

# **Business Strategy and Access to Medicines in Developing Countries**

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*The availability of generic ARVs was important for the expansion of treatment in developing countries. This paper argues that it is therefore imperative to examine which factors have shaped generics companies' decisions to supply these drugs. This will help us better understand the development of the global AIDS response in the past and how to address some of its future challenges. This paper illustrates the value of combining the investigation of political and economic dynamics with a focus on how they affect the commercial considerations of companies that supply products required by society. In doing so it contributes to the existing literature on business in global governance, which tends to focus on how business affects states' decision-making but neglects how global governance influences companies' decisions to produce some goods and not others.*

## **INTRODUCTION**

A major challenge for the global community in the fight against HIV is how to fund treatment for millions of people living with HIV also living in poverty. At the end of 2009, only about 36 percent of people living with HIV in low- and middle-income countries received anti-retroviral therapy (ART).<sup>1</sup> Given that people living with HIV require lifelong treatment and annual new infection rates have varied between 2 and 3.5 million per year since 1990, the magnitude of the problem is evident.<sup>2</sup> Against these daunting figures, however, stand more encouraging ones, namely that approximately 5.25 million people living with HIV in developing countries have gained access to antiretroviral drugs (ARVs) in the past decade.<sup>2</sup> This represents a more than 20-fold increase since 2001, when only about 240,000 people living with HIV in developing countries were receiving treatment.<sup>3</sup> While the task ahead remains enormous, experience shows that expanding treatment on a large scale is possible.

In order to explain the progress achieved in the global AIDS response during the past decade, many authors have emphasised the increased political momentum, especially on the part of governments and international organizations, as manifest in the 2001 UN General Assembly Special Session on HIV/AIDS and the 2006 UN General Assembly High Level Meeting on AIDS; the creation of new intergovernmental organizations, including the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the Global Fund to Fight AIDS, Tuberculosis and Malaria; and programmes within existing intergovernmental organizations, including the World Bank, the United Nations Children's Fund (UNICEF) and the United Nations Population Fund (UNPFA), as well as programmes launched by individual governments, such as the US President's Emergency Plan for AIDS Relief (PEPFAR).<sup>4</sup> Also the governments of some developing countries have forcefully responded to the pandemic, notably Thailand and Brazil.<sup>5</sup> By the end of the decade, eight developing countries had achieved universal access to ART.<sup>6</sup> Some authors have also pointed at the critical role played by people living with HIV as well as civil society organizations in national and global efforts to fight HIV.<sup>7</sup>

In addition, many studies mention the importance of low-cost generic ARVs becoming widely available in 2001 as a key factor enabling progress in the global AIDS response.<sup>8</sup> Stephen Lewis, former UN Special Envoy for AIDS in Africa, stated that “we wouldn’t have this extraordinary run of treatment in Africa now if it weren’t for the generic drugs.”<sup>9</sup> The availability of low-cost generic ARVs contributed to the progress of the global AIDS response both directly and indirectly. Generics contributed directly because they led to a drop in drug prices, which increased the affordability of treatment for poor people living with HIV. Initially, prices fell from approximately USD 12,000 to USD 350 per person per year.<sup>10</sup> In 2009, the weighted median price of the six most widely used first-line regimens was USD 137 per person per year in low-income countries.<sup>11</sup> A study on ARV supply in developing countries found that generics companies from India alone provided more than 80 percent of the donor-funded market.<sup>12</sup> Indirectly, the availability of low-cost generic ARVs increased access to treatment because it fuelled the political momentum that was emerging at the time. The drop in drug prices enabled governments and donors to subsidize treatment on a much larger scale than before. As the then US President Bush explained at the launch of the PEPFAR in 2003: “the cost of [ARV] drugs has dropped from USD 12,000 a year to under USD 300 a year, which places a tremendous possibility within our grasp.”<sup>13</sup>

Despite the recognition that low-cost generic ARVs contributed greatly to the progress achieved in the fight against HIV, we know very little about why they became widely available in 2001 – more than 15 years after the first ARV had come on the market and almost a decade after generic ARVs had first been produced.<sup>14</sup> This question is relevant because it may increase our understanding of the dynamics that led to the expansion of treatment in the last decade. Moreover, it may help us address some of the challenges lying ahead in the quest to provide treatment to the more than 60 percent of people living with HIV in developing countries who still do not have access to ART.

Today, the global AIDS response faces some similar problems as ten years ago. First, there is a growing gap between treatment costs and governments’ commitment to provide funding for ART in developing countries.<sup>15</sup> Second, the global AIDS response may face the problem of securing the supply of generics. Current suppliers of generic ARVs are shifting their business strategy to cater for the more lucrative markets of high-income countries, notably in North America and Europe. They may therefore lose interest in supplying pharmaceuticals to the low-price, low-profit markets of developing countries.<sup>16</sup>

The paper argues that a better understanding of why generic ARVs became widely available in 2001 can yield insights into how to expand access to treatment today and deal with the dual challenge of rising prices and potentially narrowing supply. The emphasis of this paper therefore is on empirical analysis and the development of some practical recommendations. This paper also makes a contribution to the growing literature on the role of business in global governance.

## **THEORETICAL FRAMEWORK**

The existing literature on business in global governance can be divided into two main theoretical approaches.<sup>17</sup> From a more pluralist perspective, business is conceived of as one interest group among many that are competing over influence on policymaking.<sup>18</sup> Political influence can be explained by the resources that business commands, notably organizational capacity, monetary means and information.<sup>19</sup> From a more structuralist perspective, the political influence of business has been

explained by its ability to withdraw investment.<sup>20</sup> This, it has been argued, places states in a position of structural dependency on business, which has increased through economic globalization and capital mobility.<sup>21</sup>

The literature on the role of business in the global politics of access to medicines mainly takes the first analytical perspective. In order to explain the success of global pharmaceutical companies in promoting stronger protection of intellectual property (IP), scholars such as Sell, Sell and Prakash, Weissman, Santoro and Liu highlight the companies' abilities to organize collective action and strategically shape policy discourses.<sup>22</sup>

Most of this literature focuses on pharmaceutical companies that carry out research and development for new drugs. The role of generics producers has received little attention. A few studies have undertaken economic analyses of the generics sector that contributes most to the provision of ARVs in developing countries, notably companies from India.<sup>23</sup> Only a few studies have integrated an analysis of the commercial interests and activities of generics companies with an analysis of the politics of access to medicines in developing countries.<sup>24</sup> This paper contributes to this emerging body of work on the role of generics producers in the global AIDS response. It highlights the crucial role that generic ARVs have played in fighting HIV in developing countries and points out that the availability of these drugs resulted from an interplay of political and economic factors.

The paper contributes more broadly to the literature on the role of business in global governance by incorporating the analysis of business strategy. It examines why generics producers decided to supply the products that the international community required. Integrating the analysis of corporate commercial considerations into the analysis of political processes is not commonly done.<sup>25</sup> The paper demonstrates the value of such an approach by showing that it can help us better understand how the global AIDS response developed in the past decade and how to address some of the challenges it faces in the future.

The paper is based on interviews with representatives of Indian generics companies, the government of India, delegates to WTO and WHO, and civil society organizations. In addition, it draws on media reports from India, the US and Europe and pharmaceutical trade journals. Empirical research focused on the Indian generics industry as the most important source of generic ARVs in developing countries. In the next section, this paper will examine why low-cost generic ARVs became widely available in 2001. This paper's final section argues that insights gained from this analysis can help us deal with the dual challenge of rising treatment costs and potentially narrowing supply of low-cost generic ARVs in developing countries.

### **WHY DID LOW-COST GENERIC ARVs BECOME WIDELY AVAILABLE IN 2001?**

The first generic ARVs were being produced in Brazil, Thailand and India in the early-to-mid-1990s.<sup>26</sup> This raises the question why they became widely available for procurement by other governments and donors only in 2001.

An important reason for this development was a change in the international regulation of IP protection that restricted the production and exportation of generic drugs. In 1995, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into force obliging all WTO member states to grant patents "for any inventions, whether products or processes, in all fields of technology".<sup>27</sup> When the negotiations started in the 1980s, approximately 50 countries, including Brazil, India and Thailand, did not confer patent protection for

pharmaceutical products.<sup>28</sup> TRIPS granted a transition period of ten years to all developing countries that had not previously granted patent protection for pharmaceuticals. However, many states did not make use of this period; among them Brazil and Thailand, which adjusted their legislations in 1992 and 1997 respectively.<sup>29</sup>

The change in legislation limited the ability of Brazilian and Thai generics companies to produce and export ARVs. Brazil's new patent law granted protection to drugs that had not been marketed in the country when the law was passed.<sup>30</sup> Thailand's new legislation stipulated, in addition, that drugs granted patent rights in other countries between 1986 and 1991 could be protected in Thailand for up to six years.<sup>31</sup> Both legislations contained a provision that can be used to allow the production of generic versions of patented ARVs, namely the government's authority to issue compulsory licenses.<sup>32</sup> Compulsory licenses overrule the exclusive marketing rights granted by patent protection. However, according to TRIPS, production under compulsory licenses was initially limited to the supply of predominantly the domestic market.<sup>33</sup> In other words, even if the governments of Brazil and Thailand issued a compulsory license, less than half of the production would have been available for export. For a broad expansion of treatment, however, large export volumes were crucial because most developing countries did not have domestic pharmaceutical manufacturing capacity (and many still lack manufacturing capacity today).

The situation was different in India where TRIPS did not initially restrict pharmaceutical companies' ability to produce and export generic ARVs. The reason for this is that India made full use of the transition period provided for in the Agreement and adjusted national legislation only in 2005.<sup>34</sup> Nevertheless, Indian companies began to produce significant volumes of generic ARVs and export them only in 2001. The question posed above, why generic ARVs became widely available only in 2001, can therefore not be answered by looking solely at the effects of TRIPS. Rather, we need to examine also the commercial considerations of companies regarding their entry into this market.

In the 1990s, the market available to Indian producers of generic ARVs was small. While about 33.4 million people were infected with HIV in 1998, more than 95 percent of them lived in developing countries and were unable to afford treatment.<sup>35</sup> Most of the people living with HIV who could afford ART lived in high-income countries. This market, however, was closed to generics producers because of national patent laws. Developing countries that had introduced free treatment schemes, like Brazil and Thailand, and that therefore constituted sizable markets for some generic ARVs, were also partly closed to Indian generics. The newly introduced patent laws in these countries limited the procurement of generic ARVs to the issuance of compulsory licenses. In addition, Brazil and Thailand had domestic pharmaceutical producers, which could supply ARVs under compulsory licenses.

The domestic market in India was extremely small before the government set up a program to provide free ART in 2004.<sup>36</sup> Even one year after the start of the program, in 2005, only 6,845 people living with HIV received ART in India.<sup>37</sup> In addition to the small size of the market, generic ARV production was not very attractive because the active ingredients were costly compared to many other drugs.<sup>38</sup> In 1998, one kilo of the bulk fine chemicals required for the production of some of the then most commonly used ARVs cost approximately USD 10,000.<sup>39</sup>

The question therefore is what changed in 2001? The first Indian company to produce generic ARVs on a large scale and make them available for export was Cipla. In 2001, the company announced that it would sell a Fixed Dose Combination of Stavudine, Lamivudine and Nevirapine for USD 350 to Médecins Sans Frontières

(MSF) and for USD 600 to governments in developing countries.<sup>40</sup> Two months later, Hetero declared that it would sell the drug for USD 347 and Ranbaxy announced the price of USD 295.<sup>41</sup> It seems that a combination of three factors led to these decisions: a drop in production costs; the prospect of a growing market; and a context in which these offers could have a political impact.

Cipla's Chairman Yusuf K. Hamied stated that an important factor enabling the company to begin large-scale production of ARVs at such a low price was the drop in price for the active pharmaceutical ingredients (APIs) required.<sup>42</sup> The price drop was due largely to the launch of the Brazilian treatment access program, for which the Brazilian government had purchased USD 150 to 200 million worth of bulk drugs. This created considerable economies of scale for Indian generics producers as main suppliers of these APIs.<sup>43</sup>

Second, there was a prospect of a growing market for generic ARVs in 2000/01. Humanitarian organizations, notably MSF, had become directly involved in treating people living with HIV in developing countries and were therefore searching for sources of more affordable medicines.<sup>44</sup> The involvement of donors in the funding of treatment created the prospect of a larger market for generic ARVs because it could provide access to drugs to many people living with HIV who had hitherto been unable to afford ART. And indeed, the market that opened up through the involvement of donors, including the Global Fund, the Clinton Foundation HIV/AIDS Initiative and PEPFAR, yielded considerable income for Indian generics producers. In the fiscal year 2007, Aurobindo received USD 39 million from the US PEPFAR program alone, Ranbaxy received USD 18 million and Cipla more than USD 15 million.<sup>45</sup> For smaller firms like Aurobindo, PEPFAR accounted for almost nine percent of total revenues in 2007.<sup>46</sup> For larger firms like Cipla and Ranbaxy PEPFAR still contributed one to two percent to total annual revenues.<sup>47</sup> Moreover, the growing market enabled companies to achieve considerable economies of scale that further reduced the unit costs of production.<sup>48</sup>

In addition, expectations of a growing market for generic ARVs were linked to a political campaign to re-open provisions in the TRIPS Agreement that could negatively affect the affordability of drugs in developing countries. Since the mid 1990s, a group of NGOs including Consumer Project on Technology, Health Action International, Third World Network, Treatment Action Campaign South Africa, MSF and Oxfam had launched a campaign to raise awareness of the impact of global IP standards on the price of drugs in developing countries.<sup>49</sup> This issue had gained particular urgency in light of the rapidly spreading HIV pandemic in developing countries.<sup>50</sup> In cooperation with governments from a few developing countries, notably from Africa, the issue was introduced into the World Health Assembly (WHA), which passed resolutions addressing the need to strengthen policies to increase the availability of generic drugs and to evaluate the impact of TRIPS on access to medicines.<sup>51</sup> Moreover, the issue was taken up in the WTO TRIPS Council at the request of 50 developing countries that called for an "understanding that confirms the right of Governments to ensure access to medications at affordable prices."<sup>52</sup> These countries saw the Fourth WTO Ministerial Conference, which was to take place in Doha in November 2001, as an opportunity to introduce more flexibility into the TRIPS Agreement for the use of compulsory licenses, including for export. While generics producers in India were aware that TRIPS would not be undone at the Doha conference, they considered the debate about compulsory licenses important because these licenses could help open new markets for their products.<sup>53</sup>

Finally, there is evidence to suggest that Cipla's decision to offer low-cost generic ARVs in 2001 was shaped by political considerations. The political

momentum that was gathering in the months before the WTO Conference presented an ideal context for such an offer to affect policymaking according to the interests of Indian generics producers. The establishment of global IP standards through the TRIPS Agreement had been a major setback for Indian pharmaceutical companies because it closed off markets in many developing countries that had hitherto not granted pharmaceutical patent protection.<sup>54</sup> While proprietary pharmaceutical companies from the US and Europe had lobbied heavily for the establishment of TRIPS in the 1980s and early 1990s in order to protect and expand their market share against growing generics industries in middle-income countries, several Indian generics companies had lobbied in opposition to it, albeit with much less success.<sup>55</sup> The access to medicines campaign presented a context in which Indian companies could undertake a new attempt to influence global IP regulation to include more flexible standards. Cipla's Chairman Yusuf K. Hamied and Dilip Shah, General Secretary of the Indian Pharmaceutical Alliance, frequently represented the position of Indian generics companies in European and US media and at meetings on access to medicines organized by WTO, WHO, NGOs and academia.

The political context at the time was particularly favorable because the access to medicines campaign resonated with a major concern of many governments, namely how to keep people living with HIV alive to minimize the social and economic impact of the pandemic.<sup>56</sup> Cipla's offer pointed out that it was commercially feasible to produce low-cost ARVs and therefore to subsidize on a large scale treatment for poor people living with HIV. Moreover, the offer pointed out that it was the absence of pharmaceutical product patent protection in India that enabled Indian companies to produce low-cost medicines. In other words, Cipla's offer highlighted the link between IP standards and drug prices.

While Cipla's offer had resonated greatly in the public and political debates at the time, donors were initially sceptical about manufacturing standards in India and the safety and efficacy of drugs produced there. At first it seemed that the low-cost drugs produced by Indian companies would not increase the affordability of treatment for poor people living with HIV.

It was only a change in international regulation that enabled Indian generics producers to exploit the commercial opportunities of the emerging donor-funded market and, thereby, contribute to improved treatment access. In 2001, WHO launched the Prequalification of Medicines Programme, which sets unified standards for quality, safety and efficacy of drugs and evaluates drug manufacturing facilities accordingly. In October 2002, the Global Fund announced that it would encourage developing countries to buy cheap generic medicines as long as they were prequalified by WHO.<sup>57</sup> In October 2003, the Clinton Foundation HIV/AIDS Initiative closed a deal with five generics producers from developing countries – Cipla, Ranbaxy, Hetero and Matrix from India and the South African company Aspen – to sell triple dose combination ARVs for USD 139 per patient per year in several developing countries.<sup>58</sup> In 2007, generics manufacturers had emerged as the main beneficiaries of PEPFAR providing 73 percent of all ARVs delivered by the program.<sup>59</sup>

In summary, in order to explain why generic ARVs became widely available in 2001, we need to analyse political and economic dynamics *and* examine how they shaped the commercial calculations of companies that produced the medicines. The most important factors were the costs of production and the size of the market. The emergence of a market for generic ARVs was shaped by public policies, notably the provision of donor funding for treatment and the creation of an international regulatory structure for drug quality approval.

Yet global public policy regulating the availability of low-cost medicines in developing countries has not been coherent. While the above mentioned examples have enlarged the market available to generics producers, the TRIPS Agreement has restricted it. Furthermore, the past decade has seen a growing number of bilateral free trade agreements being negotiated between the US. And more recently also the EU, on the one hand and developing countries on the other. Many of these agreements contain IP provisions that go beyond the standards agreed upon in TRIPS and can, therefore, further restrict the market available to low-cost generic ARVs.<sup>60</sup>

## LESSONS FOR TODAY'S CHALLENGES

I have argued that an analytical approach that integrates the analysis of political and economic dynamics with an examination of how they impact on the commercial calculations of producers can help us understand the development of the global AIDS response in the past. In this section I will demonstrate that it can also help us address some of the challenges we face today in further expanding treatment in developing countries.

One challenge is how to deal with rising treatment costs and the tightening budgets of governments and donor organizations. Treatment costs are rising because the number of people living with HIV who require ART is growing, due to new infections and revised WHO guidelines recommending earlier initiation of ART.<sup>61</sup> Costs are also rising because an increasing number of people on treatment require newer ARVs that are not yet available in generic versions. Newer ARVs are needed for two main reasons. First, they offer better side-effect and tolerability profiles. Second, after several years of treatment, many people develop drug resistance and have to switch from first-line to second- and even third-line regimens. Some of the newer ARVs used in the first line of treatment and particularly those used in second- and third-line regimens remain protected by patents and are, therefore, much more expensive.<sup>62</sup> As India amended its patent legislation to comply with TRIPS in 2005, Indian producers could no longer supply generic versions of these drugs.<sup>63</sup>

The rapid growth of the donor-funded market post-2001 illustrates that decreasing drug prices can contribute to the willingness of governments and donors to subsidize treatment because they increase the number of people living with HIV that can be reached with a given financial envelope. Today, the rising costs for ART in combination with tightening government budgets seem to have dampened the enthusiasm of donors to provide funding for HIV treatment. In this context, some have argued for shifting funds to prevention programs and to diseases for which interventions are more cost-effective.<sup>64</sup>

If we are not prepared to accept that poor people living with HIV have to do without treatment it is indispensable to look for ways of how treatment costs can be reduced. One way is to address the political and administrative hurdles that the companies that produce low-cost medicines face. International and national legislations that protect intellectual property also provide for mechanisms to secure the supply of generic medicines. For instance, at the national level, important legal provisions concern the ability of generics producers to rely on the clinical data provided by the original applicant to prove the safety and efficacy of their products.. At the international level, governments' right to issue compulsory licenses is provided for in Article 31 of the TRIPS Agreement and confirmed in the Doha Declaration on TRIPS and Public Health.<sup>65</sup> The paragraph restricting compulsory

licenses to the use for predominantly the domestic market was amended in a WTO General Council Decision in 2003.<sup>66</sup>

However, in a growing number of countries marketing approval for generics is delayed by the introduction of exclusivity periods during which the originator's clinical trial data may not be used to register generic versions. Generics production under compulsory licenses has involved considerable political and administrative hurdles not only for governments, but also for producers, in the past.<sup>67</sup> Easing the administrative and political burden for producers of low-cost medicines for developing countries could involve two things. First, existing flexibilities in national and international IP legislation should be maintained and periods of marketing exclusivity not be expanded through changes in the drug quality approval process. Second, intergovernmental organizations, donor groups and civil society organizations could engage directly with producers and assist them in dealing with the costs incurred by operating under the existing legal framework. The process of applying for compulsory licenses for export is administratively complicated.<sup>68</sup> From the perspective of generics companies, this creates additional costs and therefore does not render production under compulsory licenses very attractive.<sup>69</sup> Intergovernmental organizations, donors and civil society could help companies reduce these costs by providing information and facilitating interaction with government agencies. For instance, WTO is already providing training and technical assistance to policymakers from developing countries on how to use TRIPS flexibilities. Such efforts could be extended to directly engage with potential suppliers of new generic ARVs and other medicines required in developing countries.

The further expansion of treatment is threatened also by the declining interest of current suppliers of low-cost generic ARVs in catering for developing countries' markets. The profit margins to be gained from producing for developing countries' markets are extremely thin. For newer ARVs they will be stretched even further because companies have to invest resources into the development of new generic products. Current suppliers are usually large companies, mostly based in India, that have achieved a level of technological and financial capability which enables them to target more profitable niches in the global generics market. Two main strategies have been observed: the development of improved drug formulations and a shift in export markets from developing countries to high-income countries.<sup>70</sup> This is not to say that these companies will stop producing for developing countries' markets. The costs they have to shoulder to invest in the research and development of improved formulations and to pay for registration procedures in North America and Europe require the generation of significant capital. Currently, this has to come from their core generics business in developing countries.<sup>71</sup> However, as Shadlen and Gehl Sampath suggest, companies that see their future business in the high-value end of the market for niche generics and in high-income countries are unlikely to invest any more resources in developing products for markets with exceptionally thin profit margins.<sup>72</sup>

An alternative source of low-cost generic ARVs could be small producers in developing countries. These companies usually do not have the option of targeting the high-value end of the market and high-income countries because they cannot shoulder the investment costs necessary to develop improved drug formulations and comply with drug registration procedures in high-income countries. Therefore, they maintain a commercial interest in the low-profit markets of developing countries.<sup>73</sup> However, many small generics companies in developing countries do not have the technological capacity to fulfill Good Manufacturing Practice (GMP) standards, including those used by the WHO Prequalification scheme.<sup>74</sup> This means that they

are essentially excluded from the donor- and government-funded market in developing countries because most donor organizations and government procurement agencies insist on WHO prequalification for the drugs they buy.

In order to harness small generics producers in developing countries as a source of low-cost ARVs, WHO could extend the Prequalification Programme. Currently, the Programme is limited to carrying out inspections when companies apply for their drugs to be included in the WHO list of prequalified medicinal products. WHO could expand the Programme on two fronts. First, it could proactively approach small pharmaceutical producers in developing countries and explore the companies' potential to produce generic ARVs. Second, WHO, in collaboration with national and international development agencies, could provide the technical and legal assistance these companies require to comply with GMP standards and to obtain WHO certification.

Tapping into the supply of small generics companies in developing countries as a source of generic ARVs may be crucial to further expand treatment in developing countries. In addition, it may help develop local pharmaceutical manufacturing capacity. This would create the additional benefit of easing the administrative burden on companies and governments when they use compulsory licenses. Production could be carried out under compulsory licenses for predominantly the domestic market and not require companies and governments to follow the complicated procedure laid down in the WTO Decision on compulsory licenses for export. Finally, improving the capacity of local pharmaceutical companies to comply with GMPs can help tackle the problem of substandard medicines, which poses a health threat to many patients in developing countries.<sup>75</sup>

## CONCLUSIONS

This paper has demonstrated the value of integrating the study of business strategy into the analysis of global politics by illustrating that a crucial factor in the global AIDS response, the availability of generic ARVs, was the result of both political and commercial factors. Furthermore, this paper has illustrated that governments and international organizations can directly shape companies' market environment and, therefore, their commercial incentives to produce certain goods. Governments and international organizations shaped the market for low-cost generic ARVs by taking on the task of buying drugs for people living with HIV in developing countries. Furthermore, they influenced the market by creating a regulatory environment that determined which companies can participate in this market. Drawing on these insights, the paper argues that governments and international organizations can help expand treatment further by facilitating market access of producers that can supply medicines at low costs. First, they can ensure that the regulatory environment at the national and global level does not increase production costs. Second, they can engage directly with small- and medium-sized pharmaceutical manufacturers in developing countries and provide technical assistance on issues such as production under compulsory licenses, GMPs and WHO prequalification.

The history of the global AIDS response has illustrated that companies can play an important role in global politics because they provide the goods required by society. Governments and international organizations can influence business strategy and, therefore, shape which companies participate in the market and which goods are produced.

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<sup>1</sup> WHO, UNAIDS, and UNICEF, "Towards Universal Access: Scaling up Priority H.I.V./A.I.D.S. Interventions in the Health Sector. Progress Report 2010," (Geneva: WHO, 2010).

2. UNAIDS, "A.I.D.S. Epidemic Update," (Geneva: November, 2009).

<sup>3</sup> WHO and UNAIDS, "Progress on Global Access to H.I.V. Antiretroviral Therapy: A Report On "3 by 5" And Beyond," (Geneva 2006).

<sup>4</sup> PEPFAR, "The Power of Partnerships: The U.S. President's Emergency Plan for Aids Relief," in *2008 Annual Report to Congress* (Washington, DC: Office of the United States Global AIDS Coordinator, 2008).

<sup>5</sup> S. Chasombat et al., "The National Access to Antiretroviral Program for Pha (Napha) in Thailand," *The Southeast Asian Journal of Tropical Medicine and Public Health* 37, no. 4 (2006).; Maurice Cassier and Marilena Correa, "Intellectual Property and Public Health: Copying of H.I.V./A.I.D.S. Drugs by Brazilian Public and Private Pharmaceutical Laboratories," *RECIIS - Electronic Journal of Communication, Information & Innovation in Health* 1, no. 1 (2007).

<sup>6</sup> Botswana, Cambodia, Croatia, Cuba, Guyana, Oman, Romania and Rwanda; WHO, UNAIDS, and UNICEF, "Towards Universal Access: Scaling up Priority H.I.V./A.I.D.S. Interventions in the Health Sector. Progress Report 2010."

<sup>7</sup> Bertozzi, Martz, and Piot, "The Evolving H.I.V./A.I.D.S. Response and the Urgent Tasks Ahead."; S. Sell and A. Prakash, "Using Ideas Strategically: The Contest between Business and N.G.O. Networks in Intellectual Property Rights," *International Studies Quarterly* 48, no. 1 (2004).

<sup>8</sup> Waning, Diedrichsen, and Moon, "A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries." See also Colleen V. Chien, "H.I.V./A.I.D.S. Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?," *PLoS ONE* 2, no. 3 (2007).

<sup>9</sup> New Internationalist, "A.I.D.S. Without the Aid,"

<http://www.newint.org/blog/radio/2008/06/17/aids-without-the-aid/>.

<sup>10</sup> R. Zimmerman and J. Pesta, "Drug Industry, A.I.D.S. Community Is Jolted by Cipla A.I.D.S.-Drug Offer," *Wall Street Journal* 2001.

<sup>11</sup> WHO, UNAIDS, and UNICEF, "Towards Universal Access."

<sup>12</sup> Ibid.

<sup>13</sup> BBC, "State of the Union Address: Full Text,"

<http://news.bbc.co.uk/1/hi/world/americas/2704365.stm>.

<sup>14</sup> Zidovudine (AZT) was approved for marketing by the US FDA on 20 March 1987. It was sold under the name Retrovir by Burroughs-Wellcome (now GlaxoSmithKline). Kerry Dooley Young, "First H.I.V. Drug, Glaxo's Azt, Gets Generic U.S. Rivals," *Bloomberg*, 19 September 2005. The Indian company Cipla started producing a generic version of AZT in 1991. Samira Guennif, "A.I.D.S. In India: Public Health Related Aspects of Industrial and Intellectual Property Rights Policies in a Developing Country," in *CSH Occasional Paper No. 8* (Paris: Centre d'Economie de Paris Nord, Université Paris 13, 2004). Brazilian laboratories started production in 1993. Cassier and Correa, "Intellectual Property and Public Health: Copying of H.I.V./A.I.D.S. Drugs by Brazilian Public and Private Pharmaceutical Laboratories."

<sup>15</sup> Peter Piot et al., "A.I.D.S.: Lessons Learnt and Myths Dispelled," *Lancet* 374(2009); UNAIDS, "What Countries Need: Investments Needed for 2010 Targets," (Geneva 2009).

<sup>16</sup> Padmashree Gehl Sampath, "Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry," (United Nations University-INTECH, 2005); ———, "India's Pharmaceutical Sector in 2008: Emerging Strategies and Global and Local Implications for Access to Medicines," (Report prepared for the Department for International Development (DFID), UK2008); Kenneth C. Shadlen, "The Political Economy of A.I.D.S. Treatment: Intellectual Property and the Transformation of Generic Supply," *International Studies Quarterly* 51, no. 3 (2007).

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