Pharma & Healthcare Update

August 10, 2007

NOVARTIS' CHALLENGE TO SECTION 3(D) OF PATENTS ACT DISMISSED

The Madras High Court has held that Section 3(d) of the Patents Act, 1970 ("**Act**") as amended in 2005 does not violate Article 14 (right to equality) of the Constitution of India[1]. This order was delivered in two Writ Petitions filed by Swiss pharmaceutical company Novartis AG and its Indian subsidiary ("**Petitioners**"). The High Court further stated that it had no jurisdiction to decide on the validity of Section 3(d) under Agreement for Trade Related Aspects of Intellectual Rights ("**TRIPS**"). The appeal of Novartis challenging the order of the Controller of Patents that rejected its patent application for its product B-crystalline of Imatinib Mesylate (brand name Gleevec / Glivec) is still pending before the Intellectual Property Appellate Board ("**IPAB**").

BACKGROUND

TO RECAPITULATE THE DEVELOPMENTS:

1997	Novartis AG filed a patent application with the Madras Patent Office for B-crystalline of Imatinib Mesylate ("**Product**") on the ground that the beta crystalline salt form (mesylate) of the base imatinib was a new invention.
1997 – 1.1.2005	The application was kept in mailbox as required under TRIPS and the Act.
1.1.2005	India introduced product patent regime and simultaneously amended Section 3(d) of the Act[2]. Section 3(d) disallows the patenting of a new variant of an already known substance unless such new form has significant efficacy over the older version. This was introduced with a view to prevent ever-greening and granting of frivolous patents.
January 2006	The 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. Controller held that the Product was a new version of an older molecule that Novartis first patented in 1993 and the increment in efficacy is not substantial enough to receive the grant of a patent.
May 2006	Petitioners filed writ petitions before the Madras High Court against the Union of India, the Controller General of Patents & Designs ("**Controller**"), Cancer Patients Aid Association (**CPAA**), and four Indian generic companies. Novartis contended that (i) the Controller erred in interpreting the enhanced efficacy standard imbibed in Section 3(d) with regard to Product, (ii) Section 3(d) was vague, ambiguous and contrary to the requirements of TRIPS and that it violated Article 14 (right to equality) of the Constitution of India. (iii) the Controller disregarded the in-house laboratory test performed by Novartis' scientists on rats to show that a 30% increase in bioavailability between imatinib and imatinib mesylate was adequate to meet up the "enhanced efficacy" benchmark of section 3(d).
April 2007	The Central Government issued a notification under section 117G of the Act whereby all appeals from the order of Controller, pending before the High Court, were transferred to the IPAB set up in Madras. Therefore, the Madras High Court transferred the appeal from the Controller's order rejecting patent to the IPAB. However, the Madras High Court, reserved the right to pronounce its judgment on the issue of the constitutional validity of Section 3(d) of the Act.

The challenge to Section 3(d) was based on two grounds, viz.:
(i) that it is not in compliance with the TRIPS agreement; and
(ii) that it is arbitrary, illogical, vague and violative of Article 14 of the Constitution of India.

ARGUMENTS ON GROUND 1:

Concerning ground one, the Petitioners argued that (i) Section 3(d) ran contrary to various Articles under the TRIPS Agreement, specifically Article 27[3], (ii) in bringing in this amended Section, the obligations arising out of the TRIPS agreement were not carried out, and instead, by introducing the amended Section 3(d) the right to patent an invention under Article 27 was taken away.
Opposing the above views of the Petitioners, the respondents contended that firstly Section 3(d) was compatible with TRIPS and in the possibility that it was not, the Indian courts do not have the jurisdiction to adjudicate upon this issue but such dispute could only lie before the Dispute Settlement Board of the WTO. Further, every member country does

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have the right to bring in its own local law in discharging their obligation under TRIPS keeping in mind the needs of the citizens of that country.

ARGUMENTS ON GROUND 2:

Section 3(d) requires a patent applicant to show that the new form or the known substance has enhanced efficacy to be eligible for patent, but there is no guidance in this Section as to determining 'enhancement of the known efficacy'. Vesting this determination in the hands of the Patent Controller, without the presence of any guidelines, will result in arbitrary exercise of power. Hence, on this ground, this section would be violative of Article 14 of the Constitution of India.
The respondents argued that the Patent Controllers are all experts with considerable training in this field and in the event the Patent Controller does give a wrong decision, such a decision can always be corrected by the IPAB and other higher forums.

DECISION

GROUND 1

On the first ground, as stated earlier, the High Court said that it had no jurisdiction to decide whether Section 3(d) is valid under TRIPS and only the dispute resolution mechanism under WTO should be resorted to. The High Court examined that TRIPS is an agreement between WTO member countries and when the agreement provides for dispute resolution mechanism, that should be followed.

GROUND 2

The Madras High Court examined various Supreme Court decisions that deal with validity of a provision of the statute under Article 14. In one of the judgements of the Supreme Court it was observed that Article 14 can be invoked only when it is shown that in the exercise of power there is a possibility of real and substantial discrimination and such exercise interferes with the fundamental right guaranteed by the Constitution. Madras High Court observed that the amendment section has in-built measure to guide the Controller in exercising its power under the Act; the amendment section does not suffer from the vice of vagueness, ambiguity and arbitrariness; and that the amended section 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).

Appeal?An appeal would lie from the order of the Madras High Court to the Supreme Court of India. However, it is learnt that Novartis is not likely to appeal against the decision of the Madras High Court before the Supreme Court and nor is the Government of Switzerland likely to take up the Novartis allegation of non-compatibility of Indian patent law with the TRIPS agreement to the dispute settlement board of the WTO.

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Future of Novartis' Gleevec Patent in India Novartis, now has an appeal pending with the newly operational IPAB against the rejection of a patent for the Product. In July 2007, IPAB rejected Novartis' plea to challenge the appointment of S. Chandrasekharan as the IPAB technical member on the ground that he was 'an interested party' since he was the controller general of patent office when Novartis' patent application for the Product was rejected. Contesting this decision, Novartis has filed a writ petition with the Madras High Court. The Madras High Court has stayed the hearing on the Novartis case by the IPAB till September 10, 2007. The Court has ordered that the IPAB should not continue to hear the case until the High Court has issued a final decision regarding the technical member.Two aspects now remain to be seen; one, whether the High Court will permit S Chandrasekharan to hear the appeal as a technical member of the IPAB and most importantly, whether IPAB allows the Gleevec patent on the ground of novelty and efficacy. The future of product patent regime in India will depend upon the interpretation of Section 3(d) and the standard of efficacy that is accepted by IPAB and other courts for grant of patent right.

- Khushboo Baxi & Gowree Gokhale

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