

Patents and Health: The situation in industrialized countries

Thiru Balasubramaniam, Knowledge Ecology International

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A word from Bayer CEO Marijn Dekkers

“We did not develop this medicine for the Indian market. We developed it for Western patients who can afford it.”

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Compulsory licensing as a remedy to anti-competitive practices (US)

November 1995: Pharmacia/Upjohn merger

- In this dispute, the Federal Trade Commission (FTC) objected to the market share the combined company would have in the market for anticancer drugs known as a topoisomerase I inhibitors. Pharmacia had a topoisomerase I inhibitor in development known as 9-AC and Upjohn had one called CPT-11.

January 2001: Ciba-Geigy/Sandoz Ltd Merger

- Ciba-Geigy and Sandoz were required to license a large portfolio of patents, data and know-how relating to HSV-tk products, hemophilia gene rights and other products to Rhone- Poulenc Rorer. The new merged entity was also required to grant non-exclusive licenses to all requesters for patent and other rights to Cytokine products, with royalties that can be no greater than three percent (3%) of the net sales price and the Anderson gene patent for one percent.

Compulsory licensing as a remedy to anti-competitive practices (Europe)

Italy

- Merck antibiotic (Imipenem Cilastatina) patents (2005)
- Glaxo patents on migraine drug (2006)
- Merck patents on prostate cancer and male-pattern baldness drug (2007)

Germany

- Roche requests compulsory license to Chiron patents on an HCV/HIV diagnostic tool (2000)
- Shire asks German Court for compulsory licenses to Mount Sinai Fabry's Disease Patents (2011-201-2)

eBay Inc v. MercExchange, L.L.C., 547 U.S. 388 (2006)

The Supreme Court of the United States unanimously determined that an injunction should not automatically be available merely because of a finding of patent infringement. Instead, courts are required to weigh four factors to determine if an injunction should be issued. Quoting from the opinion:

“That test requires a plaintiff to demonstrate:

- (1) that it has suffered an irreparable injury;
- (2) that remedies available at law are inadequate to compensate for that injury;
- (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction. The decision to grant or deny such relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion.”

Edwards Lifesciences AG v. CoreValve, LLC, 2011

On February 7, 2011, a federal judge in Delaware rejected a request for an injunction to prevent the continued infringement of United States Patent No. 5411552, for "Valve prosthesis for implantation in the body and a catheter for implanting such valve prosthesis."

1. The compulsory licensing of the patent involves a medical technology -- at a time when the Obama Administration is trying to block mention of compulsory licensing of medical patents at a UN high level meeting on non-communicable diseases.
2. At least for now, the compulsory license will be used exclusively for manufacturing and exporting the infringing medical device. This is an example of how a compulsory license issued under Part III of the TRIPS is not bound by the restrictions on exports under a compulsory license granted under Article 31 of the TRIPS (31.f), or even the 30 August 2003 Decision of the WTO to implement Para 6 of the Doha Declaration on TRIPS and Public Health.
3. The decision to order the compulsory licensing of the invention was in part to avoid the relocation of the manufacturing from the United States to Mexico. That is, the compulsory licensing of the patent saved U.S. manufacturing jobs that would have otherwise gone to a country with no patent for the invention.

Edwards Lifesciences AG v. CoreValve, LLC, 2011

With regard to the export of the infringing product, the Court noted:

Edwards' allegations of irreparable harm are undercut because CoreValve's infringement stems not from sales of the accused product, all of which occurred outside the United States, but rather from the manufacturing of the accused product in the United States.[13] Thus, Edwards must establish that CoreValve's manufacturing operations in the United States are continuing and will continue to cause irreparable harm if not enjoined. Edwards, however, does not appear to dispute that CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States.[14] (See, e.g., D.I. 402 at 1 ("Even now, CoreValve admits that it has been moving off shore to Mexico since January 2010 and could immediately ramp up manufacturing there."); id. at 7-8; D.I. 357 at 15.) Thus, CoreValve would remain in the market with little or no interruption even if the court were to enjoin its infringing manufacturing operations in the United States, and an injunction thus would not affect the alleged harm.

October 2001 - Canada, US, anthrax and ciprofloxacin

US

In 2001, DHHS Secretary Tommy Thompson used the threat to use 28 USC 1498 to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.

New York Times - October 19th, 2001

Canada, taking an unusual step that the United States has resisted, said yesterday that it had overridden Bayer's patent for Cipro, an antibiotic to treat anthrax, and ordered a million tablets of a generic version from a Canadian company.

"These are extraordinary and unusual times," said Paige Raymond Kovach, a spokeswoman for Health Canada. "Canadians expect and demand that their government will take all steps necessary to protect their health and safety."

October 2001 - Canada, US, anthrax and ciprofloxacin

Economist - October 25th, 2001

WHEN is it right for a government to grab a company's patent rights in the interest of public health? Scared by the anthrax outbreaks south of the border, Canada's health ministry decided that public health came first. It commissioned a generic drug company to make a million doses of ciprofloxacin, a drug used to treat one of the nastier forms of the disease, for the national stockpile. But the patent to Cipro belongs to Bayer, a German drug giant. Bayer protested that it could supply Canada's needs and that, by turning to a generic rival, the ministry had broken the law. Canada's Cipro saga ended this week: Bayer donated hundreds of thousands of tablets now and promised to deliver a million later in case of an emergency. But the issue will remain. American officials too threatened to follow Canada's example in order to ensure a steady supply of drugs.

There is an irony here. Other countries want to bend patent rules in the interests of public health; indeed, this is what Brazil, South Africa and other poor countries battling with AIDS have been trying to do. And yet, these countries have come under attack from the developed world, particularly America, for subverting international intellectual-property rules. But surely millions of victims of HIV in Kenya are as much of a national emergency as a dozen cases of anthrax in America?

UK - Access to T-DM1

On October 1st, 2015, the Coalition for Affordable T-DM1, a group of cancer patients, doctors, and access to medicines advocates, sent a letter to the UK Secretary of State for Health, Jeremy Hunt, requesting the UK government to authorize the manufacture or importation of generic versions of the expensive breast cancer treatment T-DM1.

T-DM1 is used to treat late-stage breast cancer patients who test positive for a protein that causes an aggressive form of breast cancer. Roche holds the patents on T-DM1, and charges extraordinarily high prices. A year of treatment for the average patient costs £102,405, roughly 3.9 times the UK's income per capita in 2014.

On 8 August 2014, the National Institute for Health and Care Excellence (NICE) decided that T-DM1 should not be made available on the National Health Service (NHS), citing its extraordinarily high cost. NHS patients in England continued to get access to T-DM1 through the Cancer Drug Fund (CDF). The Cancer Drug Fund, however, does not extend to patients living in Northern Ireland, Scotland and Wales, demonstrating the disparity in access to high-cost medicines that exists even within one nation.

Sanders offers amendment to create compulsory licenses on medicines, for veterans

Senator Bernie Sanders proposed legislation in the US Senate to expand access to hepatitis C virus (HCV) treatments for veterans, by limiting the compensation to patent holders when prices for products are excessive and if the outlays on the products would exceed the budgetary resources available for veterans.

The amendment offered by Sanders made explicit and concrete the policy objective of providing access for "all veterans", and ensured that the agencies limited budget would be considered a constraint on the royalty payments, rather than on access. Instead of putting patients at risk, the amendment put the patent monopoly at risk.

