Straight talk from... **James Love**

In early August, a court in the southern Indian city of Chennai dismissed a lawsuit filed by pharmaceutical giant Novartis. The lawsuit was seemingly about Novartis' application for a patent on its cancer drug Gleevec. But the pharmaceutical company's loss in the courtroom was celebrated by activists worldwide as a victory for public health and for those who need access to affordable drugs in developing countries. James Love, director of the nonprofit organization Knowledge Ecology International, explains the local lawsuit's global impact.

What was the dispute at the heart of this lawsuit?

For more than 30 years, India granted patents on the processes used to make pharmaceutical products, but not the products themselves. This allowed Indian companies such as Cipla, Ranbaxy and Dr. Reddy's to make generic versions of medicines, but using different processes than the original drug makers had used. The Indian companies were clever at developing newer and often better ways to manufacture medicines, and today they are the most important global suppliers of generic medicines, including very inexpensive treatments for AIDS, cancer and other conditions.

The World Trade Organization (WTO) was created in 1995 with a new obligation to protect intellectual property, set out in the TRIPS agreement. According to the agreement, most WTO members, including India, had until 2005 to extend patent protection to pharmaceutical products. When that deadline approached, India changed its patent law. But in the final weeks of that process, the Indian Parliament offered several amendments to soften the impact of those changes. Some of these changes limited the situations in which product patents would be issued. In particular, section 3(d) of the new patent law was written to limit the 'evergreening' of patent protection for medicines—a term used to describe the extension of monopolies by patenting new uses or minor improvements—and also to discourage the granting of frivolous patents.

In May 2006, Novartis filed a lawsuit in a dispute over patents on Gleevec, its highly profitable leukemia drug, claiming that the Indian Patent Controller had erred in rejecting a patent application on the drug. The lawsuit also alleged that section 3(d) of the Indian law is vague, ambiguous and contrary to the TRIPS agreement.

What did the courts decide?

Novartis lost every argument in the case. The amendments to India's patent law stand, and it will be difficult to obtain patents in India for new uses of known substances—unless the invention enhances the effectiveness of the known substance, or results in a new product that differs significantly in efficacy.

Nearly half a million people signed a petition, floated by Médecins sans Frontières, calling on Novartis to drop this case. Why? What was at stake in the outcome?

India has the most important patent law in the world, in terms of global health. India is also the primary supplier of cheap generic drugs to the rest of the world. If India has tough patent laws and routinely extends patent protection to new uses of old medicines, it will reduce global access to medicines. On the other hand, if India wins the lawsuit, other countries will undoubtedly consider similar changes in their own patent laws.

What impact will the ruling have in other countries, such as Brazil and Thailand, that have refused to comply with patents on expensive drugs?

There is a lot of confusion about what the WTO rules actually say, and what some countries are doing. Under the WTO rules, only the 50 least developed countries can eliminate patents on pharmaceutical products. Everyone else, including India, Brazil and Thailand, must grant and enforce patents. However, any country can issue a compulsory license on a patent and allow third parties, including generic drug companies, to use the patent in return for the payment of a royalty to the patent owner. Brazil and Thailand issued patents, but also granted compulsory licenses in return for royalty payments.

Compulsory licensing is not limited to public health crises or developing countries. The US has issued at least a half-dozen compulsory licenses on patents in the past 15 months, including on automatic transmissions, software technologies and medical devices. Italy has issued compulsory licenses on three different drugs since 2005.

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The Indian Novartis dispute is about a different issue. How much discretion do WTO members have in deciding what constitutes a patentable invention? This is not only an issue in India, it is a question that was also addressed recently in the US Supreme Court.

Unless Novartis drops the suit, the Indian court case may be subject to further appeals. But assuming this decision stands, other developing countries will probably make it more difficult to obtain patents on minor innovations or on new uses for old drugs.

Novartis says the decision will destroy India's research enterprise and that companies will instead invest in China. Do you think that's true?

I don't think local patent laws are very important. The availability of domestic public-sector spending on research and development (R & D) is quite important, as is the availability of skilled researchers. Both India and China have impressive biomedical industries and growing R & D capacities. The relevant market for new inventions is not India or China, but the world, including the US, Europe and Japan. For years, Indian firms have been filing patents in Europe and in the US that they cannot obtain in India—and this will continue.

Over the longer run, people have to recognize that the current system is broken and needs to be fixed. We should not rely upon 20-year monopolies to stimulate R & D of new medicines if that system excludes most of the global population from access. The World Health Organization and some US leaders are looking at new methods of stimulating R & D that don't rely on high drug prices.

In the future, we will be talking more and more about prizes replacing high prices as the mechanism to stimulate innovation. If we can more directly reward innovators for the impact of their inventions on health care outcomes, we may be able to avoid the monopolies and the price-related access problems altogether.

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