Chapter 4

Is AIDS treatment sustainable?

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1 Introduction

The first decade of the twenty-first century witnessed a remarkable extension of antiretroviral (ARV) treatment to people living with HIV/AIDS in the developing world. Whereas antiretroviral drugs (ARVs) reached less than five percent of people in need of treatment as of 2002, by the end of the decade nearly half of those needing treatment receive treatment. But to what extent can AIDS treatment continue to be increased? Can increased treatment be sustained?

In this chapter I present a cautionary view, focusing on fundamental changes that are transpiring in treatment regimens and the generic pharmaceutical industry. These changes could create a mismatch between the demand for and the supply of high-quality and affordable ARVs. To be sure, ongoing financial commitments for scaling-up treatment, the sense of urgency with which the international donor community has come to view the HIV/AIDS epidemic, and alleviation of some significant legal obstacles to accessing affordable medicines all provide cause for optimism. Yet what has worked so far may not continue to work; more of the same may not be enough. As the demand for treatment throughout the developing world increases and evolves, the world’s ability to respond effectively may be limited. The reason why has to do with the effects that changes in the global political economy of intellectual property (IP) are likely to have on the future availability of affordable ARVs.

The key issue regards the changing relationship between the demand and supply of particular sets of ARVs. The increase in ARV treatment has been possible because the drugs demanded for use in standard regimens throughout the developing world were also ARVs that generic producers (particularly in India) were able and willing to supply – legally and financially. As countries’ treatment regimens change, however, both as first-line protocols become updated and as patients move from first-line to second-line regimens, the coincidence of what drugs are needed and what are available may dissipate. The new global political economy of IP and subsequent transformation of the generic pharmaceutical industry are likely to complicate generic firms’ ability to adjust their supply to the changed demand—or, importantly, their interest in adjusting their supply to the changed demand.

To advance this argument I build on the extensive literature on IP, pharmaceuticals, and health by problematizing what most analyses of AIDS treatment take as a constant—the existence 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 access

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them, such as how to overcome legal, IP-related barriers and how to increase purchasing power via the development of funding and pooled-procurement mechanisms; this is about increasing effective demand. But assuring adequate production and supply of essential drugs is also indispensable for increasing and extending treatment, and the constellations of political actors and strategies that facilitate the strengthening of demand may be less effective with regard to supply.

To highlight the distinct—and more complicated—political economy of production and supply, I show how Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) 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 ongoing 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. \(^1\)

The chapter consists of four sections. In the next section I highlight the remarkable increase in AIDS treatment. I provide background on the strategy led by WHO for scaling-up treatment, and I discuss the critical and indispensable role that generic drugs play in extending and increasing treatment. In the second section I introduce the new IP environment, and I explain why in examining the relationship between patents and treatment it is imperative to focus on patents in supplier countries. To that end I show how the emergence of quasi-universal pharmaceutical patenting, where new drugs are likely to be patented in all countries with the ability to produce them, creates new and more complex challenges for the global treatment campaign. In the third section I examine these challenges in more detail by examining the incentives to generic suppliers. To do so I disaggregate the generic pharmaceutical sector, distinguishing among 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. The analysis in this section is done with an eye on India, the country that is the most important supplier of generic AIDS drugs. 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.

2 HIV/AIDS, antiretrovirals, and treatment

HIV/AIDS treatment entails combining various types of ARVs in order to slow down reproduction of the virus. ARVs do not cure HIV/AIDS, but they can prevent the virus from destroying the immune system and thus allow people who are infected to live normal lives. Indeed, the introduction of combination therapy in the 1990s converted HIV/AIDS into a

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\(^1\) In this chapter I focus explicitly on the relationship between changing patterns of demand for and supply of generic ARVs necessary to sustain AIDS treatment. In doing so I build on the analysis in Shadlen (2007).
chronic condition in much of the OECD. Notwithstanding the advances in science and the effective combating of HIV/AIDS in developed countries, however, the global extension of ARV treatment progressed slowly and as of the early 2000s HIV/AIDS remained a death sentence in most of the developing world.

The daunting challenges to extending HIV/AIDS treatment in poorer countries and settings are widely acknowledged (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 medicines 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.

Despite the very real challenges, an increasing number of people living with HIV/AIDS in the developing world have begun to receive ARV treatment since the early 2000s. Figure 1 illustrates a remarkable trajectory of treatment. The solid line (corresponding to the left-hand vertical axis) shows the sharp increase in the number of people in developing countries receiving ARV treatment, from approximately 230,000 in 2002 to more than 4 million by the end of 2008. The dashed line (corresponding to the right-hand vertical axis) charts the associated growth in coverage, i.e. the number of people receiving treatment as a share of the total number of people in need of treatment, from less than five percent to over forty-two percent by the end of 2008. The WHO measures coverage as the estimated number of people receiving ARV therapy as a share of the estimated number of people age 0–49 in need of ARV therapy. Given the wide range of uncertainty regarding the number of people in a given country that have HIV/AIDS, and the further uncertainty in estimating how many of the people with HIV/AIDS at any given time are in need of ARV therapy, the figures for coverage are extremely rough. But even with these caveats and the uncertainties regarding the specific figures, the rate of increase is unmistakable.

These dramatic increases in both treatment and coverage are the result of many factors, including a coherent international strategy spearheaded by the World Health Organization (WHO), increased international financing, greater prioritization of HIV/AIDS policies within developing countries (including investments in treatment infrastructure), and the relatively simple and ample availability of affordable versions of the ARVs in demand (Waning, Kyle, Diedrichsen, Soucy, Hochstadt, Barnighausen, and Moon 2010; Kapstein and Busby 2009; Peiffer and Boussalis 2010). This final factor is the key point of the chapter, for it was the match between the profile of drugs available from multiple suppliers and the profile of ARVs demanded for initiation and expansion of AIDS treatment that facilitated the trajectory illustrated in Figure 1—and it is concern about the development of a mismatch between supply and demand that is the source of the concern about the future of ARV treatment.

Before turning to analysis of the relationship between the ARVs in supply and those in demand, it is worth making a few observations about AIDS treatment in the developing world and the interaction between drug prices and national practices. The WHO strategy for scaling up ARV treatment in the developing world is a protocol-driven public health approach based on a formulary of recommended drugs, rather than individual treatment regimens. With testing and diagnostic technologies less available, and with severely constrained budgets for procuring medicines, the WHO strategy essentially strips treatment to the bare bones, providing a simple target for treatment eligibility and reliance on a reduced

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2 Indeed, the denominator in the coverage ratio is an estimate made on the basis of a prior estimate.
set of drug combinations. The idea is that a protocol-driven approach, whereby people whose CD4 count falls to a certain level are considered for receiving treatment that is drawn from a formulary of a small number of drugs, is simpler to implement (administratively, financially, and medically) and thus more appropriate for resource-poor settings.

Specifically, the 2003 protocol called for treatment to begin when patients began showing advanced clinical disease symptoms and/or their CD4 count fell below 200 cells per cubic millimetre of blood. The recommended first-line treatment regimen consisted of combining two nucleoside reverse transcriptase inhibitors (NRTIs) with one non-nucleoside reverse transcriptase inhibitor (NNRTI). The five-drug formulary consisted of three NRTIs (lamivudine [3TC], zidovudine [AZT], and stavudine [d4T]) and two NNRTIs (efavirenz [EFZ] and nevirapine [NVP]). In 2009 the WHO announced two significant revisions to the standard protocol. First, the WHO called for treatment to begin earlier, at CD4 counts below 350 (rather than 200), and indicating that treatment should then commence regardless of symptoms. Second, the WHO promoted tenofovir (TDF) as a recommended first-line NRTI in place of the highly toxic d4T. Throughout this period, where first-line regimens are not having the intended effect of slowing down reproduction of the virus, the WHO has continued to emphasize the importance of moving patients to second-line treatment based on two NRTIs and a boosted protease inhibitor (PI). Later in this chapter I will discuss the implications of these changes for the sustainability of treatment in the developing world, but for now it is worth simply making the obvious observation that by altering the threshold for eligibility the WHO significantly increased the number of people classified as ‘in need of treatment.’

Though increasing and sustaining AIDS treatment depends on many factors, of course, the availability of the essential ARVs is absolutely indispensable. The cornerstone to

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3 The two NRTIs used perform different functions, as they are different types of analogues. The WHO’s recommendations were to combine 3TC (the ‘pivotal’ thiacytadine analogue) with either AZT or d4T, plus either EFZ or NVP. This yields the following four combinations: d4T/3TC/NVP, ZDV/3TC/NVP, d4T/3TC/EFV, ZDV/3TC/EFV. Other advanced NRTIs and NNRTIs along with later generation ARVs such as protease inhibitors, entry inhibitors, and integrase inhibitors are either reserved for second-line treatment or, in the most part, omitted from the WHO’s recommendations.

4These were not the first changes; a set of revisions were published in 2006 as well.

5By way of comparison, note that in the US and EU guidelines recommend treatment to begin at CD4 counts of 500. At the risk of stating the obvious, then, it is worth emphasizing that in developing countries, the point at which ARV treatment begins and the array and combination of drugs used in treatment (not to mention the availability of drugs for treating opportunistic infections) are substantially different than in wealthy countries.

6According to the WHO (2009, p. 2), this change was made on account of d4T’s ‘long term, cumulative, and non-reversible toxicities.’

7According to WHO (2007), as of 2006 roughly 98% of the adults receiving ARV treatment were on first-line regimens, with the tiny fraction receiving second-line therapy concentrated in Brazil. An increasing number of people in Thailand must be receiving second-line treatment as well, given that Thailand is importing the key boosted PI (lop/r).

8The WHO estimates that the new treatment guidelines increase the number of people classified as ‘in need of treatment’ by three to five million (Jack 2009).
an effective treatment program is that affordable medicines be available. Drugs are the key input 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 creativity can substitute 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 of the challenges to treatment indicates; even if drugs were free many countries may lack the infrastructure to extend treatment. Yet the key point regards the interaction between prices and infrastructure: for public health ministries operating with scarce resources, the incentives to invest in the development of the healthcare infrastructure that is essential for AIDS treatment is logically related to the price of drugs. Low prices can encourage resource mobilization, while high prices can discourage such mobilization; why bother investing in infrastructure that will go unused on account of the essential drugs being too expensive? In short, because the availability of affordable drugs can make improving healthcare infrastructure a more useful investment, lower drug prices cannot just free resources but also create incentives to invest in necessary infrastructure (Schwartländer, Stover, Walker, Bollinger, Gutierrez, McGreevey, Opuni, Forsythe, Kumaranayake, Watts, and Bertozzi, 2001; Berwick, 2002, pp. 214; Nattrass and Geffen, 2005).

A critical factor in lowering drug prices has been the existence of a vibrant market for high-quality ‘generic’ ARVs. 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. Indeed, the introduction and extension on the part of brand-name firms of tiered-pricing for ARVs has largely followed competition induced by generic suppliers (Waning, Kaplan, Fox, Boyd-Boffa, King, Lawrence, Soucy, Mahajan, Leufkens, and Gokhale 2010; Lucchini, Cisse, Duran, de Cenival, Comiti, Gaudry, and Moatti, 2003; Kovsted, 2005; MSF various years; Wainberg, 2005). Absent generic competition, the supply of ARVs at affordable prices is overly reliant on the benevolence of the brand-name industry (Shadlen, 2004b).

In considering the role of generic suppliers, it is crucial to emphasize the dynamic and temporal dimensions. Because treatment must not be terminated the need for drugs to be available is never-ending; but while the demand for drugs, in general, is constant, the demand for specific sets of drugs is not. Patients develop immunity to particular medications, resistant strands of the virus emerge, and treatment regimens need adjustment. The drugs that work today will be ineffective tomorrow; affordable and high-quality versions of new ARVs must be available as well. This means that the political, economic, and legal conditions that facilitate the availability of today’s drugs must be continuously reproduced. The remainder of the chapter examines the challenges to the durability of generic competition, and thus the stability of supply of affordable ARVs.

3 TRIPs, quasi-universal pharmaceutical patenting and generic ARVS

The existence of such an interactive effect rests on the fact that many expenditures for ARV treatment are HIV/AIDS specific. After all, if the investments are for healthcare provision more generally, then governments might find these worth making regardless of the availability of ARVs per se. But most of the investments are ARV treatment-specific, i.e. the creation of separate and parallel supply chains, storage facilities, and delivery systems.
The TRIPs Agreement sets new and universal standards to which IP regimes in all countries that are members of the WTO must conform. Prior to the introduction of TRIPs many countries did not issue patents on pharmaceutical products, meaning that multiple suppliers could and often did exist for many drugs. That situation changes with TRIPS, which requires countries to grant patents in all technological fields (Article 27). As regards the ongoing extension of AIDS treatment, the essential issue is the effect of TRIPs and pharmaceutical patents on the suppliers of ARVs.

It is worthwhile 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. Third, even where countries begin to grant patents to pharmaceuticals, products that were already on the market prior to a country changing its patent laws typically cannot be patented (i.e., only new drugs are patentable). Fourth, notwithstanding the formal availability of patents, originator firms often choose not to patent each of their drugs in all countries, especially smaller markets. 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 about the relationship between patents and access to ARVs 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 pharmaceutical ingredients (APIs) are generally imported (this is so for the most part even in big developing countries, such as Brazil, and in many developed countries too). From a treatment perspective, for example, the fact that ARV patenting is low in Malawi and Zambia is irrelevant, since neither country has the capacity to produce ARVs. Instead, they—like everyone else—are likely to depend on Indian (or Chinese) production.

Thus, 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, i.e., the potential suppliers. 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. I call this situation ‘quasi-universal pharmaceutical patenting’.

10Note that many developing countries with large and potentially 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.

11Because 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.

12This 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, Médecins Sans Frontières, Selgelid, Schuklenk, Attaran and Gillespie-White (2002) and also Grace (2005, pp. 18–9).
The most important supplier country for the sake of this analysis is India. With the most technologically sophisticated pharmaceutical sector in the developing world, 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 significant production capabilities not to offer drug patents. The high level of scientific and technological capabilities combined with the absence of pharmaceutical patents allowed India’s pharmaceutical sector to emerge as the principal supplier of generic drugs to the developing world: it is estimated that more than half of those receiving AIDS treatment in the developing world are treated with generic ARVs produced in India. Indeed, the Indian pharmaceutical sector’s 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.

Extending ARV treatment in a world where all new drugs can—and almost certainly will—be patented in all countries with advanced production capabilities is the key challenge facing the ARV treatment campaign. That is not the same challenge that the treatment campaign has had to face thus far, as the success to this point (illustrated in Figure 1) has occurred in a world where the most important ARVs are not patented in many supplier countries. In fact, all of the drugs on the WHO’s list of recommended ARVs for first-line or second-line treatment are available from generic producers in India.

That ARVs have been available from India does not by any stretch of the imagination mean that securing access and expanding ARV treatment has been a simple task. The global treatment campaign has had to confront and overcome key obstacles. One obstacle regards the ability of importing countries to use compulsory licenses (CLs) and other policy tools in their national patent regimes to facilitate access to medicines. This has been, and remains, a matter of considerable conflict. While countries have ample rights under TRIPs to issue CLs, for example, a degree of uncertainty regarding these measures and considerable external pressures for countries to exceed their TRIPs obligations appear to have inhibited many developing countries from taking the necessary steps to improve access. In this regard the Doha Declaration on the TRIPs Agreement and Public Health of November 2001 (Doha Declaration), the outcome of a protracted campaign by developing countries and treatment activists, stands out as a landmark political event. Although the Doha Declaration does not reform TRIPs, by clarifying and clearly re-affirming countries’ rights under TRIPs, it constitutes an important step in providing the political space for more countries to design and use their patent systems to secure stable access to affordable ARVs (Shadlen, 2004a). Of course, even when legal and political barriers are relaxed, drugs are still too expensive to make treatment feasible in many countries. Thus, a second obstacle has regarded funding and procurement. To that end, the global treatment campaign has relied on the creation of new mechanisms to increase importing countries’ purchasing power through pooling procurement, jointly negotiating prices through bulk purchases, and of course the release of unprecedented amounts of money for AIDS treatment.

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13 The estimate in the text was provided to me by an official from the WHO. *Medecins Sans Frontieres*, which refers to India as the “Pharmacy for the Developing World,” provides even higher figures, reporting that roughly 80 percent of the ARVs it uses in treatment locations are from India (MSF 2007). Recent analysis of nearly 13,000 donor-funded, adult first-line ARV purchases also confirms the major role of Indian suppliers (Waning, Kyle, Diedrichsen, Soucy, Hochstadt, Barnighausen, and Moon 2010).

14 I discuss Tenofovir (TDF) below, in the conclusion.
But what happens to the global treatment campaign if – when -- the ARVs are patented in India (and other export-capable countries)? That is the key question. After all, as explained above, and pending a major (and unlikely) revision of TRIPs, the world is moving toward a situation of quasi-universal pharmaceutical patenting, where all new ARVs will be patented in all countries with the ability to produce them. To understand the challenges posed by quasi-universal pharmaceutical patenting, it is essential to keep in mind the obvious point that importing a good presupposes some other actor exporting that good. But TRIPs requires that goods produced in one country under a CL be ‘predominantly’ for domestic use (Article 31.f). To the extent that new ARVs become patented in India and other export-capable countries, this requirement could hamper provision of generic versions of such drugs to developing countries. Most developing countries lack the capacity to produce drugs locally, which makes threats to issue CLs for local production empty threats—and so too are threats to issue CLs for import if potential exporters in more industrialized developing and developed countries are hamstrung by TRIPs.

Thus, the claim is not that patents in importing countries do not continue to present barriers to access, that the problems on the importing side were resolved by Doha. Patents in importing countries clearly can, have, and do present barriers, and overcoming these barriers continues to be a source of intense political conflict (witness the cases of Brazil and Thailand, to name but two countries in the spotlight). Yet patents in exporting countries pose even greater and even more significant problems, for if patents in exporting countries curtail the supply of drugs then whatever steps are taken to overcome the obstacles posed by patents in the importing countries are inconsequential. Again, importation requires and presupposes exportation.

Addressing the issue of how the supply of generic ARVs may be affected by the restrictions that TRIPs places on producers in exporting countries has proved to be extremely difficult. In October 2001, on the eve of the Doha Ministerial meeting, developing countries proposed a reading of TRIPs that would have simplified the export of generic drugs to poor countries.\footnote{See paragraph 9 of developing country proposal to TRIPs Council, WTO, IP/C/W/312, WT/GC/W/450, October 4, 2001.} 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 permission from the state or the owner of the exclusive rights (i.e. automatic exceptions to patent-holders’ rights). The developing countries sought to make a foreign public health emergency (such as an HIV/AIDS epidemic) one such condition. According to their proposal, firms in countries where a given drug is patented would be able to produce generic versions of the drug to supply countries that are experiencing public health crises but unable to produce the drug locally. 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 Zambia, even if these firms were not the patent holders in Canada or India—and they would be able to do so without requesting permission from the patent-holder or 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).

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 sufficient local manufacturing capabilities 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 temporary resolution was finally agreed. The settlement, which constitutes a partial waiver to Article
31(f), includes increased regulations for issuing CLs for export to poor countries (and extensive safeguards against 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, 2003a, 2003b), also included a list of developing and developed countries that pledged not to use the system as importers.\textsuperscript{16}

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, and numerous other countries with advanced pharmaceutical sectors have followed. In India, the final version of the amended Patent Act, passed in March 2005, also permits CLs for export in conformity with the TRIPs waiver.

Are these changes (international and national) sufficient? It is too early to tell, for most countries have been able to continue importing the ARVs they need without recourse to these rules. After all, the ARVs in demand continue to be those that are not patented in India and thus available from Indian suppliers.\textsuperscript{17} Yet while the world of quasi-universal pharmaceutical patenting is not here yet, the fact that it lies just over the horizon means that the adequacy of the existing arrangements for CL-for-export is of paramount importance for the sustainability of AIDS treatment.

To summarize, the global treatment campaign has depended, and continues to depend, on the supply of generic ARVs. When the ARVs in demand are unpatented in key supplier countries, such as India, improving access is a matter of addressing two sets of challenges: (1) assuring that patents do not create obstacles to importation in the country where the drugs will be used; and (2) negotiating prices with the generic suppliers and obtaining the resources to purchase the drugs at affordable prices. The international community has directed most of its efforts toward addressing these two challenges since the early 2000s, and tremendous advances have been made on account of the Doha Declaration and actors such as the WHO, UNAIDS, UNITAID, the Global Fund against Aids, Tuberculosis, and Malaria, the World Bank, the Clinton Foundation, the Gates Foundation, and the United States’ Presidents’ Emergency Plan for AIDS Relief (PEPFAR). However, when the ARVs are patented in supplier countries, e.g. India, expanding treatment in developing countries (low-income and middle-income)\textsuperscript{18} requires addressing a third—and arguably more difficult—set of challenges.

\textsuperscript{16}Both the agreement and the supplementary statement were proposed as a permanent amendment to TRIPs in December 2005, though the formal process of enough WTO members ratifying this amendment to make the change permanent remains incomplete as of April 2010.

\textsuperscript{17}In 2008 a Canadian firm (Apotex) exported a standard first-line combination based on ARVs that are patented in Canada to Rwanda (Elliott 2008). To date this is the only instance of the CL-for-export rule being used. The fact that the 2003/05 waiver to Article 31.f has only been invoked once does not mean much in and of itself. After all, as noted, most ARVs in demand in developing countries are still unpatented in India, so there is little need to use the waiver. In fact, why it was invoked even this one time is unclear. Multiple Indian firms produce the drugs that Apotex exported to Rwanda, so why Rwanda turned to a Canadian firm that had to jump through extensive hoops imposed by TRIPs and the Canadian legislation rather than simply import from India is an unanswered question that has produced a great deal of global head-scratching. I suspect that the answer is that this motivated in part by an effort to demonstrate the complexity (and thus user-unfriendliness) of the Canadian legislation, but this remains a conjecture.

\textsuperscript{18}The Doha Declaration (and much of the writing on this topic), makes a distinction between the challenges facing developing countries with sufficient local manufacturing
presented by such patents in exporting countries. The following section examines these challenges in more detail, focusing not just on the law but also the politics of supply.

4 Incentives, interests and capacities in the generic pharmaceutical sector

To understand the challenges to extending ARV treatment in an emerging world of quasi-universal pharmaceutical patenting, it is essential to shift our analytic attention from law to politics. After all, 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. Do the actors that might seek to elicit necessary measures by public officials have the interests and capacities to do so?

The central contention advanced in this section is that the global treatment campaign is threatened by a mismatch 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 for export. 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 generic pharmaceutical exports according to three segments: commodity generics, specialty generics, and hybrid generics.19 Commodity generics (CGs) are drugs whose patents have expired (or perhaps never existed) in both exporting and importing countries. Ibuprofen is a version of a CG: the molecule is in the public domain, and any pharmaceutical firm in any country can produce ibuprofen (marketing and sales, however, depend on approval from national health authorities). Thousands of generic firms in the world produce CGs, and low barriers to entry make this an intensely competitive segment of the market. 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 United States and the European Union have recently expired or are about to expire, the most lucrative end of the generic market. In the United States, for 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

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19 This typology is drawn from Shadlen (2007), but the reader will notice that my definition of the categories and the application of these categories to ARV markets is different in the present text.
competes only against the brand-name product. Hybrid generics (HGs) refer to drugs that are under patent in at least one country involved in trade (either importer or exporter), and thus made available through use of legally-derived limits or exceptions to patent rights. Drugs that are under patent in countries with greater manufacturing capacities but produced under CL-for-export fit this HG description.

Table 1 presents a basic overview of the variable price:cost ratios facing producers in the three 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—i.e., 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 segment of the industry.

As regards HGs, and with specific reference to ARVs produced under CL-for-export mechanisms, these are likely to have the least favourable price:cost ratios. Prices will be low, for they will be sold for the most part in poorer countries with minimal purchasing power. Theoretically this need not be the case, but the fact that a number of middle-income developing and transition economies that do have greater purchasing power pledged not to import generic drugs under the TRIPS waiver to Art. 31.f. greatly increases the probability that HGs of this sort will go to poor countries at exceptionally low prices. The costs of HGs can vary, depending on the age and complexity of the drug in question, but generally the costs of learning to produce and market generic versions of new, still-patented drugs are relatively high. Obviously, the costs involved in the production 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 learning how to replicate newer drugs is more difficult and expensive than replicating older drugs. Firms need to dedicate resources toward researching the compound and learning how to produce particular pharmaceutical formulations that are useful and satisfy demand. Furthermore, firms engaging in the production of HGs face transaction costs that derive from the political and legal environment, such as the necessity of making sure the drugs they seek to produce conform with national legislation on CL-for-export, requesting CLs from the government, and, potentially, defending themselves against complaints of patent infringement.

--- Table 1 ---

The generic ARVs currently used in HIV/AIDS treatment throughout the developing world can be regarded as CGs, as they are not protected by patents in India, the most

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20Specialty generics are also referred to as ‘value-added generics.’ Many analysts use the SG label to refer exclusively to new 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.
important producer-exporting country. Indian firms, thus, face no legal, patent-related
barriers to supplying these drugs to countries where they are not patented, and as discussed,
mobilizing this source of supply has been a key to expanding treatment. Because of the tight
margins involved, a crucial instrument for mobilizing supply has been the aggregation of
demand through coordinated, bulk purchasing processes, largely facilitated by the Clinton
Foundation and UNITAID (Waning, Kyle, Diedrichsen, Soucy, Hochstadt, Barnighausen,
and Moon 2010). Yet the onset of quasi-universal pharmaceutical patenting changes this:
newer ARVs are and will continue to be HGs, as they are patentable in India. The higher
costs of HGs of this sort is worth underscoring: the costs of learning how to reverse-engineer
and replicate new molecules and drugs that are not yet in the public domain have not yet been
borne, and ARVs for export often must meet the higher standards of good manufacturing
practices that are conditions for participating in most international donor-funded access
programs.

The takeaway from this simple analysis is that the future expansion and maintenance
of the treatment campaign becomes increasingly dependent on HGs. What this means for
production and supply is worrying, for the actors that are being counted on to supply these
essential drugs that have low prices but high costs are for-profit enterprises operating under
increasingly competitive conditions. But because firms that are capable 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.

A cursory examination of the case of India appears to bear out these concerns. The
leading suppliers of ARVs are the more sophisticated and capable firms (Gehl Sampath,
2005; Grace, 2005). In fact, the bulk purchasing that has contributed so critically to the initial
expansion of treatment has also had the effect of greatly concentrating supply among a
consolidated set of firms (Waning, Kyle, Diedrichsen, Soucy, Hochstadt, Barnighausen,
and Moon 2010). Yet in the context of TRIPS the prevailing strategy among India’s leading firms
has been to upgrade into SGs: they are developing new drug delivery systems and non-
infringing processes for export to regulated markets (Chaudhuri, 2005; Gehl Sampath, 2005).
Much of these firms’ 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 United States (Bhandari, 2005). Not only have exports to regulated markets been the
fastest-growing component of Indian firms’ portfolios (Chaudhuri, 2005), but the
government’s Pharmaceutical Export Promotion Council reports that since 1998 Indian firms
have filed more applications with the FDA than firms from any other country. A detailed

\[21\] That is, provided they do not face difficulties in transhipment in European ports.

\[22\] See also the comments of India’s Minister of Commerce and Industry (Express Pharma
Pulse, 2005) and (Singh and Chatterjee, 2004).

\[23\] 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.

\[24\] The data refer to drug master files (DMFs), the documents that producers must submit to
register APIs and bulk drugs with US regulators. With 29.25% of the DMFs from 1998
through September 2009, Indian firms accounted for nearly twice as many as US firms,
which submitted 15.6% of the total DMFs (Unnikrishnan, 2010).
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 India’s CL-for-export provisions (Article 92A) as useful option. And of the minority that regard Article 92A 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 reported, 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. A recent study of the Indian pharmaceutical sector’s exports to Africa (Chaudhuri, Mackintosh, and Mujinja, 2010) reports similar figures: ‘Among the major Indian companies which dominate both the domestic and the export market, Africa is a substantial foreign market only for Cipla.’ The article then goes on to note that in 2006 58% of Ranbaxy’s sales went to the United States and Europe with only 6.9% to Africa, and that ‘for other major Indian companies such as Dr Reddy’s, Wockhardt, Kupin, Glenmark, and Torrent, Africa is in the residual category.’

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 in more regulated SG markets. Moreover, they are now competing for market shares in an intensely competitive global environment, against some of the largest and best-resourced firms in the world. In such an environment, the strategies of the very same firms the world is counting on to export generic ARVs (the firms that MSF has referred to as the “Pharmacy of the Developing World”) 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, p. 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. Again, the fact aggregating demand, which was critical for lowering prices, has also consolidated supply, makes the situation that much more alarming since the set of firms the world is depending on is quite small.

The analysis becomes yet more worrying when we move from market structure to politics. 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

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25 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, p. 65).

26 These data were provided by a market analyst researching the Indian pharmaceutical sector.

27 This point, that an an international public policy measure to achieve one goal can affect market structure in such a way as to make subsequent policy measures to achieve other goals more difficult is a key point made by Waning, Kyle, Diedrichsen, Soucy, Hochstadt, Barnighausen, and Moon 2010).
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 faraway 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 CLs 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. Quite simply, poor people with HIV/AIDS in sub-Saharan Africa are not powerful or important constituents in India. Instead, they are 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; Siplon and Smith, 2006; Kapstein and Busby, 2009), 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 will now also need to get 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.

5 Conclusion

A key factor facilitating the expansion of treatment in the developing world has been that the main drugs in the WHO-recommended formulary are CGs that are easily provided by a number of large pharmaceutical firms in India. As the WHO’s recommended protocol becomes updated and as patients move from first line to second (and third, and nth) line treatments, however, the drugs that will be demanded will increasingly be HGs – patented in India and available only through rather complex CL-for-export schemes. Not only do HGs present producers with less favourable incentives in terms of price:cost rations, but this change in demand is occurring at the same time as the principal suppliers who have fuelled the global treatment campaign are directing their efforts toward SGs.

Unless this mismatch is addressed, it is difficult to see how the current measures for increasing and extending treatment, measures which have focused on increasing importing countries’ abilities to demand drugs by relaxing patent-derived barriers in importing countries
and by aggregating demand and financing demand, can continue to achieve the desired results.

The emerging international regulations on IP engender changes that threaten the supply of high-quality, generic ARVs needed for AIDS treatment. Let’s remember that the ARV treatment campaign depends on the decisions made by private firms. We have to ask, then, to what extent we should expect private, for-profit enterprises to find it rational to include ARV provision in their business models. To that end 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 recognize the danger that looms over the horizon: at a time of projected increase in global demand for generic ARVs, supply may struggle to keep pace. Poorer developing countries, international organizations, and non-governmental healthcare providers may demand these drugs, but the critical sources of supply—and upon which the world currently depends—may have been fundamentally transformed.

To fully appreciate the emerging mismatch between demand and supply, it is necessary to return briefly to the WHO’s revised treatment guidelines. As indicated, the WHO recommends first-line treatment consisting of two NRTIs (3TC and either AZT or TDF) and one NNRTI (EFZ or NVP). To repeat, the inclusion of TDF is new, part of the 2009 revisions to the WHO guidelines. Until recently TDF had minimal suppliers other than Gilead, which held patents on a number of polymorph versions of the molecule. While the Indian patent application was being examined, Gilead licensed TDF to a number of local firms under restrictive terms that prohibited firms from selling TDF outside of low-income countries in Gilead’s “global access program.” Only one firm, Cipla, was producing TDF unrestrained by Gilead’s license. This arrangement made TDF too expensive to include in the WHO’s formulary, despite the drug’s therapeutic benefits. In 2008, however, Gilead’s patent was overturned in the United States, and the application was later rejected in India (it was also invalidated in Brazil). These events change the status of TDF from a drug controlled by one supplier (plus one renegade—and ultimately vindicated—Indian firm) to a drug that is open to generic competition, which in turn will lower the price of TDF. Thus, the potential crunch created by a new WHO recommendation leading to increased demand for a scarce drug with a single supplier was averted by legal decisions: d4T was replaced by TDF just as legal rulings transformed the latter from an HG (high legal barriers to exporting) to a CG (no CL or other legal hoops need to export). But this timing is not coincidence: the WHO did not recommend TDF previously because of price, and the eventual revisions to include TDF in the recommended first-line formulary followed these developments.

Yet legal events (in this case favourable to extending treatment) only push the crunch into the future. Just as d4T has been phased out and replaced by TDF, TDF or AZT or 3TC will eventually need to be phased out and replaced by other NRTIs (and EFZ and NVP will be replaced by other NNRTIs), and there is no reason to expect the cycle by which the treatment regime is altered to coincide with the cycle by which HGs become CGs. Some drugs needed for treatment will be patented. Will it be worth firms’ efforts to expend

28 At the same time Cipla was collaborating with Indian NGOs to oppose Gilead’s patent application. See Amin, Rajkumar, Radhakrishnan, and Kesselheim (2009).

29 Nevertheless, the WHO’s revision was reported as a windfall for Gilead (Jack, 2009). For more discussion of TDF, including both conflicts over the patent and the relationship with the WHO recommendations, see Amin, Rajkumar, Radhakrishnan, and Kesselheim (2009).
considerable resources to learn how to reverse engineer them and meet the legal requirements for CL-for-export in order to sell them at low cost? 30

The bottom line is that first-line regimens for people just beginning treatment need to be continually updated, as resistant strands of the virus emerge. There is no reason to expect the combinations of ARVs that will be used for those starting treatment in 2015 or 2020 to be the same as those that are used for those starting treatment in 2010. The reasons are not just because there may be better drugs available, but because the drugs that serve as effective first-line treatments now will no longer be effective down the line. Likewise, patients receiving treatment need to move from first-line to second-line and third-line treatments and so on, and these regimens need to be updated too. When these updates are necessary and what drugs are included in the revised treatment regimens are questions of science. Yet whereas cycles of drug demand are driven by science, cycles of what drugs are patented or not patented in key exporting countries (i.e. what drugs are SGs or CGs) are driven by entirely different factors, including patent filing strategies, opposition strategies, and legal decisions. There is no reason to expect these two types of cycles to match, as they so fortuitously have since the early 2000s.

How might the pending problem of undersupply be overcome? One strategy might be to shift attention away from larger, export-capable countries and focus instead on pharmaceutical manufacturing in poorer countries themselves. 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. 31 Any generic produced in these countries would be a CG. Yet the challenges to creating sufficient generic pharmaceutical production capabilities 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 obliged to have done so, but re-revising 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; Chaudhuri et al 2010). 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, pp. 30–60). 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 ten 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. Any firm responding to the incentives to scale up generic production in an LDC would do so knowing that the end point of this strategy’s feasibility is just around the corner.

30 According to the Financial Times (Jack 2009), Cipla’s CEO Yusuf Hamied ‘said his concern was still more recent and expensive third and fourth generation medicines, which are subject in India to tougher patent restrictions. ‘Even if I received permission for those today, it would take three to five years to bring them to market,’ he said’.

31 Bangladesh, Kenya, and Tanzania are frequently cited as potential production sites.
A more sensible 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 accomplished, by removing the legal and political obstacles that pharmaceutical firms in producing and exporting generic ARVs (see discussion above). This too would make all ARVs for consumption in the developing world CGs, but it would do so in a way that firms with already-existing capabilities could participate as exporters. Of course, this proposal had little political viability in the past, so it may be logical to expect it to have no traction now either (Matthews, 2004; Shadlen, 2007). Yet this remains sensible from a public health perspective and perhaps it may be more politically feasible now, with TRIPs fully implemented in production-capable countries, than it was when first visited in the context of TRIPs implementation still being ongoing.

An alternative solution, however, one that does not require anything so magical as rapidly creating pharmaceutical capabilities in poor countries or obtaining agreement on a fundamental revision to TRIPs, is for India to embark on a universal treatment program. Were India to do so, even if new ARVs were patented in India the government could grant CLs to local producers under the term of TRIPs and the Doha Declaration. Local firms would have ample incentive to produce the drugs, because of the size of local demand (India has roughly 5 million people who are HIV positive). And the firms producing the drugs would be largely free to export: so long as the drugs produced in India were ‘predominantly’ for local market, as they would be, then the residual can be exported without any legal obstacles imposed by TRIPS Art. 31.f or any need to invoke CL-for-export mechanisms. The virtues of this scenario are not just that universal treatment in India would make substantial contributions to WHO treatment targets, but that it would mobilize generic ARV production in the most important ARV provider and thus allow the supply of ARVs to respond flexibly to changing demand.
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Figure 1:
AIDS Treatment in the Developing World

Table 1:
Disaggregating the Generic Drug Sector

<table>
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<th>Principal Export Markets</th>
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<td>Low</td>
<td>Low</td>
<td>Developing and Least Developed ('less regulated')</td>
</tr>
<tr>
<td>Specialty Generics (SGs)</td>
<td>High</td>
<td>High</td>
<td>Developed ('regulated')</td>
</tr>
<tr>
<td>Hybrid Generics (HGs)</td>
<td>Low</td>
<td>High</td>
<td>Developing and Least Developed ('less regulated')</td>
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Source: Author’s elaboration