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Ruling On Novartis Challenge To WTO Rules In India Could Come Early

By Tatum Anderson for *Intellectual Property Watch*
A decision on whether the Indian patent law is compliant with World Trade Organisation intellectual property rules could be made sooner than expected, after a dramatic turn of events in the ongoing legal challenge brought by Swiss pharmaceutical company Novartis.

Last week, the case was expected to drag on until at least the summer and perhaps longer, despite being fast-tracked through the Indian system. However, it has emerged this week that the case will now be split between the High Court and a newly-functioning Intellectual Property Appellate Board (IPAB) in India. Sources close to the case say a judgment on compliance with the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), therefore, could be could be made as early as next month.

The case revolves around a patent application filed by Novartis for its anti-cancer drug Glivec. The patent was rejected by the Indian patent office in January 2006 on the grounds that it was not inventive enough to merit a patent under the 2005 Indian law.

In response, Novartis approached the Madras High Court in Chennai on 17 May, 2006, challenging two distinct elements: the grounds on which the Indian patent office, led by the Patent Controller, rejected the patent, and separately, a section of India's patent law that formed the basis of the patent office decision, which Novartis said not only contravenes TRIPS but Article 14 of the Indian Constitution, which ensures equality before the law.

Novartis, which has patented Glivec in nearly 40 countries worldwide, has said it wants clarification on the Indian law, because it wants to ensure that it will get adequate patent protection for any drugs it plans to offer in India in the future. "For a research-based organisation like Novartis, patents are non-negotiable, said a spokesperson for Novartis. "This is the core of our business model and we cannot work in markets where there aren't effective patent systems. It's not about stopping generics. We are a major generics manufacturer."

A two-judge panel at the High Court has been hearing both elements of the case since it began in February. It had been expected to reach a decision on both elements of the case at the same time.

However, the High Court has decided that it will continue to deal with the validity of Indian law, but has referred the appeal, challenging the grounds used by the Patent Controller to reject the patent, to the appellate board. Until this week, the appellate board existed in theory but was not in operation with functioning board members.

Since many of arguments heard over the last two months have related, largely, to the validity of Indian law, experts say it is likely that this particular case has almost completed. Specific arguments on the Patent Controller's decision in the High Court only began on 28 March.

A swift decision will be welcomed, not only by Novartis, but by the diverse factions watching the case from the non-governmental Médecins Sans Frontières, which has led a global campaign to drop the case, to the US Chamber of Commerce, which supports Novartis, and politicians across the world (*IPW*, 15 February 2007, Developing Country Policy).

A WTO Challenge in National Court

The entire case revolves around section 3(d) of India's 2005 Patent Amendment Act, which interprets the TRIPS treaty. Section 3(d) (see below) prohibits a new form of a known substance from being patented unless that new form has considerably better efficacy, a measure of its usefulness.

The Indian Patent Controller rejected the Novartis patent application because, according to section 3(d), Glivec is a new form of an older molecule that Novartis first patented in 1993 and the enhancement in efficacy over the old form was not large enough to warrant a patent.

The stakes are high, say activists, because Novartis has challenged Indian law. "Should Novartis succeed in its challenge, it will mark the first time that the demands of a private multinational corporation have overridden a sovereign country's right to protect the health of its people," said Chan Park of the Lawyers' Collective HIV/AIDS Unit in New Delhi, which has campaigned against the case.

Lawyers representing Novartis, and generic manufacturers, cancer patients and the government have put forward myriad arguments and counter-arguments since the case began in February. However, four main strands stand out, said Professor Brook K. Baker of Northeastern University's School of Law (US) and spokesman for Health GAP, a US NGO that focuses on access to medicines.

Opposition lawyers have argued that the Indian court should not hear the case because member states, not companies like Novartis, can dispute TRIPS compliance. So Switzerland should bring a case against India through the WTO dispute settlement process, and not the Indian courts. The premise of this argument is that TRIPS is unenforceable in India because when India signed the treaty, like the US, it did not automatically become national law.

Lawyers have argued that the Patent Act cannot, therefore, breach TRIPS, thereby violating the Indian

Constitution because the treaty does not technically exist in Indian law. “The lawyers are arguing that TRIPS is not independently enforceable,” he said.

Trade Flexibilities and Evergreening

The second set of arguments has addressed whether section 3(d) is TRIPS-compliant. Novartis lawyers argue that Indian law breaches TRIPS Article 27, which lists categories exempt from patenting, does not include new forms of existing substances. In addition, they said Indian law breaches TRIPS Article 1, which sets minimum standards, and does not permit member states to go beyond these minimums.

Opposition lawyers have argued that TRIPS flexibilities do exist, particularly in the rest of Article 1. In addition, Anand Grover, appearing for the Cancer Patients Aid Association, stated that because many countries have excluded other categories from patenting, including business methods, forms of presentation, computer programs, and aesthetic creations, Article 27 is not an exhaustive list.

Such flexibilities enable richer countries to define an inventive step to include an incremental new use of an existing substance. And poorer countries like India, opposing lawyers argued, can use the same flexibilities to craft specific rules against “evergreening,” where pharmaceutical companies patent frivolous changes to their drugs in order to extend patent protection, thereby preventing generic companies from manufacturing cheaper drugs the poor can better afford.

Thirdly, Novartis has argued that section 3(d) discriminates against a particular field of technology, which is prohibited by Article 27 of TRIPS, because it refers specifically to pharmaceutical molecules, and not other elements bound by intellectual property rules in India. They argue that this violates Article 14 of the Constitution, which guarantees equality before the law.

Krishna Sarma of Corporate Law Group, a law firm that represents numerous originator pharmaceutical firms including Eli Lilly and Pfizer in India, said: “Novartis has argued that pharmaceutical patents have been treated differently from other patents, without being given a compelling reason to do so.”

Lastly, the court has discussed efficacy in recent days. The Patent Controller had rejected data showing that Glivec offers 30 percent more bioavailability, a particular method of measuring efficacy, over the molecule first patented by Novartis in 1993. Novartis has also argued, to considerable opposition, that “enhancement of the known efficacy” in section 3(d) is vague because are no guidelines on what percentage would constitute significant enhancement.

However, it is unclear whether additional evidence related to efficacy might be permissible during the new case at the appellate board. Novartis has, in the past, argued that an appeal would enable it to offer additional evidence on the effectiveness of Glivec.

However, Leena Menghaney, a campaigner for access to medicines at MSF in India said only evidence that has been provided to the High Court so far will be permitted at the appellate board. Since

bioavailability is the not the only way to prove efficacy, the turn of events might put Novartis at a disadvantage, she added.

Novartis said it is concerned that the creation of the appellate board may delay the decision on Glivec yet further.

Section 3 (d) (source; Indian Patent Office)

3. In section 3 of the principal Act, for clause (d), the following shall be substituted, namely:-

"(d) 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;".

Tatum Anderson may be reached at info@ip-watch.ch.
