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Delhi High Court frees Indian drug regulator from the shackles of “patent linkage”

IP-Pharma Team

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Delhi High Court frees Indian drug regulator from the shackles of "patent linkage"

Bayer's bid to convince the court to usher patent linkage fails.

A linkage between the drug regulator and the patent office has been on the wish list of 'originator' drug companies for long. The implication of a drug regulator-patent office linkage, commonly referred to as "patent linkage" is that the drug regulator does not grant marketing approval to generic versions of drugs for which a valid patent exists in that jurisdiction. This prevents the entry of generic versions into the market till the life of the patented drug.

Owing to the apparent benefits of this system for 'originator' drug companies, especially in the absence of data exclusivity laws in India, certain drug originators have been mooting for regulator-patent linkage to be implemented in India.

One such effort recently failed when the Delhi High Court refused to entertain the petitioners' plea in *Bayer Corporation and Ors. vs. Union of India and Ors*.[1] in respect of Cipla's drug *Soranib*.

I. Facts of the matter

Bayer AG, a German chemical and pharmaceutical company, alongwith its Indian subsidiary (together, the "**Petitioners**") filed a Writ Petition[2] with the High Court of Delhi ("**Court**") against Cipla Ltd., an Indian pharmaceutical company ("**Cipla**"). The Petitioners sought to restrain Cipla from being granted a licence to manufacture, sell and distribute its drug "*Soranib*" from the Drug Controller General of India (**DCGI**). The DCGI and the Union of India were also impleaded as co-defendants to the Writ Petition. The Petitioners claimed that the drug in question "*Soranib*" is an imitation of, or substitute for Bayer AG's patented drug sorafenib tosylate[3], which is marketed as "*Nexavar*" and used for the treatment of primary kidney cancer (advanced renal cell carcinoma) and advanced primary liver cancer (hepatocellular carcinoma)[4]. Sorafenib tosylate is protected under patent number 215758 granted by the Indian Patent Office on March 3, 2008.

II. Contentions put forth by the Petitioners

The Petitioners primarily claimed that:

- Cipla's *Soranib*, is a "spurious drug" as defined in Section 17-B of the Drugs and Cosmetics Act, 1940 ("**Drugs Act**");

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[1] Decision dated August 18, 2009

[2] WP(C) No.7833/2008

[3] Sorafenib tosylate has the chemical name *4-(4-{3-[4-Chloro-3-(trifluoromethyl)phenyl]ureido}phenoxy)N2-methylpyridine-2-carboxamide 4*-methylbenzenesulfonate as available on http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=789424

4 Sorafenib tosylate received USFDA approval for the treatment of renal cell carcinoma in December, 2005 and of advanced hepatocelluar carcinoma in November, 2007.

- Grant of marketing approval to *Soranib* would lead to violation of its patent rights available to patentee under Section 48[5] of the Patents Act, 1970 ("**Patents Act**");
- A combined reading of provisions of the Drugs Act and Patents Act leads one to conclude that India has an inbuilt mechanism for "patent linkage".

Following were the Petitioners' arguments:

Soranib is a spurious drug

The Petitioners claimed that *Soranib* is an imitation of and/or substitute for *Nexavar*. They refer to the definition of "spurious drug" under Section 17-B of the Drugs Act which reads as follows:

"*a drug shall be deemed to be spurious 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*[6]".

Bayer contended that so long as the Petitioners' product remains protected under a patent, Cipla's product is not a "generic" but a "spurious" drug.

India recognizes the concept of Patent linkage by way of existing legislation

The Petitioners contended that Section 17-B of the Drugs Act is to be read in light of the pharmaceutical product patent regime introduced in India in 2005.

Further, Section 2[7] of the Drugs Act makes evident the legislative intention of reading provisions of the Drugs Act in addition to, and not in derogation of any law for the time being in force. The Petitioners contend that one such law that cannot be derogated while reading the Drugs Act is the Patents Act, and in particular Section 48 that spells out the rights of a patentee. Reading all these provisions together, provide for the concept of "patent linkage" in India

In short, the Petitioners put forth an equation before the Court:

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[5] ***Section 48. Rights 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 the 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 from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:*

[6] Section 17-B, Clause (b) of the Drugs Act

[7] Section 2 of Drugs Act: "***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 17-B of the Drugs Act + Section 2 of the Drugs Act + Section 48 of the Patents Act = drug regulator-patent linkage in India

Thus, DCGI can grant marketing approval for *Soranib* only once the Petitioners' patent for sorefnib tosylate expires, or Cipla obtains a licence from the patentee.

Form 44 implies patent linkage

Form 44[8] of the Drugs and Cosmetics Rules, 1945 ("**Drug Rules**"), the Form required to be filed with the DCGI while making an application for grant of marketing approval for a new drug, requires disclosure of patent status of the drug. The Petitioners presume that Cipla, while making its application, would have mentioned the patent that was granted to Petitioners for sorafenib tosylate. Hence, they contend, by a mere reading of Form 44 submitted by Cipla, and also by virtue of publication of grant of the subject patent, it would be well within the knowledge of the DCGI that the product for which approval was being sought was patented. Thus, if marketing approval were granted, it would attract the provisions of Section 17B of the Drugs Act, as well as violate the provisions of Section 48 of the Patents Act.

Section 156 of the Patents Act

The Petitioners further contend that the object of Section 2 of the Drugs Act is further reinforced by Section 156 of the Patents Act which reads as follows: "*Patent to bind Government- Subject to the other provisions contained in this Act, a patent shall have to all intents the like effect as against Government as it has against any person*". The Petitioners argue that by virtue of this Section, read with Section 2 of the Drugs Act, authorities under the Drugs Act, being functionaries of the Central Government, are equally bound by, and obliged to, respect the patent granted to Petitioners.

The petition aims to prevent future litigation

The Petitioners contended that the writ petition was being filed in order to prevent and pre-empt Cipla from introducing their drug in the market. The Petitioners sought declaration that if Cipla introduced *Soranib* in the market, it would amount to infringement of the Petitioners' patent. Such declaration would "*put Cipla on notice and prevent it from introducing the infringing product in question in the market, thereby preventing future litigation*".

Cipla's reliance on 'Bolar provision' is misplaced

The Indian Patents Act contains a provision on the lines of the 'Bolar provision' under US patent law in Section 107A(a)[9], also known as the "early working exception", under which use of a

[8] Form 44 is titled "Application for Grant of Permission to Import or Manufacture a New Drug or to Undertake Clinical Trial"

[9] Section 107A(a) states that "*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*

patent solely for the reasons of submission of information to regulatory authorities (like DCGI) does not amount to infringement of the patent. In relation to Cipla taking shelter under this Section, the Petitioners stated that the legislative intention was to enable generic producers to market their version as soon as the patent expires or is invalidated, but not to market their version when the patent is in force.

Cases relied upon by Petitioners

(i) The Petitioners draw support from a decision of the High Court of Allahabad of *Cattle Remedies and Anr. Vs. Licensing Authority/ Director of Ayurvedic and Unani Services*[10], that had held:

"*The licence to manufacture drugs that fall under the category of patents and proprietary medicines' cannot be granted if these drugs are patents of anyone else….At the time of grant of licence, the licensing authority should consider the following two points: (i) Whether the name is trade mark of anyone else or not, and (ii) Whether the medicines are patented under the Patent Act (sic) or not*."

(ii) The Petitioners also cite *Hoechst Pharmaceuticals Vs. C.V.S. Mani*[11], in which the High Court of Delhi emphasized the significance of Section 2 of the Drugs Act. It said: "*Indeed, the Act, as Section 2 lays down, is in addition to and not in derogation of any other law and the real purpose of the enactment is to ensure quality and standards of drugs manufactured, imported, distributed and sold in the country*." The Court further said that Section 2 must be read along with Section 12 and Section 33 of the Trade Marks Act, 1999.

III. Contentions put forth by Cipla

Grant of regulatory approval in itself does not amount to patent infringement

Cipla stated that its case clearly fell under the ambit of Section 107A[12] of the Patents Act. It further contended that to argue that the act of approval in itself amounts to an infringement, when all acts leading upto the stage of drug approval were exempt from patent infringement, was unreasonable.

Determination of patent infringement is exclusive jurisdiction of the Courts

Cipla contended that the existence of patent infringement has to be clearly established before a court of law in accordance with the infringement provisions mentioned under the Patents Act. It

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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 shall not be considered as a infringement of patent rights"

[10] 2007 (2) AWC 1093

[11] ILR 1983 Delhi 548

[12] See **supra** note 9

cannot be assumed merely at the insistence of the patentee. Under the Patents Act, a suit for patent infringement must be instituted at the District Court having jurisdiction[13]. Further, the Drugs Act, the legislation that governs the DCGI, does not authorise the DCGI to assess patent infringement. Cipla doubted the institutional competence possessed by the DCGI to make such assessment.

The Petitioners have misinterpreted the term "spurious drugs"

Cipla stated that the terms "*limitation*" and "*substitute*" in Section 17B (b) of the Drugs Act could not be read in isolation but were to be read along with the rest of the sub-clause ("*another drug in a manner likely to deceive*"). Thus, the situation envisaged under this Section was that of passing off a drug as that of another by using deceptive marks or packaging. Cipla claimed it was not attempting to pass off its drug as that of the Petitioners and the provision was hence inapplicable to Cipla's *Soranib*.

There is no patent linkage regime in India

Cipla further stated that there was no patent linkage regime, in India. Legislation through interpretation was impermissible for courts to do. Further, patent linkage was a TRIPS plus[14] provision, unsupported by legislation.

IV. Contentions put forth by DCGI

The arguments of the DCGI were similar to those of Cipla.

The Patents Act is the only legislation for enforcing patentee's rights

The DCGI contended that the Patents Act was a self-contained code setting out all issues relating to patents including infringement of patent. Similarly, the Drugs Act was also a self-contained code pertaining to various aspects of drugs and cosmetics.

Private rights vs. Public rights

The DCGI distinguished between the nature of the rights under the two legislations under question. Patent rights are private rights which the DCGI could not enforce. The Drugs Act and

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[13] Section 104: *Jurisdiction- No suit for a declaration under section 105 or for any relief under section 106 or for infringement of a patent shall be instituted in any court inferior to a district court having jurisdiction to try the suit: Provided that where a counter-claim for revocation of the patent is made by the defendant, the suit, along with the counter-claim, shall be transferred to the High Court for decision.*

[14] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO) sets down minimum standards for certain forms of intellectual property laws for member nations, including for patent law. TRIPS plus provisions are those obligations that go beyond those imposed by the WTO.

the provisions relating to spurious drugs in particular, were on the other hand related to community health.

DCGI cannot refuse marketing approval based on patent status of drug In response to the contention of the Petitioners in relation to Form 44 of the Drugs Rules that requires, the DCGI stated that inspite of the Form requiring disclosure of patent status of the drug, the DCGI did not have the legislative mandate to refuse marketing approval based on this information. The DCGI further stated that it lacked "*institutional expertise to deal with complex patent issues*".

V. Decision of the Court

The Court based its decision on two issues:

(i) Whether a combined reading of the Drugs Act and the Patents Act could lead to the conclusion that marketing approval could be refused to applicants for drugs or formulations, of which others are patent owners.

(ii) Whether drugs or formulations which infringe patents are "spurious drugs" under the Drugs Act.

(i) On the combined reading of the Drugs Act and the Patents Act

- *Private rights vs. Public rights*

Taking forward the DCGI's arguments on the difference in the nature of rights in the two legislations, the Court observed that the objectives of the two Acts are distinct and disparate. The Drugs Act is a public regulatory measure to ensure safety of marketed drugs, whereas the Patents Act concerns grant of private monopoly. The expertise that the Controller of Patents necessarily has may not be possessed by officials under the Drugs Act.

The Court also observed that in jurisdictions where patent linkage has been implemented, it has been done by way of express legislation. The role of the courts includes interpreting statutory gaps, but not when the gaps are of *"oceanic proportions"*. The Court relied upon several precedents wherein it has been established that: "*It is not the domain of the court to embark upon unchartered ocean of public policy in an exercise to consider as to whether a particular public policy is wise or a better public policy can be evolved. Such exercise must be left to the discretion of the executive and legislative authorities as the case may be.*[15]"

- *Parliament has not intended to link the two legislations*

The Court was of the opinion that the Parliament, in 2005, has introduced several amendments to the law in relation to the pharmaceutical sector[16]. The amendments, which made significant policy changes, were proof that the Parliament was "*alive to pharmaceutical patents".* The Parliament has clearly avoided patent linkage at the time of making such other amendments.

- *Explicit legislation required for patent linkage*

In response to the Petitioners' contention that the requirement of disclosure of patent status in Form 44 brings out the intention of the Parliament to link patents with marketing approval, the Court said that in all countries where patent linkage is in force, the same has been done through explicit legislation. The Indian Parliament also would have done so, rather than in a surreptitious manner.

For the above reasons, the Court concluded that combined reading of the Drugs Act and the Patents Act does not establish the patent linkage.

- *Determination of patent infringement is exclusive jurisdiction of the Courts*

Accepting Cipla's arguments, the Court stated that patent infringement needs to be established before a court of law, not assumed merely from a representation by the patentee, which adjudication is beyond the jurisdiction of the DCGI. The Court further stated that accepting the Petitioners' arguments would mean stripping the powers of the authorities under the Patents Act and forcing them upon authorities under the Drugs Act.

The Court using a principle of statutory interpretation relied upon the observations of the Supreme Court[17]: "*Whenever two enactments are overlapping each other on the same area then the courts should be cautious in interpreting those provisions. It should not exceed the limit provided by the statute."*

- *Section 156 of Patents Act has no bearing in present matter*

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[15] Held in *Premium Granites v. State of T.N.* 1994 (2) SCC 691

[16] Amendments include: Section 2(ta); Explanation to Section 3(d); Section 92, Section 92-A of the Patents Act.

[17] Held in *State of Goa v. Western Builders,* (2006) 6 SCC 239

The Court stated that the implication of Section 156 is that Government should respect patents as any other person should, and hence not infringe them. This Section did not bind DCGI to go beyond their statutory functions.

- *Cases cited by Petitioners rejected*

The Court found the Petitioners' reliance on the Hoechst case inappropriate since it dealt with the issue of non-derogation in relation to trade mark law, and not patent law.

The Court also refused to rely on the second case relied upon by the Petitioners'. The Court stated that it did not agree with the conclusions of the Cattle Remedies case, since the decision did not take into account the nuances of patent law and was, in any case, not concerned with the interface between the Patents Act and the Drugs Act.

- *Negative feedback on patent linkage from countries having such provision*

The Court also relied upon a "*Pharmaceutical Sector Enquiry - Preliminary Report*"[18] dated November 28, 2008 prepared by the Directorate General for Competition, European Commission. The report *inter alia* examines the "*strategies employed and actions brought by originator companies before regulatory bodies other than patent offices…*" which the Court likens to the matter before it. The Court cites a paragraph from the Report that concludes that "*Patent-linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83*."

(ii) **On whether drugs or formulations infringing patents are "spurious drugs" under the Drugs Act**

The Court rejected this contention of the Petitioners, stating that such interpretation is contrary to the intent of the Drugs Act. The key elements of "spuriousness" being deception by way of imitation or misrepresentation as to origin of the drug, the Court held that it could not conclude that that unpatented drugs are "spurious drugs".

VI. The Petitioners' attempt fails

The Court took a stern view on the Petitioners' endeavour to "*tweak public policy*" and dismissed the Writ Petition with costs quantified at INR 675,000[19] (approximately USD 14,466.86[20]) payable in equal shares to the Union of India and Cipla within four weeks from the date of judgment.

The Petitioners subsequently appealed against this order of the Single Bench before a Division Bench[21] of the same court. The Division Bench reportedly directed the DCGI to start processing

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[18] Available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf last visited September 8, 2009

[19] The Court calculated the amount by considering costs of INR 75,000 for each "miscellaneous" hearing and INR 150,000 for each final hearing.

[20] 1 USD = 46.6584 INR on October 22, 2009

the application of Cipla for *Soranib*.[22] Interestingly, the Court has also directed Cipla not to launch its product without its permission. It stated that the licence, if granted by the DCGI, would be subject to the final decision of the court on the case.

VII. History of the decision

This decision of the Court comes as a complete contrast to its decision at the interim stage. It had, on November 11, 2008, granted the Petitioners interim injunction, restricting the DCGI from approving Cipla's *Soranib* application.

The Petitioners, on learning of Cipla's application for marketing approval of sorafenib tosylate, had written to the DCGI on July 31, 2008, requesting it to reject the application and conduct a hearing before taking a decision on the matter. The Petitioners had stated that a marketing approval to Cipla "would lead to multiplicity of proceedings; besides it would lead to serious prejudice to the rights of the petitioner, who is the owner of the patent." They subsequently filed a suit in the Court against Cipla, impleading the Union Government and DCGI as co-defendants.

VIII. The Bristol-Myers Squibb vs. Hetero Drugs Ltd. order

The same Court (albeit a different Judge), in *Bristol-Myers Squibb vs. Hetero Drugs Ltd.*[23], had in an *ex parte* interim order restrained Hetero Drugs Ltd. from manufacturing, selling, distributing, advertising, exporting, offering for sale or in any manner dealing directly or indirectly in any product infringing the Bristol-Myers Squibb's patent number 203937. The product in this case was Dasatinib, sold by Bristol-Myers Squibb under the brand *Sprycel*. What attracted controversy was the Court's general observation that "*It is expected that the Drug Controller General of India 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 be granted to the defendants*."

The contrary *Soranib* order has put a question mark on the fate of the Bristol-Myers Squibb case.

IX. Why Bayer may have chosen to knock the doors of the Court in anticipation of infringement rather than after infringement

Assuming for a moment that *Soranib* did infringe Bayer's *Nexavar,* one wonders why the Petitioners may have chosen to ask the court to stop DCGI from granting a marketing approval for *Soranib,* rather than wait for *Soranib* to be actually manufactured, and then file a suit for infringement against its manufacturer.

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[21] A Bench of two judges is referred to as Division Bench, to which lies the appeal of a Single Bench.

[22] Source: http://pharmabiz.com/article/detnews.asp?articleid=51522 and http://www.business-standard.com/india/news/process-cipla%5Cs-licence-for-%5Csoranib%5C-hc/369155/ last viewed on October 23, 2009

[23] Decision dated December 19, 2008 [CS(OS) No. 2680/2008]

The answer to this could be either or both of the following two issues:

(i) **Lack of data exclusivity law in India**

In countries where data exclusivity laws exist, a generic drug manufacturer seeking marketing approval from a drug regulator needs to repeat the clinical studies that were carried out by an originator company, a process that involves substantial expenditure of time and money. In a country like India, however, where data exclusivity laws do not exist, the drug regulator is permitted to rely on data generated from conduct of Bioavailability/ Bioequivalence tests (or BA/BE studies, also known as PK/PD[24] studies) while considering an application of a generic manufacturer. Thus, a generic manufacturer is able to quickly obtain manufacturing and marketing approvals for its drugs. Combining this with a situation where the generic drug also happens to infringe the patent in the originator drug leaves the originator with only one remedy: to file a suit for infringement against the generic manufacturer.

A recent Delhi High Court order in *Syngenta India Limited vs. Union of India*[25] confirmed the absence of data exclusivity law in India in the context of the agrochemical industry. The petitioner in this matter, a member of the Syngenta group of companies headquartered in Switzerland[26], attempted to prove that the concept of data exclusivity exists in India. Syngenta India Limited contended that Satwant Reddy Committee[27] of the Government of India that had recommended implementing data exclusivity in India, read with Article 39.3[28] of TRIPS, prevents a statutory authority from relying on data submitted by the originator for the purpose of approving the subsequent applications for the same insecticide. The statutory authority being referred to in this case was the Registration Committee under the Insecticides Act, 1968 that governs manufacture and import of insecticides in India. The Court, however, refused to accept this contention and instead penalized the petitioner[29].

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[24] Pharmacokinetics and Pharmacodynamics studies

[25] W.P. (C) 8123/2008; Decision dated August 11, 2009

[26] Syngenta India Limited was formed in November 2000 by the merger of the agri-businesses of Novartis AG and AstraZeneca Plc.

[27] The Satwant Reddy Committee was set up in the year 2004 by the Government of India to determine the implications of introduction of data exclusivity law in India, in the context of Article 39.3 of the TRIPS and to make recommendations. The Committee submitted its report to the Government in 2007, in which it recommended that the office of drug regulator (Drug Controller General of India) should be under an obligation to keep secret the undisclosed information submitted to it for approval of new drug. These are mere recommendations and there is no law/amendment in this regard yet.

[28] Article 39.3: *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.*

[29] The matter was dismissed by the Court with costs of INR. 100,000 (approximately USD 2,138.55)

(ii) **The "Public Interest" factor**

The originator company approaches the court claiming that its patent is being infringed, seeking immediate relief by way of interim injunction, hoping that the generic manufacturer would be prevented from selling/manufacturing the drug in question. In a similar scenario, F.Hoffmann-La Roche AG ("**Roche**") in January, 2008, filed a suit against Cipla in Delhi High Court. In its Single Bench order, the court refused interim injunction to Roche on the grounds of Roche's Tarceva being three times more expensive than the generic version *Erlocip*. The Court stated that Cipla's drug cost INR 1600 per tablet as compared to Roche's *Tarceva* at INR 4800 per tablet. As a consequence of this interim order, which was upheld by the Division Bench on appeal, presumably, patent holders of life saving drugs are now apprehensive of not getting favourable orders on the ground of cost difference that invariably exists between a life saving patented drug and its generic version.

X. The early working exception

The Division Bench in its subsequent order[30] has given its green signal to DCGI to continue processing the *Soranib* application alongwith stating that DCGI's approval did not by itself empower Cipla to market *Soranib* till the rights of the parties are finally settled before it. This means the Court has interpreted the early working exception (also known as the "Bolar provision") built in Section 107A(a)[31] of the Patents Act in a manner that does not restrict the DCGI from processing applications for marketing approval in the pendency of a suit that alleges infringement by the applicant.

XI. Observations

On the international front, presently, only few countries like the USA, China, Mexico and Chile have such patent linkage systems in place. The linkage has not being mandated by the TRIPS.

The Court has by way of its order, has not only clarified the absence of patent linkage in India, but also expressed its displeasure at such attempts of the Petitioners "*possessed of vast resources*" to keep competition at bay through interim orders.

The present *Bayer* case and the *Sygenta* case discussed above, display a trend of sorts, whereby multinational companies are trying to get the Indian courts to bring into force/ implement what they find as "missing" from India's legislation. The Court has notwithstanding their assertions remained firm on its stand- that it shall not take the functions of the law-making Executive into its hands.

Sources - Pharmabiz, Business Standard, Delhi High Court order dated August 18, 2009 available at http://lobis.nic.in/dhc/SRB/judgement/18-08-2009/SRB18082009MATC78332008.pdf.

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[30] See **supra** note 22

[31] See **supra** note 9

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