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Innovation The Research Concept

Law of Patent and Life Saving Medicines: An Overview

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Abstract

There have been wide-ranging debates about the introduction of patents on pharmaceuticals in developing countries. On the one hand, it has been argued that it should give incentives to the pharmaceutical industry to undertake more research and development on tropical diseases. On the other hand, the patenting of pharmaceuticals has been criticised as raising human rights issues regarding access to life-saving drugs. To others, patents have prevented access to cheap generic versions of life-saving drugs which such countries badly need, such as for the HIV/AIDS pandemic. This brief examines to what extent it is possible to justify the patenting of live-saving drugs. The examination includes an investigation into the role of the patent system, the moral limits of patents, how the exclusion of a patent can create social costs, the rationale for the patenting of live saving-drugs and the incentive theory and how this can be balanced with access to live-saving drugs.

Keywords: Patent, HIV/AIDS, Pharmaceutical, TRIPS.

Introduction

Two kinds of justifications for the protection of intellectual property dominate the debate on the patenting of life-saving drugs. The first centres on fairness or compensatory justice concerns, and the second on arguments about the relationship between protection of new inventions and domestic and global economic welfare. Thus, the traditional role of the patent system, which seeks to balance the competing objectives of encouraging innovation through appropriate incentives and providing reasonable access to, and use of, the knowledge and information thereof, persists today in the granting of patents to life-saving drugs. Not only does legal protection for the fruits of innovation enable the patent owner to benefit from an “exclusive market position" with the temporary ability to set prices above the marginal costs of production, but there is also great societal benefit in the dissemination of, and access to, knowledge and information that may be derived thereof. The patent system needs to achieve an appropriate trade-off between protection and access while maintaining competition, particularly in relation to life-saving drugs.

Objectives of the Study

The patent system provides protection to for life-saving drugs and restricts compulsory licensing. There appears to be a justification for patent monopoly through control over pharmaceuticals which ensures royalties for patent rights therein. However, a patent regime that confers excessive protection may engender abusive practices that are detrimental to its goals. The current patent system controls the use and supply of pharmaceutical and creates barriers to the access life-saving drugs for poor and low income countries. Its impact particularly in relation to access to life-saving drugs needs to be carefully re-assessed, since rising prices may impede patient access to affordable life-saving drugs and fall especially hard upon poor people. How the life saving drugs can be re- assessed and rising price of the drugs can be controlled with the help of legal tools is the main objective of this study.

Review of the Literature

“Benefits of stronger intellectual property rights (IPRs) are most likely to accrue principally to those who own the existing IPRs…at the expense of those who must rely on their ability to acquire/use those technologies at minimum cost” ~ Harmsen and Subramanian (Abdelgafar 2006, p. 4) In contrast to those supporting the merits of a strong patent system, proponents of weaker IP legislation argue that patents only moderately, if at all, promote broad and deep innovation. Moreover, this group also contends that strong patent systems are not only ineffective, but also harmful to the innovation process. First, critics argue that patents lead to uncompetitive monopolies, which prevents new and potentially more

innovative firms from entering the industry thereby reducing the chances of deep innovation (Lilja et. al. 2008, p. 102). With the rising capital costs associated with developing new technologies, fledgling firms are often unable to commit groundbreaking research on a new drug and thereby are incapable of earning the all-important patent rights. This reinforces the trend of concentrating patents in the hands of a few large firms (Lamoreaux & Sokoloff 2007, p. 234). Consequently, it has become increasingly difficult for independent investors to justify expenditures on explorations for new discoveries 4 (Lamoreaux & Sokoloff 2007, p. 234). Artificial monopolies, it is argued, are the result of this concentration of patents and capital, as "new technology shifted inventive activity away from independent inventors towards large companies," which has led to a decline in patenting rates per capita (Lamoreaux & Sokoloff 2007, p. 236).

A second argument asserted by those supporting weaker IP legislation states that ordinary patent incentives simply do not work, especially in developing companies, in terms of stimulating broad innovation among "neglected diseases" (Hollis 2007, p. 75). These diseases include malaria, tuberculosis, chagas disease, and African sleeping sickness, among others. The root cause of this inattention is often attributed to the lack of profitability that these diseases present because of the reality that most of their victims live in poverty and cannot pay the high prices for life-saving medication (Hollis 2007, p. 76). As argued by Hollis, there is a strong positive relationship between the incomes of those affected by a disease and the amount of research undertaken into pharmaceuticals for that disease (Hollis 2007, p. 77). Consequently, investments in neglected diseases are seen to be unprofitable, and patent incentives fail to fill this gap.

Method of The Study

To accomplish the present study analytical method has been used with the help of relevant case law and literature available in the form of report, journals, commentaries, and cases in order to achieve the objective of the study.

Origin, Meaning And Importance of Patents

The Patent[1] is a form of Intellectual Property Right granted and protected under the law. It is an exclusive right granted to a person who has invented a new and useful article or an improvement of an existing article or a new process of making an article. The question as to whether a particular invention is new and useful is extremely difficult to decide and has to be determined based on the prior art in the particular field which includes publications on the subject as well as prior usage.[2]

The origin of Patents law in India can be traced back to the law and practice on patents in the United Kingdom. The Indian Patents Act of 1970[3] was modeled on the British Patents Act of 1949 as amended. However there exists a stark difference between the Indian Patents Act of 1970 and the British Patents Act of 1949 in the sense that the Indian Act granted product patents for food, medicines and chemicals only from January 1st 2005 unlike the British Act which provided such patents under the 1949 Act and continue to do so.

The term Patents has been defined under Section 2(m) of the Indian Patents Act of 1970. A Patent confers on the Patents owner or the patentee a negative right to exclude others from working or operating the invention for a limited period of time and hence grants the patentee exclusive monopoly rights over his patented invention. The term of a Patent under the Indian Patents (amendment) Act, 2005 is for a period of 20 years after which the invention falls into the public domain and anybody can make use of the invention. It is then said to have become a part of prior art in the existing field. A patent right being a creation of a statute is territorial in extent. Hence the patent which has been granted in one country cannot be enforced in another country unless it has been enforced in that country also. [4] m Patents represent one of the most powerful Intellectual property rights and can bring about substantial income through the manufacture and licensing of the invention covered by the patent.

Patent of Pharmaceutical Product

Scenario pre-TRIPs[5]

The Indian Pharmaceutical industry is one of the largest in the developing world and is ranked as the fourth largest in terms of production and 13th largest in terms of domestic consumption value. Over the past 30 years Indian drug industry has emerged from almost non-existent to a world leader in the production of generic drugs. With the changes brought about by the patents act of 1970, Indian drug manufactures became experts in the field of reverse engineering and increased its supply of less expensive copies of the world's best-selling patent protected drugs. This could only be possible because there was no product patents system for drugs and medicines. While the patent act of 1970 in its original form does provide a distinction between product patents and process patents, the exception provided in section 5 of the act of 1970 (which has been omitted by the amendment of 2005) offered only a process patent for food, medicine or drug substances and specifically excluded product patents for the same. Thus India was able to copy foreign patented drugs without paying a license fee and was able to make it available to the masses at one-tenth of the original price. Moreover the Drug Price control Order, 1970 put a cap on the maximum price that could be charged and ensured that the life saving drugs are available at reasonable prices. The Act of 1970 could be considered to be one of the most progressive statutes which safeguard both the interest of the inventor and the consumer in a balanced manner. The Act has been promulgated keeping Directive Principles of State Policy contained in Article 39 of the Constitution in mind. Hence with a regulatory system focusing on process patents and being in the grip of a rigid price control framework, the Indian pharmaceutical industry has emerged from a import dependent industry to in the 1950's to having achieved worldwide recognition as a low cost producer of high quality pharmaceutical products with an annual export turnover of more than $ 1.5 billion

dollars.[6] The distinction between a product patent and process patent that existed prior to the 1995 TRIPs agreement helped India develop a huge generic drug industry which had its basis on reverse engineering of brand name drugs through slightly modified processes.

Scenario Post-TRIPs

The most important amendment which had to be introduced by the amendment of 2005 in order to make the existing patent regime in India TRIPs compliant was the introduction of pharmaceutical product patents. The amendment of 2005 extends full TRIPS coverage to food, drugs and medicines.[7] It requires patents to be provided to products as well, while the patent regime provided by the act of 1970 required patents only to be granted for chemical processes which resulted in the production of a particular drug. The other implications for the pharmaceutical sector under the new act are as, "The term of a patent protection has been extended to twenty years compared to the seven years which was provided by the act of 1970. This was made applicable to all the member countries and hence rules out all the differences with respect to patent protection which prevailed in different countries."[8]

If the law of the country provides so, then the use of the subject matter of the patent shall be permitted without the authorization of the patent holder, including use by the government or any other third party authorized by the government. However such use shall be permitted only if prior to such use, the user has made efforts to obtain the authorization of the patent holder and such efforts have not been successful within a reasonable period of time. This requirement can be waived in case of a national emergency after notifying the patent holder.The burden of proof with respect to infringement matters have been reversed under the new act. The onus of proving on a legal complaint that the process used by one enterprise is totally different from that which has been used by another would lie on the defendant. Prior to the amendment the responsibility was on the patent holder to establish patent infringement.

The new amendment was not to affect the drugs which were in the market prior to 1995. As far as those drugs which were produced between 1995 and 2005, they will have the right to continue to produce them in return for the payment of a fixed royalty to the patent holder. The main problem arises for those drugs which are now being manufactured and patented. The only way by which such drugs can be manufactured in India is by way of compulsory licenses. Such compulsory licenses are granted by the government on grounds such as non availability, high prices, public interest etc. The process ought to be simple and easy but the problem lies in the fact that the procedure has been left very ambiguous by the new Act.

The immediate and the most drastic effect that TRIPs compliance and introduction of the new Act of 2005 will have will be with respect to the health sector in India. The patients are the ultimate beneficiaries of the pharmaceutical research and development. By denying product patents India will be able to encourage bulk generic drug production at cheap prices. However generics are not the only solution to counter the problem of access to medicines. Generic production of drugs will not necessarily result in the innovation of new and more effective drugs and by not acknowledging innovation India will run the risk of not having access to future medicines which will in turn affect public health. Denying patents and allowing the generic companies to freely copy the new drugs cannot be the solution to deliver medication to the patients too poor to buy them, be it rural or urban India.

The actual problem lies in the fact that the product patents not only increase the cost of the drugs and medicines, but that most of them fail to introduce research and development in the neglected diseases. Lack of access to affordable medicines was a reason for the vast majority of deaths that took place due to HIV/AIDS in the developing countries. Hence while on one side the introduction of product patents will help in development of new and more effective drugs, the problem still remains that the research and development undertaken by the drug manufactures evade the neglected diseases and the diseases which are region specific such as medicines for malaria and tuberculosis which are found prevailing in developing countries like India.[9]

Unlike in the developed countries, the lack of the penetration of medical insurance makes the people directly affected by the increase in the prices and hence decreases the affordability. The patent system makes the lives of the people outside the sphere of social security, which forms majority in the developing countries, impossible. A product patent system will make India dependent on the multinational companies for technology and for permission to produce the patented drug. Exorbitant prices will be charged and the Indian pharmaceutical industry will become subservient to the MNC's[10]. They will lose the position that they had gained in the wake of the Act of 1970.[11]

Solution to the Product Patent issue

The most practicable solution to the problem which at the same time allows for TRIPs compliance would be granting of dual licenses. This would mean that the patent would be partly product patent and after a reasonable time being given to the inventor to make a reasonably large profit it would be converted to a process patent whereby the patented drug can be manufactured by competing manufacturers using an alternative process. This would solve the problem of excessive hike in prices and would render the drugs more accessible to the millions suffering. Collaboration with the MNC's[12] on various fronts such as research and development, manufacturing and marketing will help Indian Pharma companies make profitable breakthroughs.

The non-provision of product patents has been one of the strongest aspects of our Patents Act. Complete compliance with all aspects of the TRIPs agreement is prejudicial to our national interest and the TRIPs agreement itself places limitations on our ability to enact out national legislations in public interest. To prevent public interest from being

prejudicially effected it is imminent to mobilize public opinion against complete compliance of the obligation under TRIPS. It must always be remembered that pharmaceutical industry owes a moral responsibility to the society. The monopoly granted by patents to the Drug companies should not be exercised without responsibility. Hence it can be safely said that India having rushed through with the third amendment of 2005 to the patents act without proper parliamentary scrutiny and without having tactfully dealt with issues relating to food, health and technology was not in public interest.

Growth of Health Crises, Access to Medicines and The Poor's

Many of the diseases and health conditions that account for a large part of the disease burden in low- and middle-income countries are far less common in high-income countries. These burdens are primarily associated with infectious diseases, reproductive health, and childhood illnesses. Just eight diseases and conditions account for 29 percent of all deaths in low- and middle-income countries: TB, HIV/AIDS, and diarrheal diseases, vaccine-preventable diseases of childhood, malaria, respiratory infections, maternal conditions, and neonatal deaths.[13] Approximately 17.6 million people in low- and middle-income countries die each year from communicable diseases and maternal and neonatal conditions. Both the occurrence of and the death rates from such diseases and conditions are far lower in all high-income countries.[14]

Millions of people in developing countries die of diseases for which treatments exist that can relieve suffering and save, or at least prolong, people's lives. High-profile pandemics like HIV/ AIDS understandably attract considerable attention. Millions of people have died of this terrible disease 2.6 million in 2003 and 2.8 million in 2005, of which Sub-Saharan Africa contributed 1.9 million and 2.0 million respectively.[15] The obvious reason why treatment access is such a problem is poverty. People do not have the money to buy the drugs, and governments, even those that are not corrupt or otherwise woefully dysfunctional, lack the resources and infrastructure to get them to those who need them but cannot afford them. The pharmaceutical industry certainly prefers to blame poverty and poor governance, and rejects arguments that patent rights allow them to set high prices that keep life saving drugs out of the reach of the poor.[16] Up to a point, the industry is right. But to suggest this is a sufficient explanation is to be disingenuous.

High drug prices are not of course the only factor limiting patients' access to them. Access even to very cheap drugs tends to be inadequate too. Poor people often live far away from clinics and hospitals. Also, many countries are short of medical practitioners trained to prescribe drugs to patients in the appropriate combinations and dosages. Nonetheless, high prices obviously have a profound impact on the ability of cash-strapped governments and other healthcare providing organizations to deliver drugs to the poor. National pharmaceutical markets are often highly regulated, and companies are not always free to set prices entirely as they wish. Yet companies holding patent monopolies are in a strong bargaining position for as long as they can keep out the generic competition, which potentially could drive prices downwards towards the marginal cost of making the drug in question.[17]

Conclusion

The determinants of growth for the pharmaceutical industry are still in the nascent stage, a factor that makes the industry, investors and consumers optimistic about the future. For instance, and of the repeated example to highlight the future potential is the low coverage of allopathic medicines among the population.[18] In a population of about 935 million, only around one third is believed to have access to allopathic medicines. Given this limited coverage, the industrys' potential is enormous. While other industries may be similarly placed, the sensitive and critical nature of drugs increases the possibility of this industries' potential being fulfilled.[19]

The nature of the products has largely insulated the industry from the vagaries of the business cycle. The amendment to the Patents Act definitely marks a watershed for Indian pharmaceuticals.[20] Greater intellectual property protection will entail both costs and benefits India. The economic impact of reforms will tend to depend on the responsiveness of FDI[21], and of domestic innovators to higher protection, or demand elasticities for protected products, the volume of existing local infringing activity and other factors.[22]

An opportunity which excites many Indian companies is the growing market for generics. With many patented molecules expected to lose patent protection in the developed markets over the next few years, Indian companies are expected to make a big splash there. The generics market is broadly characterised by low unit margins and volume-led business. A few Indian companies like Ranbaxy and Wockhardt are well placed to make good in this environment.[23] The salient feature of their move is the strategy of entering into alliance with companies abroad or in some cases, the acquisition of a company located in the target market.

Generally, it should be expected that actual system cost, that is, the cost of introducing and maintaining intellectual property, may not be unreasonably high, particularly when a country opts for registration rather than a full-fledged examination system, and introduces its enforcement mechanism gradually. New R&D activities[24] spurred by stronger intellectual protection may draw resources away from other economic activity. Finally, the risk of anticompetitive behaviour of the intellectual property owner, generally believed to lead to higher prices, and higher entry barriers to newcomers, may be at least partly contained or reduced as in most cases protection does not prevent legal imitation.[25] One should keep in mind that in the Indian context, the patent regime is only one of a set of complex factors affecting the pharmaceutical sector and the impact of a stronger IPR[26] regime will be conditioned by other factors such as price controls, licensing policy, etc. Because patenting has not been considered a critical function so far, few pharmas have invested in

developing best-in- class patenting approaches and capabilities. Pursuing a comprehensive approach to patent writing, defence and litigation requires developing a range of capabilities. As it becomes easier to defend innovation through patenting, patenting will need to shift from a downstream support function to an early and integral strategic capability. Leading-edge companies may choose to name a chief patent officer and will move patenting decisions closer to the center of strategy.[27] And finally, it is important to note that the public interest was also upheld by a provision allowing for government use. So, apply a balancing approach between public health and law of patent, it is noted that maintenance of public health is *prime facie* duty of any Government.

References

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3. *The Patent Act 1970 was later amended in 1999, 2002 and again in 2005 to bring the Indian Patent Act in line with the TRIPs Agreement.*
4. *See, Raj Prakash v. Mangat Ram Chowdhury, AIR 1978 Del 1 p. 11.*
5. *The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994.*
6. *www.who.int/intellectualproperty/documents.*
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9. *Source: World Health Organization (WHO), Investing in Health Research and Development: Report of the Ad Hoc Committee on Health Research Relating to Future Intervention Options 102 (WHO, 2009).*
10. *Multinational Corporation.*
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12. *Multinational Corporations; sometimes referred to as a "transnational corporation".*
13. *Supra Note 7. See also, www.wto.org.*
14. *Dean T. Jamison et al., Cost-Effective Strategies for the Excess Burden of Disease in Developing Countries, in Priorities in Health 59, 59 (2006), files.dcp2.org/pdf/PIH/PIH04 .pdf.*
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