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The Impact of Patent Linkage on Marketing of Generic Drugs

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Reasonable prices and innovation are two fundamental goals of health policies. On one hand, governments have the task of attracting FDI in the pharmaceutical sector and on the other hand, they have to control drug prices, quality and availability. There is continuous international pressure on developing countries to extend the scope of pharmaceutical patent protection beyond the TRIPS standard. Patent linkage is one such area which developed countries such as US are pursuing through bilateral or multilateral agreements. It is important to analyse the viability of patent linkage in developing countries. This article analyses the consequences of adopting patent linkage through the experiences of other jurisdictions.

Keywords: Competition, abuse of dominance, patent linkage, generic drug, marketing approval

Accessibility and availability of drugs are the main objectives of public health policy in almost all countries. For instance, objectives of the Indian Draft National Pharmaceutical Policy, 2006 are to ensure accessibility, availability of drugs at reasonable prices and to promote further research and development. Mechanisms have been developed to promote low priced and innovative drugs in various countries.[1] Generally, more exclusivity to an originator drug is deemed as pro-innovation and low price pro-consumer interest. There is a direct connection between the drug prices and availability of generics. Preliminary study of the pharmaceutical sector by the European Commission in 2008 revealed that there is a significant decrease in drug prices after the entry of generic drug companies into the market.[2] Both the objectives of reasonable price and innovation need to be balanced as a prerequisite to achieve overall policy goals. R&D of drugs is a highly capital intensive and uncertain activity because it is based on trial and error with a very low success rate.[3] On an average, it takes 12-15 years for a new drug to be developed and commercialized.[4] Only five out of five thousand new drugs go up to the human testing level and a mere one out of five is approved for human usage.[5] Due to the exorbitant cost of R&D, pharmaceutical companies want to gain as much revenue as they can earn from the few blockbuster drugs and use patent strategies as a tool to maximize their revenues.

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Patent linkage is one of the strategies used to enhance patent monopoly. It involves linking generic drug marketing approval with the originator drug's patent status and refusing marketing approval until the relevant patent expires.[6] The linkage system presupposes marketing approval as violation of patent. Patent linkage has global impact due to its widening scope and geographical coverage. Patent linkage has been extending to developing countries rapidly through bilateral agreements. In 2011, sixteen countries: Chile, Singapore, Jordan, Morocco, Bahrain, Oman, Colombia, Peru, El Salvador, Honduras, Guatemala, Nicaragua, Costa Rica, Dominican Republic, Peru and South Korea signed bilateral agreements with US for patent linkage and it is expected that other countries may also join soon.[7] In the pharmaceutical sector, since a molecule is itself patentable, there is a greater dominance on the basis of patents, because independent development of same molecule is not possible during patent term. Competitors can invent around the patent but cannot make the same molecule because of patent exclusivity, which may, many a time, be the basis of abuse of dominance. Earlier, tying up of a patented good with non-patented goods was deemed as abuse of patent rights, now it has been extended to patent misuse.[8] The European Commission in case of AstraZeneca held that even strategic and fraudulent acquisition of patents may violate competition law.[9] Acquisition of IPRs to abuse dominance has been held anti-competitive in several cases such as

Broadcom Corporation v *Qualcomm Inc*[10] and *Rambus Inc* v *Infineon Techs AG*[11]. As it is evident that patent linkage is extending to various generic-producing developing countries through foreign trade agreements, it is probable that other developing countries may be pushed to incorporate patent linkage in their patent law. In this backdrop, the paper intends to examine the effect of patent linkage systems in various countries to know the nature and effects of it.

Patent Linkage System in US

The patent linkage system originated in the US and was later adopted by other countries. The US patent linkage model is used as a reference in this paper. The distinguishing features of the US patent linkage system are: (i) the patent status referral source (Orange Book), (ii) four types of certifications based on patent status, (iii) different pathways for small molecule drugs and biological drugs, (iv) 180 days exclusivity to the first generic applicant that challenges the validity of patent, (v) 30 months stay on the marketing approval after suit filed by the originator drug company in fixed time or until the case disposed of and (vi) finality of judgement on patent validity for all purposes. Patent linkage works both ways – as one of the mechanisms to extend the exclusivity of originator drugs to incentivize innovation in the pharmaceutical sector and at the same time to encourage generic drug companies to challenge weak drug patents by giving 180 days exclusivity to the first generic company who can successfully invalidate the originator drug patent. In US, there is an extensive administrative system to deal with patent linkage. Patent listing of branded drugs is done by the Food and Drug Administration (FDA) in the Orange Book and a generic applicant has to choose one out of four certifications on the basis of patent status relating to the relevant drug in question. These certifications of Abridged New Drug Application (ANDA) are applicable when: (1) there is no existing patent related to generic drug application, (2) the relevant patent has expired, (3) the marketing approval is sought after existing patent expires and (4) contesting the validity of relevant patent. The patentee can bring an action for infringement under Section 271(e)(2)(A) of the 35 USCA within 45 days of receiving the notice required under Section 355(j)(2)(B) of the 21 USC. If the originator company chooses to sue for infringement of the patent, the approval of generic drug will be held up for 30 months.[12]

Before the Drug Price Competition and Patent Term Restoration Act (Hatch Waxman Act) 1984, there was a lack of generic competition in the pharmaceutical market even after expiry of patent term as generic companies were required to conduct all the clinical trials similar to a new drug. Thus, there was a huge cost involved in getting regulatory approval due to duplication of the clinical trial data. Under the Hatch Waxman Act, the requirement to reproduce all clinical trials was put to an end and generic companies could use the data produced by originator drug companies.

There are various empirical studies on the effect of the patent linkage on generics competition and innovation in US. The study by Bouchard *et al.*[13] revealed that pharmaceutical companies list a significant number of patents to delay the entry of generics. While there appeared to be no enhancement in innovation level due to patent linkage, the relevant legislation indeed resulted in multiplicity of litigation. Further, the main purpose of the legislation was compromised due to settlements between generic and branded companies. Such out of court settlement of patent disputes became necessary for generic firms to recover the heavy cost of litigation. This study attributes the patent linkage provision to delay in the entry of generics.[13]

A Federal Trade Commission (FTC) empirical study on generics' entry before the expiration of patent found that from 1992 to 2000, in 8 instances branded drug companies filed patents after the filing of ANDA. For these products, the delay caused by originator companies ranged 4 to 40 months. Before 1992, only three generic products were provided 180 days exclusivity on account of being the first generic applicant. Interestingly, between 1992 and 1998, FDA did not provide exclusivity to any first generic drug applicant. In 1998, with the changed regulations due to a court ruling and FDA granted exclusivity to 31 out of 104 first generic drug applicants. In 19 cases (out of the 31 cases), commercial marketing triggered exclusivity and in 12 cases favourable court orders triggered exclusivity.

As observed under the FTC report, pending generic drug applications may be subject to multiple overlapping 30 month stays due to multiple patent filings after the ANDA application. It is also observed

that patent linkage increases patent litigation and only large generic companies can afford to challenge the validity of patents. Even after the enactment of Hatch-Waxman Act, the competition between branded drug companies and generics is not balanced. The 30 month stay on generic drug approval on just filing for a patent infringement, without going into the merits of the case is a system that lacks proper check and balances; it does not fulfil the public policy goal of promoting generics.

Patent linkage has increased patent litigation and reverse settlements. The leading cases include *Bristol-Myers Squibb Company* v *Royce Laboratories Inc*[14] and *Merck & Co Inc* v *Kessler.*[15] As a consequence, the cost of production of drugs increases and the consumer has to bear the burden. Exclusivity to first generic successfully invalidating the patent is only for six months. This period may not be sufficient for generic companies to recover the cost of litigation. So, it is a far better bargain to accept money from originator companies and stay out of the market. This would have an anti-competitive impact and delay the entry of generics.

Patent Linkage System and Position of EU

EU pharmaceutical policy is mainly directed towards harmonizing the drug regulation in all member countries. It aims among other things, at innovation, market access and public health. There are various EU based branded drug multinational companies. It is interesting to note that even though it is a home to various branded companies, the EU ideology is that patent linkage delays generic entry and may impact access to drugs.[16]

The European Medicines Agency (EMEA) is the drug marketing approving authority under the EU law. It does not allow linking marketing authorization to the patent status of the originator reference product. Article 81 of Regulation EC 726/2004 and Article 126 of Directive EC 2001/83 provide that authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. Since the status of a patent is not included in the grounds set out in the Regulation and the Directive, market approval is not linked to patent status.[17]

However, EU incentivizes the originator's interest by providing long term data exclusivity. The EU has longest data exclusivity period in the world, for a new chemical entity. The new EU Directive 2004/27/EC adopted in 2004 created a harmonized eight-year EU data exclusivity provision with an additional two-year market exclusivity provision. This effective 10 year market exclusivity can be extended by an additional one year (maximum) if, during the first eight years of those ten years, there is a significant improvement in existing drug. This pattern of 8+2+1 year exclusivity applies to new chemical entities in all EU member states.

As a consequence of data exclusivity, generic application for marketing authorization can be submitted only after 8 years, and the product cannot be marketed until after the 10th or 11th year.[18] There is a national procedure for drug approval in each member country and also the EC directive. In contrast to EU, the US model provides a shorter data exclusivity period with patent linkage. As a consequence, some European firms prefer US as their main place of operations.

Nevertheless, some countries, in EU, have been using patent linkage system. In Hungary, Article 7(9) of Decree 52/2005 of the Ministry of Health requires generic companies seeking marketing approval to declare that they are not infringing any patent right and will not market the product until patent expires. Similarly, in Italy, drug marketing agency requires a certification by the generic company that marketing approval application does not infringe any patent. Originator companies can take legal action against generic companies for marketing approval. Portugal and Slovak Republic also enforce patent linkage. In Portugal, originator companies can sue generic companies for getting marketing approval. In Slovak Republic, marketing approval comes into force only after expiry of patent.[19]

Patent Linkage in Other Foreign Jurisdictions

As discussed earlier, patent linkage is not restricted to US alone; countries such as Canada (in 1993), Mexico (in 2003) and Australia (in 2005) and 16 other countries (in 2011) have adopted patent linkage. Multinational pharmaceutical companies are trying to enforce patent linkage in many countries through litigation strategies. For instance, Bayer and Bristol-Myers Squibb have been trying to enforce patent linkage in India.

Canada

Canada has the second oldest system on patent linkage. It is interesting to note that Canada has the parallel patent status referral system similar to the

US FDA Orange book listings. It is called Patent Register and is an alphabetical listing of drug ingredients and their related patents, the patent expiry dates and other relevant information, established in accordance with the Patented Medicines (Notice of Compliance) Regulations [SOR/133-93] under the mandate of Subsection 55.2(4) of the Patent Act, 1985. Under paragraph 4 of the said Regulation, a person who files a new drug application has to submit a patent list in relation to the drug. The courts have interpreted patent linkage narrowly in a few cases. In the case of *AstraZeneca Can Inc* v *Canada (Minister of Health)*[20], the court held that under Notice of Compliance Regulations, it was necessary to undertake a patent specific analysis rather than a wide construction of drug submission and patent listing. Similar judgements were passed in *Biolyse Pharma Corporation* v *Bristol-Myers Squibb Company*[21] *and Bristol-Myers Squibb Canada Inc.*[22] Regarding incentives for generics, unlike the US, Canadian patent linkage system does not provide exclusivity to the first generic company to contest the validity of patent. Also, if a patentee files a case for patent violation within 45 days, then there is a stay of 24 months on marketing approval. The finality of patent litigation in relation to patent linkage is only between parties to the suit. Also, the system for deciding patent validity cases with respect to patent linkage in Canada is expeditious. Unlike four certification categories in US on classification of patents, there are two main categories which encompass all the areas covered by US FDA classification. The first category is where applicant wants drug marketing approval after the expiry of patent while the second category is where applicant contests the relevant patent rights. There are further four types of certification for challenging patent rights of the originator drug company by an applicant for marketing approval of generic drug under the second category. In the first type of certification, the applicant claims that the originator does not have exclusive right or ownership over relevant patent; in the second type of certification, the relevant patent has expired; the third type of certification is one in which the patent is claimed to be invalid and in the fourth type of certification there will be no patent infringement due to the marketing approval.

Mexico

Mexico maintains a patent linkage system which includes a record of pharmaceutical patents like the US Orange Book. These patents on allopathic pharmaceutical products are published in the extraordinary official gazette twice a year by the Mexican Institute of Industrial Property (IMPI). However, complete patent applications are not entered in the extraordinary gazette. The entry in the gazette consists of name of the patentee, the title of the invention, the most relevant claims, the generic name of the pharmaceutical product, information on licensee and the term of the patent remaining. The sanitary authority (COFEPRIS) does not grant marketing approval to anybody other than patent holder or licensee. There are ambiguities and difference of opinion regarding patent linkage system in Mexico. Patent authorities believe that patent linkage should only apply to the active ingredient patent but the Supreme Court in various cases ordered that patent linkage should be applied to compositions, dosage patents and new use patents as well, although not to process patents.[23] It is interesting to note that, as in Canada, there is no exclusivity to first generic applicant for successfully invalidating originator's patent listed in referral book. Mexico does not have patent status referral certifications for originator drug patents like US, Canada and Singapore.

Singapore

Singapore has provisions similar to those for patent linkage in US. In Singapore, patent linkage is provided to restrict generic competition under Section 12 A of the Medicines Act, 1975. Singapore has four types of patent classification like US: Category A1 application where there is no patent in force, Category A2 where the applicant for the marketing approval is the patentee or assignee, Category A3 where the approval is for grant after the expiry of patent, and Category B which is similar to Para 4 applications in US. In this type of application, the applicant does not have permission from patentee and contests the validity of patent. If the patentee files a case against the applicant within 45 days of market application filing, then the market approval is stayed up to 30 months as in the case of US.

Australia

Australia has restricted patent linkage provisions for minimising the adverse effects of patent linkage over generics in contrast to US, China and Singapore due to the experiences in these countries. There are provisions against ever-greening and drug patents are to be based strictly on proved therapeutic importance

of the drug. There is also a patent linkage provision under Section 26(B) of Therapeutic Goods Administration Act, 1989. The most striking feature of the Australian patent linkage provision is that, heavy penalty is imposed for false and misleading information.

China

China has one of the strictest patent linkage systems in the world. China in order to attract investments in the pharmaceutical sector has made various changes in its patent law. It adopted data exclusivity for a term of six years and added provisions on patent linkage in 2002, in the Drug Registration Regulation.[24] Article 11 of the Drug Registration Regulation provides that an applicant for drug marketing approval should explain the relevant patent status and non-infringement of patents clearly.[25] Article 12 of the Drug Registration Regulation provides that if an infringement dispute happens post-registration, the parties shall try negotiation to settle the issue or resort to judicial remedies. The provision in favour of generics is Article 13 of the Regulation which provides that generic companies may apply for registration within two years prior to the patent expiration. Chinese patent linkage provisions are more pro-originator drugs than the US provision. Chinese provisions apply to all the drugs where there is an existing similar drug, whereas, the US provision applies only to those drugs that seek to benefit from the clinical data of the originating companies in the form of abridged clinical trials. The Chinese patent linkage provision applies equally to small molecule drugs and biological drugs unlike in the US.[26] Also, in China there is no system equivalent to the Orange Book for patent status reference.

Patent Linkage in India

The strength of Indian drug companies lies in generics and bio-similar drugs. It is evident from the evolution of patent linkage in other counties that patent linkage crept into the system when a flourishing generic industry existed. So it is highly probable that branded drug companies may push for patent linkage in India. As observed through empirical studies such as Bouchard[13], patent linkage results in ever-greening of pharmaceutical patents. Indian patent law intends to control ever-greening of drug patents though patentability criteria of efficacy enhancement under Section 3(d) and pre-grant opposition under Section 25(1)(a) of Patents Act. Presently, there is no express provision on patent linkage in India. There are however, at least three cases, where pharmaceutical companies have tried to enforce patent linkage in India. It was first discussed in *Bristol-Myers Squibb* v *Hetero Drugs Limited*.[27] In this case, the Delhi High court restrained Hetero Drugs Ltd from getting marketing approval due to a valid patent of Bristol-Myers Squibb implying application of patent linkage. In 2008, Bristol-Myers Squibb filed a case on the same drug, Dastanib, against Natco too.[28] This case is *sub judice*. In this case, Bristol Myers Squibb contended that Natco was advertising its product Dasant, the generic version of Dastanib. So it would have filed for marketing approval also. Natco denied any intention to market or manufacture this product. This case appears to be an attempt to enforce patent linkage. It was followed by a leading case of *Bayer Corporation and others* v *Union of India.*[29] In this case, the Delhi High Court discussed the experiences of various countries like Canada, US and European Commission with reference to patent linkage. It also discussed the incapability of drug authority to judge the status of patent and TRIPS mandate on patent linkage. It concluded that there is no patent linkage in India.

Interface between the Drugs and Cosmetics Act and the Patents Act

The objectives of both laws do not indicate any interface between the Drugs and Cosmetics Act, 1940 and the Patents Act, 1970. The legislative intent behind the Drugs and Cosmetics Act is to examine the safety and security of drugs and good manufacturing practices which are to be applied by every importer or manufacturer of a drug. On the other hand, the Patents Act creates a regime containing standards for conferring private rights to inventors. The Controller of Patents and other patent authorities are experts in examining patentability of inventions. This expertise extends to all technology areas including the pharmaceutical sector. However, mere grant of patents is not a conclusive proof of validity. Patents can be opposed pre-grant as well as post-grant (Section 25 of the Patents Act) or even revoked (Section 64). Section 13(4) provides that the examination and investigations required under Section 12 is not conclusive proof of validity of any patent. The Central Government is in no way responsible for the validity of a patent.

As per the Drugs and Cosmetics Act 1940, authorities have expertise in testing the safety of the product and the therapeutic efficacy claimed. Nevertheless, the drug authorities do not have any legislative backing to examine the patent validity.[30] Moreover, if an applicant fulfils all the essential conditions for grant of marketing approval under the Drugs and Cosmetics Act 1940, the Drugs Controller of India (DCGI) is under a statutory duty to grant the manufacturing approval and marketing licence. Allowing linking of patent status to drug regulatory approval will result in deciding of the patent validity question by the drug controller for which there is no legislative basis. The Patents Act was amended in 2005, when several important amendments were introduced, such as Section 2(ta), explanation to Section 3(d), Section 92 and Section 92A, particularly pertaining to the pharmaceutical sector. Even so, there is no legislative intent to provide for patent linkage in India under the Patent Act, 1970 or Drugs and Cosmetics Act, 1940 (ref. 31).

Conclusion

Patent linkage systems in various jurisdictions vary to a large extent. For instance, at least three countries have patent referral system and application certification system in various categories for the purpose of patent linkage whilst others do not have such system. The subject matter of the patent linkage too varies in different systems. In the US, there are different pathways for small molecule drugs and biological drugs. Patent linkage applies only to an abridged new drug application. In China, it applies to all types of drugs. In Mexico, process patents are not listed on the reference list. The incentive to generics in the form of exclusivity is not available in all countries. Unlike US, at least five countries have no exclusivity for the first generic applicant for market approval by successfully invalidating the relevant drug patent. At least two countries, US and Canada, impose a stay on generic for a period of 30 and 24 months, respectively. The finality of patent suit also varies in patent linkage cases. For instance, in US, the decision is final for all purposes. In Canada, the judgement applies to the parties to dispute only.

In US and Canada, empirical studies have shown the negligible effect of patent linkage on decrease in prices. Patent linkage has induced incremental innovation and patenting around one's own basic patent to maintain exclusivity, thus resulting in ever-greening. Even when originator companies know that they are going to lose the litigation, they still have incentive of at least 30 months extension of monopoly to contest and litigate infringement of patent; delaying the entry of generics in the market. Further, the exclusivity period starts from the day courts pass order or commercialization of generic drug, whichever is earlier. The consequence could be that the generic may not enter the market for the whole exclusivity period.

The Indian case of *Bayer* v *Union of India*[29] discusses the institutional incompetence and power of drug authority to examine the validity of patent. Even in US, where there is patent linkage, FDA is not empowered to examine the validity of patents. Besides, such an authority is not desired even, as it will create confusion between two authorities and unnecessary delay the entry of generics further. The main reason that India does not have patent linkage is the lack of legislative basis and policy. Even if patent linkage is implemented, it will require enhanced institutional capacity for countries like India.

Some countries have adopted patent linkage system to attract the investment in the pharmaceutical sector. China has adopted stricter patent linkage in comparison to the US to attract investments and encourage introduction of branded and new drugs in China first.

On the future of patent linkage in India, there are diverse opinions. Mrs Satwant Reddy Committee Report suggested that in future India can adopt a patent linkage system. However, if India does incorporate patent linkage in future, there are a few issues which should be taken care of. It should avoid multiple stays on the generics approval as in US. Even if there are new patents filed after the filing of generic marketing approval application, the stay on generic should be only after *prima facie* maintaining the validity of patent not on just filing of infringement case. The exclusivity should be extended to as many generic companies that join hands in the litigation for challenging validity of a drug patent, so that companies can jointly bear the litigation cost and are not compelled to enter into settlement with branded companies. These measures could remove the anti-competitive effects of reverse payment.

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