Chapter 8
Compulsory Licensing of Patents in India

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ABSTRACT

Compulsory licensing is defined generally as the granting of a license by a government to use a patent without the patent-holder’s permission. As applied to international intellectual property rights, it allows governments to grant licenses for patent use in situations where the patent-holder is either not using the patent within the country or is not using it adequately. Most of the drugs for which compulsory licenses have been granted in India are used for treatment of life-threatening diseases. The pharmaceutical companies however object on the ground of violation of their patent rights. This chapter discusses the provisions for compulsory licensing in TRIPs and the India patent system.

INTRODUCTION

Compulsory licensing is defined generally as the granting of a license by a government to use a patent without the patent-holder’s permission. As applied to international intellectual property rights, it allows governments to grant licenses for patent use in situations where the patent-holder is either not using the patent within the country or is not using it adequately. Although compulsory licensing is not a new concept, it recently has received considerable attention as pharmaceutical companies and
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Activist groups seek to advance their respective political agendas over the right to drug access for life-threatening diseases. When governments issue compulsory licenses, the result is often a sharp decrease in prices, similar to the introduction of other competitive forces like generic drugs. For this reason, many developing nations argue for the right to issue compulsory licenses for pharmaceuticals that are normally very expensive for their citizens. During the negotiations for the TRIPs agreement (Agreement on Trade Related Aspects of Intellectual Property), however, most developed nations argued for strict restrictions on compulsory licenses to safeguard their domestic industries. In this backdrop, this paper presents a discussion on the provisions for compulsory licensing in TRIPs and India patent system.

The Agreement on Trade Related Aspects of Intellectual Property (TRIPS)

TRIPs agreement was adopted at the conclusion of the Uruguay Round in Marrakesh in April 1994. TRIPs outlined a framework for minimum intellectual property standards that bind all WTO Member nations. TRIPS was significantly disparate from all earlier efforts that were made to achieve harmonization of intellectual property rights worldwide. As part of the founding of the WTO, TRIPS clearly tied intellectual property rights to trade. The TRIPS mandates minimum substantive patent protections for a wide range of inventions. Under TRIPS, member states of the WTO are not permitted to exclude any field of technology from patentability, including pharmaceuticals. Also, WTO members are required to provide a uniform term of twenty years of patent protection from the filing date of any invention. TRIPS further forbids parties from providing patent protection that differentiates between inventions based on place of invention or from requiring that inventions be produced locally. TRIPS introduced some remarkably new patent provisions in the international intellectual property law most significant out of them was that TRIPs allowed for compulsory licensing amidst several other provisions in its Article 31.

Article 31 of TRIPS, entitled “Other Use Without Authorization of the Right Holder,” lays down the conditions under which WTO member countries can authorize compulsory licenses for patented inventions. This provision requires that WTO member countries first engage in negotiations for a reasonable period of time to obtain authorization from the patent holder on reasonable commercial terms and conditions before authorizing a compulsory license. In the case of a “national emergency” or other “circumstances of extreme urgency,” these requirements can be waived by the WTO member country. Even in these circumstances, however, the WTO member country authorizing the compulsory license has a responsibility to inform the patent holder of its actions. The use of a compulsory licenses under
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