

The Global Political Economy of Anti-Retroviral Treatment in the Developing World: Challenges to Overcoming the Price-Infrastructure Trap*

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August 2004

Abstract

In this paper I draw attention to how broad changes in the global political economy affect responses to the HIV/AIDS epidemic in the developing world. I argue that stable access to affordable medicines is essential for developing countries to tackle HIV/AIDS epidemics. Developing countries must overcome the “price-infrastructure trap,” where high prices reduce the feasibility of scaling-up treatment programs, reduced feasibility of treatment decreases the incentives to invest in public health infrastructure, and poor public health infrastructure makes even limited treatment programs less effective than they could otherwise be. I examine four mechanisms designed to increase developing countries’ access to affordable drugs. I consider the political economy obstacles to scaling up treatment based on each of these mechanisms, with particular attention paid to the impediments posed by the new global regime on intellectual property rights. I show how each mechanism remains inadequate for realizing the central objective, that of achieving sufficient stability of supply so to stimulate domestic mobilization of resources and thereby escape from the price-infrastructure trap.

Keywords: HIV/AIDS, treatment, antiretrovirals (ARVs), patents, TRIPS, WTO

*Paper prepared for delivery at the 2004 Annual Meeting of the American Political Science Association, September 2 - September 5, 2004. A shorter version is forthcoming in the *Journal of International Development* (Shadlen 2004a). I am extremely grateful to Christopher Garrison for sharing his insights with me. Susan Martin also made helpful suggestions.

The Global Political Economy of Anti-Retroviral Treatment in the Developing World: Challenges to Overcoming the Price-Infrastructure Trap

Responding to the HIV/AIDS epidemic necessarily entails treatment of people infected with the virus. Not even the most advanced drugs can cure patients with HIV/AIDS, but anti-retroviral (ARV) therapy can prolong lives and reduce transmission. In contrast to the situation in most OECD countries, however, treatment remains a rarity in the developing world, where roughly seven percent of the people in need of treatment have access to ARVs (UNAIDS, 2004).

Treatment, of course, is only part of the equation, along with prevention and impact mitigation; but increasingly treatment has come to be regarded as an essential component of national and international responses to the epidemic. This change is evident in bilateral assistance programs, most of which now include treatment, and a host of multilateral initiatives. Indeed, the World Health Organization's (WHO) "3 by 5" initiative promises to see that three million people in the developing world have access to ARV therapy by the end of 2005. Thus, it is fair to say that a corner has been turned in the global response to the epidemic: debates over the appropriateness, possibility, and feasibility of integrating treatment into national and international HIV/AIDS strategies are a thing of the past.¹

But while the importance of scaling up treatment is recognized, attempting to do so presents a multitude of difficult political and economic problems. A key challenge for national treatment campaigns is that countries have access to a *stable* flow of drugs at *affordable* prices. These two dimensions need to be considered jointly: it is not just an issue of lowering the price of ARVs (and other drugs), but of ensuring that countries have uninterrupted ability to acquire inexpensive drugs. Only a stable supply of affordable drugs

¹Note the theme of the 15th Annual International Aids Conference, held in Bangkok in July 2004, "Access for All."

can create an environment that includes incentives to mobilize sufficient resources to scale-up treatment campaigns. Otherwise countries face the “price-infrastructure trap,” where high prices reduce the feasibility of scaling-up treatment programs, reduced feasibility of treatment decreases the incentives to invest in public health infrastructure, and poor public health infrastructure makes even limited treatment programs less effective than they might otherwise be.

In this paper I identify four mechanisms by which countries can potentially increase access to affordable drugs, and I consider the political economy obstacles to scaling up treatment based on each mechanism. I show how each mechanism remains inadequate for realizing the central objective, that of providing developing countries with sufficient stability of supply so to stimulate domestic mobilization of resources and thereby escape from the price-infrastructure trap. My objective is not to analyze the process of treatment *per se*, but rather the underlying international political economy issues that affect countries’ abilities to secure stable supplies of affordable drugs.

In particular, I examine obstacles to increasing treatment that are derived from the international regime that governs the establishment and treatment of intellectual property rights (IPRs). The World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets new and universal standards to which IPR regimes in all countries that are members of the WTO must conform. Most importantly, TRIPS requires countries to grant patents in all fields of technology, including pharmaceuticals, and sets limits on how countries regulate patent holders.² Although not all developing countries are members of the WTO and many poorer countries that are members have limited IPR-related obligations under TRIPS, all the larger countries – developed and

²Prior to the Uruguay Round trade negotiations, which produced the WTO and the TRIPS agreement, countries had autonomy with regard to determining what sorts of innovations were eligible for patents. Many countries did not issue patents on pharmaceutical products.

developing – with the capacity to produce and export ARVs are (or are becoming) WTO members and are therefore constrained by the TRIPS agreement.

TRIPS does not make securing access to affordable drugs impossible, but it introduces significant obstacles and complications (CIPR, 2002: Chapter 2; Granville, 2002). Moreover, the difficulties are not distributed evenly around the globe: for a small number of developing countries the obstacles, though serious, are surmountable; but for most of the developing world, the new global political economy of IPRs makes it exceedingly difficult to mount effective campaigns. The reason is that for most countries, the global pharmaceutical market engendered by TRIPS creates an environment that deprives them of the ability to secure stable supplies of affordable drugs.

I focus on IPRs to drive home an essential point about the contemporary global political economy. Analyses of international responses to the spread of HIV/AIDS in the developing world typically emphasize funding, in particular the lack of resources provided to multilateral organizations such as the Global Fund for the Treatment of AIDS, Tuberculosis, and Malaria (GFATM) and anaemic foreign aid programs. But the challenges – and, more critically, the *obstacles* – to treatment go beyond funding. Financial assistance has indeed been meagre, and substantially more funding will be necessary to mount an effective response to the epidemic, but the key point is how funding interacts with international regimes that regulate state behavior, such as the TRIPS agreement. Or, to put it another way, the goal is to move our attention beyond multilateral and bilateral resource flows and instead focus on the hard-wiring of the global economy that makes it difficult for most developing countries to overcome the price-infrastructure trap and thereby mount effective treatment campaigns. Were aid budgets spilling over and the GFATM awash with funds, fundamental changes in new global regime governing IPRs would still make expanding treatment immensely difficult.

Treatment, Price, and Infrastructure

The challenges to scaling up treatment in the developing world are daunting (WHO, 2004; Tayler, 2004; World Bank, 2004). Drugs are expensive, as is diagnostic equipment. Trained healthcare professionals are needed for diagnosing patients, delivering ARVs, monitoring patients, responding to medical emergencies and dealing with the emergence of opportunistic infections. The list goes on; no one would deny the extent of the challenge. Yet we know that treatment is possible, even in resource-poor settings in the developing world.³

The cornerstone to an effective treatment program is that the medicines be affordable. Drug prices, of course, are not the only relevant issue. Given the complexity of ARV therapy, even if drugs were free many countries would be unable to provide adequate treatment. Yet drug prices unquestionably play a critical role, for drugs are the key input into any treatment program. The high price of ARVs limits the feasibility of treating HIV/AIDS patients in poorer countries with limited resources. Moreover, for public health ministries operating with scarce resources, the high price of drugs can serve as a disincentive to invest in the development of the healthcare infrastructure that is essential for treatment. When drugs are affordable, in contrast, improving healthcare infrastructure may appear as a more worthwhile task. Thus, lower drug prices can create incentives (and free resources) to build necessary infrastructure (Berwick, 2002: 214; Schwarzlander et al., 2001).

The critical issue is not simply the affordability of essential drugs, but also the *stability* of the supply of affordable drugs. Officials need to know that the source of affordable drugs is reliable – that the existing set of essential drugs are not simply available today but that subsequent generations of essential drugs will also be available, at affordable prices, in the future. Governments need to make significant investments in treatment and

healthcare infrastructure to meet the challenges of the epidemic. Because patients infected with HIV need treatment for the rest of their lives (pending discovery of a cure), the investments are not just expensive but open-ended. Yet the incentives to mobilize resources for such investments are reduced without reliable access to affordable medicines. The decisions to build treatment facilities and to purchase specialized laboratory equipment, for example, all entail long-term expenditure commitments. Hence the importance of stability and predictability: policymakers need to know that that the critical inputs at the center of healthcare – the drugs – will remain available at affordable prices

The importance of the time dimension needs to be underscored, for it takes on particular weight in light of the specifics of treating this specific virus. Patients and populations develop immunity to ARVs, so regimens need to be updated with new medicines. Just as yesterday's ARVs have been replaced by a newer generation, the ARVs that are most effective today will need to be replaced by a subsequent generation, and so on. The crux of the problem lies in the future. Currently, countries can import cheap and effective ARVs from India, such as Trioummune, a fixed-dose cocktail produced by Cipla; and they will always be able to do so. But, as I shall explain, post-2005, supply of new ARVs becomes less stable because of TRIPS. Countries will still be able to import the present crop of ARVs, but drugs such as Triommmune will lose effectiveness over time – and affordable supplies of subsequent generations necessary for treatment may not be acquired as readily. Thus, developing countries face perverse incentives. What's the purpose of investing scarce resources in a treatment campaign that is likely to become either ineffective or unsustainable within a decade?

³See, among others, Galvão (2002); Mukherjee et al (2003); Schechter (2004); UNAIDS (2004); Farmer et al. (2001).

Mechanisms for Increasing Access to ARVs

The fundamental question is how developing countries can secure stable supplies of affordable drugs. Figure 1 presents four basic mechanisms for achieving this objective, according to whether the drugs are brand-name or generic, and whether the drugs are produced locally or imported. Treatment programs can use locally-produced brand-name drugs (mechanism A), locally-produced generic drugs (mechanism B), imported brand-name drugs (mechanism C), and imported generic drugs (mechanism D). Although these mechanisms are not mutually exclusive, they are not equally available to all countries. For most developing countries mechanisms A and B, involving local production, are less relevant and important than mechanisms C and D, based on importation.⁴ Yet it is with regard to overcoming the political economy challenges to these latter two mechanisms that TRIPS presents the most significant and enduring impediments.

Figure 1: Mechanisms for Accessing Discounted Drugs

		Type of Drug	
		<i>Brand-Name</i>	<i>Generic</i>
Source of Supply	<i>Local Production</i>	A	B
	<i>Import</i>	C	D

Before proceeding, two points of clarification are in order. First, throughout this paper I use the terms “patented” and “brand-name” drugs interchangeably. Technically this is misleading, for when a patent expires a firm can retain exclusive rights over its brand name through trademark protection, another form of intellectual property (hence the existence on

⁴In fact, mechanism D is important to all developing countries.

non-patented brand-name drugs, such as “Excedrin” or “Tylenol”). The difficulty is that referring to drugs simply as “patented” would be misleading as well, because patents are national, and as we shall see, drugs that are patented in some countries may not be patented in other countries. For the purposes of this paper the reader should interpret the term “brand-name” as referring to drugs that are patented in some countries.⁵

Second, my discussion of imported generic drugs (mechanism D) is based on drugs that have received prequalification from the WHO as “bioequivalent” to the brand-name drugs they imitate. Thus, from a medical perspective, mechanisms C and D can be regarded as indistinguishable. Although the WHO’s prequalification process is not formally equal to approval by national drug regulatory authorities, it is accepted by the Global Fund and World Bank (and also the Clinton Foundation). Indeed, the Bank encourages developing countries to consider procurement of generic ARVs (World Bank 2004; Tayler 2004). In fact, because fixed-dose combinations (FDCs) lead to greater compliance and are easier for health systems to deliver and manage (patients take fewer pills per day on simpler schedules and organizing the supply chain and monitoring delivery are both easier), but because it is easier for generic manufacturers to produce FDCs than brand-name producers (patents on individual drugs in most FDCs are held by different companies), then a case can be made that mechanism D is optimal for treatment.⁶

Local-Brand Name

Local production of brand-name drugs (mechanism A) features a patent-holding firm, in most instances an OECD-based transnational corporation (TNC), manufacturing the drug in a

⁵Some analysts refer to these as “originator” drugs. The terminology is made even more confusing by the fact that Cipla has patents in roughly 15-20 countries on its three-in-one fixed dose combination pill, Triimmune, which is based on three generic medicines.

⁶This statement would have to be qualified to the extent that brand-name pharmaceutical firms overcome patent and anti-trust obstacles and introduce their own FDCs, as some are beginning to do.

given country. Mechanism A is only relevant in countries where TNCs have obtained patents and have a manufacturing presence. Because these conditions are not widespread in the developing world, this is the least relevant of the four mechanisms: in most developing countries, either the ARVs are not patented, or even if they are patented the patent-holding TNCs do not have local manufacturing facilities.⁷

Where these two conditions are met, however, for this mechanism to be useful for obtaining a stable supply of affordable drugs, the country must have the capacity to negotiate lower prices with the local subsidiary of the patent-holding TNC. This brings our attention to IPRs, and in particular to national patent regimes. Key tools for inducing patent-holding pharmaceutical companies to reduce prices are compulsory licenses and parallel imports. With a compulsory license, the host government allows a local entity (a private firm and/or government agency) to produce and distribute a good under patent, without the consent of the patentee.⁸ For example, a country's patent regime might permit the government to classify high prices or limited supply as violations of public interest or forms of patent abuse, and subsequently threaten to issue a license to an alternative firm if the patent holder fails to lower the price or increase supply.⁹ With parallel imports, the government allows patented drugs to enter the market once the patent holder places them on the market elsewhere.

Of course, the threat to issue a compulsory license or permit parallel imports may be sufficient to encourage firms with patents to lower the prices at which they provide the goods over they have control. But – and this is the key point – whether or not a country can make a

⁷Patents provide exclusive rights for importation as well as production, so a firm that has a patent in a given country will not necessarily manufacture the drug in that country.

⁸Compulsory licenses can be issued for importation as well, not just production. The point is that the government compels the patentee the license the exclusive rights of production, importation, and distribution that are conferred by the patent. Compulsory licenses are often referred to as “non-voluntary licenses.” See Correa (2000); Reichman and Hasenzahl (2003); Tayler (2004: Chapter 2).

⁹In 2001, following concern of anthrax attacks, the United States used a threat of compulsory license to induce Bayer to reduce the price of the drug Ciprofloxacin (“Cipro”) to the Department of Health and Human Services. The Canadian government acted similarly at this time.

credible threat depends largely on its patent regime. The ability to lower prices in these ways depends on the conditions under which a government can threaten a compulsory license, for example, which ministries have the power to do so, whether the ruling could be appealed, and so on.¹⁰

Brazil offers the most prominent case of a developing country obtaining a stable and affordable supply of ARVs through this mechanism (Galvão, 2002; Granville, 2002). Brazil did not issue patents on pharmaceuticals prior to April 1997, and because patents are not offered retroactively to existing drugs that were already on the market, most ARVs in Brazil are supplied by local manufacturers of generic drugs (mechanism B). The problem the Brazilian government has faced is that newer, patented ARVs included in its national HIV/AIDS treatment program – the ones that came on the market after April 1997 – consume disproportionate amount of state resources allocated to purchasing medicines. In response, the government has used the facilities under its patent law to negotiate price reductions. For example, in August 2001 Brazil announced its intention to issue a compulsory license on an HIV/AIDS drug to which the patent was held by the Swiss firm Roche. Roche responded to the threat by reducing the price of the drug in Brazil, and subsequently no license was issued. A similar episode occurred with three firms in 2003. These threats are only effective negotiating tools because they are credible, and the threats are credible because the Brazilian government has made good use of the flexibilities under the TRIPS agreement and integrated public health provisions into the national patent regime.

To summarize, local production of brand-name drugs is not relevant for most developing countries (e.g. those with few drugs under patent or with limited pharmaceutical

¹⁰Were the host government to actually issue a compulsory license or permit parallel importation, the means of access would be shifted from mechanism A to one of the other three mechanisms: local production of generic (mechanism C) if the license is issued to a local firm, importation of generic (mechanism D) if the license is issued to a foreign firm, importation of brand-name (mechanism B) if the government used parallel importing to introduce the brand-name drug into the country from another market where the patent holder had placed it on the market at a lower price.

sectors), and in those countries where it is relevant, the mechanism is only available to the extent that countries have patent regimes with appropriate public health provisions (Correa, 2000). The Doha Declaration on the TRIPS Agreement and Public Health, adopted in November 2001,¹¹ marks an important advance for this reduced sub-set of middle-income developing countries with well-developed pharmaceutical sectors, potentially providing the political space for more countries to emulate Brazil in terms of the design and use of the patent system to secure stable access to affordable ARVs (Shadlen, 2004).

Local-Generic

Although many developing countries can, theoretically, obtain generic drugs from local producers (mechanism B), this is not a useful mechanism for most countries either. Understanding why requires consideration of the complex patterns of pharmaceutical patent protection in the developing world.

Mechanism B features local firms producing generic versions of drugs that are not patented locally.¹² One reason for the lack of a patent on new drugs is that patents may not be available in a given country. Historically, many developing (and developed) countries did not offer patents on pharmaceutical products, and only recently, in compliance with TRIPS, have they begun to do so. But there are exceptions, and as a result drug patents are simply not yet available in many countries. According to TRIPS (Article 65.4), those countries that did not grant patents to pharmaceuticals prior to 1995 did not have to begin doing so until 2005.

¹¹<http://docsonline.wto.org/DDFDocuments/t/WT/Min01/DEC2.doc>

¹²Although generic versions of drugs that are under patent can be produced locally under compulsory license, this is rare. Instead, as explained above, the threat to issue a compulsory license – or perhaps the capacity to threaten to issue a compulsory license – can encourage patent holders to lower prices or voluntarily license production rights to a local firm.

Although few countries took full advantage of this exception,¹³ India has taken full advantage of its rights under TRIPS, delaying the availability of product patents on pharmaceuticals until 2005; and “least developed countries” have until 2016 to issue pharmaceutical patents.¹⁴ Even in the case of countries that have recently begun to issue patents, patentability tends not to be retroactive, so drugs that were already on the market prior to a country changing its patent laws typically cannot receive patents.¹⁵ Another explanation for the lack of a patent on a new drug could be that the originator firm chose not to patent the drug in a given country.¹⁶ Thus, many drugs that are patented in the OECD are still not patented in many developing countries, providing opportunities for local production of generics.

Taking advantage of the opportunities for mechanism B requires the existence of local production capacity, and there is a gross mismatch between those countries that have such capacity and those countries with low levels of pharmaceutical patents. There are probably no more than fifteen developing countries with the capacity to produce sophisticated drugs,¹⁷ these countries grant patents on new pharmaceutical products (India, until 2005, providing the crucial exception), and originator firms tend to patent in all these countries. In contrast, the countries in which few pharmaceutical products are patented tend to have minimal production capacity. For example, Attaran and Gillespie-White’s (2001) frequently-cited study, which demonstrates fairly low levels of drug patenting in Sub-Saharan Africa, does, in

¹³Many countries that did not grant patents to pharmaceuticals as of 1995 were doing so by 2000, when developing countries were required to be in full-compliance with TRIPS. WTO (2001) indicates the countries that notified the WTO of their intent to use the transition period granted by Article 65.4.

¹⁴To be clear, the 2016 date refers to approximately 30 countries, and many of them have already changed their laws and offer pharmaceutical patents.

¹⁵See discussion of Brazil in previous section.

¹⁶If the market is small, firms may decide that the costs of obtaining and maintaining a patent outweigh the benefits of doing so.

¹⁷A non-exhaustive list would include Argentina, Brazil, China, India, Indonesia, Mexico, Korea, South Africa, and Thailand – all fairly large and industrialized countries. Even those with such capacity would struggle to produce sufficient quantities of the full array of ARVs.

fact, reveal a substantial number of patents in South Africa, the only country in the region that has significant capacity to manufacture pharmaceuticals.

As is evident from this and the previous section, few countries can obtain stable supplies of affordable drugs via local production of either brand-name or generic ARVs. Treatment programs in most of the developing world will have to rely almost exclusively on importation, either of brand-name drugs (mechanism C) or generics (mechanism D). In fact, even those countries that can use mechanisms A and B will have to rely heavily on importation as well, for demand for ARVs will almost certainly outpace local supply capacity.

Imported-Brand Name

Because a significant amount of potential demand for ARVs is in countries where patent-holding firms have little or no production presence, increasing access via importation of brand-name drugs (mechanism C) is an essential component of treatment.

The relevance of this mechanism has inspired a number of national, regional, and multilateral programs that are based on importation of brand-name drugs. One such program is the Accelerating Access Initiative (AAI), launched in May 2000 by UNAIDS, along with WHO and the World Bank. AAI brokers agreements on price reductions between developing countries and participating pharmaceutical firms, with the goal of making ARVs available to developing countries at low prices and providing support for treatment programs. AAI represents a concerted international effort to increase developing countries' capacity to import ARVs, but exclusively brand-name drugs.¹⁸

¹⁸The initiative began in partnership with Boehringer-Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, GlaxoSmithKline, and Merck, and soon thereafter Abbott Laboratories and Pfizer joined, bringing the total number of participating firms to seven.

AAI contributes to a wider trend of price reductions on brand-name drugs, where many pharmaceutical firms have their own discount programs that they run independently of UNAIDS.¹⁹ Discounted pricing schemes have proliferated since 2000 and the prices of drugs in the developing world – not just generic but name-brand – have fallen substantially (MSF, 2004). Indeed, a significant number of countries (particularly in Sub-Saharan Africa) have received drugs through this mechanism, via the AAI or the GFATM, via direct negotiations with brand-name pharmaceutical firms, and via philanthropic organizations such as the Gates Foundation; and much HIV/AIDS-oriented bilateral assistance is based on this mechanism as well.

The principal limitations with this mechanism regard the lack of transparency and, subsequently, the lack of stability that they offer developing countries. Discounts are restricted to specific drugs, with terms, quantities, and prices determined by the supplier. Because the programs are non-binding, participating firms, which make separate agreements with individual countries, can change the terms of the program at any time. For example, some of the firms' discount pricing schemes are based on per capita income and extent of the epidemic in a given country, and since those terms are subject to change, countries lack certainty regarding the price and availability of given medicines that may form crucial parts of their treatment programs.²⁰ The predictability and stability that are necessary to overcome the price-infrastructure trap, and thus mobilize resources for treatment, are not sufficiently

¹⁹Pharmaceutical firms have many incentives to participate in and develop such programs, even donating the drugs at times, so long as they maintain control over the distribution of the drugs. After all, doing so presents the firms with minimal opportunity costs, since in they will sell few drugs in poor countries without significant price reductions; and donation schemes can bring much-desired positive reporting and public relations to a sector that has acquired a generally negative public image. More strategically, these schemes can serve as loss-leaders, potentially help increase sales to other products, and they can keep competitors out of markets.

²⁰Many health activists also note that some drug donation schemes make developing countries' eligibility conditional upon agreements to purchase other name-brand products and not to purchase generic equivalents.

delivered by arrangements in which developing countries receive affordable drugs through the benevolence of drug companies' tiered pricing programs.

Consider, for example, the brief history of delavirdine and the International Dispensary Association (IDA), a Dutch organization that produces and distributes essential medicines to poor countries. In January 2003 IDA obtained a voluntary license from Pharmacia on delavirdine ("Rescriptor"), a drug that blocks HIV reproduction. According to the license, IDA would pay Pharmacia a small fee in exchange for rights to produce and distribute the drug in roughly 80 developing countries. The program was announced with some fanfare at the World Economic Forum in January 2003, not because of the drug itself (delavirdine is not a commonly used medication and not recommended by the WHO), but because of its innovative characteristics as a way to increase access. A voluntary license with minimal royalties would allow the drugs to be provided cheaply and would avoid the legal complications regarding breaking (or threatening to break) patents; and IDA's reputation as a trustworthy organization minimized concerns of transshipment.²¹ Yet soon thereafter Pharmacia was purchased by Pfizer, which then revoked the license.²² Of course, any country that was planning a treatment program and including delavirdine in the program would have been in for an unpleasant shock. But the upshot of this goes beyond this particular drug and program. To repeat, initiatives to reduce prices on imported brand-name drugs that are based heavily on the voluntary actions of patent-holding pharmaceutical firms are unlikely to provide sufficient stability, predictability, and reliability to overcome the price-infrastructure trap.

²¹Transshipment is a prominent concern of the brand-name pharmaceutical firms, as they are concerned that cheap drugs intended for developing countries will be diverted to OECD countries. To address these concerns, in May 2003 the EU announced a plan that offered companies agreeing to sell drugs at significant discounts use of a special logo on packaging that would clearly identify the drugs as part of a program to supply ARVs to sub-Saharan Africa.

²²"Pfizer Makes Aid Pledge, Breaks Pact on AIDS Drug," *Wall Street Journal*, 12 November 2003.

Imported-Generic

The most important mechanism for increasing access to a stable supply of affordable ARVs is via the importation of generic drugs (mechanism D). Importing generics removes some of the vulnerabilities attached to importing brand-name drugs, because the transaction is not based on a removable concession. Rather, the transaction is derived from one country's demand and ability to import and another country's ability to supply via export. Stable access, almost by definition, cannot be derived from pharmaceutical firms' concessions. It is a function of developing countries having the tools – the use of which they retain control – to purchase less expensive generic drugs (mechanisms B and D) and thereby negotiate reduced prices on brand-name drugs (mechanisms A and C).

Because of the delicate intellectual property issues involved in this mechanism, use of the term “generic” needs to be treated carefully, with reference to the exporting or importing country. If the drug is under patent in the importing country but not in the exporting country (call this mechanism D₁), use of the local-generic mechanism depends on the existence of a national patent regime with provisions for compulsory licensing to facilitate the importation of generics.²³ If the drug is not patented in either the exporting or importing country (D₂), there are no IPR-related obstacles to access other than data exclusivity.²⁴ This is the most common form of imported-generic mechanism, with Indian firms supplying generic ARVs to

²³To underscore the important indirect effects of mechanism D, such a patent regime can also increase access to brand-name drugs as the threat of generic competition should induce the firm holding the patent in the recipient country to reduce prices (as discussed above with reference to mechanism A).

²⁴Data exclusivity refers to rules regarding access to data that firms provide to national drug regulatory authorities in requesting approval. If the IPR regime gives excessive data protection it may be difficult for generic drugs to gain the necessary approval to enter the market, regardless of patent status.

countries where certain drugs are not patented.²⁵ Indeed, significant amounts of the medicines used in ARV treatment in the developing world are procured via this mechanism, particularly in treatment programs run by non-governmental healthcare organizations (MSF-WHO-UNAIDS, 2003). National governments in countries where drugs are not patented also negotiate price reductions directly with generic suppliers. Though smaller, individual developing countries with limited absolute demand (even if high rates of disease prevalence) are likely to encounter difficulty negotiating lower prices on their own, use of this mechanism is facilitated by bulk procurement.²⁶

If the drug is patented in the exporting country, however, the challenges to securing stable access become considerably more complicated, regardless of the patent situation in the importing country. If a country cannot obtain affordable supply via domestic production, either because of technological or scale limitations, then the drug must be imported: if there is no local patent (mechanism D₃) the developing country government needs to find an external supplier, and if there is a local patent (mechanism D₄) the government not only must find an external supplier but also needs to be able to issue a compulsory license for importation.²⁷ But the differences between mechanisms D₃ and D₄ are less than the similarities: if the drug is patented in potential *exporting* countries, then regardless of the situation in the importing country, a number of serious IPR-related difficulties emerge. The principal problem is that the supply of such generics may be limited, because of the restrictions that TRIPS places on compulsory licenses in the exporting country. The point, quite simply, is that importing a

²⁵India is the largest supplier of generic ARVs, but it is not the only supplier. Any country that has sufficient pharmaceutical production capacities but lacks patents on some drugs (e.g. Brazil, Thailand) can provide ARVs through this mechanism.

²⁶Prominent examples of this include an arrangement made in 2003 by a group of Latin American and Caribbean countries to purchase generic ARVs and the joint-purchases facilitated by the Clinton Foundation.

²⁷TRIPS gives countries the right to issue such licenses, as confirmed by Doha Declaration, but countries must have appropriate patent regimes to take advantage of these rights and opportunities. Not all developing countries do.

good presupposes someone else exporting that good, and TRIPS requires that goods produced in one country under a compulsory license must be “predominantly” for domestic use (Article 31.f). To the extent that ARVs are patented in export-capable countries, this clause in TRIPS can impede provision of generic versions of such drugs to developing countries.

The problem is not immediate. Because India will not offer pharmaceutical patents until 2005, Indian pharmaceutical firms can continue supplying generic ARVs; and, as indicated, some older ARVs are not patented in other export-capable countries such as Brazil and Thailand. But after 2005, when the transition periods on pharmaceutical patents end for all but the poorest countries, new drugs will be patentable – and almost certainly patented – in all export-capable countries, including India.

Imagine a point in the future, beyond 2016, when all countries are members of the WTO, and all WTO members – developed (rich), developing (poor), and least developed (very poor) – are required to issue pharmaceutical patents. Even in this world of global pharmaceutical patentability, there will still be plenty of new drugs that are not patented in many parts of the world. Global pharmaceutical patentability does not mean global pharmaceutical patenting, because firms will not necessarily bother to obtain patents in all countries. Yet global pharmaceutical patentability *will* mean “global” (or complete) pharmaceutical patenting among all countries with somewhat developed pharmaceutical sectors, because brand-name firms will certainly obtain patents on new products in these countries. At such a point mechanisms D_1 and D_2 will simply cease to exist, and acquiring ARVs through the import-generic mechanism will be obstructed by patents in export-capable countries. And that date is not in the distant future, but just on the other side of 2005.²⁸

²⁸The problem may actually be worse than depicted, depending on the eventual patent situation in India of post-1995 drugs. As indicated, countries such as India that did not offer pharmaceutical patents prior to 1995 are allowed to wait until 2005 to do so; but any country taking advantage of this transition period is required to accept patent applications in a “mailbox” and process the applications in 2005 as if they were newly filed. What this means, in short, is that some of the drugs that are currently in the public domain in India could become patented after 2005. (Note that this form of

To illustrate the difficulties that will be faced by most developing countries on account of the export restrictions, return to the example of Brazil's threats to issue compulsory licenses for the import of generic ARVs. In the previous discussion I noted that Brazil's threats are credible because of its patent regime. Yet another reason why Brazil's threats are credible is because Brazil has the capacity to produce the drugs locally. Patent-holding pharmaceutical firms know that Brazil has both the legal and the economic capacity to introduce generic competition, and they respond by lowering their own prices. Brazil, though not unique, is special. As indicated, most developing countries lack the capacity to produce drugs locally. For them, then, the threat to issue a compulsory license for local production is laughable, and the threat to issue a compulsory license for import is an empty threat without the ability to obtain the drugs from abroad.

Much of the contemporary politics of IPRs in the WTO has revolved around this issue. In October 2001, on the eve of the Doha Ministerial meeting, the developing countries had proposed an interpretation of Article 30 of the TRIPS Agreement, on automatic exceptions to patent rights, to include a limited exception for addressing public health emergencies.²⁹ According to this proposal, a drug firm in one country would be able to supply a generic drug to a developing country unable to produce the drug locally. The exporting firm would be able to do so even if the drug is under patent in the exporting country. For example, a pharmaceutical firm in Canada would be allowed to produce a drug to export to Bangladesh, even if the firm in question was not the patent holder in Canada, and they would be able to do so without the Canadian government issuing a compulsory license.

retroactive patentability was a condition that the developed countries imposed in the Uruguay Round in exchange for granting the transition, but it is not an obligation of countries that do not take advantage of the 2005 transition period, as discussed earlier in the paper with reference to Brazil.) In any case, precisely which drugs are in India's mailbox is unclear.

²⁹See paragraph 9 of developing country proposal to TRIPS Council, WTO, IP/C/W/312, WT/GC/W/450, October 4, 2001.

In contrast, most developed countries preferred a solution based on Article 31, with compulsory licenses issued in both exporting and importing countries.³⁰

The issue was unresolved at the WTO's 2001 Ministerial meeting. Paragraph six of the Doha Declaration simply recognized the special problems that TRIPS poses for developing countries that lack local manufacturing capacity and called on the TRIPS Council to address the problem. In August 2003, after nearly two years of debate and on the eve of the WTO's Fifth Ministerial Meeting in Cancún, Mexico, a resolution was finally agreed.³¹ The settlement, based on Art. 31, included increased regulations for issuing compulsory licenses for export, safeguards against diversion, and a list of developed countries that pledged not to use the system as importers.³² The August 2003 agreement was supplemented by a statement from the Chair of the WTO's General Council, which emphasizes further measures to prevent diversion and includes a list of eleven developing countries that notified the WTO Secretariat that they would only use the system as importers "in situations of national emergency or other circumstances of extreme urgency."³³

Efforts to scale-up treatment may be affected by how this lingering issue was finally resolved in 2003. Because the settlement is cumbersome and potentially difficult to use, requiring multiple licenses of limited scope for each drug to be exported, it is unlikely to provide an adequate solution to the problem of obtaining stable supplies of affordable medicines. Manufacturers in exporting countries will have to request and be granted

³⁰ Again, compulsory licenses would be necessary only in countries where the drug in question is under patent. If a drug were not patented in the developing country that suffered from a public health crisis but lacked pharmaceutical manufacturing capacity, no such license would be required. But a license would be required in the exporting country, where, at some point after 2005, the drug is almost certainly to be patented.

³¹ Srinivas (2003) provides a concise review. See also, Mathews (2004).

³² "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of the General Council of 30 August 2003." WT/L/540. 1 September 2003. http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

³³ http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm.

compulsory licenses to export generic drugs to countries that demand them, requests that may be opposed by the firms holding the patents. The difficulty and uncertainty of these processes can be problematic from the perspective of developing countries looking for stable access to affordable drugs. Whereas the principle drawback of mechanism C was that it left developing countries dependent on the benevolence of OECD-based pharmaceutical firms (see above), the WTO's 2003 settlement transfers' importing countries' vulnerability from pharmaceutical firms to firms and governments in export-capable countries that may or may not be willing to request and issue compulsory licenses for export on behalf of distant, developing countries.³⁴

The full extent of the problem becomes clearer when we consider the issue from the perspective of generic producers. If a firm is going to invest in production of generic drugs for export, it needs to know that there is demand. But the demand exists only to the extent that countries have not just the economic but also the *political* capacity to import their goods – i.e. that the firm has the right to export and the country has the right to import. Otherwise, if the trade in generic drugs is illegal, then generic pharmaceutical manufacturers have little incentive to invest in the production of such drugs for export.

Outlawing, or significantly dampening, the market for generic ARVs has indirect effects as well, for the absence of competition removes patent-holding manufacturers' incentives to lower prices on brand-name drugs. When asked why his firm was reducing prices on drugs to developing countries, for example, Miles White, the CEO of Abbott Laboratories explained the pressures his firm faces: "Why spend money on corporate citizenship? Frankly, because it is required. If I don't provide our products in Africa, governments will license our intellectual property to others who can. Governments will

³⁴An important issue in this regard will be how export-capable countries respond to the new constraints and opportunities. Canada, in May 2004, became the first OECD country to modify its patent law to introduce compulsory licences for exports in conformity with the WTO's 2003 settlement.

intervene. Make no mistake, they will do that.”³⁵ Of course, governments’ ability to “intervene” and license patents depends on having an appropriate patent regime that takes advantage of the flexibilities in the TRIPS Agreement. The Doha Declaration thus can be said to have contributed to price reductions by confirming developing countries’ rights to take such measures. Yet while Mr. White may correctly perceive the pressures his company faces today, he is wrong about the future, when most developing countries may no longer have such tools. Once India offers pharmaceutical patents, new ARVs will be patentable (and patented) in all countries with production capacity. Then, if developing countries cannot “intervene” to license patents, because of the constraints on potential suppliers, Abbott and other similar firms will no longer feel compelled to provide their products at discount prices.

To summarize, the importation of generics is arguably the most important mechanism for overcoming the price-infrastructure trap and thereby increase access to drugs and treatment. The reasons for this are not just the direct effects, but the indirect effects too: access to imported generics (mechanism D) provides developing countries with a bargaining tool to keep obtain price reductions on brand-name drugs, whether produced locally (mechanism A) or from abroad (mechanism C). Competition from generics contributes to brand-name firms’ willingness to make their drugs available at reduced prices. But, importantly, developing countries’ ability to import generic versions of new ARVs (and thereby induce price reductions across the board) will face serious obstacles because of changes in the global IPR regime that threaten to make the generic industry throughout the world more like the generic industry in the OECD, that is specialists in older, off-patent drugs.

³⁵“Benevolence and the bottom line,” *FT.com*, 14 July 14 2004.

Conclusion

Policy responses to the HIV/AIDS epidemic increasingly include treatment. A key contention advanced in this paper is that developing countries' abilities to scale-up treatment and tackle the epidemic depends to no small degree on their enjoying stable access to affordable drugs. The absence of such reliable access to low-priced medicines serves as a disincentive to mobilize and invest scarce resources in healthcare infrastructure and implement complex treatment programs.

Even in the (unlikely) event that the WHO's "3 by 5" relatively modest targets were met, there will be a long way to travel toward universalizing treatment. Thus, it is worth considering the variety of obstacles to doing so. In this paper I have discussed four mechanisms for developing countries to secure access to discounted drugs. The objective has been to assess each mechanism according to its ability to provide developing countries with sufficient stability of supply so to stimulate domestic mobilization of resources and thereby break out of the price-infrastructure trap. In particular, I have analysed how new global regulations on IPRs complicate, constrain, and in many instances thwart developing countries' capacity to use each of the four mechanisms.

More importantly than how TRIPS affects developing countries, however, is how TRIPS is likely to affect the global pharmaceutical market after 2005. Since few countries have the ability to produce generic ARVs locally, and those that can do so are unimpeded by TRIPS, the real issue is how TRIPS threatens to eliminate (or at least significantly dampen) international trade in generic ARVs. If pharmaceutical firms in export-capable countries lack stability in their right to supply generic medicines, they have few incentives to produce them; and to the extent that generic ARVs become less available, developing countries lose a vital lever to exact price reductions from the producers of brand-name drugs.

Efforts to scale up treatment will have minimal success if (i) securing stable supplies of affordable drugs based on local production (mechanisms A and B) is unfeasible on account of economic and technological limitations in most of the developing world, and if (ii) countries' abilities to secure such supplies via import (mechanisms C and D) are seriously restricted by political constraints after 2005. Of course, one can easily envisage a two-tier system in which those who can afford new, post-2005, patented drugs receive them, and the rest are treated with off-patented drugs that generic manufacturers can export. For example, suppose the next generation of ARVs is introduced in 2006. The IPR issues discussed in this paper will make it difficult for most developing countries to access stable supplies of these medicines until their patents expire. But these countries will still be able to purchase today's ARVs, which will remain off-patent in India and other developing countries where never patented and whose patents will expire in those countries where patented.³⁶ Stability of supply could, theoretically, be maintained, even if not equality of care. Beyond the obvious ethical and normative concerns, however, such a scenario would seem to suffer from a profound medical limitation derived from the mismatch between the length of patent cycles and drug resistance cycles. We do not know precisely how long patients can use first-line ARVs until resistance sets in and new treatments are necessary, but given that we are hardly twenty years into the HIV/AIDS epidemic and already on at least the third cycle of ARVs, it is fair to say that the amount of time between using one regimen and needing to switch to another is considerably less than twenty years, the length of patent terms.

Of course, TRIPS and patents are only part of the story, but they are an important part. Increasing international financing for treatment (along with prevention) of HIV/AIDS is certainly an imperative. But even if such assistance were plentiful, the instability of the supply of affordable medicines means that countries would still struggle to break out of the

³⁶See qualification above regarding India's patent application "mailbox."

price-infrastructure trap. Again, the time dimension needs to be underscored: external funding can be used to purchase generic version of the current set of cutting-edge ARVs, but without a market for future sets of such drugs, treatment programs will become unsustainable. And the problem, to repeat, is that outcome (indeed, some might argue the intent) of the TRIPS Agreement and subsequent negotiations at Doha and in the WTO's TRIPS Council is likely to significantly dampen (if not kill) the market for generic versions of new and cutting-edge drugs by the end of the decade. Thus, the broader point is that we need to move our focus beyond resource flows and consider how the global trading system has been hard-wired in such a way that presents immense obstacles to scaling up treatment in the developing world.

A final point regarding patents, innovation, and the availability of new medicines. I have stressed the importance of developing countries having the economic and political ability to import generic versions of new, innovative, and cutting-edge drugs, and I have emphasized that the emerging arrangements on IPRs threaten to seriously reduce (if not eliminate) this ability. The concern, however, is that under alternative arrangements, arrangements that engender – rather than stifle – a market in generic ARVs, such drugs may not exist. That is, developing countries will not be able to import new ARVs if there are no new ARVs, and the firms that they expect to import them from – generic manufacturers – will not create them. This, of course, is among the central and most important issues in the contemporary global political economy of public health, how to create the incentives for originator firms to innovate and develop new drugs (something that patent systems are believed to do well), while also creating mechanisms to facilitate poor countries' ability to purchase these drugs (something where I have shown patent systems to be counterproductive). But this is not such a problem in the case of HIV/AIDS, for reasons that have to do with the virus and disease themselves. Because HIV/AIDS incidence and

prevalence are not territorially and developmentally limited (i.e. people are infected in rich countries as well as poor countries) and because ARV treatment is not temporally limited (i.e. people with HIV/AIDS will need treatment for the rest of their lives) there is and will continue to be a market for new ARVs in wealthy countries. Thus, originator firms that invest in research and development can expect to see returns in the OECD, even if competition from generic producers in developing countries' markets reduces prices in Africa, Asia, and Latin America.

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