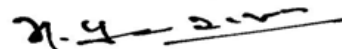


Evergreening of Patents and Section 3(d) of the Indian Patent Act

The Supreme Court ruling on the plea of the Novartis AG, challenging the section 3(d) of the Indian Patents Act, would prove crucial for affordable health care in India and abroad, as well as for the fate of Indian Pharmaceuticals Sector, which is also popularly referred to as 'Pharmacy of the Developing World'. If the plea of the Novartis is upheld and it is granted a patent on its beta crystalline form of the Imantinib mesylate, all generic manufacturers of Imantinib mesylate would be stopped from manufacturing and marketing this product, which they have been selling it between Rs. 90-130 per 100 mg capsule vis-à-vis approx Rs. 1,000 being charged by the Novartis. World over, more than 2 lakh blood cancer patients are surviving, painlessly, by consuming this medicine, being made available at affordable low and well priced by the Indian generic companies, solely by virtue of section 3(d) of the Indian Patents Act. In India alone 24,000 people are afflicted by Chronic Myeloid Leukaemia (blood cancer) every year and 18,000 succumb to the disease, mainly because they cannot afford to buy even these cheaper generic brands.

The implications of scrapping the section 3(d) of the Indian Patents Act would prove serious and might endanger the Indian pharmaceuticals sector, comprising 20,000 plus pharma companies, besides, undermining the R&D and education in the field of Pharmacy in India. Indeed, section 3(d) of the Indian Patents Act in its present form and if interpreted firmly can prevent ever greening of existing patents as it does not consider any new form of a substance as invention if it does not result in the marked increase in efficacy of that substance. Therefore, this section is vital to stop frivolous patents and evergreening of patents. By virtue of this, the generic manufacturers can introduce cheap generic versions, on the expiry of the original patents, as derivatives based on incremental research do not qualify for patents. The generic sector is the ray of hope for all those patients who cannot afford costly patented molecules. India being a leader in the area of manufacturing of generic drugs, is considered to be the provider of the life line for chronic patients spread world over and dependent upon affordable generics of Indian origin. Developing country governments, international agencies like UNICEF or foundations like Medicines Sans Frontiers (MSF) and Clinton Foundation, rely heavily on importing affordable drugs from India. Almost 84% of the antiretrovirals that MSF prescribes its patents worldwide come from Indian generic companies.

Therefore, interest has aroused world over in this case, scheduled for hearing on July 10, 2012 in Indian Supreme Court. Even protests have been organized throughout the US and Europe to pressurise Novartis to drop the case, but, that has not happened. Therefore, the final ruling of the Supreme Court shall be crucial from the point of view of affordability of health care and fate of the generic manufacturers in India.



(Prof. Bhagwati Prakash Sharma)

