The TRIPS Agreement:
Issues for Cancun and Beyond
Carlos M. Correa, University of Buenos Aires | September 2003

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) brought about a very important change in international standards relating to intellectual property rights. Because of its far-reaching implications, particularly with respect to developing countries, the agreement has been one of the most controversial components of the WTO system. Strong disagreements on the scope and content of the Agreement emerged during the Uruguay Round negotiations, both between developed and developing countries and among developed countries themselves. Implementation of the Agreement and its review under the “built-in agenda” have also been contentious with regard to many aspects of the Agreement.

The developed countries (particularly the USA) insisted upon the negotiation and adoption of standards on intellectual property rights (IPRs) in the Uruguay Round, based on the argument that strengthened protection of IPRs would promote innovation as well foreign direct investment (FDI) and technology transfer to developing countries. Although the TRIPS Agreement only became effective in advanced developing countries on January 1, 2000, meaning that there has not been much time to assess its impact, most developing countries seem to remain unconvinced about the benefits that they will obtain from the implementation of the new IPR standards. Moreover, many of them fear that the costs to be paid may be too high, particularly in critical areas such as public health. Essentially, many developing countries feel that despite the balance sought in some provisions, the Agreement mainly benefits technology-rich countries. There are a number of reasons for these concerns.

First, higher levels of IPR protection do not appear to lead to tangible increases of FDI in or technology transfer to developing countries. The evidence on the relationship between IPR protection on the one hand and FDI and technology transfer on the other continues to be inconclusive.¹ In addition, the share of developing countries in world research and development expenditures remains very low.² Certainly, IPRs may promote innovative activities to the extent that they offer the promise of extraordinary benefits based on the temporal exclusion of competitors. But in order for those benefits to be realized, an adequate industrial and technological infrastructure must exist at the national level, which is not the case in most developing countries. There is also strong evidence suggesting that most of the rewards from innovation are reaped by a small minority of successful companies, while the majority of innovative efforts confer only modest benefits, in addition to the fact that, because of the high cost of litigation, IPR enforcement is biased in favor of large organizations.³

Second, in some sectors IPRs appear to act as a powerful barrier to access to technologies and products, particularly by the poor. This is notably the case in relation to pharmaceuticals. By their very essence, patents enable pharmaceutical manufacturers to charge higher prices than those that would have existed in a competitive environment. While the high prices are said to be justified by the need to recover costly investments in R&D, the magnitude of such investment, as well as the pricing of drugs in developing countries, has been strongly contested.⁴

The AIDS crisis in Africa, and growing evidence about the negative implications of patents for access to medicines by the poor, have brought the relationship between TRIPS and health to the forefront. With more than thirty million people living with HIV, most of them in the poorest regions of the world, the need to address the problem of access to patented medicines has emerged as a global priority. While it is true, as argued by the pharmaceutical industry, that other factors such as infrastructure and professional support play an important role in determining access to drugs,⁵ it is also true that the prices that result from the existence of patents ultimately determine how many will die from AIDS and other diseases in the years to come. It is important to note that the problem of access to medi-
cines is not limited to anti-retrovirals, but involves all kinds of medicines that may fall under patent protection.

Some recent WHO-sponsored studies provide an indication of the potential effects of the TRIPS Agreement in the area of pharmaceuticals. A study undertaken in Thailand on the impact of that country’s 1992 revised patent law, which essentially applies the same standards as those required by the TRIPS agreement, found that there had been no significant increase in transfer of technology or foreign direct investment, and that spending on pharmaceuticals had increased at a higher rate than overall health care spending.6

Another study on the implications of the new Industrial Property Code (1996) on local production and access to medicines in Brazil revealed inter alia that:

Only 36 (2.6%) of the 1387 drug patent applications filed since 1996, when the new Brazilian Industrial Property Act was signed into law, were filed by residents of Brazil. More than five hundred of the filings were made by U.S. residents.

While Brazil’s total imports roughly doubled during the period 1982-98, pharmaceutical imports increased over 47 times.

The study concluded that “the greatest beneficiaries of recent changes in Brazilian legislation and the implementation of the World Trade Organisation’s TRIPS Agreement have not been Brazilian companies or institutions, but transnational companies.”7

More generally, Maskus has noted the scarcity of data on price elasticities and market-structure parameters, and the uncertainty about the potential effects of patents on prices, profitability, and innovation. However, based on available literature, he found that “the preponderance of conclusions is pessimistic about the net effects of drug patents on the economic welfare of developing countries (or, more accurately, of net importers of patented drugs).”8

Some of the concerns of developing countries about the implications of the TRIPS Agreement on public health were reflected in the negotiation and adoption of the “Doha Declaration on the TRIPS Agreement and Public Health.”9 at the Fourth WTO Ministerial Conference (November 9-14, 2001). WTO Members took the unprecedented step of adopting a special declaration10 on this controversial matter. Discussion of the declaration was one of the major issues at the Conference,11 and was the first outcome of a process that started in early 2001 when, upon the request of the African Group and other developing countries, the Council for TRIPS agreed to deal specifically with the relationship between the TRIPS Agreement and public health.12 Unfortunately, the Council for TRIPS has failed to find a solution for the supply of drugs to countries who, due to insufficient or non-existing manufacturing capacity in pharmaceuticals,13 are unable to use compulsory licenses in order to obtain access to drugs at lower prices than those charged by patent owners.

While some developed countries have announced unilateral moratoria with regard to the export of certain types of drugs, these measures do not provide a stable framework to encourage Members and the private sector to act in response to public health needs in Member countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

Even if a waiver were sanctioned under WTO rules to address this problem, it would not dissipate the legal uncertainty about actions that can be legally taken and it would be unlikely, hence, to induce potential exporting countries to encourage production for export, nor would it provide the necessary economic incentives for generic manufacturers to make the investments required to replicate the technology, produce the active ingredients and dosage forms, and obtain the respective marketing approval for the medicines in need.

A possible solution to the paragraph 6 problem should ensure:

timely access to medicines by all;
simple and speedy legal procedures in the exporting and importing countries, to allow for the fast supply of needed medicines of the required quantity and quality;
equality of opportunities for countries in need of medicines, even for products not patented in the importing country and for countries that are not WTO Members;
transparency and predictability of the applicable rules in the exporting and importing countries, so as to provide the required incentives to the private sector to act within the established framework;
the freedom of importing countries, confirmed by the Doha Declaration, to grant compulsory licenses and authorizations for government use on the grounds determined by the national law, including in cases of health emergencies;
broad coverage in terms of public health problems and
the range of medicines according to the priorities defined by the national health authorities;

stability of the international legal framework for a long-term solution;

facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries, and the realization of economies of scale.

The text of the Chairman of the Council for TRIPS of December 16, 2002 (JOB(02)/217), which received support from the great majority of Members, establishes a number of conditions for allowing exports of patented medicines, which is hardly compatible with the idea of an expeditious solution. The U.S. opposition to apply this proposed solution to all diseases, as agreed in Doha, has frustrated the approval of the Chairman’s proposal so far. A simpler and more effective approach would be based on the recognition that acts exclusively related to exports to countries with public health needs are not subject to patent rights. Given the territoriality of patent rights, the commercialization of a product in a foreign country does not affect the normal exploitation of the patent in the exporting country. Though the patented invention would be used in the latter, the effects of such use will take place in a foreign jurisdiction and be subject, therefore, to the rules applied therein. Such a limited utilization would not unreasonably prejudice the legitimate interests of the patent owner in the exporting country.

It should be noted in this regard that on October 3, 2002, the European Parliament adopted Amendment 196 to the European Medicines Directive, which provides that “manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.” This is the approach that should inspire a solution under paragraph 6 of the Doha Declaration.

Third, the adoption of the TRIPS Agreement as a component of the WTO system means that any controversy relating to compliance with the minimum standards established by the Agreement should be resolved under the multilateral procedures of the WTO. The adoption by another Member of unilateral trade sanctions would be incompatible with the multilateral rules. Any complaint should be brought to and settled according to the rules of the Dispute Settlement Understanding (DSU). Despite this, many developing countries have continued to be pressured by unilateral demands by some developed countries, notably the U.S. and the EU, in the area of IPRs, aiming not only at the implementation of the TRIPS Agreement standards, but often asking for “TRIPS-plus” protection, that is, levels of protection beyond the minimum standards required by the TRIPS Agreement. A telling case that received considerable public attention was the attempt by the U.S. government and pharmaceutical industry to block the use of parallel imports and compulsory licenses by the South African government to obtain access to cheaper HIV/AIDS drugs. In other cases, developing countries were persuaded to adopt “TRIPS-plus” standards in order to benefit from other trade concessions under bilateral agreements.

In addition, nothing seems to prevent WTO Members from applying unilateral pressure, for instance, by threatening the removal of trade preferences that go beyond WTO commitments, or cuts in development aid, or through simple moral persuasion. As noted by Primo Braga and Fink, the United States has continued to put unilateral pressure on countries where it felt that weak IPR systems disadvantaged U.S. companies. One of the most prominent cases in this context was, in addition to the South African case, the dispute with Argentina on pharmaceutical patents, which in 1997 led to the removal of 50% of Argentina’s benefits under the U.S. generalized system of preferences (GSP).

Fourth, Article 66.2 of the TRIPS Agreement establishes an outright obligation on developed countries “to provide incentives to enterprises and institutions” in their territories for the transfer of technology to least-developed countries. Though Article 66.2 leaves a great deal of leeway to developed countries to determine what kind of incentives to provide, it does require the establishment of a system to encourage technology transfer (including technology protected under intellectual property rights) to least-developed countries. The provision also provides a general standard to judge the appropriateness of such incentives, i.e., that they should enable least developed countries “to create a sound and viable technological base.” This obligation remains unfulfilled.

Fifth, developing countries possess most of the biodiversity available in the world and are the source of materials of great value for agriculture and industry (e.g., medicinal plants). Traditional farmers, for instance, have improved plant varieties and preserved biodiversity for centuries. They have provided gene pools crucial for major food crops and other plants. A major concern in
many developing countries has been how to prevent the misappropriation of their traditional and indigenous knowledge and genetic resources, and how to ensure the sharing of the benefits obtained from the commercial exploitation of biological materials and associated knowledge, as provided for by the Convention on Biological Diversity (article 15).

The misappropriation by foreign companies and researchers, notably under patents, of genetic resources and traditional knowledge found in developing countries, has been illustrated by the cases of patents granted on ayahuasca, quinoa, and turmeric, among others. Some governments and NGOs have counteracted this form of so-called “bio-piracy” by challenging (in some cases successfully) the validity of such patents or by promoting the publication of traditional knowledge in order to preempt its patentability.

Some of these concerns have been addressed by the International Treaty on Plant Genetic Resources for Food and Agriculture. The prompt ratification and entry into force of the Treaty will ensure that the access to and use of genetic resources for food and agriculture is subject to a Multilateral System under which benefit sharing is provided for. The Treaty lays down international rules to prevent the protection under intellectual property rights of materials in the Multilateral System “in the form received.”

The compulsory disclosure of the source of biological materials in patent applications may also provide a mechanism to address developing countries’ concerns about misappropriation and benefit sharing. Article 29 of the TRIPS Agreement may be amended to this effect, so as to incorporate an obligation on the applicant to make a declaration about

1. the source and the geographical origin, as known to the applicant, of any biological material claimed or on which a claim is based;
2. compliance, where appropriate, with any applicable national laws requiring prior informed consent for the access to biological material claimed or on which a claim is based.

These obligations do not create an additional patentability requirement, but rather aim at obtaining information to apply the existing standards. As a matter of principle, a patent should not be granted to a person who has not made an “inventive contribution.” Information about the source or country of origin is important to determine whether the applicant has effectively made the invention.

Inventorship is a basic element in patent law and there are no limitations under the TRIPS Agreement with regard to the means to determine it. In addition, providing such information would not impose a significant burden on the applicant, and may improve the quality of patent grants, as far the supplied information may be used to improve the examination process.

The obligation to inform about compliance of access legislation, if it exists and is applied in the country from which the material was obtained, would ensure consistency with the prior informed consent principle under the CBD.

The failure to comply with these obligations should lead to rejection of the application. It is important to note that the EU recognized disclosure of origin as a principle in the preamble to Directive 98/44 on the Legal protection of Biotechnological Inventions, and that the EU and its member states have expressed their support of a compulsory requirement relating to the “geographic origin of genetic resources or TK used in the inventions,” though they argue that noncompliance or false information should have no effect on the grant of the patent or its validity.

In sum, developing countries generally feel that the concessions they made during the Uruguay Round with respect to IPRs are not providing them with significant benefits. Strong asymmetries in the development of and access to technologies remain or are even growing. Developing countries are bearing the costs of a system of reinforced IPR protection under the WTO, while enjoying few of its potential advantages. Concrete steps should be taken to redress the asymmetries of the international IPRs system.

Carlos M. Correa is director of the Post-graduate Courses on Intellectual Property and of the Masters Program on Science and Technology Policy and Management of the University of Buenos Aires. He can be reached at <quies@infovia.com.ar>. This paper is partially based on “The TRIPS Agreement from the perspective of developing countries,” in Patrick Macrory and Arthur Appleton (Editors), in The Kluwer Companion to the World Trade Organization, Kluwer Law International, London (forthcoming 2003).
ENDNOTES

8 Maskus, supra note 3, at 160.
9 WT/MIN(01)/DEC/W/2, November 14, 2001, hereinafter “the Doha Declaration.”
10 Paragraph 17 of the general Ministerial Declaration states: “We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration.”
11 The Director General of WTO emphasized the importance of this issue on the opening day of the Conference, indicating that agreement on public health and TRIPS was the “deal breaker” of the new round. Pascal Lamy, the EU Commissioner for Trade, stated at the Conference that “… we must also find the right mix of trade and other policies—consider the passion surrounding our debate of TRIPS and Access to Medicines, which has risen so dramatically to become a clearly defining issue for us this week, and rightly so.”
12 The Conference convened special sessions (which were held in June, August, and September 2001) to deal with the relationship between health and TRIPS. See the submissions made by the European Communities and their Member States on The Relationship Between the Provisions of the TRIPS Agreement and Access to Medicines, IP/C/W/280 (June 12, 2001), the paper submitted on the same issue by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela, TRIPS and Public Health, IP/C/W/296 (June 29, 2001). See also, Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/51, (July 10, 2001).
13 See paragraph 6 of the referred to Declaration.
14 It is important to note that a solution to paragraph 6 should be found before the Cancun Ministerial Conference. This is not an issue for which developing countries should be expected to make any compensatory concession (as is the practice in WTO negotiations), since this is only a matter of implementation of an agreement reached at the Doha Ministerial Conference.
15 However, a WTO panel in a case initiated by the EC and their Member States that examined the consistency with WTO obligations of the authorization given to the U.S. government to retaliate under several provisions (such as “Special 301”) of the U.S. Trade and Tariff Act of 1984 (19 U.S.C § 2144(2)(A)) did not find—based on a commitment by the U.S. government not to apply sanctions without WTO authorization—a violation of WTO obligations. See Report of the WTO Panel, United States—Section 301-310 of the Trade Act of 1974, WT/DS152/R (2000). See also Part III.B.7 infra.
16 An estimated 20% of South Africans are infected with HIV. A very minor portion of these have access to AIDS drugs. South Africa law established provisions that were challenged by the pharmaceutical manufacturers’ trade association and 39 pharmaceutical companies before the South African Supreme Court. U.S. development aid to South Africa was also conditioned on the withdrawal of the provisions (see U.S. Public Law 105-277 (105th Congress, 1999)). After a global NGO campaign, in which activists from the U.S., Africa, and Asia opposed the U.S. government and commercial sanctions, the legal action was withdrawn. Several pharmaceutical companies offered to provide AIDS drugs at a discounted price (60-85% off the price charged in the U.S. or Europe) See, e.g., Marie Byström and Peter Einsson, TRIPS—Consequences for Developing Countries: Implications for Swedish Development Cooperation 38 (2000), Consultancy Report to the Swedish International Development Cooperation Agency, available at http://www.grain.org/docs/sida-trips-2001-en.PDF.
17 For example, the bilateral agreements entered into between the EU and South Africa (1999), Tunisia (1998), and the Palestinian Authority (1997) require the latter to ensure adequate and effective protection of intellectual property rights “in conformity with the highest international standards.” See, e.g. Peter Drahos, Developing Countries and International Intellectual Property Standard-Setting 14-18 (2002), study prepared for the UK Commission on Intellectual Property Rights, available at www.ipcommission.org.
19 See the Report of the WTO case United States-Section 211 Omnibus Appropriations Act of 1998 (WT/DS176/AB/R) where the Appellate Body (supporting the panel’s view) held that neither the TRIPS Agreement nor the Paris Convention addresses the question how the ownership of a trademark is determined, and that is an issue to be determined by national law (para. 188-189). The same doctrine is arguably valid for patents and other IPRs.
20 See Communication by the European Communities and their Member States to the TRIPS Council on the review of article 27.3 (b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore. A concept paper