Editorial

Intellectual property and biotechnology innovation: To protect or not protect?

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The intellectual property protection differences between countries is a contentious issue. Countries with strong innovation systems (technology producers) often favor strong intellectual property protection because it motivates innovation by granting innovators temporary market exclusivity for their new, nonobvious and useful inventions; countries with less-developed innovation systems (technology consumers) often prefer weaker patent protection, as it enables them to access inventions developed elsewhere without having to pay licensing or manufacturing fees that may be beyond their capacity (or desire) to pay. Although the World Trade Organization's TRIPS agreement does provide governments the right to use patented technologies without authorization, this compulsory licensing is limited to cases of 'national emergency or other circumstances of extreme urgency'. Furthermore, there is often disagreement on what constitutes a national emergency or circumstance of extreme urgency. The central question underlying TRIPS claims or unauthorized use of patents is that of their greater impact on a country's industry and economy.

A common rationale for unlicensed patent use is that improving their citizen's health is a national priority, so governments ought to produce high-value drugs domestically, without license if necessary, to serve their national interests. Price controls can be seen as a less-extreme version of unlicensed use as, instead of denying innovators profits from domestic sales, price controls give governments greater power in dictating terms. The downside of these strategies, however, is that they can deprive countries of patented technologies; several years ago AstraZeneca responded to pressures from the New Zealand government to lower prices for Zoladex by announcing that they would simply stop selling the drug in that market. Domestic industries can also be affected; Novartis recently bypassed the appeals courts in India and responded to the Indian patent office's decision not to grant its patent for Glivec (sold as Gleevec in the United States) by announcing that it would redirect hundreds of millions of dollars of R&D investments to other countries.

India and New Zealand are not alone. There are plenty of other examples of drug companies threatening to withdraw drugs or R&D investments from other developed and developing countries. The common theme in these battles is that these decisions can have broader impacts than the individual products or patents involved. While licensing decisions are often based on individual drugs or individual diseases, they can signal to companies that a given country represents a poor market and can discourage a company from domestic R&D investments or developing of drugs for endemic conditions. The result is that near-term benefits are exchanged for long-term deficits.

Although simple logic suggests that all countries – developing and developed – should offer the strongest intellectual property protection possible, that solution is rarely practical for economic reasons, and it deprives government-backed health-care systems a valuable bargaining tool. So, the battle between countries and drug manufacturers will likely continue, using patents, price controls, R&D investment and other levers. What is of particular interest is how the dynamics change as countries transition from being technology consumers to technology producers (or, possibly, the reverse). As countries that were once broad technology consumers develop technology-innovation capacity and find it increasingly favorable to strengthen their patent laws, how can they strengthen these laws while protecting legacy companies and their domestic interests in areas in which they are still net technology consumers? Additionally, as low wage-cost countries face competition from each other, how can they motivate foreign investment in a way that promotes the growth of domestic companies? Furthermore, how much leverage can countries with large markets wield?

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