TRADE LAW BRIEF
Making Trade Law Simple

The Indian Patent (Amendment) Act 2005 and the Novartis Case

*Archana A. Jatkar**

The Indian pharmaceutical industry has emerged as one of the major provider for healthcare products and caters the pharmaceutical needs of over 95 percent of population in India.[1] This industry is a prominent supplier of generic medicines at affordable price for the poor population in the world and fondly referred as pharmacy of the poorer world. There has been a paradigm shift in the policies and programs governing this sector, which has transformed the once non-existent Indian pharma industry into a $6bn industry. It currently ranks 4th and 13th in terms of global volume and value, respectively, in global pharmaceutical business. India's pharmaceutical exports constitute approximately 40 percent of total production of pharmaceuticals in India and valued at over $3.5bn.[2]

The Indian Patents (Amendment) Act, 2005 introduced product patents in India and marked the beginning of a new patent regime aimed at protecting the intellectual property rights of patent holders. The Act was in fulfilment of India's commitment to the World Trade Organisation (WTO) on matters relating to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[3] However, the multinational companies (MNCs) in pharmaceutical business in India developed an apprehension about the sincerity and intentions of India in implementing provisions of the newly amended Act in true letter and spirit of the TRIPS Agreement. Novartis filed writ petitions before the Hon'ble High Court of Judicature at Madras, challenging the legal validity of section 3(d) of the Act 2005. Section 3 (d) seeks to limit the scope of patent protection in order to prevent patenting of new forms or derivatives of a known substance. Novartis challenged this provision when Indian Patents Office (IPO) rejected patent application of its drug called 'Glivec'.

Many viewed this litigation as part of a bigger plan of the multinational pharmaceutical companies to restrain the member countries from using the flexibilities entailed in the TRIPS Agreement.[4] However, product patent is no longer considered as a challenge, it has now become a reality that the Indian pharmaceutical industry has accepted. The exact nature and scope of patentable inventions will become clearer in the times to come when the amended law is put to use, and possibly reviewed in courts. It is anticipated that the text of the law will attain more clarity in the days to come when the judges opine on the meanings of contents provided under the amended provisions.

The letter and spirit with which India transitioned into new patent regime has been put to the litmus test by Novartis. Patents granted in India could have implications worldwide because several developing countries depend on the generic medicines manufactured in India, hence this paper examines the decision in Novartis case and its implication for India and worldwide.

Legal Background

The Indian Patents Act, 1970 has been primarily responsible for laying a strong foundation for growth and development of pharmaceutical industry in independent India. One of the important provisions contained in this Act was permitting only process patents of drugs and pharmaceuticals, chemicals and certain food articles. However, during the period of 1995 to 2005, India carried out three amendments in the Indian Patent Act.

In the first amendment, provisions were made for acceptance of product patent applications and for granting of Exclusive Marketing Rights (EMRs) on such applications in the field of pharmaceuticals and agro-chemicals. In the second amendment in 2002, important substantive provisions, such as redefining patentable subject matter; extension of patent term to 20 years, amending compulsory licensing system, were included. Finally by third amendment in 2005, the Act provided for product patents which marked the beginning of new patents regime in India.

The TRIPS compatible Indian Patents (Amendment) Act, 2005 addressed few important issues regarding patent of products:

- adopting the definition of 'pharmaceutical substance';
- exclusion of 'mere discovery of new form of known substance' and the 'new use for a known substance'; and

* *Assistant Policy Analyst & Researcher (International Trade Law), CUTS*

25 years 1983 2008 CUTS International
CUTS Centre for International Trade, Economics & Environment
CUTS CITEE

No.3/2008

Box 1: The Indian Patent (Amendment) Act 2005

The Indian Patents (Amendment) Act 2005 was India's final step towards attaining TRIPS compliance. It is an attempt to balance the competing interest of its variety of stakeholders which include domestic generic manufacturers, civil society groups concerned with access to medicines, the research and development community, foreign multinational companies and the intellectual property lawyers.

However, this legislative effort catapulted to international significance because of introduction of pharmaceutical patents and the subsequent threats to an internationally famous generic industry that has, so far, guaranteed the supply of affordable drugs.

Although the dexterity in manoeuvring the competing interest is a subject of great applause yet in recent times it has generated some controversy relating to the lack of clarity in the provisions. Present case is one such case wherein the Honb'le High Court of Madras addressed this issue.

- protecting the interests of those who are already manufacturing the products which may be granted patent protection in the new regime'.[5]

Furthermore, the Act brought in new definition of the term 'new invention' and also introduced restrictions in the scope of patentability (section 3(d)).

It is explicitly mentioned in section 3(d) that patents would not be granted on the following grounds:

- the mere discovery of a known substance, which does not result in the enhancement of the known efficacy of that substance,
- the mere discovery of any new property or new use for a known substance, and;
- 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"

The section has an objective of preventing pharmaceutical companies from obtaining patents on old medicines i.e. trivial patenting and new use patents etc. Therefore, India while complying with the TRIPS agreement and introducing a product patent regime for 'new drugs that were invented', also added a safeguard enabling refusal of patents on discovery of new forms or new uses of old drugs (i.e. preventing ever-greening). It is noteworthy that the TRIPS Agreement provides in its objectives and principle[6] that each country can introduce a patent regime that is more suited to its socio-economic context.

What is the Case?

The Novartis case began in the year 1997 with patent application filed by Novartis AG for the b-crystalline of Imatinib Mesylate, brand name Glivec, which is slightly a different version of their 1993 patent, a vital anti leukaemia drug, filed before the Chennai patent office. The petition claimed that Novartis invented the beta crystalline salt form of the free base imatinib. In 2003, Glivec was granted Exclusive Marketing Rights (EMR) in the Indian Market. Meanwhile Novartis obtained orders preventing some of the generic manufacturers from generic equivalents of Glivec. It is worth mentioning that generic companies were selling their versions of Glivec at $177 to $266 while Novartis use to sell it for $2,666 per patient per year.

Pre-grant oppositions were filed by the Indian pharmaceutical companies and by an order dated January 25, 2006, the Assistant Controller of Patents and Designs, Chennai Patent Office, rejected the application under the restriction placed on the granting of patents under section 3(d) of the Patents Act, 2005. Novartis, in response to the rejection of application, challenged the constitutionality of section 3(d) before the High Court of Judicature at Madras. This challenge was based on primarily two grounds, namely:

- Section 3(d) is unconstitutional as it places restrictions on the granting of a patent that violate Article 27.1 of the TRIPS Agreement; and
- The words 'enhanced efficacy' and 'significantly differ in the properties with regard to efficacy' are not defined, that they confer unguided power on the Patent Controller who can decide the application on case-by-case basis. Hence, section 3(d) is arbitrary, illogical and vague and offends the equality guarantee in Article 14 of the Constitution of India.[7]

The petitioner (Novartis) prayed the Court to declare section 3(d) of Patent (Amendment) Act 2005 is non complaint with the TRIPS Agreement and violative of Article 14 of the Indian Constitution. The entire argument regarding violation of Article 14 Constitution of India was based on arbitrary discretionary power vested in the Patent Controller in determination of enhanced 'efficacy'.

The respondents, on the other hand, vehemently argued that section 3(d) is TRIPS complaint and that this Court is not the right forum to raise the issue rather than the WTO Dispute Settlement Body (DSB). The respondents in this case also argued that under the TRIPS Agreement, members are free to adopt laws within the framework of the TRIPS Agreement and are equally free to adopt and implement their national policies such as right to health to its citizen.

Analysis of the Madras High Court Decision

The Hon'ble High Court of Madras, on the issue of compliance of section 3(d) of the Indian Patent Act 2005, with Article 27 of the TRIPS Agreement, decided mainly on the jurisdictional issue and said that it lacked jurisdiction to entertain the issue. Court relied on using a 'contractual' approach and concluded on the basis of general principle, which states that 'non-compliance with an international obligation does not provide private parties with the right to challenge a domestic statue

Box 2: Relevant Provisions involved in the Novartis Case

Section 3(d) of the Indian Patents Act

"the mere discovery of a new form of a known substance which does not result in the enhancement of that substance or the mere discovery of any property or new use for a known substance or of the mere use of 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.

Article 27 of the TRIPS Agreement: Patentable subject matter

Article 27(1) of the TRIPS Agreement provides that:

- Patents shall be available for any inventions, whether product or process, without discrimination as to the place of invention, and in all fields of technology so long as they meet the three criteria of novelty, non-obviousness and utility; and
- Patent rights shall be enjoyable without discrimination in the field of technology.

On December 6, 2005 WTO Members agreed to amend the TRIPS Agreement to make it easier for poorer countries to obtain cheaper generic versions of patented medicines. Article 31(f) of the TRIPS Agreement says that production under compulsory licensing must be predominantly for the domestic market. The concern was that this could limit the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented. As with the 2003 waiver, the permanent amendment will allow any member country to export pharmaceutical products made under a compulsory licence for this purpose. They may need to change their own laws in order to do so.

unless the international instrument expressly grants such right'. The TRIPS Agreement in this regard grants right only to member states.

The Court further mentioned that the WTO's Dispute Settlement Understanding provides the exclusive remedy and a comprehensive dispute mechanism for violation of TRIPS Agreement. The High Court looked into various previous decisions in case of conflict between the international law and municipal law and decided that municipal law prevails in such conflict. Moreover, in India, international treaties are not directly enforceable.

Thus, the decision leaves crucial question before the Court unanswered. It is a well-founded decision both on the understanding of settling the claims under the TRIPS Agreement and also in the light of the precedents relating to the place of international law in the Indian legal regime.

It also rejected the second contention of Novartis regarding the unguided power granted to the Patent Controller by the impugned provision. While deciding on the issue the Court upheld that section 3(d) is neither vague nor arbitrary and therefore is not violative of Article 14 of the Indian Constitution. The Court also studied the requirements of the impugned provisions placed on the Patent Controller.

The whole argument of Novartis to hold section 3 (d) vague and arbitrary rested on the fact that, since the term 'efficacy' was undefined, the term 'enhanced efficacy' was ambiguous. The Court is right in its decision because undefined terms cannot essentially be deciphered as lack of guidance to the patent controller. In fact, the explanation in section 3(d) provides as to what constitutes 'enhanced efficacy'. The Court also pointed out that intention of the provision is clear and simple- for a patent to be granted it must be shown that the substance discovered has a 'better therapeutic effect'. Therefore, the Court concluded that the patent controller could competently determine the issue and the enhancement of a drug could also be most definitely determined.

Although the Court dismissed the petition, it acknowledged that the wording of section 3(d) is not perfect and it may still create interpretive problems and may lead to unintended results. However, it must be kept in mind that in this case the Court did not consider the broad question of dealing with the merits of section 3(d) but focused on the narrow issue whether it is was vague or arbitrary to the extent that it would satisfy an Article 14 challenge. Before dismissing the petition the Court made certain important observation and mentioned that the Amendment Act intended for

- preventing ever-greening;
- to provide easy access to the denizens of this country for life saving drugs; and
- to discharge their constitutional obligation of providing health care to its citizens.

Implications of the Ruling

The decision in the Novartis case was welcomed by most of the health activists and public interest groups. However, Novartis indicated that the decision might affect its future investment plan in India and quoted that the judgment would 'discourage investments in innovation' and would undermine efforts by drug companies to improve their products. The decision also attracted corporate voices suggesting that China is a better-suited place for Research and Development (R&D) in comparison to India. Experts in this sector anticipate that due to the stringent restrictions on patentibility, investment would significantly increase in other countries. In spite of the flip side of the decision, the major winners of the Novartis case are the generic drug manufacturers in India.

In upholding India's patent laws, the ruling represents a major victory for people's access to affordable medicines in developing countries. The decision makes Indian patents on essential medicines less likely. If Novartis had won the case, drug patents would have likely been granted far more widely in India, restricting generic competition and thus also restricting access to affordable medicines in the developing world.

The ruling is crucial as it encompasses vital public health consequences and influences the access of medicines to the poor. It is pertinent to note that the issue of patent protection in the health sector is particularly of great importance and has proved increasingly divisive. This is because of the fact that there is considerable tension between the aim of pharmaceutical corporations to recoup its investments and government's interest to control the costs of health care.

Further, from a theoretical point of view whether patenting system provides incentive to invent is a dubious question to answer. However, controversies regarding the theoretical and practical issues of the intellectual property system, has led countries to search for an alternative to the traditional system. Also, a significant attention has been given recently to differential pricing of the drugs/essential medicines as it influences the health care sector of countries especially the developing and the least developed countries.

Consequently, after six years of enacting the TRIPS Agreement, WTO Members recognised the needs of the poor countries to tackle public health problem and came up with Doha Declaration on TRIPS and Public Health.[8] However, even after the adoption of Doha Declaration, the pharmaceutical companies have failed to reduce the prices of the medicines especially for the treatment of diseases like cancer, HIV/AIDS. This only goes on to demonstrate that the multinational corporations do not address the health problems of the developing countries adequately. The debate on the accessibility of the drugs still remains valid. Accessibility further refers to the idea that the health policies should foster the availability of drugs at an affordable price to all those needy, worldwide.

This underlines a strong link between access to drugs and poverty. Approximately, one-third population of world does not have access to basic medicines and among this one third majority of population lives in African and Asian continent. Since price is one of the major factors in accessibility, it is of great significance that patented drugs are more expensive than the generic ones.

Although pricing is not the only issue affecting accessibility of medicines, still it plays vital role in it. It is in this context that the Novartis case would prove beneficial not only to the generic manufacturers of medicine in India but also to the needy, worldwide.

Furthermore, it is to be noted that several countries, including India, while developing their legal and policy framework in health care sector, have considered the link between patent, price of medicine and the access to drugs. The Indian court has remarkably factored public interest while deciding the case.[9] However, Novartis case has once again raised the question of patenting and pricing of medicines. It is a commonly known fact that pharmaceutical corporations practice to use ever-greening provision to continue patent protection through incremental innovation in their medicine.

Despite new inventions and enhancement in life expectancy ratios, large section of population in the developing still has no/less access to the medicines mainly due to the price barriers. The World Health Organisation (WHO) emphasises on the need to have access to medicines for the poor.

Box 3: WHO Report on Section 3(d)

The WHO's Public Health, Innovation and Intellectual Property Rights Report, 2006 affirms, in chapter-4, that countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent ever-greening patents from being granted. This affirmation was made in the report while referring to Section 3(d) of the Indian Patents (Amendment) Act, 2005. It further states that the TRIPS Agreement gives freedom to WTO Members to determine the hurdle required for the inventive step.

Source: *WHO Public Health, Innovation and Intellectual Property Rights Report, 2006*

The court's decision against Novartis will certainly help lower the cost of Glivec. However, the decision also encourages innovation, and once Indian pharmaceutical companies are forced to move along the road of innovation, R&D spending will increase, uncertainty in drug discovery will increase and these costs will be passed on to the consumer. Therefore, in order to keep the price of the medicines lower, a strong nexus between government, industry and research centre is anticipated.

Conclusion

This ruling signals to the world that India has chosen to adopt an IP regime that keeps with the spirit of WTO, however makes a provision for inexpensive access to medicines by prohibiting patent 'evergreening'. It has implications for global companies seeking to utilise the R&D and commercial opportunities in India as well for Indian generic companies seeking to develop innovative products for both domestic and international markets.

On a factual position the Madras High Court ruled that section 3(d) was constitutional. More importantly, it also stated that it did not have jurisdiction to rule on the TRIPS issue. As one can appreciate, this does not conclusively settle the TRIPS issue, but only shifts the jurisdictional venue. Notwithstanding the compatibility of section 3(d) and TRIPS Agreement, the Court acknowledged the uncertainties inherent in the section and said that wordings of the relevant section are not perfect.

Hence more clarity in the interpretation of section 3(d) is desired especially in a situation when many patent application in India today hinge on section 3(d) of the Act.

Having said this, it is still be kept in mind that the patents are nothing than a statutory right granted by the state in exchange for the useful disclosure of scientific information. As any other statutory rights, they can also be derogated from, when 'public interest' so demands. Sophisticated patent policy calls for balancing of innovation imperatives through patents against the other competing and important interests, such as right to health.

And it is this delicate balance, which the Madras High Court has strived for and achieved in its judgement. This decision will definitely go down in the annals of history as representing a milestone in patent jurisprudence in India.

References

Basheer, S. and P. Reddy, *Section 3(d) of the Indian Patents Act: Crude, Yet Constitutional*, Oxford Intellectual Property Research Centre, University of Oxford, 2008

Dhar, Biswajit, *Post 2005 TRIPS Scenario in patent protection in the pharmaceutical sector: The case of generic pharmaceutical industry in India* available at http://www.iprsonline.org/unctadictsd/docs/Dhar%20Indian%20 Pharma%20November06.pdf

FICCI Report for National Manufacturing Competitiveness Council, *Competitiveness of the Indian Pharmaceutical Industry in the New Product Regime*, March 2005

Nair, Manisha Singh, *Product Patent Regime & Pharmaceutical Industry in India* available at http://www.ipronline.com/depts/article.asp?id=1994%deptid=6

Novartis AG vs. Union of India and Others, judgement dated 06/08/2007 in WP No. 24754/06 & WP No. 24759/06

Mehta, Pradeep S., *India's Patent Law changes are a trendsetter*, Biospectrum, Cyber Media Publication, Vol. 5, Issue 9, September 2007

WHO, *Public Health, Innovation and Intellectual Property Rights Report,* 2006

WTO, *Doha Ministerial Declaration*, WT/MIN (01)/DEC/2, 20 November 2001

WTO, *Agreement on Trade Related Aspects of Intellectual Property Rights, Annex C*

Endnotes

1 FICCI Report for National Manufacturing Competitiveness Council (NMCC), Competitiveness of the Indian Pharmaceutical Industry in the New Product Regime, March 2005, available at: http://www.ficci.com/studies/pharma.pdf, accessed on May 26, 2008

2 *Ibid*

3 WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, Annex C available at http://www.wto.org/english/docs_e/legal_e/27-trips.doc, visited on May 26, 2008

4 Similar kind of litigation was witnessed in the South Africa when Novartis sued the country and challenged certain provisions of the extant Patent Act in South Africa. The litigation had to be unceremoniously withdrawn due to international pressure.

5 Biswajit Dhar, *Post 2005 TRIPS Scenario in patent protection in the pharmaceutical sector: the case of generic pharmaceutical industry in India* available at http://www.iprsonline.org/unctadictsd/docs/Dhar%20Indian%20 Pharma%20November06.pdf

6 Article 8 specifically states that member countries may adopt measures necessary to protect their public health and nutrition and to promote public interest in sectors of vital importance to their socio-economic and technological development. For details see Article 7 and Article 8 of the TRIPS Agreement.

7 Equality before law (Article 14 of the Indian Constitution) – The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.

8 WTO Doha Ministerial Declaration, WT/MIN (01)/DEC/2, 20 November 2001

9 Roche vs. CIPLA is another such case where a Court in India has heavily considered 'public interest' while granting temporary injunction.

This Briefing Paper has been researched and written for CUTS Centre for International Trade, Economics & Environment, D-217, Bhaskar Marg, Bani Park, Jaipur 302 016, India, Ph: 91.141.228 2821, Fx: 91.141.228 2485, E-mail: citee@cuts.org, Web Site: www.cuts-international.org, www.cuts-citee.org.