

Patent Linkage in India: Current Scenario and Need for Deliberation

Anshul Mittal†

National Law University, NH-65, Mandore, Jodhpur (Rajasthan) 342 304

Received 26 February 2010, revised 6 May 2010

The system of 'patent linkage' refers to the practice of linking drug marketing approval to the status of the patent of the originator's product. It directly affects the entry of generic drugs into the market. The article analyses patent linkage in different jurisdictions and finds out whether such a system can be read into existing Indian laws. It also discusses various judicial pronouncements and pertinent legislations to trace the history and scope of patent linkage in India. The Delhi High Court judgment, in *Bayer Corporation and Others v Cipla, Union of India (UOI) and Others*¹, which held that patent linkage cannot be read into existing Indian provisions, has been discussed in detail. This article tries to highlight the reasons as to why such a system should, or should not, be introduced in India.

Keywords: Patent linkage, data exclusivity, drug approval

A pharmaceutical drug can be introduced in the market, either by the originator company (i.e. a company that invents a new drug, gets a patent, conducts clinical trials, and introduces the drug in the market for the first time), or by different generic manufacturers (i.e. those that introduce 'bio-equivalents' of the originator's drugs). But for this, both, the originator and the generic manufacturers, have to first obtain marketing approval from the drug regulator of their respective countries.

Patent linkage is the practice of linking drug marketing approval to the patent status of the originator's product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term, unless consented to by the patent owner.² This article proposes to analyse the current status of patent linkage in India, in the light of the Delhi High Court judgement in the case of *Bayer Corporation and Others v Cipla, Union of India (UOI) and others*.¹

The article first delineates the existing system of patent linkage in the United States and the European Union and then examines judicial history of patent linkage in India and provides a summary of the *Bayer Corporation* case. It further discusses several issues that emerge from the *Bayer Corporation* case.

Patent Linkage in the US and the EU

Under the WTO TRIPS Agreement, member countries agree to ensure exclusive rights to patent

holders for a limited period of time. Article 28.1(a) of TRIPS talks about the rights of a patentee in case of product patents. It provides:

"where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product"

Reading Article 28 along with Article 39.3 (protection of undisclosed information), some member states introduced a system of patent linkage. The 'patent linkage' system essentially requires that the generic manufacturer proves to the drug regulator that the drug for which he seeks approval, is not covered by a valid patent. The practice of linking patent registration and drug approval prevents 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 acquiescence of the patent owner'.

Patent Linkage in United States

Under the US law, the Food and Drug Administration (FDA) provides marketing approval for pharmaceutical products. Patent linkage is provided statutorily in the United States under the legislation known as the Hatch-Waxman Act (1984). Accordingly, the FDA maintains a listing of pharmaceutical products and uses currently under patents in approved drug products with therapeutic

†Email: anshul.mtl@gmail.com

evaluation equivalents, known familiarly as the Orange Book.³ The FDA may not authorize marketing approval for a generic copy of a pharmaceutical product that is protected by a patent listed in the Orange Book.⁴ The Hatch-Waxman Act allows speedier introduction of generic competition in exchange for limited, but ironclad, periods of data protection, increased rights for drug companies to recoup patent terms that had been shortened by clinical trials and regulatory delays, and a linkage system conditionally allowing registration of generic equivalents in the absence of patent claims.⁵

The United States has a strict data-exclusivity clause which means that generic companies can launch their drug only 5 years after the original drug i.e. the generic drug manufacturer cannot use the original clinical data generated by the patent holding company to gain market approval for a period of 5 years.⁶ Clinical trials are extremely expensive and it is unlikely that any generic manufacturer could conduct his own clinical trials and still sell the drug at an affordable price.

Patent Linkage in the European Union

The European Union does not have a system of patent linkage. Originator companies have tried to introduce such a provision, but have met with strong opposition. In a 2006 press release, the European Generic Medicines Association stated that patent linkage was contrary to EU regulatory law and it undermined the Bolar provision which sought to encourage quick access to the post patent market for EU generic medicines.⁷

Under EU law, linking marketing authorization to the patent status of the originator reference product is not permitted. The status of the patent application has not been recognized as ground for refusing, suspending or revoking marketing authorization.⁸

Although Europe has no comparable system of patent linkage, in 1987 it established periods of data exclusivity even longer than those of the US. For drugs approved through the European Medicines Agency (EMA), ten-years of data exclusivity was provided while Member States were permitted to have terms of exclusivity ranging from six to ten years for their internal registration processes.⁹ The European Union substantially revised its laws on data exclusivity via revised Directive 2004/27/EC, effective 5 October 2005.¹⁰ The Directive introduced the 8+2+1 formula that now grants absolute data exclusivity for 8 years. During this period of

exclusivity, the generic company can engage in testing and pre-registration activities, but it can only apply for marketing approval after the passage of 8 years. Even though approval could be sought prematurely during this 2 year window, the approval would only be effective after ten years had passed. In addition to this now uniform ten-year period of data exclusivity, there is an additional one-year extension for 'new therapeutic indications' filed within the first 8 years, but only if the medicine provides significant clinical benefits compared to existing therapies.¹¹

Patent Linkage in India and Judicial Decisions

Before introducing a pharmaceutical drug in India, marketing approval from the Drug Controller General of India (DCGI) (hereinafter 'The Drugs Controller') is required under the Drugs and Cosmetics Act, 1940 (hereinafter 'the Drugs Act'). The Drugs Controller basically looks into whether the drug is fit for introduction into the market. In most of the cases, before applying for marketing approval, the inventor of the drug goes for patent protection under the Patents Act, 1970.

The 'patent linkage' system essentially requires that the generic manufacturer proves to the drug regulator that the drug for which he seeks approval is not covered by a valid patent. This creates a duty in favour of the Drugs Controller to ensure that marketing approval is not granted to generic manufacturers in cases where the drug is already covered by an existing patent. This system of 'patent linkage' although recognized in the United States and some other countries, has not been expressly recognized in India by the legislature. Recently, the Delhi High Court has ruled that 'patent linkage' cannot be inferred from the provisions of the Drugs and Cosmetics Act, 1940.¹ The relevant judicial decisions are discussed below.

Bristol-Myers Squibb Co v Hetero Drugs Ltd¹²

On 19 December 2008, the US drug maker, Bristol-Myers Squibb Co secured an *ex-parte* injunction from the Delhi High Court, preventing India's drug regulator from approving an off-patent (generic) version of its cancer medicine 'Dasatinib'. The drug, patented by Bristol-Myers in India, is sold under the brand name, Sprycel and is prescribed for chronic myeloid leukemia.¹³

The Delhi High Court stayed Hetero Drugs Ltd, which had sought approval for marketing 'Dasatinib', from making, selling, distributing or exporting the

medicine. The court also stopped the Drug Controller from proceeding with Hetero Drugs' application for approval of its generic version of the medicine. The court observed: "It is expected that the DCGI while performing statutory functions will not allow any party to infringe any laws and if the drug for which approval has been sought by the defendants is in breach of the patent of the plaintiffs, the approval ought not to be granted to the Defendant."

The decision created unrest amongst various generic companies, essentially raising the question whether this is a judicial manner of enforcing the much debated patent-linkage system linking the patent and the drug regulatory approval process.¹⁴ An interesting point to note was that the Drugs Controller was not a party to the case and hence was not technically bound by the order.

This order placed the onus of 'patent policing' on the Drugs Controller to ensure that none of the generic drug applications submitted for approval, violate the patent rights of any originator drug company.¹⁵ This is undesirable because assessment of a patent's validity is a complex question which only the patent office or the court can decide. Burdening the Drugs Controller's office (with no special patent expertise) with the additional duty of policing patent rights is not prudent.

Bayer Corporation and Ors v Cipla, Union of India (UOI) and Ors¹

The Delhi High Court in *Bayer Corporation and Ors v Cipla, Union of India (UOI) and Ors*, a judgement dated 18 August 2009, put to rest the controversy about patent linkage by categorically holding that no such system can be read into the existing Indian laws.

Factual Background

The writ petitioner in the case was Bayer Corporation. The second respondent in the case was the DCGI and the third respondent was Cipla. The Indian Patent Office had granted the petitioner, patent number 215758 on 3 March 2008. Therefore, by virtue of Section 48 (rights of a patentee) of the Patents Act, Bayer got the exclusive right to prevent third parties, from the acts of making, using, offering for sale, selling or importing the patented product in India, without its consent. Bayer filed the petition seeking directions to, *inter alia*, restrain grant of drug license in regard to an application by the third respondent for the license to manufacture, sell and

distribute its drug 'SoraniB'. The petitioner claimed that the said drug was an imitation of, or substitute for, its patented drug.

The Petitioner's Contentions

Bayer placed reliance on Section 2 of the Drugs Act and Section 48 of the Patents Act, 1970.

Section 2 - Application of other laws not barred - The provisions of this Act shall be in addition to and not in derogation of the Dangerous Drugs Act, 1930 (2 of 1930), and any other law for the time being in force.

Section 48 - Right of patentees- Subject to the other provisions contained in this act and the conditions specified in Section 47, a patent granted under this Act shall confer upon the patentee –

- (a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
- (b) where the subject-matter of a patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India;

Bayer contended that Section 2 manifested legislative intention, to read the provisions of the Drugs Act, in addition, and not in derogation with any law for the time being in force. Section 48 of the Patents Act was put forth as one such 'law for the time being in force', and the petitioner contended that it has to be read in, and not excluded, by the second respondent. As per the petitioner, Section 2 of the Drugs Act read with Section 48 of the Patents Act, provided the concept of 'patent linkage', which imposed a duty on the Drugs Controller to ensure that his decision regarding grant of marketing approval of a drug, should not derogate from any other law for the time being in force.

The petitioner referred to Section 17 B of the Drugs Act, which defines 'Spurious drugs'. Section 17B reads as follows:

Section 17 B - Spurious drugs - For the purposes of this chapter, a drug shall be deemed to be spurious –

- (a) If it is manufactured under a name which belongs to another drug; or

- (b) If it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
- (c) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
- (d) If it has been substituted wholly or in part by another drug or substance; or
- (e) If it purports to be the product of a manufacturer of whom it is not truly a product.

The petitioner submitted that as per Section 17 B (b), Cipla's drug was an imitation of, or substitute for its (petitioner's) patented drug. Hence, the said drug 'Soranib' was a spurious drug and the second respondent would exceed his jurisdiction in granting marketing approval to 'Soranib'.

Bayer also placed reliance on Form 44 of the Drugs and Cosmetic Rules, 1954 which, along with some other provisions, required mention of the patent status of the drug by the applicant. Hence, it was contended that by a mere reading of Form 44 and also by virtue of publication of grant of the subject patent, it would have been well within the knowledge of the Drugs Controller that the subject patent existed in relation to the product for which Cipla had applied for, and consequently, approval should not have been granted.

The petitioner also contended that the object of Section 2 was further reinforced by Section 156 of the Patents Act, which enjoined the Government, and declared for all intents and purposes that a patent granted under the Act had the same effect on the Government, as on others. It was therefore, contended that the Court should declare that the authorities under the Drugs Act, being functionaries of the Central Government, were equally bound by the patent granted to Bayer.

Bayer finally referred to the system of 'patent linkage' provided statutorily in the United States, under the legislation known as the 'Hatch-Waxman Act (1984)'. The petitioner contended that a similar patent linkage setup should be inferred from a joint reading of Section 2 of Drugs Act and Section 48 of the Patents Act.

The Respondent's Contentions

The respondents contended that Bayer's claim for patent linkage, based on an interpretation of Section 2 of the Drugs Act was misleading, because grant of drug regulatory approval by the Drugs Controller, cannot by itself amount to patent infringement. The grant of a drug regulatory approval by the DCGI to Cipla on the basis that its drug was safe and effective was not an act of 'making, using, offering for sale, selling or importing' the petitioner's patented product.

They also contended that the existence of patent infringement cannot be assumed merely because the patentee states so, but has to be clearly established before a court of law and such an assessment was beyond the statutory powers of the Drugs Controller, which was institutionally incapable of dealing with complex issues of patent scope, validity and infringement.

Cipla placed reliance on Section 107A of the Patents Act, 1970, commonly known as the 'Bolar' provision. The section reads as follows:

Section 107A – Certain acts not to be considered as infringement – For the purposes of this Act,

- (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;
- (b) importation of patented products by any person from a person, who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as infringement of patent rights.

Cipla argued that the 'Bolar' provision permitted any drug manufacturer to experiment with any patented drug with a view to generating data that could then be submitted to a drug control authority. The respondent explained the aim of the provision as that ensuring immediate entry of generic drugs on patent expiration.

With regards to Section 17 B of the Drugs Act, Cipla argued that the terms 'limitation' and 'substitute' in Section 17 B (b) cannot be read in isolation to the remainder of the sub-clause. The words 'substitute for' were to be read along with 'in a manner likely to deceive'. As per the respondents, the text of the said sub-clause revealed that the same covered a situation, where an individual was passing

off his drug as that of another by way of using deceptive marks, get-up or packaging and it did not include patents. Hence, it was incorrect to term generic applications as 'spurious drugs'.

The respondents also submitted that there was no patent linkage regime in the country, and what Bayer wanted this Court to do was to legislate it through interpretation, which was impermissible. Finally, with regards to submission of the patent status of a drug by generic companies, the respondents contended that this was merely of an informative nature and there was no legislative mandate which permitted the Drugs Controller to refuse marketing approval based on the patent status of a drug.

Issues Before the Court

The court determined two questions which needed to be answered. The first one, was the issue of permitting a reading of 'patent linkage', from the provisions of the Drugs Act and the Patents Act; and the second one, was whether generic drugs, allegedly infringing upon a patent, can be termed as 'spurious drugs' under Section 17 B of the Drugs Act.

Patent Linkage

The court rejected the arguments put forth by the petitioner and answered the above question by holding that no 'patent linkage' regime can be read into the existing legal provisions. The High Court highlighted the inherent difference between the objectives of the two statutes and said that there could be no interplay between them. The court went on to say that the Drugs Act was a public regulatory measure, which prescribed standards of safety before introduction of a drug in the market. The Patents Act on the other hand, had put in place a regime containing standards for conferring private monopoly rights in favour of inventors. The Controller of Patents and other officers were experts at judging whether the claimed products or processes were patentable. This expertise depended upon adjudging, on an objective basis, whether a product or process was novel, or contained an inventive step. Such expertise did not exist in the case of officials under the Drugs Act, who were only required to test the safety of the product, and to ensure that it conforms to the therapeutic claim put forward. To invest these regulatory authorities, with functions that were exclusive to other enactments, was beyond intentment and scope of the Drugs Act.

The High Court also observed that in the absence of a Parliament mandated regime, courts should not blaze into an obviously legislative path. Although through interpretive devices, such as purposive interpretation, or for avoiding absurd results, the courts can, 'fill in' the statutory gaps at times, yet this cannot be taken to mean such an absurd reading of the statute as to interpolate a wholly new provision that the legislature itself has 'consciously' omitted.

With regards to Section 156 of the Patents Act and Section 2 of the Drugs Act, the court said that Section 156 is a clarification that the Government, and its officials, as grantors, were bound by the patents. This means that they have to respect patents, and cannot infringe them (except to the extent it was sanctioned by law). Ascribing anything more than this clear intention, was to extend the boundaries of the patent standards.

It was observed that if the court were to establish or decree a patent linkage, desired by Bayer, it would not only be making a policy choice, avoided by Parliament, but overstepping its obvious interpretive bounds. The Court also referred to a preliminary report, dated 28 November 2008, submitted by the competition authorities of the European Union, which clearly cautioned against patent linkage.⁸ The report found evidence of innovator blocking tactics in relation to generics and causes of innovation decline.¹⁶

The court also rejected the Bayer's argument that Rule 122 B(1) (b) of the Drugs Rules, read with Form 44 and the data required (Appendix 1 to Schedule Y), gave an insight that patent linkage is intended by Parliament. The court stated a known principle of statutory construction, which said that the Parliament or the concerned legislature is deemed to be aware of existing laws when it enacts new legislative measures.¹⁷ Omission to create a specific patent linkage system shows the negative intention of the Parliament.

The court concluded the first issue by holding that a system of patent linkage could not be read into the provisions of the Drugs Act and the Patents Act and such a system was undesirable in the Indian context for the following reasons: firstly, placement of patent right policing on regulatory authorities; secondly, transformation of patent rights, which are private rights that depend on the owner's desire to enforce them, into public rights; thirdly, undermining of the 'Bolar' provision; and finally, although Article 27 of the TRIPS Agreement requires that patents are made

available without discrimination by the field of technology, yet the patent linkage was specific to the pharmaceutical sector only.

Spurious Drugs

With regards to Bayer's contention that Cipla's generic version of 'Sorafenib' fell under the definition of 'spurious drugs' in Section 17B, the court observed that if Bayer's contention were to prevail, every generic drug would *ipso facto* amount to a 'spurious drug', since they were deemed substitutes of originator (patented) drugs. Such an interpretation was untenable and contrary to the intent of the Drugs Act. The court said that the key element of 'spuriousness' was deception, in the manner of presentation of the drug concerned and in the sense that it imitated or represented itself to be something that it was not.

A declaration by the drug agency, entrusted with the task of deciding applications seeking marketing approval, that someone not holding a patent was attempting to get clearance for a 'spurious drug' would be pre-emptive and would negate the provisions which required that the enforcers should follow certain mandatory procedures, and prosecute potential offenders. For these reasons, the court held that unpatented drugs, *per se*, were not 'spurious drugs' and the writ petition was dismissed.

Division Bench Appeal

The above judgment was appealed before the Division Bench of the Delhi High Court. The court fully concurred with the well-reasoned judgement of the Hon'ble Single Judge and did not find any ground to reverse the judgement.¹⁸

Appeal before the Supreme Court

The Supreme Court has admitted the Special Leave Petition filed by Bayer Corporation against the decision of the Delhi High Court. The matter is listed for final arguments and disposal in August 2010.

Issues Arising out of the Bayer Corporation Case

This part is in the form of a discussion on some issues relating to patent linkage that arise out of the *Bayer Corporation* case.

Absence of Data Exclusivity Laws in India

The petitioner in the present case, in many ways, wanted the court to indirectly introduce data exclusivity (a non-patent form of exclusivity whereby the generic applications cannot be processed/approved

by the Drugs Controller for a certain period of time) in India.

In India, like in most countries, a pharma company wishing to market its drug is required to submit data to the Drugs Controller, to show that its drug is not only effective but also safe. The first (originator) company that makes the application for marketing approval has to submit its data relating to clinical trials to the Drug Controller. Once the Drugs Controller is satisfied that the drug is safe and effective, it can be registered. However, if another drug company wishes to market the same drug, it is required to only show that its drug is bio-equivalent to the drug of the originator company.¹⁹

The position is very different in the United States, as has already been pointed above while discussing the system of patent linkage there. United States has derived data exclusivity norms from Article 39.3 of the TRIPS Agreement, which is as follows:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The Satwant Reddy Committee, an inter-departmental group, was constituted in February, 2004, to review the protection of undisclosed information in the light of intellectual property rights set down by the provision of TRIPS. It submitted its report to the Ministry of Chemicals and Fertilizers on 31 May 2007.²⁰ The report found that Article 39.3 did not mandate 'data exclusivity' and that at that moment; it was not in India's national interest to grant 'data exclusivity' to pharmaceutical drug data. It also argued that a 'trade secrecy' form of protection was sufficient to comply with Article 39.3 and that India had already provided for this (via common law principles). However, it recommended that since there has been no instance, thus far, of common law trade secrecy provisions applying to the government, this position be made more explicit in the Drugs Act. Although it advocated that test data for

pharmaceutical drugs be protected as a trade secret under common law, yet it recommended giving three years of exclusive rights to test data for companies registering new agro chemicals and five years of exclusive rights to test data for companies registering new traditional medicines.

The recommendations of the Satwant Reddy Committee were greatly dealt with in the case of *Syngenta India Ltd v Union of India*²¹, where the petitioner Syngenta India Ltd, claimed that Article 39.3 of the TRIPS, mandated protection for the test data submitted by the pharmaceutical and agro-chemical industries for market approval. The Hon'ble Court rejected the said claim, and held that the Court was being invited to make a policy declaration, and it could not do so under any circumstance.

In this context, Shamnad Basheer, a patent law expert, observed that TRIPS was only minimum standards legislation and any member nation was free to include a data exclusivity obligation in its national legislation. It was also proposed that a 'compensatory liability' model may be considered whereby any regulatory data can be relied upon to approve the product of the second applicant, provided adequate and fair compensation is provided to the originator of the data.²²

This provision of TRIPS is one of the most contentious ones and is very ambiguously worded. Hence it provides great leeway to the member states for interpretation. Implementation of such a policy is a decision which the government has been entrusted with, not the courts. Otherwise it would lead to dilution of the concept of separation of power.

Hence, the Delhi Court was correct in its interpretation when it held that any system of data exclusivity or patent linkage has to be specifically provided for in legislation and the courts cannot introduce something which the legislature has omitted to do. This also clarifies the position that United States and India follow a very different system of national legislation and both countries have different policy objectives. Hence, reliance on United States laws to read a similar provision of patent linkage is inherently flawed.

Bolar Provision

Bolar provision derives its name from the case of *Roche Products Inc v Bolar Pharmaceutical Co.*²³ Bolar was a generic drug manufacturer. Roche was a brand-name pharmaceutical company which made

and sold Valium, the active ingredient of which was protected by patent. Before patent expiration, Bolar used the patented chemical in experiments to determine if its generic product was bio-equivalent to Valium in order to obtain FDA approval for the generic version of Valium. Bolar argued that its use of the patented product was not infringement under the experimental use exception to the patent law. The Court of Appeals for the Federal Circuit rejected Bolar's contention holding that the experimental use exception did not apply because Bolar intended to sell its generic product in competition with Roche's Valium after patent expiration and, therefore, Bolar's experiments had a business purpose. Bolar also argued that public policy in favour of availability of generic drugs immediately following patent expiration justified the experimental use of the patented chemical because denying such use would extend Roche's monopoly beyond the date of patent expiration. The court rejected this argument, stating that such policy decisions should be made by the Congress. Shortly after *Roche v Bolar* case was decided, the Congress did pass a law permitting (Hatch-Waxman Act) use of patented products in experiments for the purpose of obtaining FDA approval which established the modern system for FDA approval of generic drugs.

The Bolar provision is the best known of the many limited exceptions to the patentee's exclusive rights under Article 30 of the TRIPS.²⁴ Such a provision has been incorporated under Section 107A of the Indian Patents Act, 1970. But for the Bolar exception in the Indian patent law, generic manufacturers would be forced to wait for the patents to expire before embarking on the mandatory tests necessary for regulatory approvals. This would allow Indian generic manufacturers to compete among themselves, ensuring the continued availability of medicines at low costs for domestic, as well as international, consumers.²⁵

This provision permits any drug manufacturer, to experiment with any patented drug, with a view to generating data that could then be submitted to a drug control authority. The aim of this section is to ensure, that generic drugs are introduced into the market as soon as the patent expires or is invalidated, so that consumers may benefit from this early entry of affordably priced drugs.

The Delhi High Court rightly pointed out, that if Bayer's argument were accepted, it would hit at the

very essence of the Bolar provision that is aimed at speeding up generic entry into the market and availability of low cost drugs to the consumer. Hence, it becomes amply clear, that introduction of a system of patent linkage would be in clear abrogation of the provisions of Section 107A.

Issues of Institutional Competence

The court rightly pointed out issues of institutional competence in its judgment. It observed that patent examination and determination of validity of the patent are very complex issues which can only be looked into by the Patent office and the courts. The Drugs Controller lacks the expertise, time, and man power and most importantly the jurisdiction to look into such matters. Moreover, the Patents Act, 1970 provides for express and elaborate provisions in case of different opposition proceedings brought against the grant of a patent. Section 25(1) of the Patents Act talks about pre-grant opposition, Section 25(2) talks about post-grant opposition, Section 64 talks about revocation of a patent by the High Court and Section 104 says that no court inferior to a District Court shall have jurisdiction in a suit for infringement. What is most important to note is that there are very specific grounds for challenge and procedure under these sections. Hence the DCGI cannot usurp the power specifically provided for under a statute especially when it does not have jurisdiction and competence.

Linkage provisions thus pose two problems for the second applicant by (1) requiring the national regulatory agency to make an assessment on the validity of the patent, and by (2) putting burden on the applicant to prove that the originator's patent is invalid. Such provisions therefore force the Drugs Controller to act as 'patent police', a role that is clearly beyond the expertise of a nation's health authority.²

Substantive *ultra vires* of Delegated Power

The court was absolutely right in pointing out that the argument about reading patent linkage from Section 2 of the Drugs Act, put forth by Bayer, was legally untenable. If the court would have come to a contrary finding in favour of Bayer, holding that a system of patent linkage can be read into the provisions of the Drugs Act and the Patents Act, then it would have given rise to severe constitutional issues. In such a case, the Drugs Authority would have been required to frame rules regarding how a system of patent linkage could be implemented and this would have been against set principles of delegated legislation.

Delegated legislation (in this case the rules framed by the DCGI) could have been easily questioned before the courts on the grounds of substantial *ultra vires*. This is the most common ground to challenge delegated legislation before the courts. This means that if the delegated legislation goes beyond the scope of power conferred by the Parent Act, or if it is in conflict with the delegating statute then it is invalid.²⁶

The Supreme Court has observed that 'It is a well-recognized principle of interpretation of a statute that conferment of rule-making power by an Act does not enable the rule-making authority to make a rule which travels beyond the scope of the enabling Act or which is inconsistent therewith or repugnant thereto.'²⁷

Since the Drugs Act does not confer power upon the Drugs Controller to make rules regarding implementation of patent linkage, any such attempt would constitute substantive *ultra vires* of the delegated power.

Data Exclusivity could Potentially be an Obstacle to the Issuance of Compulsory Licenses

Compulsory licensing is a mechanism used by governments to allow third parties to produce a product that is protected by a valid patent. If a patent owner will not license the rights to produce his protected invention, then the government can authorize a third party to manufacture the product. The TRIPS Agreement, which all WTO members have signed, provides for compulsory licensing in Article 31. The Agreement requires that a third party must first make 'efforts to obtain authorization from the right holder on reasonable commercial terms and conditions' before a compulsory license is granted. If those efforts are not successful within a 'reasonable period of time,' then a valid compulsory license may be issued in accordance with TRIPS. The data exclusivity and registration linkage provisions in US, if introduced in India in the same form, may impact a government's ability to issue a compulsory license.

Unresolved issue of 'Protection of the Right of a Legitimate Patentee'

Although the Delhi High Court judgment clearly denies any patent linkage in India, the issue of safeguarding the rights of patent owner, against an audacious attempt by generic companies to introduce generic drugs during the term of the patent has been left undecided.

A solution has been proposed to balance these competing concerns in a 'fair' manner, without

necessarily co-opting a 'linkage' mechanism. It suggests the introduction of a 'notification system'. The main highlights of such a system are:²⁸

- The office of the DCGI should list all new drug applications on its website. This way originator companies can track information on this database and move the court, if it apprehends that a generic product, for which a drug approval application has been filed, is likely to infringe its patent.
- If the court finds a *prima facie* case, i.e. the patent is valid and would be infringed by the introduction of a generic product (for which a drug approval application has been filed), it can issue a declaration to this effect.
- In return of providing 'notice', the originator company would be required to disclose all its patent registrations/applications for products/processes relating to the drug in question, while applying for drug approval. Members of public would have access and can determine which drugs are covered by what patents.

Introduction of such a system would not only promote transparency but also enable a more effective implementation of the opposition mechanism.

Lack of Presumption of Validity of a Patent in India

Under Section 13(4) of the Patents Act, 1970, the grant of a patent shall not be deemed in any way to warrant its validity and no liability shall be incurred by the Central Government in connection with any examination or investigation or any report or proceedings consequent thereon. The Supreme Court held in the case of *Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries*²⁹ that the grant of a patent does not guarantee its validity. In other words, a patent that has been granted, can be challenged in accordance with the provisions of the Patents Act and the defendant cannot take the defence of presumption of validity of the patent. Burdening the DCGI to look into the patent status of a drug, while deciding the issue of its marketing approval, would be indirectly presuming the patent to be valid. This is contrary to Section 13(4) of the Patents Act.

Conclusion

In the light of Delhi High Court's Bayer judgment, it can be clearly seen that patent linkage cannot be

introduced in India, unless the Parliament expressly recognizes this principle. Even if the Parliament comes up with such a legislation, it will lead to many other problems in a developing country like India. The same features that make registration-related data exclusivity and patent/registration linkage attractive for 'Big pharma', make it unattractive for developing countries. Patent linkage provisions are detrimental to generic markets for many of the same reasons as data exclusivity. Linkage requirements will have an impact on nearly all medications, and cumulatively will have an even more drastic effect than data exclusivity extensions. From the perspective of access to medicines, the national architecture for registering and approving medicines is already extraordinarily complex and fraught with inefficiencies, duplications, delay, and in some instances corruption.

Demerits aside, one important question that needs to be resolved is the protection of the rights of a legitimate patentee. Recent examples show that courts have even recognized 'public interest' as a ground for rejecting injunction applications. This has mandated a clear-cut need for introduction of safeguards to protect against attempts by generic manufacturers to sabotage patent rights. These safeguards cannot be in the form of a patent linkage regime. The provisions of the Drugs Act should be amended, to ensure that no data wrongfully leaks out of the Drugs Controller's office and falls into the hand of competitors. This, along with the implementation of the 'compensatory liability model', would ensure against 'unfair commercial use.'

Acknowledgement

The author would like to thank the referees for spending their valuable time in reviewing this paper and for providing invaluable comments.

References

- 1 2009(41) PTC634(Del).
- 2 Robert Galantucci, Data Protection in a US-Malaysia free trade agreement: New barriers to market access for generic drug manufacturers, *Fordham Intellectual Property, Media and Entertainment Law Journal*, 17 (2007), 1083.
- 3 Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (1 February 2010).
- 4 Finston Consulting, Overview of Patent Linkage, 07 August 2006, <http://www.finstonconsulting.com/version03/files/Overview.pdf> (10 February 2010).
- 5 Eisenberg Rebecca S, The role of the FDA in Innovation Policy, *Michigan Telecommunication and Technology Law Review*, 13 (2007) 351-53.

- 6 21 USC 355(c)(3)(E), <http://www4.law.cornell.edu/uscode/21/355.html> (1 February 2010).
- 7 European Generic Medicines Association, New strategy on patent linkage is contrary to EU law and threatens access to competitive generic medicines, 2 February 2006, <http://www.egagenerics.com/pr-2006-02-02.htm> (15 January 2010).
- 8 European Union – DG Competition, Pharmaceutical Sector Enquiry: Preliminary Report, 28 November 2008, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf (10 February 2010).
- 9 Baker Brook K, Ending drug registration apartheid: Taming data exclusivity and patent/registration linkage, *American Journal of Law and Medicine*, 34 (2008) 307.
- 10 Directive 2004/27/EC of the European Parliament and of the Council of 31st March, 2004 available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0034:0057:EN:PDF> (4 May 2010).
- 11 The EC defines the ‘new therapeutic indication’ as a new target of disease or a change from treatment to prevention or diagnosis of a disease. However, neither different stages nor severity of a disease are considered new indications, nor is an extended target population for the same disease, or a change from first line treatment to second line treatment.
- 12 Delhi High Court *ex parte* order dated 19 December 2008.
- 13 Unnikrishnan C H and Pandeya Radhieka, Bristol-Myers gets stay on Hetero’s generic drug, 7 January 2009, <http://www.livemint.com/2009/01/07231506/BristolMyers-gets-stay-on-Het.html> (12 February 2010).
- 14 Mamidanna Vandana, Drug controllers to analyse patents while patent controllers analyse efficacy, 15 January 2009, <http://duncanbucknell.com/ipthinktank.blog/539/Drug-controllers-to-analyse-patents-while-patent-controllers-analyse-efficacy> (10 January 2010).
- 15 Basheer Shamnad, Breaking news: Court orders Indian Drug Controller to ‘Police’ patents, 06 January 2009, <http://spicyipindia.blogspot.com/2009/01/breaking-news-court-orders-indian-drug.html> (10 February 2010).
- 16 Batchelor Bill, Patent attack - The EC sector inquiry interim findings, *European Competition Law Review*, 30(5) (2009) 212-215.
- 17 *Syndicate Bank v Prabha D Naik* AIR 2001 SC 1968.
- 18 *Bayer Corporation & Anr v Union of India & Ors* (Delhi High Court LPA 443/2009 – 9 February 2010).
- 19 Indian Express, ‘In public interest data exclusivity shouldn’t be made a law’, 12 July 2006, <http://www.indianexpress.com/news/in-public-interest-data-exclusivity-shouldnt-be-made-a-law/8337/> (1 February 2010).
- 20 Hiddleston Sarah, An important win for domestic pharma industry, 04 June 2007, <http://www.hindu.com/2007/06/04/stories/2007060401361300.htm> (5 January 2010).
- 21 161(2009)DLT413.
- 22 Basheer Shamnad, Protection of regulatory data under Article 39.3 of TRIPS: The Indian context, 11 July 2009, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=934269 (8 January 2010).
- 23 733 F.2d 858 (Fed. Cir. 04/23/1984).
- 24 Article 30 (TRIPS) - Countries “may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”, http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm (8 January 2010).
- 25 Ram Prabhu, India’s new “TRIPS-Compliant” Patent regime: Between drug patents and the right to health, *Chicago-Kent Journal of Intellectual Property*, 5 (2006) 203.
- 26 Jain M P & Jain S N, *Principles of Administrative Law*, 5th edn (LexisNexis Butterworths Wadhwa Nagpur, New Delhi), 2007, p. 90.
- 27 *Addl Distt Magistrate (Revenue) v Siri Ram* (2000) 5 SCC 451.
- 28 Basheer Shamnad, The potency of a middle path, 9 July 2008, <http://www.livemint.com/2008/07/09215015/The-potency-of-a-middle-path.html> (15th January 2010).
- 29 (1979) 2 SCC 511.