

How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?

Poverty, not patent policies, more often inhibits access to essential medicines in the developing world.

by Amir Attaran

ABSTRACT: This paper studies the relationship between patents and access to essential medicines. It finds that in sixty-five low- and middle-income countries, where four billion people live, patenting is rare for 319 products on the World Health Organization's Model List of Essential Medicines. Only seventeen essential medicines are patentable, although usually not actually patented, so that overall patent incidence is low (1.4 percent) and concentrated in larger markets. This and other results shed light on the policy dialogue among public health activists, the pharmaceutical industry, and governments that is often based on mistaken premises about how patents affect corporate revenues or the health of the world's poorest. Pragmatism and greater flexibility are urged, so that policy may better concentrate on the greater causes of epidemic mortality, which now pose unprecedented threats to global peace and security.

IN THE PAST TWO YEARS international concern has focused on whether pharmaceutical patents interfere with access to "essential medicines" in lower-income countries. The question has spawned an international debate, engaging the United Nations (UN), World Trade Organization (WTO), and of course activists and pharmaceutical companies. While all agree that patents should never endanger the health outcomes of the world's poorest people, there is little agreement on how significant this threat is, or what steps are best to end it.

This study tests the extent to which pharmaceutical patents in developing countries can thwart access to essential medicines. This can be done by quantifying the frequency with which "essential medicines," as defined by the World Health Organization (WHO), are patented in low- and middle-income countries, emphasizing Africa, where access to medicines is the worst. I examine these data by statistical methods, to identify correlates of patent practice and access to medi-

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cines. Briefly, I find that patents for essential medicines are uncommon in poor countries and cannot readily explain why access to those medicines is often lacking, suggesting that poverty, not patents, imposes the greater limitation on access.

Study Methods

The study ascertained the patent status of essential medicines in three steps: first, by identifying a list of medicines widely considered “essential”; second, by identifying the subset of those that were theoretically patentable in 2003; and third, by surveying pharmaceutical companies and their patent agents to determine where and how the latter are now patented in developing countries.

Because opinions necessarily differ as to which medicines are “essential,” the author did not judge this but deferred to the WHO’s Thirteenth Model List of Essential Medicines (the WHO-EML).¹ The WHO-EML is selected every one to two years by the Expert Committee on the Selection and Use of Essential Medicines, a panel of independent specialists (not WHO employees) drawn about equally from among experts based in developing and developed countries. Where a medical condition has more than one therapeutic option using different medicines, the Expert Committee designates medicines for the most cost-effective treatment to a “core list” and costlier or less appropriate medicines to a “complementary list,” both of which are considered here.

The 319 products on the WHO-EML were examined to identify the subset of products that are recent enough to be theoretically patentable. Briefly, we searched several printed and electronic pharmaceutical patent reference sources by chemical family or brand name, or both, for each specific product on the WHO-EML, to identify the earliest U.S. patent for the active pharmaceutical ingredient(s) or their combination, which we called the “basic patent.”² Global patent treaties normally require that patent applications for all countries be filed within a year of each other and stipulate a patent term of twenty years following the date of application.³ Thus, we assumed that any product for which the basic patent was sought before 1 April 1982 is no longer patented worldwide. The same applies for ancient or nonpharmacological “medicines” on the WHO-EML that appear to have no basic patent (such as aspirin, ethanol, or oxygen) and products whose description does not correspond to a single patentable product (such as condoms, influenza vaccine, or antivenom serum).

Foreign patents are also likely to exist for products whose earliest basic patent application postdates 1 April 1982. We therefore searched two commercial patent databases, INPADOC (European Patent Office, Munich) and Derwent WPI (Thomson Derwent, London), which yielded preliminary, unverified patent data for some developing countries. Because these databases can be inaccurate and omit patents of many African countries, we also issued written surveys to the manufacturer of each product. The surveys asked the respondent to disclose current patent(s) and pending application(s), including “mailbox” applications, for

which the patentee had the expectation of grant, for the formulation(s) and dosage(s) on the WHO-EML.⁴ We also asked respondents to characterize the nature of their patent claims: for example, the active pharmaceutical ingredient, manufacturing process, pharmaceutical formulation, or method of use. The survey covered sixty-five diverse countries, including all of Africa (the continent where patients' access to essential medicines is worst, hypothetically because of patents); major countries such as Brazil, China, India, Indonesia, Mexico, and Russia (each is the most populous in its geographic region and thus the most important in public health and economic terms); and if not already captured by the preceding criteria, additional middle-income countries (necessary to statistically test the hypothesis that wealth affects patenting frequency).⁵ This extensive sample comprises more than four billion people, or roughly two-thirds of the world's population, and a majority of those living in developing countries. Survey responses were entered into an Excel spreadsheet and verified by respondents for accuracy as of May 2003. Multiple regression and nonparametric hypothesis testing were done using Intercooled Stata.

Because our research method relied on surveys completed by many different respondents, a small number of errors are likely to remain even after several rounds of verification, although not so many as to materially affect our conclusions. Although this is satisfactory for an academic study, given the serious legal consequences of patent infringement, we strongly recommend that anyone wishing to rely on these findings obtain independent legal advice before doing so.

Study Results

Quantitatively, only 19 of 319 items on the WHO-EML have basic patents post-dating 1 April 1982, which means that they might still be patented in developing countries. However, the basic patents on two of these products are not actually effective: The patent rights to eflornithine were donated by its inventor to WHO for the public good, and in most countries the patent rights to tamoxifen have expired (excepting the United States, where the patent term was unusually delayed).⁶

Thus, only seventeen items on the WHO-EML might be effectively patented in developing countries now, so as to reliably exclude generic competitors. Of these, most are for HIV/AIDS, a recent disease that consequently lacks older medicines. We assembled the current country-by-country patent status of these medicines, based on the survey methods described above, except for Cipro (ciproflaxin), whose manufacturer (Bayer) refused to cooperate with repeated requests for data. Therefore, Cipro's patent status is obtained from commercial patent databases, which probably underestimate the actual patents and applications. Space limitations preclude presenting these data in detail here, but the information is available as a free online supplemental table.⁷ The data disclose three key observations.

■ **Number of medicines under patent.** The typical developing country is likely to have many fewer essential medicines under patent or pending application than

the seventeen it could theoretically have (median and mode = 4 medicines; n = 65 countries), and this remains true even when the eight countries having zero patents or applications, possibly because they lack pharmaceutical patenting laws or a functioning patent office (median and mode = 4 medicines; n = 57 countries), are excluded. The likely reason for this is that pharmaceutical companies usually did not seek patents in developing countries, even when they legally had the option. Of the 969 cases where companies probably could have obtained and maintained patents for these essential medicines (fifty-seven countries with patent laws times seventeen patentable medicines), they did so in 300 cases, or 31 percent of the time.

■ **Effect of market size.** The frequency of patenting in a country is largely explained by its market size. An inventor's incentive to patent (for medicines or otherwise) is greatest where there are more consumers having more disposable income. We found in a multiple linear regression model that the patent laws are used more frequently in developing countries having larger populations, richer per capita national income, or a higher Gini coefficient (a measure of domestic income inequality).⁸ This model should be viewed cautiously because all of these socioeconomic data are available for only a modest number of countries (n = 37), although it explains fully half of the variance in how often their patent laws were used (adjusted $R^2 = 0.54$) and accords with the theory that patents are especially infrequent in the poorest or smallest countries.

■ **Access to generics.** Owing to the several influences already described, patents very infrequently block access to generic versions of essential medicines. For the sixty-five countries we studied, where the majority of people in the developing world live, patents and patent applications exist for essential medicines 1.4 percent of the time (300 instances out of 20,735 combinations of essential medicines and countries). However, this overstates the frequency with which patents totally block access to generics, because it is only a subset of patents that are absolutely fundamental and that generic manufacturers can never circumvent (normally, a patent on the active pharmaceutical ingredient, and for medicines containing two such ingredients, a patent on their co-formulation). By this standard, there are 186 fundamental patents or applications, or 0.9 percent of the total. Thus, there are no patent barriers to accessing generic essential medicines in 98.6 percent of the cases we studied, which we stress is an overall probability and not prognostic in any specific case.

Although an absence of patents and barriers to treatment is the norm, the exceptions include certain outlying countries (such as South Africa) and outlying medicines for which patents are frequent, including antiretrovirals, whose indication is in combination therapy, so that a patent on even one medicine can limit access to fully generic-based therapy.⁹ Although the intercountry variation is readily understood in terms of the three regressors already discussed, this variation is purely idiosyncratic and reflects the highly differing views of companies on which markets are worth protecting by patent (compare, for example, the antiretrovirals of GlaxoSmithKline and Merck). Although it would be desirable to statistically

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weight the patent data together with prevalence data for the relevant diseases, this is not reliably possible because of the poor quality of epidemiological statistics in many developing countries. Nevertheless, the medical significance of each patent varies based on the epidemiological condition of the country where it is found: For example, a patent on Viramune (nevirapine), which is used for perinatal HIV prophylaxis, obviously can affect health outcomes more where HIV prevalence is high.¹⁰ For these reasons, the statistical norm must be interpreted with caution and with awareness that certain excursions from it can be highly significant for public health.

Discussion

Although it has been speculated that only a small percentage of essential medicines are patented in developing countries, this is the first study to use data at the level of single countries and products to discern between two possible causes: (1) that many essential medicines are old and no longer patentable, and (2) that companies did not frequently make use of patent laws, even where they could.¹¹

To understand why this is, consider that in very poor, low-income developing countries, predominantly in Africa, annual drug spending may be \$2 or less per person.¹² With so little revenue at stake, most drug companies decided to forgo patent protection in these countries, and patenting is commonplace only in large, middle-income countries (such as China, South Africa, and Mexico). Past decisions to forgo patenting are now largely irreversible because of deadlines in international patent treaties that bar active pharmaceutical ingredients from being retroactively patented (although improved formulations are patentable).

These data allow the reexamination of some settled assumptions. There is a belief in the activist community that patents are “a barrier in many [developing countries] to accessing affordable medicines” and, balancing it, a belief in the pharmaceutical industry that it is “necessary to protect intellectual property rights on a global scale” to assure future research and development activities and the industry’s commercial viability.¹³

Both of these views are greatly exaggerated. Patents cannot cause essential medicines to be inaccessible in “many” developing countries because they do not exist 98.6 percent of the time; similarly, patents cannot be a “global” necessity of pharmaceutical business because companies forgo them 69 percent of the time. A limited number of exceptions reduce each figure to somewhat below 100 percent, but as an empirical reality those exceptions—and therefore the contentious ground dividing these opposing views—are few.

Unfortunately, these data and their implications may tend to fuel controversy

rather than reconciliation, as did a forerunner of this study that was cited overenthusiastically by industry and condemned as “sabotage” by activists.¹⁴ But controversy misses the point: The value of these data is to illuminate the most expeditious route to improve access to medicines for the world’s poorest people and not to polarize a debate among policy elites.

■ **Potential objections.** Critics might object that our data are unreliable because respondents could have intentionally deceived us. That is possible but unlikely: Companies that admit to not having patents in a country are probably truthful because the alternative—concealing patents that do exist—invites unwanted generic competition. Avoidance of generic competition is reportedly what motivated one company (Bayer) to withhold data from this study, because the company did not want it known that its most profitable medicine (Cipro) is rarely patented.¹⁵

Another possible objection is that our analysis is too limited because it defines “essential medicines”—a subjective, imprecise term—as being only those medicines on the WHO-EML. Médecins sans Frontières (MSF), for example, writes that “many drugs that are medically essential are not included on the [WHO-EML] because they are too expensive...[or] are still under patent.”¹⁶

However, the evidence does not support MSF’s interpretation. In current and past years, the Expert Committee’s procedures state that the “patent status of a medicine is not considered” and that the “absolute cost of [a] treatment...[is] not...a reason to exclude a medicine” from the WHO-EML.¹⁷ Instead of having regard to a medicine’s patent status or cost, the Expert Committee bases its decisions on various medical criteria and the cost-effectiveness of overall treatment, of which medicines are only a part. Thus, the committee has sometimes listed off-patent medicines (such as enalapril) instead of newer, patented alternatives (such as ramipril or quinapril); and conversely, the committee has sometimes listed patented medicines (such as azithromycin) over medically less desirable but unpatented alternatives (such as tetracycline).¹⁸ Whenever a person believes that a medicine is essential and deserves a place on the WHO-EML, that person can apply to the Expert Committee using a formal procedure to have it listed, as universities, companies, and activists (including MSF) have done.

Accordingly, there is no evidence for the proposition that costly or patented medicines are automatically excluded from the WHO-EML. The Expert Committee explicitly says that it does not consider and discriminate based on patent status, and if it does so implicitly, there is a transparent procedure in which anyone can apply to correct that.

■ **Future trends.** What this means is that the Expert Committee holds medical evidence paramount in its decisions. Over time, the evidence will justify both additions to and deletions from the WHO-EML, and patents will expire—there is constant flux. The number of patented essential medicines has declined modestly, from nineteen medicines in 2002 to seventeen in 2003. That number could again rise in coming years if the Expert Committee lists some further patented medicines in

planned revisions to some therapeutic categories (the anaesthetics, antiasthmatics, antifungals, cephalosporins, and so on), or if the long drought of new medicines for tropical diseases is ended.¹⁹ Those new additions of patented medicines to the list will be offset against the inevitable expiration of patents on antiretroviral medicines, so that only a small number of essential medicines will likely be patented, now and in coming decades.

This fact lends an important perspective on one prominent hypothesis: that access to essential medicines will worsen after 2005, when the WTO's TRIPS agreement obliges most developing countries (including those that can manufacture generics, such as India) to fully adopt pharmaceutical patent laws, and again in 2016 when most least-developed countries must do so.²⁰ Although theoretically correct, in reality this hypothesis is undermined by a key observation: Many countries, including twenty-eight of the thirty least-developed African countries, adopted pharmaceutical patent laws years or decades ahead of being required to by TRIPS—meaning that the feared watersheds at 2005 and 2016 have already occurred to a large extent.²¹ Despite this, patents for essential medicines remain infrequent, both because pharmaceutical companies chose to patent their inventions in few developing countries, and because the Expert Committee only rarely chose to list patented medicines as essential. This time-proven behavior, and the fact that a large part of the ostensible “post-2005” or “post-2016” law reforms have occurred already, suggests a modest future impact on access to medicines.

■ **Legal versus targeted adjustments.** Nevertheless, developing countries are correct to demand some adjustment in the post-TRIPS legal order, because a modest future impact is not the same as zero impact. Medical ethics forbids overlooking the treatment needs of patients who might be affected by the 1.4 percent of cases where patents for essential medicines exist. The challenge is to find the wisest mitigating policies for those cases.

After years of debate, the WTO enacted a mitigating policy in August 2003, which allows patent rights to be forcibly overridden using a legal procedure called “compulsory licensing,” so that generic medicines can be manufactured and exported to poor countries that cannot manufacture their own.²² It is extremely doubtful that this use of compulsory licensing, although much celebrated, can be made practicable. Indeed, compulsory licensing is so disused that even where a country's own citizens might benefit from it—never mind foreigners in poor countries—zero generic medicines have been manufactured this way in the past decade, treating zero patients in any country worldwide.²³ Threats of compulsory licensing might be useful when rattling sabers with drug companies to lower medicine prices, but only a single (and unusually powerful) developing country, Brazil, has ever succeeded in so doing. As such, compulsory licensing or the threat of it has seldom had any practical effect for public health.

Our data suggest that the interests of both public health and the pharmaceutical industry could be met more expeditiously and with less conflict. Rather than

relying solely on law reform, as the WTO continues to contemplate, it would be easier and swifter to bring targeted relief to the few cases (1.4 percent for now) where essential medicines are patented in developing countries.²⁴ Two main options now exist to do this.

First, nearly all of the patented, brand-name essential medicines (except Cipro and Lariam) are deeply discounted in developing countries, so that the original products and their generic counterparts are often priced similarly—there is no rule that one be cheaper than the other. Price data gathered by MSF in late 2003 show that some brand-name products can cost more than generics (for example, nevirapine made by Boehringer Ingelheim and by Hetero), while others can cost less (for example, ritonavir made by Abbott and by Cipla).²⁵ These discounts have ended the order-of-magnitude price differences that formerly made generic treatment imperative, but, unfortunately, they have not cooled overwrought debate, as exemplified by accusations of pricing “genocide.”²⁶

Second, acrimony could be avoided if brand-name companies agreed to voluntarily license generic alternatives for their few patented essential medicines, on restricted terms that would allow competition to lower prices in developing countries, but which excluded that competition and preserve the core pharmaceutical markets of rich countries. How to do this using a technique called “out-licensing” is detailed elsewhere by a consensus group from the pharmaceutical industry, the nonprofit sector, and academe.²⁷ That proposal should be revisited, because the evidence is that with only seventeen out-licenses (one for each patented essential medicine), pharmaceutical companies could totally answer the concern that patents deprive the world’s poor of essential medicines, while winning praise for helping to develop new products that are badly needed for public health reasons (for example, fixed-dose combinations of antiretrovirals). Taken together, those seventeen out-licenses would affect the companies’ revenues negligibly and would signal the pharmaceutical industry’s goodwill as no other gesture has. The current counterexamples, where companies grant “voluntary” out-licenses only under the imminent threat of litigation (as did Boehringer Ingelheim and GlaxoSmithKline) or renege on promises to do so once memory fades (as did Pfizer, which acquired a promise by Pharmacia), are self-sabotaging and therefore unwise: Each such action further confirms activists’ belief that pharmaceutical companies will not yield patent rights except if confronted and attacked.²⁸ Over time those confrontations shape the public’s perception that pharmaceutical companies and patents are an evil to be fought against—and the long-term risks of that attitudinal shift in rich countries can be extremely damaging to the companies. As one observer wisely commented, “When an industry goes to the length of suing Nelson Mandela in defense of its patents [as pharmaceutical companies did in South Africa], people get the idea that patents matter.”²⁹

We therefore recommend that the industry adopt a more flexible and preemptive attitude where the small numbers of patented essential medicines in develop-

ing countries are concerned. This should include both to out-license and to deeply discount (or donate) those medicines routinely. The industry's usual reluctance to engage this recommendation is that basing these concessions on the WHO-EML would politicize the Expert Committee and expose it to intense lobbying by activists and the industry. Although that would probably happen, it also should not be feared: A debate conducted within the Expert Committee's transparent, fair, evidence-based procedures would achieve more rational outcomes both for public health and for business, compared with the heated exchanges that now shape policy incoherently.

If companies undertook these steps systematically, they would make essential medicines more accessible to the world's poor while reaffirming their unique moral stature as a industry that saves life. Both are deserving goals but are under common threat, because the pharmaceutical industry and activists often believe that patents in developing countries are more significant than they really are.

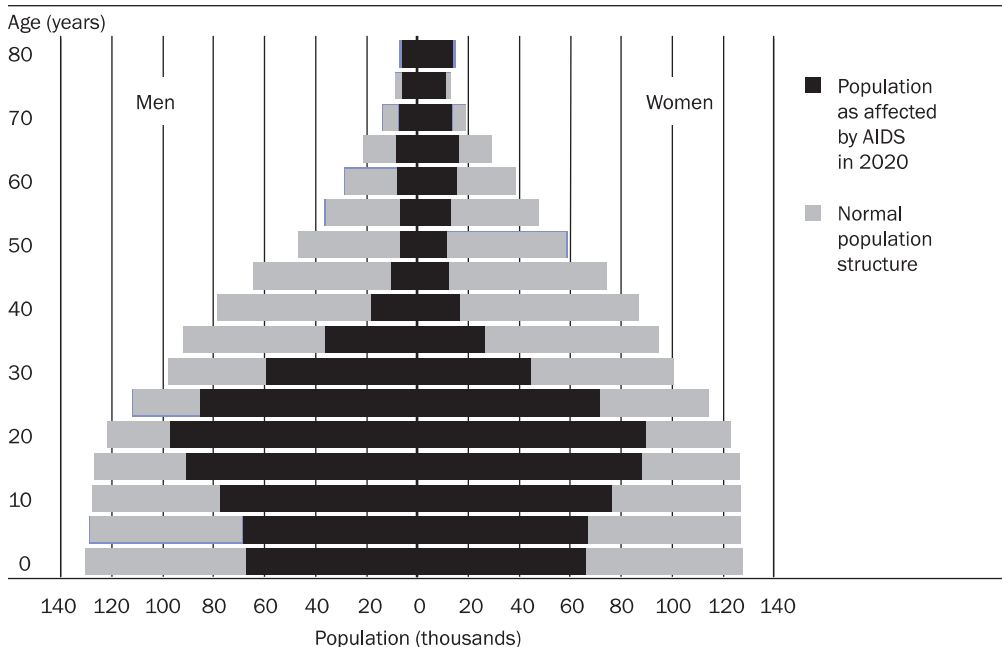
■ **Workings of poverty.** Conciliation on patents would not change the abhorrent fact that one-third of people in developing countries have no access whatsoever to essential medicines, including the vast majority that are not patented and are manufactured as generics in developing countries.³⁰ Delivering essential medicines reliably could save up to ten million lives a year—18 percent of the world's deaths.³¹ The limitation, fundamentally, is poverty. In a separate analysis we found that the “low-income” countries in our sample provide inferior access to essential medicines compared with the “middle-income” countries, and this observation is statistically highly significant ($p = .001$ by the Wilcoxon rank-sum test; $n = 60$ countries).³²

These findings deserve clear-headed attention, because while public health scholars have taken an interest in the workings of patents, far less attention is paid to the workings of poverty, although it is the more basic reason why billions of people lack medical treatment. Comparing the two most prominent global development issues now before the WTO, the public health community is greatly concerned about the few cases (1.4 percent) of patented essential medicines in developing countries but almost totally silent on the enormous agricultural subsidies (\$310 billion) of Asian, European, and North American governments, which deny the agrarian populations of poor countries the opportunity to export products and accumulate wealth.³³ The subsidies alone are roughly equal to the entire gross domestic product (GDP) of sub-Saharan Africa. Redirecting just 1 percent of this government spending to global health would more than double the foreign aid spent to control HIV/AIDS, malaria, and tuberculosis combined.

This view is shared by leaders where it matters most—in Africa. After having successfully led his country through the world's largest reduction in HIV/AIDS prevalence, President Yoweri Museveni of Uganda opines that giving priority to medicine patents in trade negotiations has been a “red herring” and that “if there were no agricultural subsidies...[Africans] would earn enough money to buy all the drugs we want.”³⁴

However contrary or wild President Museveni’s point of view might seem, the data and analysis in this paper lend general—although qualified—support to his position. The patenting data prove that patents are an infrequent determinant of access to essential medicines, while the economic data leave no doubt that the failure of billions of patients to receive necessary therapies is largely a consequence of economic policies that are in need of study and reform by public health scholars. It is no exaggeration to say that failing to engage policy on these terms amounts to a suicide pact with epidemic disease, as whole societies—and probably democratic governments—crumble in demographic conditions that are almost certain to spawn civil unrest and war (Exhibit 1). No pandemic such as AIDS has occurred since the Enlightenment, and the most evolved democratic institutions are woeful at dealing with it. Therefore, the ongoing conflict over patents must be resolved swiftly, as is easily done, and the energies now spent on that issue redirected toward these more pressing challenges, which affect health, democracy, and security collectively. That is what the data justify doing.

EXHIBIT 1
Projected Population Structure With And Without The AIDS Epidemic, Botswana, 2020



SOURCE: U.S. Census Bureau, World Population Profile 2000, as presented in Monitoring the AIDS Pandemic (MAP) Network, *The Status and Trends of the HIV/AIDS Epidemics in the World*, Provisional Report, 5–7 July 2000, www.census.gov/ipc/www/hivdurbn.html (1 March 2004).

NOTES: Botswana would ordinarily have many children and teenagers (gray bars at bottom) and declining numbers of young, middle-aged, and elderly adults (tapering gray bars). However, HIV/AIDS shatters this demographic structure (black bars), portending a society where most of the adult authority figures are dead (for example, parents, teachers, police, military), with orphaned children and teenagers as Botswana’s most numerous citizens. Similar epidemiological conditions prevail across all of southern Africa. Widespread, immediate access to antiretroviral therapy can somewhat avoid this outcome.

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 The author has consulted and acted as an adviser for Médecins sans Frontières, Novartis, the World Bank, the United Nations Development Program, and the World Health Organization. No pharmaceutical funding was accepted in the course of designing and executing this study.

NOTES

1. World Health Organization, "The Selection and Use of Essential Medicines: Report of the WHO Expert Committee (Including the Thirteenth Model List of Essential Medicines)" (draft report), 2003, www.who.int/medicines/organization/par/edl/expcom13/unedited_report.doc (17 February 2004).
2. Four published sources were consulted: U.S. Department of Health and Human Services, *Approved Drug Products*, 7th–20th eds. (Washington: GPO, various years); Pharmaceutical Research and Manufacturers of America, *Patents on Medicinal Products* (Washington: PhRMA, 1993); IMS Health, *Drug Patents International, STN Database—DRUGPAT* (London: IMS World Publications Ltd., 2002); and Merck and Company, *The Merck Index*, 13th ed. (Whitehouse Station, N.J.: Merck and Company, 2001).
3. For the one-year window to file applications, see Paris Convention for the Protection of Industrial Property, 20 March 1883 (as amended), Art. 4c. For the twenty-year patent term, a minimum that is rarely exceeded, see Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), being Annex IC to the Final Act and Agreement Establishing the World Trade Organization, 15 December 1993, Art. 33.
4. TRIPS, Art. 70:8.
5. Access-to-medicines data are found in United Nations Development Program, *Human Development Report 2001* (New York: Oxford University Press, 2001), Statistical Annex. Population data are found in United Nations Population Fund, *State of World Population* (New York: UNFPA, 2002).
6. For eflornithine, see WHO, "Orphan Drug Finds Home," Press Release, 6 December 1999, www.who.int/inf-pr-1999/en/pr99-74.html (17 February 2004). For tamoxifen, see U.S. Patent no. 4,536,516.
7. Supplemental Exhibit 1 is available online at content.healthaffairs.org/cgi/content/full/23/3/155/DC1.
8. A multiple regression of patent-related variables on thirty-seven countries yielded an adjusted R^2 value of 0.54 and the following coefficients on the independent variables: per capita gross national income (GNI) (under a natural log transformation), 1.26; population (under a natural log transformation), 1.05. The Gini coefficient was .15 and the constant was -12.35. *P* values for all coefficients and the constant were significantly different from zero at the .989 level of confidence. Populations were obtained from the Organization for Economic Cooperation and Development (OECD) Online Creditor Reporting System, Reference-Indicators Database, data year 2000, www1.oecd.org/dataoecd/50/17/5037721.htm (4 March 2004). Per capita national incomes and Gini coefficients were obtained from UNDP, *Human Development Report 2001*.
9. A. Attaran and L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" *Journal of the American Medical Association* 286, no. 15 (2001): 1886–1892.
10. R. Laing et al., "Twenty-five Years of the WHO Essential Medicines Lists: Progress and Challenges," *Lancet* 361, no. 9370 (2003): 1723–1729.
11. Panos Institute, "Patents, Pills, and Public Health: Can TRIPS Deliver?" (London: Panos Institute, 2002).
12. World Bank, *Better Health in Africa: Experience and Lessons Learned* (Washington: World Bank, 1994).
13. The activist view is found in Médecins sans Frontières, Oxfam Canada, Canadian HIV-AIDS Legal Network, Interagency Coalition on AIDS and Development, Canadian Council for International Cooperation, and Canadian Treatment Action Council, "An Open Letter to All Members of Parliament," 25 October 2001, www.msf.ca/access/pics/msf_letter_par_e.pdf (31 December 2003). The industry view is found in H.E. Bale, "The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals," *Journal of International Economic Law* 1, no. 4 (1998): 637–653.
14. The study that generated this controversy was Attaran and Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" For an example of activists' condemnation, see MSF, "Patents Do Matter in Africa According to NGOs, Joint Statement by Oxfam, Treatment Action Campaign, Consumer Project on Technology (CPT), Médecins sans Frontières (MSF), and Health GAP," 17 October 2001, www.accessmed-msf.org/prod/publications.asp?scntid=171020011428553&contenttype=PARA& (17 February 2004). For the industry's praise, excerpted and objected to in a letter by the study's author, see A. Attaran, "African AIDS Fight Held Back by Spin Doctoring," *Financial Times*, 2 April 2003.
15. This is as communicated by an anonymous Bayer employee.

16. Quotation from MSF, "Frequently Asked Questions," www.accessmed-msf.org/campaign/faq.shtml (9 June 2003). See also N. Ford and E. 't Hoen, "Generic Medicines Are Not Substandard Medicines," *Lancet* 359, no. 9314 (2002): 1351.
17. WHO, "Procedure to Update and Disseminate the WHO Model List of Essential Medicines," WHO Doc. no. EB109/8 (Annex), www.who.int/medicines/organization/par/edl/procedures.shtml (20 September 2002).
18. These examples are from the most recent revision to the WHO-EML; see Note 1.
19. For the priority in which the Expert Committee will revise these and other therapeutic categories of the WHO-EML, see Note 1.
20. TRIPS, Art. 65:4; and Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: Department for International Development, 2002).
21. For a synopsis of national patent laws, see *Manual for the Handling of Applications for Patents, Designs, and Trade-marks throughout the World*, Looseleaf (Utrecht: Manual Industrial Property BV, 2000). Also see C.M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO Doc. no. WHO/EDM/PAR/2002.3 (Geneva: WHO, 2002).
22. WTO, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," WTO doc. WT/L/540, 30 August 2003, www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (31 December 2003).
23. A. Attaran, "Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution," *Emory International Law Review* 17, no. 2 (2003): 743–780.
24. *Ibid.*; and WTO, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," paragraph 11.
25. MSF, "Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries (5th edition)," 1 December 2003, www.accessmed-msf.org/prod/publications.asp?scntid=20120041143274&contenttype=PARA& (4 March 2004).
26. P. Redfern, "Aids Drug Firms Are Accused of Genocide," *Nation* (Nairobi), 1 April 2001.
27. M. Friedman, H. den Besten, and A. Attaran, "Out-Licensing: A Practical Approach to Improving Access to Medicines in Poor Countries," *Lancet* 2003, no. 9354 (2003): 341–344.
28. S. Hensley, "Pfizer Makes Aid Pledge, Breaks Pact on AIDS Drug," *Wall Street Journal*, 12 November 2003; and J. Donnelly, "Deal Paves Way for Generic HIV Drugs," *Boston Globe*, 11 December 2003.
29. The reference is to a lawsuit brought by thirty-nine pharmaceutical companies against the government of South Africa, which was widely (although inaccurately) said to affect AIDS medicines and in which the plaintiff companies overzealously named Nelson Mandela as a respondent: *Pharmaceutical Manufacturers' Association of South Africa and others v. The President of the Republic of South Africa the Honourable Mr. N.R. Mandela and Others*, Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division). Personal communication with an anonymous source, 2003.
30. G.H. Brundtland, "Essential Medicines: Twenty-five Years of Better Health," *Journal of the American Medical Association* 288, no. 24 (2002): 2101; and H.E. Kettler and R. Modi, "Building Local Research and Development Capacity for the Prevention and Cure of Neglected Diseases: The Case of India," *Bulletin of the World Health Organization* 79, no. 8 (2001): 742–747.
31. WHO, *World Health Report 2002* (Geneva: WHO, 2002). Death statistics are found in Annex 1.
32. For 2002 the World Bank defined "low-income" and "middle-income" countries as those having a per capita gross national income of below \$735, or between \$736 and \$9,075, respectively. See World Bank, Country Classification, www.worldbank.org/data/countryclass/countryclass.html (31 December 2003). Data for access to essential medicines 2343 obtained from Attaran and Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?"
33. OECD, *Agricultural Monitoring in OECD Countries: Monitoring and Evaluation 2002* (Paris: OECD, 2002), Annex Table 7. For an introduction to the poverty-generating effects of agricultural subsidies, see the 2003 *New York Times* article collection, Harvesting Poverty, www.nytimes.com/ref/opinion/harvesting-poverty.html (31 December 2003).
34. "Africans for Drug Patents" (Editorial), *Wall Street Journal*, 7 November 2003.