Commentary

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A victory for global public health in the Indian Supreme Court

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Abstract

On 1 April of this year, the Indian Supreme Court upheld the decision of the Indian Patent Office to refuse the patent grant for Novartis imatinib mesylate (Gleevec). The patent application failed to meet the requirements for patentability under Indian law. The global public health community followed the case closely. Its outcome could affect the Indian generics industry – an important supplier of low cost medicines to the developing world.

Keywords:

patents; generic drugs; innovation; drug prices

In 2006, the Indian Patent Office rejected a patent application by Novartis for the beta crystalline form of imatinib mesylate. The drug is used to treat chronic myeloid leukaemia and is marketed by Novartis as 'Glivec' or 'Gleevec'[1]. Novartis appealed the decision of the Indian Patent Office. After a 7-year battle in the Indian courts, the Supreme Court of India, on 1 April 2013, spoke the final word, confirming that the patent application failed to meet the requirements for patentability under Indian law. Public health advocates over the world had closely monitored the court case because of its potential effect on the supply of affordable generic medicines originating in India.

The Patent Office rejected the application for the beta crystalline form of imatinib mesylate because it was not considered innovative. Indian patent law (section 3(d)) explicitly requires that patents be granted only for compounds that are truly new and innovative. For new forms and new uses of known compounds, Indian law requires patent applicants to prove significantly improved efficacy to be eligible for a patent. The Supreme Court clarified that this requirement of improved efficacy refers to therapeutic efficacy. India introduced this requirement to prevent the practice of continually extending or 'evergreening' of medicines' patents by seeking patents for minor alterations to the original molecules or known

compounds. Thus, the Supreme Court ruled that the Novartis application for a patent for imatinib mesylate did not meet the requirement of section 3(d). The original Gleevec compound was invented in the period before 1995, when India did not grant product patents.[2] In 2005, India amended its law to comply with requirements of the World Trade Organization.

Throughout the 7-year court battle, the public health community around the world paid close attention for at least two reasons:

- the expanded supply of low cost generic imatinib mesylate was at stake – as the Indian generic was priced at US$170 versus $2200 for the Novartis brand **(Figure 1)**; and
- the effectiveness of section 3(d) was at stake. Section 3(d) has been the basis for successful opposition by patient groups to patent grants that protect high prices. For example, this provision helped to increase generic supply of low cost antiretroviral medicines to treat HIV/AIDS in the developing world.

Figure 1.

Price of Gleevec and Indian generics.
Source: MSF Access Campaign India.

Full figure and legend (69K)

The Indian generic pharmaceutical industry has been termed the 'pharmacy of the developing world' for its role in supplying low cost generic HIV/AIDS medications to treatment programmes in developing countries. The Global Fund to fight AIDS, Tuberculosis and Malaria, UNITAID, and the United States President's Emergency Plan for AIDS Relief (PEPFAR) have supported the purchase of Indian generics. When India amended its Patents Act in 2005 to conform to intellectual property rules of the World Trade Organization, the head of the HIV programme of the World Health Organization (WHO), Dr Jim Kim, wrote to the Indian minister of health: "As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to antiretrovirals, without adopting unnecessary restrictions that are not required under the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement and that would impede access to medicines.[3]"

At the time, Indian lawmakers responded to such pleas from the public health community,

and section 3(d) was included in the Patents Act, as part of a series of provisions using TRIPS flexibilities. (*The Journal of Public Health Policy* has just published an article that explains TRIPS and the importance of this decision involving Gleevec to China's population).[4] In its recent decision, the Supreme Court recognized the importance of Indian patent practices for health globally. In its ruling, the Court cited letters from WHO and UNAIDS as evidence of how Indian law makers had been sensitive to the needs of other developing nations.

The public health community has been harshly critical of Novartis for bringing its suit and emphasized that Novartis erred in challenging a carefully balanced patents act.[5]

Novartis was quick to point out that the court's decision will have detrimental effects on its investments, and those of other pharmaceutical companies, in research and development (R&D). In this context, it is important to note that the US National Institutes of Health (NIH) and health charities played an important part in the development of Gleevec. The best estimates of R&D expenditure by Novartis towards the development of Gleevec are $38–96 million.[6]

Sales for Novartis' Gleevec in 2012 were $4.675 billion, or $390 million per month. These sales will not be affected by this recent court decision. Novartis did not need a patent in India to recoup its investment in the development of the drug and to protect is profits.

Perhaps the key point is that financing R&D primarily through patents poses problems for public health. In the late nineties, the challenge of providing costly patented antiretroviral medicines for the developing world focused attention on difficulties caused by patents on medicines. Today's concern is drugs for non-communicable diseases.

Responding to the Indian court case, the international president of Médecins sans Frontières (Doctors without Borders) hit the nail on the head: "At the moment medical innovation is financed through high drug prices backed up by patent monopolies, at the expense of patients and governments in developing countries who cannot afford those prices. Instead of seeking to abuse the patent system by bending the rules and claiming ever longer patent protection on older medicines, the pharmaceutical industry should focus on real innovation, and governments should develop a framework that allows for medicines to be developed in a way that also allows for affordable access.[7]"

Perhaps an unintended effect of this court case will be much needed dialogue between industry, the public health community, and government on how to share the burden of innovation costs and how this can be done in such a way that access to the fruits of innovation are ensured for all who need them. The World Health Assembly in May of this year will discuss innovation, intellectual property and public health, and the need for a new medical R&D framework. The Novartis case shows how timely this is.

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