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## Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries

Juan Rovira, Ph.D.\*

### INTRODUCTION

The price of medicines is one of the main barriers to treatment access for many poor people in developing countries due to their low purchasing power and the limited availability of public or private insurance in poor countries. It has been estimated that between fifty percent and ninety percent of pharmaceutical expenditures in developing countries are paid for out-of-pocket.<sup>1</sup> In developed countries, on the other hand, over seventy percent of such expenditures are funded through insurance or other reimbursement schemes.<sup>2</sup>

Patents and other mechanisms of market exclusivity facilitate the acutely problematic pricing of new drugs: Intellectual property rights (IPR) and regulatory protections grant a temporary monopoly to a right-holder, thereby allowing prices to be set well above marginal and direct manufacturing costs.<sup>3</sup> Although the majority of essential drugs—as defined by the World Health Organization's essential drug list<sup>4</sup>—are off-patent,

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\* Former senior Health Economist (Pharmaceuticals), World Bank. I would like to acknowledge the useful comments made to the first version of the paper by Yolanda Tayler (The World Bank), Nuria Homedes (University of Texas), and Rudolf V. Van Puymbroeck (The World Bank). The responsibility for the final text and any possible errors remains exclusively mine.

1. Jonathan Quick et al., *Twenty-five Years of Essential Medicines*, 80 BULL. WORLD HEALTH ORG. 913, 914 (2002), available at

[http://www.who.int/medicines/organization/par/cd\\_25th\\_anniversary/whobull.pdf](http://www.who.int/medicines/organization/par/cd_25th_anniversary/whobull.pdf).

2. *Id.*

3. This correspondingly encourages private investment in pharmaceutical research and development (R&D).

4. WORLD HEALTH ORG., 13TH WHO MODEL LIST OF ESSENTIAL MEDICINES (2003), available at <http://mednet3.who.int/eml> (last visited Apr. 29, 2004).

there are some important and even life-saving drugs (such as those for HIV/AIDS and cancer) and vaccines that are patent-protected.

In recent years, research intensive industries and the developed countries in which they are located have made a strong push for international IPR harmonization. Harmonization of IPR amounts to pressures for developing countries to raise their IPR protection to developed-country levels. This trend has taken place in the last decade in the multilateral context of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. In recent years, developed countries have also pushed to increase patent protection beyond the levels required by TRIPS—known as “TRIPS-plus” provisions—when negotiating bilateral free trade agreements (FTAs).<sup>5</sup>

This Case Study offers an insider's analysis of the role played by the World Bank in affecting the affordability and accessibility of drugs in developing countries in the current IPR environment. After exploring the relationship between current trade agreements, international IPR, and access to medicines, the Case Study describes the lending activities of the Bank in the pharmaceutical area and argues that the type and amount of funding that developing countries obtain from the Bank is unlikely to significantly address problems of inadequate financing for pharmaceutical purchases. However, the conditions set by the Bank for countries to procure pharmaceuticals using the Bank's funds might have positive effects on competition that could extend beyond Bank-funded purchases and increase, in the long run, the efficiency of pharmaceutical expenditures.<sup>6</sup>

This Case Study analyzes the position recently adopted by the Bank regarding IPR and the procurement of AIDS pharmaceuticals and other medical goods; the Bank seeks to encourage countries to use the flexibilities within the TRIPS Agreement and in their own legislation to

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5. See, e.g., DAVID VIVAS-EUGUI, QUAKER UNITED NATIONS OFFICE, REGIONAL AND BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE FREE TRADE AREA OF THE AMERICAS (2003), available at [http://www.geneva.quino.info/pdf/FTAA%20\(A4\).pdf?PHPSESSID=47e04ef374bf9b6ceecfe7d421a6d28c](http://www.geneva.quino.info/pdf/FTAA%20(A4).pdf?PHPSESSID=47e04ef374bf9b6ceecfe7d421a6d28c).

6. Note, however, that while the problems posed by high drug prices can often be mediated by pro-competitive interventions, this approach may not suffice to make drugs affordable to the poorest populations under all circumstances. See, e.g., MOHGA K. SMITH, GENERIC COMPETITION, PRICE AND ACCESS TO MEDICINES: THE CASE OF ANTIRETROVIRALS IN UGANDA 6 (Oxfam Briefing Paper No. 26, July 10, 2002), available at [http://www.oxfam.org/eng/pdfs/pp020710\\_no26\\_generic\\_competition\\_briefing\\_paper.pdf](http://www.oxfam.org/eng/pdfs/pp020710_no26_generic_competition_briefing_paper.pdf).

obtain the best available prices for products of guaranteed quality.

### I. ACCESS TO MEDICINES: TRIPS AND BEYOND

Many proponents of free trade agreements have claimed that the liberalization of trade improves the well-being of the participating countries by removing trade barriers, enlarging potential markets and, ultimately, allowing countries to increase their exports of goods for which they have a comparative advantage. Under this argument, both developed and developing countries benefit from increased trade.<sup>7</sup> Throughout the 1990s, intellectual property provisions were progressively included in trade agreements under this logic. The supporters of strong property rights claimed that strong IPR would not only benefit developed countries and the innovative pharmaceutical industry, which is highly concentrated in a handful of developed countries, but would also have a favorable impact on developing countries. Strong IPR, it was argued, makes new products quickly available, generates foreign investment in developing countries, and provides incentives for R&D into new therapies.<sup>8</sup>

Negotiated during the 1986-1994 Uruguay Round of the WTO and signed in 1994, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has been the primary focus of attention in the debate over IPR and access to medicines. However, IPR issues are also relevant to other multilateral and bilateral trade agreements. Overall, TRIPS and the IPR provisions of FTAs have received tremendous support from developed countries as a result of pressure from their industries, but have received mixed responses from developing country ministers.<sup>9</sup>

The debate over the effects of IPR in general and on pharmaceuticals in particular is far from closed. But there is certainly much concern among developing countries and activists about the negative effects that IPR might have on prices and, correspondingly, the affordability and accessibility of drugs.<sup>10</sup> While the World Bank has expressed its concerns about the effects

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7. See, e.g., Robert B. Zoellick, *Trade Helps Africans Help Themselves*, WALL ST. J., May 23, 2001, at A26.

8. See, e.g., Roger Bate, *The Worst Pandemic Looks To Get Worse*, TECH. CENTRAL STATION, Feb. 20, 2004, at [http://www.aei.org/news/newsID.1994,filter./news\\_detail.asp](http://www.aei.org/news/newsID.1994,filter./news_detail.asp).

9. See PETER DRAHOS & RUTH MAYNE, *GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT* (2002).

10. See, e.g., ACCESS TO ESSENTIAL MEDICINES CAMPAIGN, TESTIMONY OF DOCTORS WITHOUT BORDERS/MÉDECINS SANS FRONTIÈRES (MSF) AT THE PUBLIC HEARING CONCERNING MARKET

of IPRs on medicine pricing, there is little literature from the Bank on FTAs and practically no comment on the effects of IPR clauses included in FTAs.<sup>11</sup>

A potential balance between the demands of industry in the developed world and the interests of developing countries seemed to arrive with the 2001 signing of the *Doha Declaration on TRIPS and Public Health*, which has been discussed extensively elsewhere.<sup>12</sup> The *Declaration* was unanimously signed by WTO delegates and stated “that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.”<sup>13</sup> But some developed countries, especially the United States, seemed to consider the *Doha Declaration* an unsatisfactory solution for their own interests; as a result, they have attempted to move the cause of strong IPR to other fora, such as bilateral and regional FTAs.<sup>14</sup> Advocates for developing countries state that developing country trade ministers should refrain from signing trade agreements with “TRIPS-plus” provisions.<sup>15</sup>

One could argue that developing countries are not obliged to sign trade agreements unless they expect the benefits to outweigh the corresponding costs. But the impact of any given trade agreement is far from predictable. Whatever the specific outcomes, benefits are also likely to accrue for relatively wealthy population groups, while costs such as those associated with a lower accessibility to drugs are likely to affect the most vulnerable population groups.<sup>16</sup>

An estimation of the cost of various clauses of an FTA is not an easy task. Estimating the static effects alone requires a large amount of

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ACCESS IN THE FREE TRADE AREA OF THE AMERICAS NEGOTIATIONS OF THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (Sept. 9, 2002).

11. See Mamphela Ramphele & Nicholas Stern, *Generic Drugs Can Make the Money Last*, N.Y. TIMES, Mar. 1, 2003, at A19.

12. See, e.g., Fred M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT’L ECON. L. 469, 469-505 (2002).

13. World Trade Org., Doha WTO Ministerial 2001, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

14. See generally ACCESS TO ESSENTIAL MEDICINES CAMPAIGN, DOHA DERAILED: A PROGRESS REPORT ON TRIPS AND ACCESS TO MEDICINES 4 (2003), available at <http://www.accessmed-msf.org/documents/cancunbriefing.pdf>.

15. See, e.g., JENNIFER BRANT, ROBBING THE POOR TO PAY THE RICH? HOW THE UNITED STATES KEEPS MEDICINES FROM THE WORLD’S POOREST 31 (Oxfam Briefing Paper No. 56, Nov. 2003), available at [http://www.oxfam.org/eng/pdfs/pp031201\\_robbing\\_medicines\\_US.pdf](http://www.oxfam.org/eng/pdfs/pp031201_robbing_medicines_US.pdf).

16. See JIM KIM ET AL., DYING FOR GROWTH: GLOBAL INEQUALITY AND THE HEALTH OF THE POOR (2000).

information concerning demand elasticities, defining a counterfactual, and making risky assumptions on the evolution of the market conditions. Moreover, it is far from clear that welfare economics provides the appropriate tools for assessing the social cost and benefits of patent protection and the resulting variations in drug prices and consumption. For instance, the consumer surplus, a conventional measure of benefit in welfare economics, might not be an acceptable measure of the value of a lifesaving drug for an indigent person. It is probably safe to conclude that it would be quite difficult to agree on any scientific or objective procedure that allows us to measure the effects of an IPR regime in a conclusive way.

While it is clear that it will be difficult for developing countries to estimate the costs to their domestic welfare, developed countries must confront an ethical issue: To what extent should a developed country take advantage of the economic and political needs and weaknesses of developing countries in order to obtain some trade advantages likely to result in reduced survival and increased distress for poor countries populations? Even assuming a purely selfish approach, one might wonder whether the intangible negative effects of signing such agreements—such as anger and resentment toward developed countries—will ultimately outweigh the economic advantages attained.

A more probing question concerns the long-term evolution of access to drugs and pharmaceutical innovation—whether the present system of pharmaceutical R&D and innovation is an acceptable and efficient one, satisfying the needs and demands of both developed and developing countries. The system is currently based on patents and other exclusive marketing rights as the key incentive for private investment in drug development. Private firms are expected to make an investment that they expect later to recover in the form of extraordinary, monopoly profits. The possible negative effects of such a system are significant: reduced accessibility to the drugs among poor countries and population groups, obstacles to research by other parties in areas protected by patents, and the like. The key problem probably derives from the fact that the patent system leads R&D toward profitable diseases and conditions, rather than toward diseases that cause the most morbidity and mortality.<sup>17</sup> This explains the obstacles to creating drugs for neglected diseases, as well as the (probably excessive) research on highly-profitable “me-too” drugs that make a small

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17. Press Release, Drugs for Neglected Diseases Initiative: Teaming Up To Address Neglect (Mar. 12, 2003), <http://www.accessmed-msf.org/prod/publications.asp?scntid=12320031354463&contenttype=PARA&>.

or negligible contribution to therapeutic innovation.<sup>18</sup>

The options proposed as alternatives to the patent system are manifold. They are mostly based on the separation of R&D and the innovation market from drug manufacturing processes.<sup>19</sup> The funding of drug development in this manner would require public funding and private donations. Taking into account the global public good that most therapeutic innovation promotes, the issue should probably be addressed at a multilateral level, perhaps through an international treaty establishing how member countries should pay for the R&D and then have access to the innovation.

Under this hypothetical scheme, once the priorities for R&D are established by the members of the treaty, the funding should be allocated in some competitive way among potential research organizations. The funding could take the form of grants, allocated before the R&D activity is carried out, or prizes awarded to the innovations *a posteriori*. Under any scenario, the manufacturing sector would work under generic competition. Any manufacturer would be allowed to produce the final products free of any charge or for a fixed compensation.<sup>20</sup>

Such a scheme might sound utopian, and it would indeed be unwise to assume that the present patent system could be radically changed in the near future. The likely opposition of the research industry to such changes and the difficulties in raising the funds for an alternative system are formidable. But various proposals might well be tested as pilot experiences for specific drugs. Essential drugs for neglected diseases seem a clear category to start with: They are not adequately researched, anyway; therefore, a failed experience would not have a negative impact on drug availability.

## II. THE WORLD BANK'S FINANCING OF MEDICINE PURCHASES

Within the context established in the previous Part, this Case Study

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18. See ROBERT YOUNG & MICHAEL SURRUSCO, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" 13 (2001), *available at* [http://www.citizen.org/congress/campaign/special\\_interest/articles.cfm?ID=6538](http://www.citizen.org/congress/campaign/special_interest/articles.cfm?ID=6538).

19. See JAMES LOVE, FROM TRIPS TO RIPS: A BETTER TRADE FRAMEWORK TO SUPPORT INNOVATION IN MEDICAL TECHNOLOGIES (May 2003) (unpublished manuscript), <http://www.cptech.org/slides/trips2rips.doc> (last visited Apr. 29, 2004); see also JEAN LANJOUW, A PATENT POLICY PROPOSAL FOR GLOBAL DISEASES (Brookings Policy Brief No. 84, June 2001), *available at* <http://www.brookings.edu/views/papers/lanjouw/20010611.pdf>.

20. *Id.*

aims to demonstrate the World Bank's effect on various factors relating IPRs to medicine access. The World Bank has been lending funds for the purchase of medicines through its Health, Nutrition and Population (HNP) sector since the late 1970s. The World Bank's first project to include pharmaceutical financing was called the Peru Health project and was granted in 1983. Between 1983 and 1999, 116 Bank projects incorporated a pharmaceutical component.<sup>21</sup> Four types of pharmaceutical purchases were provided with funding: (1) those for HNP projects that financed drug procurement for specific diseases; (2) those for pharmaceutical stand-alone projects; (3) those employing pharmaceutical components as part of broader health reform projects; and (4) those linked to non-health-specific activities such as structural adjustment, critical investment, and private sector investment loans. The conclusion of a study on these lending practices indicated that a major portion of the World Bank pharmaceutical planned lending (eighty-two percent) was directed toward pharmaceutical procurement.<sup>22</sup> The remaining eighteen percent of Bank-planned lending in pharmaceutical projects included financing civil works and equipment, training of professionals, and technical assistance.

The World Bank has historically been reluctant to finance recurring expenditures.<sup>23</sup> This position has been expressed most clearly in the case of pharmaceutical lending, as the Bank has restricted the financing of pharmaceutical procurement to the following situations: (1) as a method to control specific diseases; (2) as an integral part of a national drug policy; or (3) as part of a cost recovery or other drug financing program.<sup>24</sup> The apparent contradiction between the Bank position and the results found in the above-mentioned study might be explained by the insufficiency of health care budgets, the demanding requirements of all-too-frequent humanitarian emergencies, and the preference of borrowers to spend money on tangible goods rather than in hiring consultants to provide policy advice.

A more recent study found that the total amount of procurement for pharmaceuticals and medical products (PMP) from fiscal years 1999 to

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21. EDUARDO SABATE ET. AL., FINANCIAL AND POLICY AUDIT OF THE WORLD BANK'S PHARMACEUTICALS LENDING: BACKGROUND STUDY FOR WORLD BANK PHARMACEUTICALS DISCUSSION PAPER 1 (World Bank Human Development Network, Sept. 2000).

22. RAMESH GOVINDARAJ ET. AL., WORLD BANK PHARMACEUTICALS PAPER 6 (2000).

23. See DENIS BROUN, PROCUREMENT OF PHARMACEUTICALS IN WORLD BANK PROJECTS 4 (HRO Working Papers Report No. 13525, 1994).

24. *Id.* at 4-10.



2002 under Bank loans was \$401 million (approximately \$133 million per year, on average).<sup>25</sup> According to rough estimates, pharmaceutical sales for Latin America, Asia and Pacific, Middle East, and Africa amounted to thirty-nine billion dollars in 2001.<sup>26</sup> The relative magnitude of the purchases funded from Bank loans (0.3%) is unlikely to have a substantial impact on the performance of the markets. Furthermore, if non-pharmaceutical PMP could be excluded from the computed figures, the share of pharmaceuticals might come down substantially.

For the Bank as a whole, procurement of PMP amounts to 4.3% of the procurement of all goods and to 1.4% of all procurement categories. Restricting our analysis to the HNP sector, the share of PMP procurement of all procurement categories rises to 17.7%.<sup>27</sup>

*The Effects of World Bank Lending on Competition in Pharmaceutical Markets*

The World Bank is not directly involved in the production, procurement or purchasing of pharmaceuticals, nor does it have any regulatory capacity. It can nevertheless influence market behavior and pricing in an indirect way. The Bank requires national procurement agencies to apply competitive procurement procedures, such as international competitive bidding (ICB), when using loan proceeds.<sup>28</sup> The Bank thus promotes a process—akin to generic competition—that should lead to lower, more competitive prices.<sup>29</sup> While this approach is powerless

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25. ROSA RODRIGUEZ-MONGUIO & JUAN ROVIRA, AN ANALYSIS OF PHARMACEUTICAL LENDING BY THE WORLD BANK 11-13 (HNP Discussion Paper 2004), *available at* <http://www1.worldbank.org/hnp/hsd/documents/AnAnalysisofPharmaceuticalLending.pdf>.

26. GLAXOSMITHKLINE, ANNUAL REPORT 45 (2002).

27. RODRIGUEZ-MONGUIO & ROVIRA, *supra* note 25, at 13. Note that sixty-six percent of the total procurement of PMP corresponds to the South Asian region. *Id.*

28. *See infra* Annex 1; THE WORLD BANK, HIV/AIDS MEDICINES AND RELATED SUPPLIES: CONTEMPORARY CONTEXT AND PROCUREMENT (2004), *available at* <http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf>.

29. *See* Patricia M. Danzon & Michael F. Furukava, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, W3 HEALTH AFF. 521 (2003) (comparing average price levels for drugs in eight countries); *see also* ANNA COOK, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (Congressional Budget Office 1998) (examining the impact of generic drug competition on drug prices since the passage of the 1984 Hatch-Waxman Act).

when products are patent-protected or enjoy other legal forms of market exclusivity, as is often the case with pharmaceuticals,<sup>30</sup> it is expected to facilitate competition in the presence of product differentiation, moral hazard, and other market failures and imperfections.

However, a recent study cast some doubts on the extent to which the Bank's procurement requirements—even when unobstructed by legal hurdles—effectively promote international competition. The study found that a large share of the Bank's lending for PMP during the period of FY 1999 to FY 2002 financed either the domestic pharmaceutical industry of the borrower countries or the procurement of supplies from international organizations. Nearly twenty-nine percent of the total value of loans supplied by the Bank went toward PMP provided by suppliers from the same country that had received the Bank's loan.<sup>31</sup> ICB was the procurement method for ninety percent of the contracts with the same supplier and borrower country. In the cases of Bosnia-Herzegovina, Cameroon, China, Indonesia, Macedonia, and Nicaragua, all PMP purchased were supplied by a national supplier irrespective of the procurement method used.<sup>32</sup> From a total of fifty Bank borrower countries, twenty-two suppliers accounted for ninety-nine percent of the total PMP purchased from FY 1999 to FY 2002.<sup>33</sup> International organizations such as UNICEF and the Pan American Health Organization were also key

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To respond to concerns raised with regard to the quality of the medicines subject to open-bidding procedures, the Bank requires procurement agencies to assess the quality of the manufacturers and products using prequalification of suppliers and other strategies. In the case of ARV and other HIV-AIDS drugs, the World Bank supports the initiative on prequalification of manufacturers and products led by the World Health Organization. *See, e.g.,* Helen Frankish, *WHO Steps Up Campaign on Counterfeit Drugs*, 362 *THE LANCET* 1730 (2003).

30. In those cases where the TRIPS Agreement offers countries some safeguards, parallel importation, the issuance of compulsory licenses, or the implementation of government use of a patent might be considered.

31. RODRIGUEZ-MONGUIO & ROVIRA, *supra* note 25, at 12.

32. Other countries also have a large percentage of the total procurement of PMP supplied by domestic manufacturers: Burundi (63.5%), Egypt (87%), Mexico (86.3%), Morocco (67.7%), Philippines (59.5%), and Kenya (75.9%). *Id.*

33. The Indian pharmaceutical industry was the main foreign supplier of pharmaceuticals and medical products: The Indian industry supplies 15.7% and 14.3% of the total PMP purchased by the twenty-two main Bank borrowers and by all fifty borrower countries, respectively. In spite of this apparently strong exporting capacity, Indian pharmaceutical products went mainly for domestic consumption, accounting for 89.1% of the country's total PMP. *Id.*

suppliers, jointly accounting for 44.8% of the total supply.<sup>34</sup>

### III. A NEW WORLD BANK POSITION ON GENERICS AND IPR

Bank lending for pharmaceuticals was traditionally used for the procurement of essential drugs and vaccines that are mostly off-patent. Since Bank projects have usually targeted basic health needs of poor populations, the Bank argued that these could be addressed with relatively old, well-established medicines. Since 1993, when the first Standard Bidding Procedures (SBP) for pharmaceuticals were issued, requirements were set to use international non-proprietary names (INN) for product specification. In recent years, and especially in the context of the “scaling-up” of HIV/AIDS treatment programs in developing countries, purchasers of drugs have been faced with the high cost of using some on-patent drugs, especially antiretrovirals (ARVs), which have had dramatic impacts on the survival and quality of life of people living with HIV/AIDS. Many countries could not afford the high prices of on-patent drugs. The entry into the market of generic versions of ARVs, mainly produced by Indian manufacturers, opened the opportunity for countries to dramatically reduce the costs of AIDS treatment, in turn making it possible for countries to treat a much larger number of individuals with their available budgets.<sup>35</sup>

In the early 2000s, the Bank did not have an explicit and consistent practice with regard to the procurement of generic versions of ARVs that were on-patent in most developed countries. Uncertainties on the part of both the Bank and country ministers regarding the implications of TRIPS for developing countries sometimes resulted in countries choosing originator products aimed at ensuring conformity with a country’s domestic legislation and with international agreements.<sup>36</sup>

Two recent documents have clarified the Bank position on this matter. In March 2003, two top World Bank managers published an op-ed in *The New York Times* openly endorsing the option of developing countries

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34. *Id.*

35. SMITH, *supra* note 6, at 6.

36. *See, e.g.*, THE WORLD BANK, PROJECT APPRAISAL DOCUMENT FOR PROPOSED LOANS IN THE AMOUNT OF US\$25.0 MILLION TO THE DOMINICAN REPUBLIC AND US \$15.15 MILLION TO BARBADOS IN SUPPORT OF THE FIRST PHASE OF THE US\$155.0 MILLION MULTI-COUNTRY HIV/AIDS PREVENTION AND CONTROL ADAPTABLE PROGRAM LENDING (APL) FOR THE CARIBBEAN REGION, 13 (Paper No. 22184-LAC 2001).

buying generic drugs whenever possible.<sup>37</sup> More recently, the World Bank published a Technical Guide to offer guidance to improve the performance of the agencies involved in the procurement of HIV/AIDS products.<sup>38</sup> In the Guide's chapter on IPRs, the Bank offers explicit guidance to developing countries on how to use the flexibilities of the TRIPS and of their own legislation in order to obtain the lowest possible prices while ensuring a standard quality of the supply of pharmaceuticals and other medical products. The publication of the Technical Guide was welcomed by some NGOs and activist organizations.<sup>39</sup>

The impact of the Bank's position on the global market appears limited by the relatively modest amount of its own pharmaceutical lending. However, it might have a strong demonstration effect on countries and on other institutions, such as the Global Fund for AIDS, TB and Malaria, based on the prestige and leverage that the Bank has on economic and policy issues in the international arena. The strategies and procedures initially applied in the field of HIV/AIDS products may be extended later to other therapeutic areas, where IPR-related high prices may constrain the affordability of essential drugs, especially among the poor in developing countries.

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37. Ramphela & Stern, *supra* note 11, at A19.

38. THE WORLD BANK, *supra* note 28.

39. See, e.g., Posting of Brook Baker, B.Baker@neu.edu, to IP-Health@cptech.org (Feb. 26, 2004), <http://lists.essential.org/pipermail/ip-health/2004-February/005987.html>; Posting of Michael Palmedo, mpalmedo@cptech.org, to IP-Health@cptech.org (Feb. 24, 2004), <http://lists.essential.org/pipermail/ip-health/2004-February/005982.html>.

ANNEX 1: PROCUREMENT METHODS RECOMMENDED BY THE WORLD BANK

According to the World Bank's procurement guidelines,<sup>40</sup> it is one of the Bank's roles to review the procurement process and to ensure that it is performed in accordance with the procedures established in these guidelines.

In each particular case, the procurement method and the category of goods are agreed upon by the Bank and the borrower and are specified in the loan agreement.

The procurement guidelines offer the following methods:

1. International competitive bidding (ICB) is generally required for all individual procurements valued at US\$200,000 or more. This value is different from region to region and even within regions there are differences among countries "although exceptions can be made in appropriate circumstances."<sup>41</sup>
2. National competitive bidding (NCB) is applicable in those cases where there is not enough foreign competition. National Competitive Bidding (NCB) is the competitive bidding procedure normally used for public procurement in the country of the borrower. NCB may be the preferred method of procurement where foreign bidders are not expected to be interested because: (a) the contract values are small, (b) works are scattered geographically or spread over time, (c) works are labor intensive or (d) the goods or works are available locally at prices below the international market.<sup>42</sup>
3. Limited international bidding (LIB), which is essentially an ICB conducted by invitation to the suppliers or contractors to participate, is to be applied when there is only a limited number of potential suppliers. Limited International Bidding (LIB) is essentially ICB by direct invitation without open advertisement. It may be an appropriate method of procurement when (a) the contract values are small, (b) there are only a limited number of suppliers, or (c) other exceptional reasons may justify departure

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40. See THE WORLD BANK, STANDARD BIDDING DOCUMENT PROCUREMENT OF HEALTH SECTOR GOODS (2000).

41. *Id.* at 106.

42. *Id.* at iv.

- from full ICB procedures.<sup>43</sup>
4. Shopping (International, ISH or National, NSH) is a procurement method based on comparing price quotations obtained from several suppliers, usually not less than three, and is an appropriate method for procuring readily available off the shelf goods or standard specification commodities that have a small value.<sup>44</sup>
    - a. International shopping (ISH) generally implies soliciting bids from at least three suppliers in at least two different countries and is usually restricted to procuring small volumes of goods.
    - b. National shopping (NSH) from local supplier may be used where the desired goods are ordinarily available from more than one source in the country of the borrower at competitive prices.
  5. Direct contracting (DIR) can be utilized when goods can be obtained just from one supplier. DIR without competition may be an appropriate procurement method when (a) an existing contract for goods or works may be extended for additional goods or works of a similar nature, (b) standardization of equipment or spare parts, to be compatible with existing equipment, may justify additional purchases from the original supplier, (c) the required equipment is proprietary and obtainable only from one source, (d) the contractor responsible for a process design requires the purchase of critical items from a particular supplier as a condition of a performance guarantee, or (e) in exceptional cases such as in response to natural disasters.<sup>45</sup>
  6. Procurement may be made from United Nations's sources or other agencies, applicable for a total amount of procurement up to USD\$5 million for U.N. agencies and USD\$ 250,000 for NGOs.<sup>46</sup>

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43. *Id.* at 23.

44. *Id.* at 21.

45. *Id.* at iv.

46. *Id.* at vi.

