

Gail R. Wilensky

India's decision on Gleevec®: implications for the future

India's Supreme Court recently rejected a request from Novartis for a second patent for its cancer drug Gleevec. Forty other countries, including the United States, have provided protection for the patent.

The patent is a secondary rather than a primary patent, and the court rejected it as not being a novel invention because Novartis had patented a version of Gleevec in 1993, which it later abandoned. The focus on how innovative the secondary patent is relative to the first patent has potentially large ramifications for biologics, where innovations may be step-wise and incremental. It could also affect patent requests for small molecule drugs, as well, which can occasionally amount to follow-on patents reflecting only incremental changes from the original patents.

Is India the Clear Winner?

In the short term, India's cancer patients, particularly the 40 percent of the population who earn less than a \$1.25 per day, and India's generic drug industry, particularly Cipla, the Indian company that has produced a generic version of Gleevec, are better off.

It has been estimated that as many as 16,000 patients use the branded version of Gleevec in India, although most are assumed to receive them free of charge because they are so poor, and that another 300,000 use a generic version of Gleevec. Because even the generic version of a drug will cover the cost of its actual production, once the product is developed and marketed,

there is no reason to assume that Novartis would withhold shipments of the drug to India in the future.

More complex issues that are harder to predict with any certainty are how the Novartis decision will affect Indians' access to other patented drugs that have not yet been marketed in India, the future introduction of Indian generic drugs into the United States on a first-entry basis, and the willingness of multinational firms to invest in research and development in India.

The Novartis decision is a clear indication that India has "raised the bar" regarding how innovative a patent for a new innovation must be before the Indian government will grant the patent. As a result, drug companies might well begin to insist on having patents recognized in India before they consider launching the products there. Although it is not clear that drug companies would take this position, if they did, one also can only speculate as to how long it would take India to respond and whether India would attempt to tie patent recognition to any other activity associated with the patent request.

If the company were not to seek the patent recognition before launch, it clearly would risk having its patent request rejected after the product is already available in the country, making it extremely vulnerable to the production of generic versions of the drug, as has happened in the Gleevec case.

But waiting to launch a drug until after a patent has been recognized also carries risks. Clearly, by

delaying the time to market, this approach gives competitors more time to launch other, potentially competing products in the interim. This approach also could artificially limit the size of the market available to the drug, an important factor during the early phase of drug distribution and cost recovery, by shutting out this growing marketplace for drugs.

At this time, the adverse effects on drug companies from limiting a drug's distribution in India until the patent legitimacy has been verified may be minimal, because India remains only the 14th largest market for drugs. But India's drug market is reportedly growing at an annual rate of 13 to 14 percent—much more rapidly than the larger Western market. Limiting drug distribution in a future, much larger market could have a significantly adverse effect on drug companies, although none so adverse as not having their patents recognized.

Indian patients also are not immune to future fallout from this decision. The challenge is not in providing patients with access to Gleevec, because there already is a generic version available in addition to the branded product. Novartis may attempt to compete with Cipla's generic version and produce one of its own, which would increase the availability and competitiveness of generic Gleevec, thereby benefiting Indian patients.

The risk for Indian patients lies in the possibility that the delays drug companies face in getting patents recognized in India could make it more difficult for Indian patients to access new, innovative pharmaceutical products. Job opportunities and economic growth also could be affected if multinational companies were to decide to limit their investment in research and development activities in India for fear they might be unable to secure patent protection for some of the resulting products.

Again, attempting to judge the net effect of the patent decision at this stage is difficult because

the Indian market is still relatively small. But the potential for spillover effects in other middle-income and emerging countries could greatly exacerbate the effect. India's position is clearly an attempt to gain short-term advantage with the apparent belief that the long-term cost will not be too large or at least worth whatever price is ultimately paid.

Any Implications for the United States?

Because Novartis is a Swiss and not an American company, there are no immediate implications for the United States inherent in the Gleevec case. That said, it is obvious that similar judgments will likely be made against the patents of U.S.-based companies.

The United States will likely continue honoring the issuance of patents for products that primarily represent incremental improvements, just as it does for more innovative products. Rather than attack the patent protection that is offered, private and eventually public payers (if they are authorized to do so) could become less willing to pay significantly higher prices for products that offer only incremental improvements over existing products, except in those cases where the incremental improvement appears clinically important for certain patient types. This likelihood assumes that payers will have much greater access to information on the comparative effectiveness of various products and devices than it does today, and that there will be a much greater ability and willingness to use that information in setting payment.

The United States is not ready to make such decisions at this time. But it certainly could move in that direction in the future, which would be a far better strategy than withholding patent protection. ●

Gail R. Wilensky, PhD, is a senior fellow at Project HOPE; a former administrator of HCFA, now the Centers for Medicare & Medicaid Services; and a former chair of the Medicare Payment Advisory Commission (gwilensky@projecthope.org).