The Political Economy of AIDS Treatment: Intellectual Property and the Transformation of Generic Supply

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The Political Economy of AIDS Treatment: Intellectual Property and the Transformation of Generic Supply

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This article examines the relationship between intellectual property (IP) and public health, with a focus on the extension of AIDS treatment in the developing world. While most of the literature on IP and health examines the conditions affecting poor countries’ capacities to acquire essential medicines, I show the distinct—and more complicated—political economy of production and supply. IP regulations alter the structure of generic pharmaceutical sectors in the countries capable of supplying essential medicines, and changes in market structure affect actors’ economic and political interests and capacities. These new constellations of interests and capacities have profound implications for the creation and maintenance of political coalitions in support of on-going drug supply. The result is that the global AIDS treatment campaign becomes marked by mismatches of interests and capacities: those actors capable of taking the economic, legal, and political steps necessary to increase the supply and availability of essential drugs have diminished interest in doing so, and those actors with an interest in expanding treatment may lack the capacities to address the problem of under-supply. By focusing centrally on actors’ interests in and capacities for economic and political action, the article restores political economy to analysis of an issue-area that has been dominated by attention to international law. And by examining the fragility of the coalitions supporting the production and supply of generic drugs, the article points to the limits of transnational activist networks as enduring agents of change.

Since the 1990s, the relationship between changing international regulations on intellectual property (IP) and access to medicines in the developing world has been the subject of an ever-growing body of literature. The World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that countries offer patents on pharmaceutical products. Traditionally many developing (and developed) countries did not allow drugs to

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be patented, but as of 2005 all but the poorest “Least Developed Countries” must do so. This monumental change in the global governance of IP has prompted a wave of research into the question of how the transition to near-universal pharmaceutical patenting will affect drug prices and, subsequently, developing countries’ access to essential medicines. Because patent protection can raise the price of drugs, concern has almost universally been directed toward understanding how to make IP regulations more flexible (so to increase access to more affordable generic drugs and constrain the prices of patented drugs) and how to mobilize funding to increase poor people’s and poor countries’ abilities to purchase essential drugs.

In this article, I build on the contemporary scholarship by problematizing what most analyses of access take as a constant—the existence and availability of generic versions of essential drugs. If generic drugs exist, then analysts, activists, and policymakers can focus on the steps needed to increase consumers’ ability to acquire them, such as how to overcome legal, IP-related barriers and how to increase purchasing power via the development of funding mechanisms. But production and supply precede access, and the constellations of political actors and strategies that facilitate the latter may be less effective with regard to the former.

To highlight the distinct—and more complicated—political economy of production and supply, I focus on drugs for treatment of HIV/AIDS. TRIPS—and in particular the aspects of TRIPS related to pharmaceutical patents—sets new incentives for drug producers. Because these new incentives inspire new patterns of investment and specialization, they can have significant effects on the structure of generic pharmaceutical sectors in the countries capable of supplying essential medicines. The ensuing changes in market structure affect actors’ economic and political interests and capacities, and new sets of interests and capacities have profound implications for the creation and maintenance of political coalitions in support of on-going drug supply. The result, then, is that the global AIDS treatment campaign becomes marked by mismatches of interests and capacities: those actors capable of taking the steps necessary to increase the supply and availability of high-quality, affordable drugs have diminished interest in doing so, and those actors with an interest in expanding treatment may lack the capacities to address the problem of undersupply.

The present analysis has profound—and worrying—implications for public health and the global campaign to extend AIDS treatment. Since the early 2000s an increasing number of people living with HIV/AIDS in the developing world have begun to receive treatment. Although the World Health Organization (WHO) fell short of its goal of three million people receiving treatment by the end of 2005, the trajectory is clearly one of increased treatment, and most international health experts expect further scaling up in the years to come. Indeed, the emerging consensus is that expanding treatment is not just essential but
feasible, and that with the mobilization of sufficient resources an ever-increasing number of people can benefit from AIDS treatment (WHO/UNAIDS 2006). But the analysis in this article suggests otherwise: what has worked so far in expanding treatment may not continue to work as the challenge becomes one of supply.

In addition to the obviously important implications for global public health, the analysis also advances our thinking on international political economy in three significant and closely related ways. First, by focusing centrally on actors’ interests in and capacities for economic and political action, this article should reconnect scholars’ attention away from legal provisions per se and toward politics. Much of the debate about IP and access to medicines has emphasized the legal dimensions; even the political scientists who have addressed the topic have focused on the making and changing of laws (Sell 2002, 2003; Shadlen 2004a). But legal mechanisms only define the realm of the possible; they establish the parameters of what activities are acceptable. Legal mechanisms must be activated, and any efforts to do so put private and public officials in the crosswinds of competing interests. Understanding the interests and capacities of actors to take advantage of legally sanctioned opportunities and, critically, to secure complementary actions on the part of public officials, brings us to the realm of politics. Beyond the questions of what scenarios and activities are possible, political analysis demands that attention be paid to changing constellations of interests in and capacities for pursuing different possible scenarios and activities. That is, in addition to considering what actors can do according to prevailing legal arrangements, we also need to analyze what they do do in response to the incentives embedded in laws and in accordance with their interests and capacities.

Second, by focusing on the fragility of the political arrangements that support and facilitate generic drug supply, the article points to the potential limits of transnational activist movements as agents of change. The global treatment access movement has played a vital role in expanding treatment throughout the developing world since the late 1990s (’t Hoen 2002; Sell 2002, 2006; d’Adesky 2004; Smith and Siplon 2006). Without the intense mobilization and political pressure applied by the activist movement to relax legal barriers to acquiring generic drugs and to increase global funding for treatment and care (i.e., to facilitate access), it is unlikely that we would have witnessed such remarkable increases in AIDS treatment since 2000. But as the challenges of access are supplemented by the challenges of supply, the political strategies that have worked in the past may be less effective. Indeed, one of the staples of the literature on transnational activism (and contentious politics more generally) is that the development and effectiveness of such movements is conditioned by the “opportunity structure” (Tarrow 1994; Keck and Sikkink 1998; Khagram, Riker, and Sikkink 2002; Schurman 2004). As I show, the opportunity structure is changing: broad changes in international political economy shift the political terrain on which activists must operate and fundamentally alter the nature of available alliance partners.

Third, the article shows how the temporal dimensions of social phenomena pose challenges for political action. Political scientists increasingly value the analytic importance of time, and in particular the notion that the effect of given events can vary widely depending on when the events occur (Pierson 2004). Treating AIDS, however, introduces a different perspective on time, for it is a temporally unbounded process. Because AIDS cannot be cured, only treated, people who receive treatment now will need to receive essential drugs for the rest of their lives—and because they will develop resistance they will eventually need new medicines. Politically, this means that the institutional arrangements and social coalitions that facilitate treatment (including both supply of and access to essential medicines) need to be continuously reproduced. AIDS treatment is certainly not unique in its temporal dimensions, and analysts should be
alert to the distinct issues involved in policy areas marked by a need for continuous political reproduction.

The remainder of the article consists of five sections. In section one I provide background on the HIV/AIDS epidemic and treatment, and I explain the importance of price stability for scaling up AIDS treatment. In doing so I draw attention to the key role that generic drugs play in global treatment campaigns. In section two I review, briefly, how developing countries’ strategies for obtaining reliable supplies of affordable drugs are affected by the new international political economy of IP. I explain how new international regulations can pose barriers to access, but how many of those potential barriers have been relaxed. In section three I shift attention from drug access to drug production and supply (specifically undersupply). To do so I disaggregate the generic pharmaceutical sector, distinguishing three basic segments according to price:cost ratios. I explain how new IP regulations transform market structure by turning the incentives dramatically against investing in production of generic versions of new drugs for AIDS treatment, and I consider the effects that the emerging market structure has on political coalitions for expanding treatment to meet the goals established by the international community. In section four I examine these dynamics—the effects of IP on the generic pharmaceutical sector and the political consequences of the emerging market structure—in the country that is the most important supplier of generic AIDS drugs, India. In the conclusion, I summarize the main findings and assess a range of mechanisms and strategies for restoring stability to the supply of essential medicines for AIDS treatment.

**HIV/AIDS and ARV Treatment**

HIV causes AIDS, and AIDS is fatal. By the end of 2005, approximately 39 million people worldwide were living with HIV, and each year nearly three million people die of AIDS (UNAIDS 2006: 7–50). Though HIV/AIDS is universal, the epidemic has had the greatest impact in the developing world. As Table 1 indicates, roughly ninety-five percent of the adults and children living with HIV live outside of North America, Western, and Central Europe. Sub-Saharan Africa alone accounts for three-fifths of the total.

Antiretroviral drugs (ARVs) do not cure HIV/AIDS, but they allow people inflicted with the illness to live normal lives. Although the introduction of combination therapy (where multiple drugs are taken together to slow reproduction of the virus) in the late 1990s converted AIDS into a chronic illness in much of the OECD, it remained a death sentence in most of the developing world, where the high cost of drugs made treatment generally unaffordable for all but the wealthiest. Since the early 2000s, however, an increasing number of people living with HIV/AIDS in the developing world have begun to receive ARV treatment. Whereas fewer than five percent of the people with HIV/AIDS in the developing world who needed treatment were estimated to be receiving ARV therapy in 2001, the share increased to roughly twenty percent by the end of 2005 (WHO/UNAIDS 2006). Although the World Health Organization fell short of its goal of three million people receiving treatment by the end of 2005, the trajectory is clearly one of increased treatment. From 2003 alone, when the 3 x 5 plan was launched, the number increased three-fold, and in 2005 the G8 set as a goal universal access to AIDS treatment by 2010 (WHO/UNAIDS 2006). Not everyone with HIV needs ARV treatment.

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4 “HIV/AIDS has been reported from every inhabited continent and from every country” (Barnett and Whiteside 2006: 8).

5 I use the term “illness” to refer both to people who are HIV-infected and people suffering from AIDS.
“Universal” treatment by 2010 means roughly 10 million people, a six–seven times increase over current levels.

The challenges to extending AIDS treatment in the developing world are daunting (WHO 2003; 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. Some second-line treatments have refrigeration requirements, which add further complexities to supply management and to the already-immense challenges of procurement and patient care. The list goes on; no one would deny the extent of the challenges. Yet we know that ARV treatment is possible, even in resource-poor settings in the developing world.6

The cornerstone to an effective treatment program is that affordable medicines be available. Drugs are the key input, not because they are necessarily the most expensive component of treatment, but because they are irreplaceable. Functional—if not optimal—substitutes can be found to address inadequacies in other components of treatment: different sorts of infrastructure can be made suitable, alternative healthcare providers can be deployed, and so on. But no amount of managerial and political creativity can create functional substitutes for ARVs: if drugs are not available, treatment is impossible, full stop.

Drug prices, of course, are not the only relevant issue, as the previous discussion indicates. But low (high) prices can encourage (discourage) resource mobilization necessary to address some of the complementary challenges. 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 (Schwartländer, Stover, Walker, Bollinger, Gutierrez, McGreevey, Opuni, Forsythe, Kumaranayake, Watts, and Bertozzi 2001; Berwick 2002: 214;

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6 The WHO strategy for scaling up ARV treatment in the developing world is based on a protocol-driven public health approach, rather than individual treatment regimens. The idea is that a protocol-driven approach, based on a formula of a small number of drugs, is simpler to implement (administratively and medically) and thus more appropriate for resource-poor settings. See WHO (2003). Mukherjee, Farmer, Niyizonkiza, McCorkle, Vanderwarker, Teixeira, and Kim (2003) and Sever, Leger, Charles, Noel, Bonhomme, Bois, George, Kenel-Pierre, Wright, Gulick, Johnson, William Pape, and Fitzgerald (2005) discuss the challenges to treatment in resource-poor settings.
Nattrass and Geffen 2005). The relationship between ARV prices and AIDS treatment is supported by recent experience. Since 2000 the price of key drugs declined to less than one dollar per day per patient. These price reductions, combined with significant increases in funding from governments, have provided the foundations for the expansion of ARV treatment.

A critical factor in lowering drug prices has been the existence of a vibrant market for high-quality generic ARVs. The key actors in this regard are pharmaceutical firms from India: it is estimated that more than half of those receiving treatment in the developing world are treated with generic ARVs produced in India. Table 2 provides data on ARV purchases supported by the Global Fund Against AIDS, TB, and Malaria (GFATM) in 2004. Both the importance of generics and the existence of price differentials are obvious: although nearly sixty percent of the drugs purchased were generics, these purchases accounted for just less than half of the expenditures.

The data in Table 2 greatly understate the effect of generic medicines on prices. Not only are generic drugs themselves ordinarily less expensive than their brand-name equivalents, but competition introduced by generics yields price reductions across the board (Lucchini, Cisse, Duran, de Cenival, Comiti, Gaudry, and Moatti 2003; Kovsted 2005; MSF 2005; Wainberg 2005). Thus, the “brand-name” prices reflected in Table 2 are already significantly reduced from the prices observed in the absence of generic competition.

It is important to consider the complex relationship between generic and brand-name sources of supply. After all, the introduction of generic competition has coincided with the proliferation and extension of discount, tiered-pricing (and also voluntary licensing) programs on the part of brand-name producers, and by December 2005 more than 716,000 people in low- and middle-income countries were receiving treatment with brand-name drugs (WHO/UNAIDS 2006: 21). A critical point to underscore, however, is that non-binding, concessionary schemes such as these, in addition to often having onerous conditions attached and lacking transparency, lack stability in the absence of generic competition (Lucchini et al. 2003; Shadlen 2004b). Discount prices and licensing agreements are restricted to specific drugs, for example, with terms, quantities, and other details largely set by the supplier and subject to change according to suppliers’ policy. Or take the case of voluntary licensing, where terms are formally established in negotiations between licensor and licensee: the relative bargaining power of the two parties depends on whether or not the licensor is threatened by generic competition. The point here is not that brand-name pharmaceutical firms’ tiered pricing and voluntary license programs cannot exist independently of generics. After all, such schemes, provided they allow the firms to retain control over distribution, present firms with minimal opportunity costs, since they sell few drugs in poor countries without making significant price

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7 Shadlen (2004b) discusses this in terms of a “price-infrastructure trap.”
8 This estimate was provided to me by an official from the WHO. Precise figures of this sort do not exist.
9 Note that someone using brand-name ARVs may also be using ARVs provided by generic suppliers, which is one of the reasons why precise tallying is so difficult. In any case, increased treatment has been possible because of increased availability of both generic and brand-name medicines.

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Table 2. Providers of ARVs to Global Fund, by Type of Manufacturer (2004)

<table>
<thead>
<tr>
<th>Units</th>
<th>Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand-name</td>
<td>40.7%</td>
</tr>
<tr>
<td>Generic</td>
<td>59.3%</td>
</tr>
</tbody>
</table>

reductions. Furthermore, these schemes can bring much-desired positive reporting and public relations and, more strategically, serve as loss-leaders, help increase sales of other products, and keep competitors out of markets. The point, rather, is that these schemes are insufficient, on their own, because they tend to lack stability and transparency. There are sound reasons to question whether the benevolence of brand-name firms is a sufficiently reliable and stable mechanism for securing long-term supplies of ARVs (Shadlen 2004b; MSF 2005). Because of the competition it introduces, the existence of generic alternatives makes the global AIDS treatment campaign less dependent on and vulnerable to changes in brand-name firms’ marketing and pricing decisions.\(^\text{10}\)

In sum, significant extension of AIDS treatment in the developing world has been made possible by the widespread availability of affordable and high-quality ARVs. Extending treatment (e.g., to approach the ambitious goals set out by the G8, and beyond) or even just sustaining treatment at current levels depend on high-quality ARVs remaining available and affordable. Yet here is the catch: because treatment cannot be terminated, the need for drugs to be available is never-ending; and because patients develop immunity and treatment regimens need adjustment, affordable and high-quality versions of new ARVs must be available as well. The drugs that work today will be ineffective tomorrow, meaning that the political, economic, and legal conditions that facilitate the availability of today’s drugs must be continuously reproduced. The remainder of the article examines the challenges to the durability of generic competition, and thus the stability of supply of affordable ARVs.

**TRIPS and Generic Supply**

The TRIPS agreement sets new and universal standards to which IP regimes in all countries that are members of the WTO must conform.\(^\text{11}\) For the purposes of this article, the most important aspects of TRIPS are the requirement that countries grant patents in pharmaceutical products and the greater degree of exclusivity countries must give to patent holders. As indicated, prior to the introduction of TRIPS many countries did not issue patents on pharmaceutical products, and had wide latitude on how strongly they protected the rights of patent holders. Where drugs are not patented or where the exclusive rights of patent-owners are weak, patients and healthcare providers typically face fewer obstacles obtaining generic versions of new drugs. Thus, the new obligations established by TRIPS led to extensive concern about the availability of affordable medicines in the developing world (see note 1).

It is important to note that many ARVS are not patented in many developing countries. The reasons for this are multiple. First, the poorest ("least developed countries") are not required to issue pharmaceutical patents until 2016. Second, those countries that did not grant patents to pharmaceuticals prior to 1995 did not have to begin doing so until 2005.\(^\text{12}\) Third, even where countries issue pharmaceutical patents, drugs that were already on the market prior to a country changing its patent laws typically cannot be patented (i.e., only new drugs are eligible). Fourth, notwithstanding the formal availability of patents, originator firms

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\(^{10}\) As the prominent international IP lawyer Fred Abbott notes, “developing countries on the whole have shared interests in assuring that there will be alternative production of medicines not under the control of patent holders and that they will have access to newer products, wherever produced” (Abbott 2005: 323–324). See also Katrak (2004a).

\(^{11}\) This is necessarily a very brief and schematic overview. For more detailed analysis, see, for example, Correa (2000b), Watal (2000), and Matthews (2004).

\(^{12}\) Note that many developing countries with important generic pharmaceutical sectors (e.g., Argentina, Brazil, Mexico, and Thailand) did not take full advantage of this transition period and began offering pharmaceutical patents prior to 2005.
often choose not to patent each of their drugs in all countries, especially smaller markets.\textsuperscript{13} Thus, many drugs that are patented in the OECD are still not patented in many developing countries.

The limited extent of pharmaceutical patents in the developing world has led some observers to conclude that patents are unimportant and that the concerns expressed by many are unwarranted (e.g., Attaran and Gillespie-White 2001; Attaran 2004). But such analyses, based on unweighted tallying of patents, are misleading. After all, few developing countries have the economic and technological capacity to produce their own ARVs, regardless of the patent situation. Most countries import their ARVs; and where ARVs are produced locally, the active principal ingredients (APIs) are generally imported. From a treatment perspective, for example, the fact that patenting is low in Malawi and Zambia is irrelevant, since neither country has the capacity to produce ARVs. Instead, they might depend on South African production, where the situation is unquestionably complicated by patents.\textsuperscript{14}

Rather than examining patents across the board, our attention must be directed toward the more advanced developing (and also developed) countries with sophisticated pharmaceutical sectors, that is, the potential exporters. All larger countries—developed and developing—with the capacity to produce and export ARVs are WTO members (or wish to join, e.g., Iran, Russia) and are therefore bound by TRIPS to make pharmaceutical patents available. What this means, quite simply, is that eventually all new drugs are likely to be patented in all countries with the capacity to produce them. Hence, the key question: how will ARV treatment be affected by the on-going transition toward a world where all new drugs can—and almost certainly will—be patented in all countries with production capacity?

For developing countries with more advanced pharmaceutical sectors, the challenges to securing stable supplies of affordable ARVs are manageable. Provided that the country in question has a patent regime with adequate public health provisions, countries can make drugs affordable by authorizing domestic generic manufacture, importing generics from abroad, and negotiating price reductions with brand-name producers. The key tool in a country’s patent regime is the compulsory license, whereby the 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.\textsuperscript{15} Countries meeting their TRIPS obligations can design compulsory licensing systems to encourage price competition (Correa 2000a; CIPR 2002). 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.\textsuperscript{16} Of course, the threat to issue a compulsory license may be sufficient to encourage firms with patents to lower the prices at which they provide the goods over which they have control. But whether or not countries can make credible threats depends in part on their patent regimes—the ability to lower prices in these ways depends on the grounds under which a government can issue a

\textsuperscript{13} Because patents are national, firms obtain and defend their patents in each country. Where markets are small, firms may decide that the costs of obtaining and maintaining a patent outweigh the benefits.

\textsuperscript{14} This point was made by a letter to the editor of the Journal of American Medical Association in response to Attaran and Gillespie-White (2001). See Boelaert, Lynen, Van Damme, Colebunders, Goemaere, Kaninda, Ciaffi, Mulemba, ‘t Hoen, Pécoul, Sans Frontières, Selgelid, Schuklenk, Attaran, and Gillespie-White (2002) and also Grace (2005: 18–19).

\textsuperscript{15} Compulsory licenses can be issued for importation as well, not just production. The point is that the government compels the patent owner to license the exclusive rights of production, importation, and distribution. Compulsory licenses are often referred to as “non-voluntary licenses.” See Correa (2000a,b), Reichman and Hasenzahl (2003), and Taylor (2004).

\textsuperscript{16} In 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 Ciprofloxacine (“Cipro”) to the Department of Health and Human Services. The Canadian government acted similarly at this time.
compulsory license, which ministries have the power to do so, whether the ruling could be appealed, and so on.

Brazil offers the most prominent case of a developing country obtaining a stable and affordable supply of ARVs by threatening compulsory licenses (Galvão 2002; Granville 2002; Orsi, Hasenclever, Fialho, Tigre, and Coriat 2003; Cohen and Lybeck 2005). 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 prior to 1995, local suppliers in Brazil are free to produce generic versions of many ARVs. 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 1995—consume a disproportionate amount of state resources allocated to purchasing medicines. In response, the health ministry has used the facilities under its TRIPS-compliant IP law to negotiate price reductions. For example, in August 2001 Brazil announced its intention to issue a compulsory license on an ARV 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 Roche, Abbott, and Merck in 2003, and then, again with Abbott in 2005. What makes these threats effective negotiating tools is that they are credible, and one reason why the threats are credible is because the Brazilian government exploited the flexibilities under the TRIPS agreement and integrated public health provisions into the national patent regime.

It is important to emphasize that Brazil’s measures to reduce the price of patented ARVs are entirely legal: TRIPS permits countries to design and use their patent regimes as the Brazilians have. However, the uncertainty regarding countries’ rights and the external pressures to exceed TRIPS obligations, a scenario faced by many developing countries, have inhibited other countries from emulating the Brazilian model. Thus, the Doha Declaration on the TRIPS Agreement and Public Health, adopted in November 2001, which confirms the rights set out in TRIPS, marks an important advance for this reduced sub-set of middle-income developing countries with well-developed pharmaceutical sectors. Although the Declaration does not reform TRIPS or release countries from their new obligations regarding the establishment and protection of intellectual property, it provides the political space for more countries to design and use their patent systems to secure stable access to affordable ARVs (Shadlen 2004a).

But what about poorer, less developed countries that lack the ability to produce ARVs locally? For these countries, the ability to emulate the Brazilian strategy for lowering the price of drugs depends on the ability to import generic versions. Yet doing so is difficult, on account of the restrictions that TRIPS places on compulsory licenses in exporting countries. Quite simply, importing a good presupposes someone else exporting that good, and TRIPS requires that goods produced in one country under a compulsory license be “predominantly” for domestic use (Article 31.f). To the extent that new ARVs become patented in export-capable countries, this requirement could hamper provision of generic versions of such drugs to developing countries. To illustrate this, return to the example of Brazil’s threats to issue compulsory licenses. The threats are credible because of Brazil’s patent regime, as discussed, and also because Brazil has the capacity to produce the drugs locally. Patent-holding pharmaceutical firms know that Brazil has not just

\[17\] As the article was going to press, Brazil issued a compulsory license on Efivarenz, an ARV whose patent was owned by Merck.

\[18\] In 2001, the US filed a complaint in the WTO that Brazil’s IP regime violated TRIPS, but the complaint was directed toward another aspect of Brazilian law.
the legal but also the industrial capacity to introduce generic competition, and they respond by lowering their own prices. But Brazil, though not unique, is special. Most developing countries lack the capacity to produce drugs locally, which makes threats to issue compulsory licenses for local production empty threats—but so too are threats to issue compulsory licenses for import, if potential exporters in more industrialized developing and developed countries are hamstrung by TRIPS.

Much of the contemporary politics of IP in the WTO has revolved around addressing this issue of how the supply of generic ARVs may be affected by the restrictions that TRIPS places on producers in export-capable countries. In October 2001, on the eve of the Doha Ministerial meeting, the developing countries proposed a reading of TRIPS that would have simplified the export of generic drugs to poor countries. The proposal was based on an interpretation of Article 30 of the TRIPS Agreement, which addresses the conditions under which actors can use patented knowledge without obtaining any permissions from the state or the owner of the exclusive rights. The developing countries sought to make foreign public health emergencies one such condition. According to their proposal, a drug firm in one country would be able to supply a generic drug to a country that was experiencing a public health crisis but unable to produce the drug locally. The exporting firm would be able to do so even if the drug were under patent in the exporting country. For example, pharmaceutical firms in Canada or India (post-2005) would be allowed to produce generic versions of patented drugs to export to Malawi or Nicaragua, even if these firms were not the patent holders in Canada or India—and they would be able to do so without needing any steps to be taken by the Canadian or Indian governments.

Under strong pressure from the transnational pharmaceutical industry, developed country governments, led by the US, EU, and Switzerland, rejected this proposal (Matthews 2004; Abbott 2005). Allowing automatic exceptions, they maintained, would undermine one of the basic objectives of TRIPS, which was to universalize patent protection in pharmaceutical products. Instead, most developed countries preferred a solution based on Article 31 of TRIPS, which addresses compulsory licensing. The developed countries’ proposals would condition production and trade in generic medicines on compulsory licenses being issued in all jurisdictions where required. 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 lacked pharmaceutical manufacturing capacity and sought to import, 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.

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, however, after nearly 2 years of debate and on the eve of the WTO’s Fifth Ministerial Meeting in Cancún, Mexico, a temporary resolution was finally agreed (WTO 2003a). The settlement, which partially waives Art. 31.f, included increased regulations for issuing compulsory licenses for export to poor

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19 Even for Brazil this is a problem on account of diminished domestic manufacturing capacity in APIs and the inability of local producers to supply enough drugs quickly enough to lower prices (Orsi et al. 2005: 132; Wall Street Journal 2003). As a result Brazil threatens to issue compulsory licenses not just for local production but also for importation from China and India. In short, even larger and more industrialized developing countries rely on the existence of a vibrant international market for generic ARVs.

countries (and extensive safeguards against inexpensive generic drugs being redirected back into wealthier markets). The August 2003 agreement, along with a supplementary statement from the Chair of the WTO’s General Council (WTO 2003b), also included a list of developing and developed countries that pledged not to use the system as importers. After 2 years of non-action, both the agreement and the supplementary statement were formalized as a permanent amendment to TRIPS in December 2005.

Since 2003, a number of export-capable countries have revised their patent laws to incorporate the waiver of Article 31.f (Matthews 2006). Canada was the first to do so, followed by Norway. Reforms are on course in China, the European Union, South Korea, and a number of countries with more advanced pharmaceutical sectors. In India, after significant activism by civic organizations and opposition parties, the final version of the amended Patent Act, passed in March 2005, also permits compulsory licensing for export.

The new international regulations and the subsequent changes to national IP laws create new political challenges. In Canada, for example, the requirement that drugs eligible for export under CL be included on an official list of authorized drugs means that some actor—in industry or civil society—must petition relevant public officials for inclusion. Similarly, under the Indian regulations, firms must receive approval by the Controller General of Patents to export drugs produced under CL. To understand how changes in the global IP system may fundamentally transform the supply of subsequent generations of generic ARVs, then, we need to move analytic attention beyond the actual legality of producing and exporting such drugs and examine the interests and capacities of economic and political actors that might seek to engage in such activities and to elicit necessary measures by public officials. The following sections undertake such analysis.

The Political Economy of Undersupply

The global treatment regime is marked by mismatches between interests and capacities. On the one hand, firms capable of taking advantage of legal opportunities to produce and export generic ARVs may lose interest in doing so, and if they are less vested in such operations they may also be less prepared to devote resources to get public officials to invoke the legal provisions that facilitate generic production. On the other hand, firms interested in taking advantage of legal opportunities to produce and export generic ARVs may lack capacity to do so, and the coalition of actors seeking to expand generic ARV supply may lack the resources to secure necessary public action.

To make sense of these mismatches and to understand the implications for ARV supply, it is useful to consider the generic pharmaceutical industry according to three segments: commodity generics, specialty generics, and hybrid generics. Commodity generics (CGs) are drugs whose patents have expired (or perhaps never existed). Aspirin is a version of a CG: there are no longer patents anywhere in the world on aspirin, so any pharmaceutical firm in any country can produce aspirin (distribution, however, depends on approval from national health authorities). Most of the thousands of generic firms in the world produce CGs, and low barriers to entry make this an intensely competitive segment of the market. 21

Specialty generics (SGs) refer to new drug delivery systems, novel combinations of existing drugs, and non-infringing processes of patented drugs. Included as SGs are drugs whose patents in the US and EU have recently expired or are about to expire, the most lucrative end of the generic market. In the US, for

21 Commodity generics are also referred to as “worldwide generics” and “plain vanilla generics.”
example, the first generic producer to obtain authorization from the Food and Drug Administration (FDA) can receive six months of market exclusivity, in which its product competes only against the brand-name product.22

Hybrid generics (HGs) are drugs that are under patent in some countries but not in the country where being produced (or if produced locally done so under compulsory license). HGs generally cannot be exported to countries where the drugs are patented, but they can be sold in any country that either does not have pharmaceutical patents or where the originator firm did not obtain a patent or where the importing country has issued a compulsory license. The generic ARVs that are used in HIV/AIDS treatment throughout the developing world fall into the HG category. As patents expire on some of the older ARVs (e.g., those with priority dates from he mid-late 1980s), they will become commodities, but ARVs with later priority dates will remain HGs. Most importantly, all subsequent generations of ARVs will fall into the HG category as well.

Table 3 presents a basic overview of the variable price:cost ratios facing producers in the three distinct segments of the industry. CGs have low prices, because minimal barriers to entry and intense competition drive prices down, and low costs, for production processes are well-known and there are no legal obstacles. Firms that specialize in CGs require high volumes to compensate for tight margins.

SGs have relatively high prices, as the drugs are sold in more regulated markets, and high costs, for more research and innovation are required and obtaining regulatory approval is more demanding. When a drug is no longer patented—that is, when the knowledge is in the public domain—everyone with sufficient scientific and technical capacity can engage in production and sales, but for SGs considerable resources must be invested in being the first to reverse engineer the drug. Indeed, in the case of firms seeking to exploit the opportunities presented by US legislation, if the firm is not the first to receive FDA authorization the advantages of doing so dissipate. Moreover, administrative and legal factors create fairly high barriers to entry, as considerable resources must be invested in obtaining approval in more regulated markets, and becoming “first to file” also exposes the firm to being sued for patent infringement. Thus, while only an option for those firms with sufficient technical capacity and financial and legal resources, the SG segment is the most profitable—and desirable—segment of the industry.23

Now consider generic versions of new ARVs, the example of an HG of principal concern in this article. Here the price:cost ratios are least favorable, combining low prices with the high costs. Prices of generic ARVs must be low, for it is only legal to sell them in countries without pharmaceutical patents, and these

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22 Specially generics are also referred to as “value-added generics.” Many analysts use the SG label to refer exclusively to novel delivery systems (e.g., developing versions of drugs that can be injected directly into the blood). My usage is broader, including all generics that are technologically, legally, and administratively more complex, for these are the entry barriers that make SG more upmarket.

23 Indeed, the SG segment is at the top of the value chain in the generic pharmaceutical sector, a step below new product development.
are without exception poorer countries with low purchasing power.\textsuperscript{24} But the costs of producing and marketing generic versions of new ARVs are quite high. Obviously, the costs of HGs (and also SGs) are less than the costs of developing new patentable products, but they are significantly more than those presented by commodities. The reason for this is that reverse-engineering of newer drugs is more difficult and expensive. Firms need to dedicate resources toward researching the compound and learning how to reverse engineer the drugs;\textsuperscript{25} they need to invest in developing production capacity; they must meet the higher standards of good manufacturing practices that are conditions for participating in publicly funded access programs; they need to comply with packaging requirements and find reliable distribution networks (WHO 2004). And, of course, firms engaging in the production of HGs face transaction costs that derive from the legal environment, such as the necessity of requesting compulsory licenses from the government and defending themselves against complaints of patent infringement.

These observations allow us to make a set of hypotheses regarding the political economy of ARV production and supply. Because larger firms that are capable of bearing the scientific, administrative, and legal costs of HGs are also capable of bearing the costs of SGs, they are less likely to be attracted to the low-price, high-cost HG segment of the market. At the same time, smaller firms that seek to fill the niche may not be repelled by the low prices, but they are unlikely to be able to bear the costs of the HG segment. From a treatment perspective, the problem is that the current suppliers of ARVs tend to be more sophisticated and capable firms (Gehl Sampath 2005; Grace 2005; MSF 2005; WHO 2006). Not only are very few firms involved in this segment of the market, those that are involved tend to be among the largest firms in any given country. Thus, to the extent that larger pharmaceutical firms’ interests in participating in HG markets decline, the risk of ARV undersupply increases.

The emerging industrial structure poses critical challenges for the global campaign to increase ARV treatment. The movement to secure public action for scaling up global treatment loses a potentially powerful actor: to the extent that larger firms lose interest in producing and exporting generic ARVs, they are also likely to lose interest in lobbying to secure necessary actions on the part of public officials. But at the same time, those firms with an interest in doing so, in addition to lacking scientific and legal capacity, are also likely to lack the political resources to secure public action. As a result, the principal advocates of such government action in export-capable countries are poor people in need of treatment in far-away lands, and more generally the transnational network of treatment access activists. Hence the mismatch: actors capable of securing public action for scaling up global treatment (i.e., the ability to demand compulsory licenses for export to poor people in poor countries) may have few incentives to act, while actors needing action (i.e., people with HIV/AIDS in developing countries) may lack the necessary political resources.

This is not to suggest that poor people with HIV/AIDS who depend on the existence of high-quality, generic ARVs lack representation altogether, but they face significant hurdles in securing necessary public action. Most obviously, poor people with HIV/AIDS in sub-Saharan Africa are not powerful or important constituents in export-capable countries such as Canada and India. Instead, they are

\textsuperscript{24} There are exceptions to this broad characterization of the HG market. As explained above, because patents are typically not available retroactively to products already on the market, some ARVs remain unpatented in some middle-income developing countries. Yet as the transition to full pharmaceutical patentability continues in the post-2005 environment, the exceptions to the statement in the text will become fewer and fewer (i.e., the only countries where ARVs will be unpatented will be the poorest LDCs).

\textsuperscript{25} It is important to emphasize that the costs of learning how to make generic versions of ARVs applies to future generations of drugs, not the current crop. The reverse engineering costs of today’s drugs have already been borne.
represented indirectly, through the transnational network of treatment activists. And while this activist network has been enormously successful in expanding access to generic ARVs by pressing for relaxation of legal impediments and for increases in global funding (Sell 2002; ’t Hoen 2002; d’Adesky 2004; Friedman and Mottiar 2005; Seckinelgin 2006; Smith and Siplon 2006), the new challenges in the realm of production and supply may stretch the capacities of the global treatment movement.

Indeed, it is important to emphasize how the emerging global political economy of ARV supply presents the transnational treatment activist network with new, formidable challenges. In addition to working to relax legal barriers and increase funding, treatment activists now also face the fight of getting foreign governments and,-importantly, private firms in export-capable countries that already participate in intensely competitive market segments, to take politically risky and economically costly measures for poor people in other countries. Yet the capacity of activist movements to affect outcomes when private investors are involved depends on the structure of the relevant industries (Schurman 2004). Producing generic versions of new ARVs for export to poor countries is an activity with exceptionally thin margins, a characteristic that becomes exacerbated as the costs—not just legal, but economic and political—to reverse engineering, producing, and exporting generic drugs increase. But at the same time that the new IP rules make this segment less attractive to larger, capable firms, the challenge confronting treatment activists is to get more firms involved and politically vested in this activity.

The subsequent challenges appear even more daunting when we consider the temporal dimensions of ARV treatment. Treating AIDS is not like rescuing victims of natural disasters, such as earthquakes or floods. In the latter instances, at some point the interventions are complete. Yet AIDS treatment is never complete. Patients infected with HIV need treatment for the rest of their lives (pending discovery of a cure). But patients and populations develop immunity to particular ARVs, so regimens need to be altered and 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. Politically, what this means is that actors and coalitions face the never-ending tasks of continuously reproducing conditions that are supportive and facilitative of generic ARV production and supply. Whether or not political arrangements that depend so heavily on transnational activists have sufficient endurance and stability is an open question, but the transformation in industrial structure and the subsequent thinning-effect this has on the treatment coalition certainly increases the challenges to continuous political reproduction.

TRIPS, India, and the Sustainability of ARV Supply

For the present analysis, the most important country is India, with its extensive pharmaceutical sector that has acted as a principal supplier of generic drugs to the developing world.26 India delayed the availability of product patents on pharmaceuticals until 2005, taking full advantage of the transition period allowed under TRIPS. Indeed, prior to 2005 India was the last country with an advanced pharmaceutical sector not to offer drug patents; and many Indian firms produce drugs whose quality is recognized by the World Health Organization (WHO 2006). In sum, India’s IP system contributed to the growth of a pharmaceutical sector whose active presence in the global ARV market greatly increased the feasibility of extending AIDS treatment in poor countries, directly, through the supply of affordable ARVs, and indirectly, by placing pressure on brand-name firms.

26 A good argument can be made that China is equally important (Grace 2004, 2005).
Thus, the fate of treatment in the developing world depends to a large extent on the effects that the introduction of product patents has on the Indian pharmaceutical sector. As indicated, India’s Patent Act (Article 92A) establishes conditions under which compulsory licensing for export is acceptable.

To understand the new political economy of ARV supply in India, we need to make a few quick observations about the broader changes that full implementation of TRIPS is likely to engender. The introduction of patent protection will bring about a period of consolidation and intense change in the Indian pharmaceutical sector (Lanjouw 1998; Fink 2001; Katrak 2004b; Chaudhuri 2005; Gehl Sampath 2005). Full implementation of TRIPS introduces new competitive pressures and compels firms to adopt new strategies to exploit new market opportunities. As the substantial skills that Indian firms have developed should allow them to find niche areas and take advantage of new opportunities, the introduction of product patents need not spell denationalization and a return to the pre-1970 industrial structure. Indeed, a number of India’s largest firms have responded to the pending (and now actual) reintroduction of product patents by increasing their investments in research and development, and thereby seeking to engage in more innovative activities. Ranbaxy, for example, which is India’s largest drug firm, has massively increased its R&D spending and begun a patenting strategy; other large firms have similar aspirations (Chaudhuri 2005; Gehl Sampath 2005). By combining the skills developed under the previous IP regime with the country’s impressive scientific infrastructure and low costs, many firms in India aim to develop new drugs, independently or in collaboration with OECD-based pharmaceutical firms.

Two points should be made with reference to Indian firms’ efforts to move into new product development. First, even the largest firms are probably too small to make significant in-roads into one of the world’s most capital-intensive and oligopolistic sectors. Indian firms do not invest nearly enough in R&D, notwithstanding their lower cost structures, and they lack the skills and resources that are necessary to complete the full course of drug development, from discovery of new chemical entities to formulation to clinical trials to marketing and distribution.27 Instead, we should expect manufacturing and sales of generics to remain as a critical source of revenue for most local firms. The most likely scenario is for the leading Indian firms to increase their presence in global markets for generic medicines, including competition against large OECD-based generic firms for shares of more regulated markets (i.e., SGs).

But second, and more importantly, for the purposes of this analysis the extent to which firms succeed in new product development and/or upgrade to SGs is of little consequence, for both scenarios have the same implications for ARV production and supply. As the most sophisticated local firms upgrade to SGs (and some focus on new product development), hybrid generics, with high costs and low prices, will constitute a smaller part of their operations. Even though the new Indian Patent Act permits firms to export drugs produced under compulsory license, the incentives these firms face may discourage them. The existence of legal provisions, for example, Article 92 (A), make this possible, but, again, the key issues are not simply what actors can do but what they have the interests and capacities to do. It may not be worthwhile for Indian firms to undertake the considerable scientific, legal, and political steps necessary to acquire the capacities and rights to produce and export drugs that they will then have to supply at marginal cost. They have few incentives to do so now, but they will likely have

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27 Despite recent increases, Indian firms spend considerably less on R&D than transnational brand-name firms, whether measured in terms of absolute expenditures or as percent of sales. According to Chaudhuri (2005: 167), the top twelve Indian firms’ combined R&D expenditures amount to just nine percent of the amount spent by the tenth largest brand-name firm. See also Grace (2004, 2005) and Gehl Sampath (2005).
even fewer incentives in the future—both because the costs of doing so will be greater and they will be less vested in those sorts of operations.

To be sure, engendering diversification away from commodity and hybrid generics and toward specialized generics (and, ideally, new product development) are among the central objectives of India’s amended Patent Act. If successful, a scenario that features national firms gaining ever-larger shares of the lucrative SG market in the US and making in-roads into currently underprovided European and East Asian markets will be highly developmental: we will be witnessing indigenous firms using the skills developed under the previous IP regime to consolidate their positions in market segments with significantly higher barriers to entry and, subsequently, higher returns (Schrank 2005).

But such changes in the structure and interests of India’s pharmaceutical industry may have worrying effects on the global supply of ARVs. At a time when the world may be looking to private firms to increase their capacity to produce generic ARVs, the firms capable of doing this are likely to have diminished interest in doing so. The reason is that the firms that export ARVs to poor countries, the larger ones, are precisely those firms that will come under the most intense pressure to upgrade into speciality generics in order to survive in the new competitive environment. Even those firms most intent on diversifying exports and targeting more regulated markets (i.e., upgrading to SGs) may continue to export CGs to developing countries, as this remains an easy and reliable source of revenue with low costs and little risk (Grace 2004). But this logic is less convincing when applied to the HG segment: firms are unlikely to dedicate additional resources toward the production and exports of new ARVs, with low prices and significantly higher costs and risks. That is, as new generations of ARVs emerge, they will be patented in India—unlike the current generation of drugs. And although the Patent Act will allow Indian firms to obtain permission to reverse-engineer and produce generic versions for export under compulsory licenses, the costs that more diversified firms will face in doing so from scratch are likely to outweigh the benefits.

The behavior of India’s leading pharmaceutical firms provides evidence in support of these hypothesized changes. Along with dedicating more resources toward new product innovation, since the late 1990s India’s leading firms have focused on developing new drug delivery systems and non-infringing processes for export to regulated markets, that is, specialized generics (Chaudhuri 2005; Gehl Sampath 2005). Much of their R&D effort is directed toward reverse engineering drugs nearing the end of their patent terms, with an eye toward receiving market exclusivity as “first to file” in the US (Bhandari 2005). FDA approval for export to the US market has been obtained for roughly 150 generic drugs, and more generally, exports to regulated markets have been the fastest-growing component of Indian firms’ portfolios (Chaudhuri 2005). A detailed survey of emerging business strategies in the Indian pharmaceutical sector (Gehl Sampath 2005) shows unambiguously that the highest priority for India’s largest firms is to increase their share of generic exports to regulated markets. More than three-quarters of the firms indicated that they did not regard Article 92(A)

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28 Gehl Sampath’s findings suggest otherwise, that although many firms have supplied sub-Saharan Africa and other poor countries, “there is sufficient evidence to presume that this will not continue post-2005” (2005: 39).
29 Some firms (most notably Ranbaxy), have also adopted aggressive strategies of challenging pharmaceutical patents owned by brand-name firms.
30 See also, the comments of India’s Minister of Commerce and Industry (Express Pharma Pulse 2005) and (Singh and Chatterjee 2004).
31 Indeed, the competitive pressures that Indian firms now face and the subsequent concern with upgrading export markets coincides with immense pressures in the OECD to reduce the costs of medicines, thus making India’s high-quality yet inexpensive generic drug exports more welcome.
as a useful option.\textsuperscript{32} And of the minority that regard Article 92(A) more positively, sixty percent were small firms that lack the technical capacity and political resources necessary to take advantage of the legal opportunities in any case.

These firm-level strategies are not surprising. After all, India’s generic exports mean much more to the world than they do to Indian pharmaceutical firms. As indicated, Indian generics account for roughly fifty percent of ARVs used in developing countries, but one estimate puts that figure at roughly four to ten times the importance of these exports to the firms themselves, in terms of their total sales.\textsuperscript{33} To put it simply, Indian firms do lots of things besides produce generic ARVs for the developing world, and the asymmetry in this relationship is bound to intensify over time as the firms diversify in response to the new IP environment. ARVs already constitute a small part of the portfolio for the firms engaged in this activity, and these are the ones that are most integrated internationally and best prepared to take advantage of new opportunities—and they will be in competition against the largest and best-resourced firms in the world. In such an environment, their strategies are likely to “be dictated by survival needs and not by issues related to access to medicines of the general public, whether in India or other least developed countries” (Gehl Sampath 2005: 67, emphasis added). Translated, to have a strategy “dictated by survival needs” means they will have acute concern with price:cost ratios—they are likely to avoid sectors where prices are decreasing and costs increasing. In such an environment producing generic ARVs for export to poor countries becomes less attractive.

Nor do the interests, preferences, and intentions revealed by political lobbying indicate that producing and exporting generic ARVs is a high priority. When we examine what India’s pharmaceutical firms and their trade associations lobbied for during the course of the legislative debate on amending the Patent Act in 2005, we see a concern with securing clauses to facilitate upgrading into SGs. For example, the trade organization dominated by the largest domestic drug firms, the Indian Pharmaceutical Association (IPA), worked doggedly to assure that patent rights granted to applications in the “mailbox” would have little effect on local producers already engaged in generic production, avoid “new use” patents, limit the scope of patentability so as to favor the sorts of incremental innovations that local firms do best, and allow for pre-grant opposition on patent applications.\textsuperscript{34} In doing so, the local pharmaceutical industry had the support of domestic activists (e.g., the Affordable Medicines and Treatment Campaign, Alternative Law Forum, Indian Network for People Living with HIV/AIDS, Lawyers Collective on AIDS, and National Working Group on Patent Laws) that feared the introduction of a product patent regime would raise the cost of medicines locally. With regard to securing the right to export drugs produced under compulsory licenses, however, there is little evidence that this was a high priority for the national pharmaceutical sector. That is, in contrast to the pharmaceutical sector’s focus on revising clauses of the Patent Act that would facilitate upgrading into SGs, it was principally NGOs and health activists—and particularly international NGOs such as MSF and the Consumer Project on Technology—that led the charge for revision of Article 92(A) to retain the possibility of generic drugs

\textsuperscript{32} “The common reason was that it increased the procedural hassles associated with such exports enormously, and this was not considered worthwhile, especially since the economic returns from such exports were very low” (Gehl Sampath 2005: 65).

\textsuperscript{33} These data were provided by a market analyst researching the Indian pharmaceutical sector.

\textsuperscript{34} The “mailbox” refers to India’s obligation to accept patent applications to be examined post/2005, once product patents became available. Denying “new use” patents means that new forms of pre-existing products cannot be patented without demonstration of increased efficacy. Pre-grant opposition, as the phrase suggests, allows those objecting to a patent application to express their objections prior to legal rights being granted. See Basheer (2005).
(including, but not exclusively, ARVs) being exported to poorer developing
countries lacking pharmaceutical manufacturing capacity.\textsuperscript{35}

Again, the emerging industrial structure has political implications, in that the
new constellations of interests pose immense challenges for continuous expansion
of ARV treatment. To the extent that the global treatment campaign
depends on the supply of generic ARVs from India, it depends on Indian firms
to remain vested in the HG segment, and it depends on the Indian government
to use the new Patent act in such a way as to keep the HG segment alive. The
two are related, in that the likelihood of the government standing down the
pressures that it faces from global brand-name pharmaceutical firms and OECD
governments not to facilitate generic production is greater when a powerful
domestic constituent is demanding that it do so. Yet when new ARVs are intro-
duced in coming years, drugs that will be essential as resistance develops to cur-
rent treatments, if there are few firms that are legally, financially, and
technically capable of producing high-quality generic versions for export, then
there will be few firms that are also interested and capable of securing public
action to activate the legal provisions in India’s new patent law that would clear
the way for large-scale production of generic ARVs. National and transnational
treatment activists in India will continue to push for such action, but clearly the
coalition supporting and facilitating generic ARV production will have been sig-
ificantly weakened by the new orientation of India’s leading pharmaceutical
firms. Quite simply, the emerging industrial structure in the Indian pharmaceu-
tical sector has profound implications for the ability to continuously reproduce
the political arrangements that are necessary to sustain and expand generic
ARV supply.

\textbf{Conclusion: Overcoming the Challenges to Stabilizing Supply}

Expanding and sustaining AIDS treatment in the developing world—and sustain-
ing expanded treatment—depend on the existence of generic ARVs. While the
absence of generic competition does necessarily imply unaffordability, it removes
disciplining lever that can force brand-name firms to make their own products
more readily available. This is recognized nearly universally. When, for example,
the CEO of Abbott Laboratories was asked why his firm was reducing prices on
drugs to developing countries, he explained the pressures his firm faces:
“\textquoteleft{}Frankly, because it is required. If I don’t provide our products in Africa, gov-
ernments will license our intellectual property to others who can. Governments
will intervene. Make no mistake, they will do that.\textquoteright{}\textsuperscript{36} The important thing to
remember, however, is that the ability of most developing countries to introduce
generic competition (i.e., to “intervene” and “license” IP) depends not just on
having patent regimes that take advantage of the flexibilities in the TRIPS Agree-
ment, but their ability to secure foreign suppliers.

The emerging international regulations on IP engender changes that threaten
the supply of high quality, generic ARVs needed for AIDS treatment. I have
examined how IP institutions alter the interests of private firms, and how these
transformed interests affect political coalitions needed to facilitate expanded
ARV supply. One need not be apocalyptic to appreciate the concern and recog-
nize the danger that looms over the horizon: at a time of projected increase in
global demand for generic ARVs, supply is unlikely to keep apace. Poorer devel-

\textsuperscript{35} Because many of the concerns and objectives of the various actors overlapped, it is extraordinarily difficult to
parse the interests of IPA lobbyists from NGOs, and then again the interests of Indian vs. transnational NGOs. But
when it comes to securing the right to export generic drugs produced under compulsory licenses, there is little evi-
dence that this was a high priority for national pharmaceutical firms.

\textsuperscript{36} As quoted by London (2004).
oping countries, international organizations, and non-governmental healthcare providers may demand these drugs, but the critical sources of supply—upon which the world currently depends—may have been fundamentally transformed.

How might the pending problem of undersupply be overcome? It is worth considering two strategies for reinvigorating generic ARV production. The first, and most obvious, strategy is to reform global IP rules to facilitate continued supply of generic ARVs. That is essentially what the developing countries’ 2001 proposed interpretation of TRIPS Article 30 would have done, by removing the legal and political obstacles that pharmaceutical firms face in producing and exporting generic ARVs (see discussion above). Of course, for this very reason such proposals have been rejected by governments of countries where the research-based pharmaceutical industry is based. These firms and their governments regard generic firms in less favorable light, essentially as “free riders” on the global public good of drug innovation. Indeed, one of the central objectives of TRIPS (from the OECD perspective) was to reduce “free riding” and thus provide the research-based pharmaceutical sector with protection from generic competition (Drahos 1995; Sell 2003). Thus, however sensible this strategy may be from a public health perspective, it has been shown to have little political viability (Matthews 2004).

Alternatively, then, a second strategy might be to shift attention away from larger, export-capable countries and focus instead on pharmaceutical manufacturing in poorer countries. That is, since the least developed countries are not obligated to offer pharmaceutical patents until 2016, there should be no legal barriers to local production and export of generic ARVs—the constraints of Article 31.f and the subsequent waiver do not yet apply. Yet the challenges to creating generic pharmaceutical sectors in such countries are extensive. Putting IP laws in place that are appropriate for such purposes is more difficult than one might imagine. Many of the poorest WTO members have already fully implemented their TRIPS obligations—transition periods notwithstanding—and offer product patents on pharmaceuticals. They are not obligated to have done so, but re-vising their laws to, for example, make pharmaceuticals unpatentable would expose them to intense international pressures. Furthermore, even if such legal changes were made, the technical and economic obstacles to developing pharmaceutical sectors are immense (WHO 2004; Kaplan and Laing 2005). In India, for example, the growth of the pharmaceutical sector was driven not just by the 1970 Patent Act, which made pharmaceutical products unpatentable, but also by an active state role in sponsoring research and transferring technology, knowledge, and skills from government labs to private firms (Kumar 2003; Chaudhuri 2005: 50–60). The advanced chemistry skills that proved so effective in the emergence of India’s indigenous pharmaceutical sector developed only with the assistance of concerted government policies that are largely absent in the poor countries that have until 2016. These countries would almost certainly need beyond 2016 to develop indigenous pharmaceutical sectors. Yet it may be difficult to inspire investment knowing that after 10 years the IP regime will change. Or to put it differently, the pre-TRIPS legal environment that spurred high levels of domestic investment in India, for example, cannot be replicated because that legal environment did not have a known terminal point. In any case, focusing exclusively on productive capacity without attention to scale and cost is problematic. National self-sufficiency in ARVs is not just difficult to achieve legally and technically, but even if achieved would not provide producers with sufficient

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37 Bangladesh and Kenya are frequently cited as potential production sites.
38 Formally, the 2016 deadline is flexible and countries can receive additional extensions, but only by petition and approval—and it is a pretty certain bet that developed countries would not approve an extension in a country where the local generics sector is growing.
scale as to lower costs.\[^{39}\] Quite simply, there are strong public health grounds for having foreign suppliers available.

This brings us back to where we started. Demand for ARVs is increasing and will continue to increase as international funding for ARV treatment increases. The expectation is that supply will keep pace and high-quality, affordable versions of drugs will be available. But assuring access to medicines requires attention not just to demand but supply as well. In this article I have shown that the political economy of supply is distinct from—and more complicated than—that of demand. The challenges may not be insurmountable, but the analysis should serve as a warning bell and, it is hoped, spark more inquiry into how to create and sustain political conditions supportive of large-scale generic supply.

References


\[^{39}\] This is why the inclusion of a list of middle-income developing countries that have agreed not to import generic drugs under the December 2005 waiver of Article 31.f may be problematic as well. Ultimately, that developing national self-sufficiency in drugs is being encouraged (if only implicitly) by the WTO is ironic, to say the least.


