



Zoya Nafis

Validity of patent linkage across the globe



Divya Srinivasan

Zoya Nafis and Divya Srinivasan of LexOrbis examine different approaches to patent linkage for drugs and medicines around the world and ask how long India can avoid recognizing the concept.

It is immaterial whether a drug is manufactured by a major drug company after the patent grant by way of tests, clinical trial and error methods or by a generic drug maker, in both situations the drug has to undergo a series of steps before being introduced to the market. There is a defined process for drug marketing approval in almost all jurisdictions across the globe.

In order to obtain marketing approval for manufacturing and distribution in a country, any pharmaceutical drug has to get the nod of consent from the respective drug authority of the country. But pharma companies are using a coy practice, wherein they associate/connect/link the status of the drug-marketing approval with the status of the patent of the product; thereby affecting a large mass of generic drugs (which are considered the same as a brand name drug, with respect to dosage, safety, strength, how it is consumed, its quality, performance and the intended use) manufacturers and makers from entering into the market preceding expiration of patent term, unless consent is acquired from the patent owner in question. This practice is known as 'patent linkage'.

Patent linkage falls under the aegis of the 'TRIPS Plus' theory. The TRIPS-plus theory envelopes both actions intended at increasing the level of protection for right holders beyond that which is provided in the TRIPS Agreement and those procedures targeted at decreasing the possibility or efficiency of restrictions on rights and exemptions.

The legal position in regard to patent linkage differs from jurisdiction to jurisdiction. For example, the United States (US) provides for a specific statutory provision for the same, while on the other hand, India and Europe do not recognize it as an important regulation for drug marketing approval. Indian Courts have also tried to clarify the position on the subject in various cases that have come up for adjudication before them, observing that because patent linkage is a TRIPS Plus concept and also an issue of legislative scrutiny, the same cannot be validated by a court of law.

Position under TRIPS

The TRIPS Agreement under the World Trade Organization (WTO) provides for certain obligations to the member countries, whereby exclusive rights are to be accorded to patent holders for a restricted period of time as prescribed by the domestic laws of the member country under Article 28. In addition, Article 28.1 (a) under TRIPS enshrines the rights of a patentee in the case of product patents which include the right to prevent third parties not having the patent holder's consent from making, using, offering for sale, selling, or importing the product.

Further Article 39.3, deals with undisclosed information with respect to pharma or agro-based chemical products or drugs, which are to be protected from unfair commercial use, and when read in conjunction with Article 28 one may construe it to be connected with the concept of patent linkage, though it is not specifically indicated in the TRIPS agreement. Hence, taking into consideration the understanding of most member countries as per the aforementioned juxtaposition of the Articles in question,

Résumés

Zoya Nafis, Associate, LexOrbis

Zoya earned her Masters of Law specializing in Intellectual Property Rights from NALSAR University of Law, Hyderabad. She works on trademark matters at the firm and focuses on writing for various publications on behalf of the firm. She also works on other research projects. Zoya has deep inclination towards trademarks, copyrights and IP in general and writes extensively about evolving issues on the subjects.

Divya Srinivasan, Associate, LexOrbis

Divya did her LLM in Intellectual Property Rights at the National Law University, Jodhpur. She writes for various publications on behalf of the firm, as well as working on other research projects looking at various facets of IPR. She is preferential towards Intellectual Property Rights and writes about the emerging issues on the subject.



patent linkage has been introduced by them as a system, by way of which the generic manufacturer substantiates that the drug in question, seeking market approval, does not cover a valid patent within its ambit, further verified by the drug regulator or authority. This prevalent practice, wherein the patent registration and drug approval are clubbed together, is carried out in order to prevent a drug manufacturer from obtaining market approval for a drug while the original version of that drug is still under patent, unless 'by consent or with the assent of the patent owner'.

Position under US laws

The Food and Drug Administration (FDA) is responsible for providing the marketing approval for pharmaceutical products in the US and the concept of patent linkage has been statutorily provided for under the Drug Price Competition and Patent Restoration Act, 1984 informally known as the Hatch-Waxman Act 1984. The intent of this legislation is to enable quicker market access of generic drugs, while at the same time providing stringent protection to the patent rights of pioneer drug manufacturers. The FDA maintains an 'Orange Book' containing the list of approved patented drug products having pharmaceutical and therapeutic equivalence parallels. The FDA may not ineludibly sanction the marketing approval for a generic copy of a pharmaceutical product that is protected by a patent listed in the Orange Book.

The Act aims to allow swifter introduction of generic drugs' competition in return for partial, unalterable, periods of data protection, and increased rights for drug companies to retrieve patent terms that have been condensed by clinical trials and supervisory and regulatory delays. A linkage system conditionally allowing registration of generic equivalents in the absence of patent claims is an apparent better temporal fit with respect to the pharma product's life span.

Furthermore, the strict data-exclusivity clause means that a generic drug manufacturer cannot use the original clinical data generated by the patent-holding company to gain market approval for a period of five years. It is a known fact that clinical trials burn large holes in the

“ There is no concept of patent linkage in the European Union. However, an attempt was made to introduce the concept, but it faced fierce opposition by the major pharma giants. ”

pockets, therefore it is unlikely that any generic manufacturer could conduct their individual clinical trials and additionally sell it at a reasonable price.

Position under EU laws

There is no concept of patent linkage in the European Union. However, an attempt was made to introduce the concept, but it faced fierce opposition by the major pharma giants. In a 2006 press release the European Generic Medicines Association stated that the concept of patent linkage is contrary to EU regulatory law as it undermines the Bolar provision which aims to grant speedy access to the post-patent market for EU generic medicines. The Bolar provision was framed with the idea that generic drug market entry would be speedier in order to accord low cost drugs to the consumers. Additionally, the Bolar provision authorizes any drug manufacturer for experimentation with any patented drug, with the vision of creating data that could be acquiesced to any drug control regulatory/authority. Patent linkage accordingly was considered to rout the single purpose required to be accomplished by the Bolar Provision. Hence the status of a patent application was not found to be a ground for refusal, suspension or revocation of achieving marketing authorization and approval.

The EU substantially revised its laws on data exclusivity in 2005. This presented the 8+2+1 principle that now grants absolute data exclusivity for eight years. During this exclusivity period, the generic company can participate in testing and pre-registration activities, but can only apply for marketing approval after the eight year period ends. Albeit that approval can be pursued precipitately in the two year window period, approval will only be in effect after 10 years. Besides this constant 10 year period of data exclusivity, a supplementary one-year extension lead for 'new therapeutic indications' is available, in other words a new target of disease or a change from treatment to prevention or diagnosis of a disease. A request for the one-year extension must be filed within the first eight years, provided that the medicine affords noteworthy clinical benefits in comparison to earlier existing therapies.

Position in other countries

China, Canada and Singapore follow the US system, thereby recognizing patent linkage. Drug manufacturers seeking market approval in these nations must prove that the subject application in no way infringes an existing patent. Also, Canada follows the same methodology as that of the FDA's 'Orange Book' with patents listed therein.

Position in India

Any drug that needs to be introduced in India requires a prior marketing approval. This is granted by the Drug Controller General of India, which is empowered to do so under the Drugs and Cosmetics Act, 1940 (DCA). The main responsibility of the Drugs Controller is to look into the safety quotient of the drug, namely, whether it is safe and fit enough to be introduced in the market and to be consumed safely by the consumers without any adverse effect.

Patent linkage has been discussed in the Indian courts time and again. The debate first ignited in the case of *Bristol-Myers Squibb Co. v Hetero Drugs Ltd* [CS (OS) No. 2680/2008, Dec. 19, 2008] wherein the Delhi High Court dealt with the validity of patent linkage in India. In this case the plaintiffs had secured an ex-parte injunction preventing India's Drug Controller from acceding to a generic version of its cancer medicine 'Dasatinib' manufactured by the defendants. The drug patented by the plaintiff's in India was being sold under the brand name of 'Sprycel', and had been recommended for chronic myeloid leukaemia. The Court put a stay on Hetero Drugs Ltd.'s application seeking marketing approval for its drug, for making,

selling, distributing or exporting the medicine. This judgment in totality was criticized and considered detrimental as it saddled the Drugs Controller with the additional responsibility of regulating patent rights. An assessment of a patent's validity is considered as a multifaceted question, which only the patent officer or the court should have the capability of resolving.

Subsequently in the case of *Bayer Corporation & Ors v Cipla, Union of India (UOI) & Ors* [2009 (41) PTC 634(Del)], the Hon'ble Supreme Court silenced the acceptability of patent linkage in India and firmly declared it to be inadmissible. It further went on to establish that there was a difference in the schemes and objectives of the DCA and the Indian Patent Act, 1970. The court also emphasized the fact that the Drug Controller was not prepared to tackle issues relating to patent validity. Moreover the powers and jurisdiction are restricted by the DCA and not by the Patents Act.

The Court also perceived that "generic drug" and "spurious drug" are two different concepts. Additionally, it added that patent linkage was a concept of 'TRIPS Plus' and India being signatory only to TRIPS, was not obligated under laws to take charge of the patent linkage concept. Moreover it stated that 'TRIPS Plus' are multilateral, plurilateral, regional and national intellectual property agreements that go beyond the TRIPS Agreement and therefore presently India is not under obligation to any 'TRIPS Plus' agreement. Finally the Court iterated that no patent linkage concept could be read into the existing legal provisions.

The court also clarified that since there is no provision for patent linkage in the present Indian laws the judicial authorities cannot validate it through any pronouncement. The same could only be done through legislative force and the judiciary in no stance is empowered to take over the power of a legislature in this scenario.

Conclusion

Like every coin has two sides, so it is the case with the patent linkage theory. Developed and developing nations will measure the importance of patent linkage in terms of their economic viability and access to medicines. The *Bayer* case clearly outlines issues with regard to the negative probability of the patent linkage principle in India, where generic drug makers are providing access to medicines to the majority of the population at affordable prices. Being a developing country, consumers in India would prefer financing for a drug that is easily available at affordable prices as they are not fully prepared to live in a world containing only branded drugs. It is obvious that patent linkage will seem more of a preferred option for countries like the US and China, owing to their status as developed nations; also big pharma companies would prefer to sell their drugs in a patent linkage supporting country, because it affords them stricter patent right protection and also gives them the benefit of time between expiration of patent term and entry of a generic drug. As for India, it is still an impending question as to how long the patent linkage principle will be evaded.

“It is obvious that patent linkage will seem more of a preferred option for countries like the US and China, owing to their status as developed nations.”



LexOrbis | INTELLECTUAL
PROPERTY
ATTORNEYS

709/ 710, Tolstoy House, 15-17 Tolstoy Marg
New Delhi - 110 001 India

| T 91 11 2371 6565
| F 91 11 2371 6556

| www.lexorbis.com
| mail@lexorbis.com

Identifying & Developing | Procurements | Transactions | Enforcement | Advisory & Consulting