

# Chapter 7

## Product Patent in Pharmaceuticals and Compulsory Licensing

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### ABSTRACT

*The issue of patenting is a contentious issue. Different stakeholders hold opposite views. The pharmaceutical giants demand for stricter and longer Intellectual Property Protection for the promotion of research and development. They contend IP protection to be the “bedrock of their business”. While the health activists and governments of developing nations want greater flexibility in intellectual property protection and shorter patent period protection. Article 31 of the TRIPs agreement provides certain flexibilities to cater to certain situations. The countries are free to determine the grounds to issue provisions like compulsory licensing. But despite the provisions very few countries have used them. Pharmaceuticals giants with the backing of developed countries always try to denounce the practice of compulsory licensing with economic and political pressure. This chapter explains the concept and significance of Intellectual Property with reference to Pharmaceuticals. It also traces the little history of TRIPs agreement and explains the concept of Compulsory Licensing with trends in its use. It also discusses the few instances where compulsory License has been issued in different countries and tries to find the reasons of non issuance of Compulsory License.*

### INTRODUCTION

Over the last 50 years, the world has made some significant progress in medical research and development of new drugs to combat deadly diseases. The average life expectancy across the globe has increased from around 30 years a century ago to 65 years today. This has been made possible in large part by medicines. But at the same time due to rapid technological advances, industrial pollution, global warm-

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ing, destruction of flora and fauna various new forms of diseases have emerged and people are at higher risk especially in developing and under developed countries because of poor health care facilities. The current regime of Intellectual property rights (IPRs) has further hit the health sector badly. Intellectual Property Rights received a major push with the formation of World Trade Organization (WTO) and its binding Trade related aspects of Intellectual Property (TRIPs) agreement. The TRIPs agreement made Intellectual Property (IP) protection binding in all fields of trade including food and health which was earlier excluded. Since then the most controversial aspect of World Trade Organization's TRIPs agreement is over the issue of patents for pharmaceutical drugs. . (Siddiqi, 2005)

The inherent tussle between profit-driven drug companies and welfare oriented governments seeking to ensure cheaper access to essential medicines has occupied the global centre stage after the ratification of the TRIPS agreement by the World Trade Organization. .(Sood, 2013) The Membership of WTO is conditional on the pre-condition of signing of its related agreements especially TRIPs. The countries will have to amend their IP laws to bring them in consonance with TRIPs agreement. Earlier many developing countries did not allow patent in pharmaceuticals, this represents a significant change in the pharmaceutical sector.

Worldwide, there is growing concern about the impact of the Patent system on the health sector of developing countries, on innovation and on investment, on prices of vital life saving drugs etc. Proponents believe this will lead to an increase in investment and in R&D, yet public health experts, consumer groups, health workers across the world and especially in poor countries have expressed concern about the impact of the TRIPS Agreement on the availability and prices of drugs (Jakarta, 2000). The local pharmaceutical industries in countries such as Brazil and India can no longer reverse-engineer patented foreign medicines and sell them at low prices in the markets of developing countries. .(Bond & Saggi, 2012a)

## **Intellectual Property and Pharmaceuticals**

Continuous Innovation is necessary for the prosperity of individuals, companies and nations. But Innovation is not a simple and an isolated process. It involves numerous factors such as technical know-how, Intellectual property laws, governmental support, University collaborations, risk taking behavior and availability of Investment capital. From the above referred Intellectual property was specifically created as a key driving force for stimulating innovation (Gupta, 2010).

The intellectual property rights system has been developed in order to achieve two contradictory aims:

- To promote the publication of ideas, inventions and creations, in order to make them available to others, who can then further improve them; this will nurture scientific progress or artistic inspiration;
- To provide an economic incentive for people to invent or to engage in creative efforts, by ensuring that the originator can reap the financial rewards of his/her efforts by giving a temporary monopoly, in exchange for making his/her idea known to society.

The pharmaceutical industry across the world in particular is dependent upon Intellectual Property protection for its growth and sustainability. In the pharmaceutical sector, patents<sup>1</sup> are the most important form of IPR protection. In fact, the very existence of the Trade Related aspects of Intellectual Property

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