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Insider Analysis From Nishith Desai Associates: Learning and Unlearning from Section 3(d) Of The Indian Patents Act (Part 1 of 2)

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India's profile in the pharmaceuticals and life sciences industries became more prominent following the Jan. 1, 2005, amendment to the 1970 Patents Act of India. The Patents Act was viewed with interest because India's recognition of product patents could pave the way for multinational companies to do increased business in India. However, since that date more than four years ago, the pharma industry remains in the dark about how the amendment changes how business in India is conducted.

Importantly, the amended Patents Act has certain provisions that are not perceived as on par with the World Trade Organization's Trade-related Aspects of Intellectual Property Rights, or TRIPS provisions, and the provisions of other countries, such as Section 3(d) of the Patents Act and lack of data exclusivity. Section 3(d) has grabbed the attention of the industry because patents for drugs have been rejected under this provision even though some drugs, such as Novartis' ***Glivec*** and, more recently, Boehringer Ingelheim's anti-AIDS drug ***Nevirapine,*** have received patents in other countries.

The objection to granting patents under Section 3(d) may be taken either by the Examiner, who considers the application and prepares the report, at the examination stage, or by the opponents in a pre-grant or post-grant scenario within one year from grant. A patent also may be revoked on the same grounds during its term.

The Significance Of Section 3(d)

Understanding the language of Section 3(d) and what is and is not considered appropriate for patent under this provision is important. For example, the following are not considered inventions within the meaning of the Patents Act:

"The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

"Explanation -- for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." [1]

Interpretation of "New" Under 3(d)

Section 3(d) discusses three scenarios in which an innovation is not considered patentable, as follows:

- The innovation is a new form of a known substance;
- The innovation is a new property of a known substance; and
- The innovation involved the use of a known process, machine or apparatus.

New Form Of A Known Substance

As seen in the language of Section 3(d), the word "efficacy" has significant importance, even though it has not

been defined in the Act, because unless the new form of a known substance establishes significant efficacy, the form would fail the criteria of being patentable. The word efficacy is understood well in the pharmaceutical and chemical industries; it may be assessed considering the bioavailability of the drug or the degree of effectiveness. Although it may be possible to define efficacy, a "significant increase in the efficacy" cannot be proven unless comparative data from elaborate clinical trials are provided. For medicines, efficacy is represented by "therapeutic efficacy," which means the effect of a drug that provides therapy to patients. This aspect has been discussed in detail in the Novartis case, as described below.

To overcome a patent denial on the grounds of Section 3(d), it is essential for the applicant to demonstrate the enhancement of therapeutic efficacy. Proving or establishing increased bioavailability may not suffice to be eligible for the grant of patent.

The draft patent manual published by the India Patent Office provides the following observations regarding efficacy:

- "Comparison with regard to properties or enhancement of efficacy is to be made between the known substance and the new form of known substance. In case the new form is further converted into another new form, the comparison is made between the already existing form and another new form but not between the base compound and another new form.

- "The comparison with regard to properties or enhancement of efficacy is required to be made at the time of date of filing of the application or priority date if the application is claiming the priority of any earlier application but not at the stage of subsequent development. This interpretation appears onerous as at the time of priority date the data to prove efficacy may not be available. In practice the evidence of enhanced efficacy is submitted during the prosecution of the application. In our view, the efficacy should be allowed to be proved at any stage of prosecution.

- "Since it is not possible to have a standard numerical value for efficacy for all products including pharmaceutical products it need not be quantified in terms of numerical value to determine whether the product is efficacious." [2]

New Property Of A Known Substance

The provision also mentions innovations that are a "new property" of a "known substance." Hence, per this provision, a mere discovery of a new property of a known substance that does not have any inventive step will not be considered to be a patentable invention. If drugs such as analgesic aspirin or the antipyretic paracetamol are found to be useful for certain cardiac conditions, such new use would not be considered patentable. [3]

Selection patents cover a specific compound or compounds that are individually new but fall under a broader group of compounds disclosed earlier for which a patent is claimed. Selection patents which claim either a new property or new use also may also face the hurdle of Section 3(d) to be eligible for the grant of patent.

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[Editor's note: This is the first part of a two-part feature article. Look for part two in an upcoming issue of PharmAsia News.]

[1] The Patents Act, (1970) as amended by The Patents (Amendment) Act, (2005), along with The Patents (Amendment) Rules (2006).

[2] *Draft Manual of Patent Practice and Procedure*, India Patent Office.

[3] Khader, Feroz Ali; *The Law of Patents - With a special focus on Pharmaceuticals in India* , First Edition, Year 2007.

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Insider Analysis From Nishith Desai Associates: Learning And Unlearning From Section 3(d) Of The Indian Patents Act (Part 2 of 2)

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[Editor's note: This is part two of a two-part feature. Part one appeared in PharmAsia News, June 22, 2009.]

India's profile in the pharmaceuticals and life sciences industries became more prominent following the Jan. 1, 2005, amendment to the 1970 Patents Act of India. The Patents Act was viewed with interest because India's recognition of product patents could pave the way for multinational companies to do increased business in India. However, since that date, the pharma industry remains in the dark about how the amendment changes how business in India is conducted.

Importantly, the amended Patents Act has certain provisions that are not perceived as on par with the World Trade Organization's Trade-related Aspects of Intellectual Property Rights, or TRIPS, provisions and with the provisions of other countries: Section 3(d) of the Patentds Act and lack of data exclusivity provide a good example. Section 3(d) has grabbed the attention of the industry because patents for drugs have been rejected under this provision even though these drugs have received patents in other countries such as Novartis' ***Glivec*** and, more recently, Boehringer Ingelheim's AIDS drug ***Nevirapine***.

The study of recent case law helps to illustrate how the courts in India are interpreting Section 3(d). These cases are described in brief here.

Novartis AG - Glivec Case [1]

The case involving Novartis AG was decided on Aug. 6, 2007, in the High Court of Madras.

In the case of a patent application by Novartis with the Madras Patent Office for B-crystalline of ***Glivec*** (imatinib mesylate), the Controller General of Patents (Controller) refused to grant a patent in relation to the product on the grounds that the application lacked novelty, was obvious and was not an invention in view of Section 3(d) of the Act. [2] The Controller held that the product was a new version of an older molecule that Novartis first patented in 1993 and that the increment in efficacy was not substantial enough to receive the grant of a patent.

Novartis contended in a petition before the Madras High Court that: (1) the Controller erred in interpreting the enhanced efficacy standard in Section 3(d) with regard to product; (2) Section 3(d) was vague, ambiguous and

contrary to TRIPS requirements and that it violated Article 14 (right to equality) of the Constitution of India; and (3) the Controller disregarded the in-house laboratory test performed by Novartis' scientists on rats to show that a 30-percent increase in bioavailability between imatinib and imatinib mesylate was adequate to meet the "enhanced efficacy" benchmark of Section 3(d).

The Madras High Court held that Section 3(d) as amended in 2005 does not violate Article 14 (right to equality) of the Constitution of India. The Court examined various Supreme Court decisions of India that deal with validity of a provision of the statute under Article 14 and observed that the amended section has built-in measures to guide the Controller in exercising its power under the Act; does not suffer from vagueness, ambiguity and arbitrariness; and cannot be invalidated solely on the ground that there is a possibility of misusing the power. Thus, the division bench of the High Court upheld the constitutional validity of Section 3(d).

The High Court further stated that it had no jurisdiction to decide on the validity of Section 3(d) under TRIPS. The High Court held that TRIPS is an agreement between WTO member countries and when the agreement provides for a dispute resolution mechanism, that mechanism should be utilized.

On the issue of efficacy, the High Court stated that if "the discovery of the new form of a known substance must be treated as an invention then the patent applicant should show that the substance so discovered has a better therapeutic effect." Better therapeutic efficacy is described as the enhancement in that known effect/efficacy of a known substance. The High Court referred to the dictionary meaning of the words "efficacy" and "therapeutic" and further stated that the patent applicant is expected to show how effective the new discovery would be in healing a disease or having a good effect on the body. [3]

The matter is still pending decision before the Intellectual Property Appellate Board.

Boehringer AIDS Viramune Case

This involved the decision of the Controller at the Delhi Patent Office in patent application No. 2485/DEL/1998 of Boehringer Ingelheim in the matter of pre-grant opposition by Indian Network for People Living with HIV/AIDS and Positive Women's Network India, New Delhi.

In the opposition proceedings filed by two non-governmental organizations against German pharmaceutical company Boehringer Ingelheim's product patent application for the pediatric form of anti-AIDS drug ***Viramune*** (nevirapine), the Delhi Patent Office rejected the application by relying upon the *Novartis* case and interpreting the term efficacy as therapeutic efficacy.

Boehringer Ingelheim could not provide adequate data to substantiate therapeutic effects of the known substance, and thereby failed to establish enhancement of efficacy; this led to the patent rejection, even though the company had submitted data substantiating the stability of the substance.

F. Hoffmann-La Roche v. Cipla In Tarceva Case

The case F. Hoffman-La Roche & Anr. V. Cipla was decided on March 19, 2008.

In a very high-profile patent infringement case between F. Hoffmann-La Roche & Cipla that is pending before the Delhi High Court, Roche alleged infringement of its product patent on ***Tarceva*** (erlotinib). Cipla started manufacturing and selling the generic version of Tarceva in India at a significantly reduced cost. Roche sought an injunction against the sale of this generic brand. Cipla asked the Delhi High Court to revoke the patent on the grounds that Tarceva is an improved version of a pre-1995 drug called quinazoline and that the patent application does not describe enhanced efficacy.

An interim injunction was refused on the ground of public interest, as the court took a view that a large number of lung cancer patients would be deprived of access to a life-saving drug (erlotinib) if the injunction were granted on the manufacture of the generic version, which cost one-third the price of Roche's drug. This order has been confirmed on appeal by the Division Bench of the Delhi High Court.

Astra Aktiebolag Omeprazole Case

The case Torrent Pharmaceuticals v. Astra Aktiebolag involved the Controller's decision on patent application no: 1354/DEL/98 dated May 21,1998.

In a case involving an omeprazole formulation application, the Controller found that formulation invention was physically different from the prior art formulation but the ultimate formulation did not show any additional therapeutic efficacy as compared to prior art formulation. It was observed that "present pharmaceutical formulation is a selection from the prior art formulation due to the specific selection of HPMC of cloud point above 45.6 degrees Celsius having similar medicinal use and with the same therapeutic efficacy."

The formulation was found to be as economical as the prior art formulation. Section 3(d) applied to present invention in light of the finding of "no enhancement in known efficacy" made the invention non-patentable. The Controller held: "The benefit claimed by the applicant in the present application is not accruable to the user in terms of therapeutic quality of the product, but to the manufacturer only in terms of consistency in the production of formulation…." Hence, the invention failed to meet the criteria laid down in section 3(d).

Industry Position On Section 3(d) Rulings

As mentioned earlier, Section 3(d) was viewed as an arbitrary provision not in compliance with TRIPs. However, in the *Novartis* case, the Madras High Court did not uphold challenges to that section of the law. Some industry insiders - mostly innovators - believe that by implementing Section 3(d) of the Act, the Indian Government is hindering the country's research and development activities. [4] This group believes that incremental innovation leads to the progress of medical science.

Innovators generally argue that generic players who advocate restriction of Section 3(d) - leading to restricted incremental innovation - carry out research on incremental innovations and are active in filing application for patents outside India for their incremental innovations.

Conclusions

It appears from the interpretation of the terms efficacy and therapeutic efficacy by the courts in the *Novartis* and *Boehringer* cases that applicants need to prove that the discovery on the known substance will be therapeutically effective in curing the disease to be eligible for the grant of a patent in India. Considering there are only two judicial pronouncements that defined the scope of efficacy as a capacity to cure the disease, the interpretation of the term efficacy should be determined on a case-by-case basis.

The authors believe that pharmaceutical companies looking at India need to understand these emerging issues as patents are rejected on the grounds of Section 3(d) of The Patents Act. It has been observed that the rejections primarily have been based on the grounds of lack of inventive step and obviousness. Companies need to carefully draft claims of inventive step and non-obviousness, which are supported by the expert declaration.

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[1] Pharma Hotline: http://www.nishithdesai.com/

[2] Novartis AG represented by its Power of Attorney Ranjna Mehta Dutt v. Union of India (UOI) through the Secretary, Department of Industry, Ministry of Industry and Commerce and Others. [(2007) 4 MLJ 1153] Decided on: Aug. 6, 2007, in the High Court of Madras.

[3] http://www.thehindubusinessline.com/2007/04/13/stories/2007041300930800.htm

[4] http://www.dnaindia.com/report.asp?NewsID=1083157