# REBUTTABLE PRESUMPTION OF PUBLIC INTEREST IN PROTECTING THE PUBLIC HEALTH—THE NECESSITY FOR DENYING INJUNCTIVE RELIEF IN MEDICALLY-RELATED PATENT INFRINGEMENT CASES AFTER *EBAY V. MERCEXCHANGE*

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## INTRODUCTION

The public's interest in medicine and good health is substantial. However, this interest is harmed when important medical devices or pharmaceuticals, although infringing on valid patents, are suddenly taken off the market after a court grants a permanent injunction. While permanent injunctions were automatically granted by the Federal Circuit before the Supreme Court's holding in *eBay v. MercExchange*, courts now have more discretion to deny injunctive relief. Now that courts have this newfound discretion after *eBay*, the public should no longer expect to be harmed by the sudden removal of medical supplies from the marketplace. Unfortunately, this has not been the course that all courts have taken post-*eBay*. To protect the public interest, courts should apply a rebuttable presumption in medically-related patent cases, finding that the public interest weighs against granting an injunction.

This Comment highlights the necessity for this rebuttable presumption to help protect the public health. Part I provides a brief overview of the history of injunctive relief in patent infringement cases prior to 2006 and the few exceptions applied to deny injunctions. Part II analyzes the *eBay v. MercExchange* case, from its beginning in the district court to its remand back to the district court after the landmark decision in the Supreme Court. Next, Part III provides an overview of general trends regarding injunctive relief in patent infringement cases post-*eBay* and also analyzes the courts' treatment of injunctive relief in recent cases in the medical patent space. Finally, in Part IV expresses the importance of the public interest in medicine and the public health and lays out the multiple reasons why it is necessary that the courts to apply a rebuttable presumption of public interest to deny injunctive relief in patent cases involving medically-related patents. Lastly, a set of hypothetical situations is offered to emphasize the necessity of the rebuttable presumption.

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## I. INJUNCTIVE RELIEF IN PATENT INFRINGEMENT CASES PRIOR TO 2006

### *A. Injunctive Relief Overview*

The United States Constitution provides Congress with the enumerated power "to promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries."[1] Pursuant to this power, the Patent Act of 1952, as amended, governs patent law in the United States.[2] A patent grants its holder the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States" for a certain amount of time.[3] When this right to exclude is infringed upon, courts "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."[4] Courts have traditionally established that a plaintiff seeking a permanent injunction must satisfy a four-factor test before being granted such relief.[5] These factors include:

> (1) that [the plaintiff] 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 plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[6]

However, not all courts have followed this four-factor test.

### *B. Federal Circuit's "General Rule"*

The Federal Circuit Court of Appeals, established in 1982 and given exclusive patent appellate jurisdiction,[7] did not follow this traditional four-factor test prior to 2006.[8] Instead, the Federal Circuit followed a "general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it."[9] This "automatic injunction rule," or "general rule," arose

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[1] U.S. CONST. art. I, § 8, cl. 8.

[2] 35 U.S.C. § 101 (2006); *see* Sue Ann Mota, eBay v. MercExchange*: Traditional Four-Factor Test for Injunctive Relief Applies to Patent Cases, According to the Supreme Court*, 40 AKRON L. REV. 529, 530–33 (2007) (for a brief overview of patent law).

[3] 35 U.S.C. § 154(a)(1) (2006). Currently, the term of a utility patent is twenty years from the date that the patent application is filed. *Id.* § 154(a)(2).

[4] 35 U.S.C. § 283 (2006).

[5] eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

[6] *Id.*

[7] Robin M. Davis, *Failed Attempts to Dwarf the Patent Trolls: Permanent Injunctions in Patent Infringement Cases Under the Proposed Patent Reform Act of 2005 and* eBay v. MercExchange, 17 CORNELL J.L. & PUB. POL'Y 431, 435 (2008).

[8] *eBay*, 547 U.S. at 391–94.

[9] Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247 (Fed. Cir. 1989).

because the Federal Circuit would automatically apply a presumption of irreparable harm to patentees upon a finding of infringement.[10] This presumption of irreparable harm was justified based upon the right to exclude granted by patents.[11] Thus, successful plaintiffs were granted injunctions as a matter of course for over three decades.[12]

### *C. Public Health Exception*

While most successful patentees received permanent injunctions under the general rule, there was an exception to this rule.[13] Prior to 2006, courts would deny an injunction "in order to protect the public interest."[14] For example, in *City of Milwaukee v. Activated Sludge, Inc.*, the Seventh Circuit denied permanent injunctive relief to protect the public health.[15] While the defendant had infringed on the plaintiff's patented sewage treatment process, the court found that enforcing a permanent injunction would have closed the only sewage plant in the entire community.[16] An injunction would have left the community without means to dispose of raw sewage other than running it into Lake Michigan and polluting the waters.[17] Furthermore, such an order would have posed environmental and health risks to over half a million residents.[18] The court concluded that:

> It is suggested that such harmful effect could be counteracted by chemical treatment of the sewage, but where, as here, the health and the lives of more than half a million people are involved, we think no risk should be taken, and we feel impelled to deny appellee's contention in this respect.[19]

Courts have also used the public interest exception to protect the public health when certain medically-related patents were involved.[20] For example, in *Vitamin Technologists v. Wisconsin Alumni Research Foundation*, the defendant had infringed a patented process that produced vitamin D.[21] This process

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[10] Davis, *supra* note 7, at 435–36.

[11] *See* MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005), *vacated sub nom.* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

[12] Davis, *supra* note 7, at 436.

[13] *Id.*

[14] Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1547–48 (Fed. Cir. 1995).

[15] 69 F.2d 577, 593 (7th Cir. 1934).

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *See* Hybritech Inc. v. Abbott Labs., 4 U.S.P.Q.2d (BNA) 1001 (C.D. Cal. 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988); Datascope Corp. v. Kontron, Inc., 611 F. Supp. 889 (D. Mass. 1985), *aff'd*, 786 F.2d 398 (Fed. Cir. 1986); Vitamin Technologists v. Wis. Alumni Research Found., 146 F.2d 941 (9th Cir. 1944).

[21] *Vitamin Technologists*, 146 F.2d at 942.

contributed to the cure or amelioration of the disease, rickets.[22] Even though these patents were found to be invalid, leaving the patentee without remedy, the court noted the public health implications of an injunction in dicta.[23] While the patented process at issue could have been used to help cure rickets, a disease affecting the poor, the patentee withheld the practice of the patented process for this purpose.[24] The court noted "it is a public offense to withhold such processes from any of the principal foods of the rachitic poor"[25] and concluded that such refusal warranted the denial of a permanent injunction.[26]

Further, in *Datascope Corp. v. Kontron, Inc.*, the plaintiff alleged that the defendant had infringed its patented dual lumen heart catheter (IAB)[27] and sought preliminary injunctive relief.[28] Although preliminary injunctions and permanent injunctions differ in scope, the same traditional four factors are analyzed.[29] The defendant made a showing that it would be irreparably harmed by a preliminary injunction because it would suffer losses in sales, be forced to lay off employees, its good will would be injured, and it would have to write off inventory and capital improvements.[30] More importantly, the defendant made a showing that the public interest would be harmed by a preliminary injunction because the record showed that "some physicians prefer defendant's dual lumen IABs."[31] Ultimately, the court denied the plaintiff's request for injunctive relief with respect to the defendant's dual lumen IABs.[32]

Additionally, some courts have modified permanent injunctions in medically-related patent infringement cases to allow for transition periods to accommodate the public interest.[33] In *Shiley, Inc. v. Bentley Labs., Inc.*, injunctive relief was granted against the defendant for the plaintiff's patented

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[22] *Id.*

[23] *Id.* at 944–47.

[24] *Id.* at 944.

[25] *Id.* at 945.

[26] *Id.* at 956.

[27] Datascope Corp. v. Kontron, Inc., 611 F. Supp. 889, 894 (D. Mass. 1985), *aff'd*, 786 F.2d 398 (Fed. Cir. 1986).

[28] *Id.* at 891.

[29] *Id.*

[30] *Id.* at 894.

[31] *Id.*

[32] *Id.*; *see* Hybritech Inc. v. Abbott Labs., 4 U.S.P.Q.2d (BNA) 1001, 1015 (C.D. Cal. 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988) (denying preliminary injunction for infringed cancer and hepatitis test kits due to public health interests); *see also* Cordis Corp. v. Boston Scientific Corp., No. CIV.A.03-027-SLR, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003), *aff'd*, 99 F. App'x 928 (Fed. Cir. 2004) (denying preliminary injunction for infringed drug-eluting stents due to public health risks posed by inadequate supply).

[33] *See* Schneider (Europe) AG v. SciMed Life Sys., Inc., 852 F. Supp. 813 (D. Minn. 1994); Shiley, Inc. v. Bentley Labs., Inc., 601 F. Supp. 964 (C.D. Cal. 1985).

bubble blood oxygenator.[34] However, due to concerns of potential short-term supply problems from the sudden impact of the injunction, the court ordered that the injunction "contain a six-month transition period to allow an efficient and non-disruptive changeover for those institutions who now employ the [infringing device] exclusively."[35]

While the public interest exception was used to deny some medically-related patent injunctions, most injunctions were still granted.[36] The Federal Circuit's "general rule" was abrogated, however, upon the Supreme Court's holding in *eBay Inc. v. MercExchange*.[37]

## II. *EBAY INC. V. MERCEXCHANGE, L.L.C.*

### *A. The District Court*

On May 27, 2003, following a five-week trial, a jury sitting in the District Court for the Eastern District of Virginia returned a verdict finding that the defendants, eBay Inc. and Half.com (a subsidiary of eBay Inc.), had infringed on valid patents covering methods for conducting online auctions belonging to the plaintiff, MercExchange, L.L.C.[38] Following the jury trial, MercExchange filed a motion for entry of a permanent injunction order.[39] The court's analysis began by summarizing the precedent set by the Federal Circuit's general rule, automatically granting permanent injunctions after a finding of validity and infringement, but it also reviewed the traditional four factors.[40]

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[34] *Shiley*, 601 F. Supp. at 971.

[35] *Id.*; *see Schneider*, 852 F. Supp. at 861–62 (employing a six-month transition period within permanent injunction of infringing medical catheter devices to "allow an efficient and non-disruptive changeover for those institutions and physicians who now employ the [infringing device] exclusively").

[36] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 867 (Fed. Cir. 1984) (reversing denial of injunctive relief upon finding of infringement and remanding for injunctive relief grant); Biacore v. Thermo Bioanalysis Corp., 79 F. Supp. 2d 422, 473–74 (D. Del. 1999) (finding no sound reason to deny permanent injunctive relief for infringed matrix coating suitable for use in a biosensor); Eli Lilly & Co. v. Medtronic, 7 U.S.P.Q.2d (BNA) 1439, 1445 (E.D. Pa. 1988) (granting a permanent injunction while holding that, although there is a public interest in the marketing of life saving medical devices, such as the defendant's infringing heart defibrillator, this interest is outweighed by the greater public interest in "granting injunctions to effectuate patent rights").

[37] *See* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

[38] MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 698–99 (E.D. Va. 2003), *aff'd in part, rev'd in part* 401 F.3d 1323 (Fed. Cir. 2005), *vacated sub nom.* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

[39] *Id.*

[40] *Id.* at 711.

The court then analyzed each equitable factor, beginning with irreparable harm.[41] The plaintiff argued for the presumption of irreparable harm established by precedent and argued that it would be "deprived of its ability to either pursue the development of its inventions under the protection of its patent rights, or to have the exclusive right to license its patented technology to others on the most beneficial terms available" if an injunction did not issue.[42] However, the defendant argued that the presumption of irreparable harm was rebuttable and attempted to refute the presumption by highlighting certain behaviors of the plaintiff[43] including the plaintiff's failure to practice the patent and an expressed willingness to license the patent to the defendant. The court found that the factors weighed against an injunction because the plaintiff would not be irreparably harmed if a permanent injunction did not issue.[44] Under the factor pertaining to an adequate remedy at law, the court found that this factor weighed against an injunction due to the plaintiff's previous licensing of the patent to others and their expressed willingness to license the patent to eBay.[45] Under the public interest factor, the court found that, while there was a public interest in enforcing valid patents, there was also a public interest in "using a patented business-method that the patent holder declines to practice."[46] Therefore, the court concluded that this factor equally supported both granting and denying an injunction.[47] Finally, under the balance of hardships factor, the court found that this factor tipped slightly in the defendant's favor because the plaintiff could be adequately compensated monetarily and granting an injunction would open "a Pandora's box of new problems" for both parties.[48] Ultimately, the court denied the plaintiff's motion for entry of a permanent injunction order,[49] and the case was appealed to the Federal Circuit.[50]

### B. *The Federal Circuit*

The Federal Circuit reviewed the district court's denial of a permanent injunction under an abuse of discretion standard.[51] The court opined that the public interest of using a business-method patent that the patent holder declines to practice is not "the type of important public need that justifies the unusual

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[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.* at 712–13.
[46] *Id.* at 712–14.
[47] *Id.* at 714.
[48] *Id.* at 714–15.
[49] *Id.* at 715.
[50] MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1326 (Fed. Cir. 2005), *vacated sub nom.* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).
[51] *Id.* at 1338.

step of denying injunctive relief."[52] Furthermore, the district court's fear that an injunction would open both parties to new problems was viewed to be an inadequate reason for denying injunctive relief.[53] Moreover, the fact that MercExchange was willing to license the patent was an inadequate reason for denying injunctive relief. The court reasoned that although an "injunction gives the patentee additional leverage in licensing, that is a natural consequence of the right to exclude and not an inappropriate reward to a party that does not intend to compete in the marketplace with potential infringers."[54] The Federal Circuit, seeing "no reason to depart from the general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances," granted the injunction.[55] The Supreme Court granted certiorari on November 28, 2005.[56]

### *C. The Supreme Court*

The majority opinion for *eBay Inc. v. MercExchange, L.L.C.*, written by Justice Thomas, was rather short and solely dealt with determining the appropriateness of the Federal Circuit's general rule regarding permanent injunctions.[57] The Court abrogated the general rule and mandated that, "[a]ccording to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief."[58] The Court established that a plaintiff 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 plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[59]

The Court stressed that "the creation of a right is distinct from the provision of remedies for violations of that right."[60] Analyzing the district court's suggestion that injunctive relief could not issue "in a broad swath of cases," especially where a plaintiff is willing to license the patent or does not commercially practice the patent, the Court held that "traditional equitable principles do not permit such broad classifications."[61] The Court then determined that the Federal

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[52] *Id.* at 1339.
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] eBay Inc. v. MercExchange, L.L.C., 546 U.S. 1029 (2005).
[57] *See* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 389 (2006).
[58] *Id.* at 391.
[59] *Id.*
[60] *Id.* at 392.
[61] *Id.* at 393.

Circuit's general rule created a categorical grant of injunctive relief in opposition to the traditional rules of equity.[62] The majority opinion ultimately vacated the judgment of the Federal Circuit and remanded for further proceedings.[63]

Chief Justice Roberts wrote a concurring opinion that was joined by Justice Scalia and Justice Ginsburg.[64] While Chief Justice Roberts agreed with the majority opinion's holding that the decision to grant injunctive relief must "be exercised consistent with traditional principles of equity," he highlighted the historical treatment of injunctive relief in patent infringement cases, noting that injunctive relief was granted in a vast majority of cases since the early nineteenth century.[65] The Roberts concurrence did reject the Federal Circuit general rule but also noted that district courts should let history play a role in determining whether injunctive relief should be issued rather than "writing on an entirely clean slate."[66] He concluded by noting that "[w]hen it comes to discerning and applying those standards, in this area as others, 'a page of history is worth a volume of logic.'"[67] The Roberts concurrence arguably emphasized that permanent injunctions should still be liberally granted.[68]

Justice Kennedy also wrote a concurring opinion that was joined by Justice Stevens, Justice Souter, and Justice Breyer.[69] While Justice Kennedy concurs with the majority opinion's holding and acknowledges Chief Justice Robert's emphasis on historical precedent, he pointed out three ways that the patent industry has changed since the historical decisions were decided.[70] First, the Kennedy concurrence highlighted the increased use of patent holders that "use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees."[71] Justice Kennedy noted that injunctive relief might not be a good remedy as these firms usually use their patents to charge exorbitant licensing fees.[72] Next, the opinion acknowledged that legal remedies may suffice and denial of an injunction may be in the public interest when the patent covers only a small component of a much larger commercial product and "the threat of an injunction is employed simply for undue leverage in negotiations."[73] Finally, the opinion concluded by analyzing the difference in

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[62] *Id.* at 394.
[63] *Id.*
[64] *Id.* (Roberts, C.J., concurring).
[65] *Id.* at 395.
[66] *Id.*
[67] *Id.* (quoting New York Trust Co. v. Eisner, 256 U.S. 345, 349 (1921)).
[68] George M. Newcombe et al., *Prospective Relief for Patent Infringement in a Post-eBay World*, 4 N.Y.U. J. L. & BUS. 549, 555 (2008).
[69] *eBay*, 547 U.S. at 395 (Kennedy, J., concurring).
[70] *Id.* at 395–97.
[71] *Id.* at 396.
[72] *Id.*
[73] *Id.* at 396–97.

the nature of contemporary patents compared to historical patents.[74] Justice Kennedy stated that "injunctive relief may have different consequences for the burgeoning number of patents over business methods, which were not of much economic and legal significance in earlier times. The potential vagueness and suspect validity of some of these patents may affect the calculus under the four-factor test."[75]

### *D. The District Court Remand*

On remand, the district court reanalyzed the four-factor test for injunctive relief pursuant to the preceding Supreme Court opinion.[76] It is relevant to note that subsequent to the jury verdict, MercExchange non-exclusively licensed its patent portfolio to uBid, a direct competitor of eBay.[77] Additionally, MercExchange and uBid had begun preliminary negotiations about exclusive licensing shortly after the Supreme Court's *eBay* opinion but were unable to reach an agreement successfully.[78] Before its analysis under the four-factor test, the court determined whether a presumption of irreparable harm upon a finding of validity and infringement still applied after the Supreme Court opinion.[79] After reviewing relevant post-*eBay* cases, the court determined that a presumption of irreparable harm no longer existed, but rather, the burden was on the plaintiff to prove irreparable harm.[80] However, the court was "not blind to the reality that the nature of the right protected by a patent, the right to exclude, will frequently result in a plaintiff successfully establishing irreparable harm in the wake of establishing validity and infringement."[81]

The court then applied the four-factor test to the facts of the case, beginning with the irreparable harm factor.[82] Determining that the plaintiff did not establish irreparable harm, the court concluded that this factor weighed against the entry of an injunction.[83] Based on multiple factors, the court reached

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[74] *Id.* at 397.
[75] *Id.*
[76] MercExchange, L.L.C. v. eBay, Inc., 500 F. Supp. 2d 556, 568 (E.D. Va. 2007).
[77] *Id.* at 561.
[78] *Id.* at 562.
[79] *Id.* at 568–69.
[80] *Id.*; *see* z4 Techs., Inc. v. Microsoft Corp., 434 F. Supp. 2d 437, 440 (E.D. Tex. 2006) (concluding that the language in the Supreme Court's *eBay* opinion "does not imply a presumption, but places the burden of proving irreparable injury on the plaintiff"); Paice LLC v. Toyota Motor Corp., No. 2:04–CV–211–DF, 2006 WL 2385139, at *4 (E.D. Tex. Aug.16, 2006), *aff'd in part, vacated in part*, 504 F.3d 1293 (Fed. Cir. 2007) ("The *eBay* decision demonstrates that no presumption of irreparable harm should automatically follow from a finding of infringement.").
[81] *MercExchange*, 500 F. Supp. 2d at 569.
[82] *Id.*
[83] *Id.*

this conclusion by determining that "MercExchange ha[d] acted inconsistently with defending its right to exclude and that it ha[d] failed to establish why its harm [wa]s irreparable."[84] First, the court noted MercExchange's lack of commercial activity in practicing the relevant patents.[85] The court prudentially acknowledged that this factor, while not being dispositive against granting an injunction, was "one factor that this court must consider in weighing the equities."[86] Next, the court recognized MercExchange's private and public actions indicating its desire to obtain royalties from eBay.[87] The relevant public actions included MercExchange's and its attorney's multiple public expressions regarding MercExchange's willingness to license its patents to eBay.[88] The relevant private action included pre-trial licensing negotiations between MercExchange and eBay.[89] Additionally, the court acknowledged MercExchange's failure to motion for preliminary injunction.[90] Like the non-commercial activity factor, the court recognized that this factor was also not dispositive against granting an injunction and likened the failure to motion for preliminary injunction to MercExchange's desire to obtain reasonable royalties from eBay.[91] Finally, the court raised the same concern in its previous analysis regarding the nature of the relevant patents—the business method patent and "a patent which appears to rely upon a unique combination of non-unique elements present in prior art."[92] Additionally, the court was not persuaded by MercExchange's argument that irreparable harm was proved because eBay was a market monopolist.[93] To comply with the ruling in the Supreme Court's *eBay* opinion, the court emphasized that its determination was specific to the facts in this case and "not broad classifications or categorical exclusions of certain types of patent holders."[94]

Next, the court analyzed the adequate remedy at law factor, concluding that "damages at law constitute[d] an adequate remedy for eBay's wilful infringement."[95] The court recognized that the analysis for this factor greatly overlapped the analysis for the first factor.[96] The fact that MercExchange did not commercially utilize its patent, its willingness to license to eBay, and its

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[84] *Id.* at 569–76.
[85] *Id.* at 570.
[86] *Id.* at 570.
[87] *Id.* at 572–73.
[88] *Id.* at 572.
[89] *Id.*
[90] *Id.* at 573.
[91] *Id.*
[92] *Id.* at 574–76.
[93] *Id.* at 579–80.
[94] *Id.* at 570.
[95] *Id.* at 582.
[96] *Id.*

licensing activity with others in the industry convinced the court that money damages through a royalty paid by eBay would suffice.[97]

Then, the court analyzed the third factor—the balance of hardships.[98] Based upon the uncertainty of MercExchange's negotiations with uBid, uncertainty involving eBay's ability to design around the relevant patents, and uncertainty of the patents' ability to survive reexamination.[99] If eBay could have designed around the patent, the court concluded that eBay would not have suffered hardship if an injunction were granted.[100] On the other hand, the court concluded that MercExchange would not suffer hardship if an injunction was denied due to royalties received from eBay or, in the alternative, did not suffer hardship due to the failed negotiations with uBid.[101]

Finally, the court analyzed the fourth factor—the public interest.[102] Considering "the type of patent involved, the impact on the market, the impact on the patent system, and any other factor that may impact the public at large," the court concluded that the public interest factor weighed slightly in favor against granting an injunction.[103] Under the first factor, the type of patent involved, the court acknowledged Justice Kennedy's words of caution in his *eBay* concurrence.[104] Next, although the public health was not implicated in this case and there is an interest in a strong patent system that protects patentees from infringers, the court still felt that damages at law were in the best interest of the public due to the difference in market size between eBay and MercExchange and MercExchange's intentions to neither defend its right to exclude or prevent development of its patent by others.[105] Again, the court emphasized that its analysis was based upon the specific facts of the case and did not create a general rule.[106] Then, concluding that neither allegation was given any weight to its analysis, the court reviewed the allegations by each party of inequitable conduct by the opposing party.[107] The court analyzed eBay's status as a wilful infringer in its public interest analysis and concluded that while it was significant, it was insufficient to tip the analysis in MercExchange's

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[97] *Id.* at 582–83.
[98] *Id.* at 583–86.
[99] *Id.* at 583–84.
[100] *Id.* at 584.
[101] *Id.* at 584–85.
[102] *Id.* at 586.
[103] *Id.*
[104] *Id.*; *see* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 397 (2006) (Kennedy, J., concurring) (noting that the "potential vagueness and suspect validity of some [business method patents] may affect the calculus under the four-factor test").
[105] *MercExchange*, 500 F. Supp. 2d at 586–88.
[106] *Id.* at 588.
[107] *Id.* at 588–90.

favor.[108] Ultimately, the court found the four-factor test in eBay's favor and denied MercExchange's motion for permanent injunction.[109]

## III. THE STATE OF INJUNCTIVE RELIEF IN MEDICALLY-RELATED PATENT CASES SINCE *EBAY*

### A. *General Trends of Injunctive Relief Since* eBay

After the Supreme Court handed down the *eBay v. MercExchange* opinion, courts applied the four factors differently, but the results highlighted some general trends regarding when injunctive relief would or would not be granted.[110] Commentators have performed informative studies that validate these general trends.[111] First, a study by Benjamin Petersen analyzed patent cases granting or denying injunctive relief after the *eBay* decision up to February 3, 2008, finding that injunctive relief was granted in twenty-four cases and denied in ten cases.[112] Additionally, a study by Douglas Ellis, John Jarosz, Michael Chapman, and L. Scott Oliver concluded that, out of thirty-six post-*eBay* patent cases that analyzed motions for injunctive relief, such relief was granted four out of five times.[113] Finally, a study by Rachel M. Janutis found that injunctive relief continued to be granted in most patent cases from February 2008 to October 2009.[114]

#### 1. Direct Competition

One general trend these studies observed involved direct competition between the parties.[115] Courts were more likely to grant injunctive relief when the parties were direct competitors in the same marketplace.[116] The Petersen study found that when direct competitors were involved, a denial of injunctive relief occurred only twice.[117] Additionally, the Ellis study found that in all but

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[108] *Id.*

[109] *Id.* at 590–91 (providing a good summary of the court's application of the four-factor test in the first instance).

[110] Benjamin Petersen, *Injunctive Relief in the Post-*eBay *World*, 23 BERKELEY TECH. L.J. 193, 197 (2008).

[111] *See id.* at 196–205; *see also* Rachel M. Janutis, *The Supreme Court's Unremarkable Decision in* eBay Inc. v. MercExchange, L.L.C., 14 LEWIS & CLARK L. REV. 597, 604–07 (2010); Douglas Ellis et. al, *The Economic Implications (and Uncertainties) of Obtaining Permanent Injunctive Relief After* eBay v. MercExchange, 17 FED. CIRCUIT B.J. 437, 441–64 (2008).

[112] Petersen, *supra* note 110, at 196.

[113] Ellis et al., *supra* note 111, at 441–42 (analyzing cases from mid-2006 to 2008).

[114] Janutis, *supra* note 111, at 605.

[115] *See* Petersen, *supra* note 110, at 198.

[116] *Id.*

[117] *Id.* at 199.

two cases, "permanent injunctions issued in all twenty-six cases where courts found direct competition."[118] Finally, in the Janutis study, it was determined that injunctive relief was granted in seventeen cases where direct competition was found, while only denied in four cases.[119]

The Petersen study did highlight a case, *Commonwealth Scientific & Industrial Research Org. v. Buffalo Technology, Inc.*, where the district court for the Eastern District of Texas granted the patent holder injunctive relief despite the parties' lack of direct competition.[120] The court pointed out the unique aspect of the patent holder being a governmental research agency.[121]

### 2. Licensing the Invention

Another general trend was found regarding the patent holder's licensing of the patent.[122] These studies found that courts were less likely to grant injunctive relief when the patent holder licenses his invention to other parties.[123] The Petersen study found that "[i]n five of the ten post-*eBay* cases denying permanent injunctions, the patent holder licensed his invention to other parties," and the existence of a licensing program was nearly dispositive in courts' decisions precluding injunctive relief.[124]

### 3. A Small Component of the Infringing Product

A third general trend was found when the patented product is but a small component of a larger infringing device.[125] This trend, indicating that injunctive relief is not generally granted in such cases, appears to follow from Justice Kennedy's concurring opinion in *eBay*, suggesting that injunctions might not be appropriate in cases where the patented device is merely a small component of the infringing device because "legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest."[126] The Petersen study indicated that injunctive relief was never granted when the patented device was merely a small component.[127]

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[118] Ellis et al., *supra* note 111, at 442.

[119] Janutis, *supra* note 111, at 605–06.

[120] Petersen, *supra* note 110, at 198–99; *see* Commonwealth Scientific & Indus. Research Org. v. Buffalo Tech., Inc., 492 F. Supp. 2d 600, 601 (E.D. Tex. 2007).

[121] *Commonwealth Scientific*, 492 F. Supp. 2d at 603–04.

[122] Petersen, *supra* note 110, at 199–200.

[123] *Id.*; *see* Ellis et al., *supra* note 111, at 459–61.

[124] Petersen, *supra* note 110, at 199–201.

[125] *Id.* at 201–03.

[126] *Id.* at 201–02; *see* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396–97 (2006) (Kennedy, J., concurring).

[127] Petersen, *supra* note 110, at 202.

#### 4. Practicing the Invention

Finally, a general trend surrounding the patent holder's practice of the invention has been observed.[128] Courts are more likely to grant injunctive relief when the patent holder practices the invention; however, there is a strong correlation between this trend and the direct competition trend.[129] The Petersen study acknowledged a case, *Novozymes A/S v. Genencor International, Inc.*, where, although the court granted injunctive relief despite the fact that the patent holder did not practice the invention, the patent holder had licensed the patent to one of its subsidiaries.[130] The Petersen study also pointed out that this factor was secondary to the direct competition factor, finding the direct competition factor dispositive where the two factors "yield different results."[131]

### *B. Injunctive Relief in Medically-Related Patent Cases After* eBay

While general trends surrounding the courts' treatment of injunctive relief have arisen, these trends are less apparent with regard to patent cases related to medicine. This section analyzes the courts' unpredictable treatment of injunctive relief in medically-related patent cases—patent cases that cover device, method, and pharmaceutical patents related to the treatment, management, or diagnostics of medical illnesses.

Since *eBay v. MercExchange*, district courts and the Federal Circuit have both granted and denied injunctive relief when medical patent infringement is found.[132] These courts have reached these holdings based on different arbitrary conclusions under the traditional four-factor test.[133] There have been many arguments by petitioners and respondents alike that highlight the importance of these cases.[134]

#### 1. Cases Granting Injunctive Relief

##### a. *Smith & Nephew, Inc. v. Synthes (U.S.A.)*

A couple of months after the *eBay* decision, the District Court for the Western District of Tennessee decided a motion for permanent injunction in a medical device case.[135] The court found Synthes, a medical device manufacturer, to have infringed a collection of patents belonging to Smith & Nephew, Inc., a

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[128] *See id.* at 203–04; *see also* Ellis et al., *supra* note 111, at 451–53.
[129] Peterson, *supra* note 110, at 203.
[130] *Id.* at 204.
[131] *Id.*
[132] *See infra* Part IV.B.1–2.
[133] *Id.*
[134] *Id.*
[135] Smith & Nephew, Inc. v. Synthes (U.S.A.), 466 F. Supp. 2d 978, 981 (W.D. Tenn. 2006).

competitor.[136] The patents related to bone nails and the methods used in the treatment of bone fractures.[137] The court was tasked with determining whether Smith & Nephew was entitled to injunctive relief based on the traditional four-factor test. Both parties made the following arguments:

> Synthes argues principally that (i) Smith & Nephew will not be irreparably harmed because of the limited competition between the primary Smith & Nephew product covered by the . . . patents and the infringing . . . nails, (ii) Smith & Nephew has shown a willingness to be compensated fully for its patents by money damages because in the past it has licensed the patents to its competitors and has extended several licensing offers to Synthes while this case has been pending, (iii) the overall balance of hardships favors Synthes because Smith & Nephew's business will not be significantly affected by continued sales of the infringing products, and (iv) the public health interest in having Synthes' allegedly safer and more effective TFN product available to treat femoral fractures is substantial. . . . Smith & Nephew argues that (i) irreparable harm to the sales of its patented femoral nails has been shown, together with the loss of market momentum and the ability to form customer relationships, (ii) money damages would not be adequate compensation, and (iii) the public health interest would not be adversely affected by a permanent injunction because substitute products and methods of treatment are available to the public through Plaintiff and its selected licensees. Smith & Nephew argues that it is substantially smaller than Synthes in the field of manufacturing trauma products, and, therefore, that an injunction would give Smith & Nephew the competitive support it needs to expand its customer base, increasing market competition.[138]

Ultimately, the court granted the permanent injunction[139] finding that irreparable harm had been established due to Smith & Nephew's loss of market share, and resulting lost profits and loss of brand name recognition that were both incalculable and irreparable.[140] Additionally, the court found that remedies available at law were inadequate and the balance of the hardships tipped in favor of Smith & Nephew due to the continuing threat of patent infringement.[141] Under the balance of the hardships analysis, the court held that the "[m]ere hardship incurred in the process of ceasing operations . . . is not sufficient," and there were no considerable hardships imposed on physicians or patients due to the ability of other competing product to fill any "temporary void created by the injunction."[142] Finally, analyzing the public interests, the court gave great weight

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[136] *Id.*
[137] *Id.*
[138] *Id.* at 981–82.
[139] *Id.* at 985.
[140] *Id.* at 982–83.
[141] *Id.* at 983–85.
[142] *Id.* at 984–85.

to the public interest in protecting the rights of patentees and did not find that the public would be harmed by any "minor disruption to the distribution of the infringing products."[143]

b. *Fresenius Medical Care Holdings, Inc. v. Baxter International, Inc.*

Baxter and Fresenius, both competitors in the hemodialysis device market, went before the District Court for the Northern District of California in a patent infringement suit.[144] On a motion for judgment as a matter of law, the court concluded that Fresenius had infringed Baxter's patents related to a hemodialysis machine, commonly used for kidney disease treatment.[145] Baxter then moved for permanent injunctive relief.[146]

The court analyzed the arguments set forth by both parties under the traditional four-step test.[147] The court found that the irreparable harm factor weighed in Baxter's favor due to the direct competitiveness between both parties.[148] Additionally, when analyzing the inadequacy of monetary damages, the court held that "the loss of goodwill, reputation for innovation, [and] the legal right to exclude, . . . are all forms of irreparable injury that cannot be easily and readily quantified through a simple monetary award."[149] Moreover, due to the evidence that Fresenius had offered at trial related to the "numerous, easily-implemented alternatives" available, the court found that the balance of the hardships tipped in Baxter's favor.[150] The court held that the balance of the hardships favors the patentee when the infringer can sell non-infringing items.[151] The court began its public interest analysis by noting many other courts that have granted permanent injunctions in cases where alternative products were available to the infringer.[152] Finally, the court found that Fresenius' concerns—the annual demand for dialysis machines, the lack of proof that other suppliers could meet the demand, the alleged inability to market the infringed product, and the fact that other competing products did not have the same features as the infringed product—could be addressed by Fresenius' ability to design around the infringing product and allowing a nine-month transition period to do so.[153]

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[143] *Id.* at 985.

[144] Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc., No. C 03-1431 SBA, 2008 WL 928496, at *1–2 (N.D. Cal. Apr. 4, 2008) *aff'd in part, rev'd in part sub nom.* Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288 (Fed. Cir. 2009).

[145] *Id.* at *2.

[146] *Id.* at *1–2.

[147] *Id.* at *2.

[148] *Id.* at *3–4.

[149] *Id.* at *4.

[150] *Id.*

[151] *Id.*

[152] *Id.* at *5–6.

[153] *Id.*

On appeal, Fresenius argued that the district court abused its discretion by ignoring evidence introduced at trial.[154] However, the Federal Circuit disagreed finding that the district court had not abused its discretion because it had fully analyzed each factor in the traditional four-factor test.[155] The Federal Circuit did, however, remand the case back to the district court to reconsider the injunction in light of its reversal of the district court's grant of judgment as a matter of law.[156]

c. *B. Braun Melsungen AG v. Terumo Medical Corp.*

After a 2010 jury trial, Terumo, a medical device manufacturer, was found to have infringed patents belonging to Braun, a competitor.[157] The patents covered intravenous catheters used for the delivery of fluids under the skin.[158] After trial, Braun motioned for a broad permanent injunction that would have the effect of stopping all continuous sales of Terumo's infringing product.[159] In response, Terumo argued for a narrower injunction that allowed for a "sunset" period of fifteen months to continue selling in the alternative care market (approximately 30% of the total market).[160] The District Court for the District of Delaware analyzed both proposals under the traditional four-factor test and granted the narrower injunction proposed by Terumo.[161] The court noted Braun's arguments for a broad injunction under the irreparable harm factor, including its lack of licensing the patents to any competitors and the endangerment of its right to exclude and good reputation without injunctive relief, but the court held that this factor weighed in favor of Terumo's narrower injunction because it would not create any additional irreparable harm for Braun.[162] Under the balance of the hardships analysis, the court held that this factor weighed in favor of Terumo's proposed injunction because of the hardship that would be imposed on medical professionals and the endangerment to Terumo's reputation under Braun's broad injunction.[163] Finally, under the public interest factor, the court held that this factor also weighed in favor of Terumo's proposed injunction.[164] The primary reasons for this holding included the effect on medical professionals under

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[154] Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1302–03 (Fed. Cir. 2009).
[155] *Id.*
[156] *Id.*
[157] B. Braun Melsungen AG v. Terumo Med. Corp., 778 F. Supp. 2d 506, 510–11 (D. Del. 2011).
[158] *Id.*
[159] *Id.* at 524.
[160] *Id.*
[161] *Id.* at 526.
[162] *Id.* at 524–25.
[163] *Id.* at 525.
[164] *Id.* at 525–26.

Braun's proposed injunction and "the public interest in access to competing alternatives to safe medical devices."[165]

d. *Pozen Inc. v. Par Pharmaceutical, Inc.*

After a five-day bench trial, the District Court for the Eastern District of Texas concluded that Pozen, a pharmaceutical company, had infringed patents held by its direct competitor, Par Pharmaceutical.[166] The patents at issue related to pharmaceutical formulations and methods for the treatment of migraine headaches.[167] Par motioned for permanent injunctive relief at the conclusion of the bench trial, and the district court granted the injunction after a thorough analysis under the traditional four-factor test.[168] Pozen proved that it would suffer irreparable harm without an injunction by producing evidence and arguing that a lack of injunctive relief would result in a loss of "vital revenue," an irreversible loss of market share, and price erosion.[169] Pozen also conclusively proved that monetary relief was an inadequate remedy.[170] Further, the court found that the balance of hardships tipped in Pozen's favor.[171] Finally, under the public interest analysis, the court held that the public interest weighed in favor of a permanent injunction because of the public's interest in encouraging innovation by upholding the patent holder's right to exclude.[172] Additionally, the court held that the public would not be harmed by a permanent injunction because of a large and readily-available supply of the patented product.[173]

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[165] *Id.*
[166] Pozen Inc. v. Par Pharm., Inc., 800 F. Supp. 2d 789, 805–06 (E.D. Tex. 2011).
[167] *Id.* at 796–97.
[168] *Id.* at 825.
[169] *Id.* at 824.
[170] *Id.* at 824–25.
[171] *Id.* at 825.
[172] *Id.*
[173] *Id.* There have been additional medically-related patent cases granting permanent injunctive relief. *See, e.g.*, Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1315–16 (Fed. Cir. 2012) (vacating and remanding district court's denial of permanent injunction of infringed prosthetic heart valve); Abbott Labs. v. TorPharm, Inc., 503 F.3d 1372, 1375–78 (Fed. Cir. 2007) (affirming district court's permanent injunction of infringed anti-seizure medication); Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc., No. 09-184-LPS, 2012 WL 1901267, at *3 (D. Del. May 25, 2012) (granting a permanent injunction of infringing pharmaceutical used to treat acne); Retractable Techs., Inc. v. Occupational & Med. Innovations, LTD., No. 6:08 CV 120, 2010 WL 3199624, at *6 (E.D. Tex. Aug. 11, 2010) (granting a permanent injunction of infringing tamper-proof retractable, non-reusable syringe); Smith & Nephew, Inc. v. Arthrex, Inc., No. 2:07-cv-335-TJW-CE, 2010 WL 2522428, at *4 (E.D. Tex. June 18, 2010) (granting a permanent injunction of infringing tissue graft attachment device); Amgen, Inc. v. F. Hoffman-La Roche Ltd., 581 F. Supp. 2d 160, 229 (D. Mass. 2008), *aff'd in part, vacated in part sub nom.* 580 F.3d 1340, 1386 (Fed. Cir. 2009) (granting and affirming a

2. Cases Denying Injunctive Relief

a. *Voda v. Cordis Corp.*

*Voda v. Cordis Corp.* involved patents related to angioplasty guide catheters.[174] The plaintiff, Dr. Jan Voda, successfully established at trial that the defendant, Cordis, had willfully infringed Dr. Voda's patents.[175] The District Court for the Western District of Oklahoma determined whether Dr. Voda was entitled to injunctive relief under the four-factor test, and, using the factors enunciated in the *eBay* case, the court decided that Dr. Voda was not entitled to injunctive relief and denied the motion.[176] The court made this determination based on Dr. Voda's failure to establish that he would be irreparably harmed without injunctive relief and that monetary damages were inadequate.[177] Dr. Voda did, however, argue that irreparable harm could be established by a non-party, but the court held that such harm was irrelevant in its analysis.[178] While Dr. Voda attempted to argue for a presumption of irreparable harm, the court noted that no such presumption exists after the *eBay* decision.[179] The court did not analyze the balance of the hardships or the public interests involved.

On appeal, Dr. Voda argued that the district court erred in "adopting a categorical rule that precludes a patent owner from proving its entitlement to an injunction by showing irreparable harm to its exclusive licensee."[180] The Federal Circuit, however, concluded that such ruling by the district court did not conflict with *eBay* and that the district court had not erred or abused its discretion by denying injunctive relief.[181]

b. *Advanced Cardiovascular Systems, Inc. v. Medtronic Vascular, Inc.*

In 2008, the District Court for the District of Delaware decided a motion for permanent injunction after Medtronic was found to have infringed patents

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permanent injunction of infringing naturally-occurring protein that stimulates the production of red blood cells); Acumed LLC v. Stryker Corp., No. 04-CV-513-BR, 2007 WL 4180682, at *8 (D. Or. Nov. 20, 2007), *aff'd*, 551 F.3d 1323, 1332 (Fed. Cir. 2008) (granting and affirming a permanent injunction of orthopeodic nails used to treat bone fractures); Johns Hopkins Univ. v. Datascope Corp., 513 F. Supp. 2d 578, 586 (D. Md. 2007) (granting a permanent injunction of a method for fragmenting blood clots in hemodialysis grafts).

[174] Voda v. Cordis Corp., No. CIV-03-1512-L, 2006 WL 2570614, at *1 (W.D. Okla. Sept. 5, 2006) *aff'd*, 536 F.3d 1311 (Fed. Cir. 2008).

[175] *Id.* at *5–6.

[176] *Id.*

[177] *Id.*

[178] *Id.* at *5.

[179] *Id.*

[180] Voda v. Cordis Corp., 536 F.3d 1311, 1329 (Fed. Cir. 2008).

[181] *Id.*

belonging to Advanced Cardiovascular Systems (ACS) and relating to blood vessel stents.[182] The court analyzed this motion under direction of the traditional four-factor test and concluded that a permanent injunction should be denied.[183] Under the irreparable harm factor, the court determined that ACS had failed to establish irreparable harm because there was "no indication that Medtronic [was] . . . drawing bare-metal stent sales away from ACS . . . [and] ACS [had] not identified any specific customers it [had] lost, or [stood] to lose, directly as a result of Medtronic's continued sales of infringing stents."[184] Additionally, the court determined that monetary damages were adequate based on ACS's previous licensing of the relevant patents.[185]

Of particular note was the court's analysis of the public interest factor. First, the court noted a strong public interest in maintaining diversity in the coronary stent market based on precedential support.[186] Second, the court noted evidence contained in the record demonstrating physician preference for Medtronic stents.[187] For these reasons, the court concluded that the public interest favored denial of a permanent injunction.[188] Finally, because the other factors weighed so heavily against granting injunctive relief, the court decided to "not make extensive findings with respect to the balance of hardships."[189]

c. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*

*Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.* involved an infringement of a patent related to a prosthetic vascular graft.[190] W.L. Gore, a medical device manufacturer, had infringed a patent belonging to Bard Peripheral Vascular, a direct competitor.[191] After the finding of infringement,

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[182] Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., 579 F. Supp. 2d 554, 555–56 (D. Del. 2008).

[183] *Id.* at 557–58, 563.

[184] *Id.* at 559–60.

[185] *Id.* at 560–61.

[186] *Id.* at 561; *see* Cordis Corp. v. Boston Scientific Corp., 99 F. App'x 928, 935 (Fed. Cir. 2004) ("[A] strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either . . . stent."); Cordis Corp. v. Boston Scientific. Corp., Nos. Civ. A. 03-027, 03-283, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003) (noting the "obvious concern of depriving the public of the best and safest medical devices by limiting competition").

[187] *Advanced Cardiovascular*, 579 F. Supp. 2d at 561.

[188] *Id.*

[189] *Id.* at 562.

[190] Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 670 F.3d 1171, 1175 (Fed. Cir. 2012).

[191] Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., No. CV-03-0597-PHX-MHM, 2009 WL 920300, at *4 (D. Ariz. Mar. 31, 2009), *aff'd*, 670 F.3d 1171, *vacated in part on reconsideration*, 682 F.3d 1003 (Fed. Cir. 2012), *and vacated in part on reh'g en banc*, 476 F. App'x 747 (Fed. Cir. 2012).

Bard motioned for a permanent injunction, and the court analyzed the motion under the four-factor test, primarily focusing on the adequacy of remedies at law and public interest factors.[192] Finding that both factors weighed heavily against granting a permanent injunction, the court denied the motion.[193] Under the adequacy of remedies at law factor, the court determined that Bard could be made whole through legal remedies, including an award of lost profits, a ten percent reasonable royalty rate, and the imposition of a compulsory license on the continued sales of the infringing products for the patent's remaining life.[194] Under the public interest factor, the court analyzed arguments from both parties and tried to predict the public health ramifications of granting a permanent injunction.[195] The court noted:

> Given the utility of Gore's infringing products . . . [and] the important role that these products play in aiding vascular surgeons who perform life saving medical treatments, sound public policy does not favor removing Gore's items from the market. The risk is too great. Placing Gore's infringing products out of reach of the surgeons who rely on them would only work to deny many sick patients a full range of clinically effective and potentially life saving treatments. The Court finds that the ***strength of this factor alone*** precludes it from imposing a permanent injunction.[196]

Ultimately, the court denied the motion without analyzing the other factors.[197]

On appeal, the Federal Circuit affirmed the district court's denial of a permanent injunction holding that an "award of an ongoing royalty instead of a permanent injunction to compensate for future infringement is appropriate in some cases."[198]

d. *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*

After a finding of infringement of its patents related to extended-wear contact lenses, CIBA Vision Corp. motioned for a permanent injunction against the infringer, Johnson & Johnson Vision Care, Inc.[199] While the court analyzed the motion under the traditional four-factor test and denied the motion, this case is notable for its detailed analysis regarding the public interest factor.[200] Under this factor, the court noted many ways the public would be harmed upon the

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[192] *Id.* at *4–5.
[193] *Id.* at *9.
[194] *Id.* at *5.
[195] *Id.* at *6–9.
[196] *Id.* at *9 (emphasis added).
[197] *Id.*
[198] Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 670 F.3d 1171, 1192 (Fed. Cir. 2012).
[199] Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., 712 F. Supp. 2d 1285, 1286 (M.D. Fla. 2010).
[200] *See id.* at 1290–93.

grant of a permanent injunction.[201] The court first noted the exorbitant costs that would be placed on patients to have their contact lenses refitted when the infringing lenses were no longer available on the market.[202] The court speculated that the total cost for this refitting would be close to $500 million.[203] The court also noted the "significant disruption, confusion and cost" that would occur upon a permanent injunction and the hardship that would be placed on the patients, including the time to be refitted, the risk to the patients' health by avoiding refitting, or the possibility of patients substituting lenses over the internet without a valid prescription.[204] Finally, the court highlighted the possibility of patients who may not be able to be refitted at all and would be forced to return to wearing glasses.[205] While the consequences in this case are not as grave as in the *Bard* case, the court noted that "nevertheless, this Court, sitting in equity, finds [the] consequences to be sufficiently important and adverse to millions of . . . patients that the public interest would be disserved if an injunction were to be entered."[206]

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[201] *Id.*

[202] *Id.* at 1290–91.

[203] *Id.* at 1291.

[204] *Id.* at 1291–92.

[205] *Id.*

[206] *Id.* at 1293. There have been additional medically-related patent cases denying injunctive relief. *See, e.g.*, Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1379–80 (Fed. Cir. 2008) (reversing the district court's grant of a permanent injunction for an infringing Hepatitis C diagnostic device because the patent holder had been adequately compensated to cover past and future infringement); Abbott Labs. v. Andrx Pharm., Inc., 452 F.3d 1331, 1347–48 (Fed. Cir. 2006) (vacating the district court's grant of a preliminary injunction for an antibiotic because the patent holder had not established the four factors); Bianco v. Globus Med., Inc., No. 2:12–CV–147–JRG, 2012 WL 5611054, at *2–4 (E.D. Tex. Nov. 15, 2012) (denying a preliminary injunction for an infringing intervertebral fusion device because the patent holder did not establish irreparable harm or inadequacy of monetary damages and the public interest weighed in favor of "this medical advance"); Conceptus, Inc. v. Hologic, Inc., No. C 09–02280 WHA, 2012 WL 44064, at *1–4 (N.D. Cal. Jan. 9, 2012) (denying a permanent injunction of an infringing contraceptive because the four factors weighed in favor of a denial and, primarily, the public had an interest in "having a choice of products"); Precision Med. Inc. v. Genstar Tech. Co., No. 10–5161, 2011 WL 1674354, at *19 (E.D. Pa. May 3, 2011) (denying a motion for a preliminary injunction for an infringing vacuum regulator because the patent holder failed to establish irreparable harm); Tiber Labs., LLC v. Hawthorn Pharm., Inc., 527 F. Supp. 2d 1373, 1382–83 (N.D. Ga. 2007) (denying preliminary injunctive relief for an infringing congestion medicine due to the patent holder's failure to establish irreparable harm and balance of the hardships and the public's interest in preventing the "unintended consequence of confusing—or worse yet, alarming—pediatric patients who have used these medications and their parents and doctors").

## IV. REBUTTABLE PRESUMPTION OF PUBLIC INTEREST IN MEDICAL PATENT INFRINGEMENT CASES

### *A. The Public Interest in Medicine*

The public has always had a large interest in medicine.[207] This heightened interest in medicine exists due to its role in diagnosing and treating illnesses, extending the term of life, and improving the overall health of the general population.[208] The United States patent system helps encourage innovation in medical technologies that improve the health of the population by granting exclusive rights to patent holders for limited terms.[209] President Lincoln once commented on the patent system, expressing that "the patent system added the fuel of interest to the fire of genius."[210] While the patent system plays an important role in protecting inventors and encouraging innovation, there have been multiple times that the public interest in health has superseded this system.[211] After the demise of the Federal Circuit's "general rule" to automatically grant permanent injunctions in most infringement cases, courts have been given more flexibility to protect the public interest in health by denying permanent injunctions when medically-related patents are involved.[212]

### *B. Reasons Why Permanent Injunctions Should Be Denied in Most Medically-Related Patent Infringement Cases*

After *eBay*, courts were required to apply the traditional four-factor test when deciding to grant injunctive relief.[213] The fourth factor, the public interest,

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[207] *See* Michael Beylkin, *Much Ado About Nothing: The Biotech and Pharmaceutical Industries Have Little to Fear in the Post-*eBay *World*, 6 J. TELECOMM. & HIGH TECH. L. 179, 208 (2007).

[208] *See id.* at 208–09.

[209] 35 U.S.C. § 154(a)(1) (2006). Currently, the term of a utility patent is twenty years from the date that the patent application is filed. *Id.* § 154(a)(2); *see* Beylkin, *supra* note 207, at 209; *see also* Julie A. Burger & Justin Brunner, *A Court's Dilemma: When Patents Conflict with Public Health*, 12 VA. J.L. & TECH. 7, 1–2 (2007).

[210] Ronald J. Schutz & Patrick M. Arenz, *Non-Practicing Entities and Permanent Injunctions Post-*eBay, 12 SEDONA CONF. J. 203, 209 (2011).

[211] *See* Burger & Brunner, *supra* note 209 (providing an overview of times that the public interest in health has superseded the patent system including the anthrax scare in 2001 and other various actions taken by the government to curtail patent rights in these situations).

[212] *See supra* Part II.B; *see also* Burger & Brunner, *supra* note 209, at 64–70.

[213] eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

has sparingly been used in medically-related cases to deny injunctive relief.[214] Because the public has such a great interest in medicine, courts should apply a rebuttable presumption, finding that the public interest weighs in favor of denying injunctive relief in all cases that involve medically-related patents. If a plaintiff cannot produce convincing evidence to rebut this presumption, courts should deny injunctive relief, even when the other three factors weigh in favor of granting a permanent injunction. This rebuttable presumption would not contravene *eBay* because Justice Kennedy's concurrence suggests that certain patents might not be suited for injunctive relief.[215] Furthermore, if injunctive relief was denied in these cases, the plaintiff would not be left without remedy but would be able to obtain remedies at law via monetary awards, reasonable royalties, or compulsory licenses.[216] Overall, this rebuttable presumption would protect and promote the substantial public interest in the public health.[217] Courts should apply a rebuttable presumption that the public interest weighs in favor of denying injunctive relief for the following reasons.

### 1. Judicial Uniformity

The most striking reason that courts should apply a rebuttable presumption that the public interest weighs in favor of denying injunctive relief in all cases that involve medically-related patents is judicial uniformity. Of the cases described in Part IV, one glaring conclusion is apparent: courts apply the traditional four factors unpredictably in these cases, even when devices are relatively identical.[218] Even when important devices that help sustain life are involved (i.e., prosthetic heart valves, vascular stents, and hemodialysis machines), courts unpredictably apply the factors, with some courts granting injunctive relief despite public interest concerns and other courts denying

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[214] *See* Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., 712 F. Supp. 2d 1285 (M.D. Fla. 2010); Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., No. CV-03-0597-PHX-MHM, 2009 WL 920300, at *4 (D. Ariz. Mar. 31, 2009) *aff'd*, 670 F.3d 1171, *vacated in part on reconsideration*, 682 F.3d 1003 (Fed. Cir. 2012), *and vacated in part on reh'g en banc*, 476 F. App'x 747 (Fed. Cir. 2012); Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., 579 F. Supp. 2d 554 (D. Del. 2008).

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

[216] *See* Bernard H. Chao, *After* eBay Inc. v. MercExchange*: The Changing Landscape for Patent Remedies*, 9 MINN. J.L. SCI. & TECH. 543 (2008) (for a discussion of other remedies available to patent holders when injunctive relief is denied).

[217] *See* Beylkin, *supra* note 207, at 209.

[218] *See supra* Part IV. *Compare* Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1315–16 (Fed. Cir. 2012) (vacating and remanding district court's denial of permanent injunction of an infringed prosthetic device related to the heart) *with* Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 670 F.3d 1171, 1192 (Fed. Cir. 2012) (affirming district court's denial of permanent injunction of an infringed prosthetic device related to the heart).

injunctive relief due to public interest concerns.[219] This lack of judicial uniformity creates many problems. First, patients and health practitioners are unable to predict when injunctions may occur and lack adequate time to prepare for the transition resulting from injunctions. Also, legal practitioners are unable to predict outcomes based on the facts related to their individual cases. Furthermore, courts waste scarce judicial resources to determine injunctive relief in each fact-intensive case, although no factual similarities among medically-related patent cases can explain courts' denial or grant of injunctive relief. If a rebuttable presumption was applied in medically-related cases, patients and health practitioners would no longer be blindsided by the sudden effect of a permanent injunction, legal practitioners would be able to better predict judicial outcomes based on the facts of their cases, and courts would no longer waste judicial resources to determine injunctive relief for each medically-related patent infringement case. Even if a rebuttable presumption in these cases was considered to be too expansive, courts should attempt to create predictable outcomes of injunctive relief based on specific factual differences. For example, courts could establish categorical denial or grant of injunctive relief based on certain factual trends (i.e., type of device or drug involved or medical condition treated by the device or drug).

### 2. Physician Preference

Another reason that courts should apply a rebuttable presumption of public interest is because of physician preference for the infringing device. Doctors may prefer the infringing device for many reasons including superiority of the infringing device, greater knowledge of the infringing device, or, simply, greater ease of use of the infringing device.[220] While courts have commonly used physician preference for support in denying preliminary injunctions, physician preference has rarely been used in support of denying permanent injunctions.[221] Physician preference is important because, if a permanent injunction is granted and the physician can no longer use the preferred infringing device, there are potential risks to the patient in continuing treatment. For example, in *Advanced Cardiovascular*, physician preference was used as support in denying a permanent injunction because declarations by four cardiologists each expressed

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[219] *See supra* Part IV.

[220] *See* Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., 579 F. Supp. 2d 554, 561 (D. Del. 2008); Datascope Corp. v. Kontron, Inc., 611 F. Supp. 889, 895 (D. Mass. 1985), *aff'd*, 786 F.2d 398 (Fed. Cir. 1986) ("Defendant has also made some showing that the public will be harmed by an injunction in that some physicians prefer defendant's dual lumen IABs.").

[221] *See* Robert A Matthews, Jr., 4 ANNOTATED PATENT DIGEST § 32:81 (2013).

"concern for the success of their surgeries should [the infringing] products be removed from the market."[222]

### 3. Interest in Medical Competition

A third reason supporting a rebuttable presumption of public interest is the public interest in medical competition. This interest has been used by both district courts and the Federal Circuit to deny injunctive relief in cases involving coronary stents.[223] Other courts have used this interest to support a denial of injunctive relief or limiting injunctive relief.[224] The theory behind this interest is the need for patients to have alternative safe medical devices.[225] Patients need to have more alternatives in the medical device market in order to make informed decisions about their treatment.[226] When injunctions occur, patients are at risk of having only one viable option on the market,[227] and, even worse, patients may have no viable alternatives after a permanent injunction due to supply issues with the patented product.

### 4. Supply of the Patented Product

Another reason supporting a rebuttable presumption of public interest is the risk of the patent holder being unable to meet patient demand once the infringing product is taken off the market. While some courts have noted this concern, it has found little use in supporting a denial of injunctive relief.[228] Even

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[222] *Advanced Cardiovascular*, 579 F. Supp. 2d at 561.

[223] *See id.*; *see also* Cordis Corp. v. Boston Scientific Corp., 99 F. App'x 928, 935 (Fed. Cir. 2004) ("[A] strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either . . . stent."); Cordis Corp. v. Boston Scientific Corp., Nos. Civ.A. 03-027-SLR, Civ.A. 03-283-SLR, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003) (noting the "obvious concern of depriving the public of the best and safest medical devices by limiting competition").

[224] *See* B. Braun Melsungen AG v. Terumo Med. Corp., 778 F. Supp. 2d 506, 526 (D. Del. 2011); Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., No. CV-03-0597-PHX-MHM, 2009 WL 920300, at *4–10 (D. Ariz. Mar. 31, 2009), *aff'd*, 670 F.3d 1171 (Fed. Cir. 2012), *vacated in part on reconsideration*, 682 F.3d 1003 (Fed. Cir. 2012), *and vacated in part on reh'g en banc*, 476 F. App'x 747 (Fed. Cir. 2012).

[225] *B. Braun*, 778 F. Supp. 2d at 526.

[226] *See* Conceptus, Inc. v. Hologic, Inc., No. C 09-02280 WHA, 2012 WL 44064, at *1–4 (N.D. Cal. Jan. 9, 2012) (denying a permanent injunction of an infringing contraceptive because the four factors weighed in favor of a denial and, primarily, the public had an interest in "having a choice of products").

[227] *See id.*

[228] *Compare* Pozen Inc. v. Par Pharm., Inc., 800 F. Supp. 2d 789, 799, 825 (E.D. Tex. 2011) (noting supply concerns yet granting injunctive relief), *with* Cordis Corp. v. Boston Scientific Corp., No. Civ.A. 03-027-SLR, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003), *aff'd*, 99 F. App'x 928 (Fed. Cir. 2004) (denying preliminary injunction for infringed drug-eluting stents due to public health risks posed by inadequate supply).

if a patent holder is able to meet customer demand this could potentially prove costly to patent holders who are ill-equipped to handle the rise in demand. This could make injunctive relief seem more like a curse than a blessing. Some courts have attempted to ease these supply concerns by providing transition periods that delay the time that the permanent injunction goes into effect.[229] If courts are unwilling to apply a rebuttable presumption of public interest in medically-related patent cases, courts should allow for periods of transition in all medically-related infringement cases to protect the public from potential supply issues. Finally, while unrelated to the supply of the patent holder's product, there have been expressed concerns regarding the unused supply of the infringing product when a permanent injunction ceases its distribution.[230] This can lead to waste that ultimately harms the general public.[231]

### 5. Costs of Transition

A fifth reason supporting a rebuttable presumption of public interest is the exorbitant costs of transition in the event of a permanent injunction. Patients may take on additional costs due to an increase in price for the alternative product or additional appointments with doctors to make the transition.[232] Additionally, patients may even be encouraged not to make the transition, thus placing them at increased health risks.[233] Patients are not the sole cost-bearing entity in a transition, however. Medical professionals can also experience exorbitant transitional costs including training of personnel to use the alternative device, increasing prices for the alternative device, and disposal of existing inventories of the infringing product.[234]

### 6. Other Considerations

Underlying each preceding reason is the primary concern for patient safety. However, there are additional considerations that help support the necessity for a rebuttable presumption of public interest. These considerations include potential inequitable use of the patent by the patentee, potential harm when the patentee does not commercially practice the patent, or the harm to patient privacy and the physician-patient relationship in enforcing the injunction.[235]

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[229] *See* Shiley, Inc. v. Bentley Labs., Inc., 601 F. Supp. 964, 971 (C.D. Cal. 1985).
[230] *See* Burger & Brunner, *supra* note 209, at 99–101.
[231] *See id.*
[232] *See* Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., 712 F. Supp. 2d 1285, 1291 (M.D. Fla. 2010) (speculating that the total cost of transition could reach $500 million).
[233] *See id.*
[234] *See* Burger & Brunner, *supra* note 209, at 99–101.
[235] *See id.* at 82–89, 107–09.

### *C. Hypotheticals*

The necessity for a rebuttable presumption that the public interest weighs in favor of denying injunctive relief in cases involving medically-related patents is best demonstrated by a set of hypothetical situations.

#### 1. The Teenage Girl

Consider a teenage girl who has used a specific contraceptive for many months. All of a sudden the contraceptive is taken off the market due to a permanent injunction forcing the girl to use a new contraceptive. There are three effects that could potentially occur from this injunction. First, the new contraceptive could prove less effective than her previous contraceptive. This could injure the girl both medically and financially. Second, the new contraceptive could provide the girl with a different physiological reaction than the previous contraceptive potentially causing significant harm to the girl's health. Third, the new contraceptive could be out of stock due to the increased demand, leaving the girl with no viable alternatives. Ultimately, the girl is placed at greater risks when a permanent injunction is granted.

#### 2. The Senior Citizen

Next, consider a senior citizen who has suffered many years from heart complications. For five years he has been using a coronary stent. This stent is implanted surgically and must be replaced every year. Upon the man's yearly replacement, he is informed that the stent he has been using for the past five years is no longer available due to a permanent injunction. There are four effects that could potentially occur from this injunction. First, the man could choose not to replace the stent, thus placing his health at risk. Second, the man could use a new stent that proves ineffective, thus exacerbating his existing heart condition. Third, the man's physician could be less comfortable surgically implanting the new stent, thus increasing the risk of the replacement surgery. Finally, the new stent could be unavailable due to the increased demand, leaving the man with no viable alternatives. Ultimately, the senior citizen is placed at greater risks when a permanent injunction is granted.

#### 3. The Sole Community Hospital

Finally, imagine a small community that has one hospital. This hospital uses a particular type of MRI machine. One day, the hospital is informed that the MRI machine has been subjected to a permanent injunction, and the hospital must purchase an alternative to continue performing MRIs. There are many effects that could potentially occur due to this injunction. First, the hospital may not have the resources available to purchase the new machine. This would force all patients in need of an MRI to visit alternative hospitals. This would place the hospital at financial risk and the patients at both financial and physical risk.

Second, the hospital may purchase the new machine but improperly train its personnel how to use the new machine thereby leading to inaccurate test results. Third, the hospital may purchase the new machine but be forced to make significant budget cuts, which diminishes hospital resources overall. Ultimately, the sole community hospital and the members of the community are placed at greater risks when a permanent injunction is granted.

## CONCLUSION

Injunctive relief has long been considered an "extraordinary" remedy.[236] However, this has been at odds with the frequency that district courts grant injunctive relief in patent infringement cases. Because the interest of the public is one of the factors in the traditional four-factor test, it is obvious that the public interest is of great concern to courts. However, the large number of permanent injunctions granted in medically-related patent infringement cases presents many risks and potential harm to the public; therefore, courts should play a role in helping to protect the interest in public health by applying a rebuttable presumption that the public interest weighs in favor of denying injunctive relief in cases that involve medically-related patents.

[236] Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982).