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Reports of Its Death Are Greatly Exaggerated: eBay, Bosch, and the Presumption of Irreparable Harm in Hatch-Waxman Litigation

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Keywords

patent infringement, pharmaceuticals, Hatch-Waxman, ebay

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**Reports of Its Death Are Greatly
Exaggerated: *eBay*, *Bosch*, and the
Presumption of Irreparable Harm
in Hatch-Waxman Litigation**

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Abstract

This Article examines the preliminary injunction standard in pharmaceutical patent infringement actions pursuant to the Hatch-Waxman Act. Prior to Supreme Court’s decision in *eBay v. MercExchange, L.L.C.* in 2006, federal courts applied a presumption of irreparable harm when a patent holder established a likelihood of success on the merits. While the *eBay* Court abrogated the presumption of irreparable harm in permanent injunctions, courts have been unclear as to application of *eBay* on preliminary injunctions. This Article will further examine preliminary injunctions in Hatch-Waxman actions in the District of New Jersey since *eBay* in 2006 and argue that courts still tacitly apply the irreparable harm presumption.

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INTRODUCTION

In 2010, sales of prescription drugs in the United States totaled over \$300 billion.¹ In the same year, sales of generic drugs were valued at \$78 billion.² Six of the world's ten largest pharmaceutical companies are based in the United States.³ Approximately eighty percent of the world's research in biotechnology and pharmaceuticals are conducted by

¹ Brittany Hart, *Pharmaceutical Sales Top \$300 Billion in 2010*, DAYTON BUS. J. (Apr. 19, 2011, 2:58 PM), <http://www.bizjournals.com/dayton/news/2011/04/19/pharmaceutical-sales-top-300-billion.html>.

² *The Pharmaceutical Industry in the United States*, SELECTUSA, <http://selectusa.commerce.gov/industry-snapshots/pharmaceutical-industry-united-states> (last visited Feb. 5, 2014).

³ *Pharmaceutical Industry*, WORLD HEALTH ORG., <http://www.who.int/trade/glossary/story073/en/index.html> (last visited Feb. 5, 2014).

American pharmaceutical companies.⁴ In other words, the drug business is big business in America.

The pharmaceutical industry can be roughly divided into two categories; brand name manufacturers, also called “innovator companies,” and generic manufacturers.⁵ Generic drugs are bioequivalent⁶ versions of brand name medication and present significant savings to consumers.⁷ The development cost of a generic drug is much lower in comparison to that of a brand name drug.⁸ The process of research and clinical trials for a new drug usually takes ten to fifteen years and can cost an innovator company upwards of \$800 million.⁹ Brand name medications are protected by patents and the process in which generic drugs enter the market is governed by the Hatch-Waxman Act.¹⁰

The Hatch-Waxman Act was passed with the

⁴ *The Pharmaceutical Industry in the United States*, *supra* note 2.

⁵ See *Greater Access to Generic Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143545.htm> (last visited Feb. 5, 2014).

⁶ Christopher J. Kochevar, Note, *Reforming Judicial Review of Bioequivalence Determinations*, 87 N.Y.U. L. REV. 2040, 2042 (2012) (“[B]ioequivalence’ [is] an approximation of identity between a generic drug and an approved innovator product.”).

⁷ *Greater Access to Generic Drugs*, *supra* note 5. (“[T]he average price for a prescription for a brand-name drug is \$84.20, while the average price for a generic drug prescription is \$30.56.”).

⁸ Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SC. & TECH. 441, 447 (2008).

⁹ *Id.* at 482.

¹⁰ *Greater Access to Generic Drugs*, *supra* note 5.

intention to give innovator companies additional incentives to develop new drugs while giving the American consumer savings by expanding the generics market.¹¹ Since the enactment of the Hatch-Waxman Act, the market share held by generic drugs has increased from under twenty percent in 1984 to nearly eighty percent in 2010.¹²

This Article will discuss the preliminary injunction factors as applied when an innovator company seeks to enjoin a generic maker from releasing a competing product during the course of litigation under the Hatch-Waxman Act. Specifically, this Article will argue that the presumption of irreparable harm, which was abrogated by the Supreme Court in *eBay, Inc. v. MercExchange, L.L.C.*, still exists even if the presumption is not explicitly applied. Part I will briefly discuss Federal jurisdiction in patent matters. Part II will discuss the four preliminary injunction factors and its development in patent law, including *eBay* and its subsequent line of cases. Part III will explain the historical context which led to the passage of the Hatch-Waxman Act and discuss in detail the process by which a generic drug is approved for market. Part IV will be a survey of pharmaceutical patent cases before the District of New Jersey since the *eBay* decision in 2006. This Article will conclude by arguing that the presumption of harm still exists,¹³ how a tacit application of the presumption is permissible under current law, and propose that

¹¹ See *infra* Part III.B.

¹² Liu, *supra* note 8, at 456; Karen von Koeckritz, *Generic Drug Trends – What’s Next?*, PHARMACY TIMES (Apr. 11, 2012), <http://www.pharmacytimes.com/publications/issue/2012/April2012/Generic-Drug-Trends-Whats-Next->.

¹³ This Article will only discuss the presumption of harm as it exists within the District of New Jersey.

Congress amend the Hatch-Waxman Act to allow for the presumption of harm in preliminary injunction determinations.

I. FEDERAL JURISDICTION IN PATENT MATTERS

Federal courts have original and exclusive jurisdiction in all matters “arising under any Act of Congress relating patents, . . . copyrights and trademarks.”¹⁴ Patents have been within the ambit of Federal jurisdiction since the earliest days of the Republic.¹⁵ In 1982, Congress created the United States Court of Appeals for the Federal Circuit as one of the provisions of the Federal Courts Improvement Act.¹⁶ The legislation gave the Federal Circuit exclusive jurisdiction over appeals from the district courts in patent cases.¹⁷ As a result, the new Federal Circuit’s jurisdiction in patent matters was much broader than that of one of the courts it replaced, the United States Court of Customs and Patent Appeals (CCPA).¹⁸ Previously, the CCPA only had jurisdic-

¹⁴ 28 U.S.C. § 1338(a) (2012).

¹⁵ See U.S. CONST. art. I, § 8; see also 8 DONALD S. CHISUM, CHISUM ON PATENTS § 21.02(1)(a)(i) (2013) (“Section 17 of the Patent Act of 1836 conferred jurisdiction without regard to amount over ‘all actions, suits, controversies, and cases arising under any law of the United States, granting or confirming to inventors the exclusive right to their inventions or discoveries.’”).

¹⁶ Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.).

¹⁷ 28 U.S.C. § 1295(a)(1) (2012); see also Joseph R. Re, *Brief Overview of the Jurisdiction of the U.S. Court of Appeals for the Federal Circuit Under § 1295(a)(1)*, 11 FED. CIR. B.J. 651, 654 (2001).

¹⁸ AM. BAR ASS’N, REPORT ON THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT 6-7 (2002), available at

tion over appeals from the United States Patent and Trademark Office.¹⁹ Prior to the creation of the Federal Circuit, patent suits filed in the district courts were appealed to the regional circuit courts.²⁰ Currently, circuit splits do not exist in patent law because all patent appeals are reviewed by the Federal Circuit.²¹

II. THE PRELIMINARY INJUNCTION STANDARD: PAST AND PRESENT

Congress has given courts power to “grant injunctions in accordance to the principles of equity” in patent cases.²² Courts use the traditional four equitable factors to determine whether a preliminary injunction is proper.²³

The first factor, likelihood of success on the merits, undergoes a two-step analysis in patent in-

http://www.morganlewis.com/pubs/2951F5BA-25A3-457D-B4B2CA99691EE6F1_Publication.pdf.

¹⁹ *Id.*

²⁰ *See, e.g.,* Eli Lilly & Co. v. Premo Pharm. Labs., Inc., 630 F.2d 120 (3d Cir. 1980).

²¹ *Cf.* Erin V. Klewin, Note, *Reconciling Federal Circuit Choice of Law with eBay v. MercExchange’s Abrogation of the Presumption of Irreparable Harm in Copyright Preliminary Injunctions*, 80 FORDHAM L. REV. 2113, 2118-23 (2012) (noting that in copyright matters, also affected by the holding in *eBay*, the Federal Circuit only has jurisdiction in pendant matters and applies regional circuit law in those cases).

²² 35 U.S.C. § 283 (2012).

²³ *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (citing *Reebok Int’l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994)) (“(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s favorable impact on the public interest.”).

fringement cases.²⁴ The plaintiff must establish that the defendant has infringed on the patent.²⁵ First, the court determines the scope of the patent claims.²⁶ Then, the allegedly infringing product is compared to see if it lies within the scope of the patent.²⁷ Under the doctrine of equivalents, a product may still be infringing if it performs in the same manner to achieve the same results as the original invention.²⁸

Further, the plaintiff must also establish that the patent can withstand the defendant's claim of invalidity.²⁹ Typically, defendants allege that the patented product is obvious, meaning the patent is invalid under 35 U.S.C. § 103(a).³⁰ Courts employ a four factor analysis in determining obviousness.³¹ The courts have also acknowledged that new inven-

²⁴ *Tate Access Floors, Inc. v. Interface Arch. Resources, Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002) (citing *Amazon.com*, 239 F.3d at 1351).

²⁵ *Id.*

²⁶ *Aventis Pharm., Inc. v. Barr Labs., Inc.*, 411 F.Supp.2d 490, 494 (D.N.J. 2006) (quoting *Amazon.com*, 239 F.3d at 1351).

²⁷ *Id.*

²⁸ *Syntex Pharm. Int'l, Ltd. v. K-Line Pharm., Ltd.*, 721 F.Supp. 653, 660-61 (D.N.J. 1989) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)).

²⁹ *See Tate*, 279 F.3d at 1365 (citing *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451).

³⁰ *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F.Supp.2d 666, 674 (D.N.J. 2007) *aff'g*, 566 F.3d 399 (Fed. Cir. 2009); *see also* 35 U.S.C. § 103(a) (2012).

³¹ *Id.* (citing *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1359 (Fed. Cir. 2007)) ("Factual determinations that are relevant to the obviousness inquiry are: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations or objective indicia of non-obviousness.").

tions are often built upon prior innovations.³² The Supreme Court has, on occasion, upheld patents comprised of knowledge of prior patents when the new patent aimed to solve a problem previously not apparent.³³

The second factor, irreparable harm, also called irreparable injury, is defined as “[a]n injury that cannot be adequately measured or compensated by money.”³⁴ In other words, an injury is irreparable if money damages at the conclusion of a trial are insufficient to make the plaintiff whole.³⁵ Professor Donald Chisum notes that courts have been inconsistent in irreparable harm determinations and “tend to find irreparable injury when the plaintiff makes a strong case of validity and infringement and to find no such injury when plaintiff makes only a weak case.”³⁶ This inconsistency will be discussed in depth further in this Article.³⁷

The balance of hardships generally weighs in favor of the innovator company in Hatch-Waxman litigation. When a generic is released, the innovator company suffers harm through price erosion and loss of market share.³⁸ Courts have been reluctant to weigh the factor in favor of defendants since any loss suffered by a generic maker incurred during the duration of the suit would simply be sales “time-

³² *Id.* (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418-20 (2007)).

³³ *Id.* (citing *KSR*, 550 U.S. at 419).

³⁴ BLACK'S LAW DICTIONARY 856 (9th ed. 2009).

³⁵ 7 CHISUM, *supra* note 15, at § 20.04(1)(e).

³⁶ *Id.*

³⁷ *See infra* Part IV.

³⁸ *See infra* text accompanying notes 153-54.

shifted” into the future.³⁹ Thus, the balance of hardships rarely weigh in favor of the generic maker.⁴⁰

Likewise, in Hatch-Waxman litigation, the public interest will generally weigh in favor of the plaintiff.⁴¹ Innovator companies often advance the argument that the public interest is served when the patent rights are enforced to exclude generic makers during the patent’s term of exclusivity.⁴² Further, they also argue that profits generated during the exclusivity period fund research benefiting newer medications.⁴³ Generic makers will often argue that the public interest is best served when the public has access to lower cost medication.⁴⁴ However, the Federal Circuit has been clear that the enforcement of patent rights outweighs the public’s access to more affordable medication.⁴⁵

³⁹ Albany Molecular Research, Inc. v. Dr. Reddy’s Labs., Inc., No. 09-4638 (GEB-MCA), 2010 WL 2516465, at *11 (D.N.J. June 14, 2010).

⁴⁰ King Pharm., Inc. v. Sandoz, Inc., No. 08-5973 (GEB-DEA), 2010 WL 1957640, at *1, 6 (D.N.J. May 17, 2010) (explaining that when a prior TRO enjoining the defendant from releasing a generic was dissolved when the plaintiff’s authorized generic maker released their version early, the court weighed the balance of the hardships in favor neutrally because the defendant’s exclusivity period as the first generic maker under the Hatch-Waxman Act had been encroached upon, and denied the preliminary injunction).

⁴¹ See, e.g., Pfizer, Inc. v. Teva Pharm. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (The Hatch-Waxman Act does not “encourage or excuse the infringement of infringing valid pharmaceutical patents.”).

⁴² Novartis Pharm. Corp. v. Teva Pharm. USA, Inc. (*Novartis I*), No. 05-CV-1887 (DMC), 2007 WL 2669338, at *15 (D.N.J. Sept. 6, 2007).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Pfizer, Inc. v. Teva Pharm. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (quoting Payless Shoesource, Inc. v. Reebok

A. *The Presumption of Irreparable Harm Prior to eBay*

Soon after its establishment, the Federal Circuit held that a plaintiff is entitled to a presumption of irreparable harm when it establishes a likelihood success on the merits.⁴⁶ The court further elaborated in a subsequent case that the presumption is derived “in part from the finite term of the patent grant, for patent expiration is not suspended during litigation.”⁴⁷ The value of the patent is based on exclusivity and monetary damages are insufficient to make up for lost exclusivity.⁴⁸

However, the Federal Circuit also held that presumption of irreparable harm was a rebuttable presumption.⁴⁹ The *Reebok* case illustrates an instance when the presumption of irreparable harm was rebutted through evidence.⁵⁰ In November 1992, Reebok began manufacturing and selling the SHAQ I shoe and heavily promoted the shoe with basketball great Shaquille O’Neal.⁵¹ Over a year later in December 1993, a patent was issued protecting the design of the shoe.⁵² As soon as the patent was issued, Reebok served a complaint on J. Baker alleging that their Olympian shoe infringed on the design of the

Int’l, Ltd., 998 F.2d 985, 991 (Fed. Cir. 1993)) (“Selling a lower priced product does not justify infringing a patent.”).

⁴⁶ 7 CHISUM, *supra* note 15, at § 20.04(1)(c)(iii)(e)(i) (citing Smith Int’l, Inc. v. Hughes Tool Corp., 718, F.2d 1573 (Fed. Cir. 1983)).

⁴⁷ *Id.* (quoting H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 390 (Fed. Cir. 1987)).

⁴⁸ *Id.*

⁴⁹ *Id.* (quoting Ill. Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 681 (Fed. Cir. 1990)).

⁵⁰ Reebok Int’l v. J. Baker, Inc., 32 F.3d 1552 (Fed. Cir. 1994).

⁵¹ *Id.* at 1554.

⁵² *Id.*

SHAQ I.⁵³ J. Baker had been manufacturing and selling the Olympian shoe since July 1993.⁵⁴

The district court denied Reebok's motion to enjoin J. Baker from selling their remaining inventory of the Olympians.⁵⁵ The Federal Circuit affirmed the district court's decision because J. Baker presented sufficient evidence to rebut the presumption that Reebok would suffer irreparable harm.⁵⁶ J. Baker had established that Reebok had discontinued the SHAQ I in favor a newer shoe, the SHAQ II.⁵⁷ The court reasoned that future purchasers of the Olympians "would not likely confuse that shoe" with the SHAQ I because Reebok had ceased all manufacture and promotion of the shoe.⁵⁸ Because J. Baker only had a limited supply of the Olympians, any harm Reebok would have suffered could be sufficiently compensated by money damages.⁵⁹ Thus, J. Baker was successful in rebutting Reebok's presumption of harm and the district court properly denied a preliminary injunction to Reebok.⁶⁰ However, Reebok is the exception rather than the rule; plaintiffs who establish a likelihood of success on the merits often succeed in enjoining the infringing party.⁶¹

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

It is commonly understood that the holding in

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.* at 1558.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 1559.

⁶¹ See *supra* text accompanying note 36; see also discussion *infra* Part IV.

eBay eliminated the presumption of irreparable harm in preliminary injunction determinations.⁶² However, the issue before the Supreme Court in *eBay* was a permanent injunction and neither preliminary injunctions nor the presumption of irreparable harm were explicitly mentioned.⁶³

MercExchange patented a process that “facilitate[d] the sale of goods between private individuals by establishing a central authority to promote trust among participants” in an online marketplace.⁶⁴ *eBay* and Half.com, its subsidiary, had been negotiating with MercExchange to purchase its technology but the talks broke down.⁶⁵ After the cessation of the negotiations, MercExchange filed a patent infringement suit against *eBay*.⁶⁶

A jury found at trial that MercExchange’s patent was valid, *eBay* had infringed on their patent, and awarded damages to the plaintiff.⁶⁷ However, the district court denied permanent injunctive relief to MercExchange.⁶⁸ The Federal Circuit reversed, citing to its general rule that courts will issue a per-

⁶² See, e.g., *Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, No. 03-4678 (SRC), 2009 WL 2182665, at *9 (D.N.J. July 22, 2009) (“[T]he Court is of the view that the presumption of irreparable harm did not survive the Supreme Court’s decision in [*eBay*].”) (citation omitted); Klewin, *supra* note 21, at 2129-30.

⁶³ *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390 (2006).

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*; Miranda Jones, Note, *Permanent Injunction, a Remedy by Any Other Name is Patently Not the Same: How eBay v. MercExchange Affects the Patent Right of Non-Practicing Entites*, 14 GEO. MASON L. REV. 1035, 1054-55 (2007) (explaining the dispute arose from MercExchange alleging that *eBay*’s “Buy it Now” feature infringed their patents).

⁶⁷ *eBay*, 547 U.S. at 390-91.

⁶⁸ *Id.*

manent injunction “once infringement and validity have been adjudged.”⁶⁹

Justice Thomas enunciated that courts should not depart from traditional notions of equity without legislative authorization.⁷⁰ Justice Thomas further cited to specific language in 35 U.S.C. § 283 revealing the legislative intent not to stray from equitable principles.⁷¹ Having rejected the Federal Circuit’s general rule favoring permanent injunctions, the case was remanded for proceedings consistent with the traditional four part analysis for injunctive relief.⁷² When the matter was remanded to the lower courts eBay refused to settle.⁷³ By 2008, eBay had purchased the patent and related technologies from MercExchange.⁷⁴

C. Confusion and Clarity After eBay

The Supreme Court was not clear as to whether its holding in *eBay* applied to the irreparable harm presumption in preliminary injunctions.⁷⁵ The Federal Circuit did not bring clarity when it sidestepped

⁶⁹ *Id.* at 393-94 (quoting *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005)) (internal quotations omitted).

⁷⁰ *Id.* at 391-92.

⁷¹ *Id.*

⁷² *Id.* at 394.

⁷³ Ina Steiner, *eBay v MercExchange Patent War: It’s Over*, ECOMMERCEBYTES.COM (Feb. 28, 2008), <http://www.ecommercebytes.com/cab/abn/y08/m02/i28/s00>.

⁷⁴ *Id.*

⁷⁵ *eBay*, 547 U.S. at 394 (“We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.”).

the irreparable harm presumption in one of its first patent decisions post-*eBay*.⁷⁶ In *Abbott*, the court vacated a preliminary injunction and reversed the district court's irreparable harm determination.⁷⁷ The court reasoned that Abbott was not entitled to a finding of irreparable harm on the basis that Abbott failed to establish the first factor.⁷⁸ While acknowledging the holding of *eBay*, the Federal Circuit was not clear as to the survival of the irreparable harm presumption.⁷⁹ Without offering additional reasons as to why Abbott was denied a finding of irreparable harm, the Federal Circuit did not fully decouple the first two preliminary injunction factors.⁸⁰

The Federal Circuit sidestepped the presumption of harm issue for a second time in *Sanofi-Synthelabo v. Apotex, Inc.*⁸¹ Apotex argued that the trial court erred in applying the presumption of irreparable harm contrary to the holding in *eBay*.⁸² The Federal Circuit reasoned that Sanofi had established irreparable harm and declined to rule on the

⁷⁶ See *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331 (Fed. Cir. 2006).

⁷⁷ *Id.* at 1347-48.

⁷⁸ *Id.* at 1347.

⁷⁹ *Id.* (“[W]e conclude that Abbott has not established a likelihood of success on the merits. As a result, *Abbott is no longer entitled to a presumption of irreparable harm.*”) (emphasis added).

⁸⁰ See *id.*

⁸¹ *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006).

⁸² *Id.* at 1383, n.9 (“Apotex contends that applying such a presumption is in direct contravention of the Supreme Court’s decision in *eBay Inc. v. MercExchange, L.L.C.* Because we conclude that the district court did not clearly err in finding that Sanofi established several kinds of irreparable harm, including irreversible price erosion, we need not address this contention.”) (citations omitted).

presumption.⁸³ In 2008, Federal Circuit declined to rule on presumption of harm for the third time in *Amado v. Microsoft Corporation* stating it was unnecessary for the court to make a definitive ruling on the issue.⁸⁴

The lack of a clear ruling from the Federal Circuit led to confusion among the district courts.⁸⁵ Some courts continued to apply the presumption of harm noting that *eBay* only applied to permanent injunctions.⁸⁶ Others ruled that *eBay* had eliminated the presumption.⁸⁷ There is even an instance where a court ruled that eBay had eliminated the presumption but declined to apply the presumption only because the plaintiff failed to establish success on the merits.⁸⁸

In 2011, the Federal Circuit finally announced

⁸³ *Id.*

⁸⁴ *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1359 n.1 (Fed. Cir. 2008) (“We find it unnecessary to reach this argument, however, because *regardless of whether there remains a rebuttable presumption of irreparable harm following eBay*, the district court was within its discretion to find an absence of irreparable harm based on the evidence presented at trial.”) (emphasis added).

⁸⁵ *See, e.g., Everett Labs., Inc. v. Breckenridge Pharm., Inc.*, 573 F.Supp.2d 855, 866 (D.N.J. 2008) (“In the wake of [the *eBay*] decision, the Federal Circuit has neither overruled its cases applying the presumption of irreparable harm nor offered an explicit directive on whether (1) to apply the presumption on a motion for a preliminary injunction or (2) the presumption exists at all.”).

⁸⁶ *See, e.g., Abbott Labs.v. Andrx Pharm., Inc.* 452 F.3d 1331, 1347-48 (Fed. Cir. 2006).

⁸⁷ *See, e.g., Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, No. 03-4678 (SRC), 2009 WL 2182665, at *9 (D.N.J. July 22, 2009).

⁸⁸ Klewin, *supra* note 21, at 2136 (citing *Wireless TV Studios, Inc. v. Digital Dispatch Systems, Inc.*, No. 07 CV 5103, 2008 WL 2474626, at *3 (E.D.N.Y. June 19, 2008)).

that “*eBay* jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of [preliminary] injunctive relief.”⁸⁹ However, in the absence of the presumption, courts can still reach similar results by examining the patent holder’s right to exclude.⁹⁰ In “traditional” cases of patent infringement where both the patentee and infringer are manufacturing or using the technology courts are more likely to find irreparable harm.⁹¹ This is in contrast to “non-traditional” cases like *eBay* where the patentee had not made a commercial use of the patent.⁹²

III. THE HATCH-WAXMAN ACT AND PHARMACEUTICAL PATENT ACTIONS

The Hatch-Waxman Act⁹³ was enacted to achieve two competing goals: protecting pharmaceutical patent rights and encouraging competition from generic pharmaceutical makers.⁹⁴ This Part will describe historical background the Act, the provisions of the Act, and the process outlined in the Act for the approval of generic pharmaceuticals.

⁸⁹ Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1149 (Fed. Cir. 2011).

⁹⁰ *Id.*

⁹¹ *Id.* at 1150-51.

⁹² *Id.* at 1150 (citing *eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 396-97 (Kennedy, J., concurring)).

⁹³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

⁹⁴ Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 590 (2003).

A. Pharmaceutical Approvals Prior to the Hatch-Waxman Act

The Food and Drug Administration (FDA) was empowered by the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938 to keep unsafe drugs from the market by reviewing all new drugs prior to market entry.⁹⁵ Under this Act, before a new drug was permitted to enter the market the manufacturer was required to submit a new drug application (NDA).⁹⁶ The NDA contained scientific studies attesting to the drug's safety.⁹⁷

The FDA maintained a policy that kept any unpublished information submitted with an NDA as confidential.⁹⁸ It reasoned that if competitors had access to the information contained in the NDA, they could use the information as a shortcut in their own NDA submissions.⁹⁹ The FDA further reasoned that competing companies making identical or similar drugs would be less likely to invest in testing and safety practices if they could demonstrate the safety of their own products through the research of another drug maker.¹⁰⁰ The policies promulgated by the FDA at the time presented a barrier to generic makers.¹⁰¹

In 1962, the FDCA was amended to require drug makers to establish the effectiveness of their drugs in the NDA process in addition to the prior re-

⁹⁵ *Id.* at 587; *see also* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-99f).

⁹⁶ Weiswasser & Danzis, *supra* note 94, at 587.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *See id.*

quirements.¹⁰² Over time, drug makers were often required to run at least two clinical trials in order to “demonstrat[e] statistically significant benefits for consumers.”¹⁰³ Drug makers were often required to file for a patent before clinical trials.¹⁰⁴ The new requirements burdened the drug makers with lengthy studies and trials which eroded the exclusivity periods of their patents.¹⁰⁵

In 1970, the FDA created the Abbreviated New Drug Application (ANDA), an approval process for generic drugs.¹⁰⁶ However, there were relatively few generic drugs on the market because the ANDA process primarily applied to generic versions of drugs approved prior to 1962.¹⁰⁷ Despite streamlining the ANDA process even further in 1980, there was very little generic competition in the market.¹⁰⁸

There was great concern over the rise of prescription drug prices in the early 1980s.¹⁰⁹ Drug makers, without competition from generic makers, were able to charge high prices to recoup the immense cost of the FDA application process in the short period of effective exclusivity.¹¹⁰ The need to

¹⁰² *Id.* at 588.

¹⁰³ *Id.*

¹⁰⁴ Pamela J. Clements, *The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law*, 48 IDEA 381, 386 (2008).

¹⁰⁵ *Id.* (noting that in some instances, drug makers lost “up to ten years” of exclusivity).

¹⁰⁶ Weiswasser & Danzis, *supra* note 94, at 589.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 590.

¹⁰⁹ *Id.*

¹¹⁰ See B. Scott Eidson, Note, *How Safe is the Harbor? Considering the Economic Implications of Patent Infringement in Section 271(e)(1) Analysis*, 82 WASH. U. L.Q. 1169, 1172 (2004).

reduce drug prices through competition while increasing incentives for innovation set the stage for the Hatch-Waxman Act.

B. The Hatch-Waxman Act

The Hatch-Waxman Act was enacted with the intention “to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”¹¹¹

First, Congress incentivized innovator companies by creating a process that could extend patent exclusivity by up to five years.¹¹² Secondly, a generic drug could gain approval before the patent’s expiration, enabling a generic maker to release the product to market at the moment of expiration.¹¹³ Further, the Act enabled a generic maker to challenge the patent’s validity, presenting an opportunity for generic drugs to reach the market even sooner.¹¹⁴ The Act established a new ANDA process that also enabled generic makers to market versions of drugs approved after 1962.¹¹⁵

The Act also gave additional incentives for generic makers by granting a 180 day period of marketing exclusivity for the first generic maker that

¹¹¹ Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (quoting Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds)).

¹¹² Weiswasser & Danzis, *supra* note 94, at 590-91.

¹¹³ Clements, *supra* note 104, at 388.

¹¹⁴ *Id.*

¹¹⁵ Weiswasser & Danzis, *supra* note 94, at 593.

successfully challenges a patent.¹¹⁶ However, the exclusivity to a first filer can create a bottleneck for generics; the FDA will not approve any subsequent ANDAs pending the approval of the first ANDA, even in the absence of litigation.¹¹⁷

C. The ANDA Process Under the Hatch-Waxman Act

Under the Hatch-Waxman Act, the patents of all drugs approved through the NDA are recorded in their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, more commonly known as the “Orange Book.”¹¹⁸ Innovator companies enjoy a period of “data exclusivity” for five years in which a generic maker may not submit an ANDA.¹¹⁹ After the data exclusivity period expires, generic drugs are approved provided that the generic is the “same and bioequivalent” to an approved patented drug.¹²⁰ Applications must contain the following:

- (1) a full list of articles used as components of the drug,
- (2) a full statement of the composition of the drug,
- (3) a full description of the methods used in, and the facilities and controls used for the manufacture, processing and packing of the drug,
- (4) samples of the drug and components as required by the FDA, and

¹¹⁶ *Id.* at 603.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 595.

¹¹⁹ 21 U.S.C. § 355(c)(3)(E)(ii) (2012).

¹²⁰ 21 U.S.C. §§ 355(c)(3)(E)(iii), (j)(5)(F)(iii) (2012).

(5) sample labeling.¹²¹

Generic makers must also file one of the following certifications along with their ANDA:

- (I) that there are no patents listed in the Orange Book for the drug (a “Paragraph I” certification);
- (II) that the relevant patents have expired (a “Paragraph II” certification);
- (III) that the generic manufacturer will not seek approval of the ANDA until after the expiration of the relevant patent (a “Paragraph III” certification); or
- (IV) that such a patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted (a “Paragraph IV” certification).¹²²

Generally, the first three certifications do not result in patent infringement litigation; the relevant patents have either expired or the generic maker will not release their product until after the patent’s expiration.¹²³ However, a Paragraph IV certification can be the opening salvo in litigation because the certification puts an innovator company on notice that their patent is being challenged.¹²⁴ Further, 35 U.S.C. § 271(e)(2) provides that conduct pursuant to an ANDA submittal with the purpose of challenging

¹²¹ Weisswasser & Danzis, *supra* note 94, at 595 (quoting 21 U.S.C. § 355(b)(1)(B)-(F) (2012)) (internal quotations omitted).

¹²² *Id.* at 600 (citing 21 U.S.C. § 355(j)(2)(A)(vii) (2012)).

¹²³ *Id.*

¹²⁴ *Id.*

a patent is considered infringement.¹²⁵

The patent holder has forty five days to file suit after being served notice that a Paragraph IV certification has been filed.¹²⁶ If the patent holder does not file suit within the forty five day period the ANDA may be approved and the patent holder forfeits their rights to a stay of FDA approval for the generic.¹²⁷ If the suit is filed within the forty five day period, the FDA must stay the approval of the ANDA for thirty months.¹²⁸ The stay may be cut short by the patent's expiration, the patent's invalidation by a court ruling, or a finding that the patent was not infringed.¹²⁹ The ANDA is approved upon a finding that the patent is not valid or infringed.¹³⁰

The FDA grants a thirty month stay only once.¹³¹ An applicant will not be granted an additional stay for any subsequent Paragraph IV certifications.¹³² After the expiration of the stay, the innovator company may move for a preliminary injunction to enjoin the generic maker from releasing their product.¹³³

¹²⁵ 35 U.S.C. § 271(e)(2) (2012); Clements, *supra* note 104, at 389. *But see* 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.").

¹²⁶ Weiswasser & Danzis, *supra* note 94, at 600.

¹²⁷ *Id.* at 601.

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.* at 602.

¹³² *Id.* at 603.

¹³³ *See id.* at 601-03

In the absence of a preliminary injunction, generic makers may attempt to release their product in an “at-risk launch.”¹³⁴ In such launches, the generic maker can be liable for a significant amount of damages if the generic maker is later ruled to have infringed the patent.¹³⁵ The threat of a large damage award, which can exceed the expected revenues of a generic drug, had kept at-risk launches at bay.¹³⁶ However, starting in 2007 generic makers have been more aggressive in releasing product before the conclusion of litigation.¹³⁷ Commentators have stressed the importance of preliminary injunctions by noting that preliminary injunctions have only been granted in two instances following an at-risk launch.¹³⁸

IV. SURVEY OF PRELIMINARY INJUNCTIONS IN PHARMACEUTICAL PATENT INFRINGEMENT CASES POST-*EBAY* IN THE DISTRICT OF NEW JERSEY

A Westlaw search reveals sixteen cases in the District of New Jersey since the *eBay* decision in 2006 where an innovator company sought to enjoin a generic maker from an at-risk launch.¹³⁹ Prelimi-

¹³⁴ Joseph M. O'Malley, Jr. et al., *Failure to Launch*, INTELLECTUAL PROP. MAGAZINE at 30, 30 (Apr. 2011), available at <http://www.paulhastings.com/assets/publications/1877.pdf>.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.* at 31.

¹³⁹ Hoffman-La Roche Inc. v. Apotex Inc., 496 Fed.App'x 46 (Fed. Cir. 2012) (denying preliminary injunction); Warner Chilcott Labs. Ir. Ltd. v. Mylan Pharm. Inc., 451 Fed.App'x 935 (Fed. Cir. 2011) (appealing from the District of New Jersey, holding that the trial court's grant of preliminary injunction was an abuse of discretion); Hoffman-La Roche Inc. v. Cobalt Pharm. Inc., Nos. 07-4539(SRC)(MAS), 07-454(SRC)(MAS), 08-4054(SRC)(MAS), 2010 WL 4687839 (D.N.J. Nov. 10, 2010)

nary injunctions were granted in seven instances.¹⁴⁰ Although the District of New Jersey has held in 2009 that *eBay* had abrogated the presumption of irreparable harm, a finding of likelihood of success on the merits is still heavily linked to disposition of the sec-

(granting preliminary injunction); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 09-4638(GEB-MCA), 2010 WL 2516465 (D.N.J. June 14, 2010) (granting preliminary injunction); *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, No. 07-CV-5855(DMC), 2010 WL 2428561 (D.N.J. June 9, 2010) (denying preliminary injunction); *King Pharm., Inc. v. Sandoz, Inc.*, No. 08-5974(GEB-DEA), 2010 WL 1957640 (D.N.J. May 17, 2010); *King Pharm., Inc. v. Corepharma, LLC.*, No. 10-1878(GEB-DEA), 2010 WL 1850200 (D.N.J. May 7, 2010) (granting preliminary injunction); *Graceway Pharm., LLC v. Perrigo Co.*, 697 F.Supp.2d 600 (D.N.J. 2010) (denying preliminary injunction); *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, No. 07-1299(SRC), 2009 WL 2422382 (D.N.J. Aug. 4, 2009) (denying preliminary injunction); *Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, No. 03-4678(SRC), 2009 WL 2182665 (D.N.J. July 22, 2009) (granting preliminary injunction); *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp.2d 579 (D.N.J. 2009), *aff'd* 633 F.3d 1042 (Fed. Cir. 2010) (granting preliminary injunction); *Everett Labs., Inc. v. Breckenridge Pharm., Inc.*, 573 F. Supp.2d 855 (D.N.J. Aug. 28, 2008) (granting preliminary injunction); *Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, Nos. 05-5727(HAA)(ES), 07-5489(HAA)(ES), 2008 WL 1722098 (D.N.J. Mar. 28, 2008) (granting preliminary injunction); *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp.2d 666 (D.N.J. 2007) (denying preliminary injunction); *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc. (Novartis I)*, No. 05-CV-1887(DMC), 2007 WL 2669338 (D.N.J. Sept. 6, 2007) (denying preliminary injunction); *Novartis Corp. v. Teva Pharm. USA, Inc. (Novartis II)*, Nos. 04-4473(HAA)(ES), 06-1130(HAA)(ES), 2007 WL 1695689 (D.N.J. June 11, 2007) (denying preliminary injunction).

¹⁴⁰ *Cobalt Pharm.*, 2010 WL 4687839; *Albany Molecular*, 2010 WL 2516465; *King Pharm.*, 2010 WL 1850200; *Ortho McNeil*, 2009 WL 2182665; *AstraZeneca*, 623 F. Supp 579; *Everett Labs.*, 573 F. Supp.2d 855; *Eisai*, 2008 WL 1722098.

ond injunction factor.¹⁴¹

Hoffman-La Roche, Inc. v. Apotex, Inc., a recent case before the District of New Jersey, illustrates how the first preliminary injunction factor can be dispositive.¹⁴² The drug at issue was Boniva, a treatment for osteoporosis.¹⁴³ U.S. Patent 4,927,814 (the “814 patent”) was for one of the ingredients for Boniva, while the other two patents, U.S. Patents 7,410,957 (the “957 patent”) and 7,718,634 (the “634 patent”) were for the method of treatment.¹⁴⁴ Hoffman-La Roche, referred to throughout the case as simply Roche, sought to enjoin generic makers from releasing their versions of Boniva after the expiration of the ’814 patent in March 2012.¹⁴⁵

The defendants in *Hoffman-La Roche* mounted a vigorous challenge to the validity of the ’957 and ’634 patents.¹⁴⁶ The defendants cited to numerous studies, reports, and patents dating back to the late 1990s trying to establish that the industry was researching a weekly or monthly treatment for osteoporosis.¹⁴⁷ The defendants argued that the ’957 and

¹⁴¹ See *Ortho McNeil*, 2009 WL 2182665, at *9-10 (D.N.J. July 22, 2009).

¹⁴² *Hoffmann-La Roche Inc. v. Apotex Inc.*, Nos. 07-4417(SRC)(MAS), 08-3065(SRC)(MAS), 08-4053(SRC)(MAS), 10-6241(SRC)(MAS), 07-4661(SRC)(MAS), 08-4052(SRC)(MAS), 11-0579(SRC)(MAS), 07-4540(SRC)(MAS), 08-4054(SRC)(MAS), 10-6206(SRC)(MAS), 2012 WL 869572 (D.N.J. Mar. 14, 2012).

¹⁴³ *Id.* at *1.

¹⁴⁴ U.S. Patent No. 4,927,814 (filed July 9, 1987); U.S. Patent No. 7,410,957 (filed May 6, 2003); U.S. Patent No. 7,718,634 (filed June 16, 2008).

¹⁴⁵ *Hoffman-La Roche v. Apotex*, 2012 WL 869572, at *1.

¹⁴⁶ For the obviousness standard, see *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F.Supp.2d 666, 674 (D.N.J. 2007) *aff’g*, 566 F.3d 399 (Fed. Cir. 2009).

¹⁴⁷ *Hoffman-La Roche v. Apotex*, 2012 WL 869572, at *3-6.

'634 patents would have been obvious to a pharmaceutical researcher on account of the published studies.¹⁴⁸ Moreover, Roche did not highlight “the ingenuity of the inventors,” which is unusual when defending patent validity.¹⁴⁹

The court concluded that Roche did not establish a likelihood of success on the merits and denied the motion for preliminary injunction.¹⁵⁰ However, the court declined to consider the other factors on basis of Roche failing to establish the first factor.¹⁵¹ The court similarly considered only first factor in two other instances where the plaintiff's application for preliminary injunction was denied.¹⁵²

While seeking a preliminary injunction, innovator companies often argue that an entry of a generic competitor causes price erosion and loss of market share.¹⁵³ This, in turn, causes job losses, reduction of research opportunities for newer drugs, and a loss of goodwill and brand equity.¹⁵⁴

The court in *AstraZeneca v. Apotex, Inc.*, in concluding that AstraZeneca had shown sufficient evidence of irreparable harm, analyzed each of the plaintiff's arguments in depth.¹⁵⁵ First, the court concluded that the damages stemming from a loss of market share and price erosion are not irreparable

¹⁴⁸ *Id.* at *6.

¹⁴⁹ *Id.* at *8.

¹⁵⁰ *Id.* at *8-9.

¹⁵¹ *Id.*

¹⁵² *King Pharm., Inc. v. Sandoz, Inc.*, No. 08-5974(GEB-DEA), 2010 WL 1957640, at *6 (D.N.J. May 17, 2010); *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, No. 07-1299(SRC), 2009 WL 2422382, at *7 (D.N.J. Aug. 4, 2009).

¹⁵³ *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp.2d 579, 608 (D.N.J. 2009).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 608-14.

because loss of sales and profits are generally calculable.¹⁵⁶ Moreover, the resulting loss of research opportunity and funding is also calculable.¹⁵⁷

The court also found that Apotex's at-risk launch could cause irreparable harm through personnel layoffs.¹⁵⁸ The court agreed that layoffs, while commonplace in business, can cause a loss of morale and productivity that cannot be calculated.¹⁵⁹ Finally, the court concluded an at-risk launch can cause market confusion.¹⁶⁰ Moreover, AstraZeneca's reputation could suffer if customers, after lowering prices to compete with Apotex, feel that the drug was originally priced "at an unfairly high level."¹⁶¹ Loss of goodwill as an irreparable harm is a concept originally from trademark law that has been incorporated into patent law.¹⁶²

Despite a thorough analysis in *AstraZeneca*, there is little consistency within the District of New Jersey. In some instances, the court has held that a loss of goodwill is too speculative to be an irreparable harm.¹⁶³ In other instances, the court has held that

¹⁵⁶ However, the court found that the loss of future sales could not be calculable due to a licensing agreement already in place between AstraZeneca and another generic maker who had promised not to release their generic until a later date. Thus, in this instance, lost future sales and licensing revenue constituted an irreparable harm. *Id.* at 608-11.

¹⁵⁷ *Id.* at 613.

¹⁵⁸ *Id.* at 612.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 613.

¹⁶¹ *Id.*

¹⁶² See Roy H. Wepner & Richard W. Ellis, *The Federal Circuit's Presumptively Erroneous Presumption of Irreparable Harm*, 6 TUL. J. TECH. & INTELL. PROP. 147, 163-65 (2004).

¹⁶³ *Sanofi-Aventis*, 2010 WL 2428561, at *17; *Novartis I*, 2007 WL 2669338, at *15.

a potential loss of jobs is too speculative for irreparable harm at large companies, such as many of the innovator companies.¹⁶⁴

The varied case law on how courts have evaluated irreparable harm in Hatch-Waxman actions validates Professor Chisum's observations on irreparable harm determinations.¹⁶⁵ The following cases illustrate how the court usually finds irreparable harm where it also finds a likelihood success from the plaintiff.

In *Novartis v. Teva Pharmaceuticals (Novartis II)*, the court made a preliminary finding that Novartis was unlikely to establish that Teva's generic version of Lotrel infringed on Novartis' patents.¹⁶⁶ The court also found that Novartis failed to establish Teva's infringement under the doctrine of equivalents.¹⁶⁷

Novartis further argued that Teva's at-risk launch of generic Lotrel would cause irreparable harm through "lost sales revenue, lost market share, irreversible price erosion, lost business and growth prospects, and lost research opportunities."¹⁶⁸ The court said that economic loss estimates set forth by Novartis seemed to go against their arguments for irreparable harm.¹⁶⁹ Further, the court posited that any potential economic damages are calculable and thus could "be reparable by money damages."¹⁷⁰ Thus, the irreparable harm determination in

¹⁶⁴ See *Novartis II*, 2007 WL 1695689, at *28.

¹⁶⁵ See *supra* notes 35-36, 152, 156 and accompanying text.

¹⁶⁶ See *Novartis II*, 2007 WL 1695689, at *24.

¹⁶⁷ *Id.* at *25.

¹⁶⁸ *Id.* at *26 (internal quotations omitted).

¹⁶⁹ *Id.* at *27.

¹⁷⁰ *Id.* (citing *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991)).

Novartis II is consistent with the definition in Chisum's treatise.¹⁷¹

However, the District of New Jersey found in a subsequent case that an innovator company could suffer irreparable harm while given similar economic arguments. In *Albany Molecular Research v. Dr. Reddy's Laboratories*, a preliminary injunction was sought to enjoin the defendant from an at-risk launch¹⁷² of generic fexofenadine.¹⁷³ Unlike the *Novartis* court, the court in *Albany Molecular* found that the plaintiff had demonstrated a likelihood of success on the merits.¹⁷⁴

Like in *Novartis II*, the plaintiff argued that an at-risk launch would mean a loss of market share, permanent price erosion and loss of brand equity.¹⁷⁵ Although the court noted that most of the harm suffered by the plaintiff would be monetary in nature and calculable, it held that a "loss of goodwill associated with the brand" is considered an irreparable harm.¹⁷⁶ However, in a case decided just a few days before *Albany Molecular*, a different judge in District of New Jersey ruled that loss of goodwill was too speculative for irreparable harm in Hatch-Waxman litigation.¹⁷⁷ In that case, the court declined to issue

¹⁷¹ See *supra* text accompanying note 35.

¹⁷² *Albany Molecular*, 2010 WL 2516465, at *1.

¹⁷³ Fexofenadine is an allergy medication, notable brand names include Allegra. NAT'L INST. OF HEALTH, *Fexofenadine*, MEDLINEPLUS (last visited Feb. 19, 2014), <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a697035.html>.

¹⁷⁴ *Albany Molecular*, 2010 WL 2516465, at *9.

¹⁷⁵ *Id.* at *11.

¹⁷⁶ *Id.*

¹⁷⁷ *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, No. 07-CV-5855(DMC), 2010 WL 2428561, at *17 (D.N.J. June 9, 2010).

a preliminary injunction.¹⁷⁸

In all seven instances where a preliminary injunction was granted by the District of New Jersey, the court also found that the plaintiff had a likelihood of success on the merits.¹⁷⁹ Likewise, in those nine instances, the court also found that the plaintiff had also established irreparable harm.¹⁸⁰ Conversely, when the court declines to grant a preliminary injunction, it usually finds that the plaintiff failed to establish a likelihood of success on the merits.¹⁸¹ Courts have refused to consider the remaining factors once the plaintiff fails to establish the first

¹⁷⁸ *Id.*

¹⁷⁹ *Hoffman-La Roche Inc. v. Cobalt Pharm. Inc.*, Nos. 07-4539(SRC)(MAS), 07-454(SRC)(MAS), 08-4054(SRC)(MAS), 2010 WL 4687839, at *1 (D.N.J. Nov. 10, 2010); *King Pharm., Inc. v. Corepharma, LLC.*, No. 10-1878(GEB-DEA), 2010 WL 1850200, at *5 (D.N.J. May 7, 2010); *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp.2d 579, 614 (D.N.J. 2009), *aff'd* 633 F.3d 1042 (Fed. Cir. 2010); *Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, No. 03-4678(SRC), 2009 WL 2182665, at *11 (D.N.J. July 22, 2009); *Everett Labs., Inc. v. Breckenridge Pharm., Inc.*, 573 F. Supp.2d 855, 871 (D.N.J. Aug. 28, 2008); *Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, Nos. 05-5727(HAA)(ES), 07-5489(HAA)(ES), 2008 WL 1722098, at *13 (D.N.J. Mar. 28, 2008); *see also Warner Chilcott Labs. Ir. Ltd. v. Mylan Pharm. Inc.*, 451 Fed.App'x 935, 938 (Fed. Cir. 2011) (showing that although the Federal Circuit reversed and vacated the injunction, the District of New Jersey analyzed all four factors in favor of the plaintiff).

¹⁸⁰ *See id.*

¹⁸¹ *Sanofi-Aventis*, 2010 WL 2428561, at *17; *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp.2d 666, 684 (D.N.J. 2007); *Novartis II*, 2007 WL 1695689, at *28; *Novartis I*, 2007 WL 2669338, at *13; *see also Graceway Pharm., LLC v. Perrigo Co.*, 697 F.Supp.2d 600, 610 (D.N.J. 2010) (due to the innovator company's bad faith actions and the doctrine of laches the court would have granted the preliminary injunction, found a likelihood of success and irreparable harm).

factor in some instances.¹⁸² When the courts consider all four factors, they have been consistent in determining a lack of irreparable harm when declining injunctive relief.

CONCLUSIONS

The District of New Jersey has recognized that *eBay* had abrogated the presumption of irreparable harm in preliminary injunction determinations as early as 2008.¹⁸³ However, it seems that the presumption is alive and well in Hatch-Waxman actions, in practice if not in name.¹⁸⁴ It is clear that likelihood of success on the merits influences the irreparable harm determination.¹⁸⁵ It is hard to envision that the cases cited in Part IV would have been decided differently if *eBay* did not abrogate the presumption of irreparable harm in patent cases.

A. The Irreparable Harm Presumption Is Not as Dead as the Bosch Court Would Lead You to Believe

Ironically, the case that is considered the death knell of the presumption of irreparable harm also gives courts sufficient latitude to apply the presumption tacitly.¹⁸⁶ The patent at issue in *Robert*

¹⁸² *Apotex*, 2012 WL 869572, at *9; *King Pharm., Inc. v. Sandoz, Inc.*, No. 08-5974(GEB-DEA), 2010 WL 1957640, at *6 (D.N.J. May 17, 2010); *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, No. 07-1299(SRC), 2009 WL 2422382, at *7 (D.N.J. Aug. 4, 2009).

¹⁸³ *Everett Labs.*, 573 F.Supp.2d at 866.

¹⁸⁴ See *supra* Part IV.

¹⁸⁵ See *supra* text accompanying notes 166.

¹⁸⁶ Jason Rantanen, *Bosch v. Pylon: Jettisoning the Presumption of Irreparable Harm in Injunction Relief*, PATENTLY-O (Oct. 12, 2011), <http://www.patentlyo.com/patent/2011/10/bosch-v-pylon->

Bosch LLC v. Pylon Manufacturing Corporation was for windshield wiper blades.¹⁸⁷ Bosch is part of a multinational conglomerate that manufactures and sells a wide variety of goods including automotive parts, industrial machinery, and consumer products, such as power tools.¹⁸⁸ Pylon is company based in Florida that manufactures wiper blades under license from DuPont and Michelin.¹⁸⁹ After obtaining a favorable judgment at the district court, Bosch unsuccessfully sought a permanent injunction against Pylon.¹⁹⁰

On appeal, the Federal Circuit examined the four injunction factors *de novo*.¹⁹¹ Acknowledging that neither *eBay* nor its subsequent cases clearly addressed the presumption of irreparable harm, the Federal Circuit emphatically stated that “*eBay* jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunc-

jettisoning-the-presumption-of-irreparable-harm-in-injunction-relief.html.

¹⁸⁷ *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1145 (Fed. Cir. 2011).

¹⁸⁸ *Business Sectors and Divisions*, BOSCH GROUP, http://www.bosch.com/en/com/bosch_group/business_sectors_divisions/business_sectors_divisions_2.php (last visited Feb. 21, 2014).

¹⁸⁹ *About Us*, PYLON, <http://www.pylonhq.com/company.html> (last visited Feb. 21, 2014).

¹⁹⁰ *Bosch*, 659 F.3d at 1145.

¹⁹¹ *Id.* at 1148 (The permanent injunction factors are: “(1) that it has suffered an *irreparable injury*; (2) that remedies available at law, such a *monetary damages are inadequate to compensate for that injury*; (3) that considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.”) (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)) (emphasis added).

tive relief.”¹⁹²

The court noted that plaintiffs “can no longer rely on presumptions or other short-cuts to support a request for [injunctive relief].”¹⁹³ However, the court also enunciated that “the fundamental nature of patents as property rights grant[] the owner the right to exclude.”¹⁹⁴ The court noted that in cases of traditional patent infringement, courts should not act from a “clean slate” and look to precedent in making an injunction determination.¹⁹⁵ Applying the four factor analysis, the court found that Bosch had made a showing of irreparable harm by, among other things, establishing that Pylon had taken market share through infringing product.¹⁹⁶ In reversing the trial court’s decision, at least one commentator has noted that the new standard may not be much different from the old.¹⁹⁷ The presumption of irreparable harm may be dead, but *Bosch* allows courts to apply the old presumption in traditional patent infringement cases without calling it by name.

B. Non-Practicing Entities, Patent Trolls, and Non-Traditional Patent Infringement

Given their context, both *eBay* and *Bosch* were decided correctly. MercExchange did not make commercial use of their patents; it sought to license their patents after unsuccessfully attempting to open

¹⁹² *Id.* at 1149.

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* at 1155.

¹⁹⁷ Rantanen, *supra* note 186.

on online marketplace.¹⁹⁸ MercExchange is considered a non-practicing entity (NPE), which are sometimes pejoratively known as a patent troll.¹⁹⁹ Bosch, on the other hand, is a global manufacturer that spent approximately \$5 billion in 2011 for research and development.²⁰⁰

One of the more notable examples of a non-practicing entity is Soverain Software. Soverain is the holder of patents for online “shopping carts” used in e-commerce.²⁰¹ They do not manufacture products of any kind nor do they sell goods over the internet or otherwise.²⁰² Instead, Soverain is known for initiating patent infringement suits and obtaining generous settlements and licensing agreements.²⁰³ Due to their litigious conduct, Soverain is widely known as a patent troll.²⁰⁴ In 2004, Soverain filed a patent in-

¹⁹⁸ Brief for Respondent at 4, *eBay Inc. v. MercExchange*, L.L.C., 547 U.S. 388 (2006) (No. 05-130), 2006 WL 622506, at *4 (March 10, 2006).

¹⁹⁹ Jones, *supra* note 66, at 1040.

²⁰⁰ *Bosch to Invest \$10 Million to Support Local Higher Education and Research Initiatives*, BOSCH PRESS (May 19, 2011), http://www.bosch-press.com/tbwebdb/bosch-usa/modules/oragetblob.dll/BERN%20Investment%202011.pdf?db=TBWebDB_rbna&item=TBWebDB_texpdf&id=466,1&dispo=a (last visited Feb. 21, 2014).

²⁰¹ Joe Mullin, *How Newegg Crushed the “Shopping Cart” Patent and Saved Online Retail*, ARS TECHNICA (Jan. 27, 2013, 4:00 PM), <http://arstechnica.com/tech-policy/2013/01/how-newegg-crushed-the-shopping-cart-patent-and-saved-online-retail/>.

²⁰² *Id.*

²⁰³ *Id.* Notably, the term “patent troll” was used a total of five times in Mullin’s article.

²⁰⁴ See, e.g., Don Reisinger, *Newegg Wins Key ‘Shopping Cart’ Lawsuit Against Patent Troll*, CNET (Jan. 28, 2013, 9:52 AM), http://news.cnet.com/8301-1023_3-57566195-93/newegg-wins-key-shopping-cart-lawsuit-against-patent-troll/; Mike Masnick,

fringement action against Amazon.com and The Gap alleging infringements of patents for online payment processing and shopping carts.²⁰⁵ Amazon.com later settled the case days within the start of trial for \$40 million.²⁰⁶

The Supreme Court was correct in *eBay* to abrogate the presumption of irreparable harm. By placing the burden of proof on the plaintiff to establish irreparable harm, litigation and the threat of a permanent injunction cannot be used to force a settlement or as leverage in licensing negotiations, especially in cases where the patent holder is an NPE.

C. Differences Between NPEs and the Pharmaceutical Companies and Why Congress Should Amend the Hatch-Waxman Act to Allow for the Irreparable Harm Presumption

Today, it is possible to be an NPE and own a significant amount of patents, especially those related to information technology and internet applications. Instagram is a free photo sharing app for Internet enabled smartphones.²⁰⁷ By the time Instagram was acquired by Facebook in 2012, it held around eight hundred patents.²⁰⁸ Industry experts

Newegg's 'Screw Patent Trolls!' Strategy Leads to Victory, TECHDIRT (Jan. 28, 2013, 12:48 PM), .

²⁰⁵ Dawn Kawamoto, *Amazon Pays \$40 Million to Settle Patent Dispute*, ZDNET (Aug. 11, 2005, 9:11 PM), <http://www.zdnet.com/news/amazon-pays-40-million-to-settle-patent-dispute/144171>.

²⁰⁶ *Id.*

²⁰⁷ *FAQ*, INSTAGRAM, <http://instagram.com/about/faq/> (last visited Mar. 2, 2013).

²⁰⁸ Tyler Kingkade, *What Would \$1 Billion Buy You Besides Instagram & 800 Patents?*, HUFFINGTON POST (Apr. 11, 2012, 1:46 PM), http://www.huffingtonpost.com/2012/04/11/1-billion-would-buy-you_n_1417712.html.

have valued the labor costs of developing an app similar to Instagram at under \$200,000.²⁰⁹ Even considering costs for filing patents, it does not take a significant investment to create an NPE, sit on a stable of patents, and make money purely through licensing. As mentioned before, developing a new drug can cost upwards of \$800 million.²¹⁰ Although pharmaceutical companies can negotiate licensing agreements, innovator companies will try to recoup their substantial investment by releasing product to the market themselves.

Moreover, “patent trolling” in the pharmaceutical industry is unlikely due to the nature of research. Unlike information technology patents, which may be vague, pharmaceutical patents are for a thoroughly researched chemical.²¹¹ Further, the research behind pharmaceutical patents is also protected by the Hatch-Waxman Act’s data exclusivity period.²¹² Thus, pharmaceutical patent infringement is almost always between two producing entities.

D. Moving Forward

While the Federal Circuit has made clear in *Bosch* that the irreparable harm presumption is no more, courts have the latitude to conclude similarly

²⁰⁹ Andres Garzon, *The Correct Price for \$1-Billion-Instagram is \$175,500*, PRICETAG (Apr. 23, 2012), <http://pricetaghq.com/blog/correct-price-1-billion-instagram#sthash.KkIMBklN.dpuf>; see also Roy Chomko, *The Real Cost of Developing an App*, MANUFACTURING.NET (July 30, 2012, 11:50 AM), <http://www.manufacturing.net/articles/2012/07/the-real-cost-of-developing-an-app>.

²¹⁰ See *supra* text accompanying note 9.

²¹¹ Stu Hutson, *Pharma “Patent Trolls” Remain Mostly the Stuff of Myth*, 15 NATURE MEDICINE 1240 (2009).

²¹² *Id.*; see also *supra* text accompanying note 119.

as if the presumption still applies.²¹³ Latitude is not a certainty and different jurisdictions or even judges may conclude differently for the irreparable harm factor while adhering to the holding in *Bosch*. As discussed earlier in this Article, the rulings of Federal courts in New Jersey in Hatch-Waxman actions are consistent with the irreparable harm presumption, even if they decline to apply it.²¹⁴ However, the same cannot be said of other jurisdictions.

A lack of certainty can lead to forum shopping.²¹⁵ Knowing that a patent infringement suit may take much longer than a 30 month stay, innovator companies will try to file suit in a jurisdiction where the first two preliminary injunction factors have not been decoupled.²¹⁶ This problem can be solved by amending the Hatch-Waxman Act to give courts the power to apply the irreparable harm presumption. Firstly, courts can apply tests or presumptions outside of the four factors with legislative authorization.²¹⁷ Secondly, applying the irreparable harm presumption is consistent with the legislative aims of the Act by strengthening pharmaceutical pa-

²¹³ See *supra* Conclusion, Section A.

²¹⁴ See *supra* Part IV.

²¹⁵ See Ronald T. Coleman, Jr. et al., *Applicability of the Presumption of Irreparable Harm After eBay*, 32 FRANCHISE L.J. 3, 10 (2012) (“Perhaps most important, know your jurisdiction. If a plaintiff has a choice as to where to bring a lawsuit, look for a jurisdiction that continues to apply (or at least has not foreclosed) the presumption of irreparable harm in that kind of case. A potential defendant sometimes can exercise forum selection as well by initiating a declaratory judgment action in a forum that has applied *eBay* and demands proof of irreparable harm.”).

²¹⁶ See *id.*

²¹⁷ See *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-92 (2006).

tent protections.

In conclusion, the presumption of irreparable harm is still alive in Hatch-Waxman actions despite reports to the contrary in *eBay* and *Bosch*. The tacit application of the presumption is compatible with current law because most instances of pharmaceutical patent infringement are considered to be “traditional.” Due to the immense costs of research and clinical trials, pharmaceutical patents have enjoyed heightened protection. Amending the Hatch-Waxman Act to allow for the presumption would be consistent with its original intent. However, even without legislative action, *eBay* and *Bosch* do not fundamentally change the outcomes of preliminary injunction motions in Hatch-Waxman cases.