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Compulsory licensing: India's maiden experience

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Abstract: Under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) all parties to the agreement are allowed flexibility in issuing licenses for manufacturing pharmaceutical drugs, in line with their public policy objectives. The licenses may be issued under certain conditions, even if the patent holder (innovator) has an exclusive right to the markets. India made use of this flexibility in March 2012 when it granted its first compulsory license to a domestic company for manufacturing and selling a generic version of an anti-cancer drug. This action was contested at the Intellectual Property Appellate Board, but in March 2013 the final decision was in favor of the issuing of the compulsory license.

This paper details the first attempt by the Indian patent system to strike a balance between the innovator's legal and economic rights and the public interest policies of the Government. The paper attempts to set out the various issues and challenges related to this case. An assessment of the compulsory licensing provisions under the TRIPS agreement and the Indian Patent Act shows that the intellectual property regime in India is World Trade Organization (WTO) compatible, and that public health interests need not always be compromised. The authors reason out the possible implications for the various stakeholders through a cost-benefit analysis approach.

JEL Classification: O34, K33, I18, L65

Key words: Intellectual property rights, compulsory license, pharmaceutical, public policy, patents, rights and obligations.

Contents

List of Tables

List of Figures

Introduction

India is one of the largest pharmaceutical manufacturers in the world, ranking third in terms of production volume (9.3 per cent of the global share). Yet 65 per cent of India's population still lacks access to essential medicines (Department of Industrial Policy and Promotion, 2010). This is not surprising considering the high prices of drugs, the low income levels and poor public insurance coverage in India.

Moreover, India accounts for 21 per cent of the world's global burden of diseases (World Health Organization, 2012). Developing countries such as India generally experience a high incidence of diseases because of the poor living conditions, inadequate sanitation and hygiene conditions, and low awareness of diseases and health-care measures. The burden of several diseases is also unusually high in India. For example, in India between 2 million and 2.5 million persons are suffering from cancer and some 2.5 million persons are infected with HIV/AIDS, the latter being the highest number of reported HIV/AIDS cases in the entire South Asian region (Department of Industrial Policy and Promotion, 2010).

In addition, India still continues to suffer from a host of diseases that are typical to developing countries, such as tuberculosis, malaria, dengue fever and diarrhea. It was expected that strengthening the intellectual property (IP) regimes and introducing product-based patents in developing countries under TRIPS would result in innovation and development of medicines that were of particular interest to developing countries. However, the development of new drugs in the developing countries has been limited while access to existing drugs is becoming more and more problematic under a stricter IP regime.

At the heart of any patent system lies the responsibility of policymakers to strike a balance between making an innovation available in a commercially viable form at a reasonable price to the public at large while providing fair returns to the innovator. Compulsory licensing is a tool by which a Government allows third parties (other than the patent holder) to produce and market a patented product or process without the consent of the patent owner. Compulsory licenses ensure that the monopoly rights of the innovator do not undermine the right of the people to have access to medicines at affordable prices.

The current paper discusses the various issues and challenges of India's first compulsory licensing case. Section 1 elaborates on the relevant international and national legal provisions for compulsory licensing. Section 2 cites global instances where compulsory licensing has been used in the post-TRIPS era. Section 3 discusses the legal considerations surrounding the ruling while section 4 gives the economic implications for the Indian pharmaceutical industry. Section 5 concludes by highlighting the conflicting interests of the stakeholders. Compulsory licensing appears to be a viable option that may be explored by developing countries such as India for ensuring continued access to medicines while still working within the ambit of international commitments.

1. Legal provisions

The legal underpinnings for compulsory licensing have been provided in the TRIPS Agreement, which has its antecedents in the Paris Convention. India also included clauses for compulsory licensing in its national legislation, even as it shifted from a process-based patent regime to a product-based one for pharmaceuticals, in compliance with the TRIPS Agreement.

1.1. Under the Paris Convention

The Paris Convention of 1883 envisaged provisions for each contracting State to take legislative measures for granting compulsory licenses. According to Article 5A (2) of the Paris Convention (World Intellectual Property Organization, undated):

> "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory license to prevent the abuses that might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work"[1] (Paris Convention, 1883 – amended in 1979).

The Convention provided for the granting of compulsory licenses by the member countries at least in cases of the non-working of a granted patent in a country or union. Thus, the concept of compulsory licensing also existed in the pre-WTO era. In fact, the concept of compulsory license existed as early as the 1850s in the then-named United Kingdom of Great Britain and Ireland.

1.2. Under TRIPS

Compulsory licensing is covered in the TRIPS Agreement by:

(a) Article 30, which provides limited exceptions to the rights conferred under patents,