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Pharmaceutical Patenting In India-Problem of Public Access to Health

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ABSTRACT
Intellectual property Laws in India are getting more popular these days. It bestows a relief to the novel creators that their idea will remains theirs. And among all, the patent law is one of the most significant one. However, when it comes to pharmaceutical drugs, which is a vital item for every individual, the same laws act as obstruction to the access of these necessitous medicines. This paper basically deals with the pharmaceutical drugs, and it's patenting in India, along with challenges that are faced in the public access to health.

I. INTRODUCTION

In country such as India, a considerable part of the people is living in poverty who are not in condition to meet daily healthcare expenses and it significantly shows that there is a health crisis with inadequacy of resources with respect to affordability, availability and accessibility of the medicines in India. The Indian government introduced a provision into the patent law under the obligations of world trade organisation's agreement on trade-related aspects of intellectual property rights also known as TRIPS. Section 3(d) is an exclusive provision under the Indian patent law which tries to limit the grant of "secondary" pharmaceutical patents. It attains a balance between TRIPS directive and protects access to medicine and drugs for the low-income population. whereas this situation has subjected to a change after the TRIPS regime. The Indian market being an important supplier of low priced affordable pharmaceutical products makes the patenting issue more relevant. The recent judgement including that of the Supreme Court in the NOVARTIS A Cancer Drug "GLEEVEC" case point toward that India stays to place a premium on public health in relation to pharmaceutical patent law and it is seen that the pharmaceutical patents restrict the competition which led to rise in the prices, and are a significant hurdle to access of medicines in developing countries such as India itself. IPRs and New Patent Regimes in IndiaBroadly, intellectual property refers to creation of the human mind and deals with legal rights governing the use of such creations. The IPRs exclude third parties from accessing the protected subject matter for a specific period and the same may encourage the owner to use or disclose their creation and further engagement in creativity and innovation (Watal, 2003). The Uruguay round of multilateral trade negotia-tions (from September 1986 to December 1993) under the General Agreement on Tariffs and Trade (GATT) led to the formation of World Trade Organisation (WTO). Apart from the multilateral trade agreements (MTAs) in goods and General Agreement on Trade in Services (GATS), the WTO extended its coverage to the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Since its inception in 1995, WTO showed commitment towards following TRIPS rules and aims at establishing strong minimum standards for protecting IPRs including copyrights, patents, trademarks, industrial designs, geographical indications, semiconductor topographies and undisclosed information. This has made WTO member countries and international agencies revise their laws to comply with TRIPS rules. Along with WTO, a specialized body of United Nations called World Intellectual Property Organisation (WIPO) functions as a forum for promoting strong IP regimes. A strong IP regime may encourage inventors to disclose details of their inventions in exchange for a limited monopoly and promote innovation. However, developing countries argue that IPR legisla-tions as proposed by the WTO have the opposite effects: it can restrict developing countries' access to new technologies and knowledge that emerge from innovation. When access to foreign technologies plays an important role in facilitating local production in developing countries, a stronger IPR regime may adversely affect local production in developing countries and local companies may face risk of litigation and exclusion from the market (Correa, 2015). Its impact varies across industries and nature of

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economies. For instance, patent plays an important role in the pharmaceutical industry where innovation-based firms hold large patent portfolios and control production and marketing of their drugs worldwide (Correa, 2011).

The new IP regime may affect developing countries in several ways; it may weaken their 'efforts to improve public health, and economic and technological development more generally, particularly if the effect of introducing patent protection was to increase the price and decrease the choice of sources of pharmaceuticals' (Commission on Intellectual Property Rights, 2002, p. 34). In any country, the net benefit or cost from IPRs depends on its productive profile, R&D infrastructure and other factors and policy space to adapt the IPR regime to local conditions and needs (Correa, 2015). Some see IPRs prin-cipally as economic or commercial rights, while others identify them as akin to political or human rights. Thus, access to essential drugs can be seen as a critical part of the fundamental human right to health3and private IPRs should not take precedence over human rights. Compared to other domains of IPRs, patents attracted more attention from scholars, policymakers, industrialists and the general public. Patent provides exclusive rights to an inventor to prevent others from making, selling, distributing, importing or using their invention without license or authorization for a fixed period of time. If a product patent is granted to a person over a product, no one other than the holder can make or produce the same for a specified time. Granting of process patent allows more than one producer (for the patented product), since the product can be from different processes or technolo-gies (Chaudhuri, 2006). It gives the patentee exclusive rights to make, sell or otherwise exploit the inven-tion for duration of patent.India also followed the WTO direction in strengthening the IP regime in the lines of TRIPS. In fact, India has a long history of IP regimes, since the first IPR legislation which was enacted in British India in 1856 (Table 1). It was George Alfred De-Penning, a civil engineer, who made the first patent application in India. The Government of India officially declared 'exclusive privileges' for encouraging inventions by new manufacturers on 28 February 1856. On 3 March 1856, he petitioned for the same to his 'Punkah Pulling Machine' and the application was accepted and granted the first ever IPR in India. Later he was Table 1. Milestones in India's IP Regime
Year Details of Amendments
1852 The British Patent Law
1856 The Act VI of 1856 on protection of inventions based on the British patent law of 1852
1859 The Act modified as Act XV: Amendment as re-enacted the monopoly granted as "exclusive privileges"
1865 British India Exclusive Privileges for 14 years
1872 The Patterns and Designs Protection Act' (Act XIII of 1872)
1883 The Protection of Inventions Act
1888 Consolidated as the Inventions & Designs Act
1911 The Indian Patents & Designs Act
1957 The Copyrights Act
1970 A more progressive "Indian Patent Act"
1972 The Patents Act (Act 39 of 1970) came into force on 20 April 1972
1999 Patents (Amendment) Act: The Geographical Indication of Goods (Registration & Protection) Act;
The Trademarks Act; The Design Act
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Doha Declaration and Public Health

As regards to the flexibilities various Governments extended their difficulty in interpreting these flexibilities and are also unsure of the boundary of protection of the rights. A large

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part of these flexibilities and right and obligations of the nations were settled at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14-11-2001, WTO member Governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and the creation of new medicines i.e. without obstructing the research and development. It emphasises that the TRIPS agreement should not restrict the nations to make legislations according to their socio-economic status. They have freedom to act in furtherance of their public health. TRIPS agreement posed a serious threat upon the developing nations as to the impediment caused by it on implementation of measure to promote access to affordable medicines in the interest of public health. While acknowledging the role of intellectual property protection "for the development of new medicines",the Declaration specifically recognises concerns about its effects on prices."Doha Declaration", which affirmed that public health took precedence over private patent rights, and reaffirmed the rights of Governments to use inbuilt WTO public health safeguards and other available measures to gain access to cheap medicines.The Declaration also refers to the exhaustion of intellectual property rights, and therefore addresses the question of a member's right to allow parallel imports. The Declaration makes it clear that the Trips agreement's provisions on exhaustion in effect, leave each member free to establish its own regime without challenge but subject to the general TRIPS provisions prohibiting discrimination on the basis of a person's nationality.

It can be noted that, the TRIPS agreement and the Doha Declaration represent an attempt at the international level to achieve the sensitive task of balancing the need for providing incentives for research and development on the one hand and the need to protect public health interests of making access of drug reality, on the other. Despite having such mechanism the plight of developing countries is not solved. It is pertinent to note that many developing nations choose to issue the same, since it could be perceived as indifference towards intellectual property rights and thereby seriously weakening trade relations with other nations and might discourage investors.[33] It is a well-known fact that developing countries have strict patent regime much flexible in granting compulsory licensing, due to no or minimal incentives. Developed countries have no incentive to issue compulsory licence for exports. Such obstacles are rendering these flexibilities granted by TRIPS inaccessible.

TRIPS AND PATENT EXCLUSIONS IN INDIAN LEGISLATION

The Supervisor of Patents can grant compulsory licence under Section 84, Section 91, Section 92 and Section 92-A. Provisions related to the grant of compulsory licence in India are prescribed under Sections 82-94 (Chapter XVI) of the Patents Act, 1970, and Rules 96-102 (Chapter XIII) of the Patents Rules, 2003.In the case of Natco case has initiated a transformation in pharmaceutical commerce on functioning of patents and established a harmoniousness between TRIPS and domestic laws. It has India can use the TRIPS flexibility effectively to provide health care to people. also accomplish the constitutional responsibility of right to life as envisioned under Article 21. even the Bombay High Court settled with the discoveries of the Controller General of Patents and the Tribunal concerning obligatory licensing under Section 84 of the Act.Other applications for compulsory licensing have also been filed, however, they were rejected by the Controller. One such application was filed by BDR Pharmaceuticals to manufacture the generic version of anti-cancer drug Dasatinib, patented by Bristol-Myers Squibb in India. Further, in 2015, Lee Pharma filed an application for seeking the grant of a compulsory licence for manufacturing and selling a drug named Saxagliptin. Both applications were rejected as they failed to convince the Controller of Patents to make a prima facie case for the grant of compulsory licensing.

According to the study the TRIPS compliant the compulsory licensing provisions in the country but these licences are primarily problematic. It is unfortunate that till date only one compulsory licence has been granted in vast nation such as India, the prime reason for this can be credited to the restricted usage of flexibilities is the bureaucratic complications. Theoretically this concept seems prodigious but the picture of patent office is different. To strengthen the licensing provisions there is a need of strong policy makings and a comprehensive procedure should be issued by Indian patent office.

II. CONCLUSION:

With time, inventions and technology are also at a high pace. That is why it is essential to protect the ideas, creation, and innovation of people. This is the work of the Patent Laws that give the right to the creator to earn profit from his creation. However, the scene changes when it

comes to the medicines which are required by each and every individual. Wherefore, the Country must achieve a meaningful balance between the utilization of patenting law to motivate medicine co. to develop new medications for diseases that cannot be treated today and, at the opposite hand, the requirements of patients to profit from those drugs without bankrupting either themselves or state and federal budgets.

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