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Novartis: Compulsory licenses will not expand access to drugs

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In a patent suit that has grabbed eyeballs across national and international media, the Glivec case has become more than just another piece of litigation. While Novartis has come under fire from NGOs in India who accuse it of pursuing a case that will reduce the common man's access to medicines, internationally, pharma majors are closely tracking the case to get a sense of the Indian patent law.

The Glivec case revolves around Novartis's anti-cancer medication, for which Novartis is seeking a patent based on beta crystal salt of the active compound. Novartis has appealed to the Supreme Court of India for the grant of a patent, based on increased safety due to modification of the naked chemical molecule, thus making it safe for use. In an interview with *BioSpectrum*, Mr Ranjit Shahani, vice chairman and MD, Novartis India, who is also president of Organization of Pharmaceutical Producers of India (OPPI), talks about why Novartis chooses to pursue the case, their access program, compulsory licensing and more.

What are the implications of the verdict in this case for Novartis in India?
We would not like to speculate on the outcome of the case. However, it is important to know that the available generic drugs launched in India before 2005, including HIV/AIDS medicines and generic versions of Glivec, will continue to be available under a grandfather clause in the Indian patent law, regardless of the legal outcome of our case.

Obtaining a patent for Glivec in India is important to Novartis because we want to ensure effective protection for innovation. We are seeking clarity on the application of patent law in India. Knowing that we can rely on patents in India benefits government, industry and patients because research-based organizations will then know if investing in development of better

medicines for India is a viable long-term option. The cost of a year of generic treatment is $2,100 or three-to-four times the average annual income.

The current case is challenging the court's view of not recognizing increase in efficacy as an incremental innovation, in line with the 3(d) amendment of the Indian Patents Act. Most critics argue that this is just an example of evergreening. What is yor opinion?
Novartis takes the view that Section 3(d), the Indian legal paragraph intended as a hurdle for "evergreening", is not applicable at all to Glivec.

Glivec has revolutionized the way certain cancers are treated. It has been granted a patent in 40 countries, including China, Russia, Mexico, Taiwan and all major developed countries. There is only one Glivec.

The beta crystal form of imatinib mesylate is the active ingredient of Glivec. No other drug comprising imatinib was available anywhere in the world before Glivec was launched. Scientists at Novartis developed the mesylate salt of imatinib and then the beta crystal form of imatinib mesylate to make it suitable for patients to take in a pill form that would deliver consistent, safe and effective levels of medicine. This process resulted in a viable drug which revolutionized cancer treatment. The patent filing claiming the beta crystal form of imatinib mesylate relates to the genuine product and represents the very first patent right filed in India claiming Glivec. One can arrive at the misconception of "evergreening" when referring to the present patent right only by ignoring these facts.

Another argument is that it will encourage other companies to opt for frivolous patents for minor modifications. What do you have to say?
We cannot speak for other companies, but many modifications made to existing drugs are far from frivolous. They can make the medicines safer and more effective for patients. The active substance of Glivec is the beta crystal form of Imatinib mesylate, being claimed in our patent application. Many leukaemia patients had no treatment option before Glivec became available. The drug turned a fatal disease killing its victims within three-to-five years into a non-fatal chronic disorder. From a patient perspective, this was not a minor modification.

Tell us about the access program for Glivec in detail? How patients are selected and what percentage of amounts is waived off? How many patients do you estimate to have benefited through this program?
Novartis has maintained its Glivec International Patient Assistance Program (GIPAP) in India for a decade. Assisting patients who cannot afford critical medicines is a priority for Novartis as demonstrated by our record, not only in India but in more than 80 other low- and middle-income countries. Since its inception, GIPAP has helped more than 40,000 patients worldwide. In India, 95 percent of those who are prescribed Glivec get it free of charge, and the rest are part of a generous co-pay program. GIPAP has helped more than 15,000 patients in India, and Novartis has donated, in this country alone, medicine valued at more than $1.7 billion.

Do you see Novartis setting up an R&D center in India in the near future?
Pharmaceutical companies looking to set up R&D centers anywhere in the world look for an ecosystem that fosters innovation. This is currently lacking in India.
Novartis and our generics business, Sandoz, which reaches more than 400 million people each year, are deeply committed to making low-cost generic medicines widely available around the world.

As OPPI President, what is your view on compulsory licensing?
The compulsory licensing provisions in the Indian Patents Act are basically in consonance with the TRIPS Agreement. However, provisions in the Indian compulsory licensing law regarding pricing and local working, in OPPI' s view, go beyond what is provided in the TRIPS Agreement and the Doha Declaration, and are not in line with India's obligations as a WTO member.

We believe the government can achieve its objectives for patients through collaboration without the uncertainty that arises from unilateral actions taken on compulsory licensing. In those instances where collaboration does not prove to be a fruitful approach, developing countries like India may make use of compulsory licensing as a last resort. However, the issuance of compulsory licenses to address pricing or budget constraints could come at a long-term cost, limiting important incentives for research and development that are necessary to positively impact the lives of millions of patients worldwide.

Issuing of compulsory licenses will not significantly expand access as even at reduced prices generics are out of reach of the poor in India. Once we have the right ecosystem in place that fosters innovation, then the balancing acts such as compulsory

licensing on a case by case basis, like in times of a national health emergency, can be justified. Compulsory licenses are powerful rights granted to governments to deal with extraordinary situations. And with great power comes great responsibility. It is, therefore, incumbent upon those who deal with such power to ensure that these rights are exercised judiciously.

The government has recently been in talks for a number of initiatives to promote generics, especially promoting states that have made prescribing generics a compulsory practice. How do you think such a move is perceived by pharma companies in India?
OPPI member companies are happy to partner with the government in working towards the universal goal of healthcare for all. Making medicines available, however, is not just a factor of price and the sooner we realise this, the better it will be for all concerned. Global pharma companies have already been involved in introducing innovative ways to make their drugs widely available, including tiered pricing, public private partnerships and full donation programs.

More importantly, the income generated throughout the world by branded products allows research-oriented pharmaceutical companies to invest into medicines of the future. The Indian middle-class could contribute to finance the required expensive pharmaceutical research through a robust healthcare funding system.

How do you view the current regulatory scenario in India?
India needs to tackle far more serious issues that impede healthcare in the country than look at striking at the roots of innovation. Intellectual property rights are the drivers of innovation and it is a harsh reality that if we stifle intellectual property rights, we will actually hamper innovation to the extent that we will have no new medicines to meet unmet medical needs.

Lack of access to medicines in countries like ours is caused by factors such as poverty, lack of a functioning infrastructure and the lack of will to address these issues. The government needs to address these issues on a war-footing, rather than look at ways to undermine innovative research and the pharmaceutical industry.

What do you think needs to be done to improve healthcare access in India?
Generics alone do not solve the issue of access. Issues such as lack of diagnosis, infrastructure and distribution, all act as barriers to access. Governments, NGOs and companies need to work together to find innovative solutions to these issues. There are other methods employed by pharma companies to improve access, which I have already mentioned.

The very nature of patents is that they are time-limited. Generics manufacturers rely on a constant stream of products going off patent each year that they can copy and market. That is how their businesses grows. As a major manufacturer of generics, Novartis understands and recognizes the contribution of generics once drug patents expire. Our concern is with the non-recognition of intellectual property rights that ultimately help sustain and advance pharmaceutical research and development.