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PATENTING OF PHARMACEUTICAL DRUGS: DOES IT GUARANTEE ACCESS TO MEDICINE?

DR.P.R.L.RAJAVENKATESAN[1*] & DR.E.PREMA[2]

[1,2] *Assistant Professor (Senior), VIT School of Law, VIT University, Chennai Campus-600 127.*

ABSTRACT

Intellectual property rights have been considered as most valuable assets in the technological driven era. The rights of the creators, authors and inventors etc., are being streamlined in such a way to reap the benefits of the same. Among various kinds of intellectual property rights existing in the digitalized era, pharmaceutical invention is one kind of it. The term patent itself is buzz word and getting the drugs to be patented is a subject of controversies because of ever greening methodology adopted by the pharmaceutical giant in worldwide. The present research paper is intended to focuses on patentable subject matter in general and pharmaceutical drugs in particular.

KEYWORDS: Drug, Invention, India, Patents, Pharmaceutical Industry.

DR.P.R.L.RAJAVENKATESAN*

Assistant Professor (Senior), VIT School of Law, VIT University, Chennai Campus-600127.

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INTRODUCTION

The existence of IPRs is an age old concept. The basic aim of conferring an IPR upon the person owning the same is to give a social recognition to its holder/creators and to boost them for their intellectual creativity. This social recognition can further bring economic benefits to its holders and has assured commercial exploitation also. It is just and reasonable to award a person an intellectual property rights in the form of "limited monopolistic rights" for his/her labour and efforts. It is the duty of the state also to provide full protection of creative works of author/inventor etc., There are more than seven kinds of intellectual property rights as per the Agreement on Trade Related Aspects of Intellectual Property Rights in which patent is one among them. Patents are granted for protection of the inventions. Patent is an exclusive right granted by the government to the applicant for an invention for the period of 20 years. A patent can be applied by the inventor or any other person/ company assigned by the inventor. It is the right to exclude others from unauthorized making, using, offering to sale, selling or importing the invention[1]. It means patentee has every right to exploit his invention as he/she pleases. At the same time, exceptions in the form of various licenses are also made so that public interest cannot be compromised at any point of time. The public interest and personal interests are thus reconciled in the form of limited period duration of these rights and their abuses can be tackled stringently, especially when public interest demands so. It is true that all inventions are not patentable such as against public policy, morality, known to public and public domain etc., technically, intellectual property refers to mental creations that have been granted property law protection. At its most basic level, intellectual property refers to ideas or information that spring from a person's mind. Such know-how is necessary for research, for artistic and creative endeavours, for basic activities most of us engage in, and for operating business enterprises. In property, a right to exclude is beneficial to its holder because she has an interest in the privilege of use that is indirectly protected by that right. Likewise, patent law, one of the more properties like regimes of intellectual property, employs the exclusion strategy to delegate choices among uses to holder of patent. For example, in a chemical invention, the applicant can claim a substance by stating its structure. Any use of the substance, whether foreseen by the applicant at the time of the application or not, is protected by this right to exclude. As we move towards a paradigm where patent "monopoly" appears to have assumed the "the role of a legitimate reward for innovation [2]" it may perhaps be timely to examine the double-edged sword of patent protection. No one denies that patents exclusively incentives innovation and has spawned great public benefit [3]. Basically all the intellectual property including patents should do something best for the society. Pharmaceutical patent litigation is on the rise. Nowadays, the contentious area of litigation is the surge in pharmaceutical patent challenges mounted by generic drugs manufacturers. India is a country where vast majority of people basically from poor background. The modem pharmaceutical industry has an interesting historical past. Before the seventeenth century drugs were administered by individual doctors, quacks, faith healers on a trial-and-error basis, which was not based on any established, uniform scientific practices. Seventeenth and eighteenth centuries saw some rapid progress in medical science, which resulted in a wide use of drugs essentially through drug dispensing apothecaries attached to the practicing doctors. [4] Historians of medicine and drug therapy consider Sir Alexander Fleming's discovery of penicillin in 1929 as the point, when the real foundation of modern pharmaceutical research was laid down. [5] It is the need of the hour that more research on pharmaceutical areas ought to be made and fund for the same to be allotted. Due to technological development, it is easy to copy the mode and methods of one inventor by others.

History of Pharmaceutical Industry in India

The origin of the earlier drugstores goes back to the middle Ages. The first known drugstore was opened by Arabian pharmacists in Baghdad in 754, and it gave way to many more, which soon started operating throughout the medieval Islamic world and eventually medieval Europe. Many of the drugstores in Europe and North America had gradually developed into larger pharmaceutical companies by the 19th century. The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market due to factors such as favourable government policies and limited competition from overseas [6]. The Indian pharmaceutical industry remained import dependent till 1972, deeming most of the drugs unaffordable. Political and policy developments in the early 1970"s such as the new patent acts of 1972 and Drug Price Control Order (DPCO), 1970 laid the foundation for a strong pharmaceutical industry in India[7]. In recent decades, many nations and international organizations have made a concentrated effort to homogenize the laws governing intellectual property. The attempt at standardization, however, has not been free of dissention, particularly with regard to the laws pertaining to pharmaceutical patents [8]. Arguably the most controversial aspect of the World Trade Organization's Agreement on Trade-related Aspects of International Property Rights (TRIPS) is over the issue of patents for pharmaceutical drugs [9] For many years prior to its membership in the World Trade Organization (WTO), India did not recognize product patents for pharmaceuticals [10]. Without product patents with which to contend, Indian pharmaceutical companies were able to churn out countless generic drugs, establishing India as one of the leading generic drug manufacturers in the world [11]. Yet in 2005, because of its obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), India was compelled to amend its laws to provide product patent protection to pharmaceuticals [12]. The existing frame work of intellectual property laws recognized internationally are those identified by the trade related intellectual property rights agreement (TRIPS) governed by the WTO [13] The patent policy of 1970 has catered to the needs of the

Indian poor. Drug price in India are one of the cheapest in the world today and are affordable to the population. On an average, drugs manufactured in India are more than 100% cheaper than the same drug in U.S. The government of India has achieved the Constitutional mandate of social economic balance by setting a maximum sale price while still leaving a reasonable profit. The history of India's pharmaceutical industry and the role played by multinational corporations (MNCs) and Indian companies are well known. Despite the fact that India recognized product patents in pharmaceuticals before the 1970s and despite enjoying quite a liberal investment environment, MNCs did not take much initiative to develop the industry [14].In the early 1990s before TRIPS came into effect, these MNCs spent on R&D only about 1 per cent of sales. Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are 'new, involve an inventive step and are capable of industrial application'. Under Article 70(3) of TRIPS, a WTO member country has no obligation to provide patent protection for any subject matter which has fallen into the 'public domain' before WTO came into being, i.e., before 1 January 1995. The Indian Pharmaceutical industry is the second-largest in the world by volume and is leading the manufacturing sector of India. It is also true that international agreement like Agreement on Trade Related Aspects of Intellectual Property Rights has set up some standards to maintain the uniformity to grant of patent all over the world: "the TRIPs agreement may have a severe impact, especially in the high technology sectors such as pharmaceuticals, working to the disadvantage of developing countries in two main respects: domestic manufacturers wishing to produce and commercialize products covered by patents will be forced in to licensing agreements involving royalty payments to patent holders; while research and development activities may be hindered since the TRIPs agreement is likely to inhibit reverse engineering, the process by which research based industry products are copied and adapted for developing country usage" [15].

Relationship between TRIPS and Patenting of Pharmaceutical Drugs in India

The business model of generic manufacturers is based upon manufacturing and selling at a cheaper price the same medicines developed by other pharmaceutical companies, as soon as these medicines are off patent [16]. Generic drugs are alternatives to brand name drugs and according to WHO requirements they must show pharmaceutical equivalents, which means that the amount of active ingredients dosage form, and strength are identical to those of a compared brand. Quality generic version of off-patent medicines can play a key role in meeting health needs in population around the world. The generic must also be bio-equivalent, meaning the drug must be absorbed in to the blood stream at roughly the same rate and extent as the pharmaceutically equivalent brand [17]. The TRIPs agreement is binding on all WTO members. Compliance with its provisions is a precondition of joining the WTO, which deals with the rules of trade between members at a global level. Although intellectual property rights (IPRs) and their effects on trade have been advocated for a long time, the TRIPs agreement is the first international instrument to focus on trade-related aspects of IPRs [18]. The industry feels that the TRIPs in its present form, tipped in favour of developed nations and multinational pharmaceutical firms and it is not trade related about TRIPs that the right to trade is being exploited by developed countries [19]. Some observers contended that the TRIPs agreement may lead to perverse transfer of technology and a significant decrease as in local production. Since the pharmaceuticals are important component in addressing the major causes of diseases burden, including infectious diseases, depression, and for confronting major determinants of health such as tobacco, the balance between innovation and accessibility of new technology is a crucial policy issue [20]. The TRIPs agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organization (WIPO), is undoubtedly the most significant milestone in the development of intellectual property in the twentieth century [21]. The Patents Act 1970 had excluded large areas from patentability. The 1999 Act in contrast gives Exclusive Marketing Rights (EMRs) merely on the basis of foreign patents obtained after 1 January 1995 without any scrutiny on the basis of impact on public health, public morality or the public interest [22]. In *Novartis AG v. Union of India [23],* Gleevec is used for the treatment of chronic myeloid leukemia (CML), a disease that afflicts nearly 5,000 new patients in the United States each year. Studies have shown that Gleevec, which targets specific cancer proteins, is almost ten times more effective than traditional interferon therapy. In 1993, Novartis filed patents worldwide for the active molecule imatinib. Novartis did not patent imatinib in India because the 1970 Act did not allow patenting of pharmaceutical products at that time. After India's entry into the WTO in 1995, Novartis filed a "mailbox" patent application in the Madras Patent Office for imatinib mesylate, a beta crystalline form of the free base imatinib. In 2002, Novartis started its Gleevec donation program in India to provide Gleevec to patients who were unable to afford the medicine, but halted that program after Indian drug manufacturers began to produce a generic version of Gleevec. In 2003, the Patent Office granted Novartis Exclusive Marketing Rights (EMR) in India, which allowed Novartis to enjoin generic Gleevec manufacturers and raise the price of Gleevec almost ten-fold. When the Gleevec mailbox application came up for examination in 2006, some commentators suspected that the application was fast-tracked due to controversies over the donation program and the divisive rise in price. In January 2006, the Madras Patent Office refused to grant Novartis a patent for imatinib mesylate. The first major ground for rejection was that because imatinib mesylate was a salt form of the free base imatinib, and Novartis claimed all pharmaceutical salt forms of imatinib in its 1993 patents, the Indian application therefore lacked novelty and inventiveness. The second major ground for rejection was based on Section 3(d) of the 2005 Amendment, which required that new forms of a known substance could only be patented as a product if they demonstrated "enhanced efficacy." Although Novartis disclosed information that imatinib mesylate had a 30% increase in bioavailability (the percentage of the drug

absorbed into the bloodstream) as compared with imatinib, the Patent Office found this insufficient to meet the "enhanced efficacy" requirement of Section 3(d). In May 2006, Novartis petitioned the Madras High Court, opposed by the Indian Government, the Patent Office, several Indian generic drug manufacturers and an Indian public interest group. Novartis claimed that the Patent Controller erred in rejecting the Gleevec patent application, that Section 3(d) was not compliant with TRIPs, and that Section 3(d) was vague, ambiguous and in violation of Article 14 of the Constitution of India because it was discriminatory against Novartis. The case was bifurcated between the Madras High Court and the Intellectual Property Appellate Board (IPAB). The challenges on TRIPs compliance and constitutionality of Section 3(d) were heard by the Madras High Court, which issued a judgment against Novartis on August 8, 2007. The Madras High Court held that it did not have jurisdiction to decide a case concerning the compliance of a domestic Indian law with an international treaty. Because the Madras High Court held that it did not have jurisdiction to decide whether a domestic law violated an international treaty, it refused to decide whether Section 3(d) is compliant with TRIPs. Nevertheless, the court opined that TRIPs allows flexibility for the individual needs and situations of every member country. In complying with the TRIPs obligations, India has a constitutional duty to provide good health care to its citizens, and giving them access to affordable drugs. The court held that Section 3(d) did not violate Article 14 of the Constitution of India and was not vague or arbitrary, and did not confer uncontrolled discretion to the Patent Controller. The court rejected Novartis's arguments that Section 3(d), which denies patents to new uses of known substances unless the patentee can show "enhancement of the known efficacy" or "differing significantly in properties with regard to efficacy," was ambiguous and unclear. A bench of Supreme Court Justices Aftab Alam and Ranjana Desai said: "We firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann (original) patent". The Bench said that the patent application contains a "clear and unambiguous averment" that all the therapeutic qualities of the modified form, for which the patent was applied, "are possessed' by the original version. The court held that patents can be granted only for medicines that are truly new and innovative. For new forms and new uses of existing medicines, patent applicants should prove improved efficacy. The court said that the Patents (Amendment) Act, 2005 established that the "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not an invention – for the purpose of patenting.

CONCLUSION

The traditional role of the patent system remains true today. It seeks, inter alia, to incentivise activities that promote scientific progress and the creation of useful inventions which are beneficial to society. The typically large investments associated with R&D in the pharmaceutical and biotechnology industry has led to calls for a broader interpretation of the subject matter eligibility and other validity criteria to be "guided solely by innovation goals". India has always been home to millions of people, belonging to various religions, socio-economic classes, castes and cultures. Horizon 2020 is the new EU Framework program for the funding research and innovation which has run from 2014 to 2020 with a budget of E80 billion. It is the financial instrument implementing the innovation Union, the Europe 2020 flagship initiative aimed at securing Europe's global competitiveness and driving to create new growth and jobs in the area. There is increasing attention being paid to the rising cost of health care in low-and middle income countries (LMIC's), where treatment prices as a proportion of income are often high. With regard to the effect of patent on price, monopoly rights protection from a patent for the particular medicine generates a price of patented medicines some 144-200% higher than medicines without a patent. Pharmaceutical companies appears to use a penetration pricing strategy , initially set at a lower price than the eventual market, to launch new products in Thailand. Over the time, as brand loyalty increase, the low introductory price is often raised. Price is negatively correlated with patent years left, as seen from the experience in the US. Based on the above discussions, it can be said that pharmaceutical sector are progressing tremendously day- by-day but the only problem is that people still are not able to access the drugs in full-fledged manner as there are lack of mechanisms for the effective implementation of the policy regarding pharmaceutical drugs in the context of public health. Therefore, barriers should be removed to make sure that poor and down trodden are accessing drugs without any hindrance from any corner of the world. The developed and developing countries should take steps to prevent the ever greening drugs entering into market so that genuine players will reap the benefit for their products. Members of TRIPS ought to give priorities only for public interest by way proving drugs in affordable and accessible manner in the mode of reasonable price to the people.

CONFLICT OF INTEREST

Conflict of interest declared none.

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Reviewers of this article

Dr. Dilshad Shaik

Director, School of Law, VELS University, Chennai , India

Asst.Prof.Dr. Sujata Bhattacharya

Assistant Professor, School of Biological and Environmental Sciences, Shoolini University, Solan (HP)-173212, India

Prof.Dr.K.Suriaprabha

Asst. Editor , International Journal of Pharma and Bio sciences.

Prof.P.Muthuprasanna

Managing Editor , International Journal of Pharma and Bio sciences.

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