WHO/PHI/2009.1

GUIDE FOR THE APPLICATION AND GRANTING OF COMPULSORY LICENCES AND AUTHORIZATION OF GOVERNMENT USE OF PHARMACEUTICAL PATENTS

Carlos M. Correa
University of Buenos Aires

World Health Organization

Printed by the WHO Document Production Services, Geneva, Switzerland

Table of contents

Acknowledgements

This paper has been produced with the support of the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the Directorate for International Cooperation and Development of the French Ministry for Foreign Affairs.

The concept of this paper was first discussed during a workshop organized by WHO/TCM with the cooperation of the UNICEF Supply Division and the financial support of UNAIDS. The WHO-UNICEF workshop on intellectual property coherence in procurement, which was held in Copenhagen, 4-5 August 2005, brought together representatives of UN agencies and other international organizations working on procurement and intellectual property issues. The aim was to coordinate the work of the UN agencies and international organizations, in order to meet three key objectives:

(a) facilitate and promote coherence in the perspectives on intellectual property rights in the context of medicines procurement;
(b) develop, where appropriate, common approaches and strategies on these issues; and
(c) develop legal tools and instruments for use in the procurement process.

This paper is an attempt to foster a common approach in the use of TRIPS flexibilities in medicines procurement. Since the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, it is acknowledged that countries are permitted to take measures, such as compulsory licensing and government use of patents, to ensure that patents do not constitute a barrier to access to affordable medicines. This paper aims to provide technical advice to governments, as well as procurement and nongovernmental organizations (NGOs), on the modalities for the application of compulsory licences and government use authorization. The paper focuses on the use of compulsory licences and government use authorization in the context of the purchase and import of patent-protected pharmaceutical products. It also addresses the special situation of least developed countries, as provided for in paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, which allows least developed countries a transition period until 2016, during which they need not provide for, nor enforce patents and exclusive marketing rights in relation to pharmaceutical products.

It should however, be pointed out that this paper can only provide general recommendations in the process of applying for a compulsory licence or the authorization of government use of patents. The concrete application of these recommendations will necessarily be subject to the provisions of the applicable national law.

The author wishes to acknowledge the comments and input made by participants in the WHO-UNICEF workshop, which included: Frederick Abbott, Florida State University, Hanne Bak Pedersen, UNICEF, Lombe Kasonde, UNICEF, Lori Lee, UNDP, Luca Li Bassi, GFATM, Françoise Mas, WHO, Barbara Milani WHO,

Sisule Musungu, South Centre, Béchir N'Daw, UNAIDS, Cecilia Oh, WHO, Suvi Rautio, UNICEF, and Germán Velásquez, WHO. In addition, the author wishes to thank Elisabetta Molari, GFATM and Frederick Abbott for their further review of the document and WTO for their suggestions and comments on an earlier version.

Any views expressed in this paper are the views of the author and do not necessarily reflect the views of WHO. The author is solely responsible for the opinions expressed herein.

Introduction

Patents - as well as other intellectual property rights - confer exclusive rights. This means that the title-holder may exclude competition in the manufacture and sale of the protected products and, therefore, control the production and distribution of such products and their prices.

The existence of patents on products or processes[1] may prevent in some cases the acquisition of pharmaceutical products at low prices[2] or in sufficient quantities, such as when the products are offered at prices that are not affordable to patients or government purchasing agencies, or the patent owner has no capacity to timely deliver the needed products. In these cases, patent owners may exercise their exclusive rights and prevent supplies from alternative sources.

Like other rights, however, patent rights are not absolute. There are situations in which their exercise can be limited to protect public interests. Such situations may arise, in particular, in the area of public health, when access to needed pharmaceutical products must be ensured. "Compulsory licences" and "government use for non-commercial purposes" (hereinafter referred to as "government use") are mechanisms provided for in most laws worldwide to limit the exercise of exclusive patent rights - under the circumstances specified in the respective laws - which can specifically be used to address public health needs.

For the purposes of this document:

"Compulsory licence"[3] is an authorization given by a national authority to a natural or legal person for the exploitation, without the consent of the title-holder, of the subject matter protected by a patent in order to attain certain public policy objectives.

"Government use"[4] is an act by the government authorizing a government department to exploit by itself or through a contractor a patented invention without the consent of the title-holder.

The right of States to limit the use of patents through compulsory licences has been recognized since the end of the 19th century. They were incorporated into the Paris Convention for the Protection of Industrial Property (Paris Convention) in 1925, and thereafter in most national laws. Compulsory licences and government use have become regular features in patent laws all over the world[5].

---

[1] In some countries, patents on the therapeutic *indication* or *use* of products are also allowed by the national law.

[2] Of course, there are other factors that affect prices of pharmaceutical products. See, e.g. WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, available at http://www.wto.org/english/tratop_e/TRIPs_e/tn_hosbjor_e.htm.

[3] Often also called a "non-voluntary licence".

[4] Also called "Crown use" under British and Commonwealth legislation.

[5] See, e.g. Correa C. *Intellectual property rights and the use of compulsory licenses: options for developing countries*. Trade-Related Agenda, Development and Equity, Working Papers. Geneva, South Centre, 1999; Reichman J. and Hasenzahl C. *Non-voluntary Licensing of Patented*

The right to use such mechanisms was recognized in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994[6].

The concerns of developing countries about the possible impact of patents in the pharmaceutical sector led the WTO to adopt, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health[7]. The Declaration confirmed, *inter alia*, that the granting of compulsory licences (and government use) was one of the clearly admitted flexibilities under the TRIPS Agreement[8], and that WTO Members were free to determine the reasons for the granting of such licences (see Box).

Doha Declaration on the TRIPS Agreement and Public Health: Sub-paragraph 5 (b)

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: ...

b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Compulsory licences and government use can be utilized in relation to any of the rights conferred by a patent, including the manufacture, importation or exportation (subject to the limitation imposed in Article 31(f) of the TRIPS Agreement[9]) of patent-protected products[10], and with regard to all kinds of products, including medicines, vaccines and diagnostic kits.

The present Guide aims to provide practical advice to governments, purchasing and funding entities and NGOs about the modalities for the application of compulsory licences and the utilization of government use provisions. It focuses on the utilization of such mechanisms for the *purchase* and *importation* of patent-protected pharmaceutical products[11]. It contains two sections: in the first section, the application for and granting of a compulsory licence is dealt with; and the second section considers the case of government use, subject to the general

---

Inventions: historical perspective, legal framework under TRIPS and an Overview of the Practice in Canada and the USA . UNCTAD-ICTSD Issue Paper N° 5, Geneva, 2003; *Battling HIV/AIDS. A Decision Maker's Guide to the Procurement of Medicines and Related Supplies.* Washington, DC, The World Bank, 2004.

[6] Article 31 of the TRIPS Agreement, however, does not refer to "compulsory licences" but to "other use without authorization of the right holder". This provision applies to both compulsory licences and government use.

[7] WT/MIN(01)/DEC/W/2, 14 November 2001, available at www.wto.org (full text in Annex I).

[8] On TRIPS flexibilities, see *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement.* Health Economics and Drugs Series No. 7, Revised. Geneva, World Health Organization, 1999 (WHO/DAP/98.9); Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Study commissioned by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). 2006. Available at www.who.int/intellectualproperty/studies/en/index.html.

[9] Article 31(f): "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use".

[10] The expression "patent-protected products" includes patents on products as such, as well as products directly obtained by a patented process. See Article 28.1(b) of the TRIPS Agreement.

[11] As a result, this Guide does not consider aspects that would be particularly important for the use of such mechanisms for the production of pharmaceutical products.

conditions established by domestic legislation. The special requirements that may arise in cases where a compulsory licence is granted in the *importing country* in accordance with the waivers approved by the Decision of 30 August 2003 (which address situations of lack of or insufficient manufacturing capacity in pharmaceuticals)[12] are mentioned in the text, wherever appropriate.

It is important to note that *the concrete application and grant will necessarily be subject to the provisions of the applicable national law*. Therefore, knowledge and understanding of the national law and regulations will be unavoidable in order to efficiently undertake the proceedings for obtaining and putting into practice such authorizations.

As already mentioned, the first section deals with compulsory licences and the second with government use. This sequence has been chosen only for presentation purposes: it does not mean that governments or agencies wishing to purchase medicines should consider granting a compulsory licence as the first option. As explained below, government use may in many cases be the simplest and fastest way of purchasing patented medicines, notably because it can be decided by the government ex officio without the need for a third party's request and, if issued for a public non-commercial purpose, without prior negotiation with the patent holder.