Chapter 7
Optimal Policy for Biopharmaceutical Drugs Innovation and Access in India

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ABSTRACT

In theory, patents work by providing the inventor an incentive to invent in the first place and then to disclose. Disclosure to the public is rewarded by giving the inventor a monopoly. As product patent and higher patent protection has been advocated by Art 27.1 of the TRIPs agreement on the basis that for greater innovation through transfer of technology is a necessity in developing countries like India as it provides capital to fund expensive innovations, who are otherwise not be able to fund expensive innovations on its own. On the other hand, at the same time drugs are also related with the health of the people and to take care of the health of the people is the utmost priority of any Government and there are issues like accessibility with regard to strong patent protection to biopharma products and data exclusivity. Also as per Art 7 of the TRIPs transfer of technology has to occur to the developing countries in order to promote technological innovations, which is conducive to social and economic welfare. Therefore, striking the right balance between incentive and public access creates a tension is essential. This study suggests optimal policy (Patent and other regulations) to have a balance between biopharma drugs innovation and their access in India while complying with the provisions of the TRIPs agreement by broadly categorising variables such as (1) patent policy such as the scope of biotech patents and the extent of the right in terms of breadth and length; and (2) regulatory environment such as the taxation incentive, Investment policy, Government initiative for the development of this sector etc.

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INTRODUCTION

Useful inventions in the field of biotechnology have contributed significantly in recent years for the benefit of the humanity as many different technologies in chemistry and biology are being combined to develop new therapeutics (Bioventure on Global Health, n.d.). For example, advances in the recombinant DNA technology, study of the cell growth, gene therapy proteomics, and bioinformatics contribute to the development of proteins can provide cures for many chronic and hereditary disease as Alzheimer disease (Bioventure on Global Health, n.d.). These inventions are important for a country like India where there is widespread of these diseases. According to World Health Organization Special Programme for Research and Training in Tropical Diseases (WHO/TDR) neglected diseases are leishmaniasis, schistosomiasis, onchocerciasis, lymphatic filariasis, Chagas disease, malaria, leprosy, African trypanosomiasis, tuberculosis and dengue. It is further categorized into most neglected and neglected diseases.

Neglected diseases are considered to be the highest number of patients (Commission on Intelligent Property Rights, 2003). Three main neglected diseases, HIV, tuberculosis and malaria accounts for 40% of deaths caused by infectious diseases (Bioventure for Global Health, 2006).

India is burdened with a larger HIV/AIDS epidemic than any other country in the world. It accounts for almost 13 percent of the 40 million people living with HIV/AIDS globally and over 69 percent of the 7.4 million people living with HIV/AIDS in the Asia and Pacific region in 2003 (NACO report, 2003). At the same time investment for these drugs innovations is negligible (Figure 1), therefore availability through technology transfer from the multinational innovator companies are desired.

Higher patent standards and data exclusivity provisions have been advocated on the ground that the same will contribute to greater transfer of technology which will lead to greater innovation in India (R. Rashmi, 2007). In the absence of such provisions they are reluctant in introducing new drugs in India. In biotechnology sector, discovery of entirely new drug takes years and costs million of dollars, where as the copy of the same can be manufactured in very little time and in fraction of the money spend in the discovery of new drugs. In biotech innovation only 22 percent of drugs that enter clinical trials eventually receive FDA approval (Masi, Hansen, & Grabowski, 2003). Also, it costs about $400 million, on an average, in out-of-pocket expenses to develop a new drug (Masi, Hansen, & Grabowski, 2003). Also in the absence of such, modern medicine which reaches barely 30% of India’s own population and there is no coverage for over 600 million people (Pharma, 2001). Thus, in order to recoup the high and rising costs of biotech R&D, inventors need to capture enough of the economic returns to make their investment worthwhile through stronger patent protection. As patents grant an exclusive right to exploit a specific product or process for a set period of time, which protects new products from competitors, and enable exclusive right to market. Harding’s metaphor of tragedy of commons has been used as a powerful justification for privatizing common property (Hardin, 1968) and the stronger patent protection is seen as crucial for the commercial success for the biopharmaceutical companies as they sustain the large and risky R&D expenditure needed for the product innovation (Lall, 2003). It also enables them to recoup the significant investments they have made in developing and discovering the new products and processes and bringing them to the market. Further, patent protection enables companies to generate sufficient income to support future research and develop new products. Patents, therefore, are the lynchpins of the biopharmaceutical industry (Parker, 2001). Thus, from the private interest point of view, patents are important as a reward to the innovator to stimulate private investment...
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