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**Patent or Patient**

*Link Them Properly*

*‘Patent Linkage and Competition: A Comparative Study’*

**Introduction**

Free competition is a rule and patent monopoly is an exception to this rule.\(^1\) It does not mean however, that both are accommodated by law to protect different interests. Both, i.e. competition and patent law have the same objective, to promote innovation for public welfare.\(^2\) Competition law seeks to ensure that free competition in the market promotes innovation and provides consumers access to these innovations at a competitive price. On the other hand patent law awards innovators with a limited monopoly right seeking to incentivise the creation and disclosure of innovation for the benefit of society.

Therefore it becomes necessary that every rule and provision related with these two fields of law promotes this harmony, which is often phrased as ‘a perfect balance between innovation and competition’. When it comes to the pharmaceutical sector, maintenance of such balance becomes indispensable.

In recent decades discussions over issues regarding the interplay between these two fields of law in the pharmaceutical sector have seen a tremendous increase. One such issue is the patent linkage system, which has become a matter of concern for competition authorities of many jurisdictions.

This document will focus on the issue of the ‘patent linkage system’\(^3\) and discuss how it disturbs the balance between innovation and competition, by facilitating anti-competitive practices. It will explain the manner in which this mechanism affects a generic drug’s market entry, and also whether such a system is helpful in the attainment of the object of proper balance, between innovation and competition, in the pharmaceutical sector. For the analysis over issues of patent linkage, this paper will focus on three jurisdictions i.e. the U.S, EU and the India.

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\(^1\) The Statute of Monopolies 1623 in U.K is the best example of this. Where, Section 1 of the Act declared that every form of monopolies is void, Section 6 provides an exception to this rule by allowing the grant of patent for 14 years.


\(^3\) Patent Linkage system is a mechanism under which the drug regulatory authorities, normally responsible for ensuring the safety and efficacy of the drugs, entrusted with an additional duty of policing the patent of a pharmaceutical company. It means to link the marketing approval, of a generic drug, to the patent status of branded drug, i.e. if the branded drug is protected by patent then regulatory body will not grant a marketing approval to its generic version, until the expiry of patent.
The term ‘patent’ in the title of this document represents public interest in the innovation of new drugs protected by the law of patents. On the other hand the term ‘patient’ represents the interests of the public in having access to these innovative drugs at an affordable price, promoted by competition law.

The whole document is divided into four parts that is Parts ‘A’, ‘B’, ‘C’ & ‘D’. Part A will explain how patent linkage facilitates ‘collusive practices’ like reverse payment settlements. Particularly in this part of the document, we will deal with the system of patent linkage in the United States. Firstly this part will analyse whether reverse payment settlements are pro-competitive or anti-competitive and then it will explain how patent linkage provisions facilitate such settlements.

‘Part B’ explains how the patent linkage system acts as a catalyst in promoting ‘exclusionary practices’, particularly the misuse of regulatory provisions by branded pharmaceutical companies. This part is further divided into two sub-parts, I and II. In the first sub-part, the paper will discuss the position in the European Union, where no provisions for patent linkage exist, but there have been growing demands for the introduction of such a system at the European level. Thereafter, we will also analyse, whether, in the light of serious concerns raised by the European commission, (in its pharmaceutical sector inquiry report) about the existing misuse of patent rights, it will be in the interest of EU to have such a system.

Further this part will discuss the position of India, on the issue of patent linkage and will explain how branded drug companies are using litigation as a route to create patent linkage. Then we will analyse what position India should adopt on the issue of the patent linkage, considering the ramifications of such a system on its large generic drug industry.

‘Part C’ will analyse whether patent linkage is necessary, in order to maintain a proper balance between innovation and competition, in the pharmaceutical sector. We will discuss various alternatives to the patent linkage system. The ‘Part D’ will be the conclusion.

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4 The expression ‘Collusive Practices’ connotes a situation where, two or more undertakings enter into an agreement or of form a cartel, in order to prevent the competition in the market. The effect of such collusion results in the price fixing or output reduction or the creation of entry barriers for the new market participants. In U.S, Section 1 of the Sherman Act (15 U.S.C. §§ 1–7), prohibits such type of collusions.

5 When, a dominant undertaking, instead of colluding with any other undertaking, inhibits the competition in a market by its unilateral conducts. In the EU, Art.102, of Treaty on the Functioning of European Union (TFEU) deals with such practices.

6 Commission’s Final Report, infra note.92 Para 1411 p.476

7 Commission’s Final Report, infra note.92

In U.S, the patent linkage system has been created by the Drug Price Competition and Patent Term Restoration Act, 1984, known as the Hatch Waxman Act8 (“the Act”). The Act amended the Federal Foods, Drugs and Cosmetic Act, 1938 and the U.S. Patent Act - 35 USCS.9 Since then the U.S has been engaging in a balancing exercise, in order to achieve a state of equilibrium between innovation and competition, in the pharmaceutical sector. It seeks to achieve such a balance by providing incentives for both generic as well as the branded drug companies.

It also advocates the introduction of similar provisions in other legal systems of the world.10 However, the introduction of this system has given rise to many anti-competitive issues such as ‘orange book misuse’ and ‘reverse payment settlements’. This document will only focus on the issue of reverse payment settlements. In this part the article will discuss how patent linkage provisions under the Act facilitate collusive practice like reverse payment settlements.

However, before analysing the status of patent linkage and its anti-competitive effects in the United States, it is important to explain at the very outset the concept of patent linkage.

1. What is Patent Linkage?

Patent linkage means “linking marketing approval, pricing and reimbursement or any other regulatory approval, of a generic drug, with a branded drug’s patent status”.11 Under this system a drug regulatory body ensures that no other generic firm shall get marketing approval for a drug covered by a patent. The grant of marketing approval certifies drugs as safe and effective, without which a drug cannot be put on the market.

Such a system is peculiar to the pharmaceutical sector. In this sector an exception of ‘early working’ has been provided to generic drug companies.12 This means generic drug manufacturers will get an exemption from the liability of infringement, even if they use patented inventions of branded drug companies, to produce their own drugs. In such a

8 21 U.S.C. § 355; See Caffrey, infra note.31, p.4. Senator Orrin Hatch and Representative Henry Waxman were the Sponsors of the Bill & it was enacted by amending by amending the Federal Foods, Drugs and Cosmetic Act, 1938 and U.S. Patent Act -- 35 USCS.
situation it is considered fair to give pioneer drug companies an opportunity to protect their rights conferred by a patent.\textsuperscript{13}

It can be argued whether it is justifiable for a regulatory authority, lacking expertise to deal with the complexities of patents, to stop the marketing approval of a generic drug, without knowing or determining the validity of the patent. Despite such issues, many jurisdictions have adopted this mechanism in their legal systems.\textsuperscript{14} The genesis of patent linkage worldwide is the Hatch Waxman Act, the ‘\textit{Magna Carta}’ of this system.

\section{The Hatch Waxman Act:}

Through this Act the Congress has adopted an innovative approach to incentivise both innovation as well as competition in the U.S pharmaceutical sector. To understand the objective behind the adoption of such an approach, it is necessary to throw some light on the important events which leads to the enactment of the Act.

\subsection{History of the Act: Causal Incidences}

The 1962 Amendment of the Federal Foods, Drugs and Cosmetic Act, 1938 introduced a new requirement, to prove the efficacy of a new drug, along with its safety to obtain marketing approval for that drug.\textsuperscript{15} As a result drug manufacturers had to conduct at least two adequate and well controlled clinical investigations to establish the effectiveness of their new drugs.\textsuperscript{16} Consequently, the costs of investigation and drug trial procedures have increased significantly.\textsuperscript{17}

These long clinical trials and investigative procedures have shortened effective patent terms,\textsuperscript{18} because companies are not allowed to sell new drugs without obtaining marketing approval from the Federal Drug Authority (“FDA”) even though the term of patent protection starts from the filing date of their patent applications with the U.S Patent and Trademark Office (“USPTO”).\textsuperscript{19} This long time gap between the patent grant and the marketing approval due to the regulatory procedure resulted in the erosion of the patent term.\textsuperscript{20}

The second important event, which played an important role in the enactment of the Act, was the decision of the U.S Supreme Court in \textit{Roche Products, Inc. v. Bolar Pharmaceutical Co.}.\textsuperscript{21} In this case the court held the use of patented drugs by a generic drug company for creating test data to obtain marketing approval for its drugs to be an infringement of the pioneer

\textsuperscript{13} \textit{Id}

\textsuperscript{14} \textit{Id}


\textsuperscript{16} \textit{Id}, p.588; Also 35 Fed. Reg. 7, 250.

\textsuperscript{17} Elizabeth, \textit{supra} note.15, p.588

\textsuperscript{18} \textit{Id}, p.588

\textsuperscript{19} 35 U.S.C 154(a)(2).

\textsuperscript{20} Elizabeth, \textit{supra} note.15, p.588

\textsuperscript{21} 733 F. 2D 858, (Fed. Cir. 1984)
drug’s patent. After this ruling, the ability of a generic drug company to produce generic versions of branded drugs and to introduce them in the market soon after the expiry of pioneer drug’s patent was jeopardised. This caused a threat of de-facto enhancement of patent term.

To rectify both situations, Congress amended the Federal Foods, Drugs & Cosmetic Act 1938 by introducing the Hatch Waxman Act (“the Act”). The Act provided a solution to both the problems. Firstly, it provided a mechanism for the extension of patent term up to a maximum period of five years. Secondly, it provided an exemption to generic drug companies commonly known as ‘Bolar Exemptions’. By virtue of this exemption, generic drug producers are able to rely on the data of the pioneer drug companies for the marketing approval of their own drugs.

Apart from these two solutions, Congress adopted an innovative approach to strike a proper balance between innovation and competition. For incentivising research & development in the pharmaceutical sector, the Act provides for a patent linkage system. By virtue of this system, a pioneer drug producer gets an opportunity to sue generic drug suppliers who apply for the marketing approval of a drug that falls within the scope of pioneer’s patent. Such infringement actions by the pioneer drug company results in a 30 month stay on the marketing approval of generic drugs. To ensure that this patent linkage system does not deter generic drug suppliers, thereby restricting the market entry of such drugs, the Act accords a 180-day market exclusivity to the generic drug producers, as an incentive to challenge the pioneer company’s patent and apply for the marketing approval of their drugs.

This innovative approach to incentivise both competition as well as innovation has now come to be the bane of Congress, the Courts and other regulatory bodies like the Federal Trade Commission (“FTC”) and the FDA. Before discussing these issues in more detail, it is necessary to highlight the main objective of the Act.

2.2. Objective of the Act: A Trade-off Between Innovation and Competition

“...the American people will save money, and yet receive the best medicine that pharmaceutical science can provide”.

- President Reagan, Sept. 24, 1984

The above statement by President Reagan clearly shows that the Act was a result of a compromise between two compelling needs. On one side, the need of branded drugs companies to have sufficient opportunity to recoup their investment incurred in the research and development of new and innovative drugs, on the other, those of the public to have

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22 Id, at 863; See Clements, supra note.9, p.387
23 Clements, supra note.9, p.387
24 Id, p.388
25 Elizabeth, supra note.15, p.591
26 Id, pp.604-605
27 Clements, supra note.9, pp. 388-389
28 Mehl, supra note.38, p.657
30 Elizabeth, supra note.15, p.585
In order to achieve such a state of a perfect balance between these two needs, the Act provides many mechanisms. Out of all those provisions, this paper will analyse the patent linkage system created by the Act.

3. **Mechanism of Patent Linkage Under the Act:**

Under this system a pioneer drug company ("NDA holder") is required to submit before the FDA, along with its New Drug Application ("NDA"), the details of any patent covering the subject matter of their NDA (also called as ‘listing requirement’). Thereafter the FDA lists such information in its records, commonly known as the Orange Book. The listings provide ground to the NDA holder to protect its exclusive right of patent before the marketing approval of any generic drug.

Further under this mechanism, a generic drug producer [Abbreviated New Drug Application ("ANDA") filer] is required to certify, in order to get marketing approval, that there is no infringement of the NDA holder’s patent or it will introduce its drug only after the expiry of such patent. For this it is required to file, along with its ANDA, one of the four certificates provided by the Act. Certificate–IV in particular gives rise to various anti-competitive issues, particularly those of reverse payment settlements.

4. **Consequence of Filing Paragraph-IV Certificate: A Thirty Month Stay**

If an ANDA filer files a Parag-IV Certificate, in order to get marketing approval for its drugs, the Act enables the NDA holder to bring an infringement action against such an ANDA filer. The upshot of such infringement action is that, the FDA stays the marketing approval of the ANDA for the period of 30-month.

This 30-month stay, on the approval of the first ANDA, leads to a situation, similar to ‘a cork in the bottleneck’. In such a situation, neither the first ANDA filer nor any other subsequent ANDA filer can bring its generic version into the market, because that will results in the abrogation of 180-day exclusivity period of the first ANDA filer.

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32 21 U.S.C § 355(b) (1); See Elizabeth , supra note.15, p.595
33 Approved Drug Products with Therapeutic Equivalence Evaluations, 21 U.S.C § 355(j)(2)(A)(vii); See Elizabeth, supra note.15, p.600
34 Through this certificate an ANDA filer either challenge the validity of the patent or claim that manufacturing or selling of its drugs, will not infringe the relevant patent.
35 21 U.S.C § 355(5)(B)(iii); See Elizabeth, supra note.15, p.600
36 Id; See Elizabeth , supra note.15, pp.600-601
This period of market exclusivity will only be triggered by the commencement of commercial marketing of the first ANDA filer’s drug. But without marketing approval, such commercialisation is impossible. Moreover, once the countdown of the 30-month stay commences, the marketing approval of first ANDA can only be possible after the expiry of the stay or after a decision of the court declaring the patent invalid or finding that it has not been infringed. This can also be the case when the first ANDA filer files an amended paragraph-III certificate (which is very rare because in such a case it will not be entitled to get the award of 180-day exclusivity period). This situation causes the blockage of market entry of generic drugs. In some cases even after the expiry of the NDA holder’s patent, there may not be any generic drugs present in the market.

To avoid this long delay, uncertain outcome of the case and their legal expenditure, the pioneer drug supplier and the first ANDA filer consider it better to settle their dispute through agreement, such as reverse payment agreement. However, such agreements also give rise to anti-trust concerns. Before analysing whether such agreements are anti-competitive, it is necessary to explain the meaning of such agreements.

5. **Meaning of Reverse Payment Settlements:** Compensation to the Infringer

‘Reverse payment settlement’ or ‘payment to delay’, are terms used to indicate a situation, in any patent infringement action, where a claimant instead of asking for monetary compensation from the alleged infringer, offers the defendant a huge sum of money. This money is offered to delay the defendant’s market entry. Such settlements often give rise to many anti-trust concerns. Competition authorities in the U.S have constantly maintained their stand of treating such agreements as anti-competitive.

6. **Nature of Reverse Payment Agreements:** Anti-competitive or Pro-Competitive?

In the U.S there is uncertainty over the anti-competitive nature of such agreements. While some courts treat such settlements as anti-competitive and adopt a per se rule, others have held such a rule inappropriate. For instance in the *Re: Cardizem CD Antitrust Litigation*, the Court of Appeal for the Sixth Circuit, rejected the defendant’s argument that settlement, through such agreements, should be treated as lawful enforcement of its patent right. It held that “reverse payment settlements are ‘naked horizontal restraints’ of competition”. Therefore such agreements, during an infringement action by a party with its potential competitor, are per se unlawful.
On the other hand *In Re: Tamoxifen Citrate Antitrust Litigation*, the Court of Appeal for the Second Circuit, and the court for the Eleventh Circuit in *Schering Plough v. FTC* held that such agreements are not unlawful, unless they restrain competition beyond the scope of patent.

The reasoning behind such an approach is that in some cases, the settlement of such disputes can be more pro-competitive than the final disposal of the case itself. For instance, in a case where the NDA holder successfully established the infringement of its patent, it will result in the absolute elimination of competition from the market. Therefore in such cases a settlement between patent holder and infringer may be more beneficial, particularly if the NDA holder allows the market entry of the generic drug company, for example by granting it a license before the expiry of the patent.

However, in cases like *In re Tamoxifen Citrate Antitrust Litigation*, the plaintiff alleged that the price of generic drugs sold under the licence of the NDA holder was higher than the usual generic’s price. For instance in this case the price of generic Nolvadex, sold under the licence of NDA holder, was only 5 per cent lower than the price of its branded version, instead of a usual price difference of 30-80 per cent.

This shows that even if pioneer drug producers allow marketing of generic version of their drugs, under a licence, the object of the Act may remain unfulfilled. In such a situation, consumers are still required to pay more for these drugs as compared to what they would have paid in case of unhindered competition between a pioneer drug and its generic version.

Amid conflict between circuits, the FTC, in its study has claimed that after 2005, following the approval of the reverse payment settlements by the 2nd Circuit, the number of reverse payment agreements has seen a marked increase. For instance, where in 2005 only three such agreements had been entered between such entities, that number, by the end of 2009, had become nineteen.

These increasing instances of payment for delay agreements can jeopardise the basic objective of the Hatch Waxman Act i.e. ‘to provide the public access to drugs at affordable prices’. Both branded as well as the generic companies share the monopoly profits of the branded company, without passing any on to the public. The public bears high prices for branded drugs in the absence of generic competition.

The above-mentioned FTC study also manifests this fact. According to this study, in the period from 2005 to 2009 branded companies have earned a profit of around $20 billion by

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49 402 F.3d 1056; (11th Circuit) (Schering v. FTC)
50 Id at 1064
52 Id
53 Id
54 Id
55 Joblove v. Barr, supra note. 48, at 216
56 Caffrey, supra note.31, p.30
keeping their generic competitors away from the market.\textsuperscript{58} The cost borne by consumers due to the absence of competition was around $3.5 billion.\textsuperscript{59} According to the FTC estimation this will increase and will touch the amount of $30 billion, within next ten years.\textsuperscript{60}

This is contrary to the objective of the Hatch Waxman Act, which was created with the objective of providing benefits to the consumer, resulting from competition between pioneer and generic drug companies. The fundamental object of Hatch Waxman Act is to protect public interest, indirectly, by way of promoting innovation and directly by way of ensuring competition within the pharmaceutical market. However, by entering into such agreements, these pharmaceutical sector players endanger the intended objective of the Act. Payment for delay agreements only protect the interests of parties involved in the agreements i.e. pioneer and generic drug companies.

Whether such agreements are anti-competitive or not, it cannot be denied that such agreements are not in the public interest. Public interest lies in the final disposal of such cases and not in any kind of profit sharing arrangement between branded and generic drug companies.\textsuperscript{61} In the absence of a 180-day exclusivity reward, it is only the outcome of litigation, i.e. final adjudication over the validity issue of a patent, which acts as an incentive for the subsequent ANDA filers to accelerate their market entry.\textsuperscript{62} But the settlement of such adjudication process prolongs the uncertainty over the validity of patents.\textsuperscript{63} This reduces the scope for multi-generic competition in the market by forcing other generic suppliers to slow their market entry process.\textsuperscript{64} It is competition from subsequent generic suppliers that reduces price of patented drugs considerably, by ending the duopoly of branded drugs and the first generic supplier. However, the postponement of market entry of such entities clearly deprives the public of the fruits of real generic competition. Therefore, anything against the public interest cannot be considered pro-competitive.

Even Senator Hatch (whom the Act is named after) acknowledged the anti-competitive nature of reverse payment settlements and criticised them for undermining the fundamental objectives of the Act by delaying multi source generic competition.\textsuperscript{65} Moreover, he has also appreciated the FTC’s stand against such settlements.\textsuperscript{66}

7. **The Epicentre of the Problem: Patent Linkage**

Reverse payment agreements do not always result from well-planned conspiracies between generic and branded drug companies. It is something for which complex provisions of the

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{58} Id
\item \textsuperscript{59} Id
\item \textsuperscript{60} Id
\item \textsuperscript{61} Caffrey, supra note.31, p.41, final disposal of case, establish that whether the patent is valid or not. However, this fact remains uncertain in case of reverse payment settlement agreements.
\item \textsuperscript{63} Id
\item \textsuperscript{64} Id
\item \textsuperscript{66} Id
\end{enumerate}
\end{footnotesize}
Act are equally responsible. The provisions of the Act themselves create a favourable atmosphere for such collusive arrangements as well as for unilateral anti-competitive practices (Part B of this document will give a detailed account of unilateral practices resulting from patent linkage). In particular, three features of the Act’s patent linkage mechanism are mainly responsible for such agreements.

Firstly, the listing requirement of the patent linkage system which provides a ground for initiating infringement action by branded drug companies against the first ANDA filers leading to a thirty month stay, and secondly, this thirty month stay provision, considerably lowers the bargaining power of the generic suppliers. The 30-month stay can be called a form of interim injunction, normally difficult to obtain even in regular patent infringement actions. Under the patent linkage system, branded drug companies are automatically entitled to such a remedy. Such a privilege strengthens their position in bargaining a favourable arrangement with generic counterparts. Thirdly and finally, the 180-day exclusivity provision which was introduced to counter the deterrent effect of a 30-month stay and resulting legal action, but actually encourages branded drug companies to enter into the reverse payment agreements. Entering such an agreement with only one entity can block the market entry of all generic providers. The commencement of marketing of the first ANDA filer’s drug is the triggering event for the reverse counting of 180-day exclusivity period. However, by entering into a reverse payment agreement and agreeing to delay its market entry, the first ANDA filer postpones this event. Moreover, the FDA is under an obligation not to approve the subsequent ANDA until the first ANDA filer exhausts its 180-day exclusivity right. This disables the FDA from granting marketing approval to any other generic supplier. Thus such agreements create an insurmountable hurdle for all other generic drug providers.

The FTC’s study shows that such agreements normally delay the market entry of a generic drug at least by seventeen month. Therefore, even if a branded drug company is required to make a huge payment to a single entity, then that will be a good deal for it, considering the profit that it will earn, during the absence of competition from the market.

Such arrangements are also beneficial for generic drug producers because they give them an opportunity to share the monopoly profits of branded drug companies. Particularly when it is

67 Schering v. FTC, supra note.49, at 1075
68 Hovenkamp, supra note.51, pp.1751-52
69 Id.
70 supra note 32
71 Hovenkamp, supra note.51, pp.1752-1753
72 supra note 37
73 Hovenkamp, supra note.51, p.1754
74 Id.
75 Id.
76 Id.
77 Mehl, supra note.38, p.657
78 Hovenkamp, supra note.51, p.1755
79 Id.
81 Id., p.1755
82 supra note 38
83 supra note 42
84 supra note 57
the only generic in the market and other firms can be prevented from entering into the market, through the abuse of 180-day market exclusivity provisions.85

Thus the real cause of all these situations is the patent linkage system. It creates a favourable atmosphere for a branded drug company to enter into such an agreement with the first ANDA filer and to restrict, for a significant period of time, the market entry of subsequent generic drug providers.

85 Caffrey, supra note.3, p.40
Part B: Patent Linkage System and the Unilateral Anticompetitive Practices:

The patent linkage system along with facilitating collusive practices, also acts as a tool for exercising exclusionary practices. This part will explain how the patent linkage system facilitates exclusionary practices, like restricting the marketing of a generic drug. This part is divided into two sub-parts. First we will discuss the status of patent linkage system in the European Union.

Here the paper will explain how originator pharmaceutical companies use this system as a means to achieve anti-competitive goals. However, it should be noted that there is no express statutory provisions for patent linkage at the European level. Then we will analyse whether there should be a patent linkage system in the EU to align the pharmaceutical sector with the U.S.

In the second sub-part we will explain how branded drug companies use litigation as a means to exercise exclusionary practices i.e. attempt to create patent linkage. Here we will discuss landmark Indian cases over the issue of patent linkage. We will also analyse what implications the patent linkage system may have on the generic drug industry and the public health system of India.

I. The European Pharmaceutical Sector & Patent Linkage System:

Before discussing the status of patent linkage and its misuse, it is necessary to mention the background of the European Commission’s ‘pharmaceutical sector inquiry’.

1. Background of the Sector Inquiry & the Finding of Anti-competitive Instruments:

It is not the case that misuse of regulatory provisions by the branded drug companies to prevent generic competition is peculiar only to the U.S. Such practices are also common on the other side of the Atlantic. In Europe, the first instance of such conduct of a branded drug company came to light, in AstraZeneca v. Commission.\(^{86}\) In this case, the ECJ upheld the findings of the Commission that ‘AstraZeneca’ had misused regulatory provisions with a view to restrict competition in the pharmaceutical sector.\(^ {87}\)

The anti-competitive conduct, for which the ‘AstraZeneca’ was held liable included filing false information with the regulatory body to obtain a supplementary protection certificate (for extending its patent monopoly) and seeking de-registration of the marketing authorisation of its branded drug. It applied for de-registration, with a view to deprive generic drug producers the benefit of the abridged marketing authorisation process.\(^ {88}\)

After this case, the European Commission has commenced a sector inquiry to ascertain the actual position of competition in the pharmaceutical sector and to analyse the influence of

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\(^{86}\) Case T-321/05; [2010] 5 C.M.L.R. 28; See Negrinotti, supra note 88, pp. 446-459

\(^{87}\) Id

regulatory frameworks on the market entry of the generic drugs. In its inquiry report, the Commission alleged that originator companies use a variety of tactics intending to restrict the market entry of the generic drugs. These tactics include the use of large patent portfolios, litigations, patent settlements, intervention in regulatory procedures (the patent linkage system) as well as the use of defensive patents.

According to the Commission, these practices are the anti-competitive instruments of the originator company’s ‘tool box’. Out of these anti-competitive instruments, the research will focus on the use of patent linkage, as a tool to delay placement of generic drugs on the market.

2. Status of the Patent Linkage System in Europe:

At the European Union level, there is no statutory provision for patent linkage. However, the Commission, in its inquiry report recognised that branded drug companies, often attempt to create such a mechanism, to restrict entry of generic versions of their drugs. The Commission also identified certain Member States that have provisions within their drug regulatory framework, which facilitate patent linkage.

The said report has identified that within the European pharmaceutical sector, branded drug companies use this tool at the two different levels that is, at the marketing authorisation level as well as at the stage of pricing and reimbursement of the generic drugs.

2.1 Use of Patent Linkage at the Marketing Authorisation Level

In Europe, like the U.S, it is compulsory for every pharmaceutical company to obtain marketing approval, before placing drugs on the market. Article 81(2) of Regulation (EC)
No 726/2004 and Article 126 of Directive (EC) No 2001/83 provides that marketing authorisation of any generic drug should not be refused, except on grounds mentioned in these statutory documents.\textsuperscript{97} The patent status of the original drug is not mentioned, as a ground for the refusal of a marketing authorisation,\textsuperscript{98} implying there is no patent linkage system at the European level.\textsuperscript{99}

However, often originator companies use the status of their patent as a basis to oppose marketing approvals of generic versions of their drugs.\textsuperscript{100} Innovator companies usually try to enforce such systems in two different ways. Firstly, by directly contacting the regulatory authorities and arguing that the grant of marketing approval to the generic drug will amount to the infringement of their exclusive right.\textsuperscript{101} Secondly, these companies also employ an indirect route of litigation as mean to enforce patent linkage, commonly by obtaining interim injunctions against the decisions of drug regulatory bodies.\textsuperscript{102}

The European Commission, in its sector inquiry report, identified 137 instances where branded drug companies have used the judicial process to invalidate decisions of regulatory authorities granting marketing authorisations to generic drugs.\textsuperscript{103} Patent infringement was the main basis in the majority of such actions.\textsuperscript{104} However, the outcome of the majority of cases, finally adjudicated by the courts, has been against branded drug companies.\textsuperscript{105}

Such findings indicate the primary objective behind such actions, which is to delay market entry of generic drugs. As per generic drug companies, such informal existence of the patent linkage system normally causes delay in the market entry of generic drugs.\textsuperscript{106}

2.2. The Use of the Patent Linkage System Before the Pricing and Reimbursement Authorities:

The grant of pricing and reimbursement status to a medicinal product is another regulatory requirement, without which no product can be placed on the market.\textsuperscript{107} As in the case of the marketing approval patent status is not an element that should be considered at the time of approval of the price level of a generic drug.\textsuperscript{108}

However pioneer drug manufacturers often intervene at this stage.\textsuperscript{109} In most cases, they base their opposition on the existence of their exclusive right of patent.\textsuperscript{110} Branded drug companies employ similar intervention strategies as those they usually employ at the stage of marketing.
authorisation i.e. either directly before drug regulatory bodies or indirectly by way of litigation.111

3. **Consequences of Such Interventions:**

Regular interventions by the pioneer drug companies either at the marketing approval stage or before the grant of the price and reimbursement status, affects the market entry of generic drugs.112 This is clear from the findings in the Commission’s final report. According to the said report, such interventions at the marketing authorisation level, on an average cause a 9-month delay in granting marketing approval to a generic drug.113

The Commission has also identified practices by certain ‘Member States’ drug regulatory bodies to suspend enforcement of already granted marketing authorisation, in response to the legal action taken by the originator drug company.114 Normally such suspension prevails until the final conclusion of legal proceedings.115

Such legal actions affect not only marketing authorisation of generic drugs but also impact price approval processes of a generic drug.116 For instance, in Portugal the regulatory authority responsible for approving the price level of pharmaceutical products has suspended the price approval process of generic drugs following legal action initiated by originator drug companies.117 According to the Commission’s report, in one particular case such suspension resulted in an 18-month delay over approving the price of a generic drug.118 In almost all such cases, patent linkage was used as the main ground to intervene in regulatory procedures.119

Whether it is the suspension of marketing authorisation or the price and reimbursement status approval, the ultimate consequences of such delays cause restrictions in the market entry of generic drugs. Such regulatory approvals are *sine qua non* for the placement of a generic drug on the market.120 However, even after the grant of such permission, it takes several months to introduce any drugs into the market.121

Therefore, any delay in such regulatory approvals will result in the de-facto extension of a patented drug’s monopoly period. For example, if a drug regulatory body starts the marketing or price approval process only after the expiry of a relevant patent, the time consumed in the grant of approval, production and marketing of drugs will add to the exclusivity of the patented drug.

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111 Id, Section 2.5.2.1 and Section 2.5.2.2, pp. 328-333.
112 Id, Section 2.5.1.3, Para 902, p.326.
113 Id, Para 901, p.326
114 Id, Section 2.5.1.3, Para 902, p.326.
115 Id, pp.326-327
116 Id, Section 2.5.2.2, Para 917, pp.330-331.
117 Id
118 Id
119 Id
120 Regulation and Directive, supra note. 96
121 It takes several months, in manufacturing and marketing of a drug, after the grant of marketing approval of the drug.
The findings of the sector inquiry also support this conclusion. For instance according to the Commission, branded drug company’s exclusionary practices, including the patent linkage system, have caused a seven month delay in the market entry of generic drugs, during a reference period of 2000 to 2007.\textsuperscript{122} According to the Commission, any delay in the market entry of generic drugs may have significant economic impact.\textsuperscript{123} In its report, the Commission identified that the delay caused in marketing of generic drugs during the reference period of 2000-2007 resulted in a loss of the potential savings of around € 3 billion.\textsuperscript{124} In other words this €3 billion was the additional cost which has been borne by the European public. Therefore it is not disputed that patent linkage has the potential to cause a delay in the market entry of generic drugs, and thereby contribute in maintaining high prices of branded drugs.


There has been growing pressure from branded drug companies, for the harmonisation of drug regulatory provisions of the EU and United States, in particular provisions related with marketing approval of drugs.\textsuperscript{125} Such steps will also encapsulate statutory recognition of the patent linkage system.

During public consultation on the ‘Preliminary Report of the Commission’, the ‘European Federation of the Pharmaceutical Industries & Associations’ (“EFPIA”), has suggested the introduction of a new mechanism, namely ‘clearing the way’.\textsuperscript{126} This is to avoid disputes, arising after the introduction of generic drugs into the market and costly consequences (for both the parties) resulting from such disputes.\textsuperscript{127}

The term ‘clearing the way’ can be considered a synonym to the phrase ‘patent linkage’, as it entails the creation of a mechanism identical to the patent linkage system.\textsuperscript{128} It will provide a right to a pioneer drug company to bring an infringement action against a generic drug supplier prior to the marketing approval of its drug.\textsuperscript{129} The generic drug industry has opposed it by claiming it is “\textit{back door entry for the patent linkage system}”.\textsuperscript{130} The Commission, in its observation also recognised the potential adverse impact of such a mechanism on competition in the pharmaceutical sector, particularly its deterrent effect on the first generic drug supplier.\textsuperscript{131} We will discuss this concept in more detail in ‘Part C’ of the paper.

\textsuperscript{122} Commission’s Final Report, \textit{supra} note 92, Para 1559, p.521
\textsuperscript{123} \textit{Id}, Para 1560
\textsuperscript{124} \textit{Id}, Para 219, p.81 & Para 1561, p.521
\textsuperscript{125} \textit{Id}, Para 1411, p.476
\textsuperscript{126} \textit{Id}, Para 1352-53, Section 1.6, Part D, p.459
\textsuperscript{127} \textit{Id}
\textsuperscript{128} \textit{Id}, Para 1354
\textsuperscript{129} \textit{Id}
\textsuperscript{130} \textit{Id}, Para 1355
\textsuperscript{131} \textit{Id}, Para 1358-59
However, here it should be noted that prevention of the potential deterrent impact of such a system on the first mover was one of the reasons behind the introduction of the 180-day exclusivity provision under the Hatch-Waxman Act (discussed in the Part A).\textsuperscript{132}

This document has already explained how, in the U.S, this 180-day exclusivity provision has been used as an anti-competitive tool by branded as well as generic drug suppliers. Introduction of any such mechanism may have similar adverse consequences on competition in the European pharmaceutical industry.

Even the Commission, in its observations has expressed doubt over any pro-competitive benefits of such a system.\textsuperscript{133} This can be discerned from the commission’s observation that statutory recognition of such a system within the European legal framework is very unlikely.\textsuperscript{134} In its final report, the Commission indicated that any future attempt to enforce the patent linkage mechanism at the regulatory approval stage will be subject to the Commission’s scrutiny.\textsuperscript{135}

Such a sceptical attitude, towards the patent linkage system is legitimate, considering findings made by the Commission regarding the misuse of such a system within the European pharmaceutical industry. It is also a practical fact, as recognised by the sector inquiry report, that pioneer drug companies “exploit every legally possible opportunity, to keep generics out of the market”.\textsuperscript{136} Therefore statutory approval of any such system will mean, enabling such entities, to create extra statutory hurdles in the early marketing of generic drugs.

II. **Judicial Interpretation: A New Route to Create Patent Linkage: Indian Pharmaceutical Sector & the Patent Linkage System**

Judicial proceedings could potentially be a popular route through which branded drug companies attempt to exercise exclusionary practices. We have already seen how litigation is being used as an indirect route to create a patent linkage system in Europe.\textsuperscript{137} There are many reasons behind such practices. Initiation of legal proceedings against only one generic drug company deters other generic suppliers from applying for marketing approval of their drugs. Such actions also affect regulatory procedures of drug regulating authorities, examples of which have been seen in the EU, particularly in Portugal.\textsuperscript{138} There is one more reason behind the adoption of this route. Judicial recognition of a patent linkage system, in the absence of any legislative mandate can provide the required legal sanctity to such mechanism.

These are the reasons behind the excitation of the use of judicial process for the creation of a patent linkage system. Such tactics are not restricted to the market of developed parts of the world like the EU. Employment of such practices has also been increasing in the

\textsuperscript{132} Mehl, supra note 38, p.657
\textsuperscript{133} Commission’s Final Report, supra note 92, para 1359, p.461
\textsuperscript{134} Id
\textsuperscript{135} Id, Para 1589, p.528
\textsuperscript{136} Id, Section 2.1.4.2, Para 541, p.199
\textsuperscript{137} supra note102-104 and accompanying texts
\textsuperscript{138} supra note114-117 and accompanying texts
pharmaceutical sector of developing countries.\textsuperscript{139} One example of this is India, where the issue of patent linkage has given rise to many controversies.

In this second subset of Part B the paper will discuss the status of patent linkage in India in light of the important judicial pronouncements over this issue. We will also analyse what implications recognition of patent linkage may have on the Indian generic drug industry.

1. Judicial Bewilderment Over the Issue of Patent Linkage

In India the issue of patent linkage first came to light when an interim order was issued by the Delhi High Court in \textit{Bristol-Myers Squibb Co. v Dr. BPS Reddy & ORS (Hetero Drugs Ltd)}.\textsuperscript{140} In this case the court issued an ex parte interim order, directing the ‘Drug Controller General of India’ (“DCGI”), to stay marketing approval of Hetero’s drug.\textsuperscript{141} Hetero applied for marketing approval of the generic equivalent of BMS’s patented drug ‘Dasatinib’.\textsuperscript{142} The Court, in its interim order, recognised that the marketing approval of Hetero’s drug will amount to infringement of BMS’s exclusive right.\textsuperscript{143} This judicial recognition of the patent linkage became a matter of concern, particularly for Indian generic drug companies.\textsuperscript{144}

Controversies raised by the said interim order, over existence of the patent linkage in India, were finally settled by the Delhi High Court in the case of \textit{Bayer Corporation v. Union of India & Ors.}.\textsuperscript{145} In this case Bayer, a branded drug company, filed a petition before the Delhi High Court seeking an order restricting the DCGI from granting a drug licence to Cipla (a generic drug company).\textsuperscript{146} Cipla had applied for a drug licence for its drug ‘Soranib’, a generic version of Bayer’s patented drug ‘Sorafenib Tosylate’.\textsuperscript{147}

Through its petition, Bayer tried to enforce the patent linkage system by way of judicial interpretation. In particular it argued that a cumulative reading of the provisions of the Patent Act 1970\textsuperscript{148} (“The Patent Act”) and the Drugs and Cosmetics Act, 1940\textsuperscript{149} (“The Drugs Act”), leads to the existence of the patent linkage in India.\textsuperscript{150} Bayer based its argument on the wordings of Section 2 of the Drugs Act and Section 48 of the Patent Act.\textsuperscript{151}

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\textsuperscript{141} Id

\textsuperscript{142} Id

\textsuperscript{143} Id


\textsuperscript{145} 2010 (43) PTC 12 (Del); See available at http://www.indiankanoon.org/doc/1123372/ (last updated Sept. 19, 2011) (Bayer v. U.O.I)

\textsuperscript{146} Id, Para 1

\textsuperscript{147} Id, Para 3

\textsuperscript{148} [39 OF 1970, DT. 19-09-1970], Including 2005 Amendment Act

\textsuperscript{149} [23 OF 1940], Along with the provisions of the Drugs and Cosmetic Rules, 1945

\textsuperscript{150} Bayer v. U.O.I, supra note.145, Para 8

\textsuperscript{151} Id

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Section 2 of the Drugs Act obliges the DCGI ‘to apply provisions of the Act in a manner that does not violate any other law’. Whereas Section 48 of the Patent Act confers upon the patentee, an exclusive right to restrict any third party, not having its consent, from doing certain act in relation to its patented invention. Bayer argued, that joint readings of both the aforementioned provisions, recognise the existence of patent linkage in India.\textsuperscript{152}

Bayer also placed its reliance, on the wordings of Section 156 of the Patent Act and Rule 122B (1) (b) of the Drug and Cosmetic Rule 1945 (“The Drug Rule”) read with Form 44, of ‘Schedule Y’ (annexed to the Drugs Act). Section 156 of the Patent Act puts a negative obligation on the Government and its officials to observe the rights of patent holders. While Rule 122B(1)(b) read with Form 44 of the Drug Rules, obliges an applicant seeking marketing approval for its drug, to mention, among other things, the status of any patent covering its drug. Thereby Bayer argued that Section 156 read with Section 48 of the Patent Act and Form 44 of Rule 122B(1)(b) of the Drug Rules, obliges the DCGI to police Bayer’s patent.\textsuperscript{153}

However, the Court did not find any merit in the arguments advanced by Bayer. The Court said both statutes involved in the case (the Patent Act and the Drugs Act), had different objects. Where patent law seeks to foster innovation, the Drugs Act’s objective is to ensure the safety and effectiveness of drugs. Along with this, the Court also said that the DCGI neither has the jurisdiction nor the competence to deal with issues relating to patents.\textsuperscript{154}

In its judgment the court also acknowledged anti-competitive concerns related to patent linkage. Specifically, it recognised that approval of such systems means enabling branded drug companies to block marketing of generic drugs and thereby maintain high price of its own branded drug.\textsuperscript{155} The court also considered the status of patent linkage in Europe,\textsuperscript{156} the European Commission’s findings and its scepticism over the issue of patent linkage.\textsuperscript{157}

Ultimately, the court held that in the absences of the express statutory recognition of patent linkage, it could not create such a system through judicial exegesis of statutory language.\textsuperscript{158}

Recently, the Supreme Court of India also upheld the Delhi High Court Judgement, by rejecting Bayer’s appeal against the dicta of Delhi High Court.\textsuperscript{159}

These above-discussed legal actions by branded drug companies can be considered an attempt to create a patent linkage system in India through an indirect route of litigation. These judicial proceedings, against generic companies and drug regulating authorities, are very similar to what the European Commission has declared as anti-competitive practices within

\textsuperscript{152} Id, Para 9
\textsuperscript{153} Id, Para 28
\textsuperscript{154} Id, Para 29
\textsuperscript{155} Id, Para 7(iii)
\textsuperscript{157} Bayer v. U.O.I, supra note.145, Para 32
the European pharmaceutical sector. Such attempts to create patent linkage in India have also put the Indian competition authorities on their guard.

It has been recognised in a study conducted by the ‘Centre for Trade and Development’ for the Competition Commission of India (“CCI”), that the introduction patent linkage in India may have dire consequences over the entry of generic drugs in the Indian markets. The said study also recognises the need to spread awareness among drug regulatory authorities about the anti-competitive impact of the patent linkage system. Moreover, the study has recommended that the DCGI should not entertain any patent related claims during the marketing approval process.

2. Implications of Patent Linkage in the India

India is one of the biggest generic drug suppliers in the world. The Indian generic drug industry is important, not only from the point of view of the Indian public health system, but also for other developing nations. For instance in 2005, fifty per cent of patients suffering from HIV/AIDS in all developing countries were dependent upon the supply of Indian generic drugs.

In such a scenario, any delay in the marketing of Indian generic drugs may have an adverse impact, not only on the Indian public health system, but also on other developing countries and health programmes, relying on the supply of Indian generic drugs. This is because the patent linkage system, along with its anti-competitive effects, posed one more threat for the developing world’s public health system. The threat is the impact of such a mechanism on the provisions of compulsory licensing. Many authors have argued that the introduction of

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160 supra note102-119 and accompanying texts.
161 It is a non-profit organisation, which carry out studies and research on the issues related with trade and development.
163 Id, Para 6.1.2, pp.179-180
164 Id, pp.201-202
166 Id
168 UNICEF Annual Report 2005, available http://www.unicef.org/supply/files/SD_AnnualReport_2005.pdf (last updated Sept. 20, 2011), According to this report 50% of all the essential medicines distributed by the UNICEF in all the developing countries were Indian generic drugs; See FDA Report, available at http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/AsiaandAfrica/ucm119231.htm (last updated Sept. 20, 2011), According to this report 91% of all the essential medicines used in the U.S’s Presidents anti AIDS programme are Indian generic drugs; See MSF, supra note.164.
any such system will make compulsory licence provisions redundant.\textsuperscript{170} Even if a generic drug is manufactured under a compulsory licence, its placement on the market will not be possible until it obtains marketing authorisation.\textsuperscript{171}

As a matter of fact, it will not even be possible for a generic drug producer to manufacture the drug without obtaining marketing authorisation. A drug licence by DCGI means an approval of safety and effectiveness of the drug. Therefore, without such approval regarding safety and efficacy of the drug, no company can proceed with the production of medicines. Moreover, there is no express exception under any existing patent linkage system for compulsory licensing.\textsuperscript{172}

In such a situation it will be impossible (without the permission of patent holder) for a generic drug producer to introduce its drug into the market,\textsuperscript{173} even after having a compulsory licence. This is something which will clearly undermine the objective of Doha Declaration\textsuperscript{174} and also the Indian generic drug producer’s ability to take benefit of the Doha Declaration, i.e. to export its generic drugs (made under a compulsory licence) to countries incapable of manufacturing pharmaceutical products.

It is very likely that the patent linkage system will cost the public of developing nations like India dearly. In developing nations, the cost of pharmaceuticals products is largely borne by the public itself (i.e. patients), rather than the State.\textsuperscript{175} Considering these issues and anti-competitive nature of patent linkage, it can be concluded that, any statutory recognition of such system will affect the interests of the Indian generic drug industry as well as its public health system.

\textsuperscript{171} Id
\textsuperscript{172} Id
\textsuperscript{173} Id
Part C: Balance of Interests

So far the paper has explained the status of patent linkage and its anti-competitive effects in jurisdictions like the U.S, EU and India. Along with this we discussed the adverse consequences of such a system upon the public health system of these jurisdictions.

When it comes to the pharmaceutical sector, however, care must be taken before drawing conclusions on any issue related to patents. The importance of patents for the pharmaceutical industry as well as for public benefit resulting from the innovations of new drugs is unquestionable. In Europe, renowned jurists like ‘Sir Robin Jacob’ have argued that practices (including patent linkage), which the European Commission have called the ‘tool box’ of anti-competitive instruments, are neither new nor peculiar to the pharmaceutical sector. He further warned that any attack on the patent system may inhibit future innovations in this field.

Therefore, it is necessary to analyse, whether the absence of a patent linkage system will harm any legitimate interest of branded drug companies and undermine the future innovations. In other words, this part of the research will analyse whether the patent linkage system is necessary to protect the interests of pioneer drug companies to promote innovations in this field. We will also discuss various alternatives to patent linkage, which can maintain a proper balance between innovation and competition in the pharmaceutical sector.

1. Branded Drug Companies Interest: Opportunity to Recoup Investment

Normally, the market entry of a generic drug takes place after the expiry of a relevant patent. Generic companies, however, may also flood the market with their low cost drug, before the expiry of a patent covering the branded drug, particularly if the originator drug producer fails to take appropriate action against the generic supplier, for example by obtaining an interim injunction. If the failure to obtain interim relief is a result of a weak prima facie case or invalidity of a patent, it is in the interest of the public to allow such generic entry. Any delay in such cases will restrict the generic’s marketing in lieu of a weak or an invalid patent.

It is also possible that such failure may result from the lack of prompt action on the part of originator drug supplier. For instance in U.S in Sanofi-Synthelabo v. Apotex, a five day delay on the part of ‘Sanofi’ (branded drug company), in pursuing the interim injunction proceedings provided ‘Apotex’ (generic supplier) sufficient time to flood the market with its low cost drugs. Though the 5 day delay was the result of an agreement between ‘Sanofi’

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177 Id

178 Commission’s Final Report, supra note.92, Para 1352, p.459; See Basheer, infra note.196.

179 488 F. Supp. 2d 317 (Sanofi v. Apotex)

and ‘Apotex’, and not a case of surprise marketing, it can be considered a good example of the need for quick responses in such cases.

Such delay in pursuing legal remedy by a pioneer drug company is also possible in a situation where there is a small time gap between knowledge of a generic supplier’s intention and actual supply of a generic drug. Consequently the generic entry may result in a drastic price fall. For example where in the above discussed case, ‘Sanofi’ was compelled, following a flood in the market of generic drugs by ‘Apotex’, to offer discounts and rebates to the third party payers, in order to maintain the status of its drug on a favourable drug formulary pricing tier. Such price reduction, while the original drug is still under patent protection may cause substantial harm to the pioneer drug company’s interest, i.e. interest in having a sufficient opportunity to recoup investments it incurred in R&D of its drug.

As argued by the ‘Sir Robin Jacob’, this recoupment of R&D’s cost is necessary, because of its significance for future innovations in the area of pharmaceuticals. This recovered cost is considered as the fuel for future inventions. However, once the generic drug lowers the price of a particular drug, it becomes almost impossible for a branded drug company, even after prevailing in the infringement action, to restore the original price. Often it is also very difficult to recover damages that originator drug supplier has suffered.

2. **Significance of the Patent Linkage System for the Branded Drug Company: A Barrier Against Generic Flood**

The patent linkage system is a potent weapon in the armoury of branded drug companies against generic competitors. It provides a mechanism through which a pioneer drug company can prevent the flooding of generic drugs in the market.

The patent linkage systems prevent generic supplies, during the exclusivity period, in two ways. Firstly, if the original drug is still covered by the patent, it obliges the drug regulatory authorities to stay marketing approval of the generic drug. As explained earlier, without such marketing approval, it is not possible to put generic drugs on the market. Secondly, through the notification requirement, the patent linkage system provides sufficient opportunity to branded drug companies to seek legal recourse by obtaining interim injunctions or bringing an action for infringement against generic drug suppliers.

In the absence of such a mechanism, a generic drug company can easily flood the market with its low cost drug, before the innovator drug company pursues judicial remedies. Therefore the system of patent linkage strengthens the position of branded drug suppliers against the threat of generic insurgencies. It ensures that during the monopoly period, branded drug companies get a fair opportunity to recover investment.

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181 *Id*, p.798
182 *Sanofi v. Apotex*, *supra* note.179, at 342; Pricing tiers determine the costs at which insured consumers purchase prescription drugs.
183 *Jacob*, *supra* note.176
184 *Id*
185 Commission’s Final Report, *supra* note.92, Para 1352, p.459
186 *Id*
187 For instance in U.S, 21 U.S.C § 355(j)(2)(B) of the Hatch Waxman Act, oblige the generic drug suppliers to give a notice to the branded drug producer, if it is applying for marketing approval of its drug by filing Paragraph IV certificate. The notice must sate the reason about the non-infringement or invalidity of patent.
It is necessary however to maintain a proper balance between innovation and competition. Whether it is patent or competition law, both promote innovation & seek to ensure consumer welfare. Now the issue is whether these two features (i.e. stay on the marketing approval and notification requirement) encapsulated within the patent linkage system, ensure the desired balance.

According to this paper the most appropriate way to achieve this state of equilibrium is to ensure that a branded drug company enjoys only the limited period of exclusivity, accorded by a valid patent. During this exclusivity period, however, it should be capable of preventing generic entry. It means that branded drug companies should have sufficient opportunity to exercise their monopoly right. They should get enough time, before the generic supplier floods the market with its low cost drug, allowing them to approach courts and get an appropriate remedy, for instance, an injunction against the marketing of generic drug supplier.

It should, however, also be ensured that generic drugs are available in the market, soon after the expiry of a patent. This is essential for ascertaining the state of equilibrium between competition and innovation. This document argues that patent linkage, particularly the requirement to stay marketing approval is upsetting the balance between innovation and competition. Along with aggrandizing patent protection, it also enables a branded drug company to prevent generic competition beyond the term of a patent. For instance, as established earlier, in the U.S, exiting forms of patent linkage give rise to anti-competitive practices like reverse payment settlements. Consequently they block the route of multi-source generic competition. While, in the EU and India, it facilitates exclusionary practices of branded drug companies, through which they prolong their monopoly in the market. Patent law however accords monopoly only for a limited period. Any non-statutory extension of such monopoly is neither sanctioned by patent law nor by anti-trust provisions.

3. **Alternatives to the Patent Linkage Mechanism: The Quest for a Utopian State**

Here, the paper will analyse alternatives to patent linkage, which can be helpful in attaining the goal of proper balance between competition and innovation within the pharmaceutical industry. In particular we will discuss the ‘concept of clearing the way’ and the concept of ‘notification scheme’.

3.1. **Clearing the Way**

As discussed earlier, use of this system within the European pharmaceutical sector has been proposed by the EFPIA. The proposed mechanism of ‘clearing the way’ encompasses two essential features. First a mandatory notice to a branded drug producer, about the generic

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189 Id
190 supra note 126 and accompanying text
company’s marketing approval application. Second an opportunity to the branded drug company to bring an infringement action against its generic counterpart.

Such a system can be in the interest of a generic supplier if it has less surety about the infringement of a patent. However, as mentioned earlier, obliging generic suppliers to clear all patent issues before entry, may have adverse impact upon one of the most important stimulus for generic competition i.e. first mover advantage.

The proposed mechanism will affect the first mover’s incentives in two ways. Firstly, it will alert other generic players of the first generic supplier’s possible market entry. Second, if the first generic supplier establishes the invalidity of originator’s patent, then that will clear the way for all other generic providers and expose the first generic drug supplier to multi-source generic competition. This will deprive the first generic drug supplier from enjoying a period of duopoly.

The immediate effect of such competition seems to be in the interest of the public, because of a drastic price fall. However, in the long term, the whittling away of such a ‘first mover bounty’ may affect early generic entry, because, instead of competing over being the first in the market, every generic player will wait for others to initiate and clear marketing routes for all other generics.

Moreover, in the absence of a first mover advantage and because of the threat of infringement action, it is very likely that generic providers will apply for marketing approvals only after the expiry of a relevant patent in order to avoid litigation. This may result in de-facto extension of patent terms because of the actual time consumption in regulatory approval procedures, production of drugs and finally in marketing of such a drug. Such de-facto extension of a monopoly period will disturb the balance between innovation and competition.

3.2. Notification Scheme

One more mechanism, which has been proposed as an alternative to patent linkage is the notification scheme. As per this system a drug regulatory body should maintain a data base containing information on every new application for regulatory approval. Further the branded drug company, under this system, will have to monitor the said data base. If it apprehends that any generic drug applicant is likely to infringe its patent, it can approach the judicial authorities and seek remedies like interim injunctions against such a potential infringer.

191 Commission’s Final Report, supra note 92, Para 1354, Section 1.6, Part D, p.459
192 Id
193 Id, Para 1358, p.460
194 supra note 131 and accompanying text
195 A period, during which only the branded drug company and the first generic supplier, competes in the market. This is considered as the golden period for the first generic entrant, because of high profit margin that a generic supplier can maintain during this period.
197 Id
198 Id
The mechanism of ‘notification scheme’ does not provide for a stay on regulatory approvals of generic drugs. What it envisages is the estoppel on the actual marketing of infringing generic products, instead of staying the processing of generic’s marketing approval application.\textsuperscript{199} However, advance information about the generics marketing approval application will ensure that branded drug companies get a fair opportunity to exercise their rights conferred by patent. In other words, this mechanism will provide branded drug companies sufficient time to prevent generic flooding.\textsuperscript{200}

In order to realise the fruits of this system however, branded drug companies will have to keep a track on the database of the drug regulatory body. This may put an extra burden on a branded drug company in the form of monitoring cost, which it will incur in the constant policing of the said database. Obliging generic suppliers, instead, to intimate relevant patent holders of its marketing approval application may be the one way to avoid these monitoring costs.

However, considering what is at stake i.e. monopoly in the market, worth billions of dollars, it is better for the holders of such a right to self-monitor the said data base. Self-monitoring is a better way to obtain information, in a more certain way, about potential generic entrants, instead of relying on the advance notice by generic suppliers.

\textsuperscript{199}Id
\textsuperscript{200}Id
Part D: Conclusion

Though a patent gives a monopoly to an individual, the fundamental rationale behind the allotment of such a monopoly is the recognition of public interest behind such a right. Therefore any extra entitlement to the patentee, which is intended to serve a patentee’s own interest, without any parallel public interest cannot be upheld by conventional justifications behind patent grants.

The mechanism created by patent linkage also clothes a patentee with a privilege that forwards only its own interests. It obliges state authorities to guard patentee’s rights by staying marketing approval of generic drugs. However, prior information about a generic drug’s marketing approval application is sufficient to uphold the interests of branded drug companies.

Therefore according to this paper, the notification system is appropriate to achieve the state of equilibrium, between the interests of a branded drug company and those of the public. Prior information about generic supplier’s marketing approval applications will provide an adequate time frame within which branded drug companies can approach court and obtain appropriate relief.

The absence of a stay on marketing approval, however, does not affect the interests of a branded drug company because mere marketing approval of a generic drug will not abrogate the exclusive right given by a patent. Marketing authorisations of generic drugs only declare that the authorised drug is safe and effective. Such authorisation does not make the generic drug provider immune to patent infringement.

Therefore even after a marketing approval of a generic drug has been obtained by a generic provider, the patent holder is entitled to prevent market entry of its generic counterpart through injunctions or infringement actions. Moreover, a grant of marketing approval will permit generic suppliers to proceed with manufacturing of their drugs, allowing their introduction soon after the expiry of a relevant patent.
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