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Balancing Patent Rights and Affordability of Prescription Drugs in Addressing Bio-Terrorism: An Analysis of In Re Ciprofloxacin Hydrochloride Antitrust Litigation

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BALANCING PATENT RIGHTS AND AFFORDABILITY OF PRESCRIPTION DRUGS IN ADDRESSING BIO-TERRORISM: AN ANALYSIS OF *IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION*

James Thuo Gathii *

On 1 October 2001, barely one month after the September 11 terrorist attacks on America, the United States Eastern District Court of New York issued its decision *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (*In re Ciprofloxacin*).[1] Seen against the background of attacks—the tremendous loss of life on September 11 and the ensuing bio-terrorist threat posed by at least five anthrax-related fatalities between September 11 and November

* Assistant Professor, Albany Law School. This paper discusses many of the themes presented in an earlier version of this paper, which was devoted to issues in the aftermath of September 11, 2001. This earlier version can be found at 4, 1 GOV'T LAW AND POL'Y J. 46–49 (2002).

[1] 166 F. Supp. 2d 740 (E.D.N.Y. 2001).

22, 2001[2]—the significance of this unnoticed antitrust decision has begun to emerge. 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] has shed light on the way in which Bayer's control of the market for this patented drug prior to 11 September 2001 unreasonably restrained its availability.

This suit was a consolidated action against Bayer A.G. (Bayer), a German corporation and its American subsidiary, Bayer Corporation, by prescription drug consumers from various states.[4] Bayer is the sole manufacturer and patent owner of the popular antibiotic Ciprofloxacin, which is held under patent number 4,670,444 ('444).[5] The patent was filed with the Patent and Trademark Office on 29 May 1984 and issued to Bayer on 2 June 1987.[6] For at least the last eight years, Ciprofloxacin has led worldwide sales of all antibiotics.[7] It is also the eleventh most-prescribed drug in the United States.[8] Bayer has earned more than $1 billion in sales revenue from Ciprofloxacin.[9]

Consumers contended that Bayer violated state antitrust laws by depriving them of their right to a market in which manufacturers and distributors of generic equivalents of Ciprofloxacin existed.[10] These consumers, specifically, alleged that manufacturers and distributors of generic equivalents to Ciprofloxacin made their decisions to challenge Bayer's patents and enter new markets based upon the influence of cash payments from Bayer.[11] The consumers, therefore, argued that these cash payments amounted to unreasonable restraints of trade, contrary to state antitrust and consumer laws.[12]

The facts leading to Bayer's cash payments to Barr Laboratories are as follows. In October 1991, generic manufacturers, lead by

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[2] *See, e.g.*, Paul Zielbauer, *A Nation Challenged: The Latest Case; Connecticut Woman, 94, Is Fifth from Inhalation Anthrax*, N.Y. TIMES, Nov. 22, 2001, at A1.

[3] *See* Timothy J. Burger, *Feds Push Bayer to Boost Cipro Stockpile*, N.Y. DAILY NEWS, Oct. 20, 2001, at 8 (noting calls for the United States Government to amass a stockpile of Ciprofloxacin were led in part by Sen. Chuck Schummer (D-N.Y.)).

[4] *See In re Ciprofloxacin*, 166 F. Supp. 2d at 743.

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *In re Cirprofoxacin*, 166 F. Supp. 2d at 742.

[11] *Id.* at 745.

[12] *Id.*

Barr Laboratories, challenged Bayer's '444 patent[13] under the Drug Price Competition and Patent Term Restoration Act of 1994 (Hatch/Waxman Act).[14]

In response, Bayer filed a patent suit challenging Barr Laboratories' Abbreviated New Drug Application (ANDA) filing claim.[15] Bayer's suit placed a stay on the FDA's ANDA ruling.[16] As a result, Bayer entered into a settlement agreement with Barr Laboratories, among other parties to the patent suit.[17] As part of the agreement, Bayer agreed to pay Barr Laboratories, and the other generic manufacturers involved, over $100 million.[18] 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.[19]

It is upon this agreement that consumers using Ciprofloxacin challenged Bayer. Consumers contended that Bayer's execution of the agreement constituted an unlawful restraint of trade in the market for Ciprofloxacin by effectively eliminating the possibility of generic competition.[20] In particular, consumers 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 generically made Ciprofloxacin offered at a lower price than Bayer charged for its patented bio-equivalent.[21]

Though the case before the United States Eastern District of New York substantially involved a determination as to Bayer's removal of the case from state to federal court on the grounds of

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[13] *Id.* at 743.

[14] *See generally* 21 U.S.C. § 355 (2000). The Hatch/Waxman Act provides a "simplified and shortened method of obtaining [Food and Drug Administration] (FDA) approval to bring generic bio-equivalent drugs to the marketplace." *In re Ciprofloxacin*, 166 F. Supp. 2d at 743. *But see* 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, 771–84 (2001). *See* § 355(j)(2)(A)(vi)–(viii). 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. *Id.* Alternatively, a generic manufacturer can demonstrate to the FDA that the patented drug is invalid due to specified factual and legal reasons found in its Abbreviated New Drug Application (ANDA) filing. § 355(b)(2)(A)(iv).

[15] *In re Ciprofloxacin*, 166 F. Supp. 2d at 744.

[16] *Id.* at 744.

[17] *Id.* at 745.

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *In re Ciprofloxacin*, 166 F. Supp. 2d at 745.

federal question jurisdiction, the Court's determination is instructive as to the legal quandary surrounding the relationships between patent monopoly, antitrust,[22] and public health law. This quandary may be simply characterized by two apparently opposing claims. The first of these claims favors a strong regime of patent rights as a necessary incentive for inventors to exploit resources profitably.[23] The second perspective is an anti-cartelist perspective that simultaneously incorporates interests of inventors with those of consumers.[24]

As embodied in its lengthy term—twenty-year patent protection,[25] United States patents are a necessary incentive for inventors, allowing them to undertake the risks that go with the high costs of research and development (R&D).[26] The monopoly period allows the inventor to recoup any losses by preventing competitors from selling the patented product during its grace period.

The anti-cartelist viewpoint finds authority in the Patent and Copyright Clause of the United States Constitution.[27] In *Brenner v. Manson*,[28] the United States Supreme Court in affirming a Patent Office decision to decline extending a patent since it was not "new and useful" invoked the patent clause and 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 . . . [i]t may engross a vast, unknown, and perhaps unknowable area. *Such a patent may confer power to*

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[22] 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); Note, *Professional Real Estate: The Line Between Patent and Antitrust*, 7 HARV. J.L. & TECH. 173 (1993); Lawrence A. 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 (2001); James Langenfeld, *Intellectual Property and Antitrust: Steps Toward Striking a Balance*, 52 CASE W. RES. L. REV. 91 (2001).

[23] *See* Langenfeld, *supra* note 22, at 99.

[24] *See* Note, *supra* note 22, at 1818–19.

[25] 35 U.S.C. § 154(a)(2) (2000).

[26] *But c.f.* Sullivan, *supra* note 22, at 63 (arguing that if R&D grants continue to grow per company, competition will eventually be stifled).

[27] U.S. CONST. art. I, § 8, cl. 8. The United States Constitution provides in part that Congress shall have the power "[t]o promote the progress of Science and useful arts, by securing for limited times to [a]uthors and [i]nventors the exclusive Right to their . . . discoveries." *Id.*; *see also* U.S. CONST. art. I, § 8, cl. 18. Further, Congress shall also have the power "[t]o make all Laws which shall be necessary and proper for carrying into Execution [its] foregoing powers." *Id.*

[28] 383 U.S. 519 (1966).

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.[29]

Hence, under this view the patent monopoly is granted to an inventor in return for the inventor producing a benefit to society.[30] This view contemplates a balance between the interests of the inventor and the public using the patented product.[31] Where the balance tilts too heavily either in favor of intellectual property rights, on the one hand, or in favor of the intellectual commons,[32] on the other hand, some scholars have argued that the public loses its constitutionally protected right to a vigorous public domain.[33]

Additionally, 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, and foreclosed consumers from purchasing the drug at a competitive or lower market price.[34] The premise of the consumers' case was, therefore, arguably predicated on the view that free competition was the best pricing mech-

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[29] *Brenner*, 383 U.S. at 534 (emphasis added). Note though that in recent times courts have lowered the threshold for patentability. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980). In *Diamond*, the United States 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. *Id.* at 310; State St. Bank and Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1374 (Fed. Cir. 1998). In *Signature*, the scope of patentable subject matter was extended to include a business method. *Id.* at 1374. The Federal Circuit Court of Appeals found, "the mere fact that a claimed invention involves inputing numbers, calculating numbers, outputting 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.*

[30] *See* Imperial Chemical Indus., PLC v. Barr Laboratories, 795 F. Supp. 619, 625 (S.D.N.Y. 1992).

[31] *Id.*

[32] A vigorous intellectual commons is only possible where the availability of information, knowledge and other raw data free from monopoly control is available to the public and the private sector to encourage education, research, new discoveries and free speech. *See generally* Ashley Packard, *Copyright Term Extensions, the Public domain and Intertextuality Intertwined*, 10 J. INTELL. PROP. L. 1, 18–22 (2002).

[33] *See* LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 122–41 (Basic Books 1999).

[34] *In re Ciprofloxacin*, 166 F. Supp. 2d at 745.

anism for Ciprofloxacin and that the agreement between Bayer and Barr Laboratories constituted a profit-sharing arrangement that resulted in an antitrust injury to them.[35] Further, the consumers argued that Bayer used its market power to restrict competition in the market for Ciprofloxacin and that this 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.[36] In essence, it stated that in order for the consumers to succeed on their antitrust claim against Bayer, the consumers had to show that patent '444 was invalid.[37] 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 United States Eastern District of New York can, therefore, be framed as follows: Does the patent "exception" to an 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 the validity of a patent forecloses the possibility of antitrust injury would suggest that patent holders "by virtue of their intellectual property rights, wield almost limitless power to control the market for the [patented drug]."[38] In essence, the patent exception, the Court held, does not swallow or preclude an antitrust injury.

About one month after losing this case, the anthrax scare and the attendant fears of a bio-terrorist attacks put Bayer in yet another predicament over its blockbuster drug, Ciprofloxacin. During this period, there were calls of urgency to amass Ciprofloxacin since it is the widely preferred antibiotic for patients infected

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[35] *Id.* at 747–48.

[36] *Id.* at 749.

[37] *Id.*

[38] *Id.* On 20 May 2003 the Eastern District of New York issued its ruling on the issue as to whether there was an antitrust violation. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp. 2d 188 (2003). The Court dismissed the claim alleging that Bayer's refusal to issue a license for generic Ciprofloxacin was per se illegal. *Id.* at 257–58. The Court, however, reserved its ruling on whether the agreements between Barr laboratories and Bayer violated the Antitrust laws of at least twelve states that the plaintiffs (consumers) came from. *Id.* at 257. On that issue, the Court observed it was considering appointing an academic expert(s) to provide a report on the relevant state laws. *Id.* at 209–10. The Court further noted that its findings did not indicate the agreements at issue were "conclusively legal." *Id.*

with anthrax.[39] Although the decision in *In re Ciprofloxacin* was forgotten in the aftermath of the terrorist attacks, it arguably formed part of the backdrop in Bayer's argument with respect to negotiations between the federal government and Bayer to stockpile 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.[40] 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.[41] This stockpile, would according to United States Department of Health and Human Services (HHS) Secretary, Tommy Thompson, be adequate to protect at least 10 million Americans on a two-pill regimen for sixty days in the event of a bio-terrorist attack.[42] Bayer initially agreed to lower the drugstore price of $4.67 a pill to $1.77.[43] Eventually, Bayer agreed to lower the price per pill to ninety-five cents.[44] So under the United States initial order of 100 million pills Bayer would receive $95 million.[45]

Notwithstanding the fact that Bayer conceded to lowering the price of Ciprofloxacin, observers have noted that the government

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[39] *See* Burger, *supra* note 3, at 8.

[40] 28 U.S.C. § 1498(a) (2000). The United States government does not have to seek a license or negotiate for the use of a patent or copyright. *Id.* The owner is entitled to compensation for United States Government use, but cannot enjoin the Government or a third party authorized by the Government, against the use. *Id.* Any contractor, subcontractor, person, firm, or corporation who receives authorization from the Government to use a patent or copyright is construed as though it were the Government, and cannot be sued for infringement. *Id.* Compensation is not based on lost profits or royalties, but rather on reasonable royalty, *Id.*, 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, 969 (Ct. Cl. 1979) (citing United States v. Chandler-Dunbar Co., 229 U.S. 53, 76 (1913)).

[41] *See* Burger, *supra* note 3, at 8 (reporting that United States Department of Health and Human Service (HHS) Secretary Tommy Thompson 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").

[42] Laurie Garret, *America's Ordeal; Deal on Anthrax Drug; Makers of Cipro Agree to Sell at Discount to U.S. Gov't.*, NEWSDAY (New York), Oct. 25, 2001, at A28.

[43] *Id.*

[44] *Id.*

[45] *See id.*

shortchanged American tax-payers since Indian companies sell a generic version of the same drug for less than twenty cents per pill.[46] In other words, American consumers would have been better off if the government invoked its eminent domain powers by issuing compulsory licenses for generic manufacturers to produce Ciprofloxacin at a lower cost and in more quantities as a safeguard against bio-terrorist threats.[47] Hence, critics of the federal government have argued that the United States sacrificed public health for intellectual property rights by allowing Bayer to continue to be the sole supplier of Ciprofloxacin.[48]

There is some good news in this that suggests that Congress may reverse the President's reluctance to override patents. Different versions of the *Greater Access to Affordable Pharmaceuticals Act*[49] have been passed by both the Senate[50] and House of Representatives.[51] Both versions recognize the benefits that generic drugs offer to consumers by providing for accelerated approval of generic drug applications, as well as allowing a drug to be considered a bio-equivalent of a listed drug so long as tests show that the effects have no significant difference. The House version of the bill also allows United States Citizens to import cheaper versions of prescription drugs from Canada. In addition, on 24 October 2002, not too long before the 2002 mid-term elections, the White House reversed course on its opposition to the initiative of speeding up generic drug entry into the market. On that day, President Bush announced a proposed rule that prohibited brand-name pharmaceutical companies from getting multiple

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[46] Russell Mokhiber & Robert Weissman, *The Cipro Rip-Off and the Public Health*, ZNET, Dec. 2, 2001, *at* http://www.zmag.org/sustainers/content/2001-12/02mokhiber-weissman.cfm (last visited June 30, 2003).

[47] CONSUMER PROJECT ON TECHNOLOGY, LETTER FROM RALPH NADER AND JAMES LOVE TO DHHS SECRETARY TOMMY THOMPSON (2001), *at* http://www.cptech.org/ip/health/cl/cipro/nadethom10182001.html (last visited June 30, 2003).

[48] *See id*. *But see* David Olive, *It's a Sad Sight to See Ottawa Ready to Give in to Bayer on Drug*, TORONTO STAR, Oct. 23, 2001, at E03.

[49] As of yet, the Greater Access to Affordable Pharmaceuticals Act must revisit the Senate.

[50] S. 812, 107th Cong. (2002).

[51] Associated Press, *House Backs Drug Imports to Cut Costs*, INTERNATIONAL HERALD TRIBUNE, July 26, 2003, http://www.int.com/articles/104127.htm (last visited June 30, 2003). *But see* H.R. 5311, 107 Cong. (2002); H.R. 5272, 107 Cong. (2002).

thirty-month stays before its drugs' patent protection expired, thereby, delaying entry of cheaper generic drugs to the market.[52]

Going back to the United States refusal to issue compulsory licenses over Ciprofloxacin, there is another consideration that may have led to this outcome. The United States does not want to undermine the legitimacy of its negotiating position with developing countries over whether the Agreement on *Trade-Related Aspects of Intellectual Property Rights*—TRIPS,[53] allows these countries to override patents to enable them to effectively address the HIV/AIDS pandemic.[54] The United States has consistently opposed developing countries in efforts to override patent protection, which would enable developing countries to produce generic equivalents of patented drugs used in order to treat HIV/AIDS patients.[55]

According to the United States, the TRIPS Agreement only accommodates least developing countries by giving them longer transition periods to come into compliance with the Agreement.[56] The TRIPS Agreement, the United States has argued, does not authorize developing countries to override patents.[57] Least developed countries have an extension, after 2006, to come into compliance with the TRIPS Agreement by 2016 and, if needed, additional time can be granted.[58] The United States, however, maintains that these countries should have to make a case for extension of this ten-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.

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[52] President Bush Announces FDA Proposal To Speed Access to Generic Rx Medicines, 71, 16 U.S.L.W. 2822 (2002).

[53] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1884), http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (last visited June 30, 2003) [hereinafter TRIPS Agreement].

[54] See James Thuo Gathii, *The Legal Status of the Doha Declaration on Trips and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 294 (2002).

[55] Cecilia Oh, *US Opposed to Moves to Address Public-Health Concerns about TRIPS*, TORONTO STAR, Oct. 23, 2001, *at* http://www.twnside.org.sg/title/twr131f.htm (last visited June 30, 2003).

[56] *See* Gathii, *supra* note 54, at 292.

[57] *See id.* at 296–97.

[58] Ellen T. Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 41 (2002).

According to the Director of UNAIDS, over 60 million people worldwide have been infected with the HIV/AIDS virus.[59] Since the beginning of the HIV/AIDS epidemic, 20 million of the 60 million people infected with the HIV/AIDS epidemic are dead.[60] In sub-Saharan Africa the leading cause of death continues to be HIV/AIDS.[61] In 2001 at least 2.2 million Africans in this region died of HIV/AIDS and another 28.5 million were living with the disease.[62] In that same year, 3.5 million were newly infected.[63] Infection rates in southern African countries were as high as 38.8% in Botswana, 33.7% in Zimbabwe, 33.4 in Swaziland, 31% in Lesotho, and 20.1% in South Africa.[64] These horrifying statistics continue to be deployed in pressuring the United States to yield in its order, which would allow the HIV/AIDS pandemic to be addressed.

As a result, in the recently concluded WTO Ministerial meeting in Doha, Qatar, a Declaration on TRIPS and Public Health was passed.[65] 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 polices safeguard consumer interests in the purchasing low cost medicine.[66]

Towards the end of 2002, the United States persistently objected to the TRIPS Council regarding the issue of whether countries without manufacturing capacity suffering health emergencies such as HIV/ AIDS could engage countries with manufacturing capabilities to produce essential medicines on its behalf.[67] These scuttled discussions, involving paragraph 6 of the Doha Declaration on TRIPS and Public Health, left for further deliberation to the question of countries experiencing the HIV/AIDS pan-

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[59] UNAIDS, FACT SHEET: SUB-SAHARAN AFRICA (2003), *at* http://www.unaids.org/barcelona/presskit/factsheetsFSssaftrica_en.htm (last visited June 30, 2003).
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *See* Gathii, *supra* note 54, at 298.
[66] *Id.*
[67] HEALTHGAP, THANKS TO U.S. BULLYING, NO DEAL THIS YEAR ON ACCESS TO MEDICINES AT THE WTO: POOR COUNTRIES PREVENT U.S. RE-WRITE OF THE DOHA AGREEMENT ON PUBLIC HEALTH (2002), *at* http://www.healthgap.org/press_releases/02/122002_HGAP_WTO_US_exp.html (last visited June 30, 2003).

demic and whether they could take advantage of the flexibility of overriding patents, which was ostensibly agreed upon in the Declaration. This diatribe came at a time when the Central Intelligence Agency (CIA) warned that the AIDS pandemic continued to spread in Africa and beyond in ways that heightened security risks. With these issues in play, the United States continued to frustrate any kind of agreements to this issue.[68] This changed, however, in August 2003 when the United States announced that it would acquiesce to an agreement resolving the controversy regarding compulsory licensing by countries without manufacturing capacity.[69]

To conclude, the decision of the United States Eastern District Court of New York in *In re Ciprofloxacin* is only the tip of the iceberg. The 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 assuring public health lies. In the domestic context (that is within the United States) the balance between patent protection and free competition has received considerable attention.[70] In addition, the precedent in *In re*

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[68] INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, WTO FAILS TO MEET TRIPs & HEALTH DEADLINE DUE TO US OPPOSITION (2003), *at* http://www.ictsd.org/ministerial/cancun/TRIPs_update.htm (last visited Jan. 30, 2003). In part,

> [n]egotiations on TRIPs and health broke down in the early hours of December 21 over the [United States] refusal to accept the Chairman's proposed disease coverage for the para. 6 soloution, i.e. "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" as set out in para. 1 of the Doha Declaration .... In a last-minute attempt to reach a deal, the [United States] suggested the inclusion of a footnote that would expand its previously proposed list of diseases from three (HIV/AIDS, malaria and tuberculosis) to 23 and "other epidemics of comparable gravity and scale," including those that might arise in the future. Developing countries, however, rejected this proposal, arguing that it would restrict the mandate given by the Doha Declaration, which refers more generally to "measures to protect public health" (para 4). They also rejected a proposal by the [European Union] that the [United States] could make a statement to the effect of its proposed footnote, which would then be supported by the TRIPs Council Chair as the framework for implementing the solution."

Id.

[69] Faizel Ismail, *The Doha Declaration on TRIPS and Public Health and the Negotiations in the WTO on paragraph 6—Why Phrma Needs to Join the Consensus*!, 6 J. WORLD INTELL. PROP. LAW 393, 395 (2003).

[70] *See generally* 66, 1 & 2 LAW AND CONTEMP. PROBS. 1 (2003) (containing impressive conference papers on the issue of the Public Domain).

Ciprofloxacin has also been established. Arguably, balancing patents with the public health concerns that arose following the bio-terrorism threats after 11 September 2001 is, however, a challenge that has only begun to emerge. At the international level, the budding emergency exception to patent protection is also undergoing excruciating growing 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 so than ever before. This also raises an important ethical consideration, which is the query this short piece hopes to leave the reader with: Can the United States adopt one policy at home to protect its citizens against the threat of bio-terrorism by overriding patent protection, but still maintain its opposition to developing countries that wish to address the HIV/AIDS pandemic?