

EDITOR'S CHOICE

INDIA EDITOR'S CHOICE

The Novartis case: weighing innovation against accessAnita Jain *India editor, BMJ*

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In a landmark judgment last week, the Supreme Court of India rejected the patent application by Novartis for its cancer drug, Glivec (imatinib) (doi:10.1136/bmj.f2099). This has been hailed as a victory for public health, not just in India but across the developing world.

The judgment represents a firm footed stance to protect people's right to health, in the face of stiff challenges from multinational drug companies. It builds on a critical amendment to India's patent law in 2005 in the form of section 3(d) that prohibits patents on new forms of known medicines unless they result in enhanced efficacy over the existing medicine. This provision was introduced after India became a signatory to the World Trade Organization's (WTO's) agreement on Trade-related Aspects of Intellectual Property (TRIPS), which obliges countries to grant patents on technological products, including drugs. Indian companies must wait for a patent to expire before they can produce identical, quality copies of innovator medicines for use in India and for export to poor patients around the world.

Access to medicines increasingly depends on the use of what are known as "TRIPS flexibilities"—legal measures enshrined in countries' laws to safeguard the right to health. The Doha Declaration of 2001 emphasises "that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." India's patent law has been commended as a success story by the World Health Organization and health activists, doctors, and patients across the world in widening access to HIV drugs and saving millions of lives. India is often called the "pharmacy of the developing world" because of its generic drugs industry—the recent ruling is therefore important.

I wonder if like me you are asking, so what does this mean for my patients, or for medical practice at large? I would like to direct you to an analysis (doi:10.1136/bmj.e7941) of "evergreening" strategies used by drug companies to prevent losses from sale of cheaper generic drugs and protect their market share. The article provides real examples of tactics such as chemical tricks, reformulations, fixed dose drug combinations, changes in dosage regimen, and brand promotion among others. The authors make a strong case for doctors, health systems, and governments to wake up to these. I am sure it will help you identify similar pharmaceutical tactics, the way they affect your prescribing decisions, and as a direct offshoot—whether your patients can afford these life saving drugs.

Will this move hinder innovation and medical progress? Drug companies, quite rightly, argue that there is a lofty price for research and development of new drugs, and patent protection helps fuel that. However, as Unni Karunakara, international president of Médecins Sans Frontières states, "instead of seeking to abuse the patent system by bending the rules and claiming ever longer patent protection on older medicines, the drug 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. This is a dialogue that needs to happen."

Will the Indian Supreme Court's dismissal of Novartis' petition for patent protection discourage companies from investing in new drugs? Vote yes or no in our online poll at bmj.com/india

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