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Consumer and Pharmaceutical Dimensions of Addressing Bio-Terrorism: An Analysis of In re Ciprofloxacin Hydrochloride Antitrust Litigation

James T. Gathii
Loyola University Chicago, School of Law, jgathii@luc.edu

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By James Thuo Gathii

A few short weeks after the September 11 terrorist attacks, the Eastern District of New York issued its decision in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.[1] Seen against the background of these attacks, the tremendous loss of life and the ensuing bio-terrorist threat posed by at least five anthrax-related fatalities between September 11 and November 22, 2001, the significance of this little-noticed antitrust decision begins to emerge.[2] In fact, the need on the part of the United States to amass a stockpile of Ciprofloxacin in response to the bio-terrorist threat[3] needs to be seen in light of the way in which Bayer's control of the market for this patented drug prior to September 11, 2001, was unreasonably restraining its availability.

This suit was a consolidated action against Bayer A.G., a German corporation and its American subsidiary, Bayer Corporation, by prescription drug consumers from various states. Bayer is the sole manufacturer of the popular antibiotic Ciprofloxacin. Ciprofloxacin has led worldwide sales of all antibiotics for at least the last eight years. It is also the 11 most-prescribed drug in the United States. It has earned Bayer more than $1 billion in sales revenue. Bayer holds a patent over '444, the active ingredient in Ciprofloxacin. The patent was filed with the Patent and Trademark Office on May 29, 1984, and issued to Bayer on June 2, 1987.

The consumers contended that Bayer had violated state antitrust laws by depriving them of their right to a market in which manufacturers and distributors of generic equivalents of Ciprofloxacin made their decisions about challenging patents and entering the market free from the influence of cash payments from Bayer to these generic manufacturers and distributors. The consumers therefore argued that these cash payments amounted to unreasonable restraints of trade contrary to state antitrust and consumer laws.

The facts leading to Bayer's cash payments to Barr Laboratories are as follows. In October 1991, the generic manufacturer referred to here, Barr Laboratories, had challenged Bayer's '444 patent under the Drug Price Competition and Patent Term Restoration Act of 1994 (known as the Hatch/Waxman Act). The Hatch/Waxman Act encourages generic manufacturers to compete in the sale of patented drugs by manufacturing bio-equivalent generics of already patented drugs. It does this by telescoping the long and expensive process of verifying the safety and efficacy of the drug to the Food and Drug Administration (FDA).[4] To benefit from expeditious FDA approval, a generic manufacturer needs to demonstrate to the FDA that its bio-equivalent generic contains the same active ingredient as the drug already approved by the FDA and that it will not infringe on the patented drug. Alternatively, a generic manufacturer would have to demonstrate to the FDA that the patented drug is invalid for specified factual and legal reasons in an Abbreviated New Drug Application (ANDA) filing.[5]

Bayer filed a patent suit challenging Barr Laboratories' ANDA filing claim that its '444 patent was invalid and unenforceable. Bayer lost this patent suit. As a result, Bayer entered into a settlement agreement with Barr Laboratories and other parties to the patent suit. As part of the agreement, Bayer agreed to pay Barr Laboratories over $100 million. In consideration, Barr Laboratories agreed to drop its challenge to the validity of Bayer's patent and its plans to market generic Ciprofloxacin as contemplated in its ANDA filing.[6]

It is this agreement that Ciprofloxacin prescription consumers challenged in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*. The consumers contended that Bayer's execution of the agreement constituted an unlawful restraint of trade in the market for Ciprofloxacin, particularly because it effectively eliminated the possibility of generic competition. The consumers further contended that by requiring Barr Laboratories to recognize the validity of Bayer's '444 patent, Bayer caused them injury since they were precluded from having access to generic Ciprofloxacin at a lower price than Bayer charged for its patented bio-equivalent.

Though the case before the United States Eastern District of New York substantially involved Bayer's removal of the case to federal court on grounds of federal question jurisdiction, the court's determination is instructive of the legal quandary surrounding the relationship between patent monopoly, antitrust,[7] and public health. This quandary may be simply characterized by two apparently opposing claims. The first favors a strong regime of patent rights as a necessary incentive for inventors to profitably exploit resources. The second perspective is an anti-cartelist perspective that simultan

ously incorporates the interests of inventors with those of the consumers of patented products.

According to the first of these claims, a strong property rights regime as embodied in the 20-year patent monopoly allowed under U.S. intellectual property laws is a necessary incentive to inventors to enable them to undertake the risk involved with the high costs of research and development associated with new drug development without fearing that they will be unable to recoup these costs or to be adequately rewarded for investment. The monopoly period achieves this result by preventing competitors from selling the patented product so that the inventor is able to recoup research and development costs.

The second of these claims, the anti-cartelist or balancing perspective, arguably finds authority in the Constitution's patent and copyright clause.[8] Hence, in *Brenner v. Manson*, the Supreme Court, in affirming a Patent Office decision to decline extending a patent for a process since it was not 'new and useful,' observed:

> . . . a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful . . . It may engross a vast, unknown, and perhaps unknowable area. *Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.*[9] (emphasis added) (footnote omitted).

Hence, under this view the patent monopoly is granted to an inventor in return for the inventor producing a benefit to society. This view contemplates a balance between the interests of the inventor and the consuming public. Where the balance tilts too heavily either in favor of intellectual property rights, on the one hand, or in favor of the intellectual commons, on the other, some scholars have argued that the public loses its constitutionally protected right to a vigorous public domain.[10] According to this argument, a vigorous intellectual commons is only possible where the availability of information, knowledge and other raw data is free from monopoly control and available both to the public and the private sector in order to encourage education, research, new discoveries and free speech.

Similarly, the consumers in *In re Ciprofloxacin* argued that the agreement between Bayer and Barr Laboratories tilted the market in favor of Bayer in contravention of state antitrust and consumer laws by deterring generic manufacturers from entering the market for Ciprofloxacin with the result that they were foreclosed from purchasing the drug at a competitive price, or at a minimum that they were precluded from purchasing the drug at a lower price. The premise of the consumers' case was therefore arguably predicated on the view that free competition was the best pricing mechanism for Ciprofloxacin and that the agreement between Bayer and Barr Laboratories constituted a profit-sharing arrangement that resulted in an antitrust injury to them. The consumers argued that Bayer was using its market power to restrict competition in Ciprofloxacin, which constituted an illegal misuse of its patent monopoly.

By contrast, Bayer contended that consumers have no right to purchase competing products that infringed on their patent. In essence, for the consumers to succeed on their antitrust claim against Bayer, the consumers had to show that the '444 patent was invalid. To put it starkly, Bayer argued that the existence of a valid patent forecloses the possibility of any antitrust injury. The primary issue before the Eastern District of New York can therefore be framed as follows: Does the patent 'exception' to antitrust injury swallow the prohibitions against monopolies and trusts as a whole, even when the holder of a valid patent may otherwise be subject to liability for conduct amounting to an unreasonable restraint of trade?

The court declined to agree with Bayer and observed that to argue "that existence of a valid patent forecloses the possibility of any antitrust injury, suggests that patent holders, by virtue of their intellectual property rights, wield almost limitless power to control the market for the patented product."[11] In essence, the patent exception, the court held, does not swallow or preclude antitrust injury.

About one month after losing this case, the anthrax scare and the attendant fears of a bio-terrorist attack put Bayer in yet another predicament over its blockbuster drug, Ciprofloxacin. There were immediate calls to amass Ciprofloxacin since it is the widely preferred antibiotic for patients infected with anthrax. Although the *In re Ciprofloxacin* decision was forgotten in the aftermath of the terrorist attacks, it arguably formed part of the backdrop for Bayer's considerations regarding its negotiations with the federal government to create a stockpile of Ciprofloxacin.

One alternative the government has under federal law, besides subsidizing Bayer to stockpile the drug, is its eminent domain powers to override the patent by issuing compulsory licenses to generic companies to manufacture the drug.[12] The government considered but did not invoke this power; instead it entered into an agreement with Bayer under which it agreed to subsidize Bayer's production of 1.2 billion Ciprofloxacin pills for stockpiling.[13] This stockpile would, according to Health

and Human Services Secretary Tommy Thompson, be adequate to protect at least 10 million Americans on a two-pill regimen for 60 days in the event of a bio-terrorist attack. Under this agreement between the government and Bayer, Bayer initially agreed to lower the drugstore price of $4.50 per pill to $1.89 per pill. Eventually, Bayer agreed to further lower the price of a pill to 95 cents. For its initial order of 100 million pills, the United States government therefore agreed to pay Bayer $95 million.[14]

Notwithstanding Bayer's concession to lowering the price of the drug, observers have noted that the government shortchanged American taxpayers since Indian companies sell a generic version of the same drug for less than 20 cents.[15] In other words, American consumers would have been better off if the government had invoked its eminent domain powers by issuing compulsory licenses to generic manufacturers to produce Ciprofloxacin at a lower cost and in greater quantities as a safeguard against a bio-terrorist threat.[16] Hence, critics of the federal government have argued that it sacrificed public health on the altar of intellectual property rights by allowing Bayer to continue to be the sole supplier of Ciprofloxacin.[17]

There is yet another consideration that factored into the U.S.'s refusal to issue compulsory licenses over Cipro. The U.S. does not want to undermine the legitimacy of its negotiating position with developing countries over whether the World Trade Organization (WTO) treaty, the *Trade Related Aspects of Intellectual Property Rights* (the TRIPS Agreement, which took effect on January 1, 1996), allows these countries to override patents to enable them to effectively address the HIV/AIDS pandemic. The U.S. has consistently opposed efforts by developing countries to override patent protection that would enable them to produce generic equivalents of the patented drugs used in the treatment of HIV/AIDS patients.[18]

According to the U.S., the TRIPS Agreement only accommodates developing country interests by giving them longer transition periods to come into compliance with the Agreement. The TRIPS Agreement, the U.S. has argued, does not authorize developing countries to override patents. Least developed countries have until 2006 (10 years) to come into compliance with the TRIPS Agreement and they could have more time with the WTO's approval. The U.S. has, however, maintained that least developed countries have to make a case for extension of this 10-year period, since they have not yet implemented the TRIPS Agreement and could not therefore make a case against implementing it on the basis of its impact on their public health programs.

According to the Director of UNAIDS, 20 million of the 60 million people infected with HIV/AIDS in the first 10 years of the epidemic are dead, the fastest death rate of any health epidemic.[19] In sub-Saharan Africa the leading cause of death continues to be HIV/AIDS. By 1999, at least 15 million Africans had died of HIV/AIDS and another 25 million were living with the disease. In the same year, four million were newly infected. Infection rates in southern African countries were as high as 35 percent of the population in Botswana; 25 percent in Zimbabwe and Swaziland; 23 percent in Lesotho; and 2. percent in South Africa. These horrifying statistics continue to be deployed in pressuring the U.S. to yield its position of preventing the overriding of patent protection to address the HIV/AIDS pandemic.

As a result, in the recently concluded WTO ministerial meeting in Doha, Qatar, a Declaration on TRIPS and Public Health was passed. The declaration seeks to encourage WTO members to interpret the obligations in the TRIPS Agreement not solely from the perspective of how policies and laws of member countries seeking to address the HIV/AIDS pandemic curtail rights of patent holders, but also from the perspective of how such laws or policies safeguard consumer interests in the provision of low-cost medicine.[20]

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To conclude, the decision of the United States District Court for the Eastern District of New York in *In re Ciprofloxacin* is only the tip of the iceberg. This decision, particularly following the threat of bio-terrorism in the United States, raises important questions relating to where the appropriate balance between protecting inventions, encouraging free competition and ensuring public health lies. Within the U.S. domestic context, the balance between patent protection and free competition has received considerable attention as exemplified in *In re Ciprofloxacin*. However, balancing the law as applied by the Eastern District with the public health concerns that arose following the bio-terrorism threat after September 11, 2001, is a challenge that has only begun to emerge. At the international level, the emerging emergency exception to patent protection is also undergoing excruciating birthing pains. Public health considerations sparked by threats of bio-terrorism and the HIV/AIDS pandemic are therefore beginning to challenge the boundaries of patent protection at the domestic and international level more than ever before. This also raises important ethical considerations. For example, can the United States adopt one policy at home to protect its citizens against the threat of bio-terrorism by overriding patent protection, while maintaining its opposition to developing countries

doing the same to address the HIV/AIDS pandemic? The purpose of this brief analysis has been to raise these questions and to point to the challenges that lie ahead without necessarily providing any definitive answers.

Endnotes

1. 166 F.Supp. 2d 740 (E.D.N.Y. 2001).
2. *See* Paul Zielbauer, *A Nation Challenged: The Latest Case—Connecticut Woman, 94, Is Fifth To Die From Inhalation Anthrax*, N.Y. Times, Nov. 22, 2001, at A1.
3. The calls for amassing a stockpile of Cipro were led in part by New York's senior Sen. Chuck Schumer. *See* Timothy J. Burger, *Feds Push Bayer to Boost Cipro Stockpile*, Daily News (New York), Oct. 20, 2001, Saturday Sports Final Edition, at 8.
4. James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 Fla. L. Rev. 727, 771-784 (2001).
5. 21 U.S.C. § 355(j)(2)(A)(vii).
6. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F.Supp. 2d 740, 745 (E.D.N.Y. 2001).
7. There is an endless stream of literature on this subject. *See, e.g.*, Louis Kaplow, *The Patent- Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1815 (1984); Charles C. Hsiehl, Note, *Professional Real Estate: The Line Between Patent and Antitrust*, 7 Harv. J. L. & Tech. 173 (1993); Lawrence Sullivan, *Is Competition Policy Possible in High Tech Markets? An Inquiry Into Antitrust, Intellectual Property and Broadband Regulation as Applied to the 'New Economy'* , 52 Case W. Res. L. Rev. 41-90 (2001); James Langenfeld, *Intellectual Property and Antitrust: Steps in Striking a Balance*, 52 Case W. Res. L. Rev. 91-110 (2001). For federal policy, *see* Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property, reprinted in* 4 Trade Reg. Rptr. (CCH) 13, 132 (1995). For recent comments by current FTC Chairman, *see* Timothy J. Muris, *Robert Pitofsky: Public Servant and Scholar*, 52 Case W. Res. L. Rev. 25 (2001).
8. Art. I, § 8, cls. 8, 18 provide in part that "The Congress shall have power . . . [t]o promote the progress of Science and useful arts, by securing for limited times to Authors and Inventors the exclusive right to their discoveries . . . And [t]o make all Laws which shall be necessary and proper for carrying into Execution the foregoing powers."
9. *Brenner v. Manson*, 383 U.S. 519, 534 (1965). Note, though, that in recent times courts have lowered the threshold of patentability. For example, in *Diamond v. Chakrabarty*, 447 U.S. 303, 30-7, 318 (1980), the Supreme Court expanded the scope of intellectual property rights in the absence of express congressional authorization by holding that non-naturally occurring manufacture (or genetically created micro-organisms or life forms) qualify as patentable subject matter. Similarly, in *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F. 3d 1368, 1377 (Fed. Cir. 1998), the scope of patentable subject matter was extended to include a business method. Observed the Federal Circuit Court of Appeals, "the mere fact that a claimed invention involves imputing numbers, calculating numbers, out-putting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless . . . its operation does not produce a 'useful, concrete and tangible result'". *Id.* at 1374.
10. Lawrence Lessig, *Code and Other Laws of Cyberspace* (1999); Keith Aoki, *(Intellectual) Property and Sovereignty: Notes Toward a Cultural Geography of Authorship*, 48 Stan. L. Rev. 1293 (1996).
11. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F.Supp. 2d 740, 749 (E.D.N.Y. 2001).

    28 U.S.C. § 1498(a) provides that the U.S. government does not have to seek a license or negotiate for use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright. The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent use. Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement. Compensation is not based on lost profits or royalties, but rather on reasonable royalty, or as one court has put it, since compensation is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained.' *Leesona Corp. v. United States*, 599 F. 2d. 958, 964(Ct. Cl. 1979). Section 1498(a) explicitly provides that it shall not have extra-territorial effect.
13. *See Burger, supra* note 3 (reporting that Health and Human Services Secretary Tommy Thompson had rejected an assertion by Sen. Chuck Schumer "that the government would save money by using its legal power to authorize other manufacturers to use Bayer's patent on Cipro." *Id.*
14. Press Release, HHS Press Office, *HHS, Bayer Agree to Cipro Purchase* (Oct. 24, 2001), *available at* http://www.hhs.gov/news/press/2001pres/20011024.html.
15. Russel Mokhiber & Robert Weissman, *The Cipro Rip-Off and the Public Health*, ZNET Daily Commentaries, Dec. 2, 2001, *available at* http://www.zednet. Secretary Thompson is reported to have been advised that the "United States would have to pay damages if it ordered generic Cipro, which could make the move expensive." In essence, the administration defended its unwillingness to override the Cipro patent on the ground that the federal government would have had to await an uncertain judicial determination of the extent of damages that it would pay Bayer. This, the Bush administration argued, was a far more expensive option than negotiating with Bayer to produce mass quantities of the drug. H.R. 3235, currently pending before the House of Representatives, seeks to provide the federal government with administrative authority to undertake compulsory licensing of certain patented drugs relating to health care emergencies rather than awaiting a judicial determination of the damages under present law. *See* James Love, *[IPN]CPTech Comments on H.R. 3235, the Public Health Emergency Medicines Act*, available at http://www.cptech.org. For H.R. 3235, *see* http://rs9.loc.gov/cgi-bin/bdquery/z?d107:HR03235@@@x.
16. *See* Letter from Ralph Nader and James Love to DHHS Secretary Tommy Thompson dated Oct. 18, 2001, *available at* http://www.cptech.org/ip/health/cl/cipro/nadethom/10182001.html.
17. For a similar story in Canada, *see also* David Olive, *It's Sad Sight to See Ottawa Ready to Give in to Bayer on Drug*, The Toronto Star, Mar. 20, 2002, available at http://www.thestar.com.
18. Cecilia Oh, *Developing Countries Call for Action on TRIPS at Doha WTO Ministerial Conference*, Third World Network Online, available at http://www.twnside.org.sg/title.twr.131d.htm..
19. *See* Peter Piot, UNAIDS Executive Director, Testimony to the hearing of the Committee on Foreign Relations of the United States Senate on *Halting the Global Spread of HIV/AIDS: the Future of U.S. Bilateral and Multilateral Responses* (Feb. 13, 2002), transcript available at http://www.unaids.org/whatsnew/speeches/eng/2002/PiotSenate_130202.html.
20. See James Thuo Gathii, *The Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, Harv. J. L. & Tech. (forthcoming 2002). For a contrary view, *see* Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution'*, John M. Olin L. & Econ. Working Paper No. 140 (2D Series), available at http://www.law.uchicago.edu/Lawecon/index.html.

James Thuo Gathii is an Assistant Professor of Law at Albany Law School. He focuses on the areas of International and Business Law.