Chapter 53
Influence of Patent Law on Price of Medicines: A Comparative Analysis of Various Countries

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ABSTRACT

There is a great deal of disparity between the availability and affordability of medicines in least developed, developing and developed nations. Patents are one of the major reasons of this difference. The pharmaceutical industry spends over US$10 billion to fund some 90% of 40,000-80,000 randomised controlled trails being conducted across the world at any given time. A United Nations AIDS study reported that the number of people in poor countries who have access to anti-retroviral medicines remains extremely low; only 30,000 received medication in 2002, out of an estimated 5 million in need. The proposed chapter aims to study effect of patent law on pricing of medicines. The legal and regulatory policies such as TRIPs jointly introduced by various nations to regulate the pricing of patented products will be elaborated in this chapter. Apart from national and international policies, the behaviour of pharmaceutical companies also affect price of patented products. The chapter will also cover various techniques pharmaceutical industry adopt to control price of patented products such as proliferation of me-too drugs, product reformulation, prolonging patent rights, biasing research and large promotional expenditures.

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INTRODUCTION

Patent monopoly creates a lot of problems. It allows the patentee to charge the maximum to consumers. This may not be a problem if the patented product is a luxury item, like parts that go into a smartphone, but can violate basic human rights if it involves things such as life-saving drugs. -Ha-Joon Chang (2016)

Each year millions of human lives end in death from poverty-related causes, such as respiratory infections, HIV/AIDS, tuberculosis, malaria, measles, and tropical diseases.[1]Many of these are treatable, if not curable, conditions. Lybecker (2011) further suggests that the numbers of such deaths are overwhelming and mandate an examination of the barriers to accessing medicines in developing countries, where the majority of these deaths occur. Admittedly this is an immense and complicated issue, and the economics behind pharmaceutical innovation and access is but one facet of a complete understanding of the problem.

While dwelling on the economics aspect of the pharmaceutical industry, DiMasi, Caglarcan, and Wood-Armany (2001) found out that the investment of societies around the world on biomedical research leads to important developments including the continuous discovery of new pharmaceutical compounds. It is not clear, however, whether newly developed and approved drugs cover all therapeutic areas in a relatively uniform manner. Different reasons might be postulated with respect to the driving forces of drug development.

Of all the goods and services traded in the market economy, pharmaceuticals are perhaps the most contentious. Though produced by private companies, they constitute a public good, both because they can prevent epidemics and because healthy people function better as members of society than sick ones do. They carry a moral weight that most privately traded goods do not, for there is a widespread belief that people have a right to health care that they do not have to smartphones or trainers. Innovation accounts for most of the cost of production, so the price of drugs is much higher than their cost of manufacture, making them unaffordable to many poor people. Firms protect the intellectual property (IP) that drugs represent and sue those who try to manufacture and sell patented drugs cheaply. For all these reasons, pharmaceutical companies are widely regarded as vampires who exploit the sick and ignore the sufferings of the poor (The Economist, 2014).

In Least developed and developing nations it is a cruel sight to watch our patients die because they cannot afford the drugs that could improve, extend, or save their lives. Price is not the only reason why people do not get the medicines they need, but it is a major barrier. The high cost of many life-saving drugs not only keeps patients from getting treatment, but also discourages health ministries from improving the quality of patient care through the use of newer and better medicines. While the $406 billion-strong drug industry researches, develops, markets, and prices medicines for the industrialised world, there is no mechanism to make newer medicines affordable to developing countries. Newer drugs, which are usually under patent and more expensive than those off-patent and this vicious circle has no end and keeps on playing with the lives of all those people who have poor paying capacity.[2]

The Dilemma of Pharmaceutical Patents: Policy Framework Aspect

In 1994, the World Trade Organization (WTO)[3] completed the Trade-Related Aspects of International Property Rights agreement (TRIPS)[4], which called for the standardization of IP law among all WTO members. Most of the countries prior to the WTO regime did not have a very strong Intellectual Property rights protection. However, the WTO introduced a mandatory product patent regime. As a result, most