Medicines, Patents,

Has the intellectual property pact opened a Pandora's box for the pharmaceuticals industry?

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IF YOU HAD asked the average policy wonk in the field of finance or development about TRIPS, even until a few years ago, you would probably have elicited a quizzical expression of bemusement, betraying mild condescension: how important can *that* be compared with broader and weightier matters, such as exchange rates, fiscal policy, aid, and debt?

But the agreement on TRIPS, or the Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (see box), has turned out to be among the more significant elements of international cooperation and treaty making in the past decade. Negotiated during the 1986–94 Uruguay Round of world trade talks, TRIPS introduced intellectual property rules into the multilateral trading system for the first time. For developing countries, this has had profound consequences, not all of which have been beneficial, making TRIPS a bellwether of the antiglobalization backlash of recent years. In particular, the high prices of AIDS treatments have shined an ethical spotlight on patent protection. Ironically, and as a testament to the iron law of unintended consequences, TRIPS may well prove to have as great an impact on medicines and health policy in industrial countries.

TRIPS and pharmaceuticals

For developing countries, the most important aspect of the TRIPS agreement relates to its provisions on patents, especially as they affect pharmaceuticals. Prior to TRIPS, most developing countries had "weak protection" for pharmaceutical patents. This took the form of short patent terms (typically 4–7 years), narrow scope for defining the invention to facilitate ease of imitation, and relatively permissive use of compulsory licensing to dilute the monopoly power of the patent holder. (Compulsory licenses allow third parties to exploit the technology protected by the patent. Patent holders are compensated, albeit only partially, for the dilution of their exclusive rights through the payment of royalties.) Industrial countries, in contrast, provided "strong protection," with a patent term of about 20 years and limited possibilities for imitation or dilution of monopoly power.

In the Uruguay Round, which offered scope for bargaining and the exchange of concessions between countries, developing countries sought compensation for the likely negative impact of TRIPS. Industrial countries agreed to liberalize their textiles, clothing, and agricultural markets to provide increased access to the exports of developing countries. Higher standards of protection for intellectual property in exchange for better access for clothing and agricultural goods thus constituted the grand bargain in the Uruguay Round between industrial and developing countries.

Why strengthen patents?

In the TRIPS negotiations, developing countries were asked to strengthen their patent protection to levels prevailing in industrial countries. But what is the likely economic impact on developing countries? According to economic theory, stronger patent protection has two conflicting effects on economic welfare. In the short run, it confers monopoly power on

What is TRIPS?

The TRIPS agreement of the World Trade Organization (WTO) requires all member countries to adhere to minimum standards of intellectual property protection (for example, all technological inventions must be protected for at least 20 years). TRIPS constitutes one of the three pillars on which the WTO now rests, along with trade in goods and trade in services.

The minimum standards of protection in TRIPS cover different kinds of intellectual property, including patents (which grant market exclusivity for technological inventions), copyright (for artistic and literary works), and trademarks (for names and symbols). TRIPS requires that these standards be effectively implemented by all WTO members. This means that countries should have legal and administrative procedures under the national courts that would allow holders of property rights—domestic and foreign—to seek and obtain redress in the event that their rights are infringed. If a WTO member fails to embody these standards in national law or to implement them, it can be challenged by trading partners under the WTO dispute settlement procedures.

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patent holders, reducing competition and increasing prices in the market in which the patented product is sold. In the long run, by providing rents or monopoly profits, it increases the incentive to undertake research and development (R&D), by allowing the fixed costs of R&D to be recouped. Better incentives, in turn, confer long-run dynamic gains in terms of improved technology and better products. Societies that have adopted patent protection have judged that, on balance, the dynamic gains outweigh the short-run efficiency costs.

For developing countries, however, the economic calculus is different for two reasons. First, as net users rather than net exporters of R&D–intensive products, they do not benefit from the monopoly profits that are created by patent protection. On the contrary, their consumers suffer from the higher prices that result. Second, because their markets are small in relation to global demand—at least for pharmaceutical products to treat a number of diseases such as cancer, hypertension, and ulcers—actions taken by developing countries to strengthen patent protection have little impact on the incentive to undertake additional R&D. Thus, a combination of higher costs in the short run and the likely absence of dynamic gains over time means that raising levels of protection would not benefit developing countries.

A number of studies have shown that the net economic welfare losses to developing countries of higher patent protection for pharmaceuticals could be substantial. For example, analytical models predict that the price of drugs could increase by 25–50 percent if patent protection is introduced. Simple comparisons of prices of drugs in countries with and without patent protection also support this finding. Table 1 shows the prices of selected drugs in the United States and the United Kingdom (countries with strong protection) compared with those in India and Brazil, where protection is relatively weak. In the case of the antiretroviral triple combination for fighting AIDS, prices in the industrial countries were over $10,000 compared with prices of $200–$350 in India, a differential of 4,000 percent.

More broadly, developing countries have maintained that standards of patent protection should rise naturally over time as countries develop rather than be forced up prematurely. Indeed, this has been the historical experience in relation to pharmaceutical patents. For example, Table 2 illustrates that the major industrial countries adopted strong patent protection at high levels of real income (upwards of $20,000 per capita), whereas under TRIPS, developing countries will be required to adopt similar standards at much lower income levels (between $500 and $8,000 per capita).

AIDS alters perceptions

The global AIDS crisis altered the TRIPS landscape dramatically. The ravage wreaked by AIDS underlined the very high costs of AIDS treatments and the unaffordability of relief to patients in developing countries. The focus naturally shifted to patent protection as a cause of these high costs and to whether such protection—enforced around the world by TRIPS—was defensible, not just from an economic but also from an ethical perspective.

For the poorest countries, particularly in Africa, where drug needs were especially pressing, the problem with TRIPS was serious. Lacking the expertise to produce drugs domestically and unable to afford drugs produced in industrial countries, they sought to rely on cheaper imports from other developing countries. However, a relatively obscure provision of the TRIPS agreement presented a serious obstacle to such a course of action. Spurred by the support of civil society and aided by the force of international moral outrage, the poorer countries pressed for a change to the TRIPS agreement that would allow them to import AIDS drugs and other medicines from cheaper sources in developing countries. In August 2003, agreement was reached in

Table 1
Comparison shopping

Prices of antiretroviral triple-combination AIDS drugs vary widely. (May 2003)[1]

Originator company in industrial country	$10,439
Brazilian company	$2,767
Indian company A	$350
Indian company B	$201

Source: http://www.accessmed-msf.org/documents/untangling4thapril2003.pdf.
[1]Stavudine + lamivudine + nevirapine.

Table 2

Earlier adoption

Under TRIPS, developing countries are being asked to adopt strong patent protection at much lower income levels than developed countries did.

	Year of adoption	GDP per capita (1995 U.S. dollars)
OECD adopters		
Japan	1976	24,043
Switzerland	1977	36,965
Italy	1978	13,465
Holland	1978	20,881
Sweden	1978	21,896
Canada	1983	16,296
Denmark	1983	28,010
Austria	1987	25,099
Spain	1992	14,430
Greece	1992	10,897
Norway	1992	30,389
Recent adopters		
China	1992/3	424
Brazil	1996	4,482
Argentina	2000	8,100
Uruguay	2001	6,208
Guatemala	Future	1,545
Egypt	Future	1,191
Pakistan	Future	508
India	Future	450
Malawi	Future	156

Source: Lanjouw, Jean, 2002, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, CGD Working Paper No. 5 (Washington: Center for Global Development).

Note: China GDP is for 1992. For countries adopting after 1999, the GDP per capita figure is for 1999.

Geneva among member countries of the World Trade Organization (WTO) to remove the final patent obstacle to cheap imports of drugs by the least developed countries and other developing countries. Under this agreement, countries that cannot produce drugs domestically and that seek to obtain them from cheaper sources would be allowed to do so subject to certain conditions aimed at preventing abuse, for example, reexporting the drugs to industrial country markets.

Of course, this agreement will not, of itself, address the serious health challenges facing Africa. Broader action to improve domestic delivery systems and health-related institutions is also necessary. But the recent agreement to create the conditions for drugs to be delivered to patients at the cheapest possible prices is a step in the right direction.

The Dracula effect

The immediate problems of access to affordable medicines faced by the poorest countries in the world have, to some extent, been addressed by the recent agreement. But the controversies and tensions over affordable medicines are far from over. Ostensibly, these have related to access in the poorest countries. The real battleground, however, is going to be the larger markets both in developing countries and in the industrial countries themselves.

In the larger developing countries with indigenous pharmaceutical sectors—such as Brazil, India, South Africa, and Thailand—the key issue is whether the TRIPS agreement affords them enough flexibility to dilute the monopoly power, conferred by TRIPS on pharmaceutical companies, through the use of compulsory licensing. In a series of skirmishes between developing country governments on the one hand and foreign companies and their governments on the other, the limits of what the TRIPS agreement permits have been tested. Brazil, South Africa, and Thailand have all authorized the production of patented drugs by their own firms to reduce the prices of AIDS drugs and help address their own public health challenges.

The consequences in industrial countries could be profound too. The TRIPS debate has highlighted the large wedge between the cost of supplying drugs by generic producers in developing countries and the prices charged in industrial countries. Increasing public awareness of this discrepancy—what might be called the Dracula effect because of the perceived price gouging in industrial countries—has led consumer and civil society groups in industrial countries to question whether patent protection is too restrictive and whether the resulting prices are excessively high. In their defense, major pharmaceutical producers argue that, in contrast to the generic manufacturers, they spend a significant portion of their revenues on research for new drugs. Against the background of runaway health costs in the United States and the consequent fiscal pressures, drug prices in industrial countries have also become an important public policy issue, leading to calls in the United States for imports from Canada, where prices are lower. In a number of industrial countries such as Australia, Canada, and New Zealand, public health systems use reference pricing to provide drugs at the lowest available prices.

Beyond TRIPS

The TRIPS agreement has opened a Pandora's box of issues going beyond the WTO. First, with respect to medicines, the international community has come to a collective understanding that the poorest countries need not contribute to global R&D creation. That, in short, is the significance of the recent agreement in Geneva. But there is still no consensus on the contribution to global R&D that should be made by larger or richer developing countries. It is not unreasonable for the pharmaceutical companies and the international community to ask that the rich within developing countries also contribute to the supply of global public goods, such as R&D. But even if this principle were accepted, the implementation challenges would be immense, requiring segmentation and targeting in developing countries, which have not proved successful in other areas, such as aid delivery.

A second issue relates to the incentives that need to be created for increased R&D for cures and technologies that are endemic and specific to the poorest countries. Although developing countries account for a small share of a number of common diseases (such as cancer and hypertension), they do account for a very large share of diseases endemic to the tropics, such as diphtheria, encephalitis, malaria, sleeping

sickness, measles, and polio. For these diseases, patent protection could, in principle, be an important incentive to promote innovation to find cures. The question remains whether this would be a sufficient condition given the low incomes and small markets. The focus appears to be shifting to finding the most efficient ways to fund and deliver the supply of global goods of particular and specific importance to the poorest countries, especially in Africa. Recent suggestions by Michael Kremer of Harvard and Jeffrey Sachs of Columbia to create a fund to reward the discovery of cures for malaria and AIDS are a welcome step.

A third issue is whether the current societal arrangements embodied in the system of intellectual property protection are the best way of ensuring the optimal creation and dissemination of knowledge and R&D. The intellectual property system is subject to the famous assignment problem first described by the Nobel prize winner Jan Tinbergen. Society has two objectives when it comes to such public goods as knowledge and R&D—creation and invention, on the one hand, and their diffusion and dissemination, on the other. But the intellectual property system deploys one instrument—according monopoly power to the creator—that promotes R&D creation but thwarts the objective of efficient dissemination. Hence its inadequacy. Moreover, as currently implemented, the intellectual property system is also a very blunt instrument: patent protection is awarded for 20 years for all inventions, irrespective of their type, sector, and other characteristics, even though there is no evidence that the optimal trade-off between invention and diffusion is the same for inventions in pharmaceuticals as it is in such fields as chemicals and biotechnology.

An ideal system would use two instruments: the first would provide the best incentives for creating knowledge and recovering the large fixed costs involved in this process, while the second would ensure that, once created, the invention could be made available at the marginal cost of production to maximize the benefits from diffusion and dissemination. The search for this ideal system will no doubt be a long one as new technological developments combined with changing values and politics expose existing deficiencies. But, TRIPS may well have accelerated the search for this system. ■

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