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Trade-Related Policy Coherence and Access to Essential Medicine

A Working Paper

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1. INTRODUCTION

The World Health Organization (WHO) defines 'essential medicines' as those drugs and medicines that are necessary to satisfy the healthcare needs of the majority of the world's population and therefore ought to be available to all individuals, in adequate dosage, and at affordable prices.[2] Few would dispute that adequate access to essential medicines is necessary for achieving the ultimate goal of universal healthcare for all human beings. That this goal is unlikely to be achieved anytime soon is evident from one simple fact: the WHO estimates that approximately 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.[3]

Policy coherence in trade and health has been identified as one of the principle objectives for improving international health-related welfare. During the World Health Assembly of 2006, WHO member states put forward two resolutions that touch upon the relationship between trade and health. One of them, entitled "International Trade and Health," explicitly urges member states, among others, to promote multi-stakeholder dialogue at the national level to

> *…consider the interplay between international trade and health; to take advantage of the potential opportunities and address the potential challenges that trade and trade agreements may have for health (…);* and *to apply or establish, where necessary, coordination mechanisms involving ministries of finance, health and trade, and other relevant institutions, to address public health related aspects of international trade.* Furthermore, Member States request the Director General to *(…) build the capacity to understand the implications of international trade and trade agreements for health;* and *(…) to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors (…).*[4]

In order to address some of these challenges, this paper provides an overview of the economics of access to essential medicines in order to address the following questions: What economic factors determine access to essential medicines? How do trade-related policies affect a country's access to basic medicines? What role do multilateral trade agreements such as the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) play? How does one ensure that a country's trade policies are mutually coherent as opposed to working at cross purposes from the standpoint of improving access to essential medicines? The paper argues that whether or not individuals in a country have access to basic medicines depends upon (at least) four fundamental factors: (*a*) prices; (*b*) income levels of individual citizens; (*c*) education and health related knowledge;

and (*d*) government policies and regulations (local or foreign) that affect access to medicines directly or indirectly.

But access to medicines is not the only issue: economists have noted that even if everyone could afford essential medicines, individuals would not necessarily make socially optimal decisions with respect to the consumption of medicines. For example, Kremer (2002) notes that the consumption of medicines is subject to positive as well as 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 of infection for others. But individuals will typically not take into account this 'external' benefit of their decision while choosing whether or not to vaccinate themselves. As a result, too few individuals may 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, generating negative externalities for society at large.

2. PRICES

That high prices can limit access to basic medicines is an obvious statement. But it is worth stressing that high prices are an even bigger problem when consumers lack health insurance and must meet all health care expenses out of their own pockets, as is the case for most citizens of the developing world. Furthermore, given the state of credit markets in most developing countries, external financing is also not a realistic option for the poor of the developing world.

What factors determine prices of medicines? As one might expect, such 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 seek to maximize profits and 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 global pharmaceutical industry to improving access to essential medicines, it is important to understand the economics underlying its pricing behaviour.

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 pharmaceutical companies, at least the successful ones, invest heavily in research and development (R&D) and often rely on patents and other types of intellectual property rights (IPRs) to recoup their investment costs. Even if one is sceptical of the efficacy of IPRs as a tool for encouraging innovation, it is difficult to deny that the pharmaceutical industry invests heavily in R&D and firms in the industry need to be able to recover these investment costs in one way or another.[5] The economics underlying the problem is easy to understand. Economic efficiency requires that given that a medicine exists, it should be available to all consumers at marginal cost. However, the marginal cost of producing most medicines is fairly low whereas the fixed costs involved are typically quite large (due to the R&D investments involved).[6] If all consumers were to pay only a medicine's marginal cost, the revenue generated would fail to cover a firm's total production cost. Herein lays 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 medicines would simply be beyond the reach of a majority of citizens of the developing world.

3. GLOBAL DISTRIBUTION OF INCOME

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.[7] However, as Deaton (2004) notes, the relationship between income and access to medicines is not linear. At very low income levels, this relationship is strongly positive; but beyond a certain threshold level, income is not really a significant determinant of access to most essential medicines (particularly those for which generics exist).

Not only do low income levels limit access to essential medicines, they have also played a role in helping create a disease environment in developing countries that differs quite significantly from that in the developed world (Kremer, 2002). 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 whereas they continue to afflict people in poor 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 primary market is too small. In other words, there exists an *under-provision* of dynamic

incentives for innovation 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, a narrowly perceived notion of self-interest on the part of rich countries calls for them to support such efforts more vigorously. In fact, it is heartening to see that private foundations such as the Gates and Rockefeller Foundations have made this one of their primary objectives.

Income issues are relevant not only at the international level but also *within* countries. For example, medical advances in Western countries may primarily benefit the relatively richer citizens of developing countries since their disease patterns are likely to be quite similar to their counterparts in Western countries.

4. EDUCATION, HEALTH RELATED KNOWLEDGE AND URBANISATION

Economists emphasize that one of the key determinants of a country's level of economic development, perhaps the most important one, is the level of its human capital. 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 as 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 was noted earlier, 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 primarily developed abroad. It follows then that the *international diffusion* of health-related knowledge is a fundamental determinant of access to medicines and treatments.

The standard argument in favour 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 by other countries. However, a more recent, and an even more potent argument in favour 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 fully bear the substantial fixed costs that underlie the creation of such knowledge – i.e. they do not have to reinvent the wheel. A similar point applies to the relationship between trade and health, with even greater and more immediate consequences for human welfare. In this context, the liberalization of healthcare services is of special importance. Under the General Agreement on Services (GATS), health services can be delivered internationally via four potential modes: Mode 1 (Cross-border Supply): e.g. provision of diagnosis or treatment planning services in country A from suppliers in country B; (2) Mode 2 (Consumption Abroad): e.g. patients from country A travel to country B for treatment; (3) Mode 3 (Commercial Presence): e.g. investment in country A's hospitals by residents of country B; and (4) Mode 4 (Presence of Natural Persons): e.g. healthcare provision in country A by health professionals from country B. From the viewpoint of developing countries, given the limited buying power of most of their citizens, being able to access healthcare services abroad under Modes 1 and 2 would appear to be rather limited. Similarly, while there are several non-profit organizations doing extremely valuable work in developing countries, the overwhelming majority of health care professionals in developed countries serve local consumers. In fact, given the amount of brain drain that occurs from developing countries Mode 4 might even result in a net decrease in the availability of healthcare services in developing countries. It is under Mode 3 that one might expect developing countries to experience the most significant benefits in healthcare services since foreign investment in the local healthcare sector can bring in desperately needed investment and improvements in technology, insurance and management practices. While this is true in principle, the degree of liberalization that has occurred in health services

in most developing countries has been rather limited. The General Agreement on Trade in Services (GATS) allows WTO Members to choose which service sectors as well as which modes to liberalize: relatively few developing countries have made commitments to fully liberalize investments in medical, hospital, and other health services through Mode 3. Furthermore, almost no country has made a commitment to full liberalization under Mode 4 for these services and other health-related professional services such as nurses, mid-wives, physiotherapists and para-medical personnel. While some degree of reluctance is easy to understand due to the radically different domestic health care regulations across countries, it appears that significant welfare gains are being sacrificed in this sector due to slow pace of liberalization. Overall, it seems fair to say that while the potential for improving access to medicines and healthcare is large under Modes 3 and 4, the degree of liberalization that has been undertaken thus far has been too limited to have had much of an impact on developing countries.

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 patients take 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 its overall access to essential 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. To the extent that increased international trade assists in the transformation of economies and leads to a greater allocation of people in activities that occur in urban centres, it can indirectly improve access to essential medicines. Of course, the benefits improved access to healthcare that results from relocating to urban areas might be offset by a worsening of the environment that such relocation inevitably implies (particularly in developing countries where pollution is a significant problem in most large cities). In the sense that the GATS allows WTO Members to maintain limitations and conditions when undertaking liberalization commitments, a country may also seek to improve access to essential medicines in rural areas through regulatory requirements such as universal service obligations, zoning conditions on providers of medical, hospital and other health-related services and establishing cross subsidization of services between geographical areas.

5. TRADE-RELATED POLICIES

The pharmaceutical industry contends with a variety of domestic regulations in all countries and such regulations affect both the pace at which the industry introduces new medicines as well as the global distribution of medicines. This section focuses on trade related policies from the viewpoint of those countries that are *not* themselves big producers of medicines.

5.1 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 improving access to essential medicines for its citizens, it is difficult to see how trade policy restrictions could ever be an element of its optimal policy package. The same point applies to any domestic taxes that a country might impose 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, 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 such tariffs falls on foreign exporters, 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 have the necessary information to 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.

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: such low tariffs are unlikely to play a critical 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 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 has no local production of APIs, tariffs on APIs increase the costs of production of local firms that produce finished pharmaceuticals and put them at a competitive disadvantage vis-à-vis their foreign rivals that 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 objective is to encourage local production of APIs, that can be met more effectively 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 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 non-tariff barriers 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.

Given all these considerations, 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 this 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 could not be taken very seriously.

Due to 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. Such an index should include not only data on tariffs but also non-tariff barriers that range from quotas to domestic regulations that affect the ability of foreign companies to establish adequate retail and distribution networks. 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.

5.2 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 adequate 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.[8] India's IPR regime left local firms free to undertake production of drugs that were patented abroad so long as they could *reverse-engineer* them on their own. As a result, there was room for local entrepreneurs to utilize their innovative skills and this 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.[9]

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 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 modify its IPR regime to bring it in compliance with TRIPS.

Overall, it appears that 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.

Another approach worth considering might entail the development of regional pharmaceutical production centres in LDCs and developing countries. It could help countries to address some of the challenges of domestic production by allowing them to pool resources, information and technological capacity, as well as supply larger, regional markets. However, this approach also faces several limitations, including those relating to quality controls, local distribution challenges, and political will.

In general, developing countries ought to adopt relatively open trade and investment regimes under which they can attract those stages of the production process that best fit their true pattern of comparative advantage[10]. 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 it 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. The prevalence of both types of drugs has increased in recent years and is a significant threat for public health in many developing countries that lack technical, financial, or human resources required to apply health standards and quality control in the production of medicines.

5.3 Intellectual Property Protection, the TRIPS Agreement and TRIPS-Plus

It has been argued by some that since an overwhelming majority of essential medicines are *not* patented in the developing world, patents in and of themselves are not 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 HIV/AIDS. In a country such as South Africa where 20% of the population is infected with HIV/AIDS, 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 and the resulting reduction in competition can impose potentially large welfare losses on consumers. 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 have inflicted 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 counterfactual analysis is that it allows for cross-price effects in markets for products that are 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. An important implication of this is that even patenting a few key medicines could have ripple effects in markets of those medicines that are *not* patented.

But patent enforcement is 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 three key aspects of TRIPS that are likely to have the most direct impact on access to essential medicines: (1) Parallel Trade, (2) Compulsory Licensing and (3) Test Data protection.

5.3.1 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 (Scherer and Watal, 2002). Essentially, it represents a type of price arbitrage across international boundaries. What makes this legitimate 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. 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 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.[11]

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, permitting parallel trade may reduce global efficiency and welfare.[12] 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 this 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 and UNCTAD-ICTSD, 2005). 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.[13] 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 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 (Scherer and Watal, 2002).

It is also worth noting that the standard argument for optimal discriminatory pricing across countries ignores consumer heterogeneity within countries: 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 needs to be accounted 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.

Mention should also be made 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. As already noted, both equity and efficiency considerations argue in favour of such pricing. However, such pricing is difficult to implement since law-makers and politicians in the United States and other rich countries often 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’.

5.3.2 Compulsory licensing

The TRIPS agreement allows, under certain conditions (Article 31 TRIPS), all member states to license the production, export or import 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 *inter alia* 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 anti-competitive behaviour 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 criteria set by the TRIPS agreement to permit the use of compulsory licensing for medicines (indeed of any patented inventions) is fairly flexible. However, the problem confronting most developing countries, especially the least developed ones, is that they often do 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. Prior to the August 30, 2003 Decision of the General Council of the WTO, if a generic producer in country A were to export to country B (whose government had issued a compulsory license), this producer would violate patent rights in his/her home country (Fink, 2003). However, the August 30 Decision, has addressed this problem by permitting such trade between countries: prior to the Decision, the generic firm in A was limited by the TRIPS provision that production should be "predominantly" for the local market.

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 most potent when local capacity to manufacture the relevant medicine exists or when low cost suppliers exist in neighbouring countries. 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 dispute between the United States and Brazil that occurred in 2000. 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 that such licensing was an essential part of its strategy to fight the spread of HIV/AIDS. This dispute, which was settled bilaterally, 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 might need to think of policy coherence at a more general economy-wide level in order to improve access to essential medicines.

5.3.3 Test Data

Before any drug can be brought to the market, it goes through extensive testing in order to determine its efficacy and any potential side effects. The test data generated in this process are what allow health authorities to decide whether to permit the marketing and sale of a new medicine. The TRIPS agreement protects results of all studies that constitute the test data against unfair commercial use and disclosure except when it is necessary to do so for public safety. As Correa (2004) notes, pharmaceutical companies argue that the protection of test data is important because the development of test data entails significant R&D costs and exclusive access to such data is necessary to recoup such costs. Critics debate the true costs underlying test data and view the exclusive use of such data as a strategic tool used by pharmaceutical companies to compensate for the decline in their rates of innovation.

Prior to TRIPS, countries were free to decide whether to protect test data or not. TRIPS introduced the first international standard on test data but it does allow WTO members some latitude in how the standard is implemented locally. For example, protection need not be extended to data that are publicly available; rather only undisclosed data must be protected. However, it is unclear whether this stipulation provides any real freedom to developing countries: if data is publicly available, how could it be protected anyway? Perhaps a more important type of flexibility provided within TRIPS with respect to test data is that members have some discretion in defining what constitutes a new chemical entity: as Correa (2004) notes, they do not have to protect second indications, new formulations, or dosage forms. Finally, and perhaps most significantly, test data have to be protected only when they are the result of "significant" investment. While what qualifies as significant is a matter of debate, this stipulation does prevent pharmaceutical companies for preventing disclosure of information that was not costly to produce but is worth protecting for strategic reasons (vis-à-vis their rivals).

While the US and other developed countries have argued that exclusive rights to test data should be granted to the relevant pharmaceutical firm for a minimum period of five years (ten years for agrochemicals), such exclusivity is not provided for under TRIPS. However, as is discussed below, while this has not been possible at the multilateral level; the trend in bilateral trade agreements is markedly different.

5.3.4 Bilateral Trade Agreements

In recent years, significant concern has been raised 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.[14] Examples to be considered are the US-Singapore, US-Vietnam or the US-Jordan FTAs. As Fink (2005) notes, bilateral trade agreements limit, in certain cases, flexibilities currently available under the TRIPS Agreement to WTO members which are needed to address public health concerns. Specific examples under these agreements include:

- First, in the case of the US-Singapore FTA, the title holder of the patent may limit parallel imports and thereby the parties' ability to import medicines at the lowest available prices;
- Second, in the case of the US-Vietnam FTA, compulsory licensing is permitted only in case of a national emergency, as an antitrust remedy and for public non commercial use;
- Third, In the case of the US-Jordan FTA, as well as in other recent FTAs involving the US, the patent term could be extended in cases of marketing or regulatory delays.

All three examples show how these agreements can reduce the flexibility and policy space available under the TRIPS Agreement. Mexico's experience in the field of IP with NAFTA has been similar. Mexico committed itself to protection of foreign investments and IPRs of US companies to a much greater degree than the WTO's multilateral agreements. As was alluded to above, exclusivity requirements with respect to test data (a TRIPS-plus standard) have also been successfully incorporated by the US in its recent trade agreements with many countries, such as Australia, Bahrain, Chile, Jordan, Singapore and CAFTA/DR (Correa, 2004, and Fink, 2005).

The trade-off presented by bilateral FTAs for developing countries is transparent. On the one 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 have much 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 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 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 country chooses to sign them because gains from increased trade and investment dominate the welfare losses caused by reduced access to medicines.[15] 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. While such agreements raise significant equity considerations *within* developing countries that sign them, such issues are best addressed by their domestic policies.

6. 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 suggests 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 per capita income levels 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 evidence regarding prices of individual drugs across countries is very helpful, a country's overall access to essential medicines can be better measured by the construction of an *aggregate price index for essential medicines* and tracking it over time. In this regard, further analysis of data on prices of essential medicines such as the one conducted by Gelders et. al. (2006) needs to be undertaken in individual countries. Price indices for essential medicines have to be constructed and interpreted carefully: not all medicines are sold in all countries and there is significant variation in the policy environment and the pattern of diseases across countries. In fact, it would be useful to construct 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 treats. Such a weighing scheme captures 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.

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 would be perplexing: 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 might be 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 an important role in the global economy as a supplier of low cost medicines to much of the developing world. Nevertheless, most developing countries that lack adequate access to essential medicines do not have the technological capability to be able to use trade barriers as an indirect industrial policy and would do well to eliminate all tariffs on medicines (as indeed most have done). 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 construction of indices of non-tariff barriers that measure the level of overall trade protection in 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. *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 North America where it was used as a tool of antitrust policy).

5. That industrial policy with respect to the pharmaceutical industry can have serious ramifications for improving access to essential medicines becomes evident 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 know whether and how the development of local industry in countries such as India and Brazil 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 may compromise some of 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. Most 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. Of course, it is well known that overall gains from such trade agreements do not necessarily imply that all individual citizens gain: for this to occur local governments would need to adopt domestic policies that compensate those that lose from such agreements.

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ENDNOTES

[1] see http://www.iprsonline.org/unctadictsd/dialogue/2006-11-07/2006-11-07_desc.htm

[2] 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 changes in the prevalence of diseases as well as the availability of new cures and medicines.

[3] 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, diarrhoea, measles, malaria and HIV/AIDS – effective low cost treatments can prevent at least 2/3rds of these deaths (DFID, 2004).

[4] Resolution WHA59.26 "International trade and health" put forward at the World Health Assembly on 27th May 2006.

[5] It is worth noting, however, that development and marketing costs are quite often a large proportion of the total R&D costs and that patent regulations contribute significantly to such development costs.

[6] A firm's fixed cost of production is independent of its output level whereas its marginal cost measures the incremental cost of producing an additional unit of output.

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

[8] Today, India's pharmaceutical industry's sales exceed $5 billion with $2 billion in exports, accounting for 1% of global exports.

[9] 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.

[10] Note, however, that local production can occur under licensing arrangements with foreign pharmaceutical companies and may sometimes be necessary to meet urgent local needs.

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

[12] See Maskus (2000) and Maskus and Ganslandt (2002) for comprehensive discussion of the pros and cons of parallel imports from a global perspective.

[13] A formal analysis of the impact of parallel trade on R&D is available in Li and Maskus (2006).

[14] See Roffe (2007) for a recent comprehensive view of the effects of such FTAs and the challenges member countries face in their implementation.

[15] For example, as Correa (2004) notes, data exclusivity can block generic competition even when compulsory licensing is an option.