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A Road Map for the TRIPs Ahead

Before the Uruguay Round began at Punta del Este in 1986, intellectual property developers in the United States made plain their dissatisfaction with the prevailing international system of IPRs. That system consisted first of highly variable laws and enforcement across countries and regions, with the weaker regimes responsible for tens of billions of dollars in lost sales annually, according to surveys conducted by the United States International Trade Commission (1984; 1988). Most complaints in both surveys related to straightforward counterfeiting of American trademarks and copyrights, though the later survey noted perceived damages from weak patent laws. Whatever the validity of the complaints, they did reflect considerable irritation with piracy, which was increasing rapidly because of the proliferation of low-cost means of copying.

The second feature of the system was a series of international treaties, managed primarily by WIPO, purporting to set minimum standards for IPRs as guidelines for member countries. The major treaties—the Paris Convention for the protection of industrial property and the Berne Convention for the protection of artistic and literary property—enjoyed widespread international adherence.

Perceived problems with these treaties were threefold:

1. Some standards were weak and vaguely specified. The Paris Convention, for example, essentially required only national treatment in each member's patent laws and grant of priority rights.
2. They provided no effective procedures for settling IPRs disputes and were therefore only statements of intention on the part of signatory

nations. Departures from the Paris Convention guidelines covering compulsory license issuance, for example, were common in national laws.

3. It was difficult to renegotiate the conventions rapidly and flexibly enough to handle new technologies, such as integrated circuits, software, and electronic databases, which were straining classical conceptions of intellectual property protection.[1] Among many developed economies these technical advances were pushing forward changes in IPRs, which evolve dynamically in any event, but the WIPO conventions were seen as hidebound.

In the 1980s, the accelerating globalization of intellectual property use through international trade, FDI, and licensing inevitably came into conflict with these regimes, a conflict that would only worsen in the 1990s. That is, the rising need to sell intellectual property on an *international* scale became increasingly at odds with existing IPRs based strictly on *national* or *territorial* laws and regulations. The United States first pushed for an international code on counterfeiting, introducing it at the 1982 trade ministerial meeting, but there was little enthusiasm for the initiative. Four years later, however, at the Uruguay Round meeting in Punta del Este, American negotiators, joined by representatives of the European Union and Japan, successfully introduced IPRs into the deliberations on global trade rules.

The TRIPs accord was fashioned against a backdrop of diplomatic efforts to upgrade global IPRs protection. The United States aggressively pursued improvements in numerous developing countries, ranging from South Korea and Taiwan in the late 1980s to China and Brazil in the mid-1990s. Regional trade agreements negotiated in this decade routinely contain language governing IPRs standards. This process began with NAFTA and the extensive obligations it required of Mexico, but it has been extended through partnership agreements of developing countries with the EU and through regional trade arrangements, including Mercosur, the Andean Pact, and APEC. Finally, new treaties now aim to protect copyrights in cyberspace.

The TRIPs agreement constitutes the most significant strengthening ever of global norms in the intellectual property area. Enforcement of TRIPs obligations amounts to a marked movement toward international harmonization of standards and a definite solidification of the international regime.

The negotiating history of the TRIPs agreement and its role in the establishment of the WTO, though fascinating, lies outside the scope of

1. One possible exception was the 1989 Washington Treaty, which set out standards for protecting integrated circuits. However, the treaty was considered too weak by computer chip designers in major countries, particularly Japan and the United States, and did not attract many national accessions.

the discussion here.[2] Rather, I discuss the provisions of TRIPs that require significant changes in norms of protection, along with limitations of those norms. This is useful for assessing the degree of policy change and effective harmonization that TRIPs represents. The discussion is not a close legal reading of the text, but rather an interpretation of its broad requirements that could affect economic processes as they are implemented and strengthened.[3] The treatment here presumes that readers have some familiarity with IPRs. In chapter 3, I provide fuller explanations of what these rights are and why they exist.

General Obligations

The TRIPs agreement consists of seven parts and 73 articles covering all aspects of IPRs, their enforcement, and institutional arrangements. The key provisions are listed in table 2.1, adapted from Maskus (1997a). TRIPs Part I, Article 3 provides for general obligations, including nondiscrimination in the form of national treatment and use of the most favored nation (MFN) principle. National treatment applies to persons or legal entities, rather than goods, as is the case under the GATT. This represents an important extension of standards-based legal doctrine into the WTO. The MFN obligation, placed for the first time into international intellectual property law, recognizes certain exemptions for regional trade agreements with IPRs accords and from reciprocity relations in copyright established under the Berne and Rome conventions.

Transparency is also established as a basic principle in Article 63: countries must publish laws and regulations, including judicial decisions and administrative findings that bear on the treatment of intellectual property.

Copyrights

The agreement then goes on in part II to set minimum standards in all functional IPRs areas. In copyrights, TRIPs incorporates the standards of the Berne Convention by reference, so that all WTO members must observe those rules at a minimum. However, at the insistence of the United States, TRIPs does not require the provision of moral rights as specified in the Berne Convention (Article 6bis). Extension of the Berne Convention to countries that were not previously members thereby establishes a

2. Bradley (1987) discusses the early history; Ross and Wasserman (1993) and Watal (2000) undertake extensive interpretations.

3. See also Primo Braga (1996), UNCTAD (1996), and Beier and Schricker (1996). Watal (2000) provides a comprehensive and detailed legal interpretation, with excellent commentary on many of the potential economic implications for developing nations.

Table 2.1 Substantive requirements of the TRIPs agreement in the WTO

General Obligations	Comments
1. National treatment	Applied for persons
2. Most favored nation	Reciprocity exemptions for copyright; prior regionals/bilaterals allowed
3. Transparency	
Copyright and related rights	
4. Observes Berne Convention	Does not require moral rights
5. Minimum 50-year term	Clarifies corporate copyrights
6. Programs protected as literary works	A significant change in global norms
7. Data compilations protected similarly	
8. Neighboring rights protection for phonogram producers, performers	
9. Rental rights	A significant change in global norms
Trademarks and related marks	
10. Confirms and clarifies Paris Convention	
11. Strengthens protection of well-known marks	Deters use of confusing marks and speculative registration
12. Clarifies nonuse	Deters use of collateral restrictions to invalidate marks
13. Prohibits compulsory licensing	
14. Geographical indications	Additional protection for wines and spirits
Patents	
15. Subject matter coverage	Patents provided for products and processes in all fields of technology
16. Biotechnology	Must be covered but exceptions allowed for plants and animals developed by traditional methods
17. Plant breeders' rights	Patents or effective *sui generis* system required
18. Exclusive right of importation	
19. Severe restrictions on compulsory licenses	Domestic production can no longer be required; nonexclusive licenses with adequate compensation
20. Minimum 20-year patent length from filing date	
21. Reversal of burden of proof in process patents	
22. Industrial designs	Minimum term of protection: 10 years
Integrated circuits designs	
23. Protection extended to articles incorporating infringed design	Significant change in global norms
24. Minimum 10 years protection	
Undisclosed information	
25. Trade secrets protected against unfair methods of disclosure	New in many developing countries
Abuse of IPRs	
26. Wide latitude for competition policy to control competitive abuses	Cannot contradict remainder of WTO agreement

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Table 2.1 (*continued*)

General Obligations	Comments
Enforcement measures	
27. Requires civil, criminal measures and border enforcement	Will be costly for developing countries
Transitional arrangements	
28. Transition periods	5 years for developing and transition economies; 11 for poorest countries
29. Pipeline protection for pharmaceuticals	Not required but a provision for maintaining novelty and exclusive marketing rights
Institutional arrangements	
30. TRIPs Council	Agreement to be monitored and reviewed
31. Dispute settlement	Standard approach with 5-year moratorium in some cases

Source: Maskus (1997a).

global standard that copyrights shall extend for the life of the author plus 50 years. However, TRIPs expands the Berne Convention by clarifying that copyrights owned by corporations shall extend a minimum of 50 years. A further noteworthy extension of international copyright law was the introduction into TRIPs of a requirement to provide rental rights for computer programs, audio recordings, and, to a limited extent, cinematographic films.

More significant change comes in TRIPs Article 10, which mandates that both computer software and data compilations are to be protected by copyright as literary works under terms of the Berne Convention. TRIPs does not require that programs be protected by patents if they meet conditions for patentability, as is the case in the United States, but it does not preclude that option. When TRIPs entered into force in 1995, numerous developing countries did not recognize computer programs and databases as copyrightable. Thus, this provision requires extensive legal reform. In the area of neighboring rights, TRIPs mandates a 50-year minimum term of protection for performers and producers of recorded music, which extends the protection of the Rome Convention.

Trademarks and Indications

TRIPs specifies that procedures for registering trademarks should be both transparent and independent of the characteristics of the goods and services for which protection is sought. An important requirement is that countries must extend protection to internationally well known

trademarks in order to head off speculative registration and fraudulent use of those marks. Equally significant is that countries may no longer put use requirements onto trademark registrations. A typical example is the practice of requiring that a product be present on the market in order to maintain registered rights but preventing importation, as a means of accomplishing this presence, via a trade restriction, thereby invalidating the trademark. Such practices are no longer permissible for WTO members.

While TRIPs Article 21 permits authorities to regulate the licensing and sale of trademarks, it prohibits their compulsory licensing. It should be noted that compulsory licensing in the trademark area was in any event rarely used in the developing world.

Certain EU member states and Switzerland were eager to establish an agreement protecting geographical indications. What emerged, in Article 23, was additional protection for the place names used in identifying wines and spirits, even if products made outside the legitimate region are modified by words such as "type" or "imitation." However, Article 24 set significant limitations and an agreement was reached whereby members would work toward a new solution. Those negotiations have not begun, though many countries have lists of geographical names they wish to see protected and have submitted proposals on how to go about such negotiations.

Patents

The most significant changes came in the area of patents, which is not surprising given the controversy over technology protection. Article 27 requires a broad definition of protectable subject matter. Specifically, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." Thus, many countries must extend patent protection to such important areas of technology as chemical products and processes, pharmaceutical products and processes, and food products. Broad exemptions from patentability remain, to protect public order or morality, prevent environmental deterioration, and protect animal, human, or plant life. However, these exemptions are limited by the stipulation that any inventions so excluded not be commercially exploited within a country. Exemptions are also allowed for diagnostic, therapeutic, and surgical methods, as is the standard in most nations.

Most controversial is the exemption in Article 27.3.b for biotechnological inventions. In principle, such inventions are subject to patents, and patents must be provided for microorganisms and microbiological processes. However, unlike the strongly protective American approach,

TRIPs permits exclusions from patentability for traditional breeding ("essentially biological") methods and higher life organisms (plants and animals). Yet all countries must adopt either patents or an effective *sui generis* system of protection for plant varieties. Thus, countries cannot escape the obligation to provide plant breeders' rights. This delicate compromise was not altogether appealing to biotechnological firms and TRIPs calls for a review of Article 27, beginning in 1999. That review is progressing slowly within the TRIPs Council but no report has been issued to date.

In addition to extending the required coverage of patents, TRIPs strengthens the scope of patent rights. It recognizes an exclusive right of importation in Article 28.1.a., though many legal scholars argue that this right was implicit in the right to sell. Article 27.1 establishes that importation is sufficient to meet working requirements. Because obligations to work patents through domestic production are no longer valid, they may not be used to justify compulsory licenses. However, the importation right is explicitly limited by Article 6, which specifies that each country may adopt its own regulation regarding whether the first international sale of a good would exhaust distribution rights.

This interpretation of TRIPs is not uniformly accepted: Some observers consider that Article 6 only removes parallel imports from the dispute settlement process but is otherwise governed by substantive requirements in functional IPRs areas (Cottier 1998). However, Abbott (1998) is persuasive that the importation right is attenuated by the prospect of parallel imports. This controversial question is discussed in chapter 7.

TRIPs recognizes the legitimacy of using compulsory licenses to achieve goals related to health and nutrition or other social purposes and to discipline competitive abuses of patent rights, but it significantly restricts their use.[4] Governments must negotiate beforehand with patent owners, can issue only nonexclusive, temporary (in principle) licenses meant primarily for the domestic market only, and must rescind the licenses when the conditions that triggered their use disappear. Adequate, market-based remuneration of patent holders is required of compulsory licensees. Authorities may issue compulsory licenses to permit the use of dependent patents—grants for which exploitation is tied to access to a technology protected by a prior patent. However, such licenses are permissible only when the later patent covers "an important technical advance of considerable economic significance" beyond the prior patent.

TRIPs affects harmonization of patent length by requiring a minimum term of protection of 20 years from date of filing. Moreover, it mandates that in adjudicating process patent infringement cases the burden of proof is reversed, being placed on the defendant under certain conditions. That

4. Watal (2000) argues that these conditions are not overly restrictive and allow considerable flexibility for authorities to employ compulsory licenses.

is, the defendant must demonstrate that his process does *not* infringe the plaintiff's patent. This procedure recently became the norm in many industrialized countries, where it is recognized that proving process infringement is quite difficult, though the procedure requires a change in patent laws in many developing and some developed nations. The agreement also protects industrial designs for a minimum of 10 years.

Integrated Circuits

Original designs of integrated circuits are protected for a minimum of 10 years from filing. Protection covers the layout design, chips on which it is masked, and products that incorporate the chip. Thus, articles that contain an infringing design are themselves deemed to infringe the protected design, whether wittingly or unwittingly, and may be prevented from entering commerce. Though TRIPs limits the use of compulsory licenses in integrated circuits, it specifically permits reverse engineering.

Trade Secrets

TRIPs requires, for the first time in the global economy, that countries provide effective protection of trade secrets, which are confidential business information. Trade secrets have long been considered problematic in many developing nations under the logic that protecting them without requiring disclosure of technical information failed to achieve the benefits of technology diffusion. As discussed in chapter 3, however, trade secrets constitute a potentially beneficial supplement to the patent system, particularly in technology follower countries, as they do not prevent independent discovery by honest means.

The TRIPs approach is to recognize undisclosed information as a form of intellectual property but to require its protection by actions against unfair competition as identified in Article 10bis of the Paris Convention. In this sense, actions that are "contrary to honest commercial practices" constitute infringement only when those actions are aimed at learning trade secrets maintained with sufficient care. Illegal practices include making fraudulent and confusing claims about the quality, characteristics, and origin of goods produced by competitors, making false and misleading claims about products sold by firms themselves, and the misappropriation of trade secrets or confidential information. The last term includes breach of contract, inducement of others to breach contracts, and the acquisition by third parties of information known to be disclosed dishonestly (or when failure to know the disclosure was dishonest would

constitute gross negligence). Note in particular that reverse engineering was not mentioned by the Paris Convention, meaning that it is considered a legitimate form of learning technical secrets.

With some limitations, Article 39.3 of the TRIPs accord also requires governments to protect against unfair commercial use of confidential test data submitted in the process of securing regulatory and marketing approval of new pharmaceutical products and agricultural chemical products. This is significant. No international law before TRIPs had any specific requirement for the protection of test data.

The essential issue is what constitutes unfair commercial use. While disclosure may be permitted in order to safeguard public health, release of such data to potential competitors solely to grant a market advantage is widely seen as unfair. Indeed, US pharmaceutical firms complain about the leakage of confidential information into competitive commerce through this channel.

The more substantive question is whether there should be a period during which governments may not use test data submitted by a first applicant in its approval procedures for second applicants presenting generic copies or similar products with closely similar therapeutic qualities. For example, the United States generally provides a protection period of five years, a standard that was adopted in NAFTA. Failing to provide such a period of exclusivity could absolve second comers of the costs of undertaking clinical trials, providing them with a competitive advantage.

At the same time, generic drug producers denied access to the previous test data would be forced to wait for the duration of the exclusivity period before receiving approval unless they also undertook costly testing. Moreover, such duplicative testing could be socially wasteful when performed on bioequivalent products. Some observers therefore regard proposals for such a period as an effective extension of patent protection beyond the period of patent expiry, an issue of great concern in many countries, developing and developed.

TRIPs sets no clear requirement to avoid relying on prior test data for subsequent applications; nor does it mandate a fixed period of market exclusivity. This situation has resulted in two interpretations among legal scholars (Watal 2000). First, some argue that authorities must keep test data secret, except where disclosure is required for public health purposes, but may use the data for subsequent approval of bioequivalent generic substitutes. Argentina has implemented such a law, which may become the standard approach among developing countries. Second, some scholars believe that the provision requires an exclusivity period of at least five years during which competitors may not be allowed to rely on prior test data, either directly or indirectly through official use. The United States and the European Union have rules of this kind, and similar laws have been implemented in New Zealand and Australia.

Control of Anticompetitive Practices

In negotiating TRIPs, representatives of key developing countries consistently voiced the concern that stronger patents, trademarks, and trade secrets protection could permit rights holders to impose abusive licensing conditions, thereby inhibiting the effective transfer of technology. This has been a frontal concern of developing countries for decades, and underlay the attempt in the 1980s to fashion international codes of conduct governing restrictive business practices and transfer of technology (Sell 1998).

Article 40 of TRIPs thus anticipates that the exercise of IPRs may have anticompetitive effects that may be controlled by competition regulations. The agreement lists three examples of anticompetitive practices: exclusive grantback conditions, conditions preventing challenges to validity, and coercive package licensing. Though there is debate among scholars whether these conditions are exhaustive, the list seems strictly illustrative. The agreement further provides considerable latitude for member states in setting such regulations. However, competition rules used for this purpose cannot be inconsistent with other provisions of TRIPs and the agreement calls for opportunities for consultation. One observer (Primo Braga 1996) wrote that the vague language of Article 40 is likely to generate disputes over competition regulation in IPRs without effectively disciplining abuses. Competition policy in the regulation of intellectual property rights is an area I address in a later chapter.

Enforcement

The TRIPs agreement in part III requires standards for effective enforcement of IPRs. Enforcement measures must provide for border controls, civil and criminal sanctions in some cases, and expedited procedures for disciplining infringement, including preliminary injunctions and seizure and destruction of counterfeit goods. Further, access of complainants to such measures should be fair and equitable, available to both domestic and foreign rights holders, and not overly expensive and complex. Decisions should be subject to judicial review, though TRIPs does not require that a separate arm of the judiciary be established for IPRs. At the same time, enforcement measures should not be so stringent as to constitute barriers to legitimate trade.

These comprehensive requirements will, in principle, require many developing nations to implement new legal obligations and to devote considerable resources to the enforcement of IPRs. It is noteworthy that TRIPs is the first multilateral trade agreement that sets out detailed obligations for the legal enforcement of rules and disciplines. In itself, this commitment to enhanced enforcement represents a signal victory for intellectual

property developers in industrial nations. The most visible and pervasive aspects of IPRs infringement continue to be unauthorized copying of recorded entertainment and software and counterfeiting of trademarks. Stronger prohibitions against these activities may potentially raise the global demand for legitimate goods by significant, but unknown, amounts.

Transition Periods

Countries are now well into the transition periods specified in TRIPs. Establishment of national treatment and the MFN principle was an immediate obligation of all countries, while a standstill provision prevents the introduction of weaker standards than those required by TRIPs during the transition years. Developed economies were given one year from the entry into force of the WTO, until January 1, 1996, to comply with all TRIPs requirements. Developing economies and economies in transition were given five years, until January 1, 2000. Many such countries have just finished implementing new laws, while others have not yet been able to comply.

Finally, the least-developed countries were allowed an 11-year period, until January 1, 2006, to assume their TRIPs obligations. These countries are also permitted to request open-ended extensions, suggesting that they have a quasi-permanent "opt-out" privilege. However, such an approach would frustrate the intent of TRIPs and could lead to long-term technological isolation of countries that invoke it.

Developing nations have ten years to provide patents for areas of technology that were not previously covered in developing countries, namely pharmaceutical products, agricultural and other chemicals, food products, and microorganisms. Pipeline protection of drugs and chemicals on patent elsewhere but not yet marketed in these countries is not required, thereby permitting local pharmaceutical firms to continue producing imitations. As partial compensation, however, authorities must establish a "mailbox" procedure, whereby they accept applications for patents during the transition period, providing a priority claim when such applications are ultimately examined. Moreover, if marketing approval is provided to drugs in the mailbox, authorities must provide exclusive marketing rights for the shorter of five years or the period until the patent grant is decided.

Administration of TRIPs

The final part of the agreement establishes a TRIPs Council to monitor its operation. The language also calls for developed countries to provide technical and financial assistance to countries adopting the new standards, on mutually agreed terms. It also sets up conditions for review

and modification of the agreement. Indeed, in 2000, TRIPs is scheduled for review, which has not yet begun, and every two years thereafter.

An important component of TRIPs is that it folds disputes over IPRs into the integrated dispute settlement mechanism that lies at the heart of the WTO. The agreement stipulated a five-year moratorium on the use of dispute settlement against indirect violations of TRIPs, allowing countries to select implementation strategies without this kind of interference. In systemic terms, one of the primary achievements of TRIPs in establishing a broad set of multilateral disciplines over IPRs is that future conflicts will be handled in a recognized forum. These conflicts surely will grow in number as global integration increases and the importance of IP-sensitive goods and services in international commerce grows.

Summary

The TRIPs agreement sets out substantive minimum standards in virtually all areas of intellectual property protection. Particularly significant are changes in patent eligibility, requirements for protection for plant varieties, copyrights for computer software and electronic transmissions, protection for well-known trademarks, and effective measures to safeguard confidential information. The agreement further calls for adequate administration and enforcement and incorporates intellectual property into the dispute settlement mechanism of the WTO.

Thus, TRIPs is the most significant international undertaking on IPRs in history. Because it tilts the global balance toward stronger rights for information developers, it promises to effect a short-term distribution of income in their favor from information users, in both developed and developing countries. Over the longer term, because TRIPs fundamentally alters incentives for international commerce, imitation, and innovation, it should generate dynamic benefits with a broader scope of winners. To the extent that additional social costs could emerge, it will be important to develop policies to manage such costs. These are themes that I develop in later chapters.