

A Court's Dilemma: *When Patents Conflict with Public Health*

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ABSTRACT

This article examines the revitalization of the public interest factor in patent cases in which a permanent injunction is sought against an infringer, particularly with respect to the public health. Governments internationally, the executive branch, and the U.S. Congress have taken actions to protect citizens when rights held by patent holders conflict with the public health. But decisions by the Court of Appeals for the Federal Circuit limited the judiciary's ability to protect the public health and made entry of an injunction in patent cases the norm. This categorical rule was overturned by the U.S. Supreme Court in *eBay v. MercExchange*, and the Court provided instruction that equitable considerations in patent cases should mirror those found in other cases. Based on this precedent, the judiciary has the duty and the authority to take the public health into consideration when determining whether an injunction should issue. The article concludes with several equitable considerations relating to the public interest that courts may use in making this determination.

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I. INTRODUCTION—INTELLECTUAL PROPERTY RIGHTS AT TIMES CONFLICT WITH PUBLIC HEALTH

¶1 The U.S. patent system was designed to provide an incentive for innovation—to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹ The current patent system developed as the means to this end.² As motivation, U.S. patent law³ grants patent holders the right to exclude others from their inventions for twenty years in exchange for disclosure of the invention. Yet this exclusivity may come at a cost—it may prevent research from being conducted, delay research results from being disseminated,⁴ prevent processes and methods from being used, require innovators to spend resources avoiding infringement, and result in expensive patent litigation. We justify these costs because the patent system increases innovation.

¹ U.S. CONST., art. I, § 8, cl. 8.

² See *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) (stating that the financial reward given to inventors “is secondary and merely a means” to promote innovation). This “means,” however, does not always bring about the desired end. As Justice Breyer observed in 2006, patents “can discourage research by impeding the free exchange of information.” *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2922 (2006) (dissenting).

³ Set forth at 35 U.S.C. §§ 101-376 (2000).

⁴ See David Blumenthal et al., *Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors*, 81 ACAD. MED. 137, 140-42 (2006); Eric G. Campbell et al., *Data Withholding in Academic Genetics*, 287 JAMA 473, 478 (2002).

¶2 While the patent system was created to benefit the public, patent rights have, at times, demonstrably conflicted with the public health both here and abroad. In response, countries have acted to modify patent rights when they have too much of a detrimental impact on the public health. A well-known example is South Africa's decision to allow the importation of generic drugs when the country's HIV incidence reached epidemic proportions.

¶3 The United States is not immune to public health emergencies that may be compounded by intellectual property rights. In late 2001, after the anthrax mail scare terrified the nation, then-Attorney General John Ashcroft and U.S. Senator Charles Schumer lobbied Congress to allow the generic manufacture of the anthrax antibiotic Cipro, despite pharmaceutical giant Bayer's existing patent rights to the drug.⁵ Under the economic threat of this compulsory licensing and in response to public pressure, Bayer agreed to accelerate its production schedule of Cipro and sell it to the government at reduced rates.⁶ Yet many scholars agree that patent rights on pharmaceuticals are necessary to encourage product development in an area that has very high research, development, regulatory, and liability costs. Thus, these extraordinary actions undertaken by government officials echo the questions of when can—and when should—patent rights be adjusted to respond to a great public health need.

¶4 Nevertheless, U.S. trial courts have had limited power to ensure the protection of the public in patent cases based on precedent set by the Court of Appeals for the Federal Circuit. However, with its decision in *eBay v. MercExchange*,⁷ the U.S. Supreme Court has breathed new life into the consideration of the benefits and harms to the public interest in patent cases.

¶5 This article first discusses an international reaction to pharmaceutical patents on antiviral medication identified as a major factor in the prevalence and failure to contain the spread of HIV through sub-Saharan Africa (Part II). Because of government action and public pressure, pharmaceutical companies agreed to provide low- or no-cost drugs to certain countries. Next, after summarizing key provisions of the Patent Act, Part III focuses on actions by the U.S. executive and legislative branches to curtail patent rights when these rights conflict with the public health. The Federal Trade Commission ("FTC") has acted to ensure that medical product development and biomedical research on gene therapy technologies can continue unimpeded by a patent monopoly, and Congress has acted to exempt health care providers from the enforcement of medical method patents to protect their ability to provide health care to their patients. Yet for the last few decades, the judiciary's hands have been tied in protecting the public health in patent cases.

¶6 Patent holders are given exclusive rights to their inventions—the exclusive right to make, use, sell, offer for sale, and import the inventions. These rights are not

⁵ Robert Pear, *A Nation Challenged: Drug Production; Government Talks with Drug Companies About Buying Antibiotics that Treat Anthrax*, N.Y. TIMES, Oct. 20, 2001, at B8.

⁶ Keith Bradsher, *A Nation Challenged: The Cost; Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. TIMES, Oct. 25, 2001, at B8.

⁷ *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

equivalent to the right to perform these actions; rather, the right bestowed upon a patent holder is more appropriately described as the right to exclude others from making, using, selling, offering for sale, or importing. The patent law thus provides for a permanent injunction to be granted against an adjudicated infringer preventing the infringer from performing any of the excluded actions. Decisions by the Federal Circuit made the entry of such an order nearly standard and effectively eliminated the traditional equitable considerations in injunction cases, including whether the public interest weighed in favor of or against granting an injunction. Part IV discusses the evolution of this precedent, which was recently overturned by the Supreme Court in *eBay v. MercExchange*.⁸

¶7 The *eBay* decision has vested the judiciary not only with greater freedom to ensure that patent rights do not unduly interfere with public health, but also with the duty to do so—even at the expense of the patentee's right to exclude. In Part V, the article concludes by discussing factors that courts might consider when determining whether it is necessary to limit patent rights to protect the public health.

II. AN INTERNATIONAL PERSPECTIVE ON THE IMPACT OF PATENTS ON PUBLIC HEALTH

¶8 The impact of intellectual property on the treatment and spread of HIV and AIDS in Africa is well documented. By 2001, the HIV crisis in sub-Saharan Africa had reached epidemic levels. A global study found that sub-Saharan Africa was the worst affected region of the world, with more than 70 percent of all people worldwide living with HIV residing there.⁹ A major reason for both the high mortality rate and the inability to contain the spread of the disease in Africa was that patented HIV drugs were unaffordable to the vast majority of infected persons and to the governments.¹⁰ It was estimated that compulsory licenses on patented medications could have reduced prices of drugs by as much as 95 percent, thus making them affordable to many citizens.¹¹ Even limited quantities of HIV drug treatment would have made a dramatic difference in the spread of the infection and death rates. According to one study, providing infected women with a short course of antiretroviral (“ARV”) drugs would prevent 110,000 infant HIV infections yearly in South Africa.¹²

¶9 Yet because of trade agreements, the South African government could not make or import generic drugs. In 1994, during the creation of the World Trade Organization, the Trade Related Aspects of Intellectual Property (“TRIPS”) Agreement was formed.

⁸ *Id.*

⁹ UNAIDS: JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, 2002 REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 22 (2002).

¹⁰ Matthew Leis, *Death by Treaty: South Africa's Medicines and Related Substances Amendment Act of 1997 and the Agreement on Trade Related Aspects of Intellectual Property Rights*, 3 J. INT'L BUS. & L. 221 (2004).

¹¹ Angela G. Thornton-Millard, *Intellectual Property Rights and the AIDS Epidemic in Sub-Saharan Africa*, 11 TRANSNAT'L L. & CONTEMP. PROBS. 517, 521-22 (2001) (citing Rosemary Sweeney, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445, 451-54 (2000)).

¹² *Id.* at 520 (citing Evan Wood et al., *Extent to Which Low-Level Use of Anti-Retroviral Treatment Could Curb the AIDS Epidemic in Sub-Saharan Africa*, 355 LANCET 2095 (2000)).

TRIPS provides for international intellectual property protection by member countries. In 1997, to help alleviate the growing epidemic and the restrictions placed on the importation of generic drugs by TRIPS, the government of South Africa passed the South African Medicines and Related Substances Control Amendment Act (the "Act"). This Act specifically allowed for the "generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines."¹³

¶ 10 In response, the Pharmaceutical Manufacturers Association filed a lawsuit on behalf of thirty-nine pharmaceutical companies in the Pretoria High Court against the government of South Africa.¹⁴ The complaint alleged that several of the provisions of the Act were in violation of the South African Constitution and the TRIPS Agreement.¹⁵ Because of the controversial nature of the Act (and the possibility of economic sanctions against South Africa), the South African government agreed not to implement the legislation until the court case was decided. The government feared that a breach of TRIPS could bring about the loss of both "national treatment" and "most favored nation" status.¹⁶ Activists around the globe objected to the litigation, and amid an outpouring of protests, the pharmaceutical companies bowed to the pressure and abandoned their court action in early 2001.¹⁷ Within two years, the government had decided to provide ARV treatment as part of its public health program.¹⁸

¶ 11 Implementation of the government's plan to provide ARV medication to its citizens has understandably taken time, and the full effects of the government's action will take years, or even decades, to fully realize. However, consider that as of January 2005, a reported 29,000 people were receiving ARV drugs from the government,¹⁹ but by the end of that same year, the number had increased to 190,000.²⁰ According to the South African government's plans, it expects to provide ARV treatment to 1.65 million people by March 2008.²¹ If the government meets its treatment goal, it means that there

¹³ Obijiofor Aginam, *Between Life And Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents*, 31 N.C. J. INT'L L. & COM. REG. 901, 910 (2006) (quoting Ellen t'Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 30 (2002)).

¹⁴ The companies included industry leaders such as Merck. Helene Cooper et al., *Patents Pending: AIDS Epidemic Traps Drug Firms in a Vise: Treatment vs. Profits—Suit in South Africa Seeks to Block Generic Copies; U.S. Reverses Its Policy—Activists Warn Mr. Papovich*, WALL ST. J., Mar. 2, 2001, at A1.

¹⁵ Canadian HIV/AIDS Legal Network, *Victory in South Africa, but the Struggle Continues*, <http://web.archive.org/web/20020202062403/www.aidslaw.ca/Maincontent/issues/cts/updateSA.htm> (last visited Oct. 30, 2007).

¹⁶ Most favored nation status allows a country greater access to the markets of other countries with fewer restrictions. Thornton-Millard, *supra* note 11, at 522-23.

¹⁷ Ann M. Simmons, *Firms Clear Way for Cheaper AIDS Drugs; S. Africa Patent Suit Dropped*, CHI. TRIB., Apr. 20, 2001, at 4.

¹⁸ AIDS Foundation South Africa, *HIV/AIDS in South Africa: ARV Programme*, <http://www.aids.org.za/hiv.htm#5> (last visited Oct 30, 2007). The government termed the program the Operational Plan for the Comprehensive HIV and AIDS Care, Management and Treatment for South Africa. *Id.*

¹⁹ *Id.*

²⁰ UNAIDS: JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, 2006 REPORT ON THE GLOBAL AIDS EPIDEMIC 17 (2006), available at http://www.unaids.org/en/HIV_data/2006GlobalReport/.

²¹ AIDS Foundation South Africa, *supra* note 18.

will be an 768 percent increase in treatment in South Africa in just over two years—a goal that would have been impossible to meet without threatening to void patent rights.²² Yet, as a generally accepted proposition, pharmaceutical patents are necessary to incentivize research in the field because the costs of research, development, regulatory approval, marketing, and liability are so high. The South African government's unusual actions in response to a devastating public health crisis are an interesting comparison to governmental actions taken in the United States to protect the public health.

III. THE PATENT ACT AND EXECUTIVE AND CONGRESSIONAL ACTIONS TAKEN IN THE UNITED STATES TO CURTAIL PATENT RIGHTS

¶ 12 In the U.S. Patent Act, Congress has delineated the boundaries of the patent system. Under the Patent Act, an inventor may receive a patent on “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”²³ When applying for the patent, the inventor must demonstrate that the invention is novel, nonobvious, and useful.²⁴ The inventor must also disclose written details about the invention sufficient to “enable” someone skilled in that field to make and use the invention.²⁵ In exchange for revealing and describing the invention, the details of which otherwise might be held secret by the inventor, patent holders have the exclusive rights for twenty years to make, use, sell, offer for sale, and import their inventions.²⁶ The patentee does not necessarily have the affirmative right to do all of these actions; he might not be allowed to import an invention that is illegal. But he has the right to exclude others from taking these actions. An infringer is one who makes, uses, sells, offers for sale, or imports the patented invention without the patent owner's permission.²⁷ An accused infringer can defend himself by seeking a declaration that the patent claims are invalid.²⁸ But once the accused infringer's invalidity arguments fail, and upon a finding of infringement, the patent holder can be awarded damages²⁹ and win the entry of a court order permanently enjoining the infringer from future use of the

²² Calculated from December 2005 to March 2008, using the data of 190,000 ARV treatments by December 2005, and 1,650,000 in March 2008, the percent increase is calculated by subtracting the current ARV treatments (190,000) from the future ARV treatments (1,650,000), then dividing by the previous number of treatments (190,000) and multiplying by 100.

²³ 35 U.S.C. § 101 (2000).

²⁴ 35 U.S.C.A. §§ 101-03 (2001 & Supp. 2006).

²⁵ 35 U.S.C. § 112 (2000). The disclosure provisions require that an applicant satisfy four basic requirements in patent specification: written description, enablement, best mode, and definiteness. Specifically, the law requires that the patent application “contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.” Written description relates to whether the invention as claimed has been sufficiently disclosed in the specification. Definiteness relates to the way the claim is written; the claim must “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.” *Id.*

²⁶ 35 U.S.C. § 154 (2000 & Supp. 2003).

²⁷ 35 U.S.C.A. § 271 (2001 & West Supp. 2006).

²⁸ 35 U.S.C. § 282 (2000 & Supp. 2003).

²⁹ 35 U.S.C. § 284 (2000). “Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” *Id.*

invention.³⁰

¶ 13 Before considering the equitable factors traditionally used by the judiciary to determine whether an injunction should be entered in nonpatent cases, and the erosion of those factors in patent cases, we first turn to executive and legislative actions that have been taken to curtail patent rights.

¶ 14 The executive and legislative branches of the federal government have taken action to ensure that patents are not blindly protected when that protection would conflict with other important national concerns. The executive branch has limited patent rights by forcing compulsory licensing when a concentration of intellectual property rights in an area interferes with the public's interest in the development of medical products and biomedical research. Congress has acted to curtail patent rights to ensure that patents claiming a method of performing a medical procedure cannot be enforced against health care providers.

A. Executive Branch Actions—Maintaining the Balance

¶ 15 The principles of intellectual property law, which seek to exclude others in order to incentivize more invention (thereby effectively creating a government sanctioned monopoly), and those of antitrust law, which strive to ensure that “market actors . . . do not use market power to exploit consumers,”³¹ are in perpetual tension. The executive branch employs the Antitrust Division of the Department of Justice (“DOJ”) and the FTC to enforce federal antitrust laws.³² To aid in their enforcement efforts in cases involving intellectual property, these agencies jointly issued the Antitrust Guidelines for the Licensing of Intellectual Property (“IP Guidelines”), which apply to patent and copyright licenses.³³ Under the guidelines, the agencies will not evaluate potentially anticompetitive conduct relating to intellectual property any differently than they analyze conduct relating to any other types of property:

As with other forms of private property, certain types of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect. Intellectual property is thus

³⁰ 35 U.S.C. § 283 (2000).

³¹ Hanno F. Kaiser, *Antitrust Issues in Licensing: A Brief Introduction to the Interface Between Antitrust and Intellectual Property*, 879 PRACTICING LAW INSTITUTE: PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES 493, 497 (2006). *But see* Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990) (noting “the aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.”).

³² *E.g.*, Sherman Act, 15 U.S.C. §§ 1-7 (2000 & Supp. 2004); Clayton Act, 15 U.S.C. §§ 12-27 (2000 & Supp. 2004), 29 U.S.C. §§ 52-53 (2000).

³³ U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), available at <http://www.ftc.gov/bc/0558.pdf>. After extensive hearings in 2002, the FTC issued a report analyzing the interaction between the need for competition and the patent system and making recommendations to maintain the balance between the two. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, 1-18 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them.³⁴

¶ 16 Patent holders can use the IP Guidelines to determine whether they are likely to be investigated by the agencies for anticompetitive practices.³⁵

¶ 17 At times, the FTC's exercise of its power to prevent business practices that restrain competition has simultaneously resulted in the protection of the public health. These cases involve alleged antitrust violations of companies involved in the medical or pharmaceutical fields, and the crux of the antitrust claims centers on the potential of these companies to create an anticompetitive environment that will stunt or impede the research, development, or distribution of products important to public health. Yet the protection of the public health is not the main impetus for the regulatory action.

1. *In re Baxter Intl.*

¶ 18 In 1994, the FTC began proceedings against Baxter International when Baxter initiated an acquisition of Immuno International AG—a deal that would make the merged company one of only a few companies seeking FDA approval of fibrin sealant, a topical agent used to control surgical bleeding.³⁶ At the time of the proceedings, there was no FDA-approved fibrin sealant on the market, so physicians concocted and used their own preparations.³⁷ Before the merger, the firms competed against each other in the research and development of fibrin sealant.³⁸

¶ 19 The FTC noted that once the companies merged, the new entity was not likely to have research competitors because the barriers to entry, including research costs and the low likelihood of success, were prohibitively high.³⁹ A company might spend years trying to develop a competing product and have it approved by the FDA, only to fail.⁴⁰ But competition can incite a company to work faster to accomplish its goal.⁴¹ Because competition in the fibrin sealant market was “difficult and unlikely,” the FTC found the merger would harm the public interest.⁴² Baxter eventually entered into a consent decree

³⁴ U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 33, at 3.

³⁵ *Id.* at 1. The IP Guidelines proceed with three underlying principles: (1) intellectual property is “essentially comparable” to other forms of property; (2) intellectual property is not presumed to create “market power in the antitrust context”; and (3) “intellectual property licensing allows firms to combine complementary factors of production and is generally procompetitive.” *Id.* at 2. While not binding authority, the IP Guidelines have been used as persuasive authority by courts. Kaiser, *supra* note 31, at 503.

³⁶ *In re Baxter Int'l, Inc.*, 123 F.T.C. 904, 906 (1997). The FTC claimed violations of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. § 18. *Id.* at 907.

³⁷ Press Release, Food & Drug Admin., New Fibrin Sealant Approved to Help Control Bleeding in Surgery (May 1, 1998), available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00865.html>.

³⁸ *In re Baxter Int'l*, 123 F.T.C. at 906.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ See FED. TRADE COMM'N, *supra* note 33, at 126.

⁴² *In re Baxter Int'l*, 123 F.T.C. at 906, 908.

in which it agreed to license Immuno's fibrin sealant product to a competitor.⁴³ Two years later, Baxter and the licensee were both approved fibrin sealant sellers in the United States, with Baxter maintaining 75 percent of the market share.⁴⁴

2. *In re Ciba-Geigy*

¶ 20 The FTC has also taken actions that have the effect of protecting medical research.⁴⁵ In 1997, the FTC's attention turned to the area of gene therapy research during the proposed merger between Ciba-Geigy Ltd. and Sandoz Ltd. into Novartis AG. "Gene therapy involves treating diseases or medical conditions by modifying genes and then inserting the modified genes into a patient's cells."⁴⁶ Cells can be modified "*ex vivo* [in an artificial environment outside the body] for subsequent administration" or altered "*in vivo* [within the body] by gene therapy products that are given directly to the patient."⁴⁷ In 1997, gene therapy was thought to hold the promise to provide a method to treat cancer or other diseases for which there were no other existing effective treatments or drugs in advanced development.⁴⁸

¶ 21 In March of that year, the FTC entered an order allowing the merger with specific conditions.⁴⁹ The FTC expressed concern that the merger would lessen competition or create a monopoly in gene therapy markets, including "technology and research and development."⁵⁰ It alleged that Ciba-Geigy and Sandoz controlled "the substantial proprietary rights necessary to commercialize gene therapy products" and "controlled critical gene therapy proprietary portfolios, including patents, patent applications, and know-how."⁵¹ The FTC predicted this monopoly of the crucial proprietary rights necessary to commercialize gene therapy products would inhibit long-term innovation, the preservation of which it deemed "critical."⁵²

¶ 22 The order required Novartis (the merged company) to license certain of its gene therapy patent rights to competitor Rhône-Poulenc Rorer Inc.⁵³ It also required Novartis

⁴³ *Id.* at 910-11.

⁴⁴ Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?* 18 BERKELEY TECH. L.J. 853, 898 (2003). Baxter continued its research and development, working on a different type of medium for the sealant and investing in upgraded manufacturing facilities. *Id.* at 898-99. These activities might demonstrate that it needed to stay competitive with the licensee.

⁴⁵ *But see* Atif I. Azher, *Antitrust Regulators and the Biopharmaceutical Industry: Compulsory Licensing Schemes Ignoring Gene Therapy Patients' Needs*, 25 U. PA. J. INT'L ECON. L. 383, 418-19 (2004) (arguing that compulsory licensing as a remedy to anticompetitive activity could ultimately harm research unless the licensor is allowed oversight of the licensee).

⁴⁶ ORG. FOR ECON. COOPERATION AND DEV., COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS, 209 (1998), available at <http://www.oecd.org/dataoecd/34/57/1920398.pdf>.

⁴⁷ *Id.* at 213.

⁴⁸ *Id.* at 209.

⁴⁹ *In re Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997).

⁵⁰ *Id.* at 844.

⁵¹ *Id.* at 846.

⁵² *Id.* at 895 (separate statement of Chairman Pitofsky et al.).

⁵³ *Id.* at 876.

to license certain gene therapy patents to any interested party at a reasonable royalty.⁵⁴ The compulsory licensing applied to a patent that was owned by the National Institutes of Health (NIH) and licensed exclusively to Sandoz, which Novartis gained rights to by virtue of the merger. Ciba-Geigy had participated in the gene therapy market through Chiron Corp. Chiron (which was ultimately purchased by Novartis) was also required to license its gene therapy patents.⁵⁵

¶ 23 The NIH-owned patent at issue in the order was the so-called Anderson Patent, named after one of its inventors, W. French Anderson.⁵⁶ The Anderson Patent claims a process of genetically engineering human blood cells *ex vivo* by inserting a DNA segment through a variety of mechanisms and then introducing the cells into a person.⁵⁷ When the cells are introduced in the person, they would code for a needed protein.⁵⁸ The inventors predicted they could fight cancer by enhancing the tumor-fighting properties of the cells in culture and then injecting the cells into a cancer patient.⁵⁹ They also predicted they could use gene therapy to treat other diseases, including sickle cell anemia, thalassemia, hemophilia, diabetes, Alzheimer's disease, heart disease, and defects of the immune system.⁶⁰

¶ 24 Before the merger, researchers could have licensed the technology from one company or the other or could have challenged the patent portfolio of either company.⁶¹ The merger, however, created a “killer” patent portfolio” that would eliminate researchers’ ability to work around the patents.⁶² The FTC ordered compulsory licensing instead of forced divestiture of the gene therapy business, because it did not want to disrupt the companies’ research and development efforts already in progress.⁶³

¶ 25 Since the IP Guidelines were issued, the FTC and the DOJ have had an increased interest in the anticompetitive effects of intellectual property. The agencies have also stepped up their scrutiny on the effects of intellectual property on innovation.⁶⁴ In certain cases, the agencies’ scrutiny has resulted in actions that have served to protect the public health. Yet their jurisdiction and mission is to protect the competitive process, not to

⁵⁴ *Id.* at 875.

⁵⁵ *Id.*

⁵⁶ *Id.* at 860. *See also* Gene Therapy, U.S. Patent No. 5,399,346 (filed Mar. 30, 1994) (issued Mar. 21, 1995).

⁵⁷ ’346 Patent.

⁵⁸ *Id.*

⁵⁹ *Id.* “Other genes useful in cancer therapy can be used to encode chemotactic factors which cause an inflammatory response at a specific site, thereby having a therapeutic effect.” *Id.*

⁶⁰ *Id.*

⁶¹ *In re* Ciba-Geigy, 123 F.T.C. at 897 (separate statement of Chairman Pitofsky et al.).

⁶² *Id.* Commissioner Azcuenaga, dissenting from the portion of the order relating to the gene therapy patents, argued that divestiture was a more appropriate remedy than compulsory licensing. *Id.* at 898 (separate statement of Commissioner Azcuenaga). She argued that allowing the firms to combine their technology allowed the anticompetitive combination to stand, which she predicted would consolidate the diverse research that had existed. *Id.* at 899. She also argued that freely obtaining licenses would take away the incentive to invent around existing patents, thereby reducing innovation. *Id.* at 901 n.17.

⁶³ *Id.* at 895 (separate statement of Chairman Pitofsky et al.).

⁶⁴ *See* Richard Gilbert & Willard Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43 (2001).

protect the public health.

¶ 26 For example, consider the situation where two large pharmaceutical companies compete as the only companies to have a certain drug near approval by the FDA. If the one company licenses its technology to the other company but refuses other reasonable licensing requests, consumers might end up paying increased costs for the drug because they can obtain it only from one manufacturer, thus limiting access. If the FTC or the DOJ investigates these actions, it is because they are potentially anticompetitive, not because they harm the public health.⁶⁵ Another situation the agencies might investigate is a merger between two companies that affects innovation in the development of medical products or processes.⁶⁶ But, again, the agencies pursue the potential anticompetitive actors because of the effect on innovation, not because of the effect on public health.

¶ 27 The FTC's and the DOJ's powers and policies toward intellectual property therefore do not serve to adequately protect the public health when intellectual property rights conflict with the public health.

B. The Physician Exemption—Congress Giveth and Congress Taketh Away

¶ 28 Congress has enacted laws that offer some protection of the public health in the Patent Act.⁶⁷ One statutory provision, for example, allows pharmaceutical companies to use a patented drug for testing and research.⁶⁸ The exemption applies if the company's use of the patented composition is reasonably related to an FDA submission.⁶⁹ Drug companies thus can use their competitors' patented compositions for research toward an application that will eventually be made to the FDA—for example, for testing a generic formulary. In another example, in 1996, Congress amended the patent statute to provide

⁶⁵ See, e.g., U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.7 (1995), available at www.ftc.gov/bc/0558.pdf.

⁶⁶ Gilbert, *supra* note 64.

⁶⁷ 35 U.S.C.A. § 101 *et seq.* (2001 & West Supp. 2006). Other attempts to abrogate the rights of patentees, although fairly common, have not met with unbridled enthusiasm. On October 25, 2005, U.S. Representative Sherrod Brown (D-OH) and six cosponsors introduced House Bill 4131, the "Public Health Emergency Medicines Act." The bill would have allowed the Secretary of Health and Human Services to authorize the use of "any invention relating to healthcare" without permission from the patentee if the Secretary determined the patented material was "needed to address a public health emergency." H.R. 4131, 109th Cong. § 2(a)(1) (2005). The bill further authorized the same action and allowed export of the technology if the Secretary determined there was a "global public health emergenc[y]." H.R. 4131 § 2(a)(1). The bill does not, however, define either "public health emergency" or "global public health emergency." See generally H.R. 4131. Factors to be taken into consideration in determining the patent holder's remuneration would include whether the invention was supported by publicly funded research, the public's interest as the payers for health care services, the public's health, the needs of working families and retired persons, and the need to incentivize innovation. H.R. 4131 § 2(a)(1). The bill was referred to committee and died at the expiration of the 109th Congress. H.R. 4131 (referred to House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property on Feb. 6, 2006). House Bill 4131 is nearly identical to a bill Representative Brown introduced in the 107th Congress in 2001 two months after the terrorist attacks of September 11. See Public Health Emergency Medicines Act, H.R. 3235, 107th Cong. (2001) (introduced Nov. 6, 2001). The 2001 bill also died in committee. H.R. 3235 (referred to House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property on Nov. 27, 2001).

⁶⁸ 35 U.S.C.A. § 271(e)(1) (2001 & West Supp. 2006).

⁶⁹ *Id.*

that while methods for medical treatment can be patented, an action for infringement cannot be brought against a medical professional or health care organization for using the patented procedure. The exemption was the result of public pressure on Congress to protect the public health.

¶²⁹ Until the middle of the twentieth century, the U.S. Patent and Trademark Office (formerly the Patent Office and then the Patent and Trademark Office) (“USPTO”) would not grant patents on methods of diagnosing and treating disease. In 1883, the USPTO squarely addressed the issue, holding that it would not grant a patent on a method of treating a disease.⁷⁰ The USPTO reasoned that a patented treatment would not cause the same outcome in every patient: “The methods or modes of treatment of physicians of certain diseases are not patentable; they are discoveries which may in a majority of cases under certain conditions accomplish certain results, but no particular method or mode of treatment under all circumstances, and in all cases will produce upon all persons the same result”⁷¹ For years, the few courts that addressed the issue were in agreement.⁷²

¶³⁰ Over the years, the USPTO gradually whittled away at its medical method patents ban. In *Ex parte Wappler*, the Board of Patent Appeals allowed a patent for a method for shrinking living tissue, determining that the method claimed a way to change the state of a substance rather than a treatment for a disease.⁷³ In a similar case, the Patent Board allowed a patent on a method of creating a fever in a patient, finding that the method was not directly related to curing a certain disease.⁷⁴ Thus, if an applicant had devised a method for achieving some result in a human body, the USPTO would grant a patent as long as the applicant could convince it that the method was not solely for the treatment of

⁷⁰ *Ex parte Brinkerhoff*, Case No. 182, 24 Comm’r Manuscript Dec. 349 (Comm’r Pat. Office July 5, 1883), reprinted in 27 J. PAT. & TRADEMARK OFF. SOC’Y 73, 797-98 (Nov. 1945). The treatment at issue in *Ex parte Brinkerhoff* involved the use of existing surgical instruments. The applicant already held patents on the instrument. *Id.*

⁷¹ *Id.* The USPTO continued, “[H]ence to grant a patent for a particular method of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases. . . . It should be reasonably certain in every case that the invention sought to be patented will produce a certain result.” *Id.*

⁷² For example, in 1862, a district court in New York considered whether the use of ether for anesthetic during surgery could be patented. The court held that the newly discovered use was outside the bounds of the patent statute—the existence and effect of ether was already known, and an increased dosage during surgery to render the patient “wholly insensible” was a “naked discovery of a new effect.” *Morton v. N.Y. Eye Infirmary*, 17 F. Cas. 879, 883 (S.D.N.Y. 1862). The court compared the discovery to an “increased quantity of liquors, taken into the stomach” to produce a “like result”—neither were patentable. *Id.* Almost 100 years later, a federal court sitting in Maryland questioned the ethics of patents on medical methods. *Martin v. Wyeth Inc.*, 96 F. Supp. 689 (D. Md. 1951), *aff’d*, 193 F.2d 58 (4th Cir. 1951). The court stated, “Doctors and surgeons have seldom thought it desirable to try to patent their new procedures for human relief. . . . The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage.” *Id.* at 695. Although it did not decide the case on this ground, the court’s rumination illustrates the legal community and public’s disdain for patents that might interfere with patient care. *But see Dick v. Lederle Antitoxin Lab.*, 43 F.2d 628, 630 (S.D.N.Y. 1930) (upholding a patent for a method of detecting a person’s likelihood of developing scarlet fever).

⁷³ *Ex parte Wappler*, 26 U.S.P.Q. 191, 192 (Pat. Off. Bd. App. 1934).

⁷⁴ *Ex parte Kettering*, 35 U.S.P.Q. 342, 343 (Pat. Off. Bd. App. 1936).

a disease. In this way, the exceptions threatened to swallow the rule.

¶ 31 Finally, in 1954, the Board of Patent Appeals & Interferences reversed itself and decided that medical methods were patentable subject matter.⁷⁵ In *Ex parte Scherer*, the Board determined that a method for the injection of medications into human skin via a fluid jet was patentable.⁷⁶ It noted that patent law did not expressly prohibit patents on methods of treatment.⁷⁷ It held that the “uncertainty of results” was not a valid reason for refusing to issue a patent and that, from then on, a method that involved treating the human body would not necessarily be unpatentable.⁷⁸

¶ 32 Yet, in contrast to the United States, medical method patents were rejected as unethical in other countries. At approximately the same time that *Ex parte Scherer*⁷⁹ was being decided by U.S. patent officers, the German patent office turned down patent applications that claimed methods of medical treatment, finding it unethical to allow profit from human disease and to remove treatments from use by the general public.⁸⁰ Germany was followed by Austria and Switzerland. Eventually, more than eighty countries around the world declined to provide patent protection for medical and treatment methods.⁸¹ The European Patent Convention⁸² excluded medical methods from the scope of patentable subject matter:

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as [patentable]. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.⁸³

⁷⁵ *Ex parte Scherer*, 103 U.S.P.Q. 107, 110 (Pat. Off. Bd. App. 1954).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.* at 109-10. The dissent argued that the majority erred in overturning nearly 100 years of judicial and administrative precedent. *Id.* at 111 (Geniesse, Examiner in Chief, dissenting). He pointed to a prior decision, *In re Saunders*, 154 F.2d 693 (C.C.P.A. 1946), in which claims relating to a method of medical treatment were held unpatentable.

⁷⁹ *Ex parte Scherer*, 103 U.S.P.Q. at 107.

⁸⁰ Robert M. Portman, *Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress*, 4 UNIV. BALT. INTELL. PROP. L.J. 91, 97 (1996) (citing Rainer Moufang, *Methods of Medical Treatment Under Patent Law*, 24 INT’L REV. INTELL. PROP. AND COMPETITION L. 18, 22-23 (1993)).

⁸¹ *Id.* at 98.

⁸² The European Patent Convention was first signed in Munich on October 5, 1973, and became effective in Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, and the United Kingdom on October 7, 1977; in Sweden on May 1, 1978; in Italy on December 1, 1978; in Austria on May 1, 1979; and in Liechtenstein on April 1, 1980. European Patent Convention, part XII, art. 169, n.121, Jan. 1, 2006, available at <http://www.european-patent-office.org/legal/epc/e/ar169.html#A169>. Current members of the European Patent Convention include: Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Malta, Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, and Turkey. European Patent Office, Member States of the European Patent Organisation, <http://www.epo.org/about-us/epo/member-states.html> (last visited Oct. 30, 2007).

⁸³ European Patent Convention, art. 52(4), available at <http://www.european-patent-office.org/legal/epc/e/ar52.html>. As of 1996, member states that had also adopted statutes similarly

¶ 33 As time passed, it became evident that medical method patents had the very real potential to interfere with patient care and decision making in the United States. One such patent was number 4,986,274, which disclosed a means for detecting the sex of a fetus by using ultrasound.⁸⁴ The patent claimed a method of looking at an ultrasonic image and concluding that the fetus was male if male genitalia were observed and a female if female genitalia were observed.⁸⁵ The patent holder, a physician, began demanding royalties from other practitioners.⁸⁶ Another notable example is a patent on the correlation between high levels of the hormone human chorionic gonadotropin⁸⁷ in a pregnant woman's blood and conditions like fetal Down syndrome.⁸⁸ The physician patent holder formed a company to enforce his patent and convinced the Foundation for Blood Research,⁸⁹ laboratories owned by SmithKline Beecham, and the Arizona Institute for Genetics and Fetal Medicine to pay royalties on the test.⁹⁰

¶ 34 The potential for other medical method patents to interfere with patient care was, and remains, enormous. Researchers have patented a method for using levels of tamoxifen or its metabolites in a woman's blood to determine if she is developing tamoxifen resistant tumors;⁹¹ a method for a minimally invasive hip replacement;⁹² a

excluding medical patents included Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Liechtenstein, Spain, Sweden, Switzerland, and the United Kingdom. Portman, *supra* note 80, at 98 n.47.

⁸⁴ Fetal Anatomic Sex Assignment by Ultrasonography During Early Pregnancy, U.S. Patent No. 4,986,274 (filed Dec. 4, 1989) (issued Jan. 22, 1991).

⁸⁵ *Id.*

⁸⁶ Portman, *supra* note 80, at 99-100 n.51 (citing "To Whom It May Concern" Letter from Jack Russo, Attorney for Dr. Stephens, July 8, 1993). See also *Hearing on H.R. 1127 and H.R. 2419 Before the H. Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 104th Cong. (1995) [hereinafter *Hearing on H.R. 1127 and H.R. 2419*] (testimony of Charles D. Kelman, M.D., American Society of Cataract and Refractive Surgery) (discussing physician's efforts to collect licensing fees from other physicians).

⁸⁷ Human chorionic gonadotropin is a hormone produced by the fetal placenta that is used to determine whether a woman is pregnant. *STEDMAN'S ONLINE MEDICAL DICTIONARY* (27th ed.).

⁸⁸ Method for Assessing Placental Dysfunction, U.S. Patent No. 4,874,693 (filed Oct. 10, 1986) (issued Oct. 17, 1989). The fact that Dr. Bogart's test had an admitted and disturbingly high false positive and negative rate did not prevent him from demanding royalties from labs performing the test. *Id.* The actual rates are even higher. *AGENCE D'EVALUATION DES TECHNOLOGIES ET DES MODES D'INTERVENTION EN SANTE, ISSUES CONCERNING PRENATAL SCREENING AND DIAGNOSIS OF DOWN SYNDROME* 9 tbl.3 (2001), available at <http://www.aetmis.gouv.qc.ca/site/download.php?f=a03f8c41b2a3adfdf958e0c56a3a266b> (original French version published in 1999).

⁸⁹ Kurt Eichenwald, *Push for Royalties Threatens Use of Down Syndrome Test*, N.Y. TIMES, May 23, 1997, at A1.

⁹⁰ Seth Shulman, *Cashing in on Medical Knowledge*, TECH. REV., Mar. 7, 2002 available at http://www.technologyreview.com/read_article.aspx?id=11659&ch=biztech. Kaiser Permanente, an integrated health care organization located in California and several other states, sought a declaratory judgment that the patent was unenforceable and invalid. *Kaiser Challenges Doctor on Patentability of Test to Detect Down Syndrome*, 4 No. 4 ANDREWS INTELL. PROP. LITIG. REP. 3, Sept. 17, 1997. The State of California intervened, and although the patent holder dropped the suit against Kaiser, the dispute with California continues in front of the Federal Circuit over issues of sovereign immunity. See *Biomedical Patent Mgmt. Corp. v. State of Cal., Dept. of Health Servs.*, No. 2006-1515, 2007 WL 3071687 (Fed. Cir. Feb. 27, 2007).

⁹¹ Detection of Onset of Antiestrogen Resistance in Breast Cancer, U.S. Patent No. 5,384,260 (filed Mar. 17, 1993) (issued Jan. 24, 1995).

method for creating an environment hormonally conducive to maintaining a pregnancy in a woman with nonfunctioning ovaries;⁹³ and even a method for assessing medical risk (which includes the action of considering factors such as age, race, and weight).⁹⁴

¶ 35 But perhaps most infamous of all is the patent held by Samuel Pallin, MD, a pioneer in cataract surgery. His patent caused professional and public outcry and eventually was credited with inciting congressional action protecting physicians from the enforcement of medical method patents. In 1992, the USPTO issued a patent to Dr. Pallin for a method of using a scalpel to make an inverted-*v*-shaped incision during cataract surgery.⁹⁵ The procedure eliminated the need for stitches to close the wound made by the incision because it was self-sealing.⁹⁶ That same year, surgeon Dr. Jack Singer published an article on a similar surgical technique, calling it the “frown incision.”⁹⁷

¶ 36 Following this publication, Dr. Pallin filed a patent infringement lawsuit against Dr. Singer and his employer claiming that Dr. Singer’s use of the “frown incision” in cataract surgery infringed his patent and that the publication of the method induced infringement by other physicians.⁹⁸ Dr. Pallin sought not only damages, but also an injunction that would prohibit Dr. Singer from practicing the method and from teaching others how to perform it.⁹⁹ Dr. Pallin eventually withdrew his request for injunctive relief, but he demanded thousands of dollars of royalty payments annually.¹⁰⁰

¶ 37 In March 1996, in a consent order, a federal district judge dismissed all of Dr. Pallin’s patent infringement claims, declared the claims of the patent invalid, and issued an order prohibiting Dr. Pallin from enforcing the patent against any physician or health care institution in the future.¹⁰¹ Dr. Pallin consented to the judge’s order but only after Dr. Singer presented evidence that he, along with various other American physicians, had

⁹² Method and Apparatus for Performing a Minimally Invasive Total Hip Arthroplasty, U.S. Patent No. 6,676,706 (filed Apr. 26, 2000) (issued Jan. 13, 2004).

⁹³ Method for Producing an In Vivo Environment Suitable for Human Embryo Transfer, U.S. Patent No. 4,816,257 (filed Sept. 2, 1987) (issued Mar. 28, 1989).

⁹⁴ System and Method for Assessing Medical Risk, U.S. Patent No. 5,492,117 (filed May 9, 1994) (issued Feb. 20, 1996).

⁹⁵ Method of Making Self-Sealing Episcleral Incision, U.S. Patent No. 5,080,111 (filed June 28, 1990) (issued Jan. 14, 1992).

⁹⁶ *Id.*

⁹⁷ Portman, *supra* note 80, at 101 (citing Jack A. Singer, *Review of Incision and Closure Techniques for Cataract Surgery*, OPTHALMIC PRAC., Aug. 1992, at 152). According to the court’s decision, one year earlier, Singer had also published as a video his work entitled “Frown Incision” in the *Audiovisual Journal of Cataract and Implant Surgery*. *Pallin v. Singer*, No. 5:93-202, 1995 WL 608365, at *2 n.7 (D. Vt. May 1, 1995). The journal is now known as the *Journal of Cataract and Refractive Surgery*.

⁹⁸ *Pallin*, 1995 WL 608365, at *1. At the time, Dr. Singer was an assistant professor of clinical surgery (ophthalmology) at Dartmouth Medical School and a member of the Dartmouth-affiliated Hitchcock Clinic. Singer Eye Center, Dr. Singer’s Curriculum Vitae, <http://www.singereye.com/pages/curriculum-vitae.php> (last visited Nov. 4, 2007).

⁹⁹ Portman, *supra* note 80, at 102.

¹⁰⁰ *Id.*

¹⁰¹ *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28, 1996) (“Plaintiff will take no action to enforce any feature of the patent against the parties, any physician, health care provider, hospital, clinic, teaching institution, or other entity or person of any kind.”).

actually developed and used the patented incision before Dr. Pallin claimed he “invented” it.¹⁰² Thus, although the case turned on whether Dr. Pallin’s “invention” met the statutory requirements for patentability, the ramifications of the case dealt primarily with the policy arguments against the enforcement of such patents.

¶38 In 1994, in response to the Pallin litigation, the American Medical Association (“AMA”) and a coalition of other medical associations and universities proposed a ban on “pure” medical method patents. The coalition included the American Society of Dermatological Surgery, the American Academy of Ophthalmology, the American Academy of Orthopaedic Surgeons, the American Academy of Otolaryngology Head & Neck Surgery, the American Association of Neurological Surgeons, the American College of Radiology, the American College of Surgeons, the American Society of Cataract and Refractive Surgery, the American Society of Plastic and Reconstructive Surgery, the Association of American Medical Colleges, the Society of Cardiovascular and Interventional Radiology, and the Society of Vascular Technology.¹⁰³

¶39 The medical community voiced concern regarding Dr. Pallin’s attempts to enforce his patent for several reasons and extrapolated the effects of enforcing medical method patents on the quality of health care.¹⁰⁴ First, Dr. Pallin claimed that all self-sealing (sutureless) incisions infringed his patent, even if other physicians had improved the technique.¹⁰⁵ Second, thousands of surgeons used the technique, and if Dr. Pallin’s lawsuit had been successful, they would have been vulnerable to patent infringement litigation.¹⁰⁶ If even a fraction of other medical method patents were enforced, tens of thousands of medical providers would be affected. Third, Dr. Singer and his employer were forced to spend hundreds of thousands of dollars defending themselves as a result of developing a surgical technique that naturally emerged from prior advances in the field.¹⁰⁷ The medical community claimed the health care system could not bear such oppressive litigation costs.

¶40 In addition, the medical community argued that allowing the enforcement of medical method patents was contrary to the scientific process and would harm patient care. It pointed to its long-standing tradition of encouraging the open exchange of information regarding new discoveries and procedures.¹⁰⁸ But a physician applying for a medical method patent would be conflicted between fully testing a new procedure and not wanting to reveal problems with the procedure or the existence of prior art that could cause the patent application to be denied.¹⁰⁹ In addition, another physician using the

¹⁰² Portman, *supra* note 80, at 102. Mr. Portman represented Dr. Singer in the litigation. Portman, *supra* note 80, at 91 n.d1.

¹⁰³ Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC’Y 789, 790 n.4 (1996).

¹⁰⁴ *Hearing on H.R. 1127 and H.R. 2419*, *supra* note 86 (testimony of Charles D. Kelman, M.D., American Society of Cataract and Refractive Surgery). See also Eric M. Lee, 35 U.S.C. § 287(C)—*The Physician Immunity Statute*, 79 J. PAT. & TRADEMARK OFF. SOC’Y 701, 702-03 (1997).

¹⁰⁵ Portman, *supra* note 80, at 102.

¹⁰⁶ *Id.* at 102-03.

¹⁰⁷ *Id.* at 103.

¹⁰⁸ *Hearing on H.R. 1127 and H.R. 2419*, *supra* note 86.

¹⁰⁹ Portman, *supra* note 80, at 106.

method would have an incentive not to be publicly critical because she might fear retaliation in the form of punitively higher-priced licensing fees or denial of access to licenses later.¹¹⁰ In addition, she might even fail to reveal she used the method for fear of an infringement claim.¹¹¹

¶ 41 Peer review of procedures in medicine is especially important because the FDA does not regulate medical procedures and techniques.¹¹² Whether a medical procedure is effective should be determined by medical experts, not by patent examiners. If a procedure is patented, the general public may mistake the patent for the government's "seal of approval," even if it has not been sufficiently tested through the peer-review process.¹¹³ Medical method patents increase the cost of health care, but it is against the ethical code of physicians to create financial burdens for their patients.¹¹⁴ The medical community also argued that a physician's incentives to innovate and provide better care come from respect within the medical community, not from financial rewards.¹¹⁵ In addition, significant outlays of capital resources are not required to create a new medical method.¹¹⁶ Finally, enforcing infringement actions against physicians would necessarily entail discovery into confidential medical records, thus violating patient privacy rights.¹¹⁷

¶ 42 Because of wide opposition to proposed legislation that would have removed medical methods completely from the scope of patentable subject matter,¹¹⁸ a compromise bill¹¹⁹ that would make physicians immune from liability for infringement of patented methods or processes but would not affect the ability to patent these medical procedures and methods was eventually passed¹²⁰ (known as the "physician exemption" or "medical method amendment"). While the USPTO can still grant patents on medical and surgical procedures, a health care professional can neither be held liable for

¹¹⁰ *Id.*

¹¹¹ Lee, *supra* note 104, at 703.

¹¹² Portman, *supra* note 80, at 106.

¹¹³ *Id.*

¹¹⁴ Lee, *supra* note 104, at 703.

¹¹⁵ *Id.* at 703-04.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 703. *But see id.* at 715 (arguing that confidentiality orders in litigation are sufficient to protect patient privacy rights).

¹¹⁸ *Id.* at 705-06. The pharmaceutical industry opposed a total ban because it would have taken away their ability to patent therapeutic methods, assays, and vaccines. *Id.* at 705. The Clinton Administration, intellectual property attorney associations, and the American Bar Association also objected to a total ban. *Id.*

¹¹⁹ The compromise resulted from meetings between the AMA, the Medical Procedure Patent Coalition, the Pharmaceutical Research and Manufacturers of America (PhRMA), other representatives from the biotechnology industry, and congressional representatives. Mossinghoff, *supra* note 103, at 794; Lee, *supra* note 104, at 707.

¹²⁰ "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under [the Patent Act], the provisions [allowing a civil action for infringement] shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity." 35 U.S.C. § 287(c)(1) (2000). A "medical activity" is defined as "the performance of a medical or surgical procedure on a body," but does not include "the use of a patented machine, manufacture, or composition of matter," "the practice of a patented use of a composition of matter" (such as a drug), or "the practice of a process in violation of a biotechnology patent." 35 U.S.C. § 287(c)(2)(A) (2000).

infringement nor be enjoined from performing the procedure.¹²¹

¶ 43 The provision protects surgical methods for procedures that are not necessary, such as a method for performing a facelift, as well as those that are lifesaving.¹²² This could reflect that to some extent, it is difficult to classify the medical necessity of surgical procedures, such as a face transplant or a cochlear implant. It may also reflect the concern of the supporters of the exemption that the steps that would be necessary to enforce such patents invade the privacy of patients and the discretion of physicians. It would be hard to argue that patients should be put at risk during even cosmetic procedures because the patent holder of a safer method refuses to license the patent.

¶ 44 Yet, because the final statutory exemption was a compromise between various factions, it is fairly narrow both temporally¹²³ and in its scope. If a patent applicant filed the patent application before September 30, 1996, the exemption does not apply.¹²⁴ Because patents are valid for twenty years following the date of a successful patent application, this exemption will not apply to all issued patents for another decade and does not fully protect physicians until that time.

¶ 45 Existing cases demonstrate how this exemption could impact physicians and patient health care. In *Metabolite Laboratories v. Laboratory Corp. of America Holdings*, the patentee held a patent on the correlation between high levels of homocysteine, a hormone found in the blood, and vitamin B deficiency.¹²⁵ The Federal Circuit held that LabCorp, one of the world's largest clinical laboratories, induced infringement by publishing educational material to send to physicians because the physician would infringe the patent by making the correlation.¹²⁶ Although no physicians were named in the lawsuit, the medical method amendment would not have protected any physicians if they were named because the patent application for the '658 patent was filed before September 30, 1996.¹²⁷

¶ 46 The exemption also applies only to a "medical practitioner's performance of a medical activity" that would otherwise constitute infringement.¹²⁸ Reflective of heavy lobbying by the pharmaceutical industry, biotechnology firms, and intellectual property attorney associations, "medical activity" was carefully defined to exclude drug patents, the use of patented machines, and "the practice of a process in violation of a biotechnology patent."¹²⁹ The exemption protects licensed health care workers

¹²¹ 35 U.S.C. § 287(c)(1) (2000).

¹²² 35 U.S.C. § 287(c)(2)(A) (2000).

¹²³ 35 U.S.C. § 287(c)(4) (2000).

¹²⁴ *Id.*

¹²⁵ *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-59 (Fed. Cir. 2004); Assay for Sulfhydryl Amino Acids and Methods for Detecting and Distinguishing Cobalamin and Folic Acid Deficiency, U.S. Patent No. 4,940,658 (filed Nov. 20, 1986) (issued July 10, 1990).

¹²⁶ *Metabolite Labs.*, 370 F.3d at 1365.

¹²⁷ '658 Patent, *supra* note 125.

¹²⁸ 35 U.S.C. § 287(c)(1) (2000).

¹²⁹ See 35 U.S.C. § 287(c)(2)(A) (2000). Clinical laboratory services, unless provided in a physician's office, are also excluded from the protection of the exemption. 35 U.S.C. § 287(c)(3) (2000).

performing a defined medical activity and people working for them.¹³⁰ In this way, the exemption excludes many medical researchers.¹³¹ A scientist with a doctoral degree researching a genetic disease, for example, would not be protected from an infringement suit if he were conducting research on a gene owned by another entity.

¶ 47 It is not difficult to imagine situations in which a public health exception beyond the medical methods exemption will be necessary. Consider, for example, what might happen if a residential area became contaminated with hazardous material that could be neutralized only by a patent-protected recombinant bacteria. Local, state, and federal governments would have to negotiate with the patent holder to use the bacteria before cleanup could begin. The medical methods exemption would not protect the public health in that situation because the actors are not health care providers and because the bacteria does not fall within the exemption. While negotiating, people's health could be put at risk. The physician exemption therefore does not adequately protect the public. Thus, although Congress and the executive branch have acted to protect the public health, those avenues are limited by statutory authority, fear of reprisal, or lack of popular support.

IV. JUDICIAL DECISIONS—THE EROSION AND RESURRECTION OF THE PUBLIC INTEREST FACTOR IN PATENT LITIGATION

¶ 48 These international and federal legislative and executive actions demonstrate how rights claimed by patent holders might be curtailed by governments and activists to protect the public health. In patent cases, a court has the power to issue a permanent injunction against an adjudicated infringer. Patentees typically seek this relief. Historically, American courts exercised their power to craft orders that would protect the public health by denying permanent injunctions against adjudicated infringers. Permanent injunctions are not mandatory; according to the statutory language, the court should consider equitable factors when determining whether it will enter an injunction:

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.¹³²

¹³⁰ 35 U.S.C. § 287(c)(2)(B) (2000). "Related healthcare entit[ies]" are also protected; for example, a hospital, health maintenance organization, or medical clinic employing a physician using a patented medical method cannot be held liable for infringement. 35 U.S.C. § 287(c)(2)(C)-(D) (2000).

¹³¹ Medical researchers are not fully protected by any other kind of statutory or common law exemption from patent infringement. The Federal Circuit has clarified the exemption for medical researchers, carefully limiting protected activities to those performed "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," and defining unprotected activities as those conducted "in furtherance of the alleged infringer's legitimate business." *Madey v. Duke Univ.*, 307 F.3d 1351, 1362-63 (Fed. Cir. 2002). For a discussion of the impact of the patent system on medical researchers and scientists, see Lori Andrews et al., *When Patents Threaten Science*, 314 SCI. 1395 (2006); John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCI. 2002 (2005).

¹³² 35 U.S.C. § 283 (2000). Section 283 is also the statutory basis for preliminary injunctions that may be issued during the pendency of a court action and any subsequent appeal. The Federal Circuit has deemed a preliminary injunction to be "a drastic and extraordinary remedy that is not to be routinely

¶49 Traditionally, a permanent injunction could be granted only if the movant demonstrated that four factors weighed in favor of injunctive relief: irreparable injury, no or inadequate remedies at law, the balancing of hardships to the parties, and the public interest.¹³³

¶50 But eventually, the Federal Circuit created a “general rule” in patent cases that injunctions prohibiting infringing actions should be granted against patent infringers.¹³⁴ While the Federal Circuit ostensibly acknowledged that courts could deny an injunction to protect the public interest, it instructed that this was appropriate only in “exceptional circumstances.”¹³⁵ Such cases would indeed be exceptionally rare because the weight of the public interest, rather than focusing on the protection of the public interest in health or safety, focused on the public interest in enforcing the patent system to maintain economic incentives that encourage innovation. Thus, enforcing the exclusive rights granted by the patent would nearly always win.

¶51 In *eBay v. MercExchange*, the Supreme Court overruled the Federal Circuit, holding that its permanent injunction rule flew in the face of long-held equitable rules.¹³⁶ The Court held that lower courts must fully consider the traditional injunction factors in patent cases, including the public interest.¹³⁷ Thus, the protection of public health is poised to once again become a contentious issue in patent disputes.¹³⁸ The public interest can no longer merely mean the public’s interest in the enforcement of the patent system but must also take into account public health, safety, and need.

granted.” *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (citing *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991); *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990)). One reason the court might be hesitant in granting a preliminary injunction is the alleged infringer is still just that—an alleged infringer. Under the first of the four factors, the patentee must make a “clear showing” that it is likely to prove at trial that the patent is valid, enforceable, and infringed. *Nutrition 21*, 930 F.2d at 869-70 (Fed. Cir. 1991) (quoting *Atlas Powder Co. v. Ireco Chem.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985)).

¹³³ See *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (“[T]he basis for injunctive relief in the federal courts has always been [1] irreparable injury and [2] the inadequacy of legal remedies.” In addition, courts must “[3] balance[] the conveniences of the parties and possible injuries to them” and “[4] pay particular regard for the public consequences in employing the extraordinary remedy of injunction.”) (emphasis added) (citation omitted). This article primarily addresses permanent injunctions—orders enjoining adjudicated infringers from continued infringement. The factors used to determine whether a preliminary injunction should be granted are different, and these types of injunctions are difficult to obtain because the alleged infringer has the opportunity to demonstrate that the patent claims are invalid or that it is not infringing. *Lermer Germany GmbH v. Lermer Corp.*, 94 F.3d 1575, 1577 (Fed. Cir. 1996) (noting that permanent and preliminary injunctions “are distinct forms of equitable relief that have different prerequisites and serve entirely different purposes”).

¹³⁴ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989).

¹³⁵ *MercExchange, L.L.C. v. eBay Inc.*, 401 F.3d 1323, 1338-39 (Fed. Cir. 2005), *vacated*, 126 S. Ct. 1837 (2006).

¹³⁶ *eBay*, 126 S. Ct. at 1839-40.

¹³⁷ *Id.* at 1839.

¹³⁸ *Id.*; see also *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 705 (D.N.J. 2000) (noting that the proposed injunction’s effect on the public interest “is perhaps the most contested issue in this case.”).

A. Early Cases—Protecting the Public Health

¶ 52 For years, courts across the nation found public interest considerations to be compelling reasons to deny or narrow the scope of requested injunctions.¹³⁹

¶ 53 *City of Milwaukee v. Activated Sludge, Inc.*¹⁴⁰ is one of the most commonly cited injunction cases that turned on public health, possibly because it evoked a powerful image of what could go wrong if patent rights are enforced to the detriment of the public.

¶ 54 In the early part of the twentieth century, the scientific community was struggling to develop a means to purify raw, “putrescent” sewage into more acceptable nitrogenous compounds. Scientists knew that aerobic bacteria in streams could carry out this process, but the natural nitrogen cycle could not support the massive amounts of sewage that a city produced. Although numerous inventors tried, none could harness the process that nature had engineered. Eventually, scientists identified some of the key components of the process. After an apparatus to maximize the efficiency of the process was perfected, the method and apparatus for the purification of sewage was patented.¹⁴¹

¶ 55 The City of Milwaukee consulted with the inventors and built a sewage treatment plant that incorporated the patented method and apparatus. The plant converted massive amounts of raw sewage into a purified liquid that was discharged directly into Lake Michigan.¹⁴² After the plant was operational, the patent holder brought a suit alleging infringement of his methods and apparatus for sewage purification. The Seventh Circuit Court of Appeals affirmed the district court’s determination of validity¹⁴³ and infringement.¹⁴⁴ The appellate court stated that in determining whether a permanent injunction should issue, it must first consider equitable factors, including the equities of the “many others who are indirectly concerned.”¹⁴⁵ Using these factors, the appellate court reversed the district court’s order granting an injunction, explaining,

¹³⁹ See, e.g., *Bliss v. Brooklyn*, 3 F. Cas. 706, 707 (C.C.E.D.N.Y. 1871). Brooklyn had been coupling its fire hoses with patented couplings, which the court found to be “necessary for the daily use of the city in the prevention of fires.” In light of this necessity, the court ruled that the patentee’s rights could “be fully protected without . . . resort[ing] to an injunction.” *Id.* If an injunction had issued, historians might have added Brooklyn to the list of cities, such as Chicago, Illinois, and Peshtigo, Wisconsin, that suffered deadly, uncontrolled fires only months after the decision in *Bliss v. Brooklyn*. See Chicago Public Library, Chicago: 1871 The Great Fire, <http://www.chipublib.org/004chicago/timeline/greatfire.html> (last visited Nov. 4, 2007); Deana C. Hipke, The Great Peshtigo Fire of 1871, <http://www.peshtigofire.info/> (last visited Nov. 4, 2007); see also *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941, 945 (9th Cir. 1945) (stating, *sua sponte*, that it would deny an injunction to alleviate a public health crisis); *Nerney v. N.Y., N.H. & H.R. Co.*, 83 F.2d 409, 411 (2d Cir. 1936) (denying a broad injunction against a railroad in part to avoid “inconvenience” to the public); *Electro Bleaching Gas Co. v. Village of Garden City*, 33 F.2d 209, 209-11 (E.D.N.Y. 1926) (delaying an injunction for twenty days so that the village could prepare for the impact of replacing the village’s system for chlorinating and “antisepticizing” its drinking water).

¹⁴⁰ *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934).

¹⁴¹ *Id.* at 580-84.

¹⁴² *Id.* at 589-90.

¹⁴³ *Id.* at 589.

¹⁴⁴ *Id.* at 591-92.

¹⁴⁵ *Id.* at 593.

If . . . the injunction ordered by the trial court is made permanent in this case, it would close the sewage plant, leaving the entire community without any means for the disposal of raw sewage other than running it into Lake Michigan, thereby polluting its waters and endangering the health and lives of that and other adjoining communities.¹⁴⁶

¶ 56 The court rejected the patent holder's suggestion that chemicals could counteract the harmful effect of disposing of the sewage in the lake, stating, "where, as here, the health and the lives of more than half a million people are involved, we think no risk should be taken" ¹⁴⁷ The court noted that money damages were available to the patent holder and stated that it found persuasive the argument that injunctive relief was not always necessary to protect the rights of the patentee.¹⁴⁸

¶ 57 The patent infringement in *Activated Sludge* forced the court to choose between upholding the patentee's right to exclude the infringer from the use of his invention and creating a major public health crisis, or at least the substantial likelihood thereof. The court chose to protect the public health. However, recent cases, many of which were decided after the Federal Circuit was formed, have established a trend in finding that no interest is great enough to overcome a patentee's right to exclude.

B. The Erosion of the Public Interest Factor

¶ 58 In 1982, Congress formed the Court of Appeals for the Federal Circuit and gave it exclusive jurisdiction over appeals in patent cases.¹⁴⁹ The newly formed Federal Circuit began relying on a provision of the Patent Act providing that "patents shall have the attributes of personal property."¹⁵⁰ It equated this with the right to exclude others, arguably the most important property right.¹⁵¹ The Federal Circuit explained that while the grant of injunctive relief was discretionary, it was certainly "the norm" to grant such relief.¹⁵² This "norm" was based on the conclusion that "it is contrary to the laws of

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ 28 U.S.C. § 1295(a) (2000). Commentators and scholars have argued that the propatent and probusiness Federal Circuit tends to rule in favor of patent holders and has expanded the scope of patentable subject matter. Andrews, *supra* note 131, at 1396; NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 37, 42 (Stephen A. Merrill et al. eds., 2004). "The court is pro-patent in terms of patent validity," according to patent scholar Timothy R. Holbrook. Marcia Coyle, *Critics Target Federal Circuit*, NAT'L L. J., Oct. 19, 2006, available at <http://www.law.com/jsp/article.jsp?id=1161162317072>. "The [Federal Circuit] has taken on a decidedly pro-patent bias" Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1, 26 (1989) (cited in *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 n.4 (2002) (Stevens, J., concurring)).

¹⁵⁰ 35 U.S.C. § 261 (2000).

¹⁵¹ See *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("Under . . . 35 U.S.C. § 261, a patent is a form of property right, and the right to exclude recognized in a patent is but the essence of the concept of property." (citing *Schenck v. Nortron Corp.*, 713 F.2d 782 (Fed. Cir. 1983))).

¹⁵² *KSM Fastening Sys., Inc. v. H.A. Jones Co., Inc.*, 776 F.2d 1522, 1524 (Fed. Cir. 1985) (citing *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573 (Fed. Cir. 1983)); see also *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (noting that "courts have in rare instances exercised their

property . . . to deny the patentee's right to exclude others from use of his property."¹⁵³ By 1989, the Federal Circuit had firmly stated that as a "general rule," a permanent injunction should issue against the infringer of a valid patent unless there is "a sound reason for denying it."¹⁵⁴

¶ 59 This "general rule" was favorable to patentees. In most circumstances, a patentee had to demonstrate only validity and infringement, and a court would issue an injunction as if it were a matter of right.

¶ 60 But this was not the case in other areas of law. In other property disputes, property owners had the more formidable burden of showing that the four factors tipped in favor of permanent injunctive relief. The first factor asked whether withholding a permanent injunction would irreparably harm the property owner. In a similar vein, the second factor asked whether a legal remedy, such as damages, would be an adequate substitute for a permanent injunction. Third, the court balanced the conveniences and hardships of the parties, determining whether the permanent injunction, or its absence, would significantly harm one party without benefiting the other party. Finally, the court considered whether a permanent injunction would harm the public. The court issued a permanent injunction to a property owner only if the totality of the factors weighed in his favor.

¶ 61 But even when an infringer raised the equitable factors, patentees had little reason to fear that the court would withhold permanent injunctive relief. Regarding the first factor, courts had held that the principal value of a patent is the right to exclude. Unless an injunction issued to protect that right, the patentee would be irreparably injured.¹⁵⁵

discretion to deny injunctive relief in order to protect the public interest"); *cf.* *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1372 (Fed. Cir. 2004) ("[T]he district court properly granted the injunction because LabCorp was found to infringe."). The Supreme Court later accused the Federal Circuit of "categorical[ly] grant[ing]" injunctions against adjudicated infringers without considering equitable factors. *eBay*, 126 S. Ct. at 1841.

¹⁵³ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246-47 (Fed. Cir. 1989).

¹⁵⁴ *Id.* at 1247 (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988)). Yet, even after the general rule was established, some panels of the Federal Circuit and some district courts continued to reiterate the need to take the public interest into consideration on motions for permanent injunctive relief. *See Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1272 (Fed. Cir. 1999) ("[W]hile we have stated the general rule that an injunction should follow an infringement verdict, we also recognize that district courts, as befits a question of equity, enjoy considerable discretion in determining whether the facts of a situation require it to issue an injunction." (citations omitted)); *Shiley, Inc. v. Bentley Labs., Inc.*, 601 F. Supp. 964, 969-70 (C.D. Cal. 1985) ("[T]he decision whether to grant an injunction is thus within the judge's discretion. . . . [T]he court must consider . . . whether the public interest would be served . . ."). Nevertheless, considering that the U.S. Supreme Court granted certiorari in the *eBay* case, the Federal Circuit acted as if it adhered to a de facto rule to grant permanent injunctions once an infringer had been deemed an infringer.

¹⁵⁵ *See, e.g., Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983) ("The very nature of the patent right is the right to exclude others. Once the patentee's patents have been held to be valid and infringed, he should be entitled to the full enjoyment and protection of his patent rights. The infringer should not be allowed to continue his infringement in the face of such a holding."); *Shiley*, 601 F. Supp. at 970 ("In a patent infringement case, where the infringing device will continue to infringe and thus damage plaintiff in the future, monetary damages are generally considered to be inadequate. This inadequacy results from the nature of the patent right itself—the right to exclude others.").

The same principle tipped the second factor in the patentee's favor. After all, if a patentee would be irreparably injured without a permanent injunction, then the court could not withhold that relief and simultaneously claim to have provided an adequate remedy.¹⁵⁶ In light of the irreparable injury and the inadequacy of monetary damages, the balance of hardships tipped in the patentee's favor.¹⁵⁷ Finally, the patentee argued that if the court did not support its right to exclude competitors, then inventors might stop disclosing their useful inventions and the public would be injured.¹⁵⁸

¶62 Aside from the tendency of all the factors to tip in patentees' favor, an eminent member of the bench even pointed out that it was more efficient for a judge to grant an injunction than to try his hand at setting a reasonable royalty:¹⁵⁹

The injunction [in a patent dispute] creates a property right and leads to negotiations between the parties. A private outcome of these negotiations—whether they end in a license at a particular royalty or in the exclusion of an infringer from the market—is much preferable to a judicial guesstimate about what a royalty should be. The actual market beats judicial attempts to mimic the market every time, making injunctions the normal and preferred remedy.¹⁶⁰

¶63 With so much precedent supporting permanent injunctions against infringers, courts, before May 2006,¹⁶¹ sometimes dedicated only a single sentence to explain that

¹⁵⁶ See *Odetics, Inc. v. Storage Tech. Corp.*, 14 F. Supp. 2d 785, 795 (E.D. Va. 1998). “[A]rguments that infringement and related damages are fully compensable [*sic*] in money downplay the nature of the statutory right to exclude others from making, using, or selling the patented invention throughout the United States.” *Id.* (quoting *Atlas Powder Co. v. Ireco Chem.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985)). The court in *Odetics* continued, “Although such damages might be ‘adequate’ in the sense that they could replicate what might be a reasonable royalty for such continued infringement, damages, however measured, are nonetheless inadequate because limiting [a patent holder] to damages does not allow it to exercise the monopoly power granted to it by the statute; an injunction is the only remedy that can achieve that goal.” *Id.*; see also *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383-84 (Fed. Cir. 2006) (asserting that the right to exclude is a fundamental purpose of the patent system, and such a right may tip the scales in patentee's favor regardless of “legitimate concerns” about the public's access to and ability to purchase needed medication in the face of the injunction).

¹⁵⁷ See *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 707-08 (D.N.J. 2000) (holding that “it is now clear that [the patentee] has and will suffer irreparabl[e] injury absent an injunction. The breadth and depth of this irreparable harm . . . significantly outweighs the harm which [the infringer] may suffer when it must cease infringing [the] patent.”).

¹⁵⁸ See *Odetics*, 14 F. Supp. 2d at 795 (“The public-interest factor often favors the patentee, given the public's interest in maintaining the integrity of the patent system.”); *Shiley*, 601 F. Supp. at 971 (holding that “the public interest to be served by protection of the nation's patent system outweighs” other public interest concerns).

¹⁵⁹ See *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1397 (N.D. Ill. 1993) (The Honorable Judge Frank H. Easterbrook, of the Court of Appeals for the Seventh Circuit, expounding upon the merits of permanent injunctions while sitting for the District Court for the Northern District of Illinois by designation).

¹⁶⁰ See *id.* (citing JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES §§ 1.14, 9.03[1] (1992)).

¹⁶¹ See *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1839-41 (2006) (holding that patentees must demonstrate that the four factors (irreparable harm, inadequacy of legal remedies, balance of hardships, and public interest) weigh in favor of permanent injunctive relief).

there was “no sound reason” to deny entering a permanent injunction against an infringer.¹⁶²

C. *eBay*: The Supreme Court Overturns the Federal Circuit’s “General Rule”

¶ 64 In 2006, the Supreme Court considered whether the Federal Circuit’s general rule inappropriately ignored conflicting equities in patent cases.

¶ 65 MercExchange filed suit against eBay,¹⁶³ the popular online auction house and retailer, accusing the company of infringing several patents that it owned as assignee.¹⁶⁴ Much of the litigation focused on patent number 5,845,265 (“the ’265 patent”).¹⁶⁵ The ’265 patent claims a method for structuring an “electronic market” that private individuals could trust as a safe place for the sale of goods.¹⁶⁶ eBay allegedly infringed upon the ’265 patent’s business method claims by using a “fixed-price purchasing feature,”¹⁶⁷ its “Buy It Now” feature.¹⁶⁸ The Buy It Now feature is advantageous because it allows a buyer to bypass the auction process (during which prices and competition may increase) and purchase an item immediately for a price the seller has set. It is advantageous for the seller because a bidder cannot experience buyer’s remorse and change his mind about participating in the bidding process.

¶ 66 After trial, a “jury found that [the ’265] patent was valid, that eBay and Half.com had infringed that patent, and that an award of damages was appropriate.”¹⁶⁹ Yet the district court denied MercExchange’s motion for the entry of a permanent injunction.¹⁷⁰

¹⁶² See *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1372 (Fed. Cir. 2004) (holding that the “brevity” of the district court’s finding that there was “no sound reason for denying the injunction” was acceptable); see also *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989) (“It is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it. [The infringer] has presented no such reason.” (citation omitted)). But see *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 700-08 (discussing the four factors at length, including the infringer’s argument that an injunction should be denied so that the public would not lose the benefit of its research).

¹⁶³ MercExchange also filed suit against Half.com and ReturnBuy. Half.com became a wholly owned subsidiary of eBay at least as early as March 29, 2006. *eBay*, 126 S. Ct. at 1839. ReturnBuy was dismissed from the case after entering into a settlement with MercExchange before the dispute went to trial. *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1326 (Fed. Cir. 2005), *vacated*, 126 S. Ct. at 1839.

¹⁶⁴ The patents at issue were U.S. Patent Nos. 5,845,265 (“the ’265 patent”), 6,085,176 (“the ’176 patent”), and 6,202,051 (“the ’051 patent”). *MercExchange*, 401 F.3d at 1325.

¹⁶⁵ The other two patents (the ’176 patent and the ’051 patent) were tied up in disputes over their validity at various points in the litigation. The ’176 patent was invalidated by the Federal Circuit. The district court held the ’051 patent invalid on a motion for summary judgment, but the Federal Circuit later vacated the grant of summary judgment and remanded for a determination of validity. *MercExchange*, 401 F.3d at 1326, 1333, 1337.

¹⁶⁶ *eBay*, 126 S. Ct. at 1839 (citing the ’265 patent).

¹⁶⁷ See *MercExchange*, 401 F.3d at 1325.

¹⁶⁸ See Robert E. Thomas, *Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws*, 43 AM. BUS. L.J. 689, 735 (2006).

¹⁶⁹ *eBay*, 126 S. Ct. at 1839.

¹⁷⁰ *MercExchange, L.L.C. v. eBay, Inc.*, 275 F. Supp. 2d 695, 715 (E.D. Va. 2003), *vacated*, 401 F.3d at 1326, *vacated*, 126 S. Ct. at 1839.

The district court determined in its discretion that injunctive relief should not issue in light of “traditional equitable principles,” even though it noted that under Federal Circuit precedent, “the grant of injunctive relief against [an] infringer is considered the norm.”¹⁷¹ The district court found particularly persuasive the fact that the patent holder did not use its invention itself but existed only to extract licensing fees or damages from other companies. The court found that this tactic did not benefit the public and that the patentee could be adequately compensated by monetary damages.¹⁷²

¶ 67 The Federal Circuit reversed the district court order denying injunctive relief.¹⁷³ This reversal was predicated on the Federal Circuit’s “general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.”¹⁷⁴ The Supreme Court granted certiorari to determine whether the Federal Circuit’s general rule was appropriate.¹⁷⁵

¶ 68 In May 2006, the Supreme Court held that the Federal Circuit’s rule was an anomalous departure from the “long tradition of equity practice.”¹⁷⁶ Outside of patent law, courts weighed the traditional four factors when considering a motion for permanent injunctive relief.¹⁷⁷ The Court determined that the general rule impermissibly ignored Congress’s explicit command in 35 U.S.C. § 283 that injunctions (whether permanent or preliminary) should be issued according to equitable principles, such as those embodied in the traditional four-factor test used in other disputes over injunctive relief.¹⁷⁸

¹⁷¹ *MercExchange*, 275 F. Supp. 2d at 711, 715.

¹⁷² *Id.* at 713-14.

¹⁷³ *MercExchange*, 401 F.3d at 1339.

¹⁷⁴ *Id.*

¹⁷⁵ *eBay*, 126 S. Ct. at 1839. In the order granting certiorari, the Court directed the parties to brief the question of “[w]hether this Court should reconsider its precedents, including *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 . . . (1908), on when it is appropriate to grant an injunction against a patent infringer.” Order granting eBay’s petition for *certiorari*, *eBay Inc. v. MercExchange, L.L.C.*, 546 U.S. 1029 (2005). In *Continental Paper Bag Co.*, the Supreme Court considered whether a patentee’s right to exclude should be secured by an injunction when the patentee neither practiced the invention nor licensed others to practice it. *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 422-30 (1908). The Court held that injunctive relief should not be contingent on whether the patentee made its invention available to the public. *Id.* at 429-30. The Court declined to decide whether injunctive relief might be denied in a future dispute in order to ensure that the public would have access to the invention. *Id.* at 430. In 1995, the Federal Circuit summarized these concepts from *Continental Paper Bag Co.*: “There is no requirement in this country that a patentee make, use, or sell its patented invention[, but if] a patentee’s failure to practice a patented invention frustrates an important public need for the invention, a court need not enjoin infringement of the patent.” *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995).

¹⁷⁶ See *eBay*, 126 S. Ct. at 1839, 1839-40 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982)).

¹⁷⁷ *Id.* at 1839 (“[T]he basis for injunctive relief in the federal courts has *always been* [1] irreparable injury and the [2] inadequacy of legal remedies.” In addition, courts must “[3] balance[] the conveniences of the parties” and “[4] pay particular regard [to] the public consequences in employing the extraordinary remedy of injunction.”) (emphasis added) (citing *Weinberger*, 456 U.S. at 311-13 (1982)).

¹⁷⁸ *eBay*, 126 S. Ct. at 1839-40. Chief Justice Roberts’s concurrence noted that the Court’s decision to eliminate the rule in favor of injunctive relief was not meant to give lower courts a “clean slate.” *Id.* at 1841 (Roberts, C.J., concurring). He warned that when applying the four factors, the courts should be mindful that permanent injunctions have been historically the most appropriate form of relief “in the vast majority of patent cases.” *Id.*

¶ 69 To realign equitable considerations in patent cases with equitable considerations in other areas of the law, the Supreme Court instructed courts to begin applying these factors in patent disputes.¹⁷⁹ Now, consistent with nonpatent cases, in order to succeed on a motion to permanently enjoin an infringer, a patentee must demonstrate:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the [patentee] and [infringer], a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.¹⁸⁰

¶ 70 The Court explained that a right and a remedy are distinct from each other—just because a patentee has the right to exclude others from using her invention does not mean that she will be granted the remedy that actually excludes them.¹⁸¹

V. PATENT RIGHTS CAN AND SHOULD BE LIMITED IN CERTAIN SITUATIONS WHEN THEY CONFLICT WITH THE PUBLIC INTEREST IN PUBLIC HEALTH

¶ 71 One of the potential inequities that post-*eBay* courts must consider is whether the

¹⁷⁹ *Id.* at 1841 (majority opinion) (“[T]he decision whether to grant or deny injunctive relief . . . must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.”).

¹⁸⁰ *Id.* at 1839 (citations omitted).

¹⁸¹ *Id.* at 1840-41. The Court stated that “the creation of a right is distinct from the provision of remedies for violations of that right.” *Id.* Thus, it is possible for the Patent Act to grant patent owners the right to exclude and to simultaneously authorize courts to deny motions for remedies, like permanent injunctive relief, that are designed to enforce the right to exclude. *Id.* (citing 35 U.S.C. §§ 154(a)(1), 261, 283). Upon remand of the *eBay* dispute, the district court was faced with the question of whether to issue a permanent injunction given that *eBay* had been found to have willfully infringed one of *MercExchange*’s patents. *MercExchange, L.L.C. v. eBay, Inc.*, No. 01 cv 736, 2007 U.S. Dist. LEXIS 54642, at *29 (E.D. Va. July 27, 2007). The district court allowed limited discovery and presentation of evidence on this issue. *Id.* at *5-6. Evidence revealed that subsequent to trial *MercExchange* had granted a nonexclusive license on its patent portfolio to one of *eBay*’s competitors. *Id.* at *7-9. Along with other evidence, this licensing activity made *MercExchange* appear to be “willin[g] to forgo its right to exclude in return for money.” *Id.* at *39. The collective evidence undermined *MercExchange*’s argument that it would be irreparably harmed without an injunction and convinced the district court that money damages could adequately compensate *MercExchange* for the loss of its right to exclude *eBay* from using the patented invention. *Id.* at *36-40, 71-79.

With respect to the public interest factor, the district court reiterated the Supreme Court’s admonition that courts are not allowed to apply “presumption[s]” or “categorical rules” in deciding whether an injunction would disserve the public interest. *Id.* at *86-87 (citing *eBay*, 126 S. Ct. at 1840). Courts must be especially careful when considering what weight to give to the generally accepted proposition that the “public-interest factor often favors the patentee, given the public’s interest in maintaining the integrity of the patent system.” *Id.* at *86 (quoting *Odetics Inc. v. Storage Tech. Corp.*, 14 F. Supp. 2d 785, 795 (E.D. Va. 1998)). The district court warned that courts cannot presume that the public’s general interest in a strong patent system will tip the public interest factor in favor of injunctive relief. *Id.* at *86-87. Instead, courts must make case-specific determinations of whether an injunction would serve the public interest and can consider factors such as the nature of the patent at issue and the economic effect a permanent injunction would have on the market. *Id.* at *86-101. The district court held that the public interest factor weighed against the entry of a permanent injunction. *Id.* at *101. Further finding that the balance of the hardships favored neither party, the district court denied the motion for a permanent injunction. *Id.* at *101-04.

“public interest would . . . be disserved by a permanent injunction.”¹⁸² This question is not new to patent jurisprudence.¹⁸³ If history is any indicator, infringers will continue to claim that injunctions should be denied, limited in scope, or delayed to protect the public. To completely deny an injunction, a court must accept that it is effectively granting the infringer a compulsory license.¹⁸⁴ And courts may balk at the possibility that the infringer is raising the public interest only to secure this. Accordingly, we have suggested a variety of equitable considerations that may be applied to determine whether the public interest weighs in favor of denying an injunction to protect the public health. Finally, we have attempted to create a scenario to demonstrate the potential application of these factors.

A. Equitable Considerations Under the Public Interest Factor

¶72 Courts should deny injunctions that would harm the public health or hinder critical innovative endeavors. The most important public health considerations are the first three factors discussed below. This fact-intensive decision of whether to grant or deny permanent injunctive relief must be grounded in case-by-case analysis.¹⁸⁵

¹⁸² *eBay*, 126 S. Ct. at 1839.

¹⁸³ *See, e.g.*, *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941, 944 (9th Cir. 1945); *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 700 (D.N.J. 2000); *Shiley, Inc. v. Bentley Labs., Inc.*, 601 F. Supp. 964, 969-70 (C.D. Cal. 1985). In disputes over preliminary injunctions, the Federal Circuit has required courts to consider the public interest vis-à-vis the patent system. *See, e.g.*, *Hybritech Inc. v. Abbott Lab.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988); *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986). Although preliminary and permanent injunctions “have different prerequisites and serve entirely different purposes,” see *supra* notes 132-33, many of the arguments that have been raised on the public’s behalf in preliminary injunction disputes are equally applicable in disputes over permanent injunctive relief.

¹⁸⁴ *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1555 (Fed. Cir. 1995) (quoting *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1328 (Fed. Cir. 1987) (“[The] imposition on a patent owner who would not have licensed his invention for [a certain] royalty is a form of compulsory license, against the will and interest of the person wronged, in favor of the wrongdoer.”) (alterations in original); *Odetics*, 14 F. Supp. 2d at 795 (“If no injunction issues, [the patent holder] effectively will be forced to license [its patent to the infringer], a result antithetical to a basic tenet of the patent system, namely that the decision whether to license is one that should be left to the patentee.”); *Ortho Pharm. Corp. v. Smith*, 15 U.S.P.Q.2d 1856 at ¶ 57, 1990 U.S. Dist. LEXIS 1951, at *26 (E.D. Pa. 1990) (“A compulsory license, which may arise from a refusal to enjoin, is fundamentally at odds with the right of exclusion built into our patent system.”).

¹⁸⁵ *See eBay*, 126 S. Ct. at 1840-41 (warning against the application of categorical rules when applying the traditional principles of equity). The majority of the post-*eBay* cases have not squarely faced the public health interests raised here. *E.g.*, *Commonwealth Sci. & Indust. Research Org. v. Buffalo Tech. Inc.*, 492 F. Supp. 2d 600, 607 (E.D. Tex. 2007) (“[T]here are rare and limited circumstances in which an injunction would be contrary to a significant public interest such as health and safety concerns. . . . No such interests are implicated here”); *Canon Inc. v. GCC Int’l, Ltd.*, 450 F. Supp. 2d 243, 257 (S.D.N.Y. 2006) (“None of the products at issue suffer from marketplace shortages or are otherwise necessary to the health, safety and welfare of large numbers of people.”); *TiVo Inc. v. EchoStar Commc’n Corp.*, 446 F. Supp. 2d 664, 670 (E.D. Tex. 2006) (“[T]he public interest would not be disserved by a permanent injunction [in this case]. . . . The infringing products are not related to any issue of public health or any other equally key interest; they are used for entertainment.”).

But a few courts have considered the public health implications of proposed injunctions. In *Innogenetics, N.V. v. Abbott Laboratories*, the infringer argued that it should be allowed to continue

¶73 ***How many people are affected, and are the poor or politically powerless disproportionately affected?***

¶74 The answers to the questions of how many and which people will be affected by a permanent injunction will guide a court in determining whether a permanent injunction should issue or in determining when patent rights may be abrogated. The more people that are affected, and the more severe the impact, the more these factors would weigh against granting a permanent injunction. Yet if only a limited number of people are affected, this factor would weigh in favor of granting a permanent injunction, depending on the severity of the effects.

¶75 In the *Activated Sludge* case, the court found that an entire community would be left without means for proper disposal of sewage, endangering that community and surrounding areas.¹⁸⁶ The court estimated that half a million people would be affected, and it overturned the district court's injunction order.¹⁸⁷

¶76 It is also proper to consider denying injunctive relief where a subset of the population will be disproportionately affected by the injunction. For example, in *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*, indigent people were disproportionately affected by the patent holder's restrictive licensing scheme.¹⁸⁸ Recognizing this inequality, the court refused to condone the patent holder's actions, which had left poor people without a source of an essential vitamin; it indicated its willingness to deny the patent holder's request to prohibit its competitors' use of the technology.

¶77 Parallels can be drawn between these cases and the refusal of pharmaceutical companies to license their products at rates affordable to poor and third-world nations.¹⁸⁹ In certain circumstances, racial minorities and disadvantaged persons might be

producing Hepatitis C diagnostic products because the patentee could not produce enough tests to meet public demand or provide a substitute product that was of comparable quality to the infringer's product. *Innogenetics, N.V. v. Abbott Labs.*, No. 05-cv-0575, 2007 U.S. Dist. LEXIS 3148, at *2-3 (W.D. Wis. Jan. 12, 2007). The court noted that if these allegations were supported, an injunction would cause "a serious risk to the public health." *Id.* at *75. After an evidentiary hearing on the public health issue, the court found that the patentee demonstrated by the preponderance of the evidence that the public health would not be harmed by the entry of the injunction. *Id.* at *2-3. The *Innogenetics* court recognized the importance of the public health interests at stake and appropriately ordered an additional evidentiary hearing on the issue.

In another case that considered public health, the infringer claimed that an injunction would prevent public access to its "allegedly safer and more effective" product for bone screws used to treat femoral fractures. *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 981 (W.D. Tenn. 2006). The court summarily dealt with the argument that an injunction would harm public health because "none of the data on the record establishes undisputed and enormous public reliance on [the infringer's] products and . . . other, similar products are available . . ." *Id.* at 985.

¹⁸⁶ *Activated Sludge*, 69 F.2d at 593.

¹⁸⁷ *Id.*

¹⁸⁸ See *Vitamin Technologists*, 146 F.2d at 945.

¹⁸⁹ Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AM. J. L. & MED. 159 (2006) (arguing a patent buy-out mechanism for patented pharmaceuticals for common diseases in developing countries could be enacted while still not damaging incentives for innovation).

disproportionately affected by patent holders. Post-*eBay*, courts have the responsibility to consider the effects of patent holders' actions on the health of disadvantaged, poor, or politically powerless people.

¶ 78 ***Would an injunction compromise the availability or quality of health care?***

¶ 79 The availability of a replacement product or service for the enjoined product or service is another consideration the court and government actors must undertake. At times, another equally effective noninfringing product might be available or manufacturers might be able to produce a noninfringing replacement product. With respect to method or process patents, it may be possible to work around the patent. In other factual scenarios, such alternatives might not be available. The FTC, for example, found that because Novartis owned all the relevant gene therapy technology, other companies would be hindered in their research. It was not possible to engage in research without the technology.

¶ 80 In addition to the interval needed to produce alternative products or for the patent holder to step up its production, another consideration is the time to train medical personnel. In *Shiley, Inc. v. Bentley Laboratories, Inc.*, the defendant produced evidence that the immediate demand for replacement bubble blood oxygenators might overwhelm other manufacturers.¹⁹⁰ In addition, even if manufacturers met the demand for replacements, the machines would be effectively unavailable to the public due to the “lag-time in training [hospital] staff to use another slightly different model.”¹⁹¹ Heart surgery patients could be unnecessarily endangered by the lack of availability.¹⁹² The court found that these concerns, while they “may be real,” could be alleviated by providing for a six-month transition period before the injunction became fully effective.¹⁹³

¶ 81 While a transition period before an injunction is enforced may be appropriate in some circumstances, it will not necessarily assuage concerns about availability in all cases. Forcing medical centers to replace their equipment is an expensive and time-consuming proposition. A court should seek evidence as to the financial and opportunity costs to successfully procure equipment. In addition, a short transition period might not

¹⁹⁰ *Shiley, Inc. v. Bentley Labs., Inc.*, 601 F. Supp. 964, 971 (C.D. Cal. 1985).

¹⁹¹ *Id.* The court declined to give full weight to these assertions because the patent holder claimed it did not have the opportunity to present evidence to rebut the evidence submitted by the defendant. *Id.* at 970 n.1.

¹⁹² *Id.* at 970 (“[The infringer] claims that removal of its oxygenators from the market will have an adverse effect on many candidates for open heart surgery.”).

¹⁹³ *Id.* at 971. The court determined that during the six months the hospitals could continue to use the infringing machines, allowing the industry time to recalibrate their manufacturing to meet demand, and hospitals could use the transition period to train their staff to use the replacement machines. *See id.* The infringing manufacturer would be subject to fees that increased as the six months proceeded, thereby creating an incentive for the defendant to shorten the transition period. *See id.* The *Shiley* court’s “transition period” has served as a model in other cases where the court wanted to lessen the impact of a permanent injunction on the availability of a product in the marketplace. *See, e.g., Schneider (Eur.) AG v. SciMed Life Sys., Inc.*, 852 F. Supp. 813, 861-62, 868-69 (D. Minn. 1994) (“The permanent injunction . . . shall contain a one-year transition period to allow an efficient and non-disruptive changeover” of balloon dilation catheters used to treat coronary artery disease.).

be sufficient to train staff on new equipment. At the end of the period, the staff might not be competent or comfortable in use of the equipment. A full consideration of the nuances of this factor will aid a court in crafting an appropriate remedy.

¶ 82 *Is the patentee inequitably using the monopoly?*

¶ 83 Patent holders are granted the right to exclude others from making, using, or selling their inventions. But sometimes patentees improperly or inequitably use this sanctioned monopoly to protect an industry or prevent competition to the detriment of the public's health, as seen in the landscape leading up to the physician exemption statute. For example, assume a patentee holds a patent for a method of diagnosing liver cancer (issued before the physician exemption), which consists of measuring a protein's level in the patient's blood and correlating it with the presence of liver tumors. The patent holder will license its patent only to medical centers with no religious affiliation. This arbitrary and nonmedically related licensing scheme leaves a percentage of the population without access to this test and denies others the ability to select a preferred provider. If there is no other effective blood test (as opposed to an invasive and painful biopsy, for example), a compulsory license against the patent holder might be in order.

¶ 84 In *Vitamin Technologists*, the patent holder, the Wisconsin Alumni Research Foundation ("WARF"), owned multiple patents that covered the process of irradiating food to produce vitamin D.¹⁹⁴ This lucrative technology had the potential to work a veritable public health miracle. Many people at the time of the case were afflicted with rickets,¹⁹⁵ a disorder affecting bone development that is linked to vitamin D deficiency.¹⁹⁶ WARF admitted that the addition of vitamin D to commonly eaten foods could result in the eradication of rickets, a disease that more severely affected the "poorer class of people."¹⁹⁷ But WARF, the commercial arm of the University of Wisconsin, was influenced by the Wisconsin dairy industry and would not license the technology to any producers of margarine—the "butter of the poor."¹⁹⁸ It even forced its licensees to agree to not sell their irradiated ingredients to producers of margarine.¹⁹⁹

¶ 85 The district court found that the patents were not invalid and permanently enjoined the defendant manufacturer from using the process to add vitamin D to

¹⁹⁴ *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941, 942 (9th Cir. 1945). The process had been discovered by a researcher at the University of Wisconsin and turned over to WARF for licensing and commercialization. Since 1925, WARF has been responsible for patenting and licensing discoveries that result from research conducted at the university. The irradiating technology was worth millions. WARF describes the vitamin D irradiation patents as its first commercial success and takes credit for helping to eradicate childhood rickets. Wis. Alumni Research Found., Our History, <http://www.warf.ws/about/index.jsp?cid=26> (last visited Nov. 4, 2007).

¹⁹⁵ *Vitamin Technologists*, 146 F.2d at 943.

¹⁹⁶ Rickets causes bowlegs and other deformities in children. Mayo Clinic, Rickets, Nov. 6, 2006, <http://www.mayoclinic.com/health/rickets/DS00813>. Most cases of rickets are linked to vitamin D deficiency. In addition to bowlegs, the disorder may leave children with bone deformities in the skull, chest, spine, and limbs. *Id.*

¹⁹⁷ *Vitamin Technologists*, 146 F.2d at 943 (quoting WARF's business manager).

¹⁹⁸ *Id.* at 945.

¹⁹⁹ *Id.*

margarine.²⁰⁰ Upon review, the Ninth Circuit Court of Appeals determined that the patents were invalid and that WARF, therefore, was not entitled to an injunction.²⁰¹ Yet it indicated that even if the patents had been valid, it would have withheld injunctive relief as contrary to the public interest.²⁰² Although WARF's process was a "great boon to humanity," its licensing scheme had ensured that this cure would not reach the people who were most desperate for it.²⁰³ The court found WARF's actions to be so contrary to the public interest that it referred the case to the Attorney General.²⁰⁴

¶ 86 The *Vitamin Technologists* case vividly illustrates how a patent holder's misuse of the rights afforded it can be detrimental to public health. If a patent holder is using its patent to engage in anticompetitive behavior, a court may be more likely to deny injunctive relief, or in the alternative, it may be more appropriate for a government agency to regulate the licensing of the technology. The *Vitamin Technologists* court found particularly compelling that the dairy industry was heavily influencing WARF's deliberate decision to keep its technology away from margarine manufacturers.²⁰⁵ This case also demonstrates how the monopoly afforded an inventor can disproportionately affect certain groups, such as the indigent, racial groups, and children.

¶ 87 ***Is there a nonuse of the patent?***

¶ 88 As suggested by considerations regarding the patent holders' inequitable use of a

²⁰⁰ *Id.* at 942.

²⁰¹ *See id.* at 949-53 (holding that the claims were invalid because they were anticipated by prior art, they "failed to inform the public of the limits of the area of the claimed monopoly," or they were barred by laches).

²⁰² *See id.* at 945 (raising, *sua sponte*, the negative effect on public health). The Ninth Circuit put WARF's actions into perspective by looking at two Supreme Court cases. *Id.* at 945-46. In *Mercoird Corp.*, a tying case, the patent holder would license its invention (a heating system) only to parties that promised to buy an additional, unpatented product (an unpatented switch used in the system) from it. *Mercoird Corp. v. Mid-Continent Invest. Co.*, 320 U.S. 661, 663-64 (1944); *see also* *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 490 (1942) (patentee would license its patented canning machine only if the prospective licensee agreed to use unpatented salt tablets in its canning operations), *abrogated*, *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 46 (2006) (holding that patent misuse did not create a presumption of market power in antitrust cases), *and superseded by* 35 U.S.C. § 271(d) (removing market power presumption in patent cases). In the second case, *United States v. Masonite Corp.*, the patentee convinced its competitors to cooperate in a price-fixing scheme by threatening them with patent infringement suits. *See* *United States v. Masonite Corp.*, 316 U.S. 265, 268-70, 282-83 (1942) (listing agreements from 1933 through 1941 that effectively fixed the price on a patented construction material). By comparison, WARF had "refus[ed] to license . . . its patent to protect the health of great numbers of the public." *Vitamin Technologists*, 146 F.2d at 946. "[A]rguabl[y]," WARF's actions were "vastly more against the public interest" than the other patentees' anticompetitive practices. *See id.* at 945-46 (arguing, *sua sponte*, that WARF was much worse than the patentees that the Supreme Court refused to protect with injunctions). And since the Supreme Court refused to sacrifice the public interest in each of those cases, (*see Mercoird Corp.*, 320 U.S. at 665 ("It is the public interest which is dominant in the patent system"); *Masonite Corp.*, 316 U.S. at 277 (holding that it is forbidden to use a "patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant") (quotation omitted)), the Ninth Circuit was willing to deny WARF's request for injunctive relief. *Vitamin Technologists*, 146 F.2d at 946-47 (ultimately invalidating the patents on other grounds; *see supra* note 201).

²⁰³ *See Vitamin Technologists*, 146 F.2d at 945.

²⁰⁴ *See id.* at 946.

²⁰⁵ *Id.* at 943-44, 945-46.

patent, the complete nonuse of a patent is also a factor to consider. Under U.S. law, a patent holder generally has no obligation to practice his invention.²⁰⁶ But patent nonuse has been attacked for some time—both by entities accused of infringement and by scholars.²⁰⁷ In 1908, the Supreme Court considered whether a patentee's right to exclude should be protected by an injunction when the patentee neither practiced the invention nor licensed others to practice it.²⁰⁸ The Court held that injunctive relief should not be contingent on whether the patentee made its invention available to the public. The Court declined to address whether injunctive relief might be denied in a future dispute in order to ensure that the public would have access to an invention.²⁰⁹

¶ 89 The FTC²¹⁰ and the judiciary have recognized that nonuse is now being used as a tool of parties with sharp and not entirely savory business practices. In a concurring opinion in *eBay*, Justice Kennedy observed that businesses²¹¹ have begun acquiring patents, not to practice them, but for the sole purpose of extracting “exorbitant fees” from potential licensees.²¹² Where the parties use the threat of an injunction solely to gain an advantage in negotiations, it might be in the public's interest for injunctive relief to be denied.²¹³

¶ 90 *What do experts predict would be the effect on health care?*

¶ 91 Another factor to consider is the opinions of experts as to whether granting the injunction would harm the public health. Experts include not only scientific and medical experts who might opine on the effect of an injunction on the health of the public but also practitioners and people in the affected industry.

¶ 92 In cases in which a drug, medical device, or medical procedure is at issue, a court should consider the opinion of medical professionals who use the allegedly infringing

²⁰⁶ *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429-30 (1908).

²⁰⁷ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (May 1, 1998); see also *infra* note 213.

²⁰⁸ See *Cont'l Paper Bag*, 210 U.S. at 422-30. The patent holder in *Continental Paper Bag* proffered several persuasive reasons for its nonuse, such as the high cost of incorporating the technology into its bag-making machines. *Id.* at 428-29. Compare this to the actions of the patentee in *Vitamin Technologists* that refused to license the technology to the detriment of the margarine industry and to the benefit of the butter industry. See *Vitamin Technologists*, 146 F.2d at 945-46.

²⁰⁹ See *Cont'l Paper Bag*, 210 U.S. at 430.

²¹⁰ FED. TRADE COMM'N, TO PROMOTE INNOVATION, *supra* note 33, at Ch. 3, 38-39.

²¹¹ These businesses are occasionally referred to as “patent trolls.”

²¹² *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1842 (2006) (Kennedy, J., concurring) (citing FED. TRADE COMM'N, TO PROMOTE INNOVATION, *supra* note 33, Ch. 3, 38-39, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>).

²¹³ See, e.g., *eBay*, 126 S. Ct. at 1842 (Kennedy, J., concurring). Many commentators suggest that even beyond the arguably high standard of public need, patent trolls are harmful to the economy and patent system as a whole and should be eliminated. Jeremiah Chan & Matthew Fawcett, *Footsteps of the Patent Troll*, 10 INTELL. PROP. LAW BULL. 1, 3 (2005) (“A patent troll's only goal is to extract quick cash, not to create technology development, partnerships, or cross-licensing opportunities”); Julie S. Turner, *The Non-Manufacturing Patent Owner: Toward a Theory of Efficient Infringement*, 86 CAL. L. REV. 179, 188-89 (1998) (asserting that allowing patent owners to “sit” on patent rights violates the purpose of the patent system—to spur innovation by offering a limited monopoly in exchange for public disclosure—and results in economic waste).

device and its alternatives.²¹⁴ Sometimes medical professionals prefer an infringing product to noninfringing alternatives. At a minimum, these preferences indicate that the professionals would be ill at ease using another product. Most patients would rather undergo medical procedures that are performed by professionals confident in their abilities rather than ones hesitant to use the patented technology. In addition, these preferences may indicate that the infringing product is objectively superior to noninfringing alternatives. To avoid a battle of experts, the court must carefully determine the effect on the standard of care, taking into account the preferences of the people using the devices.

¶ 93 In *Shiley*, the defendant manufacturer made a bubble blood oxygenator, which performed the same function as a lung during open heart surgery.²¹⁵ The defendant submitted many affidavits, including from perfusionists who used the machines, attesting to the superiority of the defendant's oxygenator.²¹⁶ But the court disregarded this evidence for procedural reasons, partially because the affidavits had been submitted ex parte subsequent to trial and the patent holder had no opportunity to respond.²¹⁷ The court also noted that no evidence had been submitted with respect to the public interest at the hearing.²¹⁸ Finally, the court determined that the opinions as to the superiority of the infringing product were not objective²¹⁹ but "a mere expression of preference."²²⁰

¶ 94 The court, however, could not point to any factual support for its conclusion that the preference of medical professionals should be disregarded, such as studies indicating there was no objective difference between the machines. But it could have been inferred that the defendant's product was superior given sales of over a hundred thousand units. And medical professionals' opinions are entitled to more weight than the *Shiley* court was willing to give because they are in the best position to know what product serves their needs best.²²¹

²¹⁴ See *Shiley, Inc. v. Bentley Labs., Inc.*, 601 F. Supp. 964, 970-71 (C.D. Cal. 1985).

²¹⁵ *Id.* at 966. After trial, a jury found that the defendant manufacturer had infringed the plaintiff's patents and the court held that the infringement was willful. *Id.* at 966, 968. The infringing machines were used in many hospitals. *Id.* at 969 ("In 1984, [the infringer] sold well in excess of 100,000 units.")

²¹⁶ *Id.* at 970.

²¹⁷ *Id.*

²¹⁸ *Id.* at 970 n.11.

²¹⁹ *Id.* at 970.

²²⁰ *Id.*

²²¹ E.g., *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859 (Fed. Cir. 1987). In *Cordis*, the Federal Circuit affirmed the lower court's ruling allowing a manufacturer to continue its allegedly infringing activity pending further proceedings to determine if infringement had occurred. *Id.* at 864. The devices in question were leads that connected pacemakers to the heart. *Id.* at 860. When considering the public interest, the Federal Circuit agreed with the district court "that the patent system would *not* lose its integrity" if the patentee/licensor was forced to continue allowing the alleged infringer to use its products. *Id.* at 864 (emphasis added). The Federal Circuit also held that it was not an abuse of discretion to conclude there was a public need for the licensed pacemaker anchors as they were part of a life-saving medical device. *Id.*; see *Cordis Corp. v. Medtronic, Inc.*, 2 U.S.P.Q.2d 1845, 1855, 1986 WL 15722, at *16 (D. Minn. 1986) (holding that "the supply of endocardial leads for *life-saving devices*, i.e., pacemakers, is an issue of public interest, and maintaining the greatest supply of such leads best serves that interest") (emphasis added); see also *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) (affirming denial of preliminary injunction where physicians preferred the allegedly infringing heart catheter).

¶95 A degree of subjectivity may even be appropriate. If a medical professional has a personal preference for a certain device, and it makes that professional more confident during a procedure, then that opinion is entitled to a degree of deference.²²² Rather than putting the burden on the entity using the patent holder's technology, when the issue is the health of the public, the burden should be on the patent holder to demonstrate that prohibiting use of the infringing product will not lower the standard of care that patients receive. Furthermore, because these types of cases will address issues of importance such as the well-being of open heart surgery patients, if evidence about the public interest is not proffered by either party, the court has the power, and even the duty, to *sua sponte* order such submissions.²²³

¶96 A finding that medical professionals prefer an infringing device, and that the public health will be served better by their use of that device, weighs in favor of a finding that a permanent injunction should not be granted. A finding that preventing use of the infringing device will not change or lower the standard of care, or that professionals are ambivalent about which device they use, would support a permanent injunction.

¶97 ***Is the entity accused of infringement coming to court with clean hands?***

¶98 What if the motives of the accused infringer are not necessarily pure? Perhaps the company argues it must be allowed to infringe on the patent or the public health will be harmed, but really the company just cares about its own bottom line. While this is a factor the court may want to consider for other decisions, such as the amount damages to award, it is not necessarily relevant to the determination of whether an injunction should issue. The relevant question is the effect on the public health, not the motivations of the defendant. Courts must focus on protecting the public rather than on punishing self-interested infringers.²²⁴

¶99 ***Would it be wasteful to destroy the inventory of an infringer?***

²²² *Ethicon Endo-Surgery v. U.S. Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (“The devices in controversy in this case are surgical instruments which are used continuously in operations of a most serious nature. . . . [U]nquestionably a large number of surgeons are familiar with and have been trained to use the U.S. Surgical cutters. To suddenly withdraw these devices from the market could have a serious disruptive effect on surgical practice.”). *But see* *Schneider (Eur.) AG v. SciMed Life Sys., Inc.*, 852 F. Supp. 813 (D. Minn. 1994). With respect to the medical device at issue, the court in *Schneider* held that while “[i]t is undoubtedly true that some physicians strongly prefer the [infringing catheter] . . . mere personal preference alone does not justify denying an injunction.” *Id.* at 850-51. Instead, the court wanted some “credible evidence” that “the [infringing catheter] is significantly objectively superior to other catheters in performance, or that all other catheters are defective, unsafe, or incapable of performing as intended and required during [the relevant] procedure.” *Id.* at 851.

²²³ *See, e.g., Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941, 945 (9th Cir. 1945).

²²⁴ *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1549 (Fed. Cir. 1987) (“Punishment is not the purpose of an injunction”); *see also* *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993) (“An injunction for infringement may not be punitive.”); *Moxness Prods., Inc. v. Xomed, Inc.*, 7 U.S.P.Q.2d 1877, 1988 U.S. Dist. LEXIS 16060, at *12, *16 (M.D. Fla. 1988) (delaying any subsequently ordered injunction even though the infringer had probably raised the public interest concern only to protect the profits it made through infringing sales).

¶ 100 The concept of waste is not one that usually figures predominately in litigation. Yet when crafting a remedy for patent infringement, it may be appropriate to consider whether it will be wasteful to destroy the inventory of an infringer.²²⁵ Say, for example, that a court has found that a manufacturer of a bandage is infringing on another company's patented wound dressing. Rather than ordering the manufacturer to destroy its inventory, the court might order it to distribute the bandages to free health clinics.²²⁶

¶ 101 The Federal Circuit has "stressed that a trial court . . . must narrowly tailor an injunction to fit the specific adjudged violations."²²⁷ This tailoring gives the district courts considerable discretion to decide the scope of an injunction.²²⁸ The district courts can use their discretion to minimize negative effects on the public.

¶ 102 *Should the court let industry practitioners decide whether an injunction is appropriate?*

¶ 103 At times, it may be appropriate to let the companies and people who actually use the infringing product determine whether the use should continue. In *Boehringer Ingelheim Vetmedica*, a manufacturer infringed a patented vaccine for pigs.²²⁹ The infringer argued that the public needed continued access to its vaccine because the patentee's vaccine was inferior.²³⁰ Finding this argument not completely persuasive, the district court ordered the recall of all infringing vaccines owned by the infringer, even if they were already in the hands of distributors who had not yet paid for them.²³¹ Yet the injunction did not apply equally to vaccines that the infringer had already sold.²³² The purchasers of those vaccines were given two options: they could return the vaccines for a full refund, or they could choose to keep and resell the vaccines.²³³

¶ 104 The district court therefore let the vaccine purchasers decide whether infringement was in the public's interest.²³⁴ If a purchaser chose to return the vaccines, it

²²⁵ See *Thacher v. Mayor of Baltimore*, 219 F. 909, 912 (D. Md. 1915) (refusing to extend injunction to past infringement because that would cause economic waste and burden).

²²⁶ In 2000, a district court in Massachusetts entered an order "enjoining any further production or sale of" a company's infringing stereo-speakers. See *Bose Corp. v. JBL, Inc.*, 112 F. Supp. 2d 138, 170 (D. Mass. 2000). Although the district court might have also ordered the destruction of any unsold speakers, the court stated that "the destruction of [the] remaining infringing inventory . . . seems extraordinarily wasteful." *Id.* The court instead suggested that the remaining speakers should be donated to schools or charities. *Id.* The district court used its considerable discretion to limit the scope of the injunction and ensure that it did not waste an opportunity to benefit the public.

²²⁷ *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002) (citing *Gemveto Jewelry Co. v. Jeff Cooper Inc.*, 800 F.2d 256, 259 (Fed. Cir. 1986)).

²²⁸ See *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 709-10 (D.N.J. 2000) (citing, e.g., *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1354 (Fed. Cir. 1998)).

²²⁹ *Id.* at 701-04.

²³⁰ *Id.* at 704-05.

²³¹ *Id.* at 710 ("[R]egardless of where those goods are currently located, . . . to allow others to sell infringing goods which [the infringer] still owns is no different than if [the infringer] continued to sell its own infringing products.").

²³² *Id.*

²³³ *Id.* The refund also included the return shipping costs.

²³⁴ See *id.*

benefited the public by encouraging patentees to continue developing and disclosing their discoveries.²³⁵ The second option (using the vaccines by reselling them) allowed a purchaser to decide that some other public interest outweighed the patentee's right to exclude. For example, if a purchaser thought that the pig-farming market would crash without the vaccine, the purchaser could make sure that the vaccine remained available.²³⁶ Although a purchaser might resell the vaccine for personal economic gain, the district court thought it was best to tailor the injunction so that industry insiders could accommodate the public interest.²³⁷ In this way, the court can allow an industry to police itself.

¶ 105 *Is the need for research in a particular area being met?*

¶ 106 In the past, it was common for researchers to disseminate their research methods and results. Prestige came from publication in peer-reviewed journals. Now, prestige is measured in deals with industry and by number of patents. Even at academic institutions, researchers and scientists report that they have delayed publishing results or have deliberately withheld data and other information to protect their commercial interests.²³⁸ Not surprisingly, companies have an incentive to keep their research confidential to develop products and devices. But, at times, such a concentration of research is detrimental to the public interest. In the Novartis matter, the FTC determined that having all the intellectual property necessary to perform gene therapy research held by one company was harmful to the public and anticompetitive. Competition encourages companies to "hurry up" with their research.²³⁹ The public may have an interest in having more than one company, and more than just one laboratory with limited scientists, performing certain research. In such situations, courts, after considering the other factors, may need to weigh the need for research in a particular area against the patent holder's desire to develop the technology itself.

¶ 107 *Will it be necessary to invade patient privacy and the patient physician relationship to enforce the injunction?*

¶ 108 When the issue is the public health, obtaining or enforcing an injunction without violating patient privacy may be difficult. This is a factor that might weigh against granting injunctive relief to a patent holder. For example, if a patent holder wished to

²³⁵ See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (stating "[t]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time").

²³⁶ See *Boehringer*, 106 F. Supp. 2d at 710.

²³⁷ See *id.*

²³⁸ *Campbell*, *supra* note 4; see also *Blumenthal*, *supra* note 4. Contrast this to scientific ethical standards at the turn of the century that would prohibit a scientist from presenting research at a scientific conference when he intended to profit from the outcome of the research: "[H]aving agreed to accept stock in the concern, [the scientist] could not read the paper before the scientific body without violating his professional ethics as a scientist, as it would savor of advertising his own wares on which he expected material profit, and if that fact were disclosed it might jeopardize his standing as a scientist." *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 586 (7th Cir. 1934).

²³⁹ FED. TRADE COMM'N, TO PROMOTE INNOVATION, *supra* note 33, Ch. 3, at 17 (quoting Lee Bendekgey, panelist from Incyte Genomics).

determine whether a genetics laboratory has performed genetic tests on patients, it might subpoena clinical records. Records, of course, contain not only identifiable information about patients but also the results of the genetic tests. A court could order the records to be kept confidential, but even producing such records takes numerous personnel (including outside vendors in addition to law firm employees) to pull, redact, copy, and catalog the records. The information, even if “confidential,” thus has already been seen by many people, without the knowledge or consent of the patient. Such a scenario is not far-fetched. In attempting to enforce his patent on the correlation between fetal abnormalities and high levels of a hormone in a pregnant woman’s blood, the physician’s patent enforcement company offered the Foundation for Blood Research a percentage of the royalties if it helped to identify labs who had performed the tests.²⁴⁰ Once it found the labs, there was nothing to stop it from pursuing physicians.²⁴¹ The Foundation for Blood Research refused, stating, “Your proposal is in direct conflict with the interests and rights of patients and physicians and the public at large.”²⁴²

¶ 109 Interference in the physician-patient relationship cannot be dismissed lightly. Patient rights and privacy may be factors that weigh against the grant of a permanent injunction.

¶ 110 *Does the public have a strong interest in securing a monopoly to patentees?*

¶ 111 One significant development in the *eBay* case is its assault on the assumption that the right to exclude must be remedied by injunctive relief. In many patent cases, the traditional equitable factors were found to tip in the patentees’ favor at their mere mention of their right to exclude, which they claimed was necessary for the continuation of the entire patent system. Without an injunctive remedy for violation of their right to exclude, patentees argued they would be irreparably harmed, denied an adequate legal remedy, left with a worse hardship than the other party, and the public interest would suffer from decreased incentives for invention. But the right to exclude is no longer a slam dunk. The Supreme Court stated that “the creation of a right [by statute, specifically 35 U.S.C. § 261,] is distinct from the provision of remedies for violations of that right.”²⁴³

¶ 112 In addition, patent holders have less of an interest in securing equitable relief when the patents are of “suspect validity.”²⁴⁴ Many patents, such as business method patents and patents on human genetic sequences, have been criticized as not meeting the statutory requirements of the patent system. Yet direct challenges to these types of patents have been rare or nonexistent, and the Supreme Court, because of its limited

²⁴⁰ Eichenwald, *supra* note 89.

²⁴¹ The patent was issued in 1989, well before the physician exemption was enacted. Method for Assessing Placental Dysfunction, U.S. Patent No. 4,874,693 (filed Oct. 10, 1986) (issued Oct. 17, 1989).

²⁴² Eichenwald, *supra* note 89 (quoting Gerald Petrucelli, attorney for the Foundation for Blood Research).

²⁴³ *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1840 (2006).

²⁴⁴ *Id.* at 1842 (Kennedy, J., concurring).

jurisdiction, has not had the opportunity to address their validity.²⁴⁵ This factor was persuasive when Congress decided to enact the physician exemption. One of the criticisms to the surgical incision patent held by Dr. Pallin was that it was obvious to other practitioners and, in fact, was already used by other practitioners. Other medical method patents, such as a method for determining the sex of a fetus by observing whether male or female genitalia are present in an ultrasound image, similarly are of suspect validity and were relied on by proponents of the physician exemption.

¶ 113 Post-*eBay*, courts should no longer be persuaded solely by patentees' claims that the integrity of the patent system and the future of innovation in this country depends on the use of injunctions to secure their rights to exclude. All the equitable factors, including the public's interest in health and safety, must be weighed against the impulse to blindly enforce the monopoly afforded patent holders. Courts should adhere more strictly to consideration of the equitable factors rather than allowing the patentee's right to exclude to spin out of control and tip the balance in its favor.

B. Application of the Suggested Factors

¶ 114 All of these suggested public interest factors could come into play in a single dispute over a request for permanent injunctive relief or a call for government action to protect the public health. Consider the following hypothetical scenario.

¶ 115 The Centers for Disease Control and Prevention ("CDC") reports that the first cases of African sleeping sickness have been discovered in the United States. Initially, the disease progresses somewhat mildly, mimicking flu-like symptoms (fatigue, fever, aches, and swollen lymph nodes). If allowed to progress without treatment, the parasites causing the disease will cross the blood-brain barrier and enter the central nervous system. Victims exhibit cognition problems, poor coordination, seizures, and difficulty swallowing.²⁴⁶ The CDC predicts that the outbreak would reach epidemic proportions within the next two years.

¶ 116 Tech U., a large public university, holds the patent for the genome of the parasite that causes sleeping sickness. Tech U. has granted an exclusive license to the patented genome to Pharma, a large pharmaceutical company. Tech U. does not have the administrative resources to administer multiple licenses, and in any event, an exclusive license is worth more money.

¶ 117 Using the Tech U. patent, Pharma has developed and holds a patent on a drug that had proven to be the most effective treatment for treating African sleeping sickness. Yet Pharma itself produces only small amounts of the drug that it donates to charitable

²⁴⁵ *E.g.*, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (dismissing certiorari as improvidently granted and declining to examine validity of patent claiming a naturally occurring correlation).

²⁴⁶ World Health Org., African Trypanosomiasis (2006), <http://www.who.int/mediacentre/factsheets/fs259/en/>. Centers for Disease Control and Prevention, West African Trypanosomiasis (2004), http://www.cdc.gov/ncidod/dpd/parasites/trypanosomiasis/factsht_wa_trypanosomiasis.htm#Symptoms.

organizations providing medical care to Zimbabwe as a charitable outreach and for publicity. It has licensed the drug to several small manufacturers to produce similarly small quantities of the drug for other parts of Africa. The patent becomes one of Pharma's most valuable assets once the CDC determines that the patented drug would be equally effective in treating the new cases of sleeping sickness in the United States.

¶ 118 Always thinking of its shareholder's best interests, Pharma begins planning how to make the most of the impending epidemic. Pharma decided that it would exercise an early termination clause in its licensing agreements with the small manufacturers. Then, Pharma would significantly increase its manufacturing capacity to meet the anticipated demand for its product.

¶ 119 Pharma's plan might have been successful, except that the CDC's predictions were wrong. The sleeping-sickness epidemic hit within six months, rather than two years. The beginning of the epidemic fell three months after Pharma had stopped licensing to the other manufactures but about ten months before Pharma expected its new manufacturing facility to be operational.

¶ 120 The demand for the patented drug convinces two of the former licensees that it would be financially worthwhile to begin manufacturing the drug again. Pharma sues the former licensees for patent infringement. After the patent was shown to be not invalid and that it had been infringed, the court had to determine whether to grant Pharma's motion for permanent injunctive relief that would bar the former licensees from continuing to manufacture the drug.

¶ 121 Another university, University College, has developed a nanotechnology it thinks would be useful in fighting the epidemic—a minute drug-delivery system that is engineered to cross the blood-brain barrier. University College believes the system could be used to fight the parasite that causes the sleeping sickness after the parasite enters the nervous system. University College begins experimenting with the parasite and offering the drug in its nanotechnology device. Both Tech U. and Pharma bring suit alleging University College's actions infringe on their patents and they seek a permanent injunction. University College does not raise patent invalidity as a defense to the Tech U. patent because it holds lucrative patents on portions of the human genome that it does not want to jeopardize by arguing against gene patents.

¶ 122 First, with respect to the patent on the genome of the parasite causing the epidemic, equitable factors weigh in favor of the courts compelling Tech U. to rescind its exclusive licensing deal to allow other researchers to use the patented sequence. Research is needed to develop tests to identify the presence of the organism and to find additional ways of fighting it. Preventing other researchers from using the patented work would reduce the availability of health care and potentially harm millions. Because the gene patent exists on a naturally occurring organism as opposed to an invention, it is a patent of suspect validity. Tech U. is not necessarily inequitably using the patent by granting only an exclusive license. However, considering that the research conducted to sequence the genome was paid by public grants, its interest in having the patent exclusivity enforced does not outweigh the public interest in the research and

development of a new treatment in light of a public health emergency.

¶ 123 Next, with respect to the drug patent, the supply of the drug used to treat the sleeping sickness was initially sufficient under Pharma's exclusive production. Generally speaking, preventing other manufacturers from producing generic medications before a patent on a drug expires will not compromise the availability of health care. Similar to other drug companies, Pharma spent vast sums of money developing and gaining FDA approval for the drug, so far without any significant return on its investment. Sustaining the monopoly by entering an injunction against Pharma's former licensees allows Pharma to recoup its research and development costs and does not unnecessarily burden the public health. (The former licensees' contract claims would then be determined by contract law.)

¶ 124 However, Pharma's cancellation of the licenses was solely motivated by profit. This would weigh in favor of denying injunctive relief. In addition, if Pharma decides to raise its prices to take advantage of the public health crisis, the court may be justified in requiring it to sell the drug at a reduced rate or allowing other companies to manufacture the drug. Similarly, if the transmission of the disease accelerates even more, and Pharma cannot meet the need for the drug, it might be necessary to allow production by other companies.

¶ 125 Furthermore, rescinding its licenses might be anticompetitive behavior. If a governmental agency takes action against Pharma, this might weigh against a permanent injunction. But if other agencies do not act or do not have jurisdiction to take action, this factor would swing in the other direction.

¶ 126 University College's nanotechnology drug-delivery system might be an effective way to treat the disease in its later stages. But weighing in favor of granting an injunction is the fact that not many people are afflicted with the advanced disease, which has crossed the blood-brain barrier. Yet weighing against injunctive relief is the severity of the symptoms of the advanced stage of the disease and its ultimate fatality. Although Tech U. does not use the patent itself, which weighs against injunctive relief, Pharma is not failing to use its patent (although it might be misusing it). However, if experts predict that mutations of the parasite will cause the disease to progress at a faster rate, it may be appropriate to allow more researchers to work on the cure.

¶ 127 While it is not possible to predict an exact factual situation that might someday arise, this hypothetical was designed to illustrate how the different recommended factors might be applied to determine if a permanent injunction is warranted when the public health is at stake.

VI. CONCLUSION

¶ 128 The Supreme Court in *eBay* recognized that the rights of a patent holder to exclude are not always absolute. The enforcements of certain patents might endanger the public health, such as by contaminating a public waterway, creating unnecessary risks during medical procedures, harming the health of certain populations, or creating safety

hazards. If necessary to protect the public health, courts may deny motions for permanent injunctions to enjoin infringing use after a full consideration of all equitable factors, including the public interest in health and safety.