Trade-Related Policy Coherence and Access to Essential Medicines

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I. Introduction

'Essential medicines', a term coined by the World Health Organization (WHO), refers to those drugs and medicines that satisfy the health needs of the majority of a country's population and ought to be available at all times, in adequate dosage, and at prices that all individuals can afford. In 2005, the WHO's list of essential medicines included 312 medicines and the list is revised (and usually expanded) annually to take account of the changes in the prevalence of diseases as well as cures.

Since access to essential medicines is a *necessary* first step for reaching the ultimate goal of universal health care for all human beings, it is notable that the WHO estimates that currently one third of the world's population lacks access to essential medicines, with the proportion being much higher in some of the poorest countries in Africa and Asia.[2] The million dollar question is why? What factors limit access to essential medicines? What trade-related policies affect a country's access to basic medicines? What role does the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) play? How does one ensure that a country's trade policies are coherent from the standpoint of improving access to essential medicines?

By *trade policy coherence* I simply mean that the set of trade policies a country has in place should be mutually reinforcing as opposed to working at cross purposes. Since trade policies are influenced by several independent agencies within a government, policy

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[2] The lack of access to medicines results in a staggering loss of life in the world. For example, more than 10 million *children* die every year, almost all of them in developing countries. Over half these deaths occur due to malnutrition, pneumonia, diarrhea, measles, malaria and HIV/AIDS – effective low cost treatments can prevent at least 2/3rds of these deaths (DFID, 2004).

coherence may not always obtain. Before addressing the issue of coherence, it is necessary to identify the basic economic determinants of access to essential medicines. After all, the effects of trade policy basically percolate through the economy via their effects on such fundamental determinants. Whether or not individuals in a country have access to basic medicines is determined by four fundamental things: (*a*) prices; (*b*) income levels; (*c*) Education and health related knowledge; and (*d*) Government policies and regulations (local or foreign) that impede or facilitate access to medicines.

But access to medicines is not the only issue. Suppose essential medicines were freely available to everyone in the world. Would such free access be sufficient to ensure the elimination of those diseases for which appropriate medicines exist? In other words, if all human beings could afford essential medicines will they necessarily make socially optimal decisions with respect to the consumption of such medicines? Unfortunately, the answer to this question is not an automatic yes. As Kremer (2002) notes, consumption of medicines is subject to both positive and negative externalities. Consider first an example of a positive externality. If an individual takes a vaccine that prevents him/her from catching a contagious disease, he/she lowers the risk that others will catch the disease. But individuals will typically not take into account the benefit they generate for others by keeping themselves healthy and this implies that too few individuals will take preventive medicines. But externalities could just as easily be negative if individuals take curative medicines too frequently or not consume them for the appropriate duration (particularly relevant for antibiotics). As is well known, such misuse of medicines can lead to the emergence of more resistant strains of microbes.

II. Prices

That high prices can prevent access to basic medicines is an obvious statement. But it is worth stressing that high prices are an even bigger problem when consumers do not have access to any health insurance and must meet all health care expenses out of their

own pocket (as is the case for most citizens of the developing world). Even when prices are too high relative to current income, it is possible for consumers to be able to afford medicines if they can obtain adequate financing. Unfortunately, given the state of credit markets in most developing countries, this is often not a realistic option for most poor people in the developing world.

What factors determine prices of medicines? As one might expect, drugs prices are a function of market forces and a host of government policies. On the market side, it is useful to briefly consider the essential economic aspects of the pharmaceutical business. Like most industries, firms in the global pharmaceutical industry are in business for making profits and maximizing value for their stockholders. However, pharmaceutical companies supply products that affect human welfare in a way that most other products do not: antiretroviral drugs are not coca cola. As a result, most people naturally view pharmaceutical firms in a different light relative to other firms. But regardless of one's own position regarding the contribution (or the lack of it) of the pharmaceutical industry to improving access to essential medicines, it is important to understand the economics that underlies the pricing behavior of the industry.

While the pharmaceutical business is complicated and subject to various types of regulations, the most important aspect of this business for our purposes is that most successful pharmaceutical companies invest heavily in R&D and often rely on patents and other IPRs to recoup their investments. Even if one is skeptical of the efficacy of IPRs as a tool for encouraging innovation, it is difficult to deny that R&D expenditures are among the highest in the pharmaceutical industry and for pharmaceutical firms to remain viable, they have to recover these costs in one way or another. The economics underlying the problem is easy to understand. Economic efficiency requires that given that a good exists, it should be supplied to all consumers at marginal cost. However, the marginal cost of producing most pharmaceuticals is fairly low whereas the fixed costs of producing them are very large (due to the R&D investments involved). If all consumers

pay only a medicine's marginal cost, the revenue generated would fail to cover its total production cost. Herein lies the crux of the problem: *someone* has to pay for the fixed cost of producing medicines or they would simply not be produced by private firms. But if fixed costs are spread evenly across global sales (resulting in uniform prices for all medicines), prices of most essential medicines would simply be beyond the reach of most citizens of the developing world.

III. Global Distribution of Income

The basic point with respect to income as a determinant of access to medicines is transparent: a large number of people in the world are simply too poor to be able to afford the basic necessities of life, of which essential medicines happen to be one.[3] However, the relationship between income and access to medicines is not linear. At very low income levels, this relationship is strongly positive. However, beyond a certain threshold level, income is not really a significant determinant of access to most essential medicines (particularly those for which generics exist).

As Kremer (2002) notes, not only do low income levels limit access to essential medicines, they have also played their a role in creating a disease environment in developing countries that differs quite significantly from that in the developed world. For example, infectious and parasitic diseases account for one-third of the disease burden in low-income countries whereas the corresponding number is only 3% in high income countries. Many diseases such as malaria and tuberculosis have been effectively eliminated from rich countries while they continue to afflict people in tropical countries. What makes matters worse is that privately funded research into more effective medicines for such diseases has basically come to a standstill since pharmaceutical companies have little incentive to invest in discovering new drugs for diseases whose

[3] Kremer (2002) notes the following startling fact: the state of Connecticut in the United States spends more on health than the 38 low-income countries of sub-Saharan Africa combined!

primary market is too small. In other words, there exists an *under-provision* of dynamic incentives for innovation and R&D targeted at the discovery of new medicines that benefit primarily the poorer countries. Pecoul et. al. (1999) report that of the 1233 drugs licensed globally between 1975 and 1997, only 13 were for tropical diseases and only four were developed by pharmaceutical firms specifically for tropical diseases. The global imbalance with respect to access to medicines is rather extreme: about 15% of the world's population consumes 91% of the world's pharmaceuticals by value and each year only 10% of the global R&D investment is allocated to find solutions to over 90% of the world's health problems – this is often called the 10/90 problem.

While the burden of diseases such as malaria is shared disproportionately within the world, it is worth bearing in mind that in this age of air-travel, diseases that have been wiped out in the rich countries could be reintroduced in them rather quickly. Thus even if one were to ignore the urgent moral case for jumpstarting and supporting further research into tropical diseases, it is clear that even a narrowly perceived notion of self-interest calls for rich countries to support such efforts. In fact, it is heartening to see that private foundations such as the Gates Foundation have made this one of their primary objectives.

Income issues are relevant not only at the international level but also *within* countries. For example, upper middle class people in a country like India have disease patterns quite similar to their counterparts in Western countries and are likely to benefit from medical advances that occur there. A simple example of this is cardiovascular disease, an affliction that is widely prevalent in the West and for which several preventive and curative treatments are available. The poor citizens of the developing world simply have nothing to gain from the discovery of cholesterol lowering drugs or improvements in relevant surgical procedures.

Deaton (2004) has noted that if income were the only key determinant of health and access to medicines, a developing country's trade policy would be relevant only to the extent it affects its per capita income – an issue on which the evidence is not as clear cut

as one would like. However, whatever evidence does exist is generally supportive of greater openness toward foreign trade and investment.

IV. Education, health related knowledge, and urbanization

Economists emphasize that one of the key determinants of economic development, perhaps the most important one, is the level of human capital of an economy. Adequate human capital is vital not just for supporting local research and innovation but also for having access to new ideas and technologies that are created in the rest of the world. In the jargon of development economics, a country's ability to absorb and fruitfully apply foreign technologies and ideas to local conditions is referred to its *absorptive capacity*. But absorptive capacity is not just an issue of economics since the ability of a person to comprehend and absorb *health related knowledge* directly impacts his/her well being. For example, people that are not fully aware of how HIV-AIDS is transmitted are more likely to catch the disease. Similarly, those that do not fully understand the consequences of taking an incomplete course of antibiotics may quit taking the prescribed medicine as soon as they start feeling better. As is well known, such incomplete usage of antibiotics aids the development of more resistant strains of bacteria (thereby making future infections harder to treat). In addition to weak educational systems, the scarcity of health care workers in developing countries (who are important in providing critical knowledge to patients) is also a significant problem. The 2006 World Health Report notes the following contrast: Sub-Saharan Africa has only 4% of health workers but 25% of the global burden of disease whereas the Americas have 37% of health workers and only 10% of the global burden of disease.

Deaton (2004) observes that the health and life expectancy of most people in the world, especially the developing world, depends on knowledge, ideas, treatments, and cures that are developed abroad. It follows then that the *international diffusion* of such knowledge is a fundamental determinant of the access to medicines and treatments.

The standard argument in favor of free trade is that it allows countries to specialize in activities in which they have comparative advantage with respect to the rest of the world, importing goods and services that are produced more efficiently in other countries. However, a more recent, and perhaps an even more potent argument in favor of greater openness in trade policy is that such openness facilitates the international diffusion of technology and it allows countries to adopt new ideas and techniques invented in other countries without having to bear the substantial costs that are usually necessary for the development of such knowledge – i.e. they do not have to reinvent the wheel. A similar point applies to the relationship between trade and health, perhaps with even greater consequence for human welfare.

It is no secret that access to health care services is much easier in urban areas than rural ones. As a result, the degree to which a country's population resides in rural areas is an important indicator of the difficulty its citizens face in gaining access to essential medicines. While poverty and degree of urbanization might be negatively correlated, such need not be the case always. A critical aspect of proper medical treatment is that patient's take the prescribed medicines for the proper duration and in correct dosage. Since medical supervision is typically lacking in rural areas of most poor countries, the degree to which a country's population is rural is likely to have an adverse effect on proper access to medicines. In fact, the scarcity of medical personnel and the lack of appropriate regulations contribute to the practice of self-prescription that is widely prevalent in developing countries.

V. Trade related policies

As noted earlier, the pharmaceutical industry contends with domestic regulation in all countries and this surely affects the pace at which it introduces new medicines as well as its decisions regarding the global distribution of such medicines. This section focuses on

trade related policies from the viewpoint of those countries that are *not* themselves big producers of medicines.

A. Tariffs, quotas, and other trade restrictions

A large and impressive body of literature in international trade documents the costs of restrictive trade policies such as tariffs, quotas, voluntary export restraints, antidumping duties, and similarly restrictive trade policies. This literature has shown that trade policy restrictions invariably lead to higher prices for consumers, thereby limiting their ability to purchase imports subject to such restrictions. The argument extends to medicines in a straightforward manner: if a country is concerned about providing its citizens access to essential medicines it is difficult to see how trade restrictions could ever be an element of its optimal policy package. The same point applies to any domestic taxes a country imposes on imported medicines. That being said, it is important to note that tariff revenue is generally a much larger proportion of total government revenue for developing countries and a government's incentive to tax imported goods is higher when its national tax system is underdeveloped or when local tax evasion is a significant problem. Second, and as was noted earlier, the market for medicines is far from competitive and major pharmaceutical companies enjoy substantial market power. It is well known that under such circumstances, the optimal policy of an importing country could very well involve some type of trade restrictions.

Even if one grants the notion that import tariffs against foreign firms with market power serve to transfer some revenue to importing country governments with the knowledge that some of the tariff is absorbed by the foreign exporter, such a policy can only make sense from the viewpoint of improving access to medicines if most of the tariff revenue is passed back to local consumers thereby raising their incomes (which can offset the higher prices that tariffs invariably imply). While logically correct, it is unlikely that most governments engage in such distributions and can get the tariff level right. After all, if the tariff is set too high, it will only lower national welfare. Calculating

optimal tariffs in well-specified (and parsimonious) economic models is one thing; implementing such tariffs in the messy and complicated real world is quite another. Given that, it seems clear that a coherent trade policy for developing countries ought to involve low or near zero tariffs (and domestic taxes) on essential medicines. If such is not the case, access to essential medicines is necessarily being compromised and developing country claims about unfair practices on the part of pharmaceutical companies and developed country governments ring hollow.

How widespread are tariffs on essential medicines? A recent paper by Olcay and Laing (2005) studies tariffs on pharmaceuticals in over 150 countries and they report the following:

> About 40% of the countries in their sample levy zero tariffs on both finished products and active pharmaceutical ingredients (APIs) – the biologically active compound(s) in a drug formulation that produces the desired therapeutic effect.
>
> Around 59% levy tariffs on APIs while about 61% levy tariffs on finished products.
>
> Among those that do impose tariffs, over 90% apply tariffs that fall below 10%.
>
> Tariffs on pharmaceuticals are an insignificant source of government revenue for most countries.

Thus, the news with respect to tariffs is not that bad overall: given how low tariffs on pharmaceuticals are, such tariffs are unlikely to play a crucial role in limiting access to essential medicines. Still, the question arises: what possible motivation could a country have for imposing tariffs on pharmaceuticals? Other than the unlikely explanation that such tariffs might serve to extract some rents from pharmaceutical companies, the question is almost a puzzle. However, some insight into it question can be gained by asking a slightly different question: which countries impose relatively high tariffs on

pharmaceuticals and why? Olcay and Laing (2005) note that three countries stand out: India, Iran, and Morocco. India is the only low-income country with tariffs on APIs that exceed 20%; Morocco's tariff rate is around 24%; and that of Iran is 100%. All three countries produce finished pharmaceutical products from imported APIs and among the three, India is unique in having the capacity to make APIs from scratch (although it still imports them since its local production of APIs is insufficient to meet the derived demand generated by local firms producing finished pharmaceuticals). If a country does not produce APIs at all, tariffs on APIs increase the costs of production of local firms that produce finished pharmaceuticals and in fact put them at a competitive disadvantage vis-à-vis their foreign rivals who can buy APIs at world prices. Such discrimination against local firms can hardly have any place in a coherent trade strategy. But could it potentially be rationalized as some sort of an industrial policy? By increasing local prices of APIs, a government can make production of APIs attractive to local entrepreneurs. But even so a tariff on imported APIs is not the first-best policy. If the goal is to encourage local production of APIs, that should be done more directly via the use of production subsidies.

Further insight into the structure of tariff protection in countries such as India can be gained by applying the theory of *effective protection*. The intuitive idea behind this theory is simple: how much effective protection a country grants to a local industry is measured by the proportion to which the value added of the industry under tariff ridden domestic prices exceeds that under free trade. For example, suppose 1 unit of an API is needed to produce 1 unit of a finished pharmaceutical in a small open economy that takes world prices as given. Let the free trade world price of the API be $10 while that of the finished pharmaceutical be $20. Then the value added of producing one unit of the pharmaceutical locally equals: $20-$10 = $10. Now suppose that the local government imposes a 10% tariff on the finished pharmaceutical. Such a tariff increases the domestic price of the pharmaceutical to $22 and the value added of the local industry under tariff protection equals $22-$10 = $12 which exceeds value added under free trade by 20%. The effective

rate of protection is what matters to local producers of finished pharmaceuticals since this is what pays for wages and profits. To see how and why tariffs on APIs matter, suppose there is also a 10% tariff on APIs. This tariff raises the domestic price of APIs to $11. Local value added under this two-tier tariff structure equals $22-$11 = $11, which exceeds value added under free trade by only 10% (i.e. the nominal rate of protection for finished pharmaceuticals). It is easy to see that if the tariff on APIs is 20% then the nominal tariff of 10% on finished pharmaceuticals amounts to *zero* effective protection. Thus, if the local production of finished pharmaceuticals is protected on grounds of some sort of industrial policy, it does not make sense to also impose tariffs on APIs. The lesson here is that trade protection at both levels of production works at cross purposes if the goal is to use trade policy as an instrument for encouraging local production of both finished pharmaceuticals and APIs. On top of that, as noted earlier, trade policies such as tariffs are simply a poor substitute for more direct industrial policies such as subsidies (the case for which is questionable in the first place).

What is true of tariffs is even more so of trade instruments such as quotas and voluntary export restraints. Decades of rigorous research has shown that such policies are usually worse than tariffs from the standpoint of global welfare. In fact, this is one reason why the GATT (and now the WTO) has emphasized *tariffication* – the conversion of all forms of trade protection into their tariff equivalents. Since non-tariff barriers frequently lead to more market power for local producers and can also transfer over any potential tariff revenue to foreign producers in the form of higher profits, tariffs are generally preferable even from an importing country's perspective.

The spread of antidumping (AD) duties to developing countries can only be viewed with a sense of alarm. While such policies have originated in the developed world – with the USA being the biggest user – their use in developing countries is especially ironic. By definition, AD duties are imposed when foreign firms are deemed to charge *unfairly low* prices. In the context of essential medicines, the potential use of such policies would be

farcical. Almost the first policy recommendation from the viewpoint of trade policy coherence would be to eliminate such policies in the area of medicines.

Given the potential importance of trade policy barriers in determining access to essential medicines, an extremely useful policy tool would be an index of overall trade protection in the pharmaceutical industry. While such indices are available at the aggregate level for many countries, much more can be learned about whether and how a country's overall trade policy impedes access to essential medicines by constructed more *disaggregate or /industry level* indices of non-tariff barriers and overall trade protection.

B. Industrial policy: the case for indigenous production of medicines

Importing medicines from abroad is not the only option for developing countries; for those that have sufficient technological capability and sufficiently big local markets, local production of medicines is an option (at least was an option in the pre-TRIPS world). Perhaps the best example in this regard is India's pharmaceutical industry that took root because of one key aspect of India's pre-TRIPS patent regime: India did not recognize product patents; only *processes* underlying products were protected.[4] An implication of this policy was that local firms were free to undertake local production of drugs that were patented abroad so long as they could *reverse-engineer* them on their own (thereby inventing their own processes). Such a policy left room for local entrepreneurs to utilize their innovative skills and led to the emergence of an industry that has come to occupy a central place in the global economy as supplier of generic medicines for much of the developing world. In fact, among the developing world, India is the only country in the world that is close to achieving self-sufficiency in the production of pharmaceuticals.[5]

Still, for several reasons, it is difficult to see how India's model can be replicated en masse. First, most poor nations simply do not have the market size and the technological

[4] Today, India's pharmaceutical industry's sales exceed $5 billion with $2 billion in exports, accounting for 1% of global exports.
[5] But one has to be careful here: what does self-sufficiency mean? As Kaplan and Laing (2005) note, while India is a net exporter of medicines, it still imports finished intermediates or APIs.

capacity that India does. Second, and perhaps equally importantly, in a post TRIPS world the sorts of policies India pursued are simply *unavailable* to most developing countries. For example, recall that before TRIPS India did not recognize product patents thereby permitting local firms to reverse engineer pharmaceuticals. However, post TRIPS India has had to abandon this policy. Thus, policies aimed at the encouragement of a local pharmaceutical industry cannot be part of a coherent national trade and industrial policy strategy toward access to essential medicines.

Indeed, a careful study of the case for the development of a local pharmaceutical industry in developing countries by Kaplan and Laing (2005) concludes that such local production would not make "much economic sense". As they note, local production is justified only if medicines can be produced more cheaply locally than abroad. But if this is the case, multinational firms have every incentive to locate locally as well, unless policy restrictions make it infeasible for them to do so. Overall, it appears that a much wiser strategy for developing countries is to adopt relatively open trade and investment regimes under which they will attract those stages of the production process that best fit their true pattern of comparative advantage. Such a policy prescription seems even sounder when one considers how crucial quality is in the production of medicines. It is one thing to encourage the local production of automobiles and quite another to do so for medicines: a low quality car is surely an annoyance but does not threaten the well-being of citizens in the way that an ineffective medicinal drug does. The problem of low quality manifests in its extreme version in the form of substandard and counterfeit drugs. As Pecoul et. al. (1999) note, counterfeit drugs are those that mimic authentic drugs while substandard drugs are those that are produced with inadequate attention to good manufacturing practices. The prevalence of both types of drugs has increased in recent years and is a matter of crucial importance for many developing countries that lack technical, financial, or human resources required to apply health standards and quality control in the production of medicines.

C. Intellectual property rights protection and the TRIPS agreement

The fact that an overwhelming majority of essential medicines are *not* patented in the developing world, suggests that patents in of themselves may not be a significant barrier with respect to access to such medicines (Attan, 2004). The question then becomes: why has there been so much controversy surrounding the role of patents and other IPRs in limiting global access to essential medicines? One potential answer is that not all medicines are equal and some are needed relatively more in certain countries than others. If five percent of patented medicines include those that are most urgently needed in a poor country then patents can indeed be a problem. This is clearly the case in the case of antiretroviral drugs used to treat AIDS-HIV. In a country such as South Africa where 20% of the population is infected with AIDS-HIV, the fact that most drugs used to treat the disease are patented is absolutely crucial. In fact, nothing illustrates the point more clearly than the widely publicized lawsuit filed by many South African licensed pharmaceutical distributors to overturn South Africa's 1997 Medicines Law that would permit South Africa's health minister to permit parallel imports (more on this below) in cases where the price of a patented drug is too high in the South African market.

A second potential answer to the question as to why TRIPS has been controversial in the context of medicines can be found in a recent paper by Chaudhuri, Goldberg, and Jia (2006). The key idea underlying this paper is that if foreign patents are enforced in the way that is mandated by TRIPS, local producers would have to exit the market since their production would violate TRIPS rules. Such exit can reduce competition significantly and impose potentially large welfare losses on consumers. The question is how large such losses might be. Using detailed product-level data from India, Chaudhuri, Goldberg, and Jia (2006) estimate that in the presence of price regulations, the withdrawal of the four domestic product groups in the flouroquinolone sub-segment in India would inflict welfare losses of $305 million upon the Indian economy, over 83% of which would fall on the shoulders of Indian consumers. An important aspect of their approach is that they

allow for cross-price effects in markets for products that could be substitutes for patented pharmaceuticals – the idea is that if patent enforcement increases prices of a certain medicine, producers of close substitutes will also be able to increase prices (even if their products are not patented) and this will compound the welfare loss suffered by consumers.

But patents are not the only issue; the obligations that developing countries have to meet under the TRIPS agreement are far-reaching, even taking into account the extended time horizons for compliance that are available to the least developed countries. A detailed discussion of such obligations is beyond the scope of this paper. Instead, I focus on two key aspects of TRIPS that are likely to have the most direct impact on access to essential medicines: (1) Parallel trade and (2) Compulsory Licensing.

Parallel trade

Parallel trade is said to occur when a product covered by IPRs sold by (or with the right holder's consent) in one country is resold in another country without the right holder's authorization. Essentially, it represents a type of price arbitrage across international boundaries. What makes the practice potentially controversial is that such trade occurs *without* the consent of the right holder and can potentially undermine the degree of IPR protection afforded to the right holder. It is immediately obvious that barring the existence of international price differences that exceed transportation and distribution costs, parallel trade simply would not arise. The question then becomes: why might the same medicine sell for markedly different prices in different countries?

Economic theory teaches us that barring some sort of market imperfection or policy intervention price differentials that exceed costs of transportation and distribution simply cannot exist. What sort of imperfections can arise with respect to medicines? The obvious candidate here is the market power of pharmaceutical companies – large multinational firms can indeed have the ability to segment international markets if they can tightly

control the distribution of their products. Of course in the context of pharmaceuticals, to a large degree this market power is the *intended* result of IPRs afforded to such companies.

Is parallel trade an economically desirable phenomenon? As stated, this question seems almost absurd. If trade is good, how can parallel trade be bad? However, this misses the point. After all, the possibility of parallel trade arises only in a second best world – a world in which markets do not work perfectly. In the context of medicines, as noted earlier, the market imperfection is the presence of market power on the part of pharmaceutical companies. To develop the argument further, consider the following hypothetical situation. Suppose a pharmaceutical company has a patent over a new medicine which it can market in two countries that have markedly different demands for the medicine owing to differences in per capita income. If the company does not have to concern itself with the possibility of parallel trade, it would be optimal for it to sell the medicine at different prices in the two countries, each price optimally designed to maximize its profits. However, if parallel trade from the poor to the rich country is permitted and the company wants to serve both markets, it is forced to set a common price (excluding costs of transportation etc.) for both markets or else it loses profits due to international price arbitrage by third parties that can buy the medicine in the poor country and sell it in the rich one. Note, however, that the company need *not* serve both markets: it may very well find it optimal to serve only the rich country's market.[6]

Several lessons emerge from this simple example. First, holders of IPRs can fully exercise their market power only if all countries forbid parallel trade. Otherwise, international arbitrage would allocate the relevant medicine to where it fetches the highest price. Second, poor countries might very well find that their markets are not served at all when they choose to permit parallel trade. This implies that, from a global perspective, the welfare implications of parallel trade are ambiguous. Given the market power of pharmaceutical companies that are in a position to supply unique medicines,

[6] See Malueg and Schwartz (1994) for a formal model that analyzes these considerations.

permitting parallel trade may reduce global efficiency and welfare.[7] This ambiguity is reflected in Article 6 of TRIPS which states that

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

Under national exhaustion IPRs of a right holder are exhausted only in the country which it sells the product willingly. For example, the sale of a patented product in New York does not prevent the buyer from reselling it in California regardless of whether the patent holder agrees or not. But a buyer cannot sell the product in another country. International exhaustion simply means that any product protected by IPRs sold in country A can be resold in country B without the right holder's consent. The TRIPS agreements lets each WTO member decide whether it wants to pursue national, international, or even regional exhaustion under which parallel trade is permitted within a region but not with rest of the world (Maskus, 2000). Given the flexibility provided by TRIPS, it is no surprise that different countries have adopted different rules with respect to the legality of parallel trade. For example, while the USA adheres to national exhaustion with respect to patented products, the EU adopts regional exhaustion (with the region being the EU).

Parallel trade can also have implications for the pace of innovation in the pharmaceutical industry.[8] Those opposed to parallel trade argue that by reducing profitability of the pharmaceutical industry, such trade reduces the innovation incentive of pharmaceutical companies. Proponents of parallel trade counter-argue that this criticism does not apply to the poorest countries whose markets are simply too small to have any serious bearing on the profitability (and hence innovation incentives) of the

[7] See Maskus (2000) and Maskus and Ganslandt (2002) for comprehensive discussion of the pros and cons of parallel imports from a global perspective.
[8] A formal analysis of the impact of parallel trade on R&D is available in Li and Maskus (2006).

pharmaceutical industry. Furthermore, they contend that there is little evidence that parallel trade emanates from countries that are most desperately in need of essential medicines. While this may be true, it is important to note that the actual data we have comes from a world in which companies are setting prices already *accounting* for the possibility of parallel trade. As noted earlier, the threat of parallel imports can induce firms to charge relatively similar prices in most markets. As a result, the volume of actual parallel trade that is observed can actually be quite small. But this need not imply that *the threat of parallel trade* does not significantly affect the profitability of pharmaceutical companies.

As noted earlier, given the large fixed cost of producing medicines (emanating mostly from R&D investments) if all consumers pay only a medicine's marginal cost of production, the revenue generated would not cover the total production cost of the firm. Hence, there is no way around the fact that some consumers in the world have to pay prices in excess of marginal cost. Which consumers should these be? Equity considerations suggest that these should not be consumers in the poorest countries of the world. Efficiency criteria also support this argument. For one, such consumers simply cannot afford to pay high prices. Second, their low incomes result in relatively elastic demand curves and it is economically efficient to charge low prices in markets where demand is relatively elastic. Of course, as already noted, it is difficult to see how companies can engage in such international price discrimination when parallel trade is a possibility since such trade would arbitrage away any international price differentials.

It is also worth noting that the standard argument for optimal discriminatory pricing across countries ignores the fact that consumers are heterogeneous: there exists a sizeable middle class in developing countries such as India that suffers from diseases similar to those suffered by citizens of the affluent world. This is important because even if parallel imports were feasible, there is no guarantee that pharmaceutical companies would find it

in their interest to serve those with very low incomes in order to keep prices high even in developing countries.

Yet another issue that one needs to account for is that national price controls can also undermine the logic of discriminatory pricing in the global market. In other words, parallel imports can arise simply because certain nations force prices to be below the level that pharmaceuticals would charge. Such nations would then not be contributing their share of global R&D expenses of pharmaceutical companies even when they prohibit parallel trade.

Whether or not parallel imports are permitted by a country also has implications for the feasibility of *differential pricing*, the proposal that pharmaceutical companies should charge substantially lower prices or even donate important medicines and drugs free of charge to countries where they are desperately needed. If such countries cannot credibly promise to rule out the possibility of such medicines being exported back to richer country markets, pharmaceutical companies may be quite unwilling to participate in differential pricing schemes. But if parallel trade is a threat, it is difficult to see how profit maximizing companies would engage in differential pricing to any serious degree.

Parallel trade is not the only constraint that differential pricing schemes must contend with. Many rich country governments have also played a role. For example, it is not uncommon to hear law-makers and politicians in the United States and other rich countries contend that if pharmaceutical companies are willing to sell for low prices abroad, why are they charging high prices at home? The act of demanding low prices at home by referring to prices abroad is often called ‘external referencing’.

Compulsory licensing

When public interest justifies it, the TRIPS agreement allows developing countries to license the production of a medicine to a local firm *without* the consent of the patent holder (hence the word compulsory). In general, a compulsory license can be issued on the grounds of any one of the following: refusal to license on the part of the patent

holder; public interest considerations as determined by the government; interests of public health and nutrition, including the need to ensure affordability of medicines; a situation of national emergency; the presence of antic-competitive behavior on the part of a patent holder; a scenario where a new invention requires the use of a pre-existing patented invention; and failure to locally work an invention for which a patent has been granted.

As is clear, the list of scenarios under which TRIPS permits the use of compulsory licensing of medicines (indeed of any patented inventions) is fairly large. However, the problem confronting most developing countries, especially the least developed ones, is that the ability to issue a license to a local firm is basically meaningless if the local economy does not have the ability to manufacture high quality medicines locally. To some extent this constraint can be alleviated by technical assistance and technology transfer to developing countries (as indeed is called for by TRIPS), but that takes time and medicines are often needed urgently. One obvious way out of the conundrum is to allow third countries to export medicines that are produced under compulsory licensing. Indeed this is precisely what the August 30, 2003 Decision of the General Council of the WTO permits.

As was noted earlier, most essential medicines are not really patented in developing countries. As a result, there really has not been much need for compulsory licensing. However, as Fink (2003) notes, the threat of such licensing can help lower prices of medicines (recall that such licensing can be used to combat anti-competitive prices as well as for keeping medicines affordable). Of course, the threat of compulsory licensing is *credible* only if local capacity to manufacture the relevant medicine exists and only the existence of a patent prevents such local production. This suggests that compulsory licensing can in fact become a tool for industrial policy. In fact, this nexus between compulsory licensing and industrial policy was at display during the recent dispute between the United States and Brazil. At issue was Brazil's policy that invoked

compulsory licensing for those patented inventions that were not used in domestic production (i.e. did not meet the "local working" requirement). The United States argued that such use of compulsory licensing was tantamount to a protective industrial policy and was inconsistent with the TRIPS agreement. However, Brazil's view was such licensing was an essential part of its strategy to fight the spread of HIV/AIDS. The dispute was settled bilaterally and it indicates that the various dimensions of the debate with respect to essential medicines interact in subtle and important ways. Such interaction suggests that achieving trade policy coherence is not enough; one needs to think of policy coherence at a more general economy-wide level in order to improve access to essential medicines.

VI. Bilateral trade agreements

In recent years, significant concern has been expressed about the potential adverse impact of bilateral free trade agreements (FTAs) between developed and developing countries on the latter group's ability to use TRIPS flexibilities for public health purposes and for promoting innovation targeting diseases that affect them disproportionately.[9] As an example, consider the US-Jordan free trade agreement. As Fink (2005) notes, this bilateral trade agreement has three provisions of crucial relevance. First, it forbids Jordan from being engaging in parallel trade thereby limiting its ability to import medicines at the lowest available prices. Second, compulsory licensing is permitted only in case of a national emergency. Third, Jordan can no longer insist that a patent holder agree to provide the product at a reasonable price and in adequate supply.

All three aspects of this agreement significantly reduce the flexibility that was available to Jordan under the TRIPS agreement (which permits a country to choose its own regime with respect to parallel trade; allows compulsory licensing under a broader

[9] See Roffe (2006) for a recent comprehensive view of the effects of such FTAs and the challenges member countries face in their implementation.

range of circumstances; and does not prevent countries from combating anti-competitive practices on the part of patent holders). Mexico's experience with NAFTA is similar to that of Jordan: Mexico committed itself to protection of foreign investors and IPRs of US companies to a much greater degree than the WTO's multilateral agreements.

The trade-off for countries such as Jordan and Mexico is transparent. On the hand bilateral agreements with a developed country such as the US offer the lure of better access to its large market. On the other hand, such agreements often require them to undertake reforms with respect to a variety of trade related policies, reforms which often take the form of giving up discretion and flexibility that is available under the WTO's multilateral agreements. Whether the net gain from such a bilateral agreement is positive for a developing country is an open question but one that is best answered by the country itself. Of course, the unequal distribution of economic and military power might imply that developing countries do not really have any real choice in the matter. However, the global balance of power affects *all* international decisions and negotiations. To single out bilateral trade agreements in this regard to does not appear to be useful.

When the decision to enter into a bilateral FTA in a developing country is made by a democratic government that is neither subject to widespread corruption nor symptomatic of poor widespread governance, it is reasonable to take the voluntary signing of such an agreement on face value – if a country signs them, it must be that its welfare increases from doing so. In other words, it very well could be that such agreements have an adverse impact on access to essential medicines but a developing country signs them because gains from increased trade and investment make its overall gain positive. Of course, the difficulty is the public health costs of such agreements are likely to be *concentrated* on the poorest segments of society while the benefits are probably much more diffuse. Thus, while such agreements raise significant equity considerations *within* developing countries that sign them, such issues are best addressed by their domestic policies.

VII. How to identify the binding constraints?

To be able to effectively identify the constraints that a country faces with respect to access to essential medicines, the discussion in this paper suggest that the following issues ought to be addressed:

1. Does a country's per capita income in terms of its purchasing power allow its citizens to be able to afford essential medicines? If not, the first and perhaps the most important constraint on access to essential medicines is the lack of sufficient buying power. This constraint can only be alleviated by raising growth rates and improving the distribution of income across citizens. While increased international trade can help in raising growth rates, it may exacerbate income inequality within a country (something that can be tackled with appropriate domestic policies).

2. While looking at anecdotal evidence regarding prices of individual drugs across countries can sometimes be useful, it is simply not a scientific measure of the extent of international price dispersion. In this regard, perhaps the most useful thing would be the construction of a *price index for the core group of essential medicines*. Such a price index would be difficult to construct for many reasons. For example, not all medicines are sold in all countries due to low incomes, the possibility of parallel imports, the degree of IPR protection that is locally available, and differences in diseases patterns etc. Limiting the construction of such an index to only those medicines that are locally sold runs into a selection problem. Second, since not all diseases are equally prevalent in all countries, it would also be useful to have a *weighted price index* where the weight on the local price of each medicine could be the percentage of local population that is afflicted with the disease that the medicine cures. Such a weighing scheme would capture the idea that not all essential medicines are equally important to all countries – for example, South Africa needs HIV-AIDS medicines far more desperately than most developing countries and a weighted price index would take this into account. While price indices for individual pharmaceutical molecules have been constructed for developed countries (see Danzon

and Chao, 2000), we really need to be able to compare an aggregate price index that comprises of all essential medicines. Furthermore, for developing countries, rigorous efforts at international comparisons of prices of even individual medicines have been scarce.

3. Trade policy restrictions are rarely, if ever, a sensible policy. In the context of medicines, the imposition of trade barriers by developing country governments borders on the ridiculous: if prices of medicines are too high already, why raise them further? Luckily, only a few countries apply high tariffs on pharmaceuticals. It also appears that such countries are using trade barriers as an indirect industrial policy whose goal is to encourage the development of the domestic pharmaceutical industry. Perhaps India is the leading example of this case. A classical view of India's policies would argue that such policies simply diverted resources away from other activities in which India's true comparative advantage lies. But it is also true that today India's pharmaceutical industry occupies and important role in the global economy and is poised for significant growth. Nevertheless, most poor developing countries that lack adequate access to essential medicines simply do not have the technological capability to use trade barriers as an indirect industrial policy and would do well to eliminate all tariffs on medicines. Note also, that tariffs are not the only means of protection and there exist a host of non-tariff barriers that can impede access to medicines. The World Bank constructs indices of non-tariff barriers and a disaggregated measure for the pharmaceutical industry would be very useful. Finally, in countries that also imposed tariffs on intermediates such as APIs (or on necessary technical equipment), effective rates of protection need to be calculated. As is well known, nominal rates of tariff protection can be quite misleading under such circumstances.

4. While TRIPS requires all WTO members to adopt uniform standards with respect to IPR protection (with some exceptions for developing countries), there is some flexibility within TRIPS to allow countries to address their most urgent concerns with

respects to access to medicines. Compulsory licensing and parallel imports are two important channels of such flexibility. However, we know very little about how successful a strategy compulsory licensing has been for most developing countries. The problem of course is that, in the absence of sufficient technological capacity that permits a country to actually produce medicines of adequate quality, the option of compulsory licensing is basically meaningless. *Detailed case studies* of when and where compulsory licensing has been successful could be quite illuminating. Aggregate data in this context will not be as informative since compulsory licensing has not been used widely in the developing world (although there is a rich history of it in the developed world where compulsory licensing has been used to combat anti-competitive behavior by firms).

With respect to parallel imports, we know quite a bit more but most of what we know applies to the EU. Data constraints are more severe with respect to developing countries. Another problem is that such trade can occur even when it is not allowed by some countries and this complicates the task of measurement even further. But still, at the broad level we can ask: do developing countries that permit parallel trade have superior access to medicines? As noted earlier, this is unlikely to be the case since pharmaceutical companies would optimize against the possibility of such trade and might even opt out of markets from where the possibility of re-exports threatens their more lucrative markets. Since the decision to permit or restrict parallel trade is likely to apply at the economy-wide level, a cross-country study would be needed to address this question.

5. That industrial policy with respect to the pharmaceutical industry can have serious ramifications for improving access to essential medicines seems clear when one considers India's experience. Given TRIPS and the fact that most developing countries do not have the required technological capacity to successfully develop a local pharmaceutical industry within a reasonable time horizon, it would appear that the prospects for the pursuit of clever industrial policies that can improve access to essential medicines in the poorest countries are rather dim. Still, it would be useful to have more detailed case

studies of countries such as India and Brazil to see if some other lessons, perhaps less ambitious ones than the development of a full domestic industry, could be learnt. While several good case studies in the area do exist, such studies have not focused directly on whether and how the development of local industry has helped in addressing diseases for which insufficient R&D is being done by Western pharmaceutical companies.

6. The effect of a bilateral free trade agreement between a developed and a developing country on the latter's access to essential medicines is complicated. On the one hand, such agreements can generate significant benefits in the form of increased bilateral trade and investment. On the other hand, they can sometimes compromise the flexibility that is available to developing countries under the TRIPS agreement. It is difficult to have a general position either for or against such bilateral agreements. More importantly, only a country itself can decide whether there is indeed a trade-off between market access and public health and whether its interest is best served by being party to such agreements.

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