

Monday, 26 June 2017

INNOVATION v/s AFFORDABILITY: AN ANALYSIS OF THE NOVARTIS CASE

Judgement of the Supreme Court in Novartis AG v. Union of India is one of the Land mark judgements Intellectual Property Law regime. The decision was a relief for thousands of people around the world to have access to medicines at a low cost, thereby preventing the pharmaceutical industries from “ever greening” their patents.

The judgement is thus seen as a means to ensure the availability of and accessibility to life saving drugs at an affordable price to people in India. At the same time, the decision defined the scope of S.3 (d) of the Indian Patents (Amendments) Act 2005.

In this case the SC denied granting a patent to a drug of Novartis AG on the ground that the said drug did not involve an invention which is capable of being patentable under the Indian Law.

Even though, the court ruled narrowly, and did not forget to note that the application was filed during a period of transition in Indian law relating to intellectual property, the decision generated widespread news coverage and sparked debates on

balancing public good with monopolistic pricing and innovation with affordability.

This case demonstrates how India is interpreting international law to fit domestic public good and health needs. This case needs to be seen in view of the fact that the drug does not provide cure from cancer, it only stalls its progress. Thus the patients are required to take the drug life-long. Therefore, pricing plays a critical role in cancer patient’s ability to access a continuous supply of the drug.

FACTS

In 1997, Novartis a Swiss pharmaceutical Giant filed an application to grant patent to an anti-cancer drug Glivec which is used for the treatment of a severe form of blood cancer (Chronic Myeloid Leukaemia) and gastro-intestinal stromal tumours on the ground that it invented the beta crystalline salt form of the free base. This drug was already patented about in 35 countries.

During those days India did not grant patent to pharmaceutical products. But it became subject of patent in compliance with the TRIPS agreement

Monday, 26 June 2017

from 2005. Subsequently, in 2006, the Madras Patent Office rejected the application made by Novartis for patenting its drug Glivec saying that the drug did not show any major changes in therapeutic effectiveness over its pre-existing form, which had been patented outside India.

This decision was based on S.3(d) of the Indian Patents (Amendments) Act, 2005 which provides a known substance can only be patented if its new forms exhibit “enhanced efficacy”. When the examination of Novartis’ patent application began in 2005, it came under immediate attack from oppositions initiated by generic companies that were already selling Glivec in India and by advocacy groups. Therefore, the patent office held that it did not find any enhanced efficacy in the drug Glivec.

In 2006 May, the company filed two writ petitions under Article 226 of the Constitution before the Madras High Court alleging that S.3(d) of the Indian Patents Act is violative of Art.14, since its vague, arbitrary and violative of TRIPS agreement and contested the order of the Madras Patent Office. The HC rejected the petitions and held that it did not have jurisdiction to determine whether a domestic law is contrary to an International Agreement. However the court held that the Section was not arbitrary as the legislative intention is to make easy the access to life-saving drugs.

The new stage of litigation started in Intellectual Property Appellate Board. The IPAB considered the beta-crystalline form of imatinib mesylate as

new and inventive step but denied to grant a patent to Novartis as it came under the ambit of S.3(d) of the Act. Novartis challenged the order of IPAB before the SC through a petition for Special Leave to appeal.

ISSUES

The main issues that the SC faced, were

- 1) Whether the drug is a patentable product.
- 2) Whether it involves ‘ever greening’.

CONTENTION OF THE PARTIES

Novartis tried to argue that the beta-crystalline form of imatinib mesylate should be compared with imatinib. On the other hand, the generics wanted the comparison to be with imatinib mesylate. They believed that such a comparison would make it difficult for Novartis to prove improvement in efficacy. For establishing this argument, the Generics had to first prove that imatinib mesylate was “known” in the period intervening the ‘93 Zimmerman patent for imatinib and the beta-crystalline form of imatinib mesylate.

Novartis claimed that increase in bioavailability results in enhancement of therapeutic efficacy from the known substance. It also claimed that the new properties (present in the form for which patent is sought) made the product new and superior. As claimed by them, “it stores better and is easier to process”.

Monday, 26 June 2017

JUDGEMENT

In the judgement the court reaffirmed that in view of the Patents Act, for a new product or process to qualify as an “invention”, the following criteria must be satisfied,

- 1) The product / process must be new
- 2) It must involve an innovative step, i.e. a feature of the product/process;
- 3) Involves technical advancement as compared to the existing knowledge
- 4) Has economic significance
And that makes the product/process non obvious to a person skilled in the art.
- 5) It must be capable of industrial use.

Similarly, for an innovation to be patentable, it must not fall under the categories set out in Ss.3 and 4 of the Act.

The court also accepted the arguments of the generics that imatinib mesylate was known or at least, was directly anticipated from the 1993 Zimmerman patent for imatinib.

The SC in this case has held that, the term “efficacy” in S.3(d) meant “the ability to produce a desired or intended result”. Therefore, the test of efficacy in context of S.3(d) would depend upon the result, the function or the utility that the product under consideration is desired or intended to produce. Thus the court declared that in case of a medicine that claims to cure a disease, the test of efficacy could only be “therapeutic efficacy”, that is the capacity of the pharmaceutical substance for beneficial change.

The court also held that a minor change of form with properties inherent in the substance could not be considered as a change in efficacy so as to qualify as an innovation. It was observed that the physiological properties of the drug such as more beneficial flow properties, better thermodynamic stability and lower hygroscopicity do not result in therapeutic efficacy.

Rejecting the claims of Novartis, the SC held that in order to show that increase in bioavailability would result in enhancement of therapeutic efficacy, it must be backed by necessary data and research and as Novartis failed to submit any such data, the drug also failed to meet the test of S.3(d).

The court also remarked that S.3(d) does not bar patent protection for all incremental innovations of chemical and pharmaceutical substances and it is something which is to be determined on a case-to-case basis.

CONCLUSION

The judgement of the SC was largely welcomed since it opened the way for increased accessibility of the drug in India at reasonable price. On the other hand, it was also feared that the judgement will have an adverse effect on investments in pharmaceutical research and development.

But now, we have realized that the fear was unnecessary: because the Court itself had clarified that it must not be construed as a bar on patent protection to all incremental inventions of chemical and pharmaceutical substances. Also, the judgement, in fact did uphold and affirm the

Monday, 26 June 2017

product “patent regime” and it actually protects genuine inventors.

What the court had in fact declared was that a minor change in a product, the patent of which was about to expire cannot be presented in “new clothes” to obtain new patent and as such that product is non-patentable. Therefore, it is impossible to say that the judgement was not in conformity with international IPR jurisprudence. The essence of the judgement was that new innovations must be protected as against minor changes in the existing technique/technology/methodology/process.

The scope of the judgement is very limited and therefore it will act only as a limited precedent. The judgement was very fact specific. Even though the judgement could settle the debate on

the interpretation of the term efficacy by interpreting it only to mean therapeutic efficacy, it left open the question of how exactly to interpret “therapeutic efficacy”.

Even if Novartis had won the case, it could not have prevented Indian generic companies from selling generic glivec, but such companies would have been under an obligation to pay a reasonable royalty under the Indian Law and this in turn would have increased the price at which it is offered to patients.

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