No to 'Ever-Greening'

Pharmaceutical R&D merely meant to keep off generic competitors will not be rewarded.

The Pharmaceutical Research and Manufacturers of America and the United States India Business Council are miffed over the recent Novartis judgment of the Supreme Court (SC) of India. For us, however, this ruling on the question of the patentability of the beta crystalline form of Imatinib Mesylate (IM) is one of the most significant verdicts on patent law in independent India. That it has come at a time when the pharmaceutical industry is once again tending towards tight "oligopolisation" and high prices, which was the case before 1972 when the country had pharmaceutical product patent protection, is all the more welcome.

With the coming into force, once more, of pharmaceutical product patent protection in January 2005 following the third amendment of the Indian Patents Act (IPA) of 1970, it seemed that the positive aspects of that law were on the road to being negated. Transnational pharmaceutical companies have been marketing patented medicines at exorbitant prices, particularly in the case of life-threatening diseases such as cancer, of which Novartis' Glivec for the treatment of chronic myeloid leukaemia (a form of blood cancer) has been a prime example. The company had applied for a patent for the beta crystalline form of IM on 17 July 1998, which went into the "post-box for filing" under Article 70(8) of the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), but it was granted an exclusive marketing right under Section 70(9) in 2003. Novartis was charging an unaffordable Rs 1.2 lakh per month for the required dose. Fortunately, Indian drug manufacturers such as Natco, Cipla and Ranbaxy (the latter, before its takeover by the Japanese transnational Daiichi Sankyo) entered the market with generic variants at one-tenth of that price.

Meanwhile, after 1 January 2005, when Novartis' patent application came up for examination, there were five pre-grant oppositions, including one from the Cancer Patients Aid Association (CPAA), and the patent office rejected the company's bid for a patent. Given the disclosure in the original patent for Imatinib free base, its beta crystalline form of IM was found to be "obvious" and also unable to pass the test of Section 3(d) of IPA 2005.

Novartis challenged this result in the Madras High Court, as also the constitutional validity of Section 3(d) and its compliance with Article 27 of the TRIPS Agreement. In 2007, the Madras High Court dismissed its pleas, while the Intellectual Property Appellate Board (IPAB) dismissed its appeal, on 26 June 2009, on the ground that the product did not pass the test of Section 3(d).

It was against the order of the IPAB that the appellant Novartis came to the SC. Natco and the CPAA also challenged that part of the IPAB's findings that favoured Novartis and these special leave petitions were also heard by the SC.

At the crux of the matter now were the questions concerning "invention" and patentability, here with the focus on Section 3(d). Interestingly, in a true democratic spirit, the SC judges hearing the three appeals took the view that a "statute is best understood if we know the reason for it", for this is "the safest guide to its interpretation". This took them into the history of patent legislation in India going as far back as the Patents and Designs Act of 1911 and the 1949 justice Bakshi Tek Chand and 1957 Justice N Rajagopala Ayyangar Committees' deliberations, and from there, to the IPA of 1970 that followed, its outcomes, and then the TRIPS agreement and the amendment of the IPA in line with it, including the accompanying parliamentary debates.

All this led the judges, Aftab Alam and Ranjana Prakash Desai, to appreciate the "vital distinctions" between the concepts of invention and patentability. For pharmaceutical products, they opined that Section 3(d) is meant to "leave the door open for true and genuine inventions, but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds".

Within this framework of the law, and the arguments for the appellants and respondents, the judges came to the conclusion that the medicine Glivec directly emanates from the original patent for Imatinib, whose application for patent-grant was first filed in the US in 1993. IM is present in that patent, and therefore is a known substance and its beta crystalline form is merely a new form of a known substance. Further, they came to the conclusion that the beta crystalline form of IM failed the test of enhanced efficacy under Section 3(d).

Under the TRIPS agreement and under Indian patent law, only those products whose original patent grants date from the filing of complete specifications from 1995 onwards were eligible for being considered for grant of product patent. In view of this, Novartis' claim for a patent for the beta crystalline form of IM "would only appear as an attempt to obtain a patent for IM, which would otherwise not be permissible in this country". The beta crystalline

form of IM therefore "fails both the tests of invention and patentability under clauses (j), (ja) of Section 2(1) and Section 3(d) respectively". Thus the learned judges dismissed the appeals filed by Novartis and allowed those of Natco and the CPAA.

In effect, the SC has laid down that the Indian Patents Act, 2005 is not meant to commercially reward "ever-greening" or the use of minor, almost cosmetic changes, in the product to allow continual extension of patent protection and the concomitant super-profits. R&D focused merely on extending patent protection has been disincentivised but, as Anand Grover, counsel for the CPAA, said, "It's all about incentivising only genuine research".