TRIPS Agreement and Access to Essential Medicines

■ by *Ayşegül ÖZDEMİR**

"The World Trade Organization (WTO) is the international organization dealing with the rules of trade between nations."[1] The WTO was born in the Uruguay Round, trade discussions that lasted from September 1986 to April 1994, which transformed the General Agreement on Tariffs and Trade into the World Trade Organization. One of the most significant achievements of the Uruguay Round was the **Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.** This agreement, signed in Marrakech, Morocco, on the 15th of April 1994, requires all WTO Members to provide certain minimum standards of protection for all kinds of intellectual property rights, including patents, copyrights, trademarks, trade secrets and geographical indications. The agreement also requires countries to provide for effective IPR enforcement.[2] Since then, the TRIPS Agreement has come into force and become known as the most extensive multilateral agreement on intellectual property up to now, which has had a big influence on the pharmaceutical sector and access to medicines.

During the Uruguay Round, the US was very anxious to have an IPR agreement on the agenda, especially on patents, in order to strengthen the prospects of large multinational pharmaceutical companies.[3] Since the US was successful in influencing aspects of the TRIPS agreement, it was able to universalize a system similar to the one in force in the United States. The TRIPS Agreement is the first broadly-accepted multilateral intellectual property agreement that is enforceable between governments, allowing them to resolve disputes through the WTO dispute settlement mechanism.[4]

Transitional Periods

The TRIPS Agreement allows different periods of time, called "Transitional Periods," for the WTO members, based on each country's level of development, to implement the agreement. After the lapse of the transition periods, it was expected that members would start to implement the agreement in full, including the enforcement provisions.[5]

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[1] WHO, The Doha Declaration on the TRIPS Agreement and Public Health, Parallel Importation, para. 1.

[2] 2003 Special 301 Report Executive Summary, "Text: U.S. Releases Special 301 Report on Intellectual Property," The U.S. Mission to the European Union.

[3] Ranjan, Prabhash, "A Looming Public Health Crisis?" InfoChange News & Features, February 2007, para. 1.

[4] 2003 Special 301 Report Executive Summary, "Text: U.S. Releases Special 301 Report on Intellectual Property," The U.S. Mission to the European Union.

[5] EU Enlargement Report, Screening Report Turkey, Chapter 7, Intellectual Property, page 1..

Permitting developing countries additional time to bring national legislation and practices into conformity with its provisions, the TRIPS Agreement provides three main transition periods.

- The first was from 1995-2000, in which countries were required to implement the TRIPS Agreement.
- The second was the 2000–2005 transition period, which allowed specific countries to postpone the provision of product patent protection that had not been so protected at the time the TRIPS Agreement came into effect in that country. A further 5 years were allowed for these countries to put in place a product patent framework for technologies and products, such as pharmaceuticals and agro-chemicals. From 1995 onwards, patent applications were kept pending in a patent "mailbox" until the mailbox was opened in 2005, when the applications would be assessed.
- The TRIPS Agreement, because of its economic, financial and administrative constraints, allowed a third transition period for the least-developed countries (LDCs), which extended until 2006. To implement their obligations under the agreement at the request of an LDC Member, this period may be further extended. With respect to patents on pharmaceutical products and exclusive marketing rights, in accord with the Doha Declaration on the TRIPS Agreement and Public Health, LDCs now have a further time extension, until 2016. So, until 1 January 2016, LDCs need not provide for, nor enforce patents and data protection, with respect to pharmaceutical products. Generic competition is possible.

The transition periods have meant pharmaceuticals or medicines patented before developing countries implemented their TRIPS obligations will not receive patent protection. Since developing countries have implemented their TRIPS obligations, patented medicines are progressively coming onto the market and will constitute an increasing share of marketed medicines. Since 2005, when all developing countries were required to provide patent protection for pharmaceutical products and the mailbox patents were processed, considerable progress has been made.[6]

Public health issues

Infectious diseases kill over 10 million people each year, more than 90% of whom are in the developing world.[7] The leading causes of illness and death in Africa, Asia, and the South America-regions (areas that account for four-fifths of the world's population) are HIV/AIDS, respiratory infections, malaria and tuberculosis. In particular, the magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat the disease or alleviate the suffering of those afflicted with it. An estimated eight thousand people die of AIDS in the developing world every day. There are many different reasons why developing countries do not have access to essential medicines, but one of the main reasons is the high cost of these medicines. Strong intellectual property protections and exclusive mar-

[6] WHO, The Doha Declaration on the TRIPS Agreement and public health, Parallel Importation.
[7] T'Hoen.qxd 25/06/2003 11:08 page 40. 7, Intellectual Property, page 7.

keting rights have the effect of raising the price of the needed drugs, making them unobtainable in many developing countries. When the governments of such developing countries attempt to lower the price of medicines, they come under pressure from the multinational pharmaceutical industry, which is generally based in more industrialized countries.[8]

It is also a problem that infectious diseases, which were once relatively easy to cure, are becoming increasingly resistant to existing drugs.[9] Focusing on these threats, improved access to enhanced and affordable medicines is essential, either through new patent protection or by the extension of old patent rights. The danger is that use of the next generation of drugs, needed to protect public health, will be restricted.[10]

The subject matter of patentability under the TRIPS Agreement

What can be patented? TRIPs specifies that patents must be available for all discoveries which ...”are new, involve an inventive step and are capable of industrial application.”[11] The TRIPs Agreement makes the scope of patent protection larger.

Producers of biotechnological processes and products have been extremely concerned about the impact of patenting in developing countries. These range in scope of from ethical subjects, e.g., patenting a plant life, to legal subjects, e.g. how to allocate rights between farmers in developing countries and multinational corporations, who are usually the patent owners.[12]

The TRIPS Agreement requires an invention to be “new.” For a particular drug for malaria, if traditional native doctors have historically used the components of the drug in more basic forms prior to its discovery by a modern patentee, then a national court in a developing country must refuse a patent for the particular drug. Traditional medicines or cultural knowledge are likely to be treated as a product of nature by developed countries, in that they do not satisfy the requirement of discovery.

From this point, assuming all other requirements are present, may a developing country patent an invention that fulfills the requirement of “non-obviousness,” even though it may be a trivial invention? Another related question is the “novelty” requirement; is it a definite novelty requirement or a modified novelty requirement? Clearly, in order to encourage local research in developing countries, low-level inventions are an important stimulus. A modified interpretation of Article 27 may be important for development goals, in order to allow developing countries to patent inventions where the level of inventiveness is not as high as that in developed countries.[13]

TRIPS plus provisions:

“TRIPS-plus”, a non-technical term that refers to national requirements that limit the availability of progress (such lengthening patent life beyond the 20-year TRIPS minimum), limiting compulsory licensing in ways not required, or limiting exceptions to facilitate

[8] Hoen, Ellen F. M..,“TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: Seattle, Doha and Beyond.”
[9] Brundtland, Dr. Gro Harlem, “A Call for Healthy Development,” WHO Report on Infectious Diseases, Removing Obstacles to Health Development.
[10] *Ibid.*
[11] Gana, R. L.(1996) Prospects for Developing Countries under the TRIPs Agreement.’
[12] *Ibid.*
[13] *Ibid.*