, consumer benefits are rectangle δ plus triangles ε and μ, or \$1.1 million, and the contribution to the manufacturer's quasi-profits

[13] A similar analysis may be found in Scherer and Watal (2001).

is the sum of rectangles ν and ρ, amounting to $2.2 million. This result simply demonstrates that the manufacturer would be willing to supply this market as long as the price it can charge exceeds its marginal cost. In doing so, the firm realizes additional returns to apply to its R&D costs. Total quasi-rents in both markets amount to $9.9 million per month.

Now consider the impact of a mandated uniform price, where the manufacturer simply chooses the profit-maximizing price in the integrated market. Using these demand curves, there are two possibilities, depending on the maximum willingness to pay in country B. First, if the intercept of the B demand curve lies just below $35 or higher, the manufacturer will continue to supply market B, albeit at higher price and lower quantity. Simple calculations demonstrate that with the demand curve in B having an intercept of $35, the uniform price would be set at $29.40, or a reduction of 35% in the price in A, and an increase of 31% in the price in B. As a result, the quantity demanded in A would rise to 317,000 units per month and the quantity purchased in B would fall to 80,000 per month.

The impacts of such price integration are as follows. Consumers in the high-price country gain areas (ε + η + φ), or $4.2 million. Profits earned in market A fall by area ε + η (loss on price of existing sales) but rise by area τ (gain on additional sales), which amounts to a net loss in rents of $1.5 million. Because of the higher price in the integrated equilibrium, consumers in the low-income market lose areas (δ + μ). In this example this loss is $0.89 million per month. Finally, rents earned in market B rise by δ (higher price on remaining sales) but fall by ρ (foregone rents on lost sales), which together amount to a fall in profits of $0.90 million. Overall, the rent loss to the manufacturer is $2.4 million, or 24% of profits accrued in the segmented-market case.

In a second type of equilibrium, the manufacturer would pull out of market B altogether if that country's maximum price were just below $35 or lower for then it would make more profits by ignoring this market altogether and sustaining its monopoly price ($45) in market A. It may seem odd that the firm would not supply a market that would support a price above marginal cost but the problem is the requirement that the price be the same in both A and B. With demand curves in country B having a lower intercept than that shown in Figure 1, the firm would make smaller profits supplying B and A at the same price than by foregoing B and acting as a monopolist in A. Thus, for example, in an integrated equilibrium with a maximum willingness to pay in B of $30, the firm would make quasi-rents of $6.5 million per month if it supplied A and B at the common price of $26.80. However, it would make quasi-rents in the A market of $7.7 million by charging $45 there. Clearly at a price of $45, consumers in market B would choose not to buy the drug.[14]

This observation is directly applicable to the global situation in which many countries may be ranked by their maximum willingness to pay for medicines, which is an

[14] This outcome is not guaranteed for it relies partially on my linear-demand example. It is possible under some extreme demand assumptions that the firm would be willing to supply more of the product in both markets at a still-lower price. However, this case is highly unlikely in practice.

increasing function of their size and incomes per capita.[15] The small, least-developed countries would almost certainly not be served by pharmaceutical companies in a case where there were a globally uniform price. As economies achieve middle-income status they would be more readily placed on the list of places worth supplying. Finally, note that the main beneficiaries of uniform pricing would be consumers in high-income countries.

Economic theory has long noted that price discrimination can provide positive economic benefits to society (Varian, 1985; Schmalensee, 1981). A necessary but not sufficient condition for a welfare increase is that output rises under a regime of discrimination in comparison with a regime of uniform pricing. In this case, the firm can supply more consumers (countries) with lower valuations for a product while extracting additional surplus from consumers with higher valuations. Compared to the uniform price case, the surplus gained in the newly served market segments outweighs the surplus lost in the higher-priced segments.

Malueg and Schwartz (1994) extended this logic to international trade. At the global level banning parallel trade would result in perfect discrimination in the sense that one price is set per market. On the other hand, requiring unrestrained parallel trade would establish uniform pricing by the IPR holder. Economies with large markets and inelastic demand would face higher prices under price discrimination than under uniform pricing, harming consumers. In contrast, countries with small markets and elastic demand would face lower-than-uniform prices under price discrimination.

Again, the standard view is that this situation pertains in most developing countries, though I present some cross-country price evidence in the next section that brings this assumption into question. In the presence of parallel trade, foreign rights holders may choose not to sell to such countries because local demand could be insufficient under uniform pricing. Alternatively, products that would command low prices in developing countries under a regime of national exhaustion would be exported to high-priced regions under a regime of PI. In turn, consumer prices would rise in poor nations. In this view, a global regime of international exhaustion would lower welfare of developing economies through higher prices and lower product availability.

In this regard it is curious that most developing countries express opposition to restricting parallel trade (Abbott, 1998). In part, this reflects a belief that domestic prices could actually be higher for imported goods under price discrimination. This concern is expressed frequently with respect to pharmaceuticals trade, as evidenced by the South African legislation mentioned above. The possibility that price discrimination could result in lower prices in developing countries, in the face of market power enhanced by IPR, is a leap of faith to those unfamiliar with economic theory.

[15] This ranking by per-capita income could be demonstrated in a setting with utility functions in which consumers have minimum consumption requirements, which are highest for survival goods such as shelter and food. In poor countries the need to achieve basic consumption levels in these commodities would not leave enough income to purchase many medicines or other goods with lower minimum consumption requirements. In this structure, demand for medicines would rise with per-capita incomes (Markusen, 1986).

The integrated equilibrium analyzed in Figure 1, in which prices converge in both countries, is based on strong assumptions. The cases modeled could result from a global edict that firms charge the same price in all markets, permitting the firms to choose that price without other restraint. However, it is difficult to see how such an edict could be enforced. Rather, parallel imports are the competitive mechanism that could drive prices together. However, this raises additional complications. First, goods that are parallel-imported may not be perceived to be of the same quality between markets, even if they were placed on the market originally by the manufacturer, because of differences in packaging or guarantees. In this context, PI may not be sufficient to equalize prices, except on a perceived, quality-adjusted basis. Second, if they occur in equilibrium, PI use up resources in transport costs and those resources must be counted as a welfare loss against the gains from price integration. Again, PI can only cause prices to converge up to the transport cost margin. Tariffs, port charges, distribution costs, and taxes can also sustain wedges between national prices.

It is important to take transport costs seriously if one is to assess the net benefits or costs of PI. Ganslandt and Maskus (2001) present a model that considers how manufacturers might defend themselves from PI by setting prices to deter it or by limiting their original supplies to distributors. In the model the retail price (that is, the ex-manufacturer price charged to hospitals and pharmacies) in the low-price country B is capped by a price regulation while there is no such cap in the high-price country A. There is a competitive fringe of parallel-importing (PI) firms in country B and they stand ready to ship the good to A at a transport cost per unit of $t.

In their first model, the authors suppose that an unlimited supply of a patented drug is available from wholesalers for this kind of arbitrage. In this case the PI firms will undercut the price set by the manufacturer in market A as long as the price difference is larger than the trade cost. Because the supply is unlimited, the manufacturer sells nothing in market A if there are any PI at all. Thus, the manufacturer has two strategies. He can either *deter* PI altogether by setting a sufficiently low price that there are no imports. Alternatively, he can *accommodate* PI by reacting to the level of imports chosen by PI firms. When potential arbitrage is unlimited, deterrence is more profitable than accommodation, for the latter achieves no sales except to wholesalers in market B. In the deterrence case price in market A converges to the capped price in market B plus transport cost. Note that no actual PI takes place and there are no resources wasted in transporting PI goods, which is beneficial. Consumers in market A benefit from the *threat* of PI but *no actual* PI is required in order to achieve this outcome. Of course, the manufacturer earns smaller profits as a result.

This case is illustrated in Figure 2a. The manufacturer chooses price p_h^* in country A in the case where A and B are segmented. This price earns quasi-rents in A of the area of the box below the line extending from p_h^* to A.[16] These rents may be used to cover R&D costs. The price in B is controlled at $p_f^{\wedge}$. Note that consumers in country B "free ride" on those in country A in the segmentation equilibrium for the price control

[16] We assume the marginal cost of production is zero, which does not matter for the analytical results.

provides a smaller (or no) contribution to covering R&D costs. Given the controlled price, the cost for a PI firm of shipping the good to A is $p_f^{\wedge} + t$. Thus, in the deterrence equilibrium the manufacturer is forced to reduce price to the foreign price plus tariff. The result is a transfer from the manufacturer to consumers of area $(\alpha + \beta)$ and a net consumer efficiency gain of area δ. Moreover, area $(\tau + \rho)$ gives additional rents to the manufacturer from the higher sales volume in A. Here, area τ ordinarily would be considered resources wasted in trade costs but there is no actual trade in equilibrium. There are no effects on consumers in country B by virtue of our assumption of unlimited supplies of the PI good, thereby retaining price $p_f^{\wedge}$ without pressure to rise.

The figures in Figure 2a illustrate these tradeoffs using the same demand function as before: $P_a = 80 - 0.16Q_a$. With this structure, the segmented monopolist sells 250,000 units per month at a price of $40 in country A. Quasi-rents for the monopoly manufacturer are $10 million. Suppose that the controlled price in country B is $10 and the transport cost per unit is $5. In the deterrence equilibrium, the manufacturer sets a price of $15 in country A, which generates a consumer efficiency gain (δ) of $1.95 million per month. Quasi-rents lost in the A market $(\alpha + \beta)$ are $6.25 million, while quasi-rents on additional sales $(\tau + \rho)$ are $2.34 million. Overall economic welfare in country A would decline by $1.96 million, if we assume the manufacturer is located there (e.g., the United States); it would rise by $1.95 million if the manufacturer is not located there (e.g., Australia). Because profits fall by $3.91 million per month, future R&D would be reduced.

Thus, this case illustrates an important problem for policy makers in deciding whether to permit PI. There are consumer gains in A from wider dissemination of a monopolized good. Country A ends up importing the price regulation existing in country B. However, quasi-rents in the deterrence equilibrium are lower than in the monopoly case, implying a reduction in future R&D. It is the task of policy makers to decide how they wish to strike a balance between these results.

An alternative (and more likely) model is that the manufacturer recognizes the potential impact on her profits from deterring potentially unlimited PI. One way to limit this damage for the firm is to sell a smaller quantity to the foreign wholesalers, making it impossible for them to send a sufficient quantity to market A to establish price convergence with the B market price plus transport cost. In this case, the manufacturer is able to sustain a higher price in country A but there are PI in equilibrium, thereby incurring transport costs. An *accommodation equilibrium* can arise when the potential volume of arbitrage is small and the trade cost is relatively high. Even so, the accommodation price falls as the volume of PI increases. Thus, higher PI volumes result in lower prices in country A.

The accommodation case is illustrated in Figure 2b. Again, the monopoly price is set at p_h^*. The PI firms choose to sell some quantity k in market A, permitting the manufacturer to act as a monopolist on residual demand. We may interpret k as either a physical limitation imposed on PI firms by wholesalers or as an endogenous volume selection by the PI firms. In this case, equilibrium is at point C with price p_h^m and the

manufacturer selling quantity q_h^m. The consumer efficiency gain is area σ. The manufacturer loses quasi-rents equal to the box to the left of point A plus area λ_1 (transferred to PI firms) and area τ_1 (lost to transport costs). However, the manufacturer gains quasi-rents of area χ on additional foreign sales to support the PI volume. In this case profits of λ_2 are generated for the PI firms on additional consumption in country A and total rents for the PI firms are $\lambda_1 + \lambda_2$. Resources used in transporting PI are the area $(\tau_1 + \tau_2)$. Country A may be better off or worse off as a result of accommodation. One feature that matters is whether PI firms are considered to be resident in country A or elsewhere. Note clearly in this case that PI generate only a partial convergence of prices between markets A and B.

The manufacturer would be indifferent between deterrence and accommodation where (for a given t) the parallel imports k are large enough to set residual marginal revenue equal to zero (marginal cost) at price $p_f^{\wedge} + t$. For lower PI the manufacturer would accommodate and for higher PI she would deter such trade. PI firms understand this decision (and the fact that they would achieve no profits in the deterrence case) and therefore select a limited trade volume.

Again, we may illustrate these effects with our basic demand curve in country A of $P_a = 80 - 0.16Q_a$. Suppose that the volume of PI (k) is 100,000 units per month. In this case the manufacturer would sell 200,000 units at a price of $32. Its profits would fall by $2.5 million per month overall. There would be a net consumption efficiency gain in country A of $0.8 million. Rents to PI firms would amount to $1.7 million and transport costs would come to $0.5 million per month. If both the manufacturer and the PI firms reside in A, net welfare gains there would be $0.45 million per month. If the manufacturer resides in A but the PI firms reside abroad, net welfare gains in A would be $0.7 million per month as foreign interests would absorb the transport costs.

Putting this analysis together, the essential questions it raises are as follows. First, is the threat of PI sufficient to bring prices together between PI export locations and PI import locations? Second, are PI actually observe in equilibrium? Third, are the transport costs significant when engaging in arbitrage? Finally, are the consumer gains from arbitrage sufficient to outweigh the trade costs and the potential reduction in R&D incentives? These are empirical questions and I provide some evidence on them in the next section.

4.2 Price Discrimination and Exchange-Rate Changes

Before leaving this section, it should be noted that exchange rate variations play a significant role in supporting retail price differences across markets. An extensive literature in economics discusses processes by which imperfectly competitive firms may avoid full pass-through of an exchange-rate change by setting local-currency prices that are specific to demand characteristics in each market.[17] Thus, for example, suppose that in an initial equilibrium the price of a prescription drug made in Spain is 10 pounds in the

[17] See Feenstra (1989), Knetter (1989, 1993), and Marston (1990), for example.

UK and the price in Spain is 15 Euros, with an exchange rate of 1 pound = 15 Euros. In this equilibrium the UK and Spanish prices are the same measured in either currency and there would be no arbitrate.

Now suppose the British pound sterling were to appreciate by 10 percent relative to the Euro. In this context, we would ordinarily expect that perfectly competitive pharmaceutical firms selling in Britain at a constant Euro price would see a 10-percent decline in the pound sterling price relative to the Spanish Euro price. However, because the major pharmaceutical firms are oligopolistic, they might attempt to avoid this price change (and implied changes in volumes) by keeping their price array stable in both places. In this case, with a pound price of 10 and a Euro price of 15 but an exchange rate of 1 pound = 1.65 Euros, the Spanish price is 10 percent cheaper than the British price. The pharmaceutical firms could well prefer this outcome to one in which prices adjust by 10 percent for as long as it is sustainable. Over time, however, there would be some mixture of price reduction and quantity increases, with prices tending to fall more in Britain as time passes. However, if markets are segmented the price differentials could be persistent.

For as long as this pricing-to-market behavior could be sustained the observational result would be significant differences between retail prices in the export markets and in Britain when measured in a common currency. Clearly PI firms would arbitrage on this price difference if they were permitted to do so and their operating and transport costs were below the 10-percent differential. Suppose that such costs amounted to only three percent of procurement costs. Then PI firms would purchase the drugs in bulk at a price of 15 Euros, sell them in the UK at a price of at least 15.45 Euros, which would command 9.36 pounds, a price considerably below the 10-pound price maintained by oligopolistic pharmaceutical firms. If the PI drugs were sold at any higher price the trading firms would make quasi-rents in their operations. For example, if they could sell at a price of 10 pounds they would earn 16.5 Euros, for a profit per unit of 1.05 Euros.

In this example, then, we would see that the price of PI drugs would range between 9.36 pounds sterling and 10 pounds sterling, with lower prices favoring consumers in Britain and higher prices generating quasi-rents to PI firms. An important consideration, then, is the extent to which competition among PI firms would result in a price near the lower end of the range supported by the pricing-to-market decisions of the original manufacturers. It is clear that if the number of PI firms is small, so that the sector is also imperfectly competitive, the result would likely be toward the upper price range, with little gain to consumers. One conclusion from this analysis is that if a country intends to permit PI it should make competition among the PI firms as active as possible.

The main point is that PI activities often emerge quickly as a result of significant appreciation of the importing country's currency, if that appreciation is expected to be sustainable for a period of time sufficient to organize and conduct PI. For instance, there was a marked surge of PI in cosmetics, perfume, automobiles, and other high-end trademarked goods into the United States in the early 1980s as a result of considerable real effective appreciation of the dollar (Tarr, 1985). Dollar-denominated U.S. prices

within authorized distribution outlets did not fall in this period (indeed, many rose), suggesting strongly that foreign manufacturers were pricing to market. This fact also suggests that the PI experienced in that period was insufficient to bring down U.S. prices in competition and that PI firms were considerably profitable until the dollar reversed course, at which time their activities dried up.

With fixed exchange rates in the Euro zone, PI in pharmaceuticals based on exchange-rate differences is unlikely to exist in large measure once the market is fully integrated. Thinking about developing countries, however, to the extent that drug firms engage in pricing to market in nations with overvalued real exchange rates the price-moderating effects of PI could be beneficial. Thus, suppose that a country such as Cote d'Ivoire had a high value for its currency (because of the peg to the French franc) in relation to nearby countries with falling currency values. Regional distributors of pharmaceutical companies might be expected to maintain a fixed local-currency price in each country, which would raise significant price gaps that would induce PI into the Cote d'Ivoire.

Thus, one important reason that for the observation (discussed in the next section of this report) that retail prices for drugs are often higher in poor countries than in middle-income or even rich countries is that the former group may sustain unrealistically high currency values. Pricing to market, a process that would be made yet easier if importing nations have exclusive-distributorship rules, may be expected to maintain high prices in those countries. In such cases being open to PI could be beneficial, though it would be a second-best solution in comparison with maintaining a realistic exchange rate and removing any government-mandated exclusivity in distribution.

4.3 Final Comments on Price Discrimination

Price discrimination is often viewed as anticompetitive in that it permits firms to set prices according to market power in each country. This market power is sustained by restrictions against PI, which leads some observers to view such controls as non-tariff barriers to trade in goods that have legitimately escaped the control of IPR owners (Abbott, 1998). Moreover, to the extent that market segmentation promotes collusive behavior within private territorial restraints, restricting PI serves as a facilitating device. Thus, a regime of international exhaustion is a form of competition policy and is an important limitation on the scope of intellectual property rights. The possibility that supporting exclusive territories with protection from gray-market trade could encourage collusion finds some support in U.S. economic history (Tarr, 1985; Hilke, 1988). Indeed, some developing countries are concerned that restricting parallel imports would invite collusive behavior and abusive price setting on their markets by foreign holders of local patents.

The claim that price discrimination across segmented markets is harmful and promotes collusion must be heavily qualified. The market power associated with IPR may be slight if there is extensive inter-brand competition in each location.

Thus, whether price discrimination harms or helps particular countries depends on circumstances. There are no unambiguous predictions about global welfare rankings with and without parallel trade. Malueg and Schwartz (1994) argued for banning parallel imports on the grounds that international price discrimination would result in net global output expansion and raise global welfare, while ensuring further that low-price markets are provided goods. However, this result is dependent on their restrictive assumptions. A more sensible conclusion is that parallel trade could be beneficial among countries with similar demand structures, say within a regional trade agreement, but would be harmful across nations with different demand patterns.

The claim that global welfare could be higher under price discrimination associated with restrictions on PI also must face the objection that such a regime would cause a redistribution of consumer benefits in high-price countries to consumers in low-price countries. Even if the aggregate gain were large enough to compensate the former consumers for their losses, such compensation could not be effected practically. Moreover, there would be a redistribution from consumers in high-price countries that are net importers of intellectual property-protected goods to producers in countries that are net exporters of those goods.

4.4 Vertical Price Control

The basic notion that manufacturers exercise price discrimination at the retail level is somewhat misleading. Firms typically sell to local wholesale distributors, which then deal with retailers. Thus, a second explanation for PI is that such trade may flow between international distributors or between distributors and retailers. In many circumstances efficient distribution requires permitting the right-holder a significant degree of vertical control over the operations of its licensees. Multinational enterprises build markets through establishing exclusive dealership rights in various territories. Exclusive rights make it easier to monitor marketing efforts and enforce product quality, which may be a significant issue in pharmaceuticals. However, it may be difficult or legally impossible in foreign markets to enforce private contractual provisions prohibiting sales outside the authorized distribution chain. Seen this way, restrictions against PI are a necessary complement to exclusive territorial rights (Chard and Mellor, 1989).

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, to the extent that distribution systems are poorly developed and concentrated among a few firms. This is likely another important reason why prices of some drugs tend to be higher in some developing nations. Indeed, I will present evidence in the next section that the competitiveness of local wholesaling is an important factor in setting export prices by U.S. firms to their foreign distributors, with countries in which wholesaling is more concentrated experiencing significantly higher prices. I should note

that the evidence mentioned is for a product sample that does not include prescription drugs.

Maskus and Chen (2000) and Chen and Maskus (2001) develop a theory of parallel imports and vertical price control. 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 permits distributors in the foreign market to sell the product 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. Finally, parallel trade wastes resources through transportation of goods between countries. Indeed, it is possible in their model for goods to be traded in both directions and for PI to move 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. It follows that it may raise welfare within regional trade agreements to permit PI. This result is comparable to the Malueg-Schwartz finding that regional exhaustion may be the optimal global policy. In terms of medicines, both theories would support the notion of freely permitting PI among nations of similar economic development levels and in close proximity to one another. The larger market would help discipline collusive behavior within the region, while the proximity would reduce transportation costs. However, no general propositions may be made about the global welfare effects of parallel imports.

4.5 Free Riding on Fixed Marketing Costs

A third explanation for parallel trade 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. These costs are likely to be quite significant in the area of prescription pharmaceuticals. 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 (Rozek and Rapp, 1992). To earn a return on those investments, they must charge a price markup over marginal procurement costs. Such enterprises would prefer protection from competition by parallel importers who can simply buy the goods abroad without incurring similar costs (Chard and Mellor, 1989;

Barfield and Groombridge, 1998). Indeed, this is the primary motivation for permitting privately contracted exclusive territories in the first place. The World Intellectual Property Organization advocates the principle that restrictions against PI are a natural extension of the right of IPR holders to control vertical markets.

Such restrictions on PI may be procompetitive, both through encouraging investment in inter-brand competition and through providing incentives to build markets and provide services. A failure to provide adequate protection for these investments could mean that markets would be underserved due to slower rates of introduction of new drugs. Moreover, in an attempt to differentiate their versions of the otherwise identical drugs in competition from PI, authorized dealers may engage in excessive packaging, advertising, and promotional efforts, leading to resource waste relative to the true costs of informing consumers and medical providers. Unfortunately, there are no available data or empirical studies that may be used to determine how significantly PI could harm authorized distributors through free riding on their marketing costs.

4.6 Differential Price Regulations

A fourth source of PI is that international price differences may stem from national price regulations established to achieve particular social objectives. The most prominent example arises in pharmaceuticals, a 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 (Danzon, 1997). Permission of parallel trade could defeat the purposes of regulation as distributors in more regulated (lower-price) markets ship medicines to less regulated (higher-price) markets. In turn, those exports could exacerbate any shortages in the export market of medicines arising from the regulatory standards. In this context, one argument for banning or controlling parallel exports in goods for which prices are heavily regulated stems from the need to defend the 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 (Abbott, 1998). This interpretation has not been tested at the WTO.

While there is little evidence that PI flows actually do interfere with the ability to control prices (see next section), one case provides such a stark example of these principles that it bears particular mention. The HIV/AIDS crisis in Sub-Saharan Africa, now spreading to South Asia and Southeast Asia, can only be managed without further catastrophe if drug treatments are made available at very low cost to sufferers in those regions. Annex A of this report contains a working paper on this subject, in which I (and two co-authors) call for a policy that would combine public purchase of the patent rights in target countries and provision of medicines at very low cost. Equally important, there must be *tight controls on parallel exports of these drugs out of the target countries and tight controls on parallel imports of these drugs from the target countries into rich nations*. Such trade restraints would be necessary to support what would be beneficial price discrimination (though organized in a different fashion) in this case.

4.7 PI and Effects on R&D

A more important version of the free-riding hypothesis moves one step back to the manufacturer. Original rights-holders may finds their profits diminished by the ability of PI to interfere with discriminatory price setting, maintaining vertical control, and limiting licensing revenues. It is possible that this reduction in profits would 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 tradeoff is important so I devote some commentary to it here.

4.8 General Observations

A key health-policy objective 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 limits the risk that healthy individuals could be harmed by infectious diseases upon contact with ill people. This externality is one important reason for subsidizing broad access to drugs and could also be used to justify subsidies to 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.[18] 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.[19]

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, 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.

[18] See Danzon (1997). Sachs, et al (1999) estimate the average cost for a new drug to be $300 million and predict that developing vaccines for HIV, turberculosis and malaria would ”potentially cost several times as much given the scientific challenges involved”, p. 8.
[19] Danzon (1997).

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. Such problems can be solved, at least in theory, if the short-run and long-run objectives are separated. The first-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 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.

So far we have discussed the problem of static distortions and dynamic efficiency in general terms. It is, however, important to recognize the international dimension of this issue. 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, health-care policy in one country has important implications for policy in other countries.

Starting with the issue of different objectives in industrialized and developing countries, 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. 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.[20] 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

[20] Surely an equally important difficulty is that low purchasing power provides insufficient incentives to pharmaceutical companies to introduce new drugs into the markets of poor countries. Introducing patents will be of little short-run value in relieving such poverty.

research was performed by public agencies and military authorities. Further, there is insufficient R&D in anti-malarial vaccines or drugs. Sachs, et al (1999) cite a Wellcome Trust study that 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. 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.

4.9 The Role of PI

The concern in this report is the potential impacts of PI on R&D incentives and development of new drugs. This is an extremely difficult question to answer and there are no available studies based on actual data. Even if there were data it is conceptually hard to answer for four reasons. First, the precise effects of profits on original manufacturers would depend on the particular structure of competition, though they are surely negative. Second, as discussed above, a small volume of PI does not imply small price and profit effects (consider the deterrence case, for example). We need to correlate price changes with profitability, which is difficult. Third, even if we could calculate the impacts on expected profits *ex ante*, we do not have 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.

As was illustrated earlier, permitting PI could have significantly negative impacts on returns to R&D, at least in theory. Thus, for example, in the price discrimination model of Figure 1, monthly quasi-rents would fall by 24 percent of their initial value as a consequence of uniform pricing. In the second model profits would fall by 25 percent in the case of accommodation and by 39 percent in the case of deterrence. Because these computations are rooted in optimizing behavior they demonstrate that profit impacts could be substantial even for a wide range of demand elasticities.

However, such figures are illustrative only because they do not derive from actual market data. An obvious simplification is the assumption that PI would cause price convergence, at least up to the level of transport costs. As shown in the next section there remain substantial differences across countries in ex-manufacturer's prices, even within the EU where PI are permitted internally. Thus, there appear to be significant informal impediments to full price integration. Such impediments include consumer concerns that PI drugs may be of lower quality, problems with marketing PI medicines under unfamiliar brand names, differences in packaging, and the like (NERA, 1999). It follows that even in a comparatively comprehensive regime of PI, manufacturers have means for

ensuring some market segmentation and limiting the profit reductions associated with parallel trade.

Another important observation is that because incentives for PI emerge primarily on economically successful, or "blockbuster" drugs, the effects of PI would be concentrated in such drugs. 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.

In that context, it is evident that PI have at least two 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 Figure 3. Suppose that there is free entry in the long run into R&D in the pharmaceutical sector.[21] This means that R&D costs in the first period 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 R_S) and "blockbuster" drugs (with R&D level R_B). The curve labeled Π_0 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. I have drawn it to be convex, reflecting the notion that as R_B gets lower, further small reductions in R_B would require larger marginal increases in R_S to maintain zero profits.[22] An 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 R_S to the resources saved from undertaking one less unit of R_B. The ratio of small-drug research to blockbuster research is given by $(R_S/ R_B)^0$.

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 Π_1. In this case, the *scale effect* could be read at the intersection of the ray $(R_S/R_B)^0$ and the new profit locus, with both types of research reduced. However, an additional impact to consider is

[21] Danzon (1998) argues that this is the case, though it is certainly debatable.

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

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.

Before turning to a comparison of national experiences with PI and R&D performances, it is important to consider the potentially positive role of restraints on parallel trade in motivating R&D. Danzon (1997, 1998) has put forward the case that all drug markets should be fully segmented because such segmentation would enhance the efficiency with which drug research is financed. She bases this argument on the concept of *Ramsey pricing*, in which the recovery of a given sunk cost (e.g., past R&D in a pharmaceutical product) is accomplished by charging a markup of price over marginal distribution costs to consumers in different markets based on elasticity of demand. In this view, sunk R&D costs are joint across countries in the sense that the costs are the same no matter how many consumers enjoy the product. Put differently, consumers in multiple markets benefit from the drug even though the costs are formally incurred only at the R&D location.

The question arises as to how to price the drug in different markets in order to cover these sunk costs. It is straightforward to show that if prices are set in each country such that the markup of price over marginal cost rises as the demand elasticity falls, subject to covering the sunk costs, global economic surplus is maximized. Danzon argues that market segmentation (that is, no PI and no recourse to reference pricing) would tend to replicate this solution and provide the most efficient method for financing new R&D. In this regard, a global proscription against PI, in conjunction with prices set freely by pharmaceutical firms, would be favored to promote new drug introduction.

However, this seemingly simple solution requires considerable qualification. First, strictly speaking the Ramsey formula is efficient only if a regulator aims to set prices that would generate only a normal return (that is, zero monopoly profits) for a utility with given sunk costs. However, pharmaceutical companies naturally are interested in earning more-than-normal profits and would resist efforts at global rate-of-return regulation. Second, the Ramsey model makes sense in a single economy with a single regulator. However, in the international context each national government would have different preferences between access to medicines and contributing to the costs of their development. Recognizing that costs are sunk, some countries would prefer to negotiate prices that are closer to marginal costs of supplying their markets than to Ramsey prices. In the short run, rational pharmaceutical firms would be willing to supply such drugs at near-marginal cost because any price over marginal cost makes a contribution to R&D costs. Health authorities may be unconcerned about the long-run impact on slower drug development and may believe, in any case, that its market is sufficiently small that price regulation would not have much effect on R&D. Finally, it is doubtful that true demand elasticities are revealed by market volumes in an environment of extensive price controls.

5. Empirical Evidence

Because they are simply a form of legitimate competition, parallel imports are rarely recorded separately in official trade statistics. Thus, it is exceedingly difficult to analyze their impacts on prices and competition in any general sense, though I present some evidence from Swedish data below. Rather, investigators tend to take indirect approaches, looking at international differences in drug prices to make tentative inferences about whether prices fit standard models of price discrimination and what the potential for PI might be. Here I review that evidence and also put forward some econometric evidence on price impacts of PI.

5.1 International Price Differentials

For reasons set out in Danzon and Kim (1998) it is difficult to compare pharmaceutical prices across countries. A clear difficulty arises if the researcher attempts to develop a comparable price index for patients in different countries. Such indexes should include prices of generic substitutes and local "me-too" drugs, the existence of which could affect the relative consumption of different drugs. Thus, a considerable issue surfaces with regard to selecting appropriate weights to include in such cross-country indexes. Second, the same range and quality of drugs may not be available to consumers in all countries, because of differences in preferences, information asymmetries, and regulatory differences. Third, significant differences across countries in brand name, product forms, concentrations, and pack sizes make it difficult to find precise drug products that exist in multiple jurisdictions. Indeed, this latter differentiation is surely one method by which pharmaceutical firms attempt to segment markets. Next, to the extent that regulations, taxes, and mandated discounts extend to ex-manufacturer's prices, these differences can cloud cross-country comparisons. Finally, because original prices are quoted in local currencies, the choice of exchange rates at which to convert these prices into a common unit (usually U.S. dollars) could have a significant impact on price comparisons across counties (though not across medicines within each country).[23]

To be sure, this is a daunting list of problems. However, they are least significant for a researcher considering PI. In particular, they may be effectively mitigated if the researcher focus solely on well-defined products, which I define here as a drug sold in identical concentrations, forms, and pack sizes, marketed by the original manufacturer (or its licensees). The advantage of the narrow definition is that it avoids thorny weighting problems across dosages, while the advantage of focusing only on drugs sold by the original manufacturer is that it avoids weighting problems associated with generics. In any case, the proper focus of a study of PI is international differences in ex-manufacturer's prices. Moreover, while variations in market exchange rates clearly affect prices, as I discussed earlier such exchange-rate effects are an important reason that PI

[23] Danzon and Kim (1998) point out additional problems if the researcher is interested in making welfare comparisons, which is not the focus here.

exist. Accordingly, narrow comparisons of prices converted at market exchange rates are appropriate for investigating the potential scope for PI.

To investigate how significantly prices differ across countries and whether they vary inversely with income levels, I purchased data on ex-manufacturer's prices and sales for major molecules in 14 countries in 1994 and 1998. Table 1 presents information on per-dosage prices in U.S. dollars in 1998 for 20 brand-name drugs for which prices in several nations could be identified. Keep in mind that these are the prices charged by the manufacturing firm (or its direct licensees) that owns the brand name listed at the top of each column. Thus, they are the most direct measures available of international price variability in identical products, which may be the subject of parallel trade.

Thus, for example, Norvasc cost $0.97 per 5-mg tablet in the United States in 1998, while other prices ranged from $0.09 in India to $0.83 in Brazil. Despite the potential for parallel imports, there was considerable price variability within the EU, with the British price of $0.61 being 45% higher than the price in Spain. In this simple context, it seems that the prospect of PI did not cause those prices to converge at the factory gate within the EU. Note further that Italy and Spain were in the European Monetary System in 1998 but their mutually fixed exchange rates did not induce enough arbitrage to result in identical dollar prices, with the Italian price remaining 38% above the Spanish price. Among the developing countries, prices in Mexico and Brazil were markedly higher than were those in Korea, Thailand, India, and South Africa. Note that the South African price was fully 3.7 times higher than the Indian price.

These observations are largely consistent across most of the 20 drugs. However, some important differences exist. First, prices in many drugs are lower in a number of developed countries, especially Canada, Italy, and Spain, than in Mexico, Brazil, and South Africa. This fact reflects the existence of significant price controls in such developed countries.[24] Indeed, in 10 of the 18 cases for which prices existed in both Italy and/or Spain, on the one hand, and in South Africa, on the other hand, the price was higher in South Africa. Note also that prices in developing countries sometimes exceed those in the United States, which typically has the highest prices of any country. I have marked such cases in boldface. Thus, Sandimmun 100-mg capsules were 17% more expensive in dollar terms in Mexico than they were in the United States. Such differences existed also in Mexico and Brazil for Neoral, Brazil for Cipro, Diflucan, and Cozaar, and for Mexico, Brazil, the Czech Republic, and Korea for Effexor. Taking the simple average of prices in the next-to-last column, it seems that Brazil and Mexico had the second-highest and third-highest average prices in the sample, markedly higher than Canada, Italy, Spain, and Japan.[25] Noting that such averages may be biased by the different numbers of products available per country, in the final column I report for each country the average of prices relative to U.S. prices, where a product exists in both

[24] Canada may have especially low recorded prices because of recent deterioration in the value of the Canadian dollar.

[25] Caution should be exercised in comparison of averages because these figures are not weighted by local consumption patterns.

places. Again, Brazil and Mexico are the highest-priced nations behind the United States, though by this measure their prices are barely above those in Sweden and Japan.

A central question in thinking about PI is whether multinational pharmaceutical firms do, indeed, set prices according to per-capita income differences. The standard theory of price discrimination, as noted earlier, suggests that when markets are segmented, prices will be lower in those countries with lower and more elastic demand curves, which would ordinarily be associated with poor countries. If per-capita income were a perfect index of demand elasticity, there should be a correlation of plus unity in comparing prices across countries with per-capita GNP.

The final cell in each column presents such calculations for each drug and for average prices. The first entry in the cell is the correlation between dollar price and per-capita GNP measured at market exchange rates and the second entry is the correlation between dollar price and per-capita GNP measured at purchasing-power-parity exchange rates (PPP).[26] The latter comparison is more appropriate for the present purpose (comparing price behavior at different levels of demand), though both present similar results.

Looking at the computations, 17 of the 20 individual-drug correlations are significantly positive, ranging from 0.18 (Cozaar) to 0.90 (Imitrex). Two of the PPP correlations approach unity (Pulmocort and Imitrex), suggesting for those drugs that the brand owner practices something like Ramsey pricing. Six more have correlations of at least 0.5, which might be considered to support the underlying pricing model. However, nine drugs have correlation coefficients that range between 0 and 0.5, and three are negative. Neoral and Imovane both display significantly negative correlations between income levels and prices. As noted in the penultimate column, the correlation between average prices and per-capita GNP is clearly positive but well below unity.

These results provide some support for the idea that prices for identical, brand-name drugs, are inversely related to per-capita income levels. However, there are numerous exceptions to this rule and several correlation coefficients are well below unity. Thus, the result is hardly conclusive; it seems that other factors go into national pricing decisions by the multinational pharmaceutical companies.

Before considering what those factors might be, consider three further pieces of evidence. First, Charts 1 through 7 provide further perspective on bilateral price comparisons between particular countries and the United States. By looking at bilateral comparisons without requiring that each drug have several country observations in common, more drugs may be brought into the analysis. The charts depict relative prices for brand-name drugs, with each observation showing the local price divided by the U.S. price in 1998. The tables on the pages after each chart list the individual products by company, drug name, form and concentration.

[26] These data were taken from the World Bank, *World Development Report: 1999-2000.*

For example, the observations in Chart 1 show Mexican prices divided by U.S. prices for 35 products covering 15 brand names and numerous forms and concentrations. Observations above 1.0 indicate price relatives in which the product was more expensive in Mexico than the United States in 1998. This situation held for 9 of the 35 products, with higher Mexican prices concentrated in Sandimmun, Neoral, Pravachol, and Effexor. Some of these cases may reflect unusually high prices in Mexico associated with small volumes for particular formulations. Several products, such as Lasix, Seloken, Losec, Zantac, Risperdal, and Imitrex, registered Mexican prices below 50% of the U.S. price, more consistent with Ramsey pricing. It is evident that there is considerable randomness in bilateral price comparisons.

Chart 2 depicts Canadian drug prices relative to U.S. prices. Only one product (Effexor, A tablets, 75 mg) had a higher Canadian price, though two others (Cipro, Diflucan) showed parity. Most Canadian prices were between 40 percent and 80 percent of American prices, attesting to the effects of price restraints in Canada. Chart 3 combines those drugs for which both Mexican and Canadian relative prices were available. The remarkable aspect of this chart is that for virtually all drugs Canadian prices were less than Mexican prices, often by significant margins. Mexico registered lower prices only for Imitrex. In this regard, were there free PI between these countries the direction of trade would flow in most products from Canada to Mexico.

Chart 4 demonstrates relative price ratios for five European nations. Two observations are relevant. First, while there was considerable variability in price relatives across drugs, these ratios moved together within the group of European countries. Thus, while European integration does not eliminate inter-drug price variations across countries, it does prevent much intra-drug variation. Nonetheless, this intra-drug price variation, which is the subject of PI, remained considerable in a number of products in 1998. Thus, for example, the relative prices of product 11 (Pravachol, A tablets, 20 mg) ranged from 0.50 (Czech Republic) to over 1.0 (United Kingdom). The second observation is that the within-product variation across countries was generally consistent with Ramsey pricing. In particular, the United Kingdom and Sweden registered the highest prices, while Spain and the Czech Republic had the lowest prices. Italy also displayed low relative prices, reflecting its price controls.

Relative prices for India are depicted in Chart 5. The results demonstrate that brand-name prices are far lower in India than the United States, with the highest-priced drug in India (Respirdal) under 20 percent of the U.S. price. Surely these low prices reflect in large degree the higher degree of price sensitivity in India to drug prices and lower Indian incomes. However, they also reflect the substantial competitive pressures that brand-name producers face in the Indian market from generics (Lanjouw, 1998; Watal, 2000).

The Japanese case is given in Chart 6. Three drugs registered considerably higher prices in Japan than in the United States but most were significantly lower in Japan. Finally, Chart 7 presents calculations for common drugs in several developing countries: Brazil, Mexico, the Czech Republic, Republic of Korea, Thailand, and South Africa. As

noted above, Brazil and Mexico were the highest-priced developing nations and several products had higher prices in those nations than in the United States. Other countries had considerably lower manufacturer's prices.

The charts contained information on the international distribution of product prices charged by original manufacturers. An important factor in explaining these prices is the nature of competition in various markets, including the prospects for PI. In Table 2 I provide evidence on the competitive structure of markets for omeprazole (20 milligram tablets) seven countries. In the table I show 1996 average prices for this drug (original brand name Losec or Prilosec) across all competing firms in each country. Included also are information about patent expiration date, number of domestic firms and number of PI firms where available.

It is evident from the table that price variations are considerable across countries, setting up some potential for parallel trade. The average price per pill was highest in the United States, where the product was on patent, prices were not controlled by the government, and PI were not allowed. The price was about one-third cheaper in Germay, where prices were also not controlled but PI (from elsewhere in the EU) came in at a lower price and accounted for about ten percent of the market. The UK also experienced parallel imports, which actually sold at a slightly higher price in 1996 than pills from the original manufacturer first sold there. Italy and Spain had markedly lower prices than Germany. Note the large number of producers in Spain, where the patent had expired. Spain is a common source of PI within the EU. Finally, Brazil and India did not provide patents for omeprazole. Both markets were highly competitive and the Indian price was extremely low in relation to those in the other countries. Again, therefore, were PI generally allowed in patented drugs it is likely that considerable volumes of such trade would emerge.

The third supplementary evidence comes from Scherer and Watal (2001), who presented similar data for a number of AIDS antiretroviral drugs sold under brand names by multinational pharmaceutical companies in 18 low-income and middle-income countries over the period 1994-1998. They found also that international price variations roughly approximated Ramsey pricing, though the correlation between relative prices and GNP per capita was lower, at 0.21, than most of those found here for other drugs. Across all country-drug pairs they found that the average price relative to the U.S. price was only 0.85, suggesting that prices in developing countries averaged just 15 percent below those in the United States. Indeed, in 98 cases the prices in developing countries were higher. They also found a number of large price relatives that suggested a degree of randomness (or perhaps measurement error) in the data.

Scherer and Watal performed basic regression analysis confirming that average prices rise slightly with the level of per-capita income. Over time, the average prices tended to fall across all countries. However, they also discovered, by interacting their income variable with the year dummy variable, that the strong income effect was attenuated as time went on. They interpreted this finding to mean that as products become more widely available the ability of pharmaceutical firms to sustain Ramsey-like

pricing tends to diminish and the positive relationship between per-capita income and prices becomes less pronounced. The authors also found a significantly negative relationship between prices and a variable indicating whether a country provided pharmaceutical product patents in the years in question. Their interpretation was that the result is an anomaly that must be traced to poor measurement of the patent variable. This interpretation is certainly questionable. It may be that the provision of patents is highly correlated with efficient distribution mechanisms that permit more competitive pricing. It is also possible that firms could choose to set lower prices in patented markets than in other markets for reasons discussed below.

The results on pricing found by Scherer and Watal are important, for they question the sustainability of income-based pricing. However, the basis for these findings can also be questioned. First, the econometric regressions were descriptive only and did not follow from an underlying pricing model. Second, in their interaction regression they excluded the year dummy itself for no evident reason, which exclusion has the potential to bias the remaining coefficients. More work would be valuable in this area.

5.2 Why Might Prices be Higher in Poor Countries?

A central question raised by this analysis is why ex-manufacturer's prices for identical drugs may be higher in lower-income nations. 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 phenomenon.

Perhaps most significantly, 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.[27] Then it is possible (in fact, likely under most demand parameters) that a pharmaceutical firm with market power would find it more profitable to supply the inelastic segment of the 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.

Thus, 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

[27] Scherer and Watal (2001) present a simple graphical analysis.

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.[28] 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 users may be segmented by 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 (Maskus and Lahouel, 2000).

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

5.3 Evidence on Extent and Effects of PI

Because parallel imports are rarely recorded, it is difficult to undertake formal study of their effects. A few studies shed some light on the issues we have identified in this report.

The earliest study was by REMIT Consultants (1991) under contract to the European Commission. The authors surveyed participants in the pharmaceutical sector of several countries about their perceptions of PI. Participants included manufacturers, wholesalers, PI firms, hospitals, pharmacists, and government officials. The basic goal was to identify significant impediments to PI within the European Community as of 1990. For the purpose of determining the importance of PI, they interviewed market audit organizations and parallel importing firms with direct knowledge of PI volumes and patterns. They found that, as of 1990, PI amounted to perhaps two percent of the prescription drug market in the EC overall, with penetration rates for particular countries ranging from one percent in Germany to 5-10 percent in the Netherlands and eight percent in the UK. Those drugs with large markets experienced considerably higher PI volumes, consistent with the view that PI firms target blockbuster medicines. Parallel

[28] See Maskus (2000).

exports came primarily from Belgium, France, Italy, Greece and Spain, with the last two countries rapidly increasing their shares of the business. REMIT Consultants estimated that the volume of PI would rise by perhaps 5-12 percent per year in the early 1990s. This would markedly increase its market share within the EC if the higher range of this estimate came true.

Primary impediments to expanded PI came from four sources. 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. 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.

On the beneficial side, 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.

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. Despite this free movement, there remains considerable variability in identical, branded drug products across the European Union.

In Table 3 I present calculations using data from the Swedish Medical Products Agency for a basket of 90 brand-name drugs in 1998. Average prices in Greece were 28 percent below the EU-wide average and in Germany they were 11 percent above the mean. Switzerland's average prices were yet higher. These price gaps are undoubtedly wider than associated costs of transporting and repackaging on the part of parallel traders. Simple regression analysis confirmed that these price differences are statistically significant across countries.

Considering only the set of products that were traded in all 15 countries (an indication that identical products are sold in all markets and may be sourced from anywhere), there is still significant price variation. Average prices ranged from 16 percent below the mean in Greece to 17 percent above the mean in Switzerland and 12 percent above the mean in the United Kingdom. However, these price differences are smaller than those in the first column, suggesting that the universal availability of products induces less international variation in prices. It is conceivable that this smaller variation is a result of actual or threatened PI.

It seems also from these data that individual companies choose different pricing strategies across EU members. In a sample of 25 pharmaceutical manufacturers, the standard deviation of their product prices ranged from 0.12 to 0.31. This considerable variation in prices by company (and thus by product portfolio) suggests that firms may have different methods for dealing with the potential for PI.

A formal analysis of PI within the European Union was provided by Ganslandt and Maskus (2001). Their theoretical model was described earlier in this report. However, they also analyzed data on price variations for branded drugs within the EU and on the extent of parallel imports. This task was made possible by the provision of data by the Swedish government on PI approvals and PI sales. Their results are shown in Tables 4 through 7.

In Table 4 I provide basic data on the Swedish pharmaceutical market and PI into Sweden. Valued at wholesale prices, sales of pharmaceuticals in Sweden came to 16.6 million SEK in 1998. These sales were concentrated in a number of patented molecules, with the 50 highest-sold molecules accounting for 37 percent of sales in 1998.

Sweden joined the EU in January 1995 and began taking applications for PI approvals and licenses. As may be seen in Table 4, the initial approval did not transpire until late 1996 but approvals mounted rapidly after that time. Thus, parallel imports have increased substantially since Sweden joined the EU, both in terms of sales and approvals. By 1998 PI had grown to 1.007 million SEK, corresponding to six percent of the overall pharmaceutical market, and there were 226 approvals to engage in PI. Note that while PI came to six percent of total sales, it amounted to 16 percent of sales in the 50 highest-sold molecules. Even this statement is misleading. Among those products for which PI existed, the median share of PI in sales was barely above zero. However, PI accounted for 54 percent of sales in those drugs for which PI was most concentrated. Again, PI firms target those drugs for which the largest markets exist.

From 1997 to 1998 the number of PI firms rose from four to ten. However, the top four PI firms in 1998 still accounted for 96 percent of PI sales, as noted by the figure labeled C4, while the largest PI firm had 59 percent (C1). Parallel imports from 13 countries had been approved by 1998, but the sources were heavily concentrated in low-price countries in Southern Europe. Spain, Italy and Greece were the exporters in 63 percent of all cases of approved PI.

With these data it is possible to consider some effects of PI on the Swedish market. In Table 5 I present a comparison between products which were subject to PI (that is, products for which at least one PI approval was issued) and products that were not. The calculations show average percentage price changes for products between either 1994 or 1997 and 1998. Computations are made both for samples including PI, referred to as "Mean incl. PI" and for manufacturing firms' prices. The first pair of columns present simple averages of price changes and the second pair of columns present average price changes where each product is weighted by its Swedish sales share in 1998. The figures in parentheses below each entry are standard deviations of price changes.

Consider the unweighted average price changes. Over the period 1994-1998 prices increased by 6.6 percent for all products, while manufacturers' prices rose a bit more at 7.3 percent. Average prices for products in which PI took place rose by 2.9 percent while manufacturers' prices for such goods increased by 6.4 percent, a significant difference. Note, finally, that manufacturers' prices for non-PI products rose by 7.6 percent, which was higher than the 6.4 percent increase of manufacturing prices for goods facing the threat of PI. An initial conclusion, then, is that PI limits price increases relative to other goods. Looking at the weighted average price changes, I find similar results. Recall that PI tends to target high-sales products so we would expect to find larger price-moderating impacts in this group, as we do. Thus, those products in which PI occurred actually saw prices decline by 4.4 percent over the period, while manufacturers were only able to raise prices by 0.3 percent on a weighted basis. In contrast, non-PI goods saw a 3.6 percent price increase.

These differences were more pronounced over the shorter period 1997-1998. Average prices increased 0.25 percent. Mean manufacturing firms' prices declined 0.3 percent for products subject to PI competition but rose 0.95 percent for non-PI goods. Prices of parallel-imported products fell by 3.1 percent. These relative price changes carried over qualitatively to the weighted-average calculations as well.

This basic evidence confirms that the prices of parallel-imported products, and products facing such competition, fell in the Swedish import market relative to the prices of goods not subject to PI. The main effect, approximately 75 percent of the average price fall, resulted from parallel trade while the remaining effect was due to changes in manufacturing firms' prices.

It is possible to test statistically the role of PI in such price moderation. At the simplest level, we use t-tests to see whether differences between the changes in

manufacturing firms' prices for products subject to PI, and products not subject to PI, are significant. The null hypothesis of no difference in such price changes could not be rejected at the ten-percent level for the period 1994-1998. However, this hypothesis is rejected at the five-percent level for 1997-1998, confirming that the manufacturers' prices increased significantly less for products subject to PI than did others, with the effect concentrated at the end of the period. A further t-test shows that the average price change for PI products was significantly lower than the average price change for non-PI products over both 1994-1998 and 1997-1998.

The essential inference here is that the data support a price-moderating impact from PI. In terms of the formal Ganslandt-Maskus (2001) hypotheses, the results clearly favor the accommodation model over the deterrence model, because the mean price (including both PI goods and manufacturers' prices in those goods) increased significantly less than the manufacturers' prices of non-PI goods. Over the short period 1997-1998 the change in the manufacturers' prices was significantly lower for products facing PI competition than for other drugs. Thus, manufacturing firms seem to react to the volume of arbitrage through PI with a lagged price adjustment, rather than trying to deter PI before they enter the market.

Further perspective is available from a simple regression analysis of these price changes. Two variables are included in the regression: PI SHARE, which is the share of parallel trade in total sales for specific products, and APPROVAL, which is a dummy variable equal to one when there is at least one approval in 1998 to parallel-import the good, and zero otherwise. The dependent variable, defined at the individual product level, is the relative price change of the manufacturing firms' price over the periods 1994-1998 and 1997-1998.

As shown in Table 6, ordinary least squares regressions find that the coefficients of PI SHARE and APPROVAL have the expected negative sign in every case. However, the coefficients are insignificant for the longer period 1994-1998. For the shorter period 1997-1998 the coefficient on PI SHARE is -0.039 and is significantly negative at the one-percent level. Thus, an increase of one percent in the share of a drug's sales that came from PI tended to reduce the average price increase by 3.9 percent. The coefficient on APPROVAL is -0.0125 and significant at the five-percent level. When both are included in the same regression, each coefficient has a negative sign but these coefficients are insignificant, reflecting the collinearity between the two variables measuring the extent of PI. Again, the regression results support the model of lagged accommodation by manufacturers.

We may ask further questions of the data. One issue is whether parallel trade has an effect on the price differentials between the export and import markets. Whether firms react with deterrence or accommodation strategies, one would anticipate some price convergence between the two markets. To test this hypothesis we use bilateral price comparisons between the Swedish market and the two main export markets, Italy and Spain. The data are wholesale prices in U.S. dollars in 1994 and 1998. These figures incorporated at least one pair of prices for 28 of the top 50 molecules in Sweden. Nine of

these products were subject to parallel exports from one or both of Spain and Italy. Particular product varieties in Sweden that did not have comparable products in the export market were excluded from the sample.

Prices were defined as those in export markets relative to those in Sweden for 1994 and 1998. The price change of interest was then the relative price in 1998 minus the relative price in 1994, with price convergence occurring where the relative price change was positive (assuming, as was true in all cases, that the Spanish and Italian prices were below the Swedish prices in 1994). Regressing relative price changes on a dummy variable PI TRADE (taking on the value one if there was any parallel trade and zero otherwise), we found that the estimated coefficient was 0.0180 for Italy, 0.0206 for Spain and 0.0176 for the pooled sample. These figures would indicate that PI was responsible for small tendencies to see prices converge: 1.8 percent for Italy, 2.1 percent for Spain and 1.8 percent overall. However, these impacts are statistically insignificant and, in any case, are small relative to underlying price differentials. On average in 1998, prices across Italy and Spain of these goods were 68 percent of those in Sweden.[29] In this sample, then, PI showed little ability to establish even a tendency toward price convergence.

Finally, it is possible to estimate the difference between the price in the export markets and prices set by PI firms in the Swedish market. Table 7 summarizes the PI firms' prices for products subject to such trade. The relative prices are defined as the PI prices divided by the prices charged by the manufacturing firms for identical products. Thus, the average price charged by PI firms in 1998 was 89 percent of the manufacturers' prices in Sweden. The minimum relative price was 85 percent and the maximum was 92 percent.

With these figures on prices in the export markets and in Sweden, we compute that the PI firms' margin to be approximately 21 percent of the original manufacturers' prices in the importing nation. The margins for PI from Italy ranged from nine to 39 percent and the margins for PI from Spain ranged from nine to 31 percent. Rents to the PI firms, or alternatively real resources used up in arbitrage through PI, were therefore considerable compared to the small price reductions in the Swedish market.

These margins and price impacts may be used to compute the impact of PI on consumer surplus and the rents that are shifted from manufacturers to trading firms. Recall that the effect of PI on manufacturing firms' prices was to permit them to rise by 1.2 percent less (unweighted) and by 3.3 percent less (weighted) than non-PI prices. Assuming that drugs are normal goods we obtain an upper bound on the positive effect on consumer surplus by employing the quantity consumed at the lower, PI-induced prices. The difference between (fictional) expected expenditure at the lower price and actual expenditure is the change in consumer surplus. With this approach, the effect of PI on consumer benefits in 1998 in Sweden was approximately 150 million SEK with unweighted price changes and 199 million SEK with weighted price changes.

[29] Recall also the data in Table 3.

In comparison, the rents to PI firms (which include the transport and packaging costs) could be calculated from the actual margin between these firms' prices in Sweden and wholesale prices in the export markets, multiplied by the quantity of parallel-imported drugs. Using these margins we calculate the rents to PI firms to be approximately 188 million SEK in 1998. Interestingly, and significantly, these rents are of the same magnitude as the consumer surplus gains. Put differently, the gains to Swedish consumers are effectively offset by payments to PI firms. The greater the share of PI rents that are actually transport costs, and the greater the share of rents that are garnered by foreign PI firms, the smaller is the net gain (larger the net loss) to Sweden. With our figures, it seems that the static welfare impacts in Sweden (including the profit reductions imposed on Swedish pharmaceutical firms) is negative, even without considering dynamic impacts on R&D.

5.4 Evidence on PI and R&D Performance

The findings just reviewed are fairly pessimistic about the static impacts of PI, at least within the European Union.[30] If PI may also be shown empirically to reduce the level of R&D effort among original manufacturers that compete with such trade there would be a further dynamic reason to question their utility. For this purpose one would need to correlate carefully the lagged price impacts of PI, product by product, with the R&D performance of pharmaceutical firms. One would also wish to take account of global sales and profits when correlating PI with research spending; it is possible, for example, that an American firm is most damaged by PI into Germany or Sweden. Unfortunately, available data do not make such an effort possible.

The best I can offer at this time is to look at crude indicators of relative R&D performance in the 1990s, a time of growing PI in the European Union. Chart 8 depicts changes in the ratio of business enterprise R&D in local currencies, as a percentage of sales, in the pharmaceutical sectors of 10 OECD countries. Chart 9 presents the same data in purchasing-power-parity adjusted terms.[31] Note that these figures relate to ISIC category 3522, "Drugs and Medicines", and therefore includes both R&D into new drugs and into generics.

Both charts paint a similar picture. In Italy, which is a source of parallel exports, R&D performance languished over the 1990s, but Spain saw an increase of around 80 percent in the R&D-to-sales ratio. In local currency terms, Sweden registered the highest relative increase in R&D intensity, despite being the recipient of extensive PI as discussed above. Denmark was in a similar situation. Germany's performance was stagnant until late in the decade. Canada, which does not permit parallel imports, registered large increases in its R&D ratios, in part because of a commitment by foreign pharmaceutical firms to increase research activity in their Canadian branches.

[30] See also Darba and Rovira (1998).
[31] The source of these data is OECD, ANBERD data set.

Overall, there is no detectable relationship between R&D in the pharmaceuticals sector and the permission or extent of parallel imports, at least by country. Again, a firm-level analysis focusing on basic R&D would be more appropriate if the data were available. At this simple level, however, there seems to be little reason to argue empirically that parallel imports clearly reduce R&D expenditures in pharmaceuticals.

6. Conclusions and Policy Recommendations

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 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 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 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.

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.

With this background, the empirical evidence reviewed in this report supports the following conclusions. First, there are substantial price differences across countries in identical, brand-name 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. This fact that likely may be attributed to imperfectly competitive distribution systems and a decision by firms to sell small volumes at high markups to price-insensitive consumers in poor 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. In that context, the activities of PI firms seem to incur transport costs and earn rents while failing to provide much benefit to drug consumers, at least within Sweden. 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.

Given the theory and findings in this report, the following policy recommendations seem to be supportable and sensible. These recommendations are consistent with those in Scherer and Watal (2001) but also extend them. Additional recommendations are in Ganslandt, Maskus, and Wong (2001), which is included in this report as Attachment A.

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.

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, I am persuaded that modified restraints on such trade are in the global interest.

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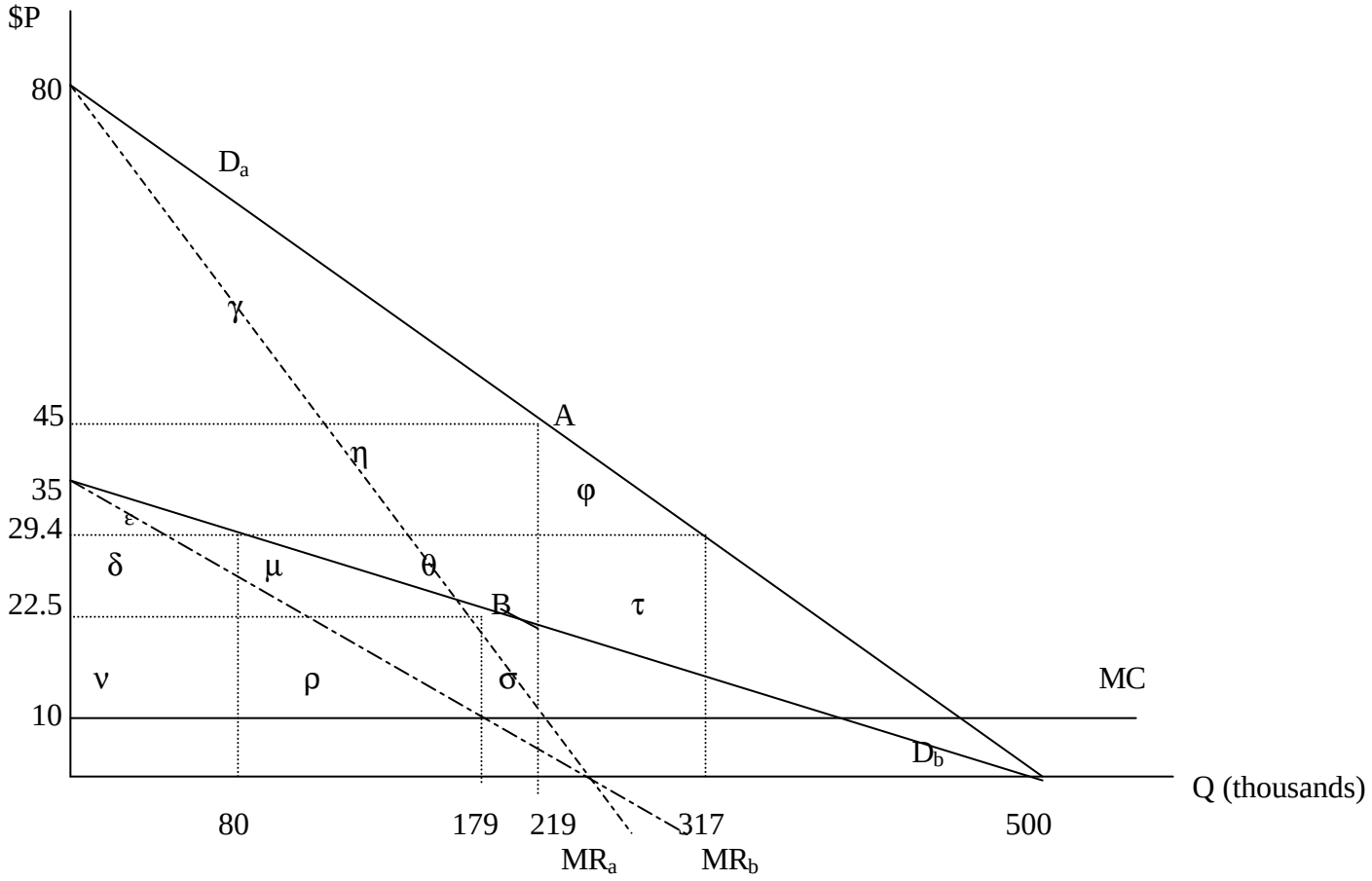

Figure 1. Segmented vs. Integrated Prices in Two Markets with Different Demands

Figure 2a. Deterrence Equilibrium

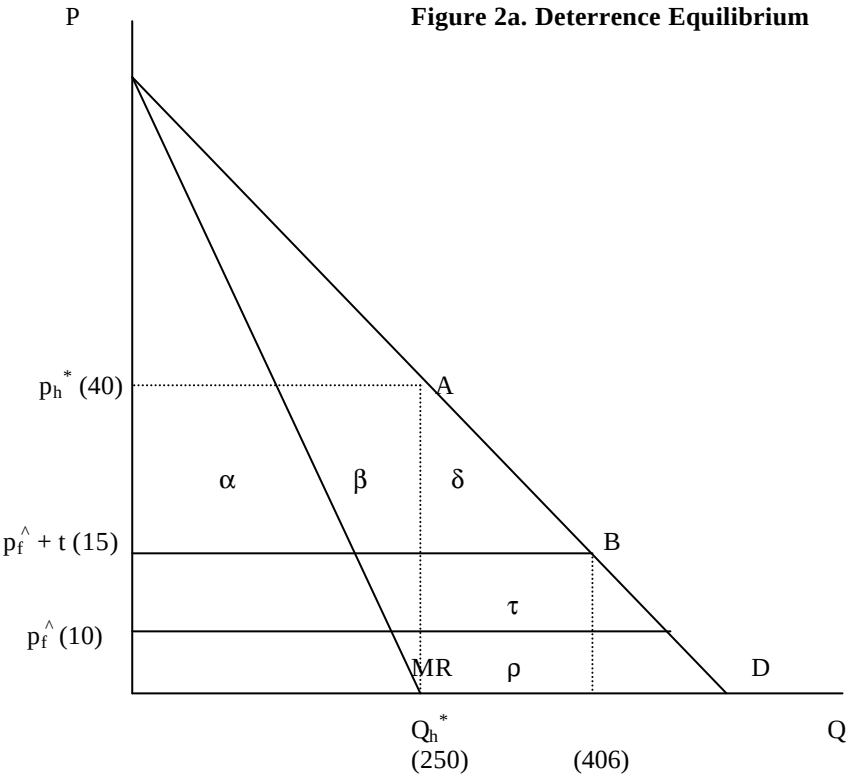

Figure 2b. Accommodation Equilibrium

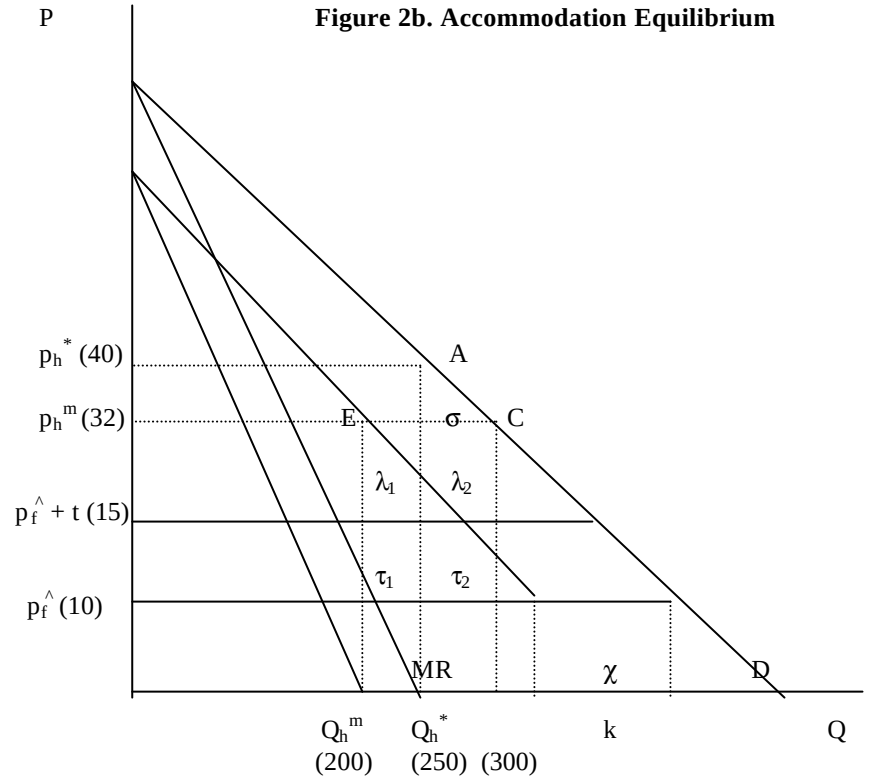

Figure 3. Equilibrium Tradeoff between Small-Drug and Blockbuster-Drug R&D

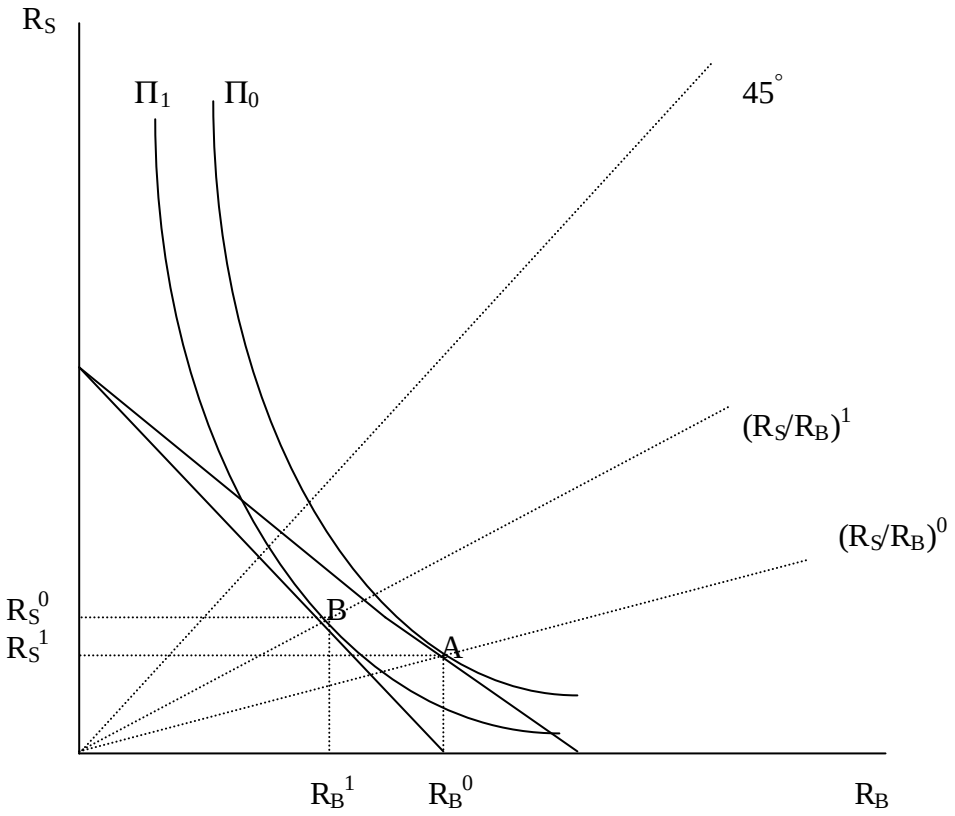

Table 1. International Comparison of per-Dosage ex-Manufacturer's Prices, 1998 ($US)

Country	Norvasc 5 mg Tabs	Lipitor 10 mg Tabs	Pulmocort 200Y P.or A.	Sandimmun 100 mg Caps	Neoral 100 mg Caps	Cipro 500 mg Tabs	Plendil 5 mg Tabs	Imovane 7.5 mg Tabs
USA	0.97	1.46	0.43	5.03	4.47	2.94	0.72	na
Canada	0.79	1.04	0.19	na	3.50	1.16	0.42	0.40
Mexico	0.71	1.17	na	**5.90**	**7.32**	1.70	0.64	0.28
Brazil	0.83	0.89	na	4.57	**4.47**	**3.76**	0.65	0.38
UK	0.61	0.98	0.27	3.69	3.69	2.06	0.43	0.23
Sweden	0.57	0.94	0.34	na	na	3.28	0.53	0.22
Italy	0.58	0.89	0.17	3.04	3.12	1.82	0.3	0.26
Spain	0.42	0.83	0.14	na	2.61	1.79	0.33	0.13
Czech Republic	0.42	0.98	0.16	na	2.98	1.70	0.28	0.13
Japan	0.65	na	na	na	na	na	0.31	na
Korea	0.40	na	0.13	3	4.28	1.46	0.63	0.18
Thailand	0.43	na	0.10	1.10	3.14	1.27	0.27	na
India	0.09	na	na	na	na	0.14	0.07	na
South Africa	0.34	na	0.08	4.19	4.45	1.35	0.53	0.35
Correlations	0.56, 0.63	0.33, 0.45	0.88, 0.82	0.16, 0.18	-0.24, -0.29	0.47, 0.36	0.16, 0.22	-0.08, -0.19

	Diflucan 50 mg Tabs	Lasix 40 mg Tabs	Claritin 10 mg Tabs	Cozaar 50 mg Tabs	Zyprexa 10 mg Tabs	Losec 20 mg C. or T.	Zantac 150 mg Tabs	Risperdal 2 mg Tabs
USA	3.47	0.20	1.70	0.92	6.48	2.99	1.38	2.94
Canada	3.07	0.07	0.54	0.70	4.40	1.39	0.69	1.26
Mexico	3.20	0.09	na	0.84	4.39	1.64	0.26	0.98
Brazil	**4.66**	0.13	0.59	**1.07**	5.73	2.41	0.52	1.61
UK	3.44	0.12	0.38	0.89	5.47	1.59	0.68	1.93
Sweden	4.27	na	0.35	0.77	5.26	1.74	na	1.58
Italy	2.21	0.08	0.32	0.69	4.03	1.43	0.54	1.10
Spain	2.48	na	0.23	0.69	4.08	1.42	0.43	na
Czech Republic	2.77	na	0.29	0.93	4.25	1.21	0.28	1.12
Japan	5.41	0.12	na	1.45	na	1.75	0.47	0.46
Korea	2.69	0.06	na	0.65	2.38	1.22	0.41	1.06
Thailand	1.62	0.06	0.24	0.78	2.88	1.13	0.47	0.94
India	na	0.01	0.21	na	na	na	0.02	0.46
South Africa	2.75	0.21	0.65	0.75	1.79	1.19	0.54	0.96
Correlations	0.51, 0.28	0.33, 0.35	0.47, 0.52	0.36, 0.18	0.36, 0.57	0.45, 0.40	0.65, 0.75	0.43, 0.55

Table 1. International Comparison of per-Dosage ex-Manufacturer's Prices, 1998 ($US), continued

							Common drugs
	Zoloft	Zocor	Imitrex	Effexor	Number of		Avg. Price
Country	50 mg Tabs	10 mg Tabs	50 mg Tabs	75 mg Tabs	Drugs	Avg. Price	Rel. to US
USA	1.70	1.52	11.36	0.92	19	2.72	1.00
Canada	1.01	1.13	8.17	1.00	19	1.63	0.63
Mexico	1.13	1.25	3.71	**1.12**	18	2.02	0.76
Brazil	1.29	0.97	3.02	**1.08**	19	2.03	0.81
UK	1.37	0.95	7.13	1.04	20	1.85	0.70
Sweden	1.03	0.82	5.69	1.19	16	1.79	0.73
Italy	0.92	0.95	4.21	1.07	20	1.39	0.55
Spain	0.80	0.62	5.03	0.86	17	1.35	0.52
Czech Republic	0.71	0.84	na	**1.09**	17	1.18	0.56
Japan	na	na	na	na	8	1.33	0.74
Korea	0.76	0.65	3.26	**1.13**	18	1.35	0.54
Thailand	0.83	0.89	2.85	na	17	1.12	0.41
India	na	na	na	na	7	0.14	0.08
South Africa	0.79	1.21	3.23	0.76	19	1.37	0.58
Correlations	0.56, 0.50	0.22, 0.27	0.84, 0.90	0.06, -0.00		0.47, 0.56	

Source: constructed by author from data provided by IMS Health

Table 2. Pharmaceutical Price Comparisons and Parallel Imports: Omeprazole 20 Milligram Tablets (1996)

Country	*Patent Expiry*	*No. of Firms*	*Avg. Price per Pill ($)*	*Sales ($m)*	*No. of PI Firms*	*Avg. Price per Pill ($)*	*Sales ($m)*
Germany	3/04/99	2	1.93	55.5	5	1.84	5.4
UK	3/04/99	1	1.73	279.6	1	1.76	2.4
Italy	3/04/99	4	1.59	151.6	na	na	na
Spain	18/01/95	24	1.52	161.2	na	na	na
USA	5/04/01	1	2.91	1289.0	na	na	na
Brazil	no patent	10	1.60	41.6	na	na	na
India*	no patent	35	0.06	15.1	na	na	na

*1997 data. Prices are ex-manufacturer charges to wholesalers. Source: IMS Health.

Table 3. Average Percent Deviation from European Mean Prices in Pharmaceutical Products, 1998

Country	*All 90 Products*	*Products in all 15 Countries*
Greece	-28	-16
Spain	-20	-12
Portugal	-13	-4
Italy	-13	-4
France	-10	-1
Finland	-2	-2
Austria	-2	+0
Norway	-1	-5
Sweden	-1	-1
Belgium	-1	+0
Netherlands	+2	+3
Denmark	+3	+3
Germany	+11	+8
United Kingdom	+19	+12
Switzerland	+25	+17

Source: Calculations by Mattias Ganslandt with data from Swedish Medical Products Authority

Table 4. The Pharmaceutical Market in Sweden

	1995	1996	1997	1998
Gross Domestic Product (MSEK)	1,649,922	1,688,200	1,738,859	1,816,042
Total pharmaceutical sales (MSEK)	13,393	15,808	14,263	16,567
Sales of top 50 molecules (MSEK)	4,576	5,977	5,201	6,203
Parallel imports (MSEK)	0	>0	269	1,007
Parallel imports of top 50 (MSEK)	0	>0	269	920
Parallel imports/Total sales	0	0	0.02	0.06
Parallel imports/Top 50 sales	0	0	0.05	0.16
Concentration ratio (C1)	n/a	1	0.85	0.59
Concentration ratio (C4)	n/a	1	1	0.96
Total number of P.I. approvals	0	1	45	226
P.I. approvals for top 50 molecules	0	1	31	131
Total number of P.I. firms	0	1	4	10

Source: Government of Sweden, Medical Products Agency. Sales are in nominal wholesale prices.

Table 5: Price Changes of Pharmaceutical Products in Sweden, 1995-1998.

		Unweighted average		Weighted average	
Sweden		1994-1998	1997-1998	1994-1998	1997-1998
All products	Mean incl. PI	0.06636	0.00253	0.008	-0.0137
		(0.1344)	(0.0352)	(0.0276)	(0.0061)
	Manuf.'s price	0.07336	0.00731	0.02791	-0.00156
		(0.1330)	(0.0308)	(0.0217)	(0.0032)
PI products	Mean incl. PI	0.02881	-0.03117	-0.04384	-0.03846
		(0.1213)	(0.0409)	(0.0448)	(0.0086)
	Manuf.'s price	0.06381	-0.00343	0.00308	-0.00668
		(0.1199)	(0.0349)	(0.0360)	(0.0052)
Non-PI prod	Mean	0.07574	0.00955	0.03646	0.0015
		(0.1365)	(0.0296)	(0.0171)	(0.0035)
No. of obs.		125	151	125	151

Source: Authors' calculations based on data from LIF.

Table 6. The Effects of PI on Manufacturing Firms' Prices

	Manufactureur's price change in the import market from base-year to 1998					
	1994	1994	1994	1997	1997	1997
CONSTANT	0.0808***	0.0747***	0.0808***	0.0115***	0.0094***	0.0115***
	(0.0152)	(0.0127)	(0.0151)	(0.003)	(0.0026)	(0.003)
PI SHARE	0.0073	-0.0217	-	-0.0266	-0.0393***	-
	(0.0830)	(0.0729)		(0.0186)	(0.0163)	
APPROVAL	-0.0206	-	-0.0194	-0.0084	-	0.0125**
	(0.0279)		(0.0244)	(0.0059)		(0.0052)
No. of obs.	125	125	125	151	151	151
Adj. R2	0	0	0	0.04	0.04	0.03

Source: Authors' calculations based on data from LIF. Standard errors are in parentheses.

Table 7. Prices of Parallel Imports and Parallel Importing Firms' Markups, 1998

	Price relative to manufacturing firm's price in Sweden					
	PI to Sweden from Italy			PI to Sweden from Spain		
Relative price in 1998	Mean (std. dev.)	Max Min	Obs	Mean (std. dev.)	Max Min	Obs
PI price in Sweden	0.8917	0.9155	28	0.8917	0.9155	28
	(0.0125)	0.8506		(0.0125)	0.8506	
PI price in export market	0.6819	0.8258	7	0.6786	0.7874	8
	(0.1145)	0.5095		(0.0683)	0.5919	
PI markup	0.214	0.389	7	0.2116	0.3071	8
	(0.1136)	0.0897		(0.0749)	0.0913	

Source: Authors' calculations based on data from LIF.

ANNEX A: Ganslandt-Maskus-Wong Paper

DEVELOPING AND DISTRIBUTING ESSENTIAL MEDICINES TO POOR COUNTRIES: THE *DEFEND* PROPOSAL

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Draft: March 28, 2001

ABSTRACT:

The poorest nations of the world suffer from extreme disease burdens, which go largely untreated because weak incomes and the prevailing system of intellectual property rights fail to provide sufficient incentives to develop new treatments and distribute them at low cost. Recent price reductions for HIV/AIDS drugs are encouraging but offer only a limited solution. We discuss the economic tradeoffs involved in supporting drug and vaccine research through exclusive rights and distributing the fruits of that research to poor countries. We offer a proposal to overcome these incentive problems. Our DEFEND ("Developing Economies' Fund for Essential New Drugs") proposal would work within the existing international legal structure but significantly would raise the returns to R&D in critical medicines and expand distribution programs. A public international organization would purchase the license rights for designated areas and distribute the drugs at low cost with a required co-payment from local governments. Furthermore, governments would restrict parallel trade to support desirable price discrimination. Costs would be funded largely by increased foreign assistance from the developed nations, but these costs would be low in relation to current aid budgets. We believe a strong program could be mounted for $8 billion to $12 billion per year and would be an extremely effective use of foreign aid.

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1. Introduction

Perhaps the most critical task currently facing the global economy is to devise mechanisms that both encourage research aimed at finding treatments for diseases that are common in impoverished nations and that achieve widespread international distribution of these treatments at sufficiently low costs to be effective and affordable. This issue has achieved prominence by virtue of the severe epidemic of the HIV virus, which inevitably leads to the onset of AIDS, in Sub-Saharan Africa and, increasingly, in South Asia and Southeast Asia.

HIV/AIDS is not the only disease that plagues poor nations, where malaria, tuberculosis, and other maladies are equally lethal and debilitating. Indeed, HIV/AIDS is unusual in that strong incentives for pharmaceutical companies to develop treatments for sufferers in high-income economies have resulted in medicines that effectively permit patients to function well for many years before onset of the disease. In that regard, the current debate is about how best to transfer these medicines to poor countries. In contrast, there is virtually no R&D aimed at producing new treatments for malaria or tuberculosis. This situation arises largely because those who suffer are overwhelmingly poor and could not afford medicines in sufficient quantities to cover R&D costs. The problem is accentuated by weak patent protection in potential markets, further reducing the willingness of pharmaceutical enterprises to develop new drugs and vaccines.

To put it in economic terms, under the current system the incentives to achieve efficient dynamic and static provision of medicines are grossly inadequate in the face of massive poverty. To deal with this problem essentially two programs have been advanced in recent years, which are considerably at odds with each other. On the one

hand, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) within the World Trade Organization requires member countries to grant and enforce patents for new pharmaceutical products (Maskus, 2000a; Gorlin, 1999). More precisely, developers of new drugs have enjoyed exclusive marketing rights (EMRs) in all WTO members since January 1, 1995. While product patents are not required until the year 2005 in the least-developed countries, EMRs provide similar protection. Various economic studies suggest that this new regime could raise prices of new drugs markedly in developing countries (Watal, 1999; Fink, 2000; Lanjouw, 1998; Subramanian 1995), though substantial uncertainty remains on this point.[1] Thus, some possibility exists that patents will raise incentives for R&D in these neglected diseases (Lanjouw, 1998). However, this policy shift does nothing directly to increase incomes of sufferers, who would, if anything, become less able to afford new medicines.[2]

Thus, on the other hand, considerable pressure has mounted on pharmaceutical companies to provide their drugs at marginal production cost (or less) to poor countries. Several firms have responded, such as Merck & Co., Bristol-Myers Squibb Co., GlaxoSmithKline PLC, and Abbott Laboratories. For example, Merck & Co. recently announced it would reduce the prices of two AIDS-controlling drugs in Africa by 40% to 55%, adding to sharp price cuts announced in 2000.[3] Abbott announced that it would sell its two AIDS drugs, Norvir and Kaletra, at a price that would earn the company no profit.[4] In some degree these actions are a competitive response to offers by two Indian

[1] See Rozek and Berkowitz (1998) for a dissenting view.
[2] See Abbott (2000) for a legal analysis of the pharmaceutical aspects of TRIPS, claiming that the agreement raises difficult contradictions between the trading system and needs for protecting public health.
[3] *Wall Street Journal*, "Price War Breaks Out Over AIDS Drugs in Africa as Generics Present Challenge," 7 March 2001.
[4] *Wall Street Journal*, "Abbott to Cut Prices on AIDS Drugs Distributed in Sub-Saharan Africa," 27 March 2001.

producers of generic AIDS drugs, Cipla Ltd. and Hetero Drugs Ltd., to provide medicines at even lower prices. As we note in the next section, however, even at these prices the drugs may be beyond the reach of most patients.

The research-intensive pharmaceutical firms that invented these drugs have three concerns about low-cost distribution programs. First, provision at marginal cost or lower adds nothing to their ability to cover the fixed costs of R&D. Second, while they may be willing to circulate their medicines cheaply, the firms are anxious to retain the exclusive distribution rights inherent in patents and EMRs. Indeed, this preference to forestall generic competition is the root of the ongoing lawsuit raised by 39 drug makers in South Africa aimed at striking down that country's 1997 Medicines and Related Substances Control Act.[5]

Third, and perhaps most significantly, original drug developers worry that the availability of far-cheaper treatments in poor countries could erode their price-setting power in rich countries. This erosion could happen directly through unauthorized parallel trade in drugs or indirectly through political pressure mounted by patients and insurance companies on health authorities to require significant price reductions. Because the vast bulk of returns to R&D are realized in the United States, the European Union, and other industrialized nations, pharmaceutical companies argue that such price spillovers would significantly hamper their incentives to develop new treatments.[6]

Control over patent rights in AIDS treatments is now before the WTO in a dispute raised by the United States against Brazil in February 2001. Under Article 71 of Brazil's 1997 Patent Act, foreign firms must manufacture patented drugs within Brazil before

[5] *Wall Street Journal*, "Big Drug Firms Defend Right to Patents on AIDS Drugs in South African Court," 6 March 2001.

three years have elapsed from patent grant. Failure to meet these "working requirements" could result in an order by the Brazilian Health Ministry to local firms to manufacture generic substitutes, a threat that currently faces makers of the AIDS drugs Efavirenz (Merck & Co.) and Nelfinavir (Roche).[7] The TRIPS Agreement would seem to restrict considerably Brazil's ability to enforce working requirements. Thus, this case could set an important precedent concerning the ability of countries to limit private rights to exploit patents.

Putting these elements together, drug development and distribution involve tradeoffs that implicate important principles underlying protection of intellectual property rights (IPRs). To begin, there is a strong global public interest in providing sufficient incentives for the continual development of new medical treatments for diseases afflicting the poor. Within the intellectual property system these incentives stem largely from exclusive production and distribution rights provided by EMRs and patents. However, such rights may be inadequate for meeting the needs of extremely poor patients that do not have enough income to purchase them even at low prices.

Further, such rights are national or territorial in scope, meaning that governments may choose their own regimes concerning whether rights holders can prevent parallel trade.[8] Indeed, the TRIPS Agreement affirms that countries have the authority to decide whether exclusive rights are exhausted at national borders. The threat that products may be shipped from lower-priced countries to higher-priced countries reduces the enthusiasm of rights holders to supply them at low cost.

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[6] *New York Times*, "Group Says Discount AIDS Drugs Endanger Research," 13 February 2001.
[7] *New York Times*, "Brazil May Defy U.S. and Make More AIDS Drugs," 14 February 2001.
[8] Maskus (2000b) provides an overview of the economics of parallel trade.

The current system generates numerous undesirable outcomes. First, there are not enough incentives to develop new treatments for endemic diseases in impoverished markets. The resulting high rates of infection and contagion impose external costs on others both within and across borders, in part because of lower productivity. Surely the industrialized economies suffer some costs from slower growth in the afflicted countries. In this sense, development and provision of effective drugs is a global public good.

Second, demands that drugs be provided at marginal cost in some countries force patients in higher-price countries to accept a disproportionate share of the burden of financing R&D cost recovery. Put another way, patients in lower-cost nations effectively free ride on the pricing systems of the United States and other industrialized nations. In fact, the free riding has at least two dimensions. In addition to the low prices in poor countries, price controls in Canada, Europe, and elsewhere mean that patients in those nations provide limited contributions to recovering fixed R&D costs.[9] In that context, American patients and insurance companies bear the brunt of paying for R&D and any losses associated with distribution programs abroad. Thus, neither pharmaceutical companies nor their patients may be expected to embrace the costs of distribution and development.

Third, pharmaceutical firms chronically under-supply the medicinal needs of poor countries, partly because of limited exclusivity in rights, including the need to restrain parallel trade.

These problems point squarely at the need for further public involvement in encouraging new drugs and in procuring and distributing medicines. In this paper we set

out a proposal for addressing the fundamental problems in a manner that is least disruptive to the international system of IPRs. It involves, first, increases in public assistance or public health budgets in the rich countries in order to fund purchases by a body such as the World Health Organization (WHO) of exclusive licenses to distribute selected medicines in poor countries. The license fees should be sufficient to cover all or a substantial portion of fixed R&D costs, thereby establishing a strong incentive for pharmaceutical and vaccine firms to produce new treatments. In terms of distributing these products in poor markets, the WHO would be free to do so at a per-unit price below its marginal private costs in recognition of the external benefits from improved health status. Finally, each country or region that avails itself of this program would be required to assert strong controls on parallel exports in order to safeguard prices in markets in high-income economies.

The procurement portion of our proposal is similar to the idea for a vaccine-purchase fund put forward by Sachs, et al (1999). However, their proposal involves a guaranteed price per dosage without contemplating difficulties in effecting distribution or in segmenting markets. It also bears similarity to current proposals for ensuring "tiered pricing" of existing HIV/AIDS drugs (Barton, 2001; Subramanian, 2001) but these programs make no provisions for managing dynamic R&D incentives. Thus, we offer our proposal as complementary to both of these ideas.

In the next section we provide basic evidence on the extent of the R&D, distribution, and pricing problems in the current system. In Section Three we discuss the economics of optimal provision in recognition of the significant externalities involved.

[9] The general nature of this problem is reflected in recent legislative proposals in the United States partially to deregulate restrictions on parallel imports of prescription pharmaceuticals in order to permit U.S.

In Section Four we set out the proposal explicitly and discuss ideas for its implementation. We conclude in Section Five.

2. Scope of the Problem

The incidence and costs of endemic diseases in poor countries are staggering. These maladies not only afflict high rates of mortality but also significantly reduce the health status and productivity of the affected population. Table 1 provides estimates by the World Health Organization of deaths and productive time lost (measured in disability-adjusted life years, or DALYs) to three major diseases in 1999 for Africa, the Americas, and Southeast Asia. HIV/AIDS is thought to have killed 2.7 million people globally in 1999, with 2.2 million of these in Africa. It claimed 81,000 victims in the Americas and 360,000 victims in Southeast Asia, where the problem is rising rapidly. The disease was also responsible for 89.8 million adjusted life-years lost to morbidity and mortality. Again, this loss was concentrated in Africa, where 74.4 million life-years were foregone.

The victims of tuberculosis (TB) are spread more evenly through the developing world. It killed 1.7 million people in 1999, with 357,000 in Africa, 59,000 in the Americas, and 723,000 in Southeast Asia. Importantly, TB is frequently contracted by HIV/AIDS sufferers and surveys suggest that up to 70 percent of tuberculosis patients are infected with HIV.[10] Such joint cases are concentrated in Sub-Saharan Africa. Malaria is also concentrated in Africa, killing perhaps 953,000 people in 1999 and sacrificing 36.8 million life-years. According to the WHO, the direct and indirect costs of malaria in

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patients to gain access to cheaper foreign sources of supply.

[10] UNAIDS Press Release: "World TB Day 2001: Access to TB Cure a Human Rights Imperative," at www.unaids.org/whatsnew/press/eng/pressarc01/TB_220301.html.

Sub-Saharan Africa exceed $2 billion per year.[11] Malaria is not at this time a large problem in the Americas.

Additional figures illustrate the scope of HIV/AIDS in Africa. There are now 25.3 million Africans living with HIV or AIDS.[12] In eight countries at least 15 percent of adults are infected. Infection rates in African women in their early 20s are three times higher than in men of the same age group. In Botswana, 36 percent of adults are now infected with HIV, while in South African the figure is 20 percent. South Africa has 4.2 million infected people, the largest number in the world. These figures are rising at alarming rates.[13] Among the 1.4 million children under the age of 15 living with HIV/AIDS at the end of 2000, 1.1 million reside in Sub-Saharan Africa. Perhaps 12.1 million children have been orphaned by the disease in that region.

Economic studies suggest that South African GDP will be perhaps 17 percent lower in 2010 than it would be without AIDS, removing $22 billion in output from the economy. In Botswana, there could be a 13-15 percent reduction in the income of the poorest households. The fiscal cost of the disease is also debilitating. It has been estimated that in seven of 16 African countries surveyed, public health spending for AIDS alone exceeded two percent of GDP in 1997, against total spending for health care of three to five percent of GDP.

These three diseases display different characteristics in terms of treatment costs and R&D incentives. Tuberculosis is curable with a single drug treatment that costs as

[11] WHO, "Fact Sheet: Malaria," at www.who.int/inf-fs/en/fact094.html.
[12] These figures are from "Fact Sheet: HIV/AIDS in Africa," at www.unaids.org/fact_sheet/files/FS_Africa.htm There are also 5.8 million living with HIV/AIDS in South Asia and Southeast Asia, see "Regional HIV/AIDS Statistics and Features, End of 2000," www.unaids.org/wac/2000/wad00/files/WAD_epidemic_report/css/WAD_epidemic_report_5.htm.
[13] At the same time, successful prevention programs in a few African countries, such as Uganda, have reduced national infection rates.

little as $10-15 per patient.[14] Unfortunately, TB is an airborne virus and in crowded environments with large numbers of sufferers, it is difficult and expensive to achieve eradication. The effective approach to TB is procurement programs to purchase and distribute these treatments widely in order to eradicate its presence, a task that lies beyond the economic reach of many health ministries in poor countries. Note also that there is little research into new treatments for TB. 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.

Malaria can be partially prevented through sanitation programs and prophylaxis, while it can be treated with available drugs. Again, these drugs may be out of the reach of poor patients. Moreover, because the disease tends to build resistance to drugs over time there is a continuous need for research into new medicines. The most effective long-term solution, in addition to vector control strategies, is the development of malaria vaccines, which could be administered to children.[15] However, there is insufficient R&D in anti-malarial vaccines or drugs. Sachs, et al (1999) cite a Wellcome Trust study that 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. Private sector spending was lower still. We should note that more 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

[14] See UNAIDS, note 9 supra.
[15] Sachs, et al (1999).

$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, and also fail to exploit private incentives within the intellectual property system.

As a final observation on the current problem, note that even though many pharmaceutical firms have slashed their prices for HIV/AIDS treatments in poor African countries, the prices on offer still do not reduce per-patient cost burdens relative to those in rich nations. In Panel A of Table 2 we show the current average prices in U.S. dollars for six AIDS drugs of an annual treatment for a single patient in the United States, Sweden, and South Africa. For South Africa we show both the prices offered by pharmaceutical companies that own patents on these drugs in the United States and prices offered by Indian generic producers. For example, the drug Viramune costs $3,508 in the United States, $2,565 in Sweden, and is now offered at $483 (original version) and $340 (generic version) in South Africa. In that context the prices are far lower in South Africa than in the United States.[16]

However, as shown in Panel B, when these prices are divided by the U.S.-dollar value of per-capita GDP in 1998, the burden of these drugs in income units is essentially the same in all three markets. Indeed, the price as a proportion of per-capita GDP is lower in South Africa than in the United States only in two drugs and is higher in three.[17]

[16] Note that Bristol-Myers Squibb Co. quite recently offered Zerit to South Africa for $54 per patient per year, making that price much less than indicated. See *Wall Street Journal*, "Bristol-Myers Squibb Offers to Sell AIDS Drugs in Africa at Below Cost," 15 March 2001.

[17] We use 1998 GDP per capita for this purpose because it is the latest year available. Note that the South African Rand depreciated by 29 percent (and the Swedish Krona by 18 percent) relative to the dollar from 1998 to 2001, making the Rand-denominated burdens yet higher to the extent that nominal depreciation reflects GDP changes.

The range of prices of available generic substitutes generally lies below the original manufacturer's price in South Africa, but not in all cases.

3. The Economics of Developing and Distributing Drugs

A key health-policy objective of most countries 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. First and foremost, pharmaceutical drugs have value to the individual, in some cases as a treatment of symptoms, in other cases as a cure. But they also have additional value to society as a method to limit the risk for healthy individuals to be harmed by infectious diseases. 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 research and development. The average cost to develop a new pharmaceutical drug is approximately $300 million and in some cases substantially higher.[18] These costs are mainly fixed and sunk once the drug is developed.

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 result of marginal-cost-pricing is, therefore, that too little investment in research and development takes place and too few drugs are developed in the long run. To correct for this market

[18] Sachs, et al (1999) estimate the average cost for a new drug to be $300 million and predict that developing vaccines for HIV, turberculosis and malaria would ”potentially cost several times as much given the scientific challenges involved.”, p. 8.

imperfection, patents exist to reduce competition and allow pharmaceutical companies to exercise some market power in order to recover their investments in R&D.

The welfare optimization problem in a closed economy, thus, involves a trade-off between giving patients access to existing drugs at reasonable costs versus profits for pharmaceutical companies, which are 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. Such problems can be solved, at least in theory, if the short-run and long-run objectives are separated. The first-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, or even below competitive prices.

While a policy to separate fixed and variable costs of pharmaceutical drug production might be unpractical 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.

So far we have discussed the problem of static distortions and dynamic efficiency in general terms. It is, however, important to recognize the international dimension of this issue. 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, health-care policy in one country has important implications for policy in other countries.

Starting with the issue of different objectives in industrialized and developing countries, 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. 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 to a larger degree prefer to give patients access to existing drugs at low costs.

Restricting our attention to the pricing problem of pharmaceutical companies, the optimal prices in local markets typically depend on the price elasticity of demand as well as the potential for arbitrage between markets. If the average income differs across two segmented markets, optimal prices for a monopolist are likely to be different in the two locations. Giving rebates to consumers with low income is often profitable for the monopolist as long as the rebated price is above the marginal cost of production and the scope for re-sale to high-income consumers is limited. When discounts for a homogenous good are the same for all consumers within a specific market but vary across different markets the pricing strategy corresponds to third-degree price discrimination.

Arbitrage between markets - often referred to as parallel imports - limits the scope for third-degree price discrimination. If both markets are served by the monopolist the

price in the low-income country is likely to rise as a result of parallel trade, while the price in the high-income country is likely to fall. The pharmaceutical company receives less revenue from both the low-income as well as the high-income market when parallel imports result in equalized prices. With large differences in average income across markets, as is the case with developing and industrialized countries, it is quite possible that parallel trade makes it unprofitable to serve low-income markets. Under such circumstances, it is beneficial for all parties – more precisely a Pareto improvement – to restrict parallel imports and increase the degree of price discrimination.[19]

The trade regime affects not only the scope for monopoly price discrimination but also, and more generally, the range of differences in health policies in different countries. More precisely, parallel trade undermines the independence of health authorities in both industrialized and developing countries. In practice, most industrialized countries maintain a policy that allows the pharmaceutical companies to recover their investment in research and development through monopoly mark-ups on existing drugs primarily in the U.S., Japanese and European markets. In this context, it is clear that marginal-cost-based pricing in developing countries could have serious effects on the incentives to introduce drugs in the poorest countries unless the price spillover to industrialized countries is limited.

A necessary, but not sufficient, condition for an effective solution to the access-development problem for pharmaceutical products in developing countries is, therefore, to limit parallel exports from the developing countries as well as parallel imports into the industrialized countries.

[19] As noted in Varian (1988), this result is quite robust. If price discrimination results in a new market being opened up, then it is typically a Pareto-improving welfare enhancement. Hausman and MacKie-Mason

4. A Proposal for a Developing Economies' Fund for Essential New Drugs

In this section we set out a new proposal that would help resolve the incentive problems plaguing development and dissemination of drugs under the current system. We term our initiative the DEFEND Proposal, for "Developing Economies' Fund for Essential New Drugs".

4.1. Criteria

The magnitude of the problem with HIV/AIDS, TB and malaria in the least developed countries, particularly in Sub-Saharan Africa, suggests that any proposal to solve the problem must meet several criteria.

First and foremost, giving the poorest countries access to existing therapies and drugs would require prices equal to, or in most cases below, marginal cost. The magnitude of the epidemic and the low level of income in the poorest countries make low prices a necessity. This point can easily be illustrated with a hypothetical experiment. Assuming that all HIV-positive individuals in sub-Saharan Africa were treated with a typical AIDS cocktail therapy (Crixivan, AZT and 3TC) bought at US prices, the total expenditure for these drugs would be more than total GDP in the Sub-Saharan countries put together.[20]

Moreover, for countries with very low median income it can be expected that even a small or moderate monopoly mark-up would generate a substantial allocative

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(1988) study this problem in the context of new patents.

[20] The total GDP in sub-Saharan Africa is approximately $285 billion according to the most recent figures from the World Bank (World Economic Indicators 2000). A therapy with Crixivan, AZT and 3TC is

inefficiency and dead-weight loss. This is a fundamental reason to separate the incentives for development of new drugs from the distribution of existing drugs. The distribution of existing drugs in the poorest countries should, therefore, be founded on cost-based pricing while the incentives for development of new drugs has to be effected by other means. We will turn to this latter problem next.

The second criterion for good policy is that it has to include incentives to encourage innovation and development of new therapies and drugs. The problem is not that it is too profitable to innovate for poor countries, but rather that it is too unprofitable. For the world's three most deadly infectious diseases – AIDS, tuberculosis and malaria – effective vaccines still have to be invented. Moreover, most of the existing treatments for HIV/AIDS have serious and sometimes lethal side effects. In other words, more research on new drugs as well as improvements of existing drugs for the poorest countries is needed in the future.

The typical incentive for research and development of new pharmaceutical products is the prospect of future profits. But we have previously argued that it would be inexpedient and unrealistic to generate sufficient incentives for R&D through monopoly mark-ups in the world's poorest countries. There are three reasons why reliance on future monopoly profits is not a desirable incentive scheme: the monopoly mark-up is distortionary, the potential rents are too small and the political risks involved are too large for the pharmaceutical companies (e.g. the risk of compulsory licencing or generic substitution). The solution to these problems is to design a scheme with fixed lump-sum payments for new innovations, partly subsidized by the industrialized countries with a

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$11,800 dollar per patient per year at U.S. prices and the total for the sub-Saharan countries would be $299 billion per year, if all 25.4 million HIV-infected individuals were treated.

long-term guarantee to the pharmaceutical companies that they will receive some reasonable return on their investment in new and effective drugs.

The third criterion any realistic proposal must meet is that it has to be developed within the limits of international law and treaties and must be supported by established international organizations. The most important examples are the rules of the WTO and the offices of the WHO. In particular, the TRIPS agreement requires all parties to give patent protection to new innovations, including pharmaceutical products. But it also leaves the question of the legality of parallel imports to national governments.

As we have previously stressed, the problem of access to existing and new drugs in the least developed countries is not only a question of trade, patents and pricing but also requires financial aid from industrialized countries. This latter task is best carried out as a coordinated program by the World Health Organization. The main functions of the WHO are to give worldwide health guidance, set global health standards, cooperate with governments to strengthen national health programs and, finally, to develop and transfer appropriate health technology, information and standards.

The fourth and final criterion is to limit coverage of inexpensive distribution to well-defined and restricted geographical areas. The health policies of most developed countries have to be taken as given and must be isolated from the strategy for access to pharmaceutical drugs in the least-developed countries. In order to avoid spillovers to the high-income, high-price OECD markets the policy should include official restrictions on parallel imports of the program drugs into the industrialized nations. Moreover, the least-developed countries need to impose restrictions on parallel exports from their own markets in order to deter slippage into countries that are not designated as recipients. Put

briefly, we envision a regime of regional exhaustion within the WHO-designated program areas but tight controls to prevent the low-cost drugs from escaping those areas.

4.2 Outline of the Proposal

In the previous section we stressed that a successful strategy to give people in developing countries access to effective medicines has to involve four components. First, the cost of giving patients access to existing drugs has to be separated from the incentives for pharmaceutical companies to improve and develop new drugs. Second, the financial incentives to invent new drugs for the world's least developed countries must be subsidized by the industrialized countries. Third, a coordinated strategy should be jointly financed by the developed countries and implemented by an established international organization within the limits of international treaties. Fourth, the strategy should be focused on the least-developed countries and price spillovers should be limited by restrictions on parallel exports. A fund for essential new drugs could potentially help to solve this problem.

The principal structure of the strategy would be an international fund managed by UNAIDS or WHO. With contribution from the developed - and possibly some middle-income developing countries - the fund would buy licenses to produce and sell patented essential drugs in those least-developed nations that choose to be part of the program. Contributions to the fund should be in the form of cash to finance current expenditure. Equally important would be binding commitments to pay for future drugs, in particular vaccines for HIV, TB and malaria.

The program should be open to the least developed countries and all countries in Sub-Saharan Africa.[21] Any government, international organization or non-governmental organization should be allowed to use the license in the participating countries under three conditions: the original patent is respected in non-participating markets, the distribution is restricted to patients in the participating countries and parallel trade to other markets is prohibited.[22] The portfolio of licenses managed by the international fund should be limited to the most essential drugs. A board representing donors would regularly review the portfolio of current and future licenses.

Payments to patent holders should be in the form of a fixed, yearly, lump-sum transfer that would feature three characteristics. First, it should guarantee successful drug and vaccine developers a net present value over the life of the program that should equal expected R&D costs. Second, it should be positively related to the social value (associated with reduced mortality, morbidity, and spillovers) of the drug in the licensed areas in order to tie R&D incentives to underlying needs. Third, given that there may be broader markets for the new drugs and vaccines, it should be positively related to the global share of patients in the licensed areas.

In addition to paying patent holders for licenses, the Fund could provide subsidies to purchase and distribute essential drugs in countries where a large fraction of the population is infected or production cost of the drug is too high in relation to the average income. For available life-extending treatments – such as the existing AIDS therapies – a

[21] The World Bank defines low-income economies as countries with a 1999 GNP per capita of $755 or less. In the most recent classification there were 64 countries in this category.

[22] Production and distribution under these licenses should not be allowed for companies that produce generic substitutes competing with the patented product in non-participating markets. The main reason for this restraint is to avoid strategic spillovers due to cost efficiencies in the production of the licensed product. If, for example, a firm in country A were certified to produce a drug under a publicly procured

possible policy would be to subsidize purchases so that a specific treatment does not cost more than a pre-defined share (e.g. forty percent) of the average GNP per capita in a particular country (the remainder would have to be financed by the local government, NGOs, donors or the patients as a form of co-payment). For vaccines these purchases could be subsidized to a larger degree (up to 100 percent) as widespread access to vaccines has positive externalities both in the local and global community.

4.3 Implementation of the Proposal

The implementation of the proposal could be gradual. Starting with HIV/AIDS treatment, the Fund could buy a portfolio of five or six licenses for the most important AIDS/HIV drugs.[23] For Sub-Saharan Africa a reasonable payment for these licenses could be in the range of $500 million to $1 billion per year.[24] Adding a subsidy for distribution of the drugs, which would guarantee that the treatment does not cost more than 40 percent of GDP per capita in a specific country, would require additional funds. Based on prices of generic substitutes, a cocktail of three AIDS/HIV drugs may be expected to cost between $400 and $600 dollars per patient per year. Thus, the subsidy from the Fund would sum up to a maximum total cost of $4.7 billion - $8.1 billion per year for all HIV infected individuals in Sub-Saharan Africa. This funding, however,

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license, with sales intended for designated recipient countries, its expanded output could provide it with a competitive advantage in non-participating countries by virtue of increasing returns to scale.

[23] Examples of drugs for an initial portfolio include 3TC, Zerit, Viramune, Stocrin, Combivir (AZT plus 3TC) and Crixivan.

[24] The lower bound of these license payments would be $442 million per year and is based on the assumption of a portfolio with ten patents, an average R&D cost of $360 million per drug (Danzon, 1997), a patent length of 20 years with approval coming eight years after the patent was filed, a five percent discount rate and a 75 percent contribution to development costs from the Fund (with the remainder bbeing covered by profits from high-income markets). The upper bound would be $1.165 billion per year and is based on the same assumptions with the discount rate changed to ten percent and the Fund's contribution to development costs raised to 100 percent.

would not be a substitute for the $3 billion dollars WHO and UNAIDS estimate to be needed for basic care and prevention efforts. The total cost for an international strategy is, therefore, in the range of $8.2 to $12.1 billion dollars annually. According to the OECD, total levels of official development assistance from bilateral donors and multilateral agencies amounted to $84.9 billion in 1999, two percent of which was devoted to basic health needs.[25] Thus, this commitment would represent a substantial portion of the current aid funding. However, it would correspond only to 0.03 – 0.05 percent of total GDP in the OECD countries in 1998. To put this in further perspective, if this amount were fully paid by the United States, the European Union, and Japan, it would come to only $13.50 per person per year. In another view, $12.1 billion may be compared with the anticipated loss in South African GDP of $22 billion in the year 2010.

5. Concluding Remarks

The poorest nations of the world suffer from extreme disease burdens, which go largely untreated because weak incomes and the prevailing system of intellectual property rights fail to provide sufficient incentives to develop new treatments and distribute them at low cost. Recent price reductions for HIV/AIDS drugs are encouraging but offer only a limited solution.

In this paper, we analyzed the economic tradeoffs involved in supporting drug and vaccine research through exclusive rights and distributing the fruits of that research to poor countries. Such research is expensive and would not be undertaken by private firms without some prospect for recovering expected R&D costs. However, even if they were developed, private property rights to the distribution of these drugs, in the form of patents

[25] See www.oecd.org/dac/htm/dacstats.htm.

and EMRs, could support inefficiently high prices and generate large deadweight welfare losses compared to the social optimum in poor countries. This system fails to account for the strong external benefits of providing additional treatments and vaccines in poor countries. These benefits accrue also to the rich countries, both for reasons of humanity and because lower economic activity in developing countries is costly in trade terms.

We offer a proposal to overcome these incentive problems. Our DEFEND ("Developing Economies' Fund for Essential New Drugs") proposal would work within the existing international legal structure but significantly would raise the returns to R&D in critical medicines and expand distribution programs. A public international organization would purchase the license rights for designated areas and distribute the drugs at low cost with a required co-payment from local governments. Furthermore, governments would restrict parallel trade to support desirable price discrimination. Costs would be funded largely by increased foreign assistance from the developed nations, but these costs would be low in relation to current aid budgets. We believe a strong program could be mounted for $8 billion to $12 billion per year and would be an extremely effective use of foreign aid.

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Table 1. Deaths and DALYs Caused by HIV/AIDS, Tuberculosis, and Malaria, 1999 (000s)

Disease	World: Deaths	World: DALYs	Africa: Deaths	Africa: DALYs	Americas: Deaths	Americas: DALYs	SE Asia: Deaths	SE Asia: DALYs
HIV/AIDS	2673	89819	2154	74449	81	2815	360	8866
TB	1669	33287	357	8721	59	1114	723	14101
Malaria	1086	44998	953	36838	2	76	69	3071

Source: World Health Organization, *World Health Report 2000* (Geneva, 2000).

Table 2. International Price Comparison for a Selection of HIV/AIDS drugs, 2001

Panel A. Prices in the USA, Sweden and South Africa, March 2001 (in USD)

Product	Sweden	USA	South Africa	South Africa
US brand	original mnf.	original mnf.	original mnf.	generic subs.
3TC	1709	3271	232	98 - 190
Zerit	3078	3589	252	47 - 70
Viramune	2565	3508	483	202 - 340
Stocrin	3231	4730	500	1179
Combivir	4535	7093	730	293 - 635
Crixivan	3339	6016	600	2300

Note: Prices are for yearly treatment of a single adult patient with regular dosage.

Source: *Wall Street Journal* 3/7/2001; LINFO, *http://www.linfo.se/fass/*

Panel B. Prices as share of GDP per capita (in percent)

Product	Sweden	USA	South Africa	South Africa
US brand	original mnf.	original mnf.	original mnf.	generic subs.
3TC	6.3	10.1	7.2	3.0 - 5.9
Zerit	11.4	11.1	7.8	1.5 - 2.2
Viramune	9.5	10.8	15.0	6.3 – 10.6
Stocrin	11.9	14.6	15.5	36.6
Combivir	16.8	21.9	22.6	9.1 – 19.7
Crixivan	12.3	18.6	18.6	71.4

Note: GDP per capita, 1998. The exchange rates in 1998 were on average 1 USD = 5.54 ZAR and 1 USD = 7.95 SEK and in 2001 (until 3/25/2001) on average 1 USD = 7.81 ZAR and 1 USD = 9.69 SEK.

Source: The World Bank, *World Development Indicators 2000*; OECD, *Main Economic Indicators may 2000*