NOTE

THE FUTURE OF MEDICAL DEVICE PATENTS: CATEGORICAL EXCLUSION AFTER *EBAY, INC. V. MERCEXCHANGE, L.L.C.*

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INTRODUCTION

Medical patents, unlike industrial and commercial patents, elicit visceral reactions indicative of the tension between the competing policies supporting patent law and public health interests.[1] The crossroads between patent law policy and the ethical concerns associated with improving health care in the United States has significant implications for the future of both areas of law.

The United States Supreme Court's decision in *eBay v. MercExchange*[2] overhauled decades of case law that presumes permanent injunctive relief following a finding of patent infringement and validity.[3] In the aftermath of the decision, critics disparaged the decision as a "broad attack" on the patent system.[4] Practically speaking, however, the *eBay* test does not appear to affect the reliability of patent protection in the majority of cases, except, perhaps, cases involving medical devices and medical methods.[5] The courts' disparate treatment of medical patent infringement cases contradicts the business incentives and public interest considerations the patent system was specifically designed to provide and balance. Recent trends raise significant questions about the future of medical device and medical procedure patentability in the United States. This Note highlights the difficulties in reconciling traditional patent law policy and public health policy, including the seemingly circular approach to handling remedies in infringement cases involving medical devices and procedures.

Part I and II of this Note introduce the legal framework of patent law in the United States and outline general patent infringement concepts. Part III emphasizes specific infringement provisions relating to medical procedures and medical devices. Part IV discusses the Supreme Court's decision in *eBay*, while Part V analyzes the development of recent case law to demonstrate the asymmetrical impact the *eBay* decision has had on medical patents. Part VI outlines various policy considerations with respect to the patent system and health care system, including comparative approaches to medical procedures and medical device patenting. Finally, Part VII and Part VII analyze the future of medical device patents and advance possible avenues for relieving the tensions between patent law policy and health law policy.

I. PATENT LAW BASICS

The United States Constitution empowers Congress to establish a patent

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[1] Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN'S L. REV. 329, 329-30 (1997).

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

[3] *Id*. at 393-94 (rejecting the "general rule" that injunctive relief issues following a finding of validity and infringement).

[4] *See infra* notes 153-155 and accompanying text.

[5] *See infra* notes 160-162, 166-168 and accompanying text.

system "to promote the Progress of Science and useful Arts."[6] Accordingly, Congress determined that as a means to meet this constitutional end, the patent system shall award exclusive rights to whomever invents a "new and useful process, machine, manufacture, or composition of matter"[7] for a limited term extending twenty years from the date of filing.[8] While patent law grants a patent holder a limited monopoly, patent rights are negative.[9] A patent holder acquires only the right to stop others from using his or her invention.[10]

A. Policy Considerations

Patent law exists to promote innovation while preserving free competition.[11] William Robinson, a leading patent scholar in the early twentieth century, analogized patent protection to a contract with society: in exchange for a new and useful invention, the inventor is entitled to the exclusive rights to said invention.[12] Under this utilitarian theory, society presumably benefits from the production of the patented invention during the patent term, though more substantially benefits from the patent's contribution to scientific and technological advancement once the patent enters into the public domain at the close of the patent term.[13]

There are well-established policy justifications for supporting exclusive monopoly rights. First, patents are granted in order to encourage innovation by granting exclusive rights to that innovation for a limited time.[14] Similarly,

[6] U.S. CONST. art. I, § 8, cl. 8; Brett G. Alten, Note, *Left to One's Devices: Congress Limits Patents on Medical Procedures*, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 837, 841-42 (1998).

[7] 35 U.S.C. § 101 (2012).

[8] 35 U.S.C. § 154(a)(2) (2012).

[9] Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J.L. & TECH. 321, 322 (2009).

[10] *Id.*

[11] Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230-31 (1964); Sinclair v. Aquarius Elecs., Inc., 42 Cal. App. 3d 216, 223 (Cal. Ct. App. 1974) (noting the differences of policies supporting trade secrets and patent law).

[12] 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 42 (1890) (explaining that full disclosure of the invention is crucial to justify the privileges of the patent system).

[13] "The patent system was not designed merely to build up a library of information by disclosure, valuable though that is, but to get new products into the marketplace during the period of exclusivity so that the public receives full benefits from the grant." Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1562-63 (Fed. Cir. 1995) (noting that Congress intended to reward inventors who enter the market and commercialize their patented invention, or license others to do so, rather than letting the invention "lay fallow").

[14] Asha S. Geire, Note, *Price Wars and Patent Law: Reducing the Cost of Health Care through Medical Device Price Transparency*, 12 TUL. J. TECH. & INTELL. PROP. 239, 243 (2009).

patents are said to encourage the dissemination of information because an inventor can retain significant benefit from reliance on his or her exclusive rights during the patent term.[15] In a world without patent protection, inventors would be more likely to rely on secrecy to reap the benefit of their innovation.[16] Consequently, patent law incentives must be great enough to induce dissemination rather than secrecy.[17] Third, the possibility of securing a patent makes research and development projects more likely to induce investment because investors gain from monopolistic prices, even if for a limited time.[18] Finally, the patent system may inspire follow-up technology.[19]

B. Patentability

In the United States, an invention secures patent protection so long as it satisfies three independent tests of patentability.[20] Modern patent law can be succinctly summarized as providing exclusive rights for inventions that are useful, novel, and nonobvious.[21]

First, an invention must be useful to secure patent protection.[22] In order to succeed in showing utility, an invention must have some practical, specific use.[23] Utility alone, however, does not secure patentability.[24] It is the bedrock of patent law that an invention also be novel.[25] The 1952 recodification of the Patent Act solidified novelty as a statutory precondition to patentability, distinct from a conception of "new" in section 101.[26] Section 102 provides

[15] *Id.*

[16] *Id.*

[17] *See generally* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

[18] Geire, *supra* note 14, at 243.

[19] *Id.*

[20] *See* Graham v. John Deere Co., 383 U.S. 1, 16, 37 (1966) (noting that Congress intended nonobviousness as a third perquisite to patentability and that the invention failed to meet patentability for failing meet the nonobviousness requirement); *see also* United States v. Adams, 383 U.S. 39, 48 (1966) (holding as valid plaintiff's patent for a wet battery because the use of prior art in such a combination was not obvious to a person reasonably skilled in the prior art).

[21] *See generally* Bilski v. Kappos, 130 S.Ct. 3218, 3236 (2010).

[22] 35 U.S.C. § 101 (2012).

[23] As Justice Story outlined, the utility requirement for patentability is one in which "the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society." Lowell v. Lewis, 15 Fed. Cas. 1018, 1019 (C.C.D. Mass. 1817). Further, Justice Story contended that patent protection does not extend to inventions with "mischievous or injurious" tendencies. *Id.*

[24] *See* Servo Corp. of Am. v. General Elec. Co., 337 F.2d. 716, 719 (4th Cir. 1964).

[25] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 337 (6th ed. 2013).

[26] "[W]hether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'" Diamond v. Diehr, 450

that in order to be patentable, an invention must not merely be a "novel use," but a "novel conception."[27] An invention fails to satisfy the novelty condition if others knew of or used the invention in the United States prior to the inventor applying for a patent.[28] In other words, the invention must not be described in print, in use, or on sale for more than a year before the application was filed.[29]

Though not included in the statutory scheme until 1952,[30] courts incorporated the concept of nonobviousness as the third requirement for patentability as early as 1850.[31] Nonobviousness sets the threshold for evaluating whether an invention is new and non-trivial to the extent that it merits patent protection.[32] The basic test for obviousness is whether a person having ordinary skill in the field of the invention would have found the invention obvious at the time of its creation.[33]

C. Patentable Subject Matter

Section 101 of the Patent Act defines patentable subject matter as "any new

U.S. 175, 190 (1981) (holding that inventions should be analyzed as a whole rather than by each component part and that a physical process controlled by running a mathematical equation in a computer program is patentable as a whole).

[27] 35 U.S.C. § 102 (2012). Metaframe Corp v. Biozonics Corp., 352 F. Supp. 1006, 1015 (D. Mass. 1972) (holding that a "new combination of old elements," or a use of an old process for a new purpose is insufficiently novel to secure patent protection).

[28] *See* Chem. Const. Corp. v. Jones & Laughlin Steel Corp., 311 F.2d 367, 373 (3d Cir. 1962).

[29] MERGES & DUFFY, *supra* note 25, at 494.

[30] 35 U.S.C. § 103 (2012). The purpose of Section 103 is to codify nonobviousness as a patentability requirement that had previously only existed by decision of the courts. H.R. REP. NO. 82-1923, at 7 (1952); Graham v. John Deere Co., 383 U.S. 1, 15 (1966) (noting that the codification of 35 U.S.C. § 103 was intended to abolish the "flash of creative genius" test); *see generally* Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941).

[31] *See generally* Hotchkiss v. Greenwood, 52 U.S. 248 (1850) (holding that where a claimed invention combines old elements, the invention is not patentable if one of ordinary skill in the field could create such a combination).

[32] 35 U.S.C. § 103 (2012); *see Graham*, 383 U.S. at 17-18.

[33] 35 U.S.C. § 103 (2012). However, variation in courts' interpretation of nonobviousness has created a wide range of standards, at its height requiring a "flash of creative genius" to qualify as nonobviousness. *See Cuno Eng'g Corp.*, 314 U.S. at 91 (holding an improvement to a cigar lighter not creative enough to be classified as patentable subject matter). The Supreme Court modified the nonobviousness analysis and required the following factual inquiries: (1) the scope and content of prior art; (2) comparison between prior art and invention; (3) level of ordinary skill in the field; and (4) objective indicia of obviousness or nonobviousness. *Graham*, 383 U.S. at 17-18.

and useful process, machine, manufacture, or composition of matter . . . ."[34] Whether a particular invention qualifies as useful, novel, and nonobvious is an inquiry distinct from whether the invention falls into a category of statutory subject matter.[35] Congress sought the broadest possible protection, "intend[ing] to extend patent protection to anything under the sun that is made by man."[36]

As science and technology advance, patent law strives to keep pace while striking a balance between protecting inventions and encouraging innovation.[37] The law recognizes as patentable subject matter: plants,[38] organisms created through genetic engineering,[39] and business methods.[40] Although the term "process" was not added to 35 U.S.C. § 101 until 1952, processes have historically enjoyed patent protection because they are considered a form of "art" under the 1793 Act.[41] For the purpose of patent law, a "process" is "an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing."[42]

The Supreme Court and the Federal Circuit have established judicial limits to patentable subject matter under section 101 of the Patent Act.[43] Every discovery is not embraced within the statutory terms.[44] A recapitulation of a

[34] 35 U.S.C. § 101 (2012).

[35] Diamond v. Chakrabarty, 447 U.S. 303, 307-09 (1980).

[36] *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

[37] Christopher Hughes & Daniel Melman, *Patentable Subject Matter in the United States: Past, Present, and Future*, INTELLECTUAL ASSET MAGAZINE, May/June 2009, at 97.

[38] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc., 534 U.S. 124, 145 (2001) (holding that plants and seeds are patentable subject matter). *But see Chakrabarty*, 447 U.S. at 309 (holding that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter").

[39] *See Chakrabarty*, 447 U.S. at 309-10.

[40] There is "strong historical evidence that a method of doing business does not constitute a 'process' under § 101." Bilski v. Kappos, 130 S.Ct. 3218, 3250 (2010) (Stevens, J., concurring) (arguing that the Court improperly declined to exclude business methods from patentable subject matter under 35 U.S.C. § 101); eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 390-91 (2006) (holding the patented business method claim asserted by MercExchange valid); State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1375-77 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d. 943, 960 (Fed. Cir. 1998) (indicating business methods may be proper patentable subject matter).

[41] Diamond v. Diehr, 450 U.S. 175, 182 (1981).

[42] *Id.* at 182-84 (quoting Cochrane v. Deener, 94 U.S. 780, 787-88 (1877)).

[43] *See Chakrabarty*, 447 U.S. at 309.

[44] *Id.*

law of nature or a process in nature is not patentable subject matter.[45] A process must be "more than a drafting effort designed to monopolize the law of nature itself."[46] Additionally, neither physical phenomena[47] nor abstract ideas, such as the application of mathematical formulas, are deemed patentable subject matter.[48]

The general foundation supporting these exclusions is that laws of nature, physical phenomena, and abstract ideas are "the basic tools of scientific and technological work."[49] Imposing a limited monopoly on the use of those tools "might tend to impede innovation more than it would tend to promote it."[50] In other words, the rationale supporting the Patent Act does not justify impeding the availability of those tools. The Supreme Court deems certain subject matter patentable to the extent that doing so furthers the policy of "promot[ing] . . . Science and useful Arts."[51]

II. PATENT INFRINGEMENT AND REMEDIES

Courts take two steps when deciding a claim of patent infringement.[52] First, as a matter of law, courts define the scope of a patent holder's right to exclude by construing the terms or limitations of the patent claim.[53] Once the

[45] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S.Ct. 1289, 1297 (2012) (noting that Einstein could not have secured a patent upon discovery of the equation for energy "[n]or could Archimedes have secured a patent for his . . . principle of floatation . . . ."). Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1938) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.")

[46] *Mayo Collaborative Servs.*, 132 S.Ct. at 1297.

[47] *Chakrabarty*, 447 U.S. at 309.

[48] *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67, 71-72 (1972) (holding a method for "converting [binary-code numerals] to pure binary numerals is non patentable as a "process" under § 101 for lack of practical application outside the context of a computer).

[49] *Mayo Collaborative Servs.*, 132 S.Ct. at 1293 (quoting *Gottschalk*, 409 U.S. at 67). The exclusion of discoveries of laws of nature from patentable subject matter rests on the understanding that they are not the kind of discovery that patent law was designed to protect. Parker v. Flook, 437 U.S. 584, 593 (1978). Patent law was not intended to exclude others from use of laws of nature. *Id.*

[50] *Mayo Collaborative Servs.*, 132 S.Ct. at 1293.

[51] U.S. CONST., art. I, § 8, cl.8; *see Gottschalk*, 409 U.S. at 72-74 (hesitating to deem a method for converting binary code as patentable subject matter without a searching investigation from Congress regarding the feasibility of such a holding).

[52] *See, e.g.*, Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1129 (Fed. Cir. 2011).

[53] In construing claims, courts focus on "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." Markman v. Westview Instruments, Inc. 52 F.3d 967, 986 (Fed. Cir. 1995).

underlying claim is properly construed, it "must be compared to the accused device or process."[54] Second, the factfinder decides whether the allegedly infringing invention meets every limitation provided in the patent holder's claim, "either literally or by a substantial equivalent."[55]

A. Direct Infringement

Making, using, selling, or offering to sell any patented invention during the patent term, without permission, triggers liability under the Patent Act.[56] Direct patent infringement is a strict liability offense.[57] Access and intent are irrelevant to this inquiry.[58] Accordingly, "the nature of the offense is only relevant in determining whether enhanced damages are warranted."[59]

In order to succeed on an infringement action for a patented device, the claimant must show that the accused device embodies every limitation of the construed claim.[60] Similarly, in order to succeed on a process or method claim, the alleged infringer must perform all the steps of the claimed method, either personally or through another person acting under his direction or control.[61] Direct infringement does not extend to cases in which multiple independent parties perform the steps of the method claim.[62] To be liable, one actor must perform all the steps in the patented process.[63]

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[54] *See, e.g.*, *Absolute Software*, 659 F.3d at 1129; Carroll Touch, Inc. v. Electro Mech. Syss., Inc., 15 F.3d. 1573, 1576 (Fed. Cir. 1993).

[55] *See, e.g.*, Freedman Seating Co. v. Am. Seating Co. 420 F.3d 1350, 1356-57 (Fed Cir. 2005).

[56] 35 U.S.C. § 271(a) (2012).

[57] *In re* Seagate Tech., LLC, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc).

[58] *Id.* ("Because patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted.").

[59] Akamai Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301, 1307 (Fed. Cir. 2012); *Seagate Tech*., 497 F.3d at 1368; *see infra* notes 75, 163 and accompanying text.

[60] Carroll Touch, Inc. v. Electro Mech. Syss., Inc., 15 F.3d. 1573, 1579 (Fed. Cir. 1993) (noting that the burden of showing infringement by a preponderance of the evidence lies with the patent holder).

[61] *Akamai Techs*., 692 F.3d at 1305-06.

[62] *Id.*

[63] *Id.* at 1307 ("Because direct infringement is a strict liability tort, it has been thought that extending liability in that manner would ensnare actors who did not themselves commit all the acts necessary to constitute infringement and who had no way of knowing that others were acting in a way that rendered their collective conduct infringing.").

B. Indirect Infringement – Contributory & Induced Infringement

Actively inducing patent infringement may also result in liability.[64] Indirect infringement protects patent rights from subversion by contributory infringers whose actions promote direct infringement by other parties.[65] Unlike direct infringement, indirect infringement is not a strict liability offense.[66] Consequently, a finding of indirect infringement requires both knowledge of the allegedly infringing activity and knowledge of the patent.[67] Further, a finding of indirect infringement is predicated on a finding of direct infringement.[68] Indirect infringement operates in the forms of induced infringement[69] and contributory infringement.[70] With respect to induced infringement, a successful claim requires that one induces or leads another, a direct infringer, in actions *known* to constitute patent infringement.[71] Contributory infringement, on the other hand, requires the manufacture and sale of a component with knowledge that the component is used in combination to infringe a patent.[72]

C. Remedies Generally

The right to exclude competitors from infringing the patent is essentially a property concept.[73] The Patent Act explicitly provides that "patents shall have the attributes of personal property"[74] including the right to exclude others from

[64] 35 U.S.C. § 271(b) (2012) ("Whoever actively induces infringement of a patent shall be liable as an infringer.").

[65] Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 188 (1980).

[66] *Akamai Technologies*, 692 F.3d at 1308.

[67] 35 U.S.C. § 271 (2012); Sandisk Corp. v. Lexar Med., Inc. 91 F. Supp. 2d 1327, 1335 (N.D. Cal. 2000).

[68] *Akamai Technologies*, 692 F.3d at 1308.

[69] 35 U.S.C. § 271(b) (2012).

[70] 35 U.S.C. § 271(c) (2012).

[71] Global-Tech. Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068 (2011) (construing 35 U.S.C. § 271(b) as requiring a knowledge standard in order to impose liability); *Akamai Technologies*, 692 F.3d at 1308 ("It is enough that the inducer 'causes, urges, encourages, or aids' in the infringing conduct.") (quoting Arris Grp., Inc. v. British Telecomms. PLC, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011)).

[72] Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 488-89 (1964).

[73] *See* Acumed LLC v. Stryker Corp., 551 F.3d 1323, 1328 (Fed. Cir. 2008) (affirming district court's grant of a permanent injunction for infringement of an orthopedic nail, despite the fact that the patent holder licensed its patent to other companies, because the patent holder and infringer were direct competitors).

[74] 35 U.S.C. § 261 (2012).

making or selling an invention.[75] A grant of a patent is also a grant of a limited monopoly over personal property,[76] to which a court of equity owes a duty to preserve by injunction.[77] Nonetheless there is a wide range of remedies available to a court deciding a patent dispute, including monetary damages for past infringement, reasonable royalties or compulsory licensing, as well as preliminary and permanent injunctions.[78] District courts have the authority to craft appropriate remedies on a case-by-case basis.[79]

Notwithstanding an award of permanent injunctive relief, a court may award a claimant damages to compensate for infringement, provided that the award is no less than a reasonable royalty for the infringer's use of the invention.[80] It is within the discretion of the court to enhance damages, up to three times, if the facts of the case warrant such action.[81]

> Issuance of injunctive relief against [the defendants] is governed by traditional equitable principles, which require consideration of (i) whether the plaintiff would face irreparable injury if the injunction did not issue, (ii) whether the plaintiff has an adequate remedy at law, (iii) whether granting the injunction is in the public interest, and (iv) whether the balance of the hardships tips in the plaintiff's favor.[82]

Permanent injunctions serve as a powerful remedy by rendering future infringement impossible. A permanent injunction is distinct from a preliminary injunction.[83] While equitable considerations are similar to that of

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[75] 35 U.S.C. § 154(a)(1) (2012); eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 392 (2006).

[76] Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229 (1964).

[77] W. Elec. Co. v. Cinema Supplies, 80 F.2d 106, 110 (8th Cir. 1935).

[78] 35 U.S.C. § 283 (2012) ("The several courts . . . may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent . . ."); 35 U.S.C. § 284 (2012) (stating that a jury may award "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.").

[79] *eBay*, 547 U.S. at 393-94 (holding that there is no "general rule" governing whether to granting injunctive relief and that courts must apply an equitable analysis to the facts of each case); Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1314-15 (Fed. Cir. 2007) (issuing on-going royalties in lieu of a permanent injunction where the patent holder sought to license the patented invention, did not practice the patent, failed to show irreparable harm).

[80] 35 U.S.C. § 284 (2012).

[81] *Id.* Usually a finding of willful infringement results in enhanced damages. *Id.*

[82] MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 711 (E.D. Va. 2003) (quoting Odetics, Inc. v. Storage Tech. Corp., 14 F. Supp. 2d 785, 794 (E.D. Va. 1998)).

[83] Granting a preliminary injunction is an extraordinary measure. Superior Elec. Co. v. Gen. Radio Corp., 194 F. Supp. 339, 347 (D.N.J. 1961).

a permanent injunction, a preliminary injunction is an extraordinary remedy available where a claimant shows a special need for relief.[84] For nearly a century, courts granted injunctive relief upon a finding of validity and infringement in the vast majority of patent cases, allowing patent holders to exclude infringing competitors from the market.[85] Though rare, exceptions to this general rule "were usually based on a critical public interest."[86]

III. CURRENT LANDSCAPE: PATENTABILITY OF MEDICAL DEVICES AND MEDICAL PROCEDURES

Medical devices fit comfortably within the statutory scheme of patentable subject matter.[87] Nonetheless, the ethics of extending patent protection to these devices has stirred controversy.[88]

Similarly, courts have long held processes to be patentable subject matter.[89] It is when the term "process" is used to represent the "means or method of producing a result that it is patentable," including means or methods unaffected by the mechanics of an invention.[90] In the 1980s, several Supreme Court

[84] To obtain a preliminary injunction, "the Court considers a party's showing on four factors. (1) reasonable likelihood of success on the merits, (2) irreparable harm, (3) the balance of hardships, (4) the impact of the injunction on the public interest." Nautilus Grp., Inc. v. Icon Health and Fitness, Inc., 308 F. Supp. 2d 1198, 1207 (W.D. Wash. 2003); *Superior Elec.*, 194 F. Supp. at 347 (noting that while granting a preliminary injunction is an extraordinary measure, such a measure is within the discretion of the court).

[85] eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 395 (2006) (Roberts, C.J., concurring) (citing this "long tradition of equity practice" as dating back to the early nineteenth century).

[86] Douglas Ellis, John Jarosz, Michael Chapman & L. Scott Oliver, *The Economic Implications (and Uncertainties) of Obtaining Permanent Injunctive Relief After eBay v. MercExchange*, 17 FED. CIR. B.J. 437, 440 (2008) (citing Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 593 (7th Cir. 1934)) (In *Activated Sludge*, the Seventh Circuit decided that granting permanent injunctive relief would have left a community with no viable means of disposing of sewage.).

[87] 35 U.S.C. § 101 (2012) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . . .").

[88] Kristen Nugent, *Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform*, 17 ANNALS HEALTH L. 135, 142 (2008) (discussing the American Medical Association's initial opposition to medical device patentability).

[89] *See* Cochrane v. Deener, 94 U.S. 780, 788 (1877) (noting that in the language of patent law a process is considered an "art" and is, therefore, patentable subject matter); *see also* Kelley v. Coe, 99 F.2d 435 (D.C. Cir. 1938) (holding hydraulic process patentable).

[90] Elizabeth D. Lauzon, *Construction and Application of Patent Act – United States Supreme Court Cases*, 27 A.L.R. FED. 2d 151, § 3 (2008).

decisions expanding patentable subject matter to lead to a sharp increases in patent applications for method patents such as medical, diagnostic, and therapeutic methods.[91] This extension of patent protection continues to sharply divide the various players in the medical community and biotechnology industry.[92] Unlike medical devices, patent rights for medical methods or procedures do not enjoy the support of the AMA.[93]

A. FDA – Premarket Approval Process

In 1976, in response to the alarming number of deaths associated with defective medical devices, Congress amended the Federal Food, Drug, and Cosmetic Act, creating mechanisms the Food and Drug Administration ("FDA") could employ in an effort to promote and protect public health.[94] "The Medical Device Amendments of 1976 . . . established three regulatory classes for medical devices."[95] Premarket Approval ("PMA") is the FDA process of scientific and regulatory review employed to evaluate the safety and performance of medical devices "that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury," also known as Class III devices.[96] PMA is the most stringent, onerous, and expensive type of

[91] Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INTELL. PROP. 280, 281 (2010).

[92] *See infra* Part III.C.

[93] *See infra* Part III.C.

[94] *Exploring HeinOnline: Medical Device Amendments of 1976 & Safe Medical Devices Act of 1990*, HEINONLINE BLOG (Dec. 30, 2009), http://home.heinonline.org/blog/2009/12/exploring-heinonline-medical-device-amendments-of-1976-safe-medical-devices-act-of-1990 ("When the Federal Food, Drug, and Cosmetics Act was passed in 1938, the FDA was charged with removing adulterated or misbranded medical devices from the market. It did not however give the FDA the ability to review medical devices before they entered the market.").

[95] *Medical Devices: PMA Approvals*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm (last updated Jan. 16, 2014).

[96] *Medical Devices: Premarket Approval (PMA)*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm (last updated Aug. 19, 2014) ("PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).").

device application required to market a new device.[97]

On October 26, 2002, the Medical Device User Fee and Modernization Act was signed into law, authorizing FDA to charge a fee for the medical device approval process.[98] The application alone costs nearly $250,000.[99] Manufacturers are required to file an application for PMA when planning to introduce a device that is dissimilar to any device already on the market.[100] Manufacturers need only file a premarket notification for Class III medical devices that are "substantially similar" to a previously approved device to qualify for a less arduous process known as the 510(k), or premarket notification, process.[101]

The 510(k) process allows an applicant to use a predicate Class III device's clinical data upon establishing that the applicant's Class III device is similar in nearly all respects to the predicate Class III device, saving the applicant significant time and money.[102]

B. Extension of Patent Term

In certain circumstances, a patent holder can successfully extend the term of his or her medical device or pharmaceutical patent.[103] Extensions are granted to restore time to the patent term as compensation for time "lost" during the regulatory processes of the FDA.[104] Extensions are available to those medical devices and pharmaceuticals that endure the most stringent, and typically longest, regulatory testing.[105] With respect to medical devices, only new Class

[97] Requirements for PMA include valid clinical information, valid scientific reasoning, and a well-organized, complete report. *Id.*

[98] *Id; see also* Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 166 Stat. 1588 (codified as amended in scattered sections of 21 U.S.C).

[99] *See Medical Devices: PMA Review Fees*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm (last updated Mar. 18, 2014).

[100] *See also FDA Submissions*, TOLTEC INTERNATIONAL, INC., http://www.toltec.biz/fda_submission.htm (last visited July 31, 2014).

[101] *Id.*

[102] *Id.* In order to achieve approval through the 510(k) process, applicant must demonstrate that its device has the same intended use as a predicate device and the same technological characteristics as the predicate device. *Id*.

[103] 35 U.S.C. § 156 (2012). *See generally* Eli Lilly & Co., v. Medtronic Inc., 496 U.S. 661 (1990).

[104] Michelle A. Sherwood, *Medical Devices and Patent Term Extensions Under the Hatch-Waxman Act*, LANDSLIDE, July/Aug. 2010, at 38.

[105] *Id.* ("The exact formula used to determine the *extension* for either a new drug or new *device* is the following:

III medical devices that require a PMA application are eligible.[106]

C. Infringement Under 35 U.S.C. 287(c)

On March 3, 1995, Representative Greg Ganske introduced The Medical Procedures Innovation and Affordability Act in an effort to eliminate patent protection for medical and surgical procedures entirely.[107] Not surprisingly, the medical community, including the American Medical Association (the "AMA"), championed the bill, while the biotechnology community fiercely opposed it.[108] In October 1995, Senator Bill Frist introduced a similar bill excluding the use of medical or surgical procedures from the definition infringing activity rather than excluding medical and surgical procedure from the definition patentable subject matter.[109]

After intense negotiations among key stakeholders, the proposed reform's focus shifted again, this time, to amending damages and remedies associated with infringement of medical and surgical procedures.[110] In 1996, President

[½ (Experimental Time)] + (Administrative Time) = *Extension***.** For *medical devices*, Experimental Time is the time from the start of clinical investigations to the date of submission of a PMA to the FDA. Administrative Time is the time from the PMA submission date to the FDA approval date.").

[106] *Id.* (noting that only new drugs that require a new drug application ("NDA") are eligible for patent term extension). *See also* 35 U.S.C. § 156(g)(3)(A) (2012).

[107] Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. (1995). ("On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture, or composition of matter may claim such technique, method, or process."). While Ganske's bill was never enacted, some of it was incorporated into the Omnibus Consolidated Appropriations Act. *See* Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208 § 616, 110 Stat. 3009 (1996).

[108] Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 789, 792 (1996). In addition to the AMA, the American Society of Cataract and Refractive Surgery ("ASCRS") and Medical Procedure Patent Coalition supported the Ganske bill. *Id*. Other groups like the Biotechnology Industry Organization ("BIO"), the Section of Intellectual Property Law of the American Bar Association ("ABA"), and the American Intellectual Property Law Association and Pharmaceutical Research and Manufacturers of America ("PhRMA") opposed the H.R. 1127. *Id.*

[109] *Id.* at 794.

[110] Key stakeholders included the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the Biotechnology Industry Organization ("BIO"), the

Clinton signed the Omnibus Consolidated Appropriations Act of 1996 into law, amending the Patent Act to include Section 287(c).[111]

Section 287(c) shields medical practitioners from liability that would have traditionally resulted from the performance of a medical process that constitutes infringement under Section 271(a) or (b).[112] In other words, under Section 287(c), when a medical practitioner performs a patented "medical procedure on a body," remedies, such as monetary damages or injunctive relief are unavailable.[113] The addition of Section 287(c) strips the patent holder of any remedy against a directly infringing medical practitioner or related health care entity.[114]

This provision, however, does not leave the patent holder completely without recourse. Section 287(c) does not shield medical practitioners from liability when performing a "medical activity" that uses a "patented machine, manufacture, composition of matter," or "the practice of . . . use of composition of matter," in violation of such patents.[115] Likewise, Section 287(c) does not shield practitioners performing a "medical activity" involving the "violation of a biotechnology patent."[116] Ultimately, medical and surgical procedures are still patentable but the rights associated with those patents are *only enforceable* against a medical practitioner or related health care entity if the procedure patent incorporates devices or pharmaceuticals.[117] Additionally, companies or individuals who induce or contribute to a physician's direct infringement may be held liable for indirect infringement.[118]

Medical Procedure Patent Coalition, and the American Society of Cataract and Refractive Surgery ("ASCRS"). *Id.* at 793-96.

[111] 35 U.S.C. § 287(c) (2012); Scott D. Anderson, Comment, *A Right Without a Remedy: The Unenforceable Medical Procedure Patent*, 3 MARQ. INTELL. PROP. L. REV. 117, 128 n.77 (1999).

[112] 35 U.S.C. § 287(c) (2012). *See supra* notes 55, 63 and accompanying text.

[113] 35 U.S.C. § 287(c) (2012); Eric M. Lee, *35 U.S.C § 287(c) – The Physicians Immunity Statute*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 701, 708 (1997).

[114] Lee, *supra* note 113, at 708.

[115] 35 U.S.C § 287(c)(2)-(3) (2012) ("The term 'patented use of a composition of matter' does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method."); *see also* Lee, *supra* note 113, at 709.

[116] 35 U.S.C § 287(c)(2)(A) (2012); Mossinghoff, *supra* note 108, at 801 ("The definition of the term 'biotechnology patent' includes a patent on a "biotechnological process" as defined in 35 U.S.C. § 103(b), as well as a patent on a process of making or using biological materials."); *see also* Lee, *supra* note 113, at 709.

[117] Anderson, *supra* note 111, at 131.

[118] 35 U.S.C §, 271(b)-(c) (2012).

D. International Intellectual Property Treaties

In 1994, the United States signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPs Agreement").[119] Effective January 1, 1995, the TRIPs Agreement, administered by the World Trade Organization (the "WTO"), outlines the minimum international standards for intellectual property law required by each member country.[120] Member countries are required to provide patent protection in all industries without discrimination to field or technology.[121]

The TRIPs Agreement allows for some flexibility by providing several public interest exceptions.[122] Article 27.2 of the TRIPs Agreement prohibits patenting of innovations contrary to "*ordre public*" or morality.[123] Article 27.3(a) of the TRIPs Agreement permits, but does not require, member countries to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."[124] Many countries have taken advantage of Article 27.3(a), declining to afford patent protection to medical, surgical, and therapeutic procedures,[125] based on the notion that "property rights should not prevent patients from having access to the very best medical treatment."[126]

IV. REMEDIES: PERMANENT INJUNCTIONS AGAINST MEDICAL PROCEDURE AND MEDICAL DEVICE INFRINGERS FOLLOWING *EBAY*

Prior to 2006, courts routinely presumed that injunctive relief unquestionably followed a finding of validity and infringement.[127] In *eBay v. MercExchange*, the Supreme Court granted certiorari to examine the lawfulness of this presumption.[128] The case involved the infringement of a

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[119] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (last visited Apr. 20, 2014).

[120] *Overview: the TRIPS Agreement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Apr. 20, 2014).

[121] *Id.*

[122] *Id.*

[123] *Id.* This exception explicitly prohibits inventions considered dangerous to human, animal, or plant life or inventions considered "seriously prejudicial" to the environment. *Id.*

[124] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 311-12 [hereinafter TRIPs].

[125] *See infra* notes 224-20 and accompanying text.

[126] MERGES & DUFFY, *supra* note 25, at 192.

[127] *See* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393-94 (2006) (Roberts, C.J., concurring).

[128] *Id.* at 391.

patented business method, and the Court struck down the Federal Circuit's long-standing rule that a patent holder is entitled to a permanent injunction against a direct infringer.[129] In the aftermath of *eBay*, some critics argued the Supreme Court essentially endorsed a system of compulsory licensing in lieu of injunctive relief.[130] Perhaps, though, the consequences of the *eBay* decision have not shaken the landscape of patent protection as suspected.

A. eBay, Inc. v. MercExchange, L.L.C.

In 1995, the Patent and Trademark Office (the "PTO") granted inventor and founder of MercExchange, L.L.C., Thomas Woolston, patent rights to a business method patent for an electronic marketplace designed to facilitate commerce and payments remotely.[131] MercExchange, however, did not itself practice the patented business method and rather opted to license rights to use the method.[132] Founded in 1995, eBay is the world's largest online marketplace, boasting more than 128 million active users.[133] The online platform that eBay launched embodied MercExchange's patented methods. Prior to filing suit, the two companies unsuccessfully attempted to reach a licensing agreement for use of the methods.[134]

A jury found eBay willfully infringed MercExchange's validly held patent.[135] The district court then looked to the traditional, equitable four-factor balancing test and determined that, because MercExchange did not practice the patented method and demonstrated willingness to license its patent, it could not demonstrate irreparable harm.[136] Moreover, the court noted that, though not a dispositive factor, "the public does not benefit from a patentee who obtains a patent yet declines to allow the public to benefit from the inventions contained

[129] *See id.*

[130] Andrew Beckerman-Rodau, *The Supreme Court Engages in Judicial Activism in Interpreting the Patent Law in eBay, Inc. v. MercExchange, L.L.C.*, 10 TUL. J. TECH. & INTELL. PROP. 165, 166 (2007)

[131] *eBay*, 547 U.S. at 390; Sue Ann Mota, *eBay v. MercExchange: Traditional Four-Fact Test for Injunctive Relief Applies to Patent Cases, According to the Supreme Court*, 40 AKRON L. REV. 529, 533 (2007). In connection with the online business method, Woolston obtained patent rights (which he assigned to MercExchange) to Internet commerce though internetworked auctions and a function to search a plurality of markets. Mota, *supra* at 533.

[132] MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 712 (E.D. Va. 2003)

[133] *Who We Are: One Company*, EBAY INC., www.ebayinc.com/who_we_are/one_company (last visited Apr. 20, 2014).

[134] *eBay*, 547 U.S. at 390.

[135] *MercExchange*, 275 F. Supp. 2d at 698-99 ("On May 27, 2003, after a five-week jury trial, the jury returned a verdict finding the defendants liable for $ 35 million for willfully infringing the plaintiff's patents.").

[136] *See id.* at 711-12.

therein."[137] The district court, therefore, found that monetary damages sufficiently remedied plaintiff's injury and denied MercExchange's motion for a permanent injunction.[138]

On appeal, the Federal Circuit Court of Appeals reversed the district court's decision following the longstanding presumption that permanent injunctive relief follows a finding of validity and infringement.[139] The court noted that prior to the *eBay* decision, only in rare instances have district courts exercised their discretion to deny injunctive relief in order to protect the public interest.[140] Further, the court rejected the contention that public interest considerations favor patent holders who practice their patents as compared to patent holders who choose to license rights to their patents.[141] The court declined to find the facts of this dispute sufficient exceptional as to warrant the denial of injunctive relief.

The Supreme Court reconciled the disagreement between the district court and the Court of Appeals by reiterating the test to balance the equities when deciding whether to grant permanent injunctive relief.[142] The Court held that a patent holder seeking a permanent injunction must make a four-part showing: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate; (3) that, considering the balance of hardships between the parties, an equitable remedy is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[143] The Court found that the permissive language of the Patent Act grants lower courts the discretion to evaluate whether injunctive relief follows traditional equitable principles.[144]

In concurrence, Justice Kennedy cautioned against allowing too much discretion but conceded that in the following three instances, the availability of such discretion is particularly warranted: (1) disputes involving non-practicing patent holders; (2) disputes in which the patented innovation or invention is only a small portion of the infringer's product; and (3) disputes involving

[137] *Id.* at 714.

[138] *Id.* at 713, 722.

[139] MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1338-39 (Fed. Cir. 2005).

[140] Rite-Hite Corp. v. Kelley, Inc., 56 F.3d 1538, 1547 (Fed. Cir. 1995); *see* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, J., concurring).

[141] *See MercExchange, L.L.C.*, 401 F.3d at 1339.

[142] The Supreme Court found that the district court had categorically denied injunctive relief improperly while the court of appeals had categorically granted injunctive relief improperly. *See eBay*, 547 U.S. at 393-94.

[143] *Id.* at 391 (holding that it is within the discretion of courts to decide whether to issue a permanent injunction based on balancing traditional notions of equity).

[144] *Id.* at 391. *See also* 35 U.S.C. § 283 (2012). ("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.").

potentially vague and suspect business method patents.[145] Justice Kennedy expressed concern regarding non-practicing patent holders, who charge excessive license fees based on the threat of injunctive relief.[146] Justice Kennedy went on to note, however, that "equitable discretion over injunctions, granted by the Patent Act, is well suited to allow courts to adapt to the rapid technological and legal developments in the patent system."[147] Chief Justice Roberts, also writing in concurrence, clarified that while the decision to grant or deny permanent injunctive relief requires discretion of the court, traditional practice informs that discretion and tradition should not be disregarded.[148]

B. Consequences of eBay

Critics were skeptical of the *eBay* holding for several reasons.[149] First, commentators contend that the Court did not apply its own test to the facts of the case.[150] The Court explicitly took "no position" on whether the *eBay* test as applied to the specific facts of the dispute between eBay and MercExchange would result in a grant or denial of injunctive relief.[151] Problematically, the Court provides little guidance with respect to the weight that should be accorded to each factor.[152] District courts are left to interpret the test and assign weight to each factor. Accordingly, critics are concerned that the Court's judicial activism represents a "broad attack" on the United States patent system, which is particularly offensive in light of the absence of any practical application of the test.[153] "[I]t is imperative that when the Supreme Court unilaterally eliminates a well-established and long-followed rule of law that it provide clear guidance in its judicial opinion explaining the rationale for its actions."[154] Without proper guidance and rationale, the Court's decisions seem arbitrary or politically driven.[155]

Second, commentators argue that courts simply should not have such wide discretion to determine whether a property right as unique as a patent is enforceable.[156] They argue that in other contexts "courts routinely enjoin

[145] *eBay*, 547 U.S. at 396-97 (Kennedy, J., concurring).

[146] *See* Ellis, Jarosz, Chapman & Oliver, *supra* note 86, at 438.

[147] *eBay*, 547 U.S. at 397 (Kennedy, J., concurring).

[148] *Id.* at 394-95 (Roberts, C.J., concurring).

[149] Rachel M Janutis, *The Supreme Court's Unremarkable Decision in eBay, Inc. v. MercExchange, L.L.C.*, 14 LEWIS & CLARK L. REV. 597, 607 (2010).

[150] *Id* at 607-08.

[151] *eBay*, 547 U.S. at 394.

[152] Beckerman-Rodau, *The Supreme Court Engages*, *supra* note 130, at 191 ("The majority decision in *eBay* failed to provide any explanation for its rejection of almost a century of precedent.").

[153] *Id.* at 166.

[154] *Id.* at 191.

[155] *Id.*

[156] *See* Janutis, *supra* note 149, at 598.

interference of property rights with little or no considerations of the equities of a given case."[157] However, according to analysis of district court cases since the *eBay* decision, lower courts have followed a predictable pattern in applying the Supreme Court's ruling.[158]

C. eBay in Practice

In practice, district courts have generally granted permanent injunctions after applying the *eBay* test.[159] According to one study, evaluating district court patent infringement decisions in the year following *eBay*, data clearly indicated that district courts continued to grant injunctive relief in the majority of cases.[160] In fact, district courts granted injunctive relief in nearly 80% of cases.[161] The study found that, while district courts cited many factors when applying the *eBay* balancing test, whether the parties directly competed with one and other was the most determinative factor in a district court's decision to grant injunctive relief.[162] In fact, district courts granted permanent injunctions in every case involving infringement between direct competitors.[163] Consistent with this trend, in almost every case in which a court denied a permanent injunction, the patent holder did not practice or commercialize his or her patent rights.[164]

A similar study conducted over the two years following the *eBay* decision evaluating thirty-six district court decisions, found that district courts granted permanent injunctive relief in roughly 78% of cases.[165] More specifically, district courts granted permanent injunctive relief in twenty-eight cases, while denying injunctive relief in only eight.[166] Again, the district court decisions

[157] *Id.* at 608.

[158] *Id.* at 604.

[159] *Id.*

[160] According to the study, district courts in twenty-two cases granted injunctive relief, where only six denied injunctive relief. All the cases cited involved patents the court found both valid and infringed. Andrew Beckerman-Rodau, *The Aftermath of eBay v. MercExchange, 12 S. Ct. 1837 (2006): A Review of Subsequent Judicial Decisions*, 89 J. PAT & TRADEMARK OFF. SOC'Y 631, 658-59.

[161] *Id.*

[162] Other factors such as willful infringement, venue, the existence of the complex invention problem, the willingness of the patent owner to license the invention and the likelihood of future infringement are not overly predictive of whether patent infringement will result in issuance or denial of a permanent injunction. *Id*. at 654-57.

[163] *Id.*

[164] *Id.* at 654-55 (noting that by definition "non-practicing entities . . . are not direct competitors.")

[165] *See* Ellis, Jarosz, Chapman & Oliver, *supra* note 86, at 441-442.

[166] *Id.*

followed predicable patterns.[167] The single most determinative factor governing a court's willingness to grant a permanent injunction was the relationship of the parties-in-suit.[168] Direct competition is largely dispositive because it easily reflects economic harm and courts deem such losses "irreparable."[169] Although the Supreme Court gave no indication that irreparable harm required such a stringent standard, several courts interpreted direct competition as requiring a two-supplier market.[170] Additionally, courts typically grant permanent injunctions in two-competitor situations because the patent holder has clearly demonstrated an unwillingness to part with his or her exclusive patent rights.[171] Interestingly, in a later case involving medical devices, the court discounted direct competition between the parties because "the patent holder had licensed its patent to two other direct competitors that had gained more market share than either the plaintiff or the defendant."[172] Though not as dispositive as direct competition, licensing agreements as well as settlement attempts influence the likelihood of injunctive relief.[173]

Ultimately, while the Supreme Court's ruling in *eBay* sparked significant criticism, the decision does not appear to have an overly profound impact on the availability of permanent injunctions in the majority of traditional patent infringement cases.[174]

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[167] *See id.*; Janutis, *supra* note 149, at 604; Benjamin Petersen, *Injunctive Relief in the Post-eBay World*, 23 BERKELEY TECH. L.J. 193, 196 (2008).

[168] *See* Ellis, Jarosz, Chapman & Oliver, *supra* note 86, at 447 (cautioning that what constitutes sufficiently direct competition is not yet consistently defined, making the standard of direct competition a difficult one to rely on).

[169] *Id*. at 444-45. ("Losses have been cited related to 'market share,' 'sales,' 'customers,' 'profits,' 'opportunities,' 'reputation,' and/or 'brand name.'").

[170] Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., 579 F. Supp. 2d 554, 559-60 (Fed. Cir. 2008) (citing TruePosition Inc. v. Andrew Corp., 568 F. Supp. 2d 500, 532 (D. Del. 2008)); Muniauction, Inc. v. Thomson Corp., 502 F. Supp. 2d 477, 482 (W.D. Pa. 2007); Novozymes A/S v. Genencor Intern., Inc., 474 F. Supp. 2d 592, 612-13 (D. Del. 2007) (noting that demonstrating irreparable harm requires direct competition in a two-supplier market).

[171] *Advanced Cardiovascular Sys.*, 579 F. Supp. at 559-60; *Muniauction, Inc.*, 502 F. Supp. at 482; *Novozymes A/S*, 474 F. Supp. at 612-13.

[172] *See* Janutis, *supra* note 149, at 607.

[173] Whether or not a licensee decides to join the licensor in suit against an infringing party can determine whether an injunction will issue, putting the licensee in a more powerful position for negotiating the value of the patent rights. Additionally, pre-litigation efforts to settle by reaching a licensing agreement can be used to indicate the licensor will not be irreparably harmed by a compulsory licenses rather than a permanent injection. *See* Ellis, Jarosz, Chapman & Oliver, *supra* note 86, at 460-63.

[174] *See* Janutis, *supra* note 149, at 604.

V. RECENT CASE LAW DEVELOPMENT

The Supreme Court admonished the practice of categorically defining the limits of patentability.[175] In the absence of a categorical approach, permanent injunctions in patent cases must be based on a case-by-case assessment.[176] Two recent cases, however, demonstrate a possible shift in courts' remedial approach to medical device and medical process infringement cases; in addition, these decisions are inconsistent with the findings discussed above regarding courts' predictability in interpreting and applying the *eBay* test.[177] Accordingly, it seems that the ruling in *eBay* impacts the biotechnology and medical device industries more significantly than other high tech industries.

A. Conceptus v. Hologic

In *Conceptus, Inc. v. Hologic, Inc.*,[178] a recent decision from the Northern District of California, the court denied a permanent injunction in a dispute between two medical device companies producing transcervical hysteroscopic sterilization devices.[179] The court found that Hologic's contraceptive device did not infringe the Conceptus' patented device.[180] Conceptus, however, had also secured patent protection on the method by which treating physicians implanted the sterilization device in the patient's body.[181] The court found that

[175] "[T]raditional equitable principles do not permit such broad classifications . . . . Just as the District court erred in its categorical of equitable relief, the Court of Appeals erred in its categorical grant of such relief." *eBay*, 547 U.S. at 393-94; *see* Janutis, *supra* note 149, at 604-05.

[176] *eBay*, 547 U.S. at 393-94.

[177] *See generally* Conceptus, Inc. v. Hologic, Inc., No. C 09-02280 WHA, 2012 WL 44064 (N.D. Cal. Jan. 9, 2012); Bard Peripheral Vascular v. W.L. Gore & Assoc., Inc., No. CV-03-0597-PHX-MHM, 2009 WL 920300 (D. Ariz., Mar. 31, 2009); *see also supra* note 175 and accompanying text.

[178] *Conceptus*, 2012 WL 44064, at *2.

[179] *Id*; *see also* Conceptus, Inc. v. Hologic, Inc., 771 F. Supp. 2d 1164 (N.D. Cal. 2010) ("The Adiana system [Hologic], like the Essure System [Conceptus], supposedly involves the minimally invasive transcervical placement of a contraceptive device into woman's fallopian tubes. . . . [Both systems are] intended to produce intrafallopian occlusion . . . .").

[180] *Conceptus*, 2012 WL 44064, at *2 ("The insert itself was accused as well but it was found to infringe in pretrial rulings."); *Conceptus*, 771 F. Supp. 2d at 1177 (holding that even applying the rule provided in *Graver*, the two devices were not similar enough to merit a finding of infringement); *see also* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950) ("[I]f two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape.").

[181] *Conceptus*, 771 F. Supp. 2d at 1170-71 ("Claims 37 and 38 (as well as independent claim 36, which

Conceptus held valid patents on method claims associated with the insertion of the contraceptive device.[182] Subsequently, the jury found that, by selling its device, Hologic induced doctors' direct infringement of the patented method, and thereby incurred liability for both direct and indirect infringement of "certain method claims of Conceptus' patent."[183] In denying Conceptus' motion for permanent injunctive relief, the judge noted:

> The public interest would undoubtedly be harmed by an injunction. Enjoining the sale of Adiana would leave only one product for transcervical hysteroscopic sterilization. Public health has benefitted, and will continue to benefit, from having a choice of products for transcervical hysteroscopic sterilization. This is especially important because *the products are different*. Removing Adiana from the market would have eliminated an important alternative for patients.[184]

Conceptus and Hologic compete directly and, at the time of the dispute, produced the only transcervical hysteroscopic sterilization devices available on the market.[185] Still, the court held that public interest in increased choice of medical devices is so strong that it is best served by denying a permanent injunction.[186] The court's reasoning fails to follow the consistent pattern typically followed by those courts applying the *eBay* decision.[187]

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they reference) cover a contraceptive method: 36. An intrafallopian contraceptive method comprising of: transcervically introducing a pre-formed resilient structure into a target region of a fallopian tube; imposing an anchoring force against a tubal wall of the fallopian tube by resiliently engaging in inner surface of the tubal wall with the resilient structure; and permanently affixing the resilient structure within the fallopian tube with a lumen-traversing region of the resilient structure so that at least a portion of the fallopian tube is open. 37. A method as claimed in claim 36, wherein the affixing step comprises promoting tissue ingrowth of the tubal wall surrounding the resilient structure. 38. A method as claimed in claim 37, wherein the tissue ingrowth occludes the fallopian tube to inhibit contraception.") (emphasis omitted).

[182] *Id.* at 1177-79.

[183] The jury awarded damages of about $18 million. *Conceptus*, 2012 WL 44064, at *2. Conceptus moved for permanent injunctive relief and enhanced money damages. *Id. See also* 35 U.S.C. § 271(b)-(c) (2012).

[184] *Conceptus*, 2012 WL 44064, at *3 (emphasis added).

[185] *Conceptus*, 771 F. Supp. 2d at 1179 ("In this action, Hologic does not dispute the fact that Conceptus' Essure product and Hologic's Adiana product were the only two transcervical intrafallopian contraception methods on the U.S. market during the relevant time period.").

[186] *Conceptus*, 2012 WL 44064, at *3.

[187] *See* Janutis, *supra* note 149, at 604 (explaining that, following the Supreme Court's holding in *eBay*, lower courts do not often deny permanent injunctions

Not only were Conceptus and Hologic direct competitors and the *only* two companies producing transcervical hysteroscopic sterilization devices at the time, Conceptus' Essure system was the company's *only* marketed device.[188] The facts of *Conceptus* are perfectly in line with the reported trend of granting injunctive relief, even pursuant to a more stringent interpretation of direct competition.[189] The court clearly grounded its decision on the notion that permanent injunction relief would seriously disservice the public.[190] Further, the decision seems to echo Justice Kennedy's concerns about the suspect nature of method patents.[191] One way to interpret *Conceptus* is that the public interest is best served by denying permanent injunction when the infringed patent is merely a medical method.[192] The next case, however, indicates the trend of denying injunctive relief expands beyond medical procedure patents.

B. Bard Peripheral Vascular v. W.L. Gore & Associates

In *Bard Peripheral Vascular v. W.L. Gore & Associates*,[193] the Federal Circuit affirmed the district court decision denying a permanent injunction despite a finding of willful infringement of a validly held medical device patent.[194]

At issue in this extremely complicated dispute was a patent for "prosthetic vascular grafts fabricated from highly-expanded polytetrafluoroethlyne ('ePTFE') vascular grafts."[195] The district court denied Bard permanent injunctive relief but the jury awarded $102,081,578.82 for lost profits and $83,508,292.20 for reasonable royalties.[196] Following the jury verdict, Bard

where the parties are direct competitors and a jury finds infringement of a valid patent.)

[188] *Conceptus*, 2012 WL 44064, at *2.

[189] *See supra* Part IV.C.

[190] *Conceptus*, 2012 WL 44064, at *3.

[191] *Id.* (noting that the insert itself infringes nothing; rather, it is merely "the *procedure* for inserting it was found by the jury to infringe the method claims in suit."). Justice Kennedy expressed doubts regarding potentially vague method patents; however, he only specifically pointed to business method patents as cause for concern. eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396-97 (2006) (Kennedy, J., concurring).

[192] *Conceptus*, 2012 WL 44064, at *3. *See generally eBay*, 547 U.S. at 396-97 (Kennedy, J., concurring).

[193] Bard Peripheral Vascular v. W.L. Gore & Assocs., 670 F.3d. 1171 (Fed. Cir. 2012).

[194] *Id.* at 1193.

[195] *Id.* at 1175 ("This has been a long and arduous journey for the parties in this litigation, but this should be the final curtain of the saga, which commenced in 1974 with the filing of the patent application that eventually matured as U.S. Patent No. 6,436,135.").

[196] *Id.* at 1178.

moved for permanent injunctive relief.[197] The court held that the public was best served by the availability of different options in the medical field regardless of evidence showing that the devices were interchangeable in the market.[198] Perhaps imprecisely, the court construed the fourth prong of the eBay test as requiring that the public interest favor the injunction.[199] The court noted that in cases involving two direct competitors, a patent holder's rights are strongest.[200] Still, the court found "that [Bard's] remedy at law provides adequate compensation . . . particularly when viewed in light of the public interest served by Gore's continued infringement."[201]

Ultimately, the Court of Appeals declined to find error with respect to the district court's denial of a permanent injunction for infringement between direct competitors.[202] Upon an *en banc* rehearing to challenge district court holding of willful infringement, the Federal Circuit Court of Appeals determined that the district court may have erred in finding the infringement willful.[203]

VI. POLICY CONSIDERATIONS

As discussed in Part II, the primary justification of the Patent Act is the utilitarian theory that patent rights incentivize investment in and the creation of new inventions.[204] On the other hand, the prohibitive costs associated with health care and inaccessibility to health care raise serious concerns about the application of general patent law principles to medical patents. Medical device and procedure patents are caught in the middle of competing policy justifications of fostering innovation and furthering public interest in health

[197] Bard Peripheral Vascular v. W.L. Gore & Assocs., No. CV-03-0597-PHX-MHM, 2009 WL 920300 (D. Ariz. Mar. 31, 2009).

[198] *Id.* at *5-6.

[199] *Id*. ("This test is familiar to the Court, and involves the following factors: (1) whether plaintiff has suffered irreparable harm; (2) there is no adequate remedy at law; (3) the balance of hardships favors injunction; and (4) the public interest favors imposing an injunction."). The fourth prong of the *eBay* test requires balancing whether granting injunctive relief disserves the public interest. eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

[200] *Bard*, 2009 WL 920300, at *6 ("Nor does the Court dispute the accuracy of Plaintiffs argument that "[i]ntellectual property enjoys its highest value when asserted against a direct competitor in the plaintiff's market.") (quoting Acumed LLC v. Stryker Corp., 2007 WL 4180682, *4 (D. Or. 2007)).

[201] *Id.* at *8.

[202] *Bard*, 670 F.3d at 1192-93.

[203] As a result, the court expounded a new formulation of willful infringement and remanded the case. Beckerman-Rodau, *The Aftermath of eBay*, *supra* note 160, at 656 ("Willful infringement, arguably, should be relevant when the remedy being sought, such as permanent injunctive relief, is equitable in nature.").

[204] MERGES & DUFFY, *supra* note 25, at 50.

care. The Supreme Court's reluctance to indicate how the *eBay* test should operate in application exasperates to the difficulty in resolving these issues.

A. Patent Law Policy – Medical Devices

Patents are granted in order to encourage innovation and dissemination of information by awarding the inventor exclusive rights to that innovation for a limited time.[205] An inventor can retain significant financial benefit from relying on his or her exclusive rights granted through the patent system.[206] While in other contexts, lack of patent protection might lead to reliance on secrecy, inventors of medical devices have no choice but to rely on patent protection given the wide array of required regulatory hurdles associated with marketing medical devices.[207] The grant of a limited monopoly allows pioneer medical device firms to obtain financing required for the tremendous expense associated with research and development, clinical trials, and the expensive PMA process.[208] On average, it costs $94 million to get a medical device through the PMA process and $31 million to get a medical device through the 510(k) process.[209] In an industry where less than 25% of startup companies survive, obtaining requisite financing is incredibly difficult but necessary for the innovation of new medical devices.[210] As a result, investors require high returns for such taking on risky investments. The patent system is designed to facilitate this kind of investment.

Additionally, though Justice Kennedy expressed skepticism with respect to firms who own patents exclusively to charge exorbitant licensing fees based on the threat of injunctive relief, patent trolls are not prevalent in the biotechnology sector.[211] "Biotechnology companies have not been as vulnerable because their patents are not as broad as software patents, and require more time and expertise to develop."[212] Perhaps, therefore, a rationale for the *eBay* test is inapplicable to medical devices.

Finally, a limited monopoly for medical devices, particularly Class III, is actually more limited than in other areas of patent law given regulatory

[205] *See* Geire, *supra* note 14, at 243.

[206] *Id.*

[207] *Id.*

[208] *Id.*

[209] Bill Evans, *A Near-term look at MedTech Investing*, MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY, (May 16, 2012), http://www.mddionline.com/article/near-term-look-medtech-investing.

[210] *Id*. (noting that in today's economic environment obtaining financing from venture capital firms is more difficult in the medical technology sector than in other technology sectors).

[211] Erika Check Hayden, "*Patent Trolls" target biotechnology firms*, NATURE, Sept. 29, 2011, at 521.

[212] Subsequent case law indicates, however, that biotech companies could be more vulnerable to patent troll driven litigation. *Id.*

constraints that delay effectuation of any meaningful profit.[213] The greater the time and expense required to take an invention from creation to commercialization, the more important patent protection becomes.[214]

B. Health Care Policy

Conversely, from a health care perspective, the underlying policy argument favoring the denial of a permanent injunction is the considerable public interest in the availability of a greater number of treatment options and fostering competition in order to increase accessibility by driving down costs.[215] A deeper examination of the policy considerations supporting a public health-centric stance on medical patents highlights the weight of these policy justifications.

i. Patenting Medical and Surgical Procedures

The AMA has taken a firm stance against the patenting of medical and surgical procedures, calling such patents unethical.[216] The primary force behind "the medical community's opposition to medical procedure patents is . . . the medical profession's purported history and tradition of free and open exchange of information on medical advances and discoveries."[217]

According to the AMA Principles of Medical Ethics, a physician is obligated to "continue to study, apply, and advance scientific knowledge [and] make relevant information available to patients, colleagues and the public . . . ."[218] Other ethical concerns include restricting access to certain procedures through expensive licensing fees and the possibility of a physician choosing an inferior procedure in order to avoid those licensing fees.[219] The AMA maintains that "[t]he use of patents, trade secrets, confidentiality

[213] *See* Timothy John McCoy, *FDA Medical Device Approval: The Noninfringing Experimental Use Defense is Expanded: Eli Lilly & Co. v. Medtronic, Inc., 110 S. Ct. 2683 (1990)*, 14 HAMLINE L. REV. 201, 205-06 (1990); *supra* note 106 and accompanying text.

[214] Michael A Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 823-24 (2002).

[215] *See* Conceptus, Inc. v. Hologic, Inc., 771 F. Supp. 2d 1164 (N.D. Cal. 2010); Bard Peripheral Vascular v. W.L. Gore & Assocs., 670 F.3d. 1171, 1192 (Fed. Cir. 2012) (finding it served the public interest to allow competition in medical devices).

[216] Peggy Peck, *AMA Patents for Procedures Raise Ethical Hackles*, MEDPAGETODAY.COM, June 27, 2012, http://www.medpagetoday.com/MeetingCoverage/AMA/6044.

[217] Lee, *supra* note 113, at 710.

[218] AMERICAN MED. ASS'N, Council on Ethical and Judicial Affairs, *Ethical Issues in the Patenting of Medical Procedures*, 53 FOOD & DRUG L.J. 341, 343 (1998) (quoting AMERICAN MED. ASS'N, CODE OF MEDICAL ETHICS (1994)).

[219] *Id* at 344.

agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge."[220] Therefore, those practices are unethical.[221]

ii. Comparative Policy

More than eighty countries exclude medical procedures from patentability.[222] Medical methods are statutorily excluded from patentability in Brunei Darussalam, Chile, Malaysia, Mexico, Peru, Singapore, and Vietnam.[223] In many other countries, case law, rather than statute, precludes the patenting of certain medical procedures.[224] In Canada, for example, medical procedures are not statutorily precluded from patentability, but case law prohibits patents on surgical and therapeutic methods, only allowing patents on diagnostic methods.[225] Similarly, in New Zealand, case law rejects medical procedure patents.[226] The only two countries in the world including medical procedures as patentable subject matter by statute and case law are Australia and the United States.[227] Like the AMA, the World Medical Association (the "WMA") rebuffs the argument that patents are necessary to spur invention of medical procedures and that without patent protection there would be fewer beneficial medical procedures for patients.[228]

In an effort to provide protection to biotechnological advances in Europe, the European Union (the "EU") issued a Biotechnology Directive in 1998.[229] The directive provided that inventions are unpatentable if commercial exploitation of the invention leads to results contrary to public order or morality.[230] In other words, "humanitarian concerns, it is thought, 'trump' the

[220] AMERICAN MED. ASS'N, CODE OF MEDICAL ETHICS § 9.095 (2007), *available at* https://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/.

[221] *Id*.

[222] The development of medical procedures consists of physicians attaining and perfecting manual and intellectual skills. *WMA Statement on Patenting Medical Procedures*, WORLD MEDICAL ASSOCIATION, http://www.wma.net/en/30publications/10policies/m30/ (last visited July 17, 2014). Physicians already have both obligations to engage in these professional activities as well as rewards for doing so. *Id.*

[223] Adrianna Lee Benedict, *Is the USTR Trading Away Doctors' Rights to Freely Perform Medical Procedures?*, HARVARD LAW BLOGS (Sept. 8, 2012), http://blogs.law.harvard.edu/billofhealth/2012/09/08/is-the-ustr-trading-away-doctors-rights-to-freely-perform-medical-procedures/.

[224] *Id.*

[225] *Id.*

[226] *Id.*

[227] *Id.*

[228] *WMA Statement on Patenting Medical Procedures*, *supra* note 222.

[229] Council Directive 98/44, art. 1, 1998 O.J. (L 213) (EU).

[230] *Id.*

claims of a potential patentee."[231] Many of these ethical concerns surrounding the patentability of medical procedures translate easily to the concerns surrounding patent treatment of medical devices.[232]

iii. Patenting Medical Devices

That the law affords patent protections to medical devices does not itself stir controversy in the medical community.[233] Presumably more than medical procedures, the production of medical devices requires colossal investment for research and development.[234] Inordinate costs of medical devices during the patent term raise concerns about whether traditional patent policy should apply if it effectively stifles public access to new technology. "[D]evice manufacturers command as much as $1,600 for a single screw used in spinal surgery and over $10,000 for artificial knees."[235] From April 2013 to April 2014, Medtronic, Inc., one of the largest medical device manufacturers, has generated 16.4 billion in revenue.[236] Problematically, however, medical device costs are distorted by disconnect between patient, doctors, providers, and insurance companies.[237] It is difficult to tell how much strain the cost of medical devices exerts on the cost of health care.[238]

Given the state of the health care in the United States, lowering costs of procedures and devices while increasing public choice of medical care receives somewhat visceral support. Through this lens, it does not seem surprising that courts might be inclined to weigh public interest more heavily in cases involving patented medical procedures and medical devices. Public health and the availability of quality health care provide a strong foundation for the courts' rationales in *Conceptus* and *Bard*.[239]

VII. THE FUTURE OF MEDICAL PATENTS

The competing justifications of policy favoring patent enforceability and

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[231] MERGES & DUFFY, *supra* note 25, at 191.

[232] *See* Nugent, *supra* note 88, at 143.

[233] *See supra* notes 88-89 and accompanying text.

[234] *WMA Statement on Patenting Medical Procedures*, *supra* note 222.

[235] *See* Geire, *supra* note 14, at 246.

[236] *Medtronic, Inc. News*, NYTIMES.COM, http://topics.nytimes.com/top/news/business/ companies/medtronic_inc/index.html (last visited Apr. 12, 2013).

[237] *See* John Tozzi, *How Much Do Medical Devices Cost? Doctors Have No Idea*, BLOOMBERG BUSINESSWEEK, (Jan. 23, 2014), http://www.businessweek.com/articles/2014-01-10/how-much-do-medical-devices-cost-doctors-have-no-idea.

[238] *See* Geire, *supra* note 14, at 246.

[239] *See generally* Conceptus, Inc. v. Hologic, Inc., No. C 09-02280 WHA, 2012 WL 44064 (N.D. Cal. Jan. 9, 2012); Bard Peripheral Vascular v. W.L. Gore & Assocs., 670 F.3d. 1171 (Fed. Cir. 2012).

policy supporting increased access to cutting edge healthcare seem completely incompatible. The courts' reasoning in *Conceptus* and *Bard* illuminates the distinct tension between public policy concerns and patent law ideals created by medical patent.[240]

The rationale in the *Conceptus* case outlines the discomfort with enjoining the production of a concededly non-infringing device when only the procedure of insertion, not the device, infringed a valid medical procedure.[241] Similarly, in *Bard*, the court denied a permanent injunction despite direct competitor willfully infringing a vascular graft patent.[242] Both courts declined the predictable patterns district courts followed in the years following in the decision embracing arguments relying largely on public interest motivations.[243] As the *Conceptus* Court emphasized: "[p]ublic health has benefitted, and will continue to benefit, from having a choice of products."[244] The public's interest in having more available health care choices would be too severely injured if the courts were to grant permanent injunctive relief.[245]

Even in the wake of *eBay*, practicing patent holders in direct competition with the infringer almost universally receive an injunctive relief upon a finding of infringement and validity.[246] Still, both the *Conceptus* Court and the *Bard* Court indicate that the availability of only one product on the market hurts the public's access to quality healthcare.[247] Ultimately, then, it seems clear the Supreme Court's decision in *eBay* most disparately impacts the medical patent arena.

It is somewhat circular for courts to hold that the public interest supporting the denial of a permanent injunction is the harm resulting from the availability of only one medical option. The fundamental basis of patent law is to grant *exclusive rights* for a limited time.[248] In other words, the desired effect of the patent system is precisely to have only one option for statutorily limited time. Taken to its logical conclusion, this argument seems to indicate that it is contrary to public interest to allow any patent protection for medical procedures and medical devices in an effort to foster competition and increase the availability of alternative products. Still, in *Bard*, the court deemed the two devices at issue interchangeable.[249] If that is the case, does the denial of a permanent injunction actually serve the purpose of providing more options to

[240] *See* Conceptus, Inc. v. Hologic, Inc., 771 F. Supp. 2d 1164, 1164 (N.D. Cal. 2010; *Bard*, 670 F.3d. at 1171.

[241] *Conceptus*, 2012 WL 44064, at *3.

[242] *Bard*, 670 F.3d. at 1192.

[243] *See supra* notes 154-159 and accompanying text.

[244] *Conceptus*, 2012 WL 44064, at *3.

[245] *Id* at *4; *Bard*, 670 F.3d. at 1192.

[246] Janutis, *supra* note 149, at 604.

[247] *Conceptus*, 2012 WL 44064, at *3; *Bard*, 2009 WL 920300, at *7.

[248] *See supra* notes 6-8 and accompanying text.

[249] *See supra* note 199 and accompanying text.

the public?

Public interest is not solely allocated to concerns regarding the cost and availability of health care. Society also has an interest in incentivizing innovation, from which the public benefits during the patent term (though perhaps at a higher cost) and, more importantly, after the patent term upon the invention's entrance to the public domain.[250] Patent law aims to foster competition only after the patent term expires.[251]

There is significant concern about the impact rulings like these could have on the business decisions behind medical device production if investors and patent holders cannot rely on robust preservation of their exclusive rights.[252] "The *eBay* decision applies both to previously issued patents and to patents applied for in the future."[253] Many of the business decisions to patent and licenses new devices were based, in part, on the understanding that court would enforce exclusive rights.[254] The fast-tracked 510(k) approval process combined with the courts' willingness to award compulsory licensing or on-going royalties in lieu of permanent injunctive relief also shifts business incentives, ultimately increasing the likelihood of a generic medical device market.[255] A large company could decide that it makes more financial sense to manufacture a device "substantially similar" to a patented device, spend less on the 510(k) process, and risk compulsory licensing fees for infringement than go through the process of creating a pioneer device. Likewise, the company may reasonably calculate it could capture enough of the market share to cover those costs. This possibility reduces the value of a medical device patent and makes investing in these opportunities less attractive and further may actually chill the development of such technologies.

There is evidence that the Patent Act has been interpreted by the courts in a way that may seem to limit the scope of patent protection.[256] Here, however, Congress has had several opportunities to redefine the scope of patent protection for medical devices and procedures but declined to do so.[257] Judicial activism is particularly problematic given the disproportionate impact

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[250] *Supra* notes 12-13 and accompanying text.

[251] *See* Carrier, supra note 214, at 762-63.

[252] Dave Healy, *No Permanent Injunction Against Willful Infringer of Direct Competitor's Medical Device Patent: Are "On-going Equitable Royalties" The New Normal?*, PATENTMATH.COM (Feb. 12, 2012), http://patentmath.com/no-permanent-injunction-against-willful-infringer-of-direct-competitor's-medical-device-patent-are-"on-going-equitable-royalties"-the-new-normal/.

[253] *See* Beckerman-Rodau, *The Supreme Court Engages*, *supra* note 130, at 192.

[254] *Id.*

[255] *Generic Medical Devices Could Become an Economic Reality*, MEDCITY NEWS (Dec. 3, 2010), http://medcitynews.com/2010/12/generic-medical-devices-could-become-economic-reality/ (lasted visited Apr. 12, 2013).

[256] *See supra* Part I.C.

[257] *See supra* notes 107-110 and accompanying text.

of the *eBay* decision on medical patents.

VIII. SOLUTIONS

It is generally undisputed that medical devices merit patent protection.[258] The problem we presently face is how to define the scope and strength of this protection. The *eBay* Court explicitly recognized the lower courts' discretion with respect to granting permanent injunctions; however, denying the basic principles of patent law for a particular industry indicates a need for a recalibration of the *eBay* test or new legislation altering the patent system with respect to medical device patent. This author suggests several possible alternatives.

First, tensions may subside, following suit with the vast majority of countries around the world, through removal of medical procedures from the repertoire of patentable subject matter. This strategy allows medical device firms to continue marketing devices that do not infringe another patented device, but are removed completely from the market due to violation of a medical procedure patent. This option, alone, however, may be inadequate to address the public health concerns stemming from the availability and reduction of costs associated with medical devices.

Second, because of the strong public health concerns, the term of exclusive patent rights for medical devices should be shortened in order to foster competition and the availability of more health care choices more quickly. As mentioned above, the arduous regulatory approval process already cuts into the standard twenty-year grant of patent protection.[259] This option must be carefully considered as shortening the patent term might make it economically infeasible. Further, a shorter patent term requires strict enforcement of injunctive relief in order to enhance the strength of patent rights during the shortened term.

Another potential solution is to maintain the compulsory licensing scheme for medical devices, but to increase punitive damages upon a finding of validity and infringement between direct competitors. However, increasing punitive damages may effectively operate as an injunction by creating a cost prohibitive barrier to infringing company.

IX. CONCLUSION

Following *eBay*, innovators cannot count on the "guarantee" of permanent injunctive relief following a finding of validity and infringement. Medical device firms, particularly, are unable to rely on stringent protection from the

[258] *See* AMERICAN MED. ASS'N, CODE OF MEDICAL ETHICS § 9.09 (2007), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion909.page; *supra* notes 87-88 and accompanying text.

[259] *See supra* note 98 and accompanying text.

patent system. Given the strength of the health care policy arguments supporting access and availability of enhanced healthcare, these firms have a seemingly insurmountable standard to meet in order to secure injunctive relief. Despite the Supreme Court's efforts to avoid categorical approval or denial of injunctive relief, in practice, a problematic, pattern of categorical application may be emerging based on the subject matter of the patent.