

EDITORIAL COMMENTARY

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Patent Piracy

Pharmaceutical patents deserve the same protection as other property rights

Imagine your outrage if the government made it illegal to protect your wallet from pickpockets. Yet this is life on the economic streets for pharmaceutical companies that apply for "ancillary" patents to protect and extend their exclusive rights to profit from drugs they discovered. Bristol-Myers Squibb, for example, recently was

fined \$680 million for using such devices to protect the patents on its anti-anxiety drug BuSpar and on its cancer drug Taxol. Pfizer was criticized for receiving a patent extension on its epilepsy drug Neurontin. And the Federal Trade Commission has barred the Canadian drug company Biovail from using ancillary patent filings to protect its heart drug Tiazac.

FTC Chairman Timothy Muris accuses big drug companies of using ancillary patents to "game the system, securing greater profits for themselves without providing a corresponding benefit to consumers." Sen. John McCain claims that such patents are cruel because they force seniors to choose between food and drugs. Lost under this flood of criticism is the fact that pharmaceutical companies need ancillary patents because of the diminishing economic value of their original patents.

Current law sets the patent term at 20 years from the date of earliest filing. This means that the clock starts on drug patents as soon as a company applies for FDA approval—not after the new drug goes on the market. Given the glacial pace of the FDA's testing and approval process, the effective life for drug patents is about nine years, as compared to around 18½ years for other patentable products. It is this regulatory hobbling of pharmaceutical patents that pushes drug companies to seek ancillary patents out of sheer need for economic self-preservation. The irony, of course, is that if companies do not file for such patents, they will bleed red ink and then be sued by investors and publicity-seeking attorneys general for failure to perform.

The U.S. legal code recognizes that a patent is a type of property: "Patents shall have all the attributes of Personal Property." This means that a drug company has the exclusive right to use, control, and profit from a patent for the entire 20-year term.

Extension of Piracy

The economic value of a patent is derived from the profits earned during the legally protected time an inventor has sole rights to market and profit from his creation. However, the FDA's version of due process seriously reduces the value of a pharmaceutical company's property by cutting in half the effective life of patents. Some constitutional authorities suggest that firms ought to receive compensation for their loss under the "takings" clause of the Fifth Amendment. A simpler and fairer solution—and one that would staunch the need for ancillary patents—would be a new law stating that the 20-year patent term starts only after a product receives regulatory approval.

Patent pirates, however, want to steal even more of a drug company's property. Their justification is the need for "humanitarian" aid. They offer the notion that it is unethical for companies such as GlaxoSmithKline, Roche and Pfizer to put their patents and profits above the suffering of those in Africa and other needy places who are afflicted with HIV, malaria, tuberculosis and other treatable diseases.

"I believe it is evil," says Larry Kramer, founder of the Act Up organization, "for drug companies to possess a means of saving lives and then not provide it to the desperate people who need it. What kind of hideous people have we become? It is time to throw out the selfish notion that these companies have the right not to share their patents."

The pirates' weapon of choice is "compulsory licensing": government confiscation of the fruits of medical research. The 2001 Doha Declaration on the Trade Related Aspects of Intellectual Property Rights states that any WTO member country can pirate any pharmaceutical patent if it declares a "national emergency" or "extreme urgency." The declaration also says "least developed" countries can bust any drug patent for any reason—national emergency or not—until 2016. The Doha agreement legalizes the theft of a drug company's property by declaring that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted—it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or circumstances of extreme urgency."

Compulsory licensing was used by Brazil to bust the patent of Pfizer's protease inhibitor Viracept—an act of plunder justified by health minister Jose Serra on the grounds that "we must insist that lives come before profits." It permits generics in India, for example, to pilfer Roche's anti-HIV drug Fuzeon, and gives them legal cover to steal sildenafil, the active ingredient in Viagra, and then to sell it to pharmacists in Italy, who then manufacture knock-off Viagra. During the anthrax scare, the Canadian government used compulsory "licensing" to loot Bayer's patent on Cipro—an act of theft also threatened by the United States until Bayer agreed to sell it Cipro for pennies on the dollar.

The debate today is no longer over the justice of this legalized pirating, but rather over how poor countries will make the pirated drugs. They lack manufacturing capacity and the Doha Declaration does not yet allow them to transfer their compulsory license to an industrialized country.

Inhumane Regulation

FDA regulatory process and delay is responsible for real damage to consumers. Over the past decade,

despite numerous scientific and technological innovations, the average cost of drug development doubled from \$400 million to \$800 million. According to former FDA official Dr. Henry Miller, "costs are spiraling out of control because the FDA meddles endlessly in clinical trials and keeps raising the bar for approval. The average number of clinical trials performed on an average drug increased from 30 in the early 1980s to 68 during 1994-1995, while the average number of patients in clinical trials for each drug more than tripled."

When the FDA debases a drug patent by cutting in half its effective life, it kills Americans. "By a conservative estimate," says Robert Goldberg, Director of the Manhattan Institute's Center for Medical Progress, "FDA delays in allowing U.S. marketing of drugs used safely and effectively elsewhere around the world have cost the lives of at least 200,000 Americans over the past 30 years."

The FDA delayed for seven years the approval of beta-blockers as heart medication. According to Dr. Louis Lasagna, former director of Tuft University's Center for the Study of Drug Development, about 119,000 Americans died because of the delay. Thousands more died unnecessarily when the FDA took 3½ years to approve the kidney cancer drug Interleukin-2. Untold numbers with certain types of advanced prostate or lung cancer have suffered and died senselessly because the FDA made it illegal to purchase cancer vaccines such as Provenge and growth-factor inhibitors such as Iressa.

Such are the consequences of believing that it is humane to violate an inventor's property rights.

Price of Investment

We all marvel at the new drugs and medical devices that continuously improve and lengthen human life. Yet nobody raises the alarm that patents—the moral and legal foundation of the industry—are under assault. Part of the reason for this complacency is that people recklessly call these inventions "miracle medicines," as if they emit from a genie's lamp.

The fact is that drug invention requires a complex process of scientific thinking, a high degree of managerial skill, and the long-range risk of massive capital. As patent piracy increases, drug companies are less able and less willing to take those risks.

"The progressive development of man," said Nikola Tesla, "is vitally dependent on invention. It is the most important product of his creative brain. Its ultimate purpose is the complete mastery of mind over the material world, the harnessing of the forces of nature to human needs. This is the difficult task of the inventor, who is often misunderstood and unrewarded."

The right to patent secures a creator's property right to his invention. We should not be fooled into thinking that it is "practical" or "necessary" or "humane" to violate another person's right, or a corporation's right, to property. ■