THE WTO AND INDIA'S PHARMACEUTICAL INDUSTRY
(Patent Protection, TRIPS, and Developing Countries)

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The book relates the current status of pharma industry with market research with special focus on patent protection, TRIPS, and developing countries pharmaceuticals sector status. The reviewed book is of Ist edition with three impressions. The book is published by Oxford Press; New Delhi. The author is professor of economics at Indian Institute of Management, Calcutta. His research includes work on role of MNCs and indigenous enterprises, industrial policies, problems of globalization and liberalization in the Indian context.

With the introduction of sulpha drugs in mid-1930s and penicillin in early 1940s, the international pharmaceutical industry went through what is usually referred to as a therapeutic revolution. Accomplished by several other discoveries and inventions, the pharmaceutical industry was transformed into a vast research and development (R&D)-intensive industry. The establishment of the world trade organization (WTO) in 1995 brought about significant changes in international economic relations between countries. To comply the Trade Related Aspect of Intellectual Property Rights(TRIPS) agreement of WTO, India introduced product patent protection in pharmaceuticals from January 2005.TRIPS has generated a huge controversy in India and aboard & India has emerged as low cost , quality drugs for the entire world and thus plays an important role. The present book analyses: the remarkable growth of the Indian pharmaceutical industry since the early 1970s when product patent protection in pharmaceuticals was abolished; weather the claimed benefits for developing countries, under TRIPS, have materialized; what can be done, if as apprehended, the policies of patent protected drug rise; and whether, and to what extent, developing countries have been able to use the provision and the flexibilities promised under TRIPS.

In Chapter 1 i.e. the Introduction, he introduced various national and Multi-National Companies which acquires a large coverage of R&D for new drugs. Out of which the PFIZER (New York, USA) is the largest pharmaceutical MNC. With a brief introduction of TRIPS (Trade Related Aspect of Intellectual Property Rights) its objective is studied and it is basically to assess the cost and benefits and try to analyze the impact of TRIPS on the Indian pharmaceutical industry, pharmaceutical production, innovation and prices in developing countries. He also mentioned the major problems of international structure of Indian pharmaceutical industry. One of them is MNCs neglects the drug development for poor countries.

In Chapter 2, focuses on the pre –TRIPS situations in India. It is discussed how, by using patent rights, the MNCs prevented a developing country from realizing its potential of industrial growth. It is analyzed how, by using a different patent law and other industrial policies, India was able to dislodge the MNCs from the position of dominance and how the local pharmaceutical industry achieved remarkable growth. He studied the national patents, industrial policies, and rise & growth of pharma industry in India. Emergence of India as a major pharmaceutical producing nation is due to tradition of development of process-technology by indigenous enterprises; the externalities associated with the setting up of two major public enterprises; the close association between manufacturers and government laboratories; and the patent and industrial policies since the 1970s. This chapter will first trace the evolution of the indigenous sector and discuss how its potential could not be realized before the 1970s because of the existing patent systems and unsupportive industrial policies. Thereafter it will discuss the complete transformation and remarkable growth achieved by the industry after the introduction of the new patents Act, 1970 accompanied by other policies. He described the indigenous pharma industry under product patent and its benefits as well as the contribution of CSIR and its laboratories with the slight summary. He elaborated that India has a long tradition of drug manufacturing. But the full potential could not be

realized because of the constraints imposed by the British Patent Act of 1911 which was in force till 1972.

In Chapter 3 deals with the implementation of TRIPS and the changes in India patent regime. This chapter describes the key features of the amendments and the analysis whether the amendment act has taken advantages of the provisions and the flexibilities, which are promised in the trips to strike a balance between the private rights of patentees and the socioeconomic needs and objectives of the country. He introduced the TRIPS in detailed view, implementation of TRIPS in India with a three stage frame i.e. introduction of facility to receive and hold product patent applications in the fields of pharmaceuticals, compliance from 1st January 2000, with other obligations of TRIPS and introduction of full product patent protection in pharma sector with its flexibilities like provide exemptions from grant of patents in certain cases; provide exceptions to product patent rights in certain cases; limit data protection; provide for government use; and provide compulsory licenses to non patentees. Under TRIPS, it is mandatory for all member countries of WTO to provide patent protection for all products (pharmaceuticals).This chapter also deals with dependence on national patent laws, patents are possible not only for NCEs (New Chemical Entities), that is, the active ingredients present in the new drugs, patents can also be taken out for new processes of manufacturing, new formulations, new combinations, new uses of existing, and new drugs.

In Chapters 4 and 5, he discussed that a patentee could prevent others from producing a new patented drug by describing all the known and all the possible processes and, hence effectively enjoyed product patent rights. The Act of 1970, by the permitting a patentee to patent only one process, abolished such product patent rights**.** He gave a detailed account on role of MNCs in Indian pharmaceutical industry. One of the arguments in favor of TRIPS is that, as the MNCs begin to feel that their intellectual property assets are secure in developing countries, like India, there will be flow of FDI and technology transfer. He studied the drug manufacturing after Independence and how MNCs prevented Indian Companies from manufacturing. With industrial policies changes, Liberalization and reaction of MNCs in which he discussed the import and export production .

He took up the two important issues as followings:

1. As the MNCs begins to feel their intellectual property assets are secure in developing countries, there will be an increase in the flow of foreign direct investment(FDI).and technology transfer resulting in greater technological and economic growth in developing countries.
2. As the local pharmaceutical companies in developing countries feel that they can reap the benefits from investments in R & D for developing new drugs for diseases neglected by the global MNCs.

These chapters analyses response of the MNCs to TRIPS and the implications for the growth of the industry in INDIA It would be interesting to consider there behavior both before and after patent act , 1970. Chapter 5 first reviews the nature of the neglect. Then it discussed the response of the Indian companies so far as R & D. is concerned tries to analyze weather TRIPS is likely to result in the development of new drugs for neglected diseases. Restriction of the activities of the MNCs in India is also discussed that they have been withdrawn since the mid-1990s and on imports since the early 1990s.

Chapter 6 Titled: Growth And Prospects Of Generic Pharmaceutical Export From India. In which he studied entry barriers in the United State generic markets with brief discussion on the sections named regulatory barriers, cost and risks of litigation, timing and operations scale with the status of Indian exporters in the US market and the future prospects of Indian pharma exports. He also studied the patent system and the nature of anti-barriers in the generics market in the US is first discussed and then in the light of past performances, the prospectus of further generics exports from India is analyzed. In last he reported an appendix (pp216) of case study of role of patent act 1970 on India's exporters, in which he taken some national and international companies. He mentioned the opportunities to gain the necessary experiences and earn resources to enter in US market.

In Chapter 7 briefly reviews the debate discussion on the topic that in the multilateral trade negotiations leading to a formation of WTO, what has been most debated is the impact of TRIPS on the accessibility of drugs. Then in the context of India and the light of her past experience, lesions

are drawn about the post -2005 period when a full fledged product patent system will be in force in India. In this chapter he discussed the status and potential of such different pricing and other initiatives which the MNCs, the governments of the developed countries, and international organizations may take.

Chapter 8 discusses the drug price control. the nature of price control both before and after the patent act 1970 is taken up and the problems of using price control measures effectively in the product patent regime under TRIPS is analyzed. He analyzed the government success in reducing the price differentials in the retail formulation marketing some cases and finalized that it is due to of improper implementations of the price control provisions and also because of the dilution of price control over the years. He also wrote that price control is not a substitute for generic competition because the getting procedure for both is different for each other. He measured the extent to adopt drug price control and the discipline the MNCs in a product patent regime.

In the last chapter i.e. **the Chapter 9** titled 'should developing countries provide patent protection in pharmaceutical products?' is in the light of findings, in particular, should be forced to provide product patent protections in pharmaceuticals. In this chapter he demonstrated the principal economic rationale granting patents. He advised some important proposals with the request of implementation for improved availability and accessibility of drugs without any adverse impact on innovation.

This book will be helpful to introduce and identify the relations of Indian pharmaceutical industry with international market and their research status and a great source of its historical background. It introduced to various national policies for growth of pharma industry, patent system in India with complete introduction of drug price control. This book will be interest of interest not only to academics but also to policymakers, pharmaceutical industries, business analysis, management students, NGOs, and other interested in the impact of globalization under the WTO.

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