TRIPS, Medicines, and Patents

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

Arvind Subramanian

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 surprise and bemusement, betraying mild condescension: how important can that be compared to broader and weightier matters such as exchange rates, fiscal policy, aid, and debt?

But TRIPS, or the Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (see box), has turned out to be one of the more significant elements of international cooperation and treaty-making in the last decade. Negotiated in the 1986-94 Uruguay Round of the World Trade Organization (WTO), TRIPS introduced intellectual property rules into the multilateral trading system for the first time and had profound consequences for developing countries. These consequences have not all been beneficial, making TRIPS a bellwether of the anti-globalization backlash in recent years, with the high prices of AIDS treatments putting 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 durations for the patent term (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. Industrial countries, in contrast,
provided “strong protection,” comprising a patent term of about 20 years, with 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 was thus the grand bargain in the Uruguay Round between
industrial and developing countries for TRIPS. In the absence of such compensation, it would
probably have been very difficult for developing countries to agree to TRIPS

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, strengthening patent protection has
two conflicting effects on economic welfare. In the short-run, it confers monopoly power on
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, by allowing the fixed costs of R&D to
be recouped. This in turn confers 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, the economic calculus is, however, different for two reasons. First, as net users rather than net exporters of research and development-intensive products, they do not benefit from the monopoly profits that are created by patent protection although, their consumers suffer from the higher prices that result. Second, because their markets are small in relation to global demand—at least for a number of diseases such as cancer, hypertension, and ulcers—actions by them to strengthen patent protection has 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 be beneficial to them.

A number of studies have shown that the net economic welfare losses to developing countries of higher patent protection for pharmaceuticals could be substantial. Evidence for this comes from two sources. For example, analytical models predict price increases for drugs consequent upon the introduction of patent protection of between 25 and 50 percent. Suggestive evidence is also provided by simple comparisons of prices of drugs in countries with and without patent protection. For example, Table 1 provides 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 anti-retroviral triple combination for fighting AIDS, prices in the industrial countries were over $10,000 compared, with prices of between $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 being 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 shed light on 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 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 imports from other developing countries as a cheaper source for drugs (Table 1 illustrates the cost differential). 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 Geneva amongst WTO member countries 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 elsewhere would be allowed to do so subject to certain conditions aimed at preventing abuse, for example, in the form of re-exporting 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 are also necessary. But the recent agreement is a step in the right direction, creating the conditions for drugs to be delivered to patients at the cheapest possible prices.

**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 relates to whether the TRIPS agreement leaves them with 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 has been
tested. Brazil, Thailand, and South Africa have all authorized the production of patented
drugs by their own firms to reduce prices of AIDS drugs and help address their public health
challenges.

The consequences in industrial countries could be profound too. The TRIPS debate
has thrown the spotlight on the large wedge between the cost of supplying drugs by generic
producers in developing countries and 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 level of prices is overly high. Against the background of runaway health costs in the
United States and the consequent fiscal pressures, drug prices have become an important
public policy issue. This has led to calls for imports from Canada, where prices are lower. In
a number of industrial countries such as Australia, Canada, and New Zealand, public health
systems seek to provide drugs at the lowest available prices, the practice of reference pricing.

**Beyond TRIPS**

TRIPS has opened a Pandora’s box of issues going beyond the WTO. First, in relation 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. On
the one hand, 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 proven successful in other areas such as aid-delivery.

The second issue relates to the incentives that need to be created for increased R&D on cures and technologies that are endemic and specific to the poorest countries. Although developing countries account for a small share of global demand for a number of common diseases (such as cancer or 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 finding 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 Jeffrey Sachs and Michael Kremer to create a fund to reward the discovery of cures for malaria and AIDS are a welcome step in the right direction.

The third issue relates to 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 public goods such as knowledge and R&D—creation and invention on the one hand, and its diffusion/dissemination on the other. But the intellectual property system deploys one instrument—according monopoly power to the creator—which 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 other fields such as chemicals or biotechnology.

An ideal system would use two instruments: the first would provide the best incentives to 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, hopefully, TRIPS has accelerated the search for this system.

*The author is a Division Chief in the IMF’s African Department and worked on the TRIPS agreement as a member of the GATT Secretariat during the Uruguay Round.*

*Further reading:*

Table 1

Comparison shopping

Prices of anti-retroviral triple-combination AIDS drugs vary widely

(May 2003) /1

<table>
<thead>
<tr>
<th>Originator company in industrial country</th>
<th>$10,439</th>
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<tbody>
<tr>
<td>Brazilian company</td>
<td>$2,767</td>
</tr>
<tr>
<td>Indian company</td>
<td>$350</td>
</tr>
<tr>
<td>Indian company</td>
<td>$201</td>
</tr>
</tbody>
</table>

1/ stavudine+lamivudine+nevirapine

Table 2

Development Level on Adoption of Pharmaceutical Product Patents

<table>
<thead>
<tr>
<th>Panel A: OECD Adopters</th>
<th>Year of Adoption</th>
<th>GDP per capita (1995 U.S. $)</th>
</tr>
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<tbody>
<tr>
<td>Japan</td>
<td>1976</td>
<td>24,043</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1977</td>
<td>36,965</td>
</tr>
<tr>
<td>Italy</td>
<td>1978</td>
<td>13,465</td>
</tr>
<tr>
<td>Holland</td>
<td>1978</td>
<td>20,881</td>
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<tr>
<td>Sweden</td>
<td>1978</td>
<td>21,896</td>
</tr>
<tr>
<td>Canada</td>
<td>1983</td>
<td>16,296</td>
</tr>
<tr>
<td>Denmark</td>
<td>1983</td>
<td>28,010</td>
</tr>
<tr>
<td>Austria</td>
<td>1987</td>
<td>25,099</td>
</tr>
<tr>
<td>Spain</td>
<td>1992</td>
<td>14,430</td>
</tr>
<tr>
<td>Portugal</td>
<td>1992</td>
<td>10,469</td>
</tr>
<tr>
<td>Greece</td>
<td>1992</td>
<td>10,897</td>
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<td>Norway</td>
<td>1992</td>
<td>30,389</td>
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</table>

<table>
<thead>
<tr>
<th>Panel B: Recent Adopters</th>
<th>Year of Adoption</th>
<th>GDP per capita</th>
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</thead>
<tbody>
<tr>
<td>China</td>
<td>1992/3</td>
<td>424</td>
</tr>
<tr>
<td>Brazil</td>
<td>1996</td>
<td>4,482</td>
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<tr>
<td>Argentina</td>
<td>2000</td>
<td>8,100</td>
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<td>Uruguay</td>
<td>2001</td>
<td>6,208</td>
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<tr>
<td>Guatemala</td>
<td>Future</td>
<td>1,545</td>
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<td>Egypt</td>
<td>Future</td>
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<td>Future</td>
<td>508</td>
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<tr>
<td>India</td>
<td>Future</td>
<td>450</td>
</tr>
<tr>
<td>Malawi</td>
<td>Future</td>
<td>156</td>
</tr>
</tbody>
</table>

Box

What is TRIPS?

TRIPS is an agreement of the World Trade Organization (WTO) requiring 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, along with trade in goods, and trade in services, constitutes the three pillars on which the WTO now rests.

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 in 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.