

In 1994 the creation of the World Trade Organization caused the implementation of a new treaty, the largest ever adopted, on the rights of intellectual property. It is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). For the first time this Agreement relates questions of intellectual property with commercial questions, and sets up a multilateral mechanism of dispute resolution between States. The TRIPS Agreement demands that all the WTO Member States introduce into their legislation minimal universal standards for almost all rights in this field, for example the copyright, patents and brands*. Moreover the Agreement limits considerably the freedom enjoyed so far by countries to elaborate and apply their own systems of intellectual property**. According to this Agreement all the WTO members are from now on compelled to protect by a patent for a period of 20 years minimum any invention of a product or of a pharmaceutical process which meets the criteria of novelty, invention and usefulness. Such an obligation did not exist under the previous international agreements. Indeed in the past every nation was considered to have the right to legislate in this field. The international agreements prior to the TRIPS Agreement did not set any minimal standards relative to intellectual property rights. Before the TRIPS Agreement 40 countries did not protect pharmaceutical products by a patent; many did protect by a patent the processes but not the products, and in many countries the patents duration was largely inferior to 20 years.

At present it is recognized that the regime in force of protection by "globalized" patent through the TRIPS has important repercussions on the pharmaceutical sector. Moreover one is concerned by the fact that the standards specified in the TRIPS Agreement are not necessarily adapted to the countries fighting for the satisfaction of their needs in matter of health and development. For this very reason the British Commission of rights advised, in its 2002 report, the countries to see to it that their regime of protection of intellectual property does not jeopardize their public health policy, that they be coherent with their policies and that they promote them.

A patent is a title granted by official authorities on the basis of which a temporary monopoly is given for exploiting an invention to a person who publishes it, describes it sufficiently clearly and completely and claims a monopoly over it. The criteria required for granting a patent demand that the product or the manufacturing process meets the necessary conditions for being able to be protected by a patent, i.e. novelty, inventive characteristics and usefulness.

The world had never had at its disposal such a large array of treatments for fighting the diseases plaguing mankind. At the same time very many persons die through lack of certain medicines and/or vaccines. This situation is due to emerging diseases but also to the serious threat represented by the accrued resistance to the medicines used against common lethal diseases such as AIDS, paludism, tuberculosis, bacterial meningitis and pneumonia.

For developing new medicines some mechanisms will have to be found which promote the innovation and development of new products and which, at the same time, make sure that patients have a fast access to the results of this research.

Preface

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(translated from Spanish)

* Velásquez et Boulet, *Journal de l'OMS* 1999, 77 (3) Essential drugs in the new international economic environment.

** Correa, *Journal de l'OMS* 2001, 79 (5) Health and Intellectual Property rights.

The increasing concern as to how the international trade agreements, in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), could limit the access to medicines led to the adoption of the Doha Ministerial Declaration relative to the TRIPS Agreement and public health. The Doha Declaration was a milestone in the discussions on intellectual property rights and access to medicines by stating that the TRIPS Agreement will have to be interpreted and applied so as to support the right of WTO members to protect the public health and in particular to promote the access to medicines for all. In this sense the Doha Declaration consecrates the principles defended by WHO and promoted publicly throughout many years, i.e. reaffirming the right of WTO members to apply fully the safeguard dispositions foreseen by the TRIPS Agreement, so as to protect public health and promote access to medicines.

From 1999 in the successive resolutions of the World Health Assembly WHO was asked to make sure that its pharmaceutical strategy deals with the important question of the effect of international trade agreements on public health and access to medicines. So the World Health Assembly asked WHO to cooperate with the Member States and the international organizations in view of monitoring and analysing the pharmaceutical and sanitary consequences of international trade agreements; this was done in order to help Member States to evaluate and develop pharmaceutical and sanitary policies and regulations which optimise the positive effects of these agreements and attenuate their negative ones. By these resolutions WHO was given a mandate which can be summarised in this way: 1) analyse and monitor the effects of globalisation on public health, the intellectual property rights and the trade agreements and report to the Assembly; 2) help the Member States to reinforce their pharmaceutical policies and practices; 3) provide a technical assistance and a support to Member States to apply the protections and flexibilities in matter of public health foreseen by the TRIPS Agreement.

More recent resolutions did concentrate in greater detail on the central aspect of these general objectives. In its resolution WHA56.27 of May 2003 the World Health Assembly declares itself «mindful of concerns about the current patent protection system, especially as regards access to medicines in developing countries», and urges Member States «to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)». The Report of the intellectual property Commission created by this resolution is already available and contains important recommendations to countries on this topic. Moreover resolution WHA57.14 of the 22nd May 2004 urges Member States «to take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-related Aspects of Intellectual Property Rights and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)».

WHO has elaborated political prospects on trade agreements, public health and access to essential medicines. These prospects orientate and ensure the coherence of awareness and support for WHO countries. WHO's political prospects deal

with questions relative to the TRIPS Agreement, intellectual property rights and access to medicines. They can be summarized in this way:

- Access to essential and good quality medicines is a human right;
- The price of essential medicines is a public health priority;
- Essential medicines are not basic products like other ones ;
- Patents must be administered in an impartial way, protecting the interests of the patent owner and preserving public health principles, what makes it essential that flexibilities and safeguards foreseen by the TRIPS Agreement are used adequately.

Even if all the analyses and comments of this book do not necessarily represent WHO's views, this booklet of the Centrale Sanitaire Suisse Romande is an excellent contribution to understanding the problem of access to medicines in the present international context. From the creation of the Action Programme for Essential medicines the Swiss Cooperation has played an important role in supporting WHO's action in different countries. This is why we are most happy with this initiative of the Centrale Sanitaire Suisse Romande with which WHO is pleased to collaborate.