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India: Novartis' failed action

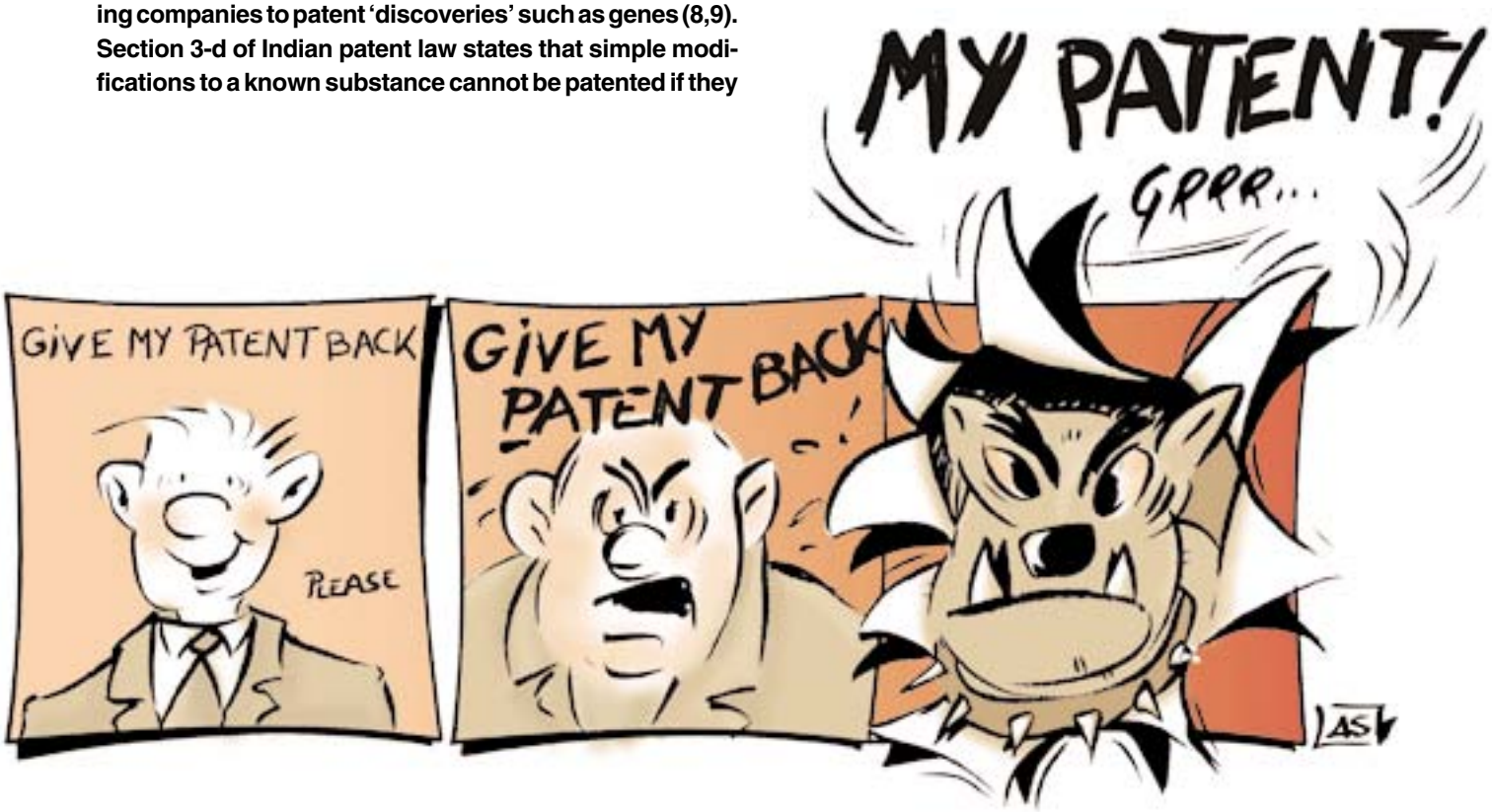
India is currently one of the only countries capable of large-scale manufacture of high-quality, low-cost generics. India is also one of the few countries to have integrated the flexibilities provided by international patent agreements into its national legislation, in order to facilitate access to affordable new drugs in India and other poor countries (**a**)(1-5).

Following rejection of its Indian patent application for imatinib (Glivec°), a drug used to treat various rare forms of cancer, Novartis has taken legal action against one of the key provisions of Indian patent law. By doing so, Novartis threatened not only India but, more generally, access to new essential drugs for the poor in a large number of third-world countries.

In India, intellectual property is linked to therapeutic advantages. Among the essential provisions of the Indian patent law passed in 2005 is a strict definition of the three standard criteria required for a patent to be granted: 'inventive step', 'novelty', and 'industrial applicability' (**b**)(6,7).

Industrialised countries have gradually adopted an increasingly watered down definition of these criteria, allowing companies to patent 'discoveries' such as genes (8,9). Section 3-d of Indian patent law states that simple modifications to a known substance cannot be patented if they do not lead to better efficacy (6). The law states that "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" (6). The Indian law was based on European Directive 2004/27/EC which also considers, in the definition of generic drugs, that: "The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy (…)" (10).

Rejection of a second patent application for the same drug: no novelty or innovation. Novartis obtained a patent for imatinib in Europe and the United States in 1993, at which time India was not legally bound to recognize drug patents (11). Novartis submitted another



patent application for imatinib in India in 1998, when India had to accept patent applications, but only with a view to possible granting of patents after 2005.

Several Indian drug companies began to market generic versions of imatinib, bringing the price of one month's treatment down from the usual 2600 dollars to about 200 dollars (12,13). This is why the Indian Cancer Patients Aid Association (CPAA) and several Indian firms producing generic imatinib opposed Novartis' 1998 patent request, which would have given Glivec° a monopoly.

After a thorough technical debate, the Indian Patent Office decided that the version of imatinib for which a patent had been requested in 1998 differed only marginally from that already patented in 1993: in practice there was no evidence of novelty, no innovation and no extra therapeutic efficacy. The Indian Patent Office publicly announced its decision to reject Novartis' 1998 patent request on 25 January 2006 (11).

Novartis tightens the screws. **Novartis decided to contest the patent office's decision in the Indian courts. There would not have been a major reaction had the company not also challenged section 3d of the Indian patent law regarding the definition of novelty. The company hoped that the Indian court would conclude that this section was not in keeping with India's obligations with respect to international patent agreements.**

There was indeed a risk that the court might come to this conclusion as there is no general consensus in India concerning the Indian law on intellectual property. Some people believe that the country should try to attract investment from the West and should ally itself with western companies rather than stubbornly play the role of 'poor people's pharmacy' for countries with little clout in the global economy.

The significance of this trial had little to do with Glivec° itself, but rather threatens the poorest populations' access to new essential drugs, which will mainly depend in future on the existence of flexibilities in patent law (c).

Legal actions of this type at least show us exactly where drug companies stand: their claims of 'social responsibility' are nothing more than a smokescreen aimed at masking their huge appetite for market share.

On August 6th 2007 the Indian High court decided to reject Novartis legal challenge, a decision the company should not appeal against. This has been praised by nongovernmental organisations and condemned by company representatives (14). But a representative from the Swiss governement declared that Switzerland respected this decision and would not refer to WTO (15).

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a- World Trade Organization (WTO) agreements on intellectual property (TRIPS agreements) provide flexibility (such as compulsory licences) for all countries. Particular provisions for poor countries are dealt with in the Doha Declaration on Public Health and the WTO agreement of 30 August 2003 (refs 1-5).

b- The TRIPS agreements mention these standard criteria of patentability in article 27 (ref 16).

c- Many nongovernmental organisations in India and elsewhere unsuccessfully called on Novartis to withdraw its action. Doctors Without Borders (MSF) posted a petition on their website http://www.msf.fr (refs 17,18).

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