

# PATENT RIGHTS V. PUBLIC ACCESS: INTERPRETING THE PUBLIC INTEREST FACTOR IN PHARMACEUTICAL PATENT INFRINGEMENT CASES

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## I. INTRODUCTION

“Patents have long been the crown jewels of the pharma industry. They protect pioneer therapies from generic competition and underwrite the enormous investment required for new drug research and development.”<sup>1</sup> The estimated average cost per new prescription drug approval from the U.S. Food and Drug Administration is over \$2.5 billion.<sup>2</sup> For this reason, the pharmaceutical industry depends strongly on patent rights to recover from their investments and fund further research and development.<sup>3</sup>

Brand name drugs have been developed and tested over a course of many years to show that they meet safety and efficacy requirements by the Food and Drug Administration.<sup>4</sup> Pharmaceutical companies developing brand name drugs rely on the exclusivity provided by patents in order to charge a premium price while under protection.<sup>5</sup> Absent patent protection, other companies are free to make generic versions, causing the price to significantly drop.<sup>6</sup> A generic drug requires no discovery process because

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1. Terry G. Mahn, *Generics Behaving Badly: Carve Outs, Off-Label Uses*, LAW360 (Mar. 24, 2009, 12:00 A.M.), <http://www.law360.com/articles/93495/generics-behaving-badly-%20carve-outs-off-label-uses>.
2. Joseph A. DeMasi, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, TUFTS CTR. FOR THE STUDY OF DRUG DEV. (Nov. 18, 2014), [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014.pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf).
3. Vernon Winters, *Let's Fix the Patent-Specific Preliminary Injunction Test*, LAW360 (Apr. 05, 2013, 11:47 AM), <https://www.law360.com/articles/424868/let-s-fix-the-patent-specific-preliminary-injunction-test>.
4. Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 431 (2014) (The developmental stages can take years because the entity not only must find a chemical compound but there are several stages of clinical trials to prove safety).
5. *Id.*
6. *Id.* (“After a term of less than twenty years, companies can make generic versions, and when there are multiple generic versions, the price drops substantially”).

generics essentially copy successful brand name drugs that have already been approved, meaning the costs to enter into the market are significantly lower than costs brand name drug companies face.<sup>7</sup>

Courts use injunctions as a remedy against patent infringement because calculating monetary damages for future harm by an infringer is extremely difficult, if not impossible, to determine.<sup>8</sup> Traditionally, courts granted permanent injunctions to patent holders who had a valid patent that was infringed.<sup>9</sup> This method of patent protection was ideal for the pharmaceutical companies investing hundreds of millions of dollars into research because the patent holder would be able to practice its exclusivity in the marketplace and recoup for damages made in the developmental stages.

However, in 2006, the Supreme Court significantly changed the structure of the patent system for obtaining permanent injunctions.<sup>10</sup> The holding in *eBay v. MercExchange* reduced the frequency in which courts were granting injunctive relief,<sup>11</sup> and required that the traditional four-factor test for equitable relief be used when considering permanent injunctions.<sup>12</sup> The traditional test is stated as follows:

According 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. 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.<sup>13</sup>

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7. *Id.* at 432 (“[T]he FDA refers to applications to sell generic drugs as abbreviated applications because much less is required. First, there is no discovery process . . . In addition, although a generic still needs FDA approval, it only needs minimal testing to be approved”).
  8. David. B. Conrad, *Mining the Patent Thicket: The Supreme Court’s Rejection of the Automatic Injunction Rule in eBay v. MercExchange*, 26 REV. LITIG. 119, 123 (Winter 2007) (“placing a dollar sign upon future harm from the continued actions of the defendant is usually very complex, and often, an uncertain and impossible task”).
  9. *See infra* Part II, Section A; Mark P. Gergen et al., *The Supreme Court’s Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 204 (2012) (“a permanent injunction will issue once infringement and validity have been adjudged”).
  10. *Id.* at 205 (describing the *eBay* decision as having a “cataclysmic effect”).
  11. Douglas Ellis et al., *The Economic Implications (And Uncertainties) of Obtaining Permanent Injunctive Relief After eBay v. MercExchange*, 17 FED. CIRCUIT B.J. 437, 437 (2008) (“Since the May 2006 decision, thirty-six district court decisions, including the remand in the *eBay* case, have applied the Court’s decision. The net result has been diminished power for patent holders and increased uncertainties for licensing parties and litigants.”).
  12. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).
  13. *Id.*

In consideration of the public interest factor, “a plaintiff is now required to affirmatively demonstrate each of the four factors, meaning a plaintiff must raise and negate public interest concerns.”<sup>14</sup>

There is a substantial amount of literature addressing *eBay* and the effects of the four-factor test.<sup>15</sup> Some of the writings focus on the pharmaceutical industry as well, but the public interest factor has been the least explored factor of all.<sup>16</sup> The public interest factor of the analysis is arguably the most important factor in determining injunctive relief for pharmaceutical companies.<sup>17</sup>

This Note analyzes the least talked about factor of the *eBay* decision—public interest. The patent owner’s right to exclude others benefits the public in the following ways: by providing for the disclosure of inventions, allowing entrance into the market of valuable products whose invention might have been delayed but for the incentives provided by the patent laws, and increasing competition the patented product creates in the marketplace.<sup>18</sup> The United States patent system promotes the innovation of new pharmaceuticals that improve the health of the population by providing inventors with an incentive to publicly disclose their inventions.<sup>19</sup>

The Supreme Court has stated, “There is a clear rule of our law in favor of inventors, and to carry into effect the obvious object of the Constitution and laws, to give liberal construction to the language of all patents and specifications . . . so as to protect, and not destroy, the rights of real inventors.”<sup>20</sup> While the patent system plays an important role in protecting inventors and encouraging innovation, there have been multiple times that

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14. Scott A. Allen, “Justifying” the Public Interest in Patent Litigation, 88 INDIANA L.J. 1047, 1054 (2013).
  15. See Rachel M. Janutis, *The Supreme Court’s Unremarkable Decision in eBay Inc. v. MercExchange, L.L.C.*, 14 Lewis & Clark L. Rev. 597 (2010); see also Andrew Beckerman-Rodau, *The Aftermath of eBay v. MercExchange*, 126 S. Ct. 1837 (2006): *A Review of Subsequent Judicial Decisions*, 89 J. PAT. & TRADEMARK OFF. SOC’Y 631 (2007); Ryan T. Holte, *The Misinterpretation of eBay v. MercExchange and Why: An Analysis of Case History, Precedent and Parties*, 18 CHAPMAN L. REV. 677 (2015).
  16. Andrew Riley, *How Courts Consider Patent Injunction’s Impact on Public*, FINNEGAN (Sep. 11, 2013), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=60b7bb4b-a1ee-4b7b-ab9e-a918c626cf1b>.
  17. See generally Allen, *supra* note 14 (“Regardless of whether it is a new factor required for permanent injunctions or possibly a restatement of a traditional consideration, the public interest will clearly be a concern going forward.”).
  18. *SCM v. Xerox Corp.*, 645 F.2d 1195, 1203 (2d. Cir. 1981).
  19. Whitney E. Frasier Tiedemann, *First-to-File: Promoting the Goals of the United States Patent System Through the Biotechnology Industry*, 41 U.S.F. L. REV. 477, 477 (2007).
  20. Bradford E. Kile, *Legal X-Games Risk: Officer & Director Passive Retention of Personal Risk for Patent Infringement*, 19 ANDREWS INS. INDUS. LITIG. REP. 15 (Mar. 21, 2001) (citing *Klein v. Russell*, 86 U.S. 433, 466 (1873)).

the public interest in health has supplanted this system.<sup>21</sup> Because of the departure from the “categorical approach,” courts now have more power to deny permanent injunctions.<sup>22</sup>

This Note explains why courts should not only pay special attention to the public interest factor when determining injunctive relief in pharmaceutical cases, but also why they should consider the rights of the patentee to favor the public interest over the convenience of cheaper drugs to the public.

Accordingly, Part II of this note provides the history of the Patent Act and the statutory guidelines behind patent enforcement. This section also provides a layout of how the grant and denial of patent injunctions were decided prior to 2006 and the decision in *eBay*. This part of the note likewise explains how the court reached its holding in *eBay v. MercExchange* and how this decision altered the long-used “categorical approach.” Part II also addresses the latest trends in injunctive relief for pharmaceutical companies and the different types of analysis applied to the public interest factor of the four-factor equitable test. Part II provides examples of courts both granting and denying patent injunctions in pharmaceutical cases, inconsistently applying the factors, and creating discrepancies in what the public interest factor entails.

Part III of this note discusses the various arguments in how the public interest factor should be applied, as well as the discrepancies in how the factor has been applied throughout the court system over the years. Courts are split on how the public interest is served in granting permanent injunctions in pharmaceutical cases.<sup>23</sup> Part IV specifically addresses the public interest factor, and argues the courts need to place more emphasis on the public interest factor in pharmaceutical cases than in injunctions for any other industry. Part IV also argues the public is best served when the court grants permanent injunctions in pharmaceutical patent infringement cases.

## II. BACKGROUND

Patent holders are given exclusive rights to their inventions, including the right to exclude others from making, using, selling, offering for sale, or importing the invention.<sup>24</sup> Patent law provides the remedy of a permanent injunction to be granted against an unlawful infringer, which prevents the

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21. Lance Wyatt, *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*, 13 CHI.-KENT J. INTELL. PROP. 298, 320 (2013).

22. *Id.* at 321–22.

23. *See infra* Part II, Section B.

24. 35 U.S.C. §271(a) (2010).

infringer from performing any of the excluded actions.<sup>25</sup> The *eBay* decision has bestowed upon the judiciary the freedom to ensure that patent rights do not interfere with public health, even at the expense of the patentee's right to exclude.<sup>26</sup>

#### A. The Traditional Approach

The United States Constitution provides through the patent and copyright clause, "Congress shall have Power To . . . promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their. . . Discoveries."<sup>27</sup> Obtaining a patent guarantees the owner "the right to exclude others from using, offering for sale or selling throughout the United States"<sup>28</sup> ". . . for a term beginning on the date on which the patent issues and ending twenty years from the date on which the application for the patent was filed in the United States."<sup>29</sup> One remedy for patent owners when their patent has been infringed upon is an injunction.<sup>30</sup>

Traditionally, a plaintiff seeking a permanent injunction had to satisfy a four-factor test based on well-established principles of equity.<sup>31</sup> A permanent injunction would be granted if the movant demonstrated the four factors weighed in favor of injunctive relief.<sup>32</sup> However, there was a major departure from this rule for some time. The Federal Circuit created a "general rule," and courts were issuing permanent injunctions to halt infringing activity once the patent was found to be both valid and infringed, absent exceptional circumstances.<sup>33</sup> These cases were exceptionally rare because the weight of the public interest factor focused on the public interest

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25. Burger, *supra* note 22, at 20.

26. *Id.*

27. U.S. CONST. art. I, § 8, cl.8.

28. 35 U.S.C. §154(a)(1) (2012).

29. 35 U.S.C. §154(a)(2) (2012).

30. 35 U.S.C. § 283 (2006).

31. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). According 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. 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. *Id.*

32. Burger, *supra* note 22, at 20 ("irreparable injury, no or inadequate remedies at law, the balancing of hardships to the parties, and the public interest").

33. *See eBay*, 547 U.S. at 395 (Roberts, C.J., concurring) ("From at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases"); *see also* *Tiber Labs., LLC v. Hawthorn Pharms., Inc.*, 527 F. Supp. 2d 1373, 1378 (2007) ("For more than twenty years, the Federal Circuit has applied a categorical rule in patent cases that 'an injunction will issue when infringement has been adjudged, absent a sound reason for denying it'" (quoting *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989)).

in enforcing patent rights to maintain economic incentives that encourage innovation.<sup>34</sup> This “general rule” was favorable to patentees because upon the showing of a valid and infringed patent, a court would issue an injunction as if it were a matter of right.<sup>35</sup>

### B. *eBay v. MercExchange*

The decision in *eBay v. MercExchange* changed the traditional framework dramatically.<sup>36</sup> In 2006, the Supreme Court of the United States held that a court considering whether to award permanent injunctive relief to a plaintiff under the Patent Act must apply the four-factor test “historically employed by courts of equity.”<sup>37</sup>

In this revolutionary case, MercExchange sued eBay for patent infringement over eBay’s “Buy It Now” feature.<sup>38</sup> MercExchange had attempted to license their business method patent to eBay but was unable to reach an agreement.<sup>39</sup> eBay went ahead with its website using the “Buy It Now” feature, so MercExchange filed suit in the Eastern District of Virginia.<sup>40</sup> The jury found the patent valid and infringed and awarded damages in the amount of \$35 million to MercExchange.<sup>41</sup> MercExchange then filed for a permanent injunction but was denied, finding MercExchange would be compensable in damages rather than permanently enjoining eBay since they did not practice the invention and had previously licensed its patents to others.<sup>42</sup>

MercExchange appealed and the Federal Circuit reversed, reasoning that the traditional framework will grant injunctions “absent exceptional circumstances.”<sup>43</sup> eBay filed a petition for a writ of certiorari with the United States Supreme Court.<sup>44</sup> Biotechnology and pharmaceutical industries favoring permanent injunctions supported MercExchange by filing amicus

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34. Burger, *supra* note 22, at 20.

35. *Id.* at 23.

36. Benjamin Peterson, *Injunctive Relief in the Post-eBay World*, 23 BERKELEY TECH L.J. 193, 196 (2008) (“In the two years after the Supreme Court’s ruling in *eBay*, there were thirty-three district court decisions that interpreted *eBay* when determining whether to grant injunctive relief to a patent holder. Of these decisions, twenty-four have granted permanent injunctions and ten have denied injunctions.”); see also Edward D. Manzo, *Injunctions in Patent Cases After eBay*, 7 J. MARSHALL REV. INTELL. PROP. L. 44, 47 (2007) (“*eBay* has made courts consider the equities more closely, and it has become somewhat more difficult for a prevailing patent owner to obtain an injunction against an infringer”).

37. *eBay*, 547 U.S. at 390.

38. *Id.*

39. *Id.*

40. *Id.*

41. MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 698 (2006).

42. *Id.* at 711–13.

43. *eBay*, 547 U.S. at 391.

44. *Id.* at 391.

briefs with the court, arguing “any unpredictability with regard to the ability of a patent owner to enforce his exclusive rights will reduce investment in research and development activities to the ultimate detriment of the public.”<sup>45</sup>

The Supreme Court vacated the judgment, holding that a plaintiff seeking permanent injunction must show:

(1) it has suffered irreparable injury; (2) remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) considering balance of hardships between plaintiff and defendant, remedy in equity is warranted; and (4) public interest would not be disserved by permanent injunction.<sup>46</sup>

In analyzing the public interest factor, the Court discussed the public’s interest in maintaining the integrity of the patent system favors enjoining an infringer’s activities.<sup>47</sup>

Based on *eBay*, a court’s decision about injunctions is no longer based on a “categorical rule,” but rather “an act of equitable discretion” based on the four factor-test.<sup>48</sup> Accordingly, patent owners are no longer automatically granted an injunction.<sup>49</sup>

### C. The Public Interest Factor

Since the *eBay* decision, the probability for likelihood of success of patentees has changed in the way that the Supreme Court intended.<sup>50</sup> The public interest factor has come to mean more than the public’s interest in the enforcement of the patent system, but also the public health, safety, and need.<sup>51</sup>

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45. 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. & INTEL. PROP. 165, 181 (2008).

46. *eBay*, 547 U.S. at 391.

47. Holte, *supra* note 15, at 687.

48. *Id.*; *see infra* Part IV.

49. Tiber Labs., LLC v. Hawthorn Pharms., Inc., 527 F. Supp. 2d 1373, 1378 (N.D. Ga., Sept. 12, 2007) (“For more than twenty years, the Federal Circuit has applied a categorical rule in patent cases that ‘an injunction will issue when infringement has been adjudged, absent a sound reason for denying it.’”) (quoting *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1247 (Fed.Cir.1989)).

50. Benjamin Simler, *A Model for Predicting Permanent Injunctions After eBay v. MercExchange*, BLOOMBERG LAW REPORTS (2011), [https://www.hollandhart.com/files/model\\_for\\_predicting\\_permanent\\_injunctions\\_after\\_eba.pdf](https://www.hollandhart.com/files/model_for_predicting_permanent_injunctions_after_eba.pdf) (“The percentage of cases in which an injunction is entered is in stark contrast to pre-*eBay* statistics: in the year prior to *eBay*, 100% of courts to consider the issue granted an injunction”).

51. Burger, *supra* note 22, at 20.

The decision in *eBay* has done little to provide a structured framework in granting injunctions.<sup>52</sup> District courts have widely diverged in the analyses of the four-factor test.<sup>53</sup> For example, some courts have interpreted the public interest factor to include interests of the general public, while others have included the harm suffered by the infringer's employees if an injunction were to issue as a matter of public interest.<sup>54</sup> Therefore, the public interest factor can be the decisive factor in determining whether an injunction will issue.<sup>55</sup>

The public interest factor is the most important factor in the pharmaceutical industry because these are the companies that make drugs that save and improve patients' lives every day.<sup>56</sup> New medicines deliver astonishing value to our health care system by helping avoid the need for hospitalizations and expensive surgeries.<sup>57</sup> Patent rights not only award the company, but also continuously provide improved products for patients over many generations.<sup>58</sup>

In *Johnson & Johnson Vision Care Inc. v. Ciba Vision Corp.*, the court turned predominantly on public interest concerns in denying Ciba Vision Corp's motion for a permanent injunction.<sup>59</sup> Ciba argued that an injunction of Johnson & Johnson's silicone hydrogel contact lenses does not "implicate public health" and contact lenses are not medically necessary, but merely a convenience.<sup>60</sup> The court relied on Johnson & Johnson's arguments about comfort, which sounded more health-related than convenient.<sup>61</sup> Here, the court found the public interest to be with the "millions of contact lens wearers" that would suffer adverse consequences if Johnson & Johnson were enjoined.<sup>62</sup> This court analyzed public interest to be the comfort of the public rather than the enforcement of patent rights.<sup>63</sup>

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52. Wyatt, *supra* note 21, at 311 ("Since *eBay v. MercExchange*, district courts and the Federal Circuit have both granted and denied injunctive relief when medical patent infringement is found. These courts have reached these holdings based on different arbitrary conclusions under the traditional four-factor test").

53. Peterson, *supra* note 36, at 197.

54. *Id.*

55. Riley, *supra* note 16.

56. Pharmaceutical Research and Manufacturers of America, *2015 Biopharmaceutical Research Industry Profile*, (Apr. 2015), [http://www.phrma.org/sites/default/files/pdf/2015\\_phrma\\_profile.pdf](http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf).

57. *Id.*

58. *Intellectual Property Patents: The vehicle for innovation*, EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (2016), <http://www.efpia.eu/topics/innovation/intellectual-property>.

59. *Johnson & Johnson Vision Care, Inc., v. CIBA Vision Corp.*, 712 F.Supp.2d 1285 (M. D. Fla., Apr. 27, 2010).

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*



Pharmaceutical patent infringement cases are unique from patent infringement cases in other industries. Even when applying the traditional approach in *eBay*, the Court of Appeals addressed the exception in cases related to public health.<sup>64</sup>

Pharmaceutical companies rely mainly on patents to protect their investment in new drugs because a patent permits a pharmaceutical company to legally exclude all others from making or selling the identical.<sup>65</sup> The ability to exclude others from making the patented drug permits the patent-owner to sell its drug at a substantial premium and recoup costs from research and development.<sup>66</sup> However, when patent protection for the drug ends, there is typically strong competition from multiple generic companies, and the price of the drug drops substantially.<sup>67</sup> Therefore, the ability of pharmaceutical companies to exclude competitors from generic entry into the marketplace is essential.

However, federal courts do not establish in what direction the public interest factor should be interpreted. The Federal Circuit cases are either ambiguous or silent as to how public interest should be viewed.<sup>68</sup>

#### D. Courts Granting Injunctions Post-*eBay*

##### 1. *Teva v. Eli Lilly*

Teva marketed a generic version of Eli Lilly's drug, Evista, a drug that aids in the prevention of postmenopausal osteoporosis.<sup>69</sup> In June 2006, Lilly sued Teva for patent infringement.<sup>70</sup> In 2009, the Federal Circuit approved Lilly's motion for a preliminary injunction to prevent market entry of the generic by Teva.<sup>71</sup> Their reasoning was that Eli Lilly's loss of marketing exclusivity with respect to Evista would result in a rapid loss of market share and revenue that would be difficult, if not impossible, for Lilly to recover given the issues associated with the recovery of its preferred status on formularies.<sup>72</sup> The district court also found that even if Lilly were able to fully recover its position in the market, it would nonetheless suffer

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64. *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005) (In their holding, the Court of Appeals stated that a court may deny an injunction in exceptional circumstances, such as "when 'a patentee's failure to practice the patented invention frustrates an important public need for the invention' such as . . . to protect public health.").

65. Ho, *supra* note 4, at 433.

66. *Id.*

67. *Id.*

68. See generally Damian Myers, *Reeling in the Patent Troll: Was eBay v. MercExchange Enough?*, 14 J. INTEL. PROP. L. 333, 348 (2007).

69. *Eli Lilly and Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010).

70. *Id.*

71. *Id.*

72. *Id.*

irreparable damage to its relationship with physicians and customers.<sup>73</sup> Finally, the court found that an injunction was necessary to prevent disruption of research that would have been sponsored or completed by Lilly.<sup>74</sup>

## 2. *Pozen Inc. v. Par Pharmaceutical, Inc.*

The District Court for the Eastern District of Texas granted Pozen's request for permanent injunction against defendants Par Pharmaceutical Inc., Alphapharm Pty LTD, and Dr. Reddy's Laboratories, Inc.<sup>75</sup> Pozen's patent was a migraine therapy marketed as Treximet.<sup>76</sup> The district court provided a detailed analysis of the four-factor test.<sup>77</sup>

Pozen showed sufficient evidence that it would suffer irreparable harm without an injunction by loss of vital revenue, an irreversible loss of market share, and price erosion.<sup>78</sup> Pozen also successfully proved that monetary damages could not adequately compensate the "cascade of consequences."<sup>79</sup> The court also found that the balance of equities tipped in Pozen's favor since the defendants' products had not entered the market.<sup>80</sup> Analyzing the public interest factor, the court noted the public's interest in encouraging innovation by upholding the patent holder's right to exclude.<sup>81</sup> The court further explained that the public would not be harmed by a permanent injunction because the public already had access to the brand name Treximet.<sup>82</sup>

## E. Courts Denying Pharmaceutical Injunctions Post-*eBay*

### 1. *Tiber Laboratories, LLC v. Hawthorn Pharmaceuticals, Inc.*

This action arose from allegations of patent infringement by Hawthorn Pharmaceuticals on Tiber Laboratories' patent for a pharmaceutical that treats upper respiratory and congestion symptoms in pediatric patients.<sup>83</sup> In analyzing the four factors, Tiber contended that an injunction would cause them to suffer irreparable harm in "losing the benefit of the exclusionary

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73. *Id.*

74. *Id.*

75. *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 825 (E.D. Tex., Aug. 5, 2011).

76. *Id.* at 796.

77. *Id.* at 824-25.

78. *Id.* at 789.

79. *Id.* at 824-25.

80. *Id.* at 825.

81. *Id.*

82. *Id.*

83. *Tiber Labs., LLC v. Hawthorn Pharms., Inc.*, 527 F. Supp. 2d 1373, 1375 (N.D. Ga., Sept. 12, 2007).

effect” on their patent.<sup>84</sup> The court disagreed with this argument because Tiber had waited too long to enforce its patent.<sup>85</sup> The court found that balance of hardships did not tip in Tiber’s favor, as Tiber failed to meet its burden by not providing evidence to balance the equities.<sup>86</sup> Finally, the court conceded that “public interest is usually ‘best served by enforcing patents that are likely valid and infringed.’”<sup>87</sup> However, in this case the court found that public interest would be best served by maintaining the status quo the generic entry had produced.<sup>88</sup> Because of these reasons, the court concluded Tiber had failed to show its entitlement to injunctive relief and the motion was denied.<sup>89</sup>

## 2. Abbott Laboratories v. Andrx Pharmaceuticals, Inc.

Abbot Laboratories brought a patent infringement suit against Teva Pharmaceuticals Inc. based on Abbot’s patents on an extended release formulation of the antibiotic, clarithromycin.<sup>90</sup> The district court granted Abbot’s motion for a preliminary injunction by analyzing the four-factor test.<sup>91</sup> The district court found a presumption of irreparable harm because of the irreversible market share loss that Abbot would experience from generic entry.<sup>92</sup> The court found the balance of hardships to tip in Abbot’s favor as well, and determined that the public interest factor was best served by enforcing Abbot’s patent rights.<sup>93</sup>

However, the Court of Appeals disagreed with the district court’s analysis and vacated the grant of a preliminary injunction.<sup>94</sup> In analyzing the four factors, the federal circuit found that although generic completion would impact Abbot’s sales of the brand name drug, this alone did not establish irreparable harm.<sup>95</sup> The court of appeals agreed with the district court that the balance of hardships favored Abbot and the public is best served by enforcing patents that are valid and infringed.<sup>96</sup> However, since Abbot had

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84. *Id.* at 1378.

85. *Id.* at 1378 (finding that irreparable injury was precluded by Tiber’s dilatory conduct in prosecuting patent action and its demonstrated willingness to license the ‘689 Patent).

86. *Id.* at 1382.

87. *Id.* at 1383 (quoting *Gemmy Indus. Corp. v. Chrisha Creations Ltd.*, 452 F.3d 1353, 1358 (Fed. Cir. 2006)).

88. *Id.*

89. *Id.*

90. *Abbot Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1332 (Fed. Cir. 2006).

91. *Id.*

92. *Id.* at 1334.

93. *Id.*

94. *Id.* at 1332.

95. *Id.* at 1348.

96. *Id.*

not established a likelihood of success on the merits, the court found that an injunction should be denied.<sup>97</sup>

#### F. Public Interest in Pharmaceutical Cases

Requiring courts to apply the four-factor injunction test gives the courts discretion to consider the issue of public interest in denying permanent injunctive relief.<sup>98</sup> Scholars are split over the application of the public interest factor in patent injunction framework.<sup>99</sup> Some believe the public is harmed when pharmaceuticals, although infringing on valid patents, are taken off the market after a court grants a permanent injunction.<sup>100</sup> Others believe preserving the patent system is in the best interest of the public by encouraging innovation.<sup>101</sup>

Before the decision in *eBay*, courts found that the public's interest in health and safety was insignificant compared to the pharmaceutical patent owner's right of exclusivity to its invention.<sup>102</sup> However, *eBay* has cast doubt on this logic, and courts have since exercised inconsistent discretion in applying the public interest factor.

In light of the tremendous public discussion and focus on the need for more affordable medicines and therapies, as well as the purported promise of generics to achieve this aim, some have speculated that *eBay*—and in particular the Supreme Court's finding that all four factors must be evaluated in deciding whether to grant a permanent injunction—appears to favor a shift towards denying permanent injunctive relief in order to enable patented products to become more available at lower costs.<sup>103</sup>

However, a decrease in permanent injunctions would discourage investments in research and development for pharmaceuticals, where large financial investments are required and the resulting product is incapable of being protected as a trade secret.<sup>104</sup> Pharmaceuticals are unable to be

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97. *Id.*

98. Bryan C. Diner et al., *The Effect of the U.S. Supreme Court's Decision in eBay v. MercExchange on the Biopharmaceutical Industry*, FINNEGAN (May 1, 2006), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=db03e683-c202-41fd-8b7d-57418d133746>.

99. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 855 (2003).

100. Wyatt, *supra* note 21, at 320–21.

101. Chien, *supra* note 99.

102. Mark P. Kessler et al., *How Will eBay v. MercExchange Affect Pharmaceutical and Biotechnology Patent Owners?*, LOWENSTEIN SANDLER, LLP, <https://www.lowenstein.com/files/Publication/90b4a236-929e-48e0-82c0-0188c076c362/Presentation/PublicationAttachment/7fa69224-88e3-4fc8-8b83-12460fd8554c/eBay%20v.%20MercExchange-07-06.pdf>.

103. *Id.*

104. Beckerman-Rodau, *supra* note 45, at 168; *see also* Ron A. Bouchard, *The Pas De Deux of Pharmaceutical Regulation and Innovation: Who's Leading Whom?*, 24 BERKELEY TECH. L.J. 1461, 1483 (2009) (“pharmaceutical companies have a vested interest in protecting the market on their most profitable drugs, and the primary means of doing so is via patenting”).

protected by trade secret law because the Food and Drug Administration will not approve a drug whose composition is a secret.<sup>105</sup> Competitors would also have the ability to reverse engineer the drug upon market entry.<sup>106</sup> Therefore, the rights of patent holders must be enforced for pharmaceutical companies to survive since it is their main source of intellectual property protection.

### III. ENFORCING THE INTEGRITY OF THE PATENT SYSTEM

Published surveys from 1986 and 2000 both concluded that the “pharmaceutical, biotechnology, and chemical industries rely more heavily on patents than other industries.”<sup>107</sup> These industries were able to rely on a strong patent system to protect their rights, but since *eBay* this reliance is no longer certain.<sup>108</sup> In determining whether to grant or deny a patent injunction in a pharmaceutical case, the public interest factor has become the most important factor because there are sound arguments for each side. It is important for the public to receive cheaper medications, but it is also important that the integrity of the patent system be enforced. Patents give inventors the right to exclusivity; however this exclusivity may come at a cost.<sup>109</sup> Such exclusivity “may prevent research from being conducted, delay research results from being disseminated, prevent processes and methods from being used, require innovators to spend resources avoiding infringement, and result in expensive patent litigation.”<sup>110</sup> Although it seems these are high costs for exclusivity, these costs are justified “because the patent system increases innovation.”<sup>111</sup>

#### A. Why the Public Interest Factor is Important

The *eBay* decision has done little to clarify to courts how to apply each the factor and the weight they should be given. Requiring courts to apply the four-factor injunction test gives courts too much discretion in denying permanent injunctive relief.<sup>112</sup> While the public interest may seem

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105. See Requirements On Content And Format Of Labeling For Human Prescription Drug And Biological Products, 21 C.F.R. § 201.56 (2015).

106. See Arvind K. Bansal & Vishal Koradia, *The Role of Reverse Engineering in the Development or Generic Formulations*, 29 PHARMACEUTICAL TECH., no. 8, 1 (2005).

107. Chien, *supra* note 99, at 865.

108. See Holte, *supra* note 15, at 682 (“injunction grants have gone from pre-*eBay* rates of 94%–100% to post-*eBay* rates of 73% for all patent owners and 16% for patentees that do not practice the patents they own”).

109. Burger, *supra* note 22, at 1.

110. *Id.*

111. *Id.*

112. See generally James M. Fischer, *The Right to Injunctive Relief for Patent Infringement*, 24 SANTA CLARA HIGH TECH. L.J. 1 (2007); Peterson, *supra* note 36, at 197 (“although the equitable factors provide courts with flexibility in their analysis, that same flexibility renders futile any attempt to

less important in other cases, cases involving pharmaceutical development requires a closer look at public interest since the inventions being produced are directly for the health of the public.<sup>113</sup> Furthermore, public interest is better served by promoting innovation driven by a robust patent system than by the potential short-term benefits to consumers.<sup>114</sup> Thus, the possibility of the public saving money from a generic drug that is infringing upon a valid patent does not establish a persuasive public need.<sup>115</sup>

Biotechnology and pharmaceutical cases alike “usually involve a single component patent,” meaning, “an entire firm’s viability often depends on one invention,” which results in a greater need for injunctive relief to protect research and development costs.<sup>116</sup> Because the business model of pharmaceutical companies primarily relies on a few or even one “blockbuster drug” for the majority of their profits, termination of a single patent, whether by expiration or infringement, would reduce their profits substantially.<sup>117</sup>

Taking a promising drug candidate through development, clinical trials, and onto the market is a notoriously expensive and high-risk gamble. Only a small fraction of the drug candidates in which pharmaceutical companies invest become commercially successful products. Drug companies spend millions, even hundreds of millions of dollars on a promising drug candidate only to find out that the compound lacks the safety and efficacy profile necessary to meet the stringent standards of FDA approval.<sup>118</sup>

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compare the analysis of the various courts based on the four factors”); *see also* Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 664 (2011) (criticizing the decision in *eBay* as the Supreme Court once again rejecting a relatively bright line rule in favor of a more flexible standard which permits the court more discretion to consider the facts presented).

113. *See generally* Jay Dratler Junior, *eBay’s Practical Effect: Two Differing Visions*, 2 AKRON INTELL. PROP. J. 35, 44-45 (2008) (“It also makes a difference, for example, that an injunction would deprive the public of a medicine, medical test, or medical device that the patentee is not yet ready to produce . . . If the Court’s decision means anything, it requires individual assessment of the four equitable factors on the facts of the case, not hand-waving on abstract principle”).

114. Diner, *supra* note 98.

115. *See generally* Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (holding that “Selling a lower priced product does not justify infringing a patent”) (quoting Payless Shoesource, Inc. v. Reebok Int’l Ltd., 998 F.2d 985, 991 (Fed. Cir. 1993)).

116. Engey Elrefaie, Note, *Injunctive Relief Post Ebay and the Various Applications of the Four-Factor Test in Differing Technological Industries*, 2 HASTINGS SCI. & TECH. L.J. 219, 221, 229 (2010). The Pharmaceutical Research and Manufacturers of America, a nonprofit association representing pharmaceutical and biotech companies, submitted an amicus brief in *eBay v. MercExchange* which focused on the importance of protecting patent rights in the pharma and biotech industries given the time and financial expenses of developing drugs, which can last up to 15 years. *Id.* at 223.

117. Ho, *supra* note 4, at 428.

118. Holman, *supra* note 112, at 649.

The *Johnson & Johnson* case illustrates that public interest does not tip in a certain direction.<sup>119</sup> While maintaining a strong patent system is a public interest that favors injunctions, some believe product diversity and availability can require the denial of an injunction.<sup>120</sup> The deciding factor in public interest cases should address the technology at issue. While the public interest factor is extremely important in pharmaceutical cases, public interest is certainly less important in other industries.<sup>121</sup> For example, if the case involves the invention of a new software program versus the development of a new life-saving drug, the public suffers little to no harm from an injunction involving software, whereas there can be significant repercussions in halting the production of a life-saving drug.

“The pharmaceutical industry relies heavily on patent rights to protect [the] creation of innovative medicines” because they can easily “be reverse-engineered and copied.”<sup>122</sup> Inventors lose the incentive to disclose their inventions if the patent scheme allows infringers to take patented pharmaceuticals without the relief of an injunction.<sup>123</sup>

The pharmaceutical company exerts all their resources to formulate and pass government inspections of a new drug only for a different company to easily reverse engineer the product. Because of the simplicity in bringing the drug to market from the infringer, the company is able to sell the drug for a much lower price, attracting the consumer, and reaping the benefits of the patentee’s work. Without the threat of an injunction, the infringer is more likely to participate in these deceptive practices because they can get away with paying the minimal damages for infringement and continue to benefit from the sale of the new drug.

Therefore, as far as public interest is concerned, “[t]he public maintains an interest in protecting the rights of patent holders as well as enforcing adequate remedies for patent infringement,” and “[p]ermanent injunctions serve that interest.”<sup>124</sup>

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119. See *supra* Section II.C.

120. Mark J. Feldstein, *Permanent Injunctions and Running Royalties in a Post eBay World*, FINNEGAN (Sep. 1, 2009), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=9ab31765-b1b2-43ac-b4fe-01a5477485a6>.

121. *Id.* (“While injunctions have been denied for some medical devices based on strong public interest considerations, in other cases there was no public interest in dual computer screen display or entertaining technology that outweighed the importance of a strong patent system. The public’s continued access to existing products, e.g., Microsoft® Word, has also been found to weigh against injunction”).

122. Beckerman-Rodau, *supra* note 45, at 206–07.

123. William R. Everding, “*Heads-I-Win, Tails-You-Lose*”: *The Predicament Legitimate Small Entities Face Post Ebay and the Essential Role of Willful Infringement in the Four-Factor Permanent Injunction Analysis*, 41 J. MARSHALL L. REV. 189, 217 (2007).

124. *Id.* (quoting *Commonwealth Sci. & Indus. Research Org. v. Buffalo Tech., Inc.*, 492 F. Supp. 2d 600, 607 (E.D. Tex. 2007)).

Those in favor of denying injunctive relief believe patent owners would be able to obtain remedies at law “via monetary awards, reasonable royalties, or compulsory licenses.”<sup>125</sup>

However, even if a court were to award damages in the form of an ongoing royalty payment instead of granting the pharmaceutical firm an injunction, it is highly unlikely that the court or jury will choose to, or even be able to, award exactly the monopoly price the pharmaceutical firm would have made as an award for damages.<sup>126</sup> The company will make less money regardless of if the court sets the royalty at a level higher or lower than the monopoly price, than if it were awarded an injunction.<sup>127</sup> Therefore, it is reasonably evident “that the pharmaceutical firm will receive less than what they expected when they chose to innovate. The result [here] is that *eBay* [has had] a dampening effect on innovation in the pharmaceutical industry.”<sup>128</sup> Without the threat of an automatic injunction, pharmaceutical companies could lose substantial leverage in negotiations.<sup>129</sup>

## B. Misapplication

There are inconsistencies in how the public interest factor has been applied throughout courts over time. Specifically, courts are split on how the public interest is served in granting permanent injunctions in pharmaceutical cases.<sup>130</sup>

The *eBay* decision has done little to clarify to courts how to apply each factor and the weight they should be given.<sup>131</sup> “The public interest factor is

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125. Wyatt, *supra* note 21, at 321.

126. See Jeremiah S. Helm, *Why Pharmaceutical Firms Support Patent Trolls: The Disparate Impact of eBay v. MercExchange on Innovation*, 13 MICH. TELECOMM. & TECH. L. REV. 331, 342 (2006); see also Theresa Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT’L LAW 835, 837 (1996) (“[t]he government can grant the inventor an exclusive right to monopolize the invention for a period of time, in exchange for disclosure of the invention to the public. The U.S. patent system is a good example of providing inventors with limited monopoly in exchange for full disclosure of their inventions.”).

127. Helm, *supra* note 126. By owning a patent to a pharmaceutical, the firm basically has a monopoly to the extent that the patent is valid. By having a monopoly, the company is able to charge a monopoly price on the pharmaceutical. *Id.* By definition, the monopoly price is profit maximizing and any other price other than the monopoly price leads to a decrease in profit. *Id.* at 342 n.72.

128. *Id.* at 342.

129. See generally *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (2005); see also Diner, *supra* note 98 (“[P]layers in the biopharmaceutical industry most heavily hit by the Supreme Court’s decision will be the smaller companies looking to license their patented innovations. Without the threat of an automatic permanent injunction, they will certainly see a substantial erosion of their leverage in negotiations to license their patents”).

130. See *supra* Part II.

131. See Myers, *supra* note 68 (Due to the Supreme Court’s failure to provide guidance as to how to apply the test, district courts may apply factors differently, resulting in conflicting holdings). “[A]s a result of the Supreme Court’s lack of guidance, decisions on whether to grant injunctive relief have been inconsistent across districts.” *Id.* at 351.



being pulled in two [different] directions: the public interest is in a patent system that maintains incentives for innovation [versus] the public interest [being] served by denying injunctions in order to permit public access to an invention.”<sup>132</sup>

In *Amgen, Inc. v. F. Hoffman La Roche Ltd.*, the court interpreted the public interest factor as “a robust patent system that maintains incentives for pharmaceutical innovation [which] outweighs the highly speculative” benefits that “might occur” from a denial of an injunction.<sup>133</sup> Whereas in other cases, the public interest factor has been interpreted in the opposite way. The Southern District of New York believed “[e]njoining the release of a new and less invasive treatment for diabetes would quite obviously be contrary to the public interest.”<sup>134</sup> Here, the court found that the public interest weighed in favor of a denial of the motion for an injunction.<sup>135</sup>

The most recent analyses of *eBay* occurred in 2017, when the District of Delaware granted Amgen’s request for a permanent injunction against Regeneron’s PCSK9-inhibitor cholesterol drug.<sup>136</sup> Both parties spent billions of dollars and over a decade of work to bring the cholesterol drugs to market.<sup>137</sup> In granting the motion, Judge Robinson focused on the four *eBay* factors, concluding that the “irreparable injury” and “remedy” factor both weighed in favor of Amgen,<sup>138</sup> while the balance of hardships was neutral to both parties.<sup>139</sup> The court found itself to be “between a rock and a hard place” concerning the public interest factor,<sup>140</sup> but ultimately decided “the public is generally better served by having a choice of available treatments.”<sup>141</sup> The court lacked an analysis of the opposing benefits of the two pharmaceuticals, where Regeneron offered a lower dose, and how that supersedes the basis of patent system.<sup>142</sup> Despite finding that an injunction would “disserve” the public interest, the injunction was granted.<sup>143</sup>

On appeal, the Federal Circuit held that the District Court’s analysis was improper for two reasons.<sup>144</sup> First, the district court misapplied *eBay*,

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132. Jack Brodsky, Note, *The Health of ebay: The Impact of ebay on the Future of Trips—Like Pharmaceutical Compulsory Licenses in the United States*, 41 AM. J.L. & MED. 656, 670 (2015).

133. *Amgen, Inc. v. F. Hoffman La Roche Ltd.*, 581 F. Supp. 2d 160, 210 (D. Mass. 2008).

134. *Novo Nordisk A/S v. Pfizer Inc.*, No. 06 CIV. 5819 (LBS), 2006 WL 3714312, at \*6 (S.D.N.Y. Dec. 14, 2006).

135. *Id.* at \*7.

136. *Amgen Inc. v. Sanofi*, No. CV 14-1317-SLR, 2017 WL 61725, at \*1 (D. Del. Jan. 5, 2017).

137. *Id.* at \*3.

138. *Id.* at \*2-3.

139. *Id.* at \*3.

140. *Id.*

141. *Id.*

142. *Id.* at \*1.

143. *Id.* at \*3.

144. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (quoting *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)) (emphasis added).

because in *eBay* the Supreme Court held that “[a] plaintiff seeking a permanent injunction *must satisfy* a four factor test before a court may grant such relief. A plaintiff *must demonstrate* . . . that the public interest would not be disserved by a permanent injunction.”<sup>145</sup> The district court improperly applied this analysis, because although the district court found that issuing a permanent injunction would disserve the public interest, the injunction was still granted.<sup>146</sup> This, according to the Federal Circuit, is a “clear violation of *eBay*.”<sup>147</sup>

Furthermore, the Federal Circuit declared that the district court’s analysis of the “public interest” was in error.<sup>148</sup> The district court ultimately decided that the public interest of having a choice of drugs should prevail, and the effect of an injunction would be to “tak[e] an independently developed, helpful drug off the market,” disserving the public interest.<sup>149</sup> According to the Federal Circuit, under this approach a court could never enjoin an infringing drug because it would always involve taking a helpful drug off the market.<sup>150</sup> Therefore the court decided to vacate the permanent injunction and remand for further proceedings.<sup>151</sup>

The public interest factor has been described as a “wild-card, which, under certain yet to occur conditions, may trump direct competition.”<sup>152</sup> Unpredictability in patent law acts as a “disincentiv[e] to investment in innovation, particularly in the pharmaceutical sector,” and decreased investments transform into “decreased output of innovative products from the drug pipeline.”<sup>153</sup> Therefore, as long as the Court remains ambiguous in its interpretation of not only the public interest factor, but the remaining factors as well, the pharmaceutical industry will continue to lose investments to support research and development of new drugs.

#### IV. PROPOSAL

Ideally, for the pharmaceutical industry, the Court would return to the “categorical approach” of issuing permanent injunctions once the patent was found to be both valid and infringed. However, as long as the four-factor analysis is still in use, the courts should place more emphasis on the public interest factor in pharmaceutical cases than in any other industry because the public is best served when the court grants

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145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.*

151. *Id.* at 1382.

152. Brodsky, *supra* note 132.

153. Holman, *supra* note 112, at 661, 646.

permanent injunctions in pharmaceutical patent infringement cases. “Scholars note, ‘[n]owhere is the impact of [intellectual property protection] more clearly evident than in the pharmaceutical industry, where discovery costs for products are high, but reproduction costs are low.’”<sup>154</sup>

“[P]atent protection is . . . essential for the promotion of research and development of innovative medicines.”<sup>155</sup> However, the patent system should be receptive to the fundamental importance of novel medications to public health, including the ability to afford and access medicine to those in need.<sup>156</sup> Evidence shows patents encourage innovation by creating strong incentives to invent topnotch products that improve previous medications.<sup>157</sup> Since the tradeoff of these incentives is so multifaceted, the United States has not issued an opinion yet attempting to balance the incentives to innovate with supporting public health.<sup>158</sup>

#### A. Permanent Injunctions Should be Granted in Pharmaceutical Patent Infringement Cases

As a consequence of the *eBay* decision, the frequency of permanent injunctions as a remedy for patent infringement suits has significantly decreased.<sup>159</sup> Courts have consistently become more “hesitant to deny injunctive relief when the parties to litigation are direct competitors.”<sup>160</sup>

In deciding patent infringement cases, courts should not only weigh the public interest factor more heavily than the other three remaining factors in cases involving pharmaceuticals, but should also consider the public interest of protecting the rights of the patentee over the convenience of cheaper drugs to the public. The public interest factor should “favor the patentee, given the public’s interest in maintaining the integrity of the patent system.”<sup>161</sup> “From ancient times, law and social conventions have supported the right to exclude—a fundamental component of the concept of personal and real property.”<sup>162</sup> Those investing in the production of goods are thus able to

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154. Brodsky, *supra* note 132 (quoting Richard P. Rozek & Ruth Berkowitz, *The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?*, 1 J. WORLD INTELL. PROP. 179, 179 (1998)).

155. *Id.*

156. *Id.*

157. *Intellectual Property, Unlocking the Cures of Tomorrow*, EUR. FED. OF PHARMACEUTICAL INDUSTRIES AND ASS’NS, <https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/> (last visited Nov. 29, 2017).

158. Brodsky, *supra* note 132, at 670-71.

159. *Id.* at 671.

160. *Id.* at 668.

161. *MercExchange LLC. v. eBay, Inc.*, 500 F. Supp. 2d 556, 586 (E.D. Va. 2007) (quoting *Odetics Inc. v. Storage Tech. Corp.*, 14 F. Supp. 2d 785, 795 (E.D. Va. 2007)).

162. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 193, 198 (2005).

procure a return for their efforts given that the law creates a property right in that which is produced.<sup>163</sup>

In *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs*, the Federal Circuit held that the district court did not abuse its discretion in relying heavily on the public interest factor.<sup>164</sup> Brand-name drug companies lose a majority of their sales to the generic equivalent upon generic entry.<sup>165</sup> There is a greater public interest in protecting companies that expect to regain their investment when using substantial resources to innovate new drugs.<sup>166</sup>

This point is further supported by the amici briefs filed by those in favor of permanent injunctions in *eBay v. MercExchange*. Companies such as General Electric, 3M, Procter & Gamble, E.I. Du Pont De Nemours and Company, and Johnson & Johnson filed briefs for the court in favor of the respondents, eBay, relying on the huge investment in research and development in the biotechnology and pharmaceutical in their argument.<sup>167</sup> The briefs explain that “this industry bases its practices on the understanding that an enforceable right to exclude others is inherent to the patent” and argued that the “industry’s investments and future incentives to continue investing would be greatly reduced” if denied automatic equitable relief.<sup>168</sup> The Pharmaceutical Research and Manufacturers of America (“PhRMA”) subsequently filed their brief with the court arguing that they had a strong interest in protection by injunctions to ensure “future innovation and the timely development of new medicines.”<sup>169</sup> Furthermore, the protection of patents in this field would also help patentees recoup their rather costly investments, which, with a lack of incentive, “would ‘negatively impact the amount of research and development resources available to member companies’ and ‘negatively impact public health and welfare.’”<sup>170</sup>

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163. *Id.*

164. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1192 (Fed. Cir. 2012).

165. Maria Salgado, *Economics of Irreparable Harm in Pharma Patent Litigation*, LAW360 (Nov. 18, 2013, 2:13 PM), <http://www.law360.com/articles/489198/economics-of-irreparable-harm-in-pharma-patent-litigation>. Without intellectual property laws, inventors would incur all research costs, including failures, and generic drug companies, “free riders,” would benefit from significantly lower cost structures. Outterson, *supra* note 162, at 200–01.

166. John C. Paul, *Court Enjoins Infringing Drug Seller Despite Previously Denying a Preliminary Injunction and Payments by Patent Owner to its Exclusive Licensee to Offset Harm of a Generic Drug Entering the Market*, FINNEGAN (Feb. 27, 2012), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=875debf6-9847-4a11-86b1-676f4f8233da>.

167. Elrefaie, *supra* note 116, at 222.

168. *Id.*

169. *Id.* at 223 (quoting Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Respondent, *eBay, Inc. et al. v. MercExchange, L.L.C.*, 547 US 388 (2006) (No. 05-130), 2006 WL 622122 at 2).

170. *Id.* (quoting Brief for Biotechnology Industry Organization as Amicus Curiae in Support of Respondent, at 1).

The process of discovering, researching, and developing a new pharmaceutical typically takes 12-15 years.<sup>171</sup> Unlike other fields inventing new products, bringing pharmaceuticals to market requires a showing of both safety and efficacy through costly clinical trials.<sup>172</sup> Even so, pharmaceuticals that are successful in terms of safety and efficacy return an income stream that is greater than the cost of their research and development only every two out of ten times.<sup>173</sup> Absent intellectual property rights and the ability of pharmaceutical firms to price their products above marginal manufacturing costs, “no investor . . . would spend the [resources] to discover and develop this information,” which has taken “many years and hundreds of millions of dollars to obtain.”<sup>174</sup> It is imperative that there be enough incentive to induce research and development activities.<sup>175</sup>

By allowing the pharmaceutical company the exclusive right to exclude, they can set the price of the new drug at a cost that will allow them to recoup the damages lost in the developmental stages. Although the price may be high for consumers, this incentive encourages the inventors to create more life-saving pharmaceuticals to help the public. Without the incentive, innovation would cease, and the public would suffer because no one would want to exhaust their resources in creating a new drug only to have it taken away from them by generic drug companies.

Without protection, pharmaceutical companies would terminate investment in drug development. Companies producing generic drugs contribute nothing to innovation.<sup>176</sup> They do, however, take 90% of sales away from the brand-name drug makers who have risked the time and money to bring breakthrough treatments to the market.<sup>177</sup> Only two out of ten newly approved drugs will be profitable.<sup>178</sup> The profits must fund all the failed research programs as well as drugs that were launched and lost money.<sup>179</sup>

A strong patent system encourages both innovation and consequent generic competition. Without new products and cures continually entering the market, the industry would not prosper, leaving the public in a severely

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171. John A. Vernon, *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 AM. J.L. & MED. 175, 183 (2006).

172. WAYNE WINEGARDEN, *THE ECONOMICS OF PHARMACEUTICAL PRICING*, PAC. RES. INST. 5 (2014), <http://www.pacificresearch.org/wp-content/uploads/2017/06/PhamaPricingF.pdf>.

173. *Id.*

174. Vernon, *supra* note 171.

175. *Id.*

176. Josh Bloom, *Should Patents on Pharmaceuticals Be Extended to Encourage Innovation?*, WALL STREET J. (Jan. 23, 2012), <http://www.wsj.com/articles/SB10001424052970204542404577156993191655000>.

177. *Id.*

178. *Id.*

179. *Id.*

detrimental state.<sup>180</sup> By weighing the public interest factor in favor of the patentee's rights in pharmaceutical infringement cases, the public is best served.

## V. CONCLUSION

The Supreme Court's decision in *eBay v. MercExchange* gave courts more flexibility in granting and denying injunctions as courts must now make this decision by balancing four equitable factors.<sup>181</sup> One of these factors is whether the "public interest would not be disserved by permanent injunction."<sup>182</sup> This factor should be of the most significance in deciding the grant or denial of an injunction in pharmaceutical patent infringement cases. Not only is this factor the most significant in this type of case, but also it should be interpreted to favor the rights of the patentee as serving the public interest.

The patent system was put into place to provide a benefit to society by granting the inventor a period of market exclusivity for the invention.<sup>183</sup> Allowing generic companies to infringe upon valid patents without the guarantee of an injunction completely undermines the purpose of this system.<sup>184</sup> There is no doubt that the public would benefit from lower cost drugs through generic entry into the marketplace. However, these life-saving drugs would have never been created if not for the time and money afforded by pharmaceutical companies to develop name brand drugs. The market exclusivity granted by a patent allows pharmaceutical companies to recover the billions of dollars spent on research and developmental phases. Granting injunctions on the infringement of valid patents best serves the public by reinforcing patent rights, including exclusivity.

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180. Harvey E. Bale, Jr., *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. INT'L L. & POL. 95, 97 (1997).

181. *See supra* Part I.

182. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

183. Tiedemann, *supra* note 19.

184. *Id.* ("[T]he patent system promotes innovation by requiring public disclosure while compensating the inventor with certainty of protection against unauthorized use of the invention").