TRIPS: Controversies and potential reform

BY KEITH E. MASKUS

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The WTO Ministerial Conferences in Seattle in 1999 and Doha in 2001 may have marked a new era in global trade negotiations. In particular, governments of developing countries are becoming increasingly assertive in criticizing the structure of the trading system and presenting their own positions. The Seattle meeting failed in part because developing countries pushed for changes in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and were unwilling to countenance strengthening its standards as advocated by the United States. At Doha, the WTO members agreed to relaxed interpretations of the obligations many of the least-developed countries found onerous or impossible to meet, most significantly in the treatment of patents for essential medicines.

FROM SEATTLE TO DOHA

The road from Seattle to Doha was not travelled by trade ministers alone. As it became clear that TRIPS standards could restrain government policies in health care, agriculture, environmental protection, education, and technology supports, wider official interests questioned the utility of these standards. Numerous NGOs made their views known about how TRIPS might make more costly the provision of global collective goods in such areas as medicines, food security, and biodiversity. In turn, media interest has mushroomed with regard to the implications of global protection of intellectual property rights (IPRs). Official organizations, such as the WTO, the World Health Organization, the World Bank, and UNCTAD (UN Conference on Trade and Development), now devote increasing resources to conceptualizing IPRs as a development issue.

TRIPS raises a number of controversies, ranging from concerns over costs and availability of medicines, agricultural chemicals, new seed varieties, and software, to the implications of asserting private ownership rights over life forms, genetic resources, and biotechnological inventions. For such reasons, there are numerous proposals to scale back, alter, or clarify the provisions of TRIPS.

At the same time, developing countries wonder if there might be gains

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- through continuous negotiations it exerts constant pressure to open services to foreign commercial providers;
- the GATS MFN rule helps consolidate commercialization;
- the GATS monopoly provisions make it more difficult for governments to maintain public services by hamstringing their ability to compete;
- where GATS commitments are made, the GATS restricts the ability of governments to restore, revitalize or expand public services; and
- in such cases, compensation must be negotiated or retaliatory sanctions faced.

Similarly, the GATS does not *eliminate* governments' ability to regulate, however,

- the recognition of the right to regulate in the preamble has little legal effect;
- the GATS clearly applies to government regulatory measures, whatever their form or purpose;
- the GATS applies a very tough test of non-discrimination when considering the possible adverse effects of domestic governmental measures on foreigners;
- the GATS prohibits certain types of measures, whether they are discriminatory or not; and
- negotiations to apply a necessity test to non-discriminatory domestic regulation pose a very serious threat to crucial regulatory instruments.

Apparently, the GATS strongest proponents would prefer to keep these threats out of public view. But they are unlikely to succeed in this. The negotiations to broaden and deepen GATS coverage will make services one of the centrepieces of the new round of WTO negotiations launched recently in Doha. The existing GATS and the negotiation to expand it raise such serious challenges to democratic governance that they are certain to stimulate even greater public interest and controversy.

With only modest effort, non-governmental organizations, elected officials, and ordinary citizens are more than capable of understanding the GATS and its critical implications for public policy. When they do, they are likely to react with disapproval at how far this, nominally, *trade* agreement intrudes into the crucial regulatory prerogatives of democratic *governance*. Hopefully, this will result in greater public mobilization to bring citizens' considerable influence to bear on their respective governments, both to change the nature of GATS negotiations now underway in Geneva and to chart a more balanced future for the multilateral system.

from extending TRIPS to areas of their own comparative advantage. Chief among these are geographical indications for food products and collective marks for textile designs and other products of traditional knowledge. For their part, developed countries (chiefly the United States and the European Union) remain interested in incorporating stronger protection for copyrights on Internet transmissions, databases, and other areas.

The stage is set for additional negotiations in the next WTO round. Whether there is scope for agreement depends on numerous factors. A reasonable prediction is that TRIPS is unlikely to be strengthened in the interests of intellectual property (IP) developers unless there are serious commitments by the rich countries to provide additional market access to poor countries in agriculture and labour-intensive goods and services. Beyond that, it is difficult to foresee what might emerge.

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WHAT DOES DOHA SAY ABOUT IPRs?

The Doha meeting produced declarations on two issues of great concern to developing countries.

First, members agreed that TRIPS does not prevent countries from taking measures to protect public health and promote access to medicines for all. They affirmed that members have freedom to determine grounds on which compulsory licenses may be granted and to establish exhaustion regimes. Members instructed the TRIPS Council to find a solution before the end of 2002 for the problem that countries with weak manufacturing capabilities may not be able to use compulsory licences effectively. Least-developed countries were excused from the obligation to patent pharmaceutical products and to safeguard confidential test data until the year 2016. While this compromise did not go as far as many developing countries wished, it provides considerable leeway for poor countries to limit patent rights in their territories for purposes of public health.

Second, members affirmed that the provisions of article 66.2 of TRIPS are mandatory, so that developed countries must establish incentives for their enterprises to transfer technology to least-developed members. Many developing countries are frustrated that, despite claims made by advocates of TRIPS, little has been done to promote such technology transfer. This issue alone threatened to derail any prospect for moving forward in the IP area.

Both TRIPS advocates and critics hailed these agreements as victories. The agreement on pharmaceuticals and compulsory licences essentially recognized that poor countries could not meet their obligations and needed flexibility in procuring medicines in light of major health difficulties. In that regard, it affirmed the limitations inherent in TRIPS without explicitly abandoning the patentability of new drugs per se.

TRIPS CONTROVERSIES

There are many issues currently under international debate. First, many developing countries find the requirement to establish administrative systems and effective enforcement procedures for IPRs to be costly relative to any gains they might anticipate, particularly because economic benefits will go largely to foreign firms over the intermediate term. Technical and financial assistance for funding these costs has been small in relation to overall needs. If IPR holders wish to see their rights protected in poor countries, some international mechanism for generating such funds must be found. In a related vein, pressures are building for developed countries to make effective their commitments to encourage technology transfer.

Second, countries are exploring the flexibility provided by TRIPS in the area of patent eligibility, scope, compulsory licensing, and other exemptions. Of particular concern are the implications of pharmaceutical product patents for prices and availability of new drugs and for generic competition. It is fair to claim that TRIPS implicitly condemns weak patent rights as a means of industrial policy (consider the WTO panel ruling against Canada's provisions for early stockpiling) while condoning them as health policy in cases of emergency. In practice this distinction will be difficult to make as

the recent Brazilian case suggests. Required patents will place considerable pressure on countries with significant generic industries, such as India and China. For the least-developed countries, the issue will remain costly procurement under difficult conditions. It is evident that no comprehensive and lasting solution may be found for this problem without significant infusion of public monies from the rich nations.

PATENTING LIFE FORMS

Article 27.3 of TRIPS is a delicate—some would say confused—compromise about patenting life forms. It requires patenting of microorganisms, micro-biological processes and non-biological processes, while permitting members to exclude traditional breeding methods and higher (generally interpreted as multicellular) life organisms. Thus, countries must make complex determinations of what is a micro-organism, what is non-biological, and whether to patent such items as genetic sequences, biotechnological research tools, cloned animals and plants, and genetically modified plants and animals, such as the Harvard Oncomouse. A number of poor countries have opted for strong protection, essentially adopting WIPO (World Intellectual Property Organization) model laws in this regard—a questionable tactic.

The area of patents in biotechnology is intensely controversial. Within developed economies, many scientists worry that the award of broad claims on genetic sequences and research tools is overly protective and may diminish future research progress. At the international level, while developing countries might choose not to patent certain products emerging from biogenetic processes, they cannot prevent other countries, such as the United States, from issuing patents on products that use resources extracted from their territories unless they can demonstrate the existence of written prior art. Thus, considerable concerns exist about "biopiracy," or the uncompensated extraction of genetic resources for making pharmaceuticals and cosmetics. TRIPS, which recognizes private rights to such products, and the Convention on Biodiversity (CBD), which claims that the underlying resources are owned, or managed by, sovereign nations, are inconsistent in this regard. Efforts to date to establish systems of prior informed consent and benefit-sharing agreements in such resources have been limited.

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NEW PLANT VARIETIES AND PROTECTION FOR GEOGRAPHICAL INDICATORS

Third, whether they adopt patents in the area or not, countries are required to provide effective protection for new plant varieties, in the form of plant breeders' rights (PBRs). Such systems provide exclusive marketing rights for developers of new plant varieties (including those of genetic modification) but permit farmers to retain seeds for replanting and some scope for rival firms to use the protected materials as parents for their own breeding programs. A number of countries have followed the US model of permitting plant developers to opt for PBRs, patents, or both, which raises questions about the consistency of rights. A looming controversy relates to whether so-called genetic-use restriction technologies (GURTs) must be patented under TRIPS.

Fourth, TRIPS requires governments to protect confidential test data issued in the act of achieving regulatory approval for medicines, foods, and other products. TRIPS is silent on the length of time required for this protection and countries have adopted several different standards. The United States has advocated a global standard of at least five years of protection, while Argentina and Brazil have opted for far-shorter periods. In its accession agreement with the WTO, China adopted a 10-year term of protection, making its standard higher than most international norms.

Fifth, a number of countries are now pushing for an extension of the WTO system for protecting geographical indications for wines and spirits to foodstuffs and plant strains for which the regional location of production imparts certain characteristics desired by consumers. In this way it is thought that countries might assert protection over such widely used terms as basmati rice and Darjeeling tea, though the prospects for doing so are weak. For new, or not widely known, products with geographical characteristics, however, this approach could be of some value to exporters. Some observers advocate

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applying geographical indications to such items as textile and carpet design, which would be more problematic. A more promising approach would be the establishment of collective marks that identify groups within which distinctive designs would be registered.

WHERE TRIPS MIGHT EVOLVE

Given these complex questions, it is difficult to predict where the agreement might move in the next round. As noted earlier, any strengthening of TRIPS, and perhaps any attempt to avoid its being weakened, likely will depend on serious commitments on market access in agriculture and textiles by the rich countries. Beyond that basic observation, however, we might expect to see negotiations along several lines.

To begin, some resolution of the issues discussed above must be found. Some of the inconsistencies may be sorted out through dispute settlement over the next several years, particularly with regard to enforcement obligations. Most complex is the area of biotechnology patents and genetic resources, along with the inconsistency between TRIPS and the CBD. Also important are the scope of geographical indications across products and the duration of protection for test data.

A further complex question is whether the TRIPS agreement is the appropriate location for establishing protection norms for collective and traditional knowledge, including oral histories, artistic works, music, designs, medical preparations, and methods of production. It is difficult to protect these items with traditional IPRs because they are traditional (not novel) and collectively known.

Thus, programs to develop new rights, combining elements of collective marks, copyrights, and trade secrets along with *sui generis* recognition of traditional practices, will be advanced forcefully by developing countries. One highly contentious issue is whether patents should be available anywhere for items that had been known to the public by means of oral tradition, permitting oral prior art to defeat patent applications. The United States is adamantly opposed to this possibility.

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The scope of copyright protection for digital products placed on the Internet, involving rights for artists, producers, and performers, remains unclear. The WIPO Copyright Treaty and Phonograms Treaty provide a means for incorporating these rights into TRIPS, so long as countries retain flexibility to establish liberal fair use of Internet transmissions for educational and research purposes.

Finally, developing countries are faced with the prospect of establishing competition regimes with regard to abuses of intellectual property rights. In this context there is some potential for international negotiations over broader competition issues.

MOVEMENT TOWARD GLOBAL HARMONIZATION

By setting out high minimum standards, albeit with some flexibility in their application, TRIPS establishes a significant movement toward global harmonization of IP norms. To economists, this is remarkable given the evident differences in costs and benefits from IPRs across countries at different levels of development. For example, the agreement mandates a minimum 20-year patent term in all countries. TRIPS is, therefore, a "one size fits all" approach to a complex set of economic, political, and social factors. While harmonization may generate global efficiency gains in principle, the distributional effects may make the agreement internationally unsustainable without effective compensation to developing nations. So far there is little evidence of such compensation being paid, either explicitly or implicitly. Indeed, the tendency seems to be one of a "race to the top"—for example, the nearly completed Patent Harmonization Treaty would considerably harmonize examination standards across countries, most likely on the US and European models.

An alternative approach would be to recognize the importance of private IPRs but to depart from global harmonization. To some degree, the Doha Declaration already achieved this by extending transition periods for least-developed countries in pharmaceuticals. However, the principle could be broadened to other departures from unity, such as differential terms of patent protection keyed to levels of economic development.