TITLE- COMPULSORY LICENSING AND GENERIC DRUGS: ISSUES AND CHALLENGES -A CASE STUDY OF INDIA

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Abstract:

This study is dealing with the aftermath of compulsory licensing granted for the first time in India in a famous judgment delivered in Natco v. Bayer case, 2012. The research has taken various aspects such as price fixing of drugs, the Indian pharmaceutical industry and their future growth through generic drugs, voluntary licensing and compulsory licensing and TRIPS flexibilities etc. to understand the realm and need of compulsory licensing and to comprehend the approach to accessibility, affordability and availability of drugs to the poor public. Also this study took a profound interpretation of laws specified in Indian Patent Act, 2013 from sec. 84 to sec. 92 A by keeping in view the initiatives taken under TRIPS and Doha Declaration. Although this study is a based on India still a comparative study on South Africa, USA, Thailand, European Union and Canada is being done to come out with suitable suggestions in relation to compulsory licensing in patent.

Key Words:

Compulsory Licensing Patent, TRIPS, Generic Medicines, pharmaceutical company.

The reasons for the lack of access to essential medicines are manifold, however, in many cases, the high prices of drugs are a barrier needed treatments. Such exorbitant, and thus, prohibitive drug prices are often the result of strong intellectual property protection especially patent. Despite the enormous burden of disease, drug discovery and development targeted at infectious and parasitic diseases in poor countries has ground to a standstill because drug companies in developed and developing nations simply cannot recoup the cost of R&D for products to treat diseases that abound in developing countries. A number of new medicines vital for the survival of millions are already too costly for the vast majority of the people in poor countries. In addition, the investment in Research and Development (R&D) towards the health needs of people in developing countries has almost come to a standstill. Developing countries, where three-quarters of the world population lives, accounts for less than l0% of the global pharmaceutical market. The research is focusing on the role of TRIPS as well where the origin, patentability and flexibilities are discussed in details. The TRIPS Agreement, effective from January l, 1995, is the most comprehensive multilateral treaty on intellectual property rights till date (TRIPS,1994). This Agreement sets out the minimum standards for protection of intellectual property, including provisions to be made for product patents for drugs and pharmaceuticals (Article 27.1), which member states must comply with. The Agreement,

keeping in mind the needs of the developing countries, have afforded certain flexibilities, which may be harnessed by developing and underdeveloped countries, in order to control over-pricing of the drugs, so that medicines are within reach of the economically disadvantaged sections. Under the TRIPS Agreement, developing countries that did not provide patent protection for pharmaceutical and agricultural chemical products were given 10-year transition period to establish such protection. In the interim, however, these countries were required to establish a "mail box system" to receive and date patent applications. [n addition to the grant of mail applications, as designed to preserve the novelty of the inventions and priority of the applications during the transition period, the TRIPS Agreement also required the countries to grant Exclusive Marketing Rights (EMRs) to certain products that are subject to mail box applications.

Finally the study on the issues and challenges relating to generic medicines and compulsory licensing in India is divided mainly into 4 segments. The first segment is devoted towards the patent meaning, concept and the need of patent system. The second segment is tilted towards compulsory licensing meaning and the related provisions of developed and developing countries into it. The third segment is based on the area of pharmaceutical companies, their development and more especially in the field of generic drugs and their import and export. The forth area is focused towards the issues and challenges where the assessment is done on the basis of the response taken through the patent attorneys, patent agents, doctors and patients. Thus as per the above classification, it can be concluded on the basis of the analysis of the first three chapters where the need, objectives, patent theories and international laws relating to the same discussed in detail. So the analysis says that Indian patent system is not only inherently nationalistic but aggressively nationalistic. In other words, there are no universal or standardized requirements or qualifications for patentee patentability in the world. The trend of extreme patent imperialism has been such that it is often challenging, if not impossible, to identify in realistic terms conditions for patents issued.

The comparative study of various nations reflected in the research of this chapter shows as under that the effect of the permitting framework on advancement, the compulsory licensing in the long run didn't influence the expenses of research and development in connection to new prescriptions following the execution of exemptions to licences. The fifth chapter research is fully in the line of the development of pharmaceutical companies and their growing business in worldwide. The importance and value to business of patent process is considered to be helpful to product-based companies. The study acknowledges that the problem of access to medicines in developing countries is a multifaceted problem that needs multiple responses. The research of the seventh chapter which is entirely based on an empirical work and where the views of patent attorneys, doctors, pharmaceutical companies and patients were taken on this issue demonstrates separately the following submissions: Most of the patent attorneys and patent agents are not satisfied with TRIPS arrangement and its flexibilities but in the context of India the same is required without any hiccups. The experts were also of the view that the present regime needs to be modified but not due to the pressure of USTR. Most of the doctors are not found to be satisfied with detailing made to them by the medical representatives about information, usage and side effects of the Pharmaceutical products.