Intellectual Property Protection in the World Trade Organization

Major Issues in the Millennium Round

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Trade-related aspects of intellectual property rights (TRIPS) and the Uruguay Round

The negotiation to launch the Uruguay Round negotiation took almost as long as the entire Tokyo Round negotiations of the 1970s. The Americans had been trying to launch a new round since the early 1980s because of dissatisfaction with the results of the Tokyo Round and rising protectionist fury in Congress (mainly because of the over-valued dollar). After a number of near failures, the Uruguay Round was launched in Punta del Este in September 1986 and formally concluded in Marrakesh, Morocco in April 1994, several years later than the target completion date originally announced. The extraordinary difficulty in both initiating and completing the Round stemmed essentially from two fundamental factors: the nearly insuperable problem of finishing the unfinished business of past negotiations, most of all business about agriculture, and the equally contentious issue of introducing quite new agenda items, notably trade in services and intellectual property and, though in a more limited way, investment. The Europeans blocked the opening of negotiations to avoid coming to grips with the Common

Notes will be found on page 204.

Agricultural Policy (CAP) and a number of developing countries, led by Brazil and India, were bitterly opposed to including these so-called new issues. In the end, the final trade-off involved a deal across the old and new issues, a deal that transformed the world trading system.

Although the new issues are *not* identical—obviously negotiations on telecommunications or financial services differ from intellectual property rights—they do have one common characteristic: they involve not the border barriers of the original GATT but domestic policies embedded in the institutional infrastructure of the economy. The barriers to access for service providers stem from laws, administrative actions, or regulations that impede cross-border trade and investment. Further, since these laws and administrative actions are for the most part invisible, a key element in any negotiation is *transparency*—i.e. the publication of all relevant laws, regulations, and administrative procedures. These principles are now embodied in the General Agreement on Trade in Services or GATS, an integral part of the new world trading system housed in the WTO.

While GATS was hailed as a major breakthrough, especially since the United States had been trying since the 1970s to include trade in services in GATT negotiations, the inclusion of intellectual property rights in the world trading system was arguably an even more radical transformation of the traditional concept of a trading system. In the case of intellectual property, the negotiations covered not only comprehensive *standards* for domestic laws but, perhaps more importantly, detailed provisions for *enforcement procedures*. And, transparency was highlighted by the establishment of a separate council to which notification of all regulations and administrative arrangements must be made and this council is mandated to monitor compliance.

Perhaps most significantly, the preamble to the TRIPS Agreement states that intellectual property rights are "private rights" that must be enforced by member countries. If such rights are not enforced, the WTO dispute settlement procedures—"the most ambitious worldwide system for the settlement of disputes among more than 130 states ever adopted in the history of international law" (Petersmann 1998: 183)—provides the ultimate guarantee of protection. It is important to note that a major reason business lobbies wanted intellectual property in the Uruguay Round (see below) was that the United Nations agency, World Intellectual Property Organization (WIPO), had no enforcement mechanism.

The inclusion of the new issues in the Uruguay Round was entirely an American initiative and the policy was largely driven by the American multinational enterprises (MNEs). Indeed, without a fundamental rebalancing of the GATT, it seems highly improbable that the American

business community or politicians would have continued to support the multilateral system for much longer (Ostry 1990: 23). On the intellectual property issue, the main impetus came from the pharmaceutical, software, and entertainment industries with the CEO of Pfizer playing a lead role as Chairman of the Intellectual Property Rights Committee (IPC). At the Punta del Este meeting in September 1986, many delegates were somewhat surprised to learn that the top priority of President Reagan for the Uruguay Round was to stop piracy since, unlike the services issue, the position of the United States on intellectual property had only been formalized a few months earlier.[1] But, by May 1988 the IPC, which had created an international business coalition including European and Japanese business organizations, presented a proposal that went well beyond eliminating piracy and included "minimum standards, enforcement mechanisms, and dispute settlement" (Ostry 1990: 24). This became the official American position and was supported by the European Union and Japan, who had been lukewarm or even hostile to including Intellectual Property Rights (IPRs) in a "trade" negotiation until prodded by their corporations.

While business lobbying was a major force in securing the TRIPS agreement, the role of the American government cannot be overlooked. Given the divide between North and South at the outset, the United States launched a multi-track policy. The NAFTA, completed two years prior to the conclusion of the Uruguay Round, helped the ratification of TRIPS not only by "locking-in" high standards but also by undermining Latin American cohesion in opposition. Equally effective was the use of unilateralism in the form of a new Special 301 of the 1988 Trade and Competitiveness Act targeted at developing countries with inadequate standards and enforcement procedures for the protection of intellectual property. Given a choice between American sanctions or a negotiated multilateral arrangement, the TRIPS agreement began to look better.

While TRIPS delivered the basic elements of the Intellectual Property Rights Committee (IPC) agenda, because all complex negotiations involve trade-offs—and the Uruguay Round was the most complex and ambitious in history—some key issues were left unsettled. These will be tackled in new negotiations, both regional and multilateral. What I want to deal with in the remainder of this paper are those that, in my judgement, are the most significant for the WTO's Millennium Round.

Intellectual property and the Millennium Round

The TRIPS Agreement rested on a trade-off between the North and the South that gave improved access to OECD markets for Southern agricultural and industrial products in exchange for a restructuring of the trading system in line with OECD countries' comparative advantage.

The new agenda will include some of the unfinished business of the Uruguay Round: cross-cutting issues such as parallel imports; the role of competition policy; the monitoring and enforcement and perhaps upgrading of standards. But, in the overall negotiations, these and, indeed, all other issues in the new intellectual-property negotiations will be profoundly shaped by the ongoing revolution in biotechnology and information technology, especially the former because of linkage with other key items in the agenda.

Biotechnology and environmental concerns

The TRIPS Agreement allows members to exclude from patentability certain plant and animal inventions. Article 27.3(b) provided for a review of these provisions in 1999 as part of the so-called built-in agenda. However, there have been such major changes in biotechnology in the 1990s that it is highly unlikely that the TRIPS Council can grapple with the issue. It will have to await a new round of negotiations.

As we have seen, the American pharmaceutical industry played a leading role in establishing TRIPS as a key part of the new trading system. The industry began undergoing a fundamental change in the 1990s as a consequence of what is called the molecular revolution, launched over 40 years ago by the discovery of DNA. Major advances in basic biological research, new experimental techniques such as X-ray crystallography and nuclear magnetic resonance, and vastly increased computing power have combined to transform the structure of the pharmaceutical industry. The large pharmaceutical companies have utilized scientific advances in genetics and molecular biology to "design" and manufacture synthetic drugs. At the same time, small-scale new entrants—often university spin-offs—are exploiting the techniques of genetic engineering, which involves the manufacture of proteins for treatment of disease. Collaborative arrangements such as research and development contracts, joint ventures, and venture capital investment are proliferating. The result of all this is a resurgent industry that has established a dominant position in world markets. As is shown by patent data in the 1990s, the United States has vastly outstripped Europe and Japan in biotechnology (Kortum and Lerner 1997). In the early 1990s, American companies held patents for 92 of the 100 most prescribed drugs.[2]

As described earlier, the American pharmaceutical companies led the international business coalition that forged the TRIPS Agreement and, since the stakes are even higher today, they are likely to play a similar role in the new negotiations. But the deal between North and South that underlay the Uruguay agreement is no longer feasible because of the prominence of environmental issues as a feature of trade negotiations.

The issues linking biotechnology and environment are complex. At the same time as the pharmaceutical industry was transformed by the technological revolution in biotechnology, another revolution in information and communication technology (ICT) was transforming the policy environment. The International Non-Governmental Organizations (INGOs) have existed for decades or longer but are far more active in the policy process today because ICT permits rapid and inexpensive global networking. And, they are very skilled in dealing with the media, especially television. The most prominent INGOs are the greens and they were already evident during the final stages of the TRIPS negotiations, covering Swiss highway bridges with graffiti admonishing "GATT: no patents on life!" and draping GATT headquarters building with a huge banner carrying the same message (Croome 1995: 255). Shortly after, Geneva was plastered with Gattzilla posters in response to a 1991 panel ruling that the United States violated its GATT obligations by banning Mexican tuna caught by a process that killed dolphins. But, their power today is far greater than in the early 1990s: marching in cyberspace is much cheaper and more effective than covering bridges with graffiti and buildings with posters. Moreover, the greens have mobilized impressive support among a wide range of other advocacy groups who, although for different reasons, see the WTO as an institution captured by, and serving only corporate interests. The green message seems to be the most effective rallying point because it is attractive to a large proportion of the populations, especially the younger generation searching for a worthy cause.

By way of a brief digression to illustrate this point, it is worth describing the successful campaign by the INGOs to defeat the OECD negotiations for a Multilateral Agreement on Investment (MAI) since it vividly illustrates the power of these new transnational actors. In October 1997, 47 NGOs from 23 countries and 5 continents met in Paris at OECD headquarters. The consultation had been arranged at the request of the World Wildlife Fund and some national representatives who had been lobbied by domestic advocacy organizations. The INGOs argued that the MAI would undermine sustainable development and national sovereignty. The most powerful case for this argument concerned the MAI's investor-protection mechanism. This replicated the investment provisions in NAFTA, which included procedures for resolving disputes by which private parties as well as governments could take action and adopted a very broad definition of investment expropriation, so broad it could lead to investor claims against government regulation in, say, environmental or health areas that negatively affect the value of investment. In Canada, American corporations had launched several cases against the government that

aroused a storm of opposition led by a coalition of NGOs. These same NGOs were among the most prominent in Paris in October 1997.

After the consultation, the groups at the meeting organized an anti-MAI coalition and launched an international campaign to stop the negotiations. A World Wide MAI Website List[3] displays 55 sites mainly from OECD countries and covering a wide range of interests; environmental and legal groups together accounted for more than half the total. Groups in Canada and the United States provided a constant flow of information to coordinate the campaign. By October 1998, the negotiations had been suspended and in December, after the official withdrawal of the French government at the request of the red-green members of the coalition, they were officially terminated. (The action of the French government is not without significance. While North American greens have chosen an advocacy route to contest the market for policy ideas, the European environmentalists have formed political parties and greens are now members of government coalitions in four countries in the European Union—Germany, France, Italy, and Finland—as well as increasingly prominent in the European parliament.)

Of course, there were a number of reasons why the MAI failed but there seems little doubt that the INGOs played a key role. At the press conference announcing the suspension of the negotiations, the two key problems cited were "countries' sovereignty with respect to regulation without being charged with expropriation and without being sued for compensation" and "the issue of protecting labour and the environment" (OECD Nations Forego MAI Decision, Agree to Examine Possible Changes 1998).

The example of opposition to the MAI illustrates the new contestability of the market for ideas shaping the policy process. And, whereas the ideas for TRIPS came mainly from the business community, the INGOs now are major players in the policy domain covering trade and the environment. While a full exploration of the trade and the environment agenda go well beyond the subject of this conference, the issue of IPRs is of central importance in the ongoing debate about how the WTO will handle environmental issues.

The WTO's Committee on Trade and Environment (CTE) was established at the Marrakesh meeting that concluded the Uruguay Round in April 1994 and its mandate was renewed in Singapore in December 1996. To date, however, it has accomplished little in achieving consensus on contentious issues such as patents for "genetically modified organisms" (GMOs) as well as the impact of inventions on the environment. In a recent review of the CTE's discussions prepared for a WTO Symposium on Trade and Environment in Geneva on March 15/16, 1999, the serious North-South conflicts are discreetly mentioned:

The Relevant Provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Item 8 of the Work Programme)

The objective of the TRIPS Agreement is to promote effective and adequate protection of intellectual property rights (IPRs). IPRs serve various functions, including the encouragement of innovation and the disclosure of information on inventions, including environmentally sound technology. In the context of trade and environment, the TRIPS Agreement has assumed increasing significance.

With respect to technology transfer, patents are perceived by some as increasing the difficulty and costs of obtaining new technologies which are required either due to changes agreed under certain MEAs (such as the Montreal Protocol) or in order to meet environmental requirements, both generally and in certain export markets. Also, there has been an increasing concern for the conservation and sustainable use of biological diversity. The rapid progress in the area of biotechnology has meant that greater importance is attached to easy access to genetic resources. Developing countries (many of which are the main suppliers of such genetic resources and biological diversity) have emphasized a *quid pro quo* in this context, involving easier transfer of technologies in return for them providing access to their genetic resources, and for undertaking policies aimed at conservation and sustainable use of biological diversity.

This has proven to be a particularly sensitive element of the CTE's work programme, particularly for India (who has proposed that exceptions be made in the TRIPS Agreement on environmental grounds for the transfer of technology mandated for use in an MEA), and for the United States (who defend IPRs as a necessary precondition for the transfer of technology). The links between TRIPS and the environment are complex and many of the issues involved are contentious.

The CTE has recommended that further work be undertaken on several issues. The issues which it raised include: the transfer of environmentally friendly technology, the protection of traditional rights and knowledge, controlling adverse environmental effects of technologies such as biotechnology, the WTO-consistency of certain provisions of the Convention on Biological Diversity (an MEA), and the agreement that would prevail if there was to be a conflict between the TRIPS Agreement and the Convention on Biological Diversity.

(World Trade Organization 1999: Annex 1, [7])

What is hinted at in this summary was much more explicit in the debate at the Symposium, which included government officials, representatives from intergovernmental institutions, and a large number of INGOs from both OECD and developing countries: a different kind of deal involving the transfer of funds and technology in exchange for access to the South's genetic resources between North and South would be needed to achieve consensus on IPRs in biotechnology . The idea of some sort of "distributional deal" aimed at achieving global environmental objectives had already been raised at the 1994 United Nations Conference on Environment and Development—the Rio Earth Summit— but there was no policy follow-up. And, the issue of IPRs adds another layer of complexity to the distributional matrix.

At the risk of great oversimplification, the basics of the game that will have to be played out involve two players: the OECD (mainly the United States), which generates the technology and know-how for the innovation process, and the less developed countries, which own 90 percent of the world's genetic resources that provide the major input for the innovation process. The legal system that will define rights to genetic resources will also help determine the allocation of the gains of innovation. Added to this dichotomy between North and South is the question of preserving biodiversity, the main concern of the Northern INGOs. Thus, while Northern and Southern INGOs often disagree, they were able to form a coalition on this subject—a good example of their skill in issue and venue shifting as required.

And, of course, it is not only the pharmaceutical industry with stakes in the outcome. As the 1999 Conference on Biosafety so vividly illustrated, the agriculture industries are also major stakeholders and, in this sector, countries like Mexico and Argentina, which are exporters, joined forces with the United States and Canada to foil the completion of an agreement. So, even the LDC alliance has some cracks in it. On the other hand, the profound differences now apparent between the attitudes of European and American consumers with respect to food made from genetically modified plants (what some British groups call "Frankenstein food") or hormone-treated beef demonstrate that all is not quiet on the Western front either.

So what does all this augur for IPR negotiations in the Millennium Round? Those without a reliable crystal ball would be wise to say it's impossible to forecast at this stage. It is reasonably clear, however, that while arguments can be made for the potential benefits to developing countries from the biotechnology revolution—for example, improving agricultural productivity with new plant varieties customized for specific climates, developing new drugs against disease prevalent in the developing world, using genetically modified micro organisms for en-

vironmental clean-up—the *quid pro quo* issue will remain and the final bargain will include a distributional element, not necessarily confined to IPRs but perhaps covering the negotiations as a whole.

Although biotechnology patents will be at the forefront of the new negotiations, because of the revolution in ICT a number of copyright issues will also have to be re-visited. These will be contentious but there is no clear divide between North and South. Rather, within the OECD countries themselves there are deep divisions among different interest groups (content producers, on-line service providers, hardware producers, and, of course, users or consumers). Thus the spillover from the copyright discussions to the rest of the negotiating agenda is likely to be constrained. The WTO has established a work program on electronic commerce as requested by the May 1998 Ministerial Meeting and this program includes an examination by the TRIPS Council of the implications for copyrights and other related issues. The results of this new program are unlikely to be conclusive but should provide a useful background to the new negotiations.

Finally, the built-in agenda of TRIPS also includes a number of important cross-cutting or generic issues left open at the end of the Uruguay Round. Of these, the most difficult is likely to be parallel imports or "exhaustion" in legal parlance. But it is also useful to review briefly competition policy and the basic issue of monitoring and enforcement.

TRIPS built-in agenda: generic issues

A key, but unsettled, issue in the TRIPS agreement concerns the question of where and when the property rights are "exhausted." Since IPRs are granted in a given country, they ensure that the owner can prevent others from producing and distributing the good or service in that country. But what about the same goods imported from other countries on the basis of local ownership of IPRs? Different countries have different rules about such "parallel imports": the European Union permits parallel trade internally but forbids it externally and the United States has a total ban on parallel imports. TRIPS negotiators failed to reach an agreement on the subject and thus Article (6) in effect permits each WTO member to treat parallel imports in the manner it considers best-suited to its own interests: "For the purpose of dispute settlement under this Agreement ... nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights." Related to this question of parallel imports is the interrelationships of IPRs and competition policy since, in effect, restriction of parallel imports amounts to government permission for vertical restraints in a specified territory. The TRIPS agreement does not spell out what practices should be treated as illegal but provides some

illustrative examples that could be treated as abuses; i.e. the Agreement is permissive rather than mandatory.

The ongoing debate among IPR experts and economists about the pros and cons has been well presented in a number of legal and economic journals; indeed a cottage industry has now emerged in preparation for the Millennium Round (Special Issue [JIEL] 1998; Barfield and Groombridge 1999). One version of the argument in favour of restriction of parallel imports is that the positive dynamic benefits that would accrue from the MNE's ability to customize production (and prices) for different markets would outweigh the static efficiency losses from restricting trade. Further, along this line of thought, if there is a competition policy problem in any given market, it is likely to arise from lack of horizontal (*inter*-brand) rather than vertical (*intra*-brand) competition and should be handled by anti-trust and not intellectual property policy.

The arguments against restriction—supported most strongly by the LDCs—usually begin by noting the irony or paradox of a WTO based on liberalizing trade but supporting protectionism. Of course this gambit gives way quickly to the more sophisticated arguments: *viz.* the impact of exhaustion must be assessed on a case-by-case basis since it will vary by type of IPR; type of technology; type of economy. This issue of the impact on LDCs of a global ban on parallel imports (likely to be the American position in the new negotiations) must also be examined by detailed empirical studies. Do IPRs increase foreign direct investment, enhance technology transfer, and improve trade? In other words, are the static efficiency losses outweighed by dynamic efficiency gains? Just by way of a footnote, it may be that American antitrust policy and innovation is undergoing a sea-change, at least with respect to network industries, as the cases against Microsoft and Intel seem to suggest. But this seems unlikely to affect the American position, which would be to amend Article (6) to ban parallel imports, or change the push by some LDCs for a global exhaustion rule.

Another issue likely to be re-visited in the new negotiations concerns standards. As noted earlier, the inclusion of standards was not proposed at the outset of the Uruguay Round but emerged a couple of years later as a result of the international business coalition led by the Americans. The standards incorporated in the TRIPS Agreement represented a consensus among the OECD countries. They cannot be described as minimal but even so there is likely to be a push for higher standards in some areas and, perhaps more importantly, for more harmonization among countries. In both instances it is important to note that significant differences exist among major OECD countries.

Before explicitly moving to harmonization, there is still an important question that remains unsettled with respect to the existing stan-

dards in TRIPS: how much "wiggle room" remains for diversity in domestic laws, a diversity likely to be exploited mainly by LDCs (Special Issue [JIEL] 1998: 591). The answer will depend on the dispute settlement system, and thus far only one significant case (the United States versus India) involving a developing country has reached the Appellate Board. The result is instructive , though obviously one cannot generalize on the basis of a single case. There will be many more, however, when the LDCs have to implement the TRIPS standards in 2000 (see below).

The case concerned the so-called mailbox for filing patent applications for pharmaceutical and agricultural chemical products which India had failed to establish at the outset of the TRIPS Agreement (Articles 70.8 and 70.9). While the Appellate Board upheld the panel's decision that India had violated its commitments, it adopted a much more cautious stance on several other aspects of the Panel report, sending a strong signal of deference to domestic law (Special Issue [JIEL] 1998: 595). This concept of a deferential standard of review means that when several interpretations of a particular article are possible, the Appellate Board should accept that of the national administrative body—as the United States insisted in the case of WTO anti-dumping provisions (Dreyfuss and Lowenfeld 1997: 321).

As a final point on the issue of standards, the TRIPS Agreement involved, as I have noted, a more radical transformation of the concept of the global "trading" system than the other new issue (e.g. trade in services) because it involved protection of individual property rights. By incorporating standards and due process for one factor of production—capital—the door was opened to claims for similar treatment for the two other factors, i.e. labour and land (read "the environment"). Thus many INGOs are now presenting proposals for basic labour rights and environmental standards to be incorporated into the WTO. While these issues are not directly related to the new negotiations on TRIPS, because of the complex dynamics of the multilateral negotiations, it would be prudent not to rule out the possibility of some linkage in the final deal.

The last generic issue I want to mention concerns enforcement. The cost of establishing the institutional infrastructure for enforcing IPRs is likely to be very high not only for the poorest countries but for many middle-income or emerging market economies with inadequate monitoring capabilities and weak civil-justice systems. The extent and nature of the gaps in enforcement will become evident as the TRIPS Council begins its own monitoring process in 2000. Although Article 67 of the TRIPS Agreement recognizes the need for technical assistance, the language is vague and involves no real commitment on the part of the developed countries. Since the WTO has very limited

resources for training or technical assistance, the task has been undertaken by WIPO, a very rich institution. Cooperation between the WTO and WIPO is essential and a joint initiative in technical assistance was launched in July 1998 (Special Issue [JIEL] 1998: 529–30). A matter for consideration, as part of this cooperative effort, should be a time-limited "peace accord" which would exempt LDCs from the dispute settlement process contingent on their sustained improvement in enforcement capabilities. There is a danger that as the monitoring process beginning in 2000 reveals more gaps in implementation, a flurry of disputes could overburden the WTO dispute body and poison the atmosphere for the new negotiations.

Conclusions

A central theme of this paper is that the TRIPS Agreement exemplifies the transition from the traditional GATT focus on border barriers to the new agenda of deeper integration in a more radical fashion than was the case in services. The TRIPS Agreement was conceived and facilitated mainly by American MNEs and the deal reflected a North-South trade-off between traditional GATT issues and a radical "new issue." For a variety of reasons explained in the discussion—including technological change and new policy actors—the TRIPS negotiations in the Millennial Round will be far more complex and contentious. However, despite the importance of the MNEs and the INGOs, it is governments who will sit at the bargaining table. And, as in the past, it will be government leadership that will determine the final outcome. All things considered, the demands on leadership in the next round will be far greater than at any time in the past 50 years. Given the current state of transatlantic trade tensions, the absence of American fast track, and so on, the next round of WTO Ministerial negotiations should be very interesting—in the Chinese sense of that word!

Notes

1 Preeg 1995: 65; the American statement on piracy was not "official" but informal and derived from my own recollections.
2 Barfield and Groombridge 1999: 22. This paper provides an excellent analysis of the impact of technological change on the structure of the pharmaceutical industry.
3 MAI Websites—World Wide: An Annotated listing. Prepared by Janet M. Eaton (jeaton@fox.nstn.ca) for the Nova Scotia Network for Creative Change Website (www.chebucto.ns.ca/CommunitySupport/NCC/MAI4 www.html) and for the general use of Citizens and Groups everywhere (November 10, 1999).

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