Health and intellectual property rights

A new and comprehensive treaty on intellectual property rights was established in 1994, within the framework of the World Trade Organization (WTO). It is called the Agreement on Trade-Related Aspects of Intellectual Property Rights – the TRIPS agreement for short. It requires all WTO member countries to adopt in their laws minimum standards of protection for patents, trademarks, copyrights and other intellectual property rights. It has substantially limited the freedom that countries enjoyed until then to design and implement their own intellectual property systems.

The agreement established a common set of standards for all countries, without differentiating on the basis of socioeconomic and technological development. Developing countries, however were allowed a transition period in which they could delay implementation of the new standards for specified amounts of time.

Although it has many implications for public health, the TRIPS agreement was negotiated with little or no participation from public health authorities. The obligations it sets forth to protect inventions include the following: recognizing patents for pharmaceuticals without distinction between imported and locally produced products; granting patent protection for at least 20 years from the date of application; limiting the scope of exemptions from patent rights; and effectively enforcing patent rights through administrative and judicial mechanisms.

Under this agreement all WTO member countries are now bound to grant patents for pharmaceutical products. This obligation did not exist under previous international conventions. The agreement also provides compulsory protection against "unfair commercial use" of data submitted for the marketing approval of new pharmaceutical products. Complying with the TRIPS agreement in these respects has posed a special challenge for developing countries and raised considerable concerns from a public health perspective. These may be summarized as follows.

First, the patent holder can exclude direct competition, and charge higher prices for patented medicines than would have prevailed in a competitive market. Life-saving drugs can thus be made unaffordable, as has been seen particularly dramatically in the case of HIV/AIDS in sub-Saharan Africa.

Second, most developing countries are excluded from the benefits of protection for inventions because they lack the scientific infrastructure and the capital needed for research and development of patentable pharmaceuticals is beyond the reach of most of them.

Third, the pharmaceutical companies that do invest in R&D focus mainly on the diseases likely to yield the highest return for their shareholders. Diseases of the poor, such as malaria, tuberculosis and bloody diarrhoea are thus neglected.

Fourth, despite some theories and expectations to the contrary, the TRIPS agreement has not stimulated increased foreign direct investment or technology transfer in pharmaceuticals production in developing countries. The experience of some Latin American countries has been the opposite; after the adoption of product patents for medicines, many local firms have been denationalized and several plants have been closed down.

Fifth, a significant part of industry's R&D expenditure goes not on developing new drugs but on expanding the coverage and lifetime of patent protection for existing ones. This is done by patenting minor improvements or modifications such as new crystalline forms, isomers, combinations and formulations.

These considerations do not mean that patents cannot help to stimulate costly research on much needed new drugs. They do suggest, however, that strengthened intellectual property rights will affect developing countries differently from technologically advanced ones. In the latter at present they are apt to lead to increased profits and more innovation, in the former, to higher prices.

Academics, UN bodies and nongovernmental organizations have increasingly voiced their concern about these issues. WHO has stressed the need to reconcile the commercial interests of the patent owners with broader public health interests (1,2).

An important question in this context is the extent to which the TRIPS agreement is flexible enough to allow public health objectives to be met within the framework of the existing rules (3).

The agreement does not impose uniform legal requirements upon the WTO member countries. Countries have to meet the minimum standards it calls for, but are left with considerable leeway within which to develop their own patent laws according to the characteristics of their legal systems, public health situations and development needs. In implementing the TRIPS provisions, they can adopt measures aimed at promoting social and economic welfare (Article 7 of the agreement) and preventing the abuse of intellectual property rights (Articles 8.1 and 8.2).

Developing countries can also adopt measures that mitigate the impact of exclusive rights, promote competition and facilitate access to medicines. This is the case, for instance, with the principle of "international exhaustion", under which "parallel imports" can be allowed. These may apply, for example, to the import of drugs from the countries in which they are cheapest. This is not a means of denying the patentee's right to remuneration (which is received with the first sale of the product), but rather of ensuring that patents work to the mutual advantage of the producers and the users of technological knowledge.

Another important measure to promote competition is the so-called "Bolar" exception. This makes it possible to use an invention to conduct tests on a drug and obtain marketing approval for it *before* the expiration date of the patent, so that a generic version of the drug can be marketed as soon as the patent expires. Argentina, Australia, Canada, Israel, the USA and other countries have legalized this exception.

In addition, Article 31 of the TRIPS agreement allows governments to issue compulsory licences to deal with public health emergencies, counteract anti-competitive practices and meet other needs, as determined by the national law, subject to the conditions (particularly regarding compensation of the patent holder) set forth by the agreement.

In sum, the ways in which the agreement is implemented in national laws can have a significant impact on public health policies and particularly on the population's access to drugs. Developing countries have some flexibility under the agreement which they can use to design national laws that respond to health policy objectives. Other WTO members must respect this flexibility, and recognize that letting commercial interests override public health interests can have disastrous consequences. Patent protection may be necessary for future investments in R&D, but the lives and well-being of millions of people in the developing world depend on this protection being effectively integrated with public health concerns.

References

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