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

Kenneth C. Louis
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I. 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 American


pharmaceutical companies. 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. Generic drugs are bioequivalent versions of brand name medication and present significant savings to consumers. The development cost of a generic drug is much lower in comparison to brand name drugs.

4 SelectUSA, supra note 2.


7 U.S. Food & Drug Admin., 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.”)

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.\textsuperscript{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.\textsuperscript{10}

The Hatch-Waxman Act was passed with the intention to give innovator companies additional incentives to develop new drugs while giving the American consumer savings by expanding the generics market.\textsuperscript{11} Since the enactment of the Hatch-Waxman Act the market share held by generic drugs have increased from under twenty percent in 1984 to nearly eighty percent in 2010.\textsuperscript{12}

This note will discuss the preliminary injunction factors as applied when an innovator company seeks to enjoin a generic maker from releasing competing product during the course of litigation under the Hatch-Waxman Act. Specifically, this note will argue that the presumption of irreparable harm, which was

\begin{itemize}
  \item \textsuperscript{9}Id. at 482-83.
  \item \textsuperscript{10} U.S. FOOD & DRUG ADMINISTRATION, supra note 5.
  \item \textsuperscript{11} See infra Part III(b).
\end{itemize}
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. Part V will conclude by arguing that the presumption of harm still exists, how a tacit application of the presumption is permissible under current law, and propose that 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.” Patents have been within the ambit of Federal jurisdiction since the earliest days of the

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

Republic. 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. The legislation gave the Federal Circuit exclusive jurisdiction over appeals from the district courts in patent cases. 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”). Previously, the CCPA

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15 See U.S. Const. art. I, § 8. See also Donald Chisum, Chisum on Patents § 21.02(1)(a)(i) (2012) (“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.’”).


only had jurisdiction over appeals from the United States Patent and Trademark Office.\textsuperscript{19} Prior to the creation of the Federal Circuit, patent suits filed in the district courts were appealed to the regional circuit courts.\textsuperscript{20} Currently, circuit splits do not exist in patent law because all patent appeals are reviewed by the Federal Circuit.\textsuperscript{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.\textsuperscript{22} Courts

\textsuperscript{19} Id.

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

\textsuperscript{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) (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).

\textsuperscript{22} 35 U.S.C. § 283.
use the traditional four equitable factors to determine whether a preliminary injunction is proper.\textsuperscript{23}

The first factor, likelihood of success on the merits, undergoes a two-step analysis in patent infringement cases.\textsuperscript{24} The plaintiff must establish that the defendant has infringed on the patent.\textsuperscript{25} First, the court determines the scope of the patent claims.\textsuperscript{26} Then, the allegedly infringing product is compared to see if it lies within the scope of the patent.\textsuperscript{27} Under the doctrine of equivalents, a product may still be infringing if it

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\item \textsuperscript{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, 1557 (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.”).
\item \textsuperscript{24} Tate Access Floors, Inc. v. Interface Arch. Resources, Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002).
\item \textsuperscript{25} Id.
\item \textsuperscript{26} Aventis Pharm., Inc. v. Barr Labs., Inc., 411 F.Supp.2d 490, 494 (D.N.J. 2006).
\item \textsuperscript{27} Id.
\end{itemize}
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 inventions are often built upon

²⁹ Tate, 279 F.3d at 1365.
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.”).
prior innovations. The Supreme Court has, on occasion, upheld the patents comprised of knowledge of prior patents when the new patent aimed to solve a problem previously not apparent.

The second factor, irreparable harm, also called irreparable injury, is defined as “[a]n injury that cannot be adequately measured or compensated by money.” In other words, an injury is irreparable if money damages at the conclusion of a trial are insufficient to make the plaintiff whole. 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.” This inconsistency will be discussed in depth further in the note.

The balance of hardships generally weighs in favor of the innovator company in Hatch-Waxman litigation. When a generic is

32 Id. (citing KSR Int’l Co. v. Teleflex, Inc., 550 U.S. 398, 418-20 (2007)).
33 Id.
34 BLACK’S LAW DICTIONARY 856 (9th ed. 2009).
35 CHISUM, supra note 15 at § 20.04(1)(a)(i)(e)
36 Id.
37 See infra Part IV.
released, the innovator company suffers harm through price erosion and loss of market share.\textsuperscript{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-shifted” into the future.\textsuperscript{39} Thus, the balance of hardships rarely way in favor of the generic maker.\textsuperscript{40}

Likewise, in Hatch-Waxman litigation, the public interest will generally weigh in favor of the plaintiff.\textsuperscript{41}

\textsuperscript{38} Id.


\textsuperscript{40} King Pharm., Inc. v. Sandoz, Inc., No. 08-5973 (GEB-DEA), 2010 WL 1957640, *1, 6 (D.N.J. May 17, 2010) (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, preliminary injunction denied).

\textsuperscript{41} See, e.g., Novartis Pharm. Corp. v. Teva Pharm. USA, Inc. (Novartis I), No. 05-CV-1187(DMC), 2007 WL 2669338, *15 (D.N.J. Sept. 6, 2007).
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.\textsuperscript{42} Further, they also argue that profits generated during the exclusivity period fund research benefiting newer medications.\textsuperscript{43} Generic makers will often argue that the public interest is best served when the public has access to lower cost medication.\textsuperscript{44} However, the Federal Circuit has been clear that the enforcement of patent rights outweighs the public’s access to more affordable medication.\textsuperscript{45}

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

\textsuperscript{42} Id.

\textsuperscript{43} Id.

\textsuperscript{44} Id.

\textsuperscript{45} Pfizer, Inc. v. Teva Pharm. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (quoting Payless Shoesource, Inc. v. Reebok Int’l, Ltd., 998 F.2d 985, 981 (Fed. Cir. 1993) (“[S]elling a lower priced product does not justify infringing a patent.”)).
when it establishes a likelihood success on the merits.\textsuperscript{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.”\textsuperscript{47} The value of the patent is based on exclusivity and monetary damages are insufficient to make up for lost exclusivity.\textsuperscript{48}

However, the Federal Circuit also held that presumption of irreparable harm was a rebuttable presumption.\textsuperscript{49} The Reebok case illustrates an instance when the presumption of irreparable harm was rebutted through evidence. In November, 1992, Reebok began manufacturing and selling the SHAQ I shoe and heavily promoted the shoe with basketball great Shaquille O’Neal.\textsuperscript{50} Over a year later in December, 1993, a patent was issued protecting the

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

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

\textsuperscript{48} Id.

\textsuperscript{49} Ill. Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 681 (Fed. Cir. 1990).

\textsuperscript{50} Reebok, 32 F.3d at 1554.
design of the shoe.\textsuperscript{51} As soon as the patent was issued, Reebok served a complaint to J. Baker alleging that their Olympian shoe infringed on the design of the SHAQ I.\textsuperscript{52} J. Baker had been manufacturing and selling the Olympian shoe since July, 1993.\textsuperscript{53}

The district court denied Reebok’s motion to enjoin J. Baker from selling their remaining inventory of the Olympians.\textsuperscript{54} 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.\textsuperscript{55} J. Baker had established that Reebok had discontinued the SHAQ I in favor a newer shoe, the SHAQ II. 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.\textsuperscript{56} Because J. Baker only had a limited supply of the Olympians, any harm Reebok would have suffered could be sufficiently compensated by money damages.\textsuperscript{57} Thus, J. 

\begin{footnotes}
\footnotetext{51} Id.
\footnotetext{52} Id.
\footnotetext{53} Id.
\footnotetext{54} Id.
\footnotetext{55} Id. at 1558.
\footnotetext{56} Id.
\footnotetext{57} Id.
\end{footnotes}
Baker was successful in rebutting Reebok’s presumption of harm and the district court properly denied a preliminary injunction to Reebok. 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.

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

It is commonly understood that the holding in eBay eliminated the presumption of irreparable harm in preliminary injunction determinations. However, the issue before the Court in eBay was a permanent injunction and neither preliminary injunctions nor the presumption of irreparable harm were explicitly mentioned.

MercExchange patented a process that “facilitate[d] the sale of goods between private individuals by establishing a

58 Id.
59 See, supra note 36 and accompanying text; Part IV infra.
60 See, e.g., Ortho-McNeil Pharm., Inc. v. Barr Labs., Inc., No. 03-4678 (SRC), 2009 WL 2182665, *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].”); Klewin, supra note 21, at 2129-30.
central authority to promote trust among participants” in an online marketplace. eBay and Half.com, its subsidiary, had been negotiating with MercExchange to purchase its technology but the talks broke down. After the cessation of the negotiations, MercExchange filed a patent infringement suit against eBay.

A jury found at trial that MercExchange’s patent was valid, eBay had infringed on their patent, and awarded damages to the plaintiff. However, the district court denied permanent injunctive relief to MercExchange. The Federal Circuit reversed, citing to its general rule that courts will issue a permanent injunction “once infringement and validity have been adjudged.”

62 Id.
63 Id.
65 eBay, 547 U.S. at 390-91.
66 Id.
67 Id. at 393-94 (quoting MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005)).
Justice Thomas enunciated that courts should not depart from traditional notions of equity without legislative authorization.\textsuperscript{68} Justice Thomas further cited to specific language in 35 U.S.C. § 283 revealing the legislative intent not to stray from equitable principles.\textsuperscript{69} 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.\textsuperscript{70} When the matter was remanded to the lower courts eBay refused to settle.\textsuperscript{71} By 2008, eBay had purchased the patent and related technologies from MercExchange.\textsuperscript{72}

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

\textsuperscript{68} Id. at 391-92.
\textsuperscript{69} Id.
\textsuperscript{70} Id. at 394.
\textsuperscript{71} 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.
\textsuperscript{72} Id.
preliminary injunctions.\textsuperscript{73} The Federal Circuit did not bring clarity when it sidestepped the irreparable harm presumption in one of its first patent decisions post-\textit{eBay}.\textsuperscript{74} In \textit{Abbott}, the court vacated a preliminary injunction and reversed the district court’s irreparable harm determination.\textsuperscript{75} 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.\textsuperscript{76} While acknowledging the holding of \textit{eBay}, the Federal Circuit was not clear as to the survival of the irreparable harm presumption.\textsuperscript{77} Without offering additional reasons as to why Abbott was denied

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\textsuperscript{73} \textit{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.”)
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\textsuperscript{74} \textit{Abbott Labs. v. Andrx Pharm., Inc.}, 452 F.3d 1331 (Fed. Cir. 2006).
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\textsuperscript{75} \textit{Id.} at 1347-48.
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\textsuperscript{76} \textit{Id.}
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\textsuperscript{77} \textit{Id.} (“[W]e conclude that Abbott has not established a likelihood of success on the merits. As a result, \textit{Abbott is no longer entitled to a presumption of irreparable harm.”}) (emphasis added).
\end{flushleft}
a finding of irreparable harm, the Federal Circuit did not fully decouple the first two preliminary injunction factors.\textsuperscript{78}

The Federal Circuit sidestepped the presumption of harm issue for a second time in \textit{Sanofi-Synthelabo v. Apotex, Inc.}\textsuperscript{79} Apotex argued that the trial court erred in applying the presumption of irreparable harm contrary to the holding in \textit{eBay}.\textsuperscript{80} The Federal Circuit reasoned that Sanofi had established irreparable harm and declined to rule on the presumption.\textsuperscript{81} In 2008, Federal Circuit declined to rule on presumption of harm for the third time in \textit{Amado v. Microsoft Corp.} stating it was

\textsuperscript{78} See \textit{id.}

\textsuperscript{79} \textit{Sanfi-Synthelabo v. Apotex, Inc.}, 470 F.3d 1368 (Fed. Cir. 2006)

\textsuperscript{80} \textit{Id.} at 1383, n. 9 (“Apotex contends that applying such a presumption is in direct contravention of the Supreme Court’s decision in \textit{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).

\textsuperscript{81} \textit{Id.}
unnecessary for the court to make a definitive ruling on the issue.\textsuperscript{82}

The lack of a clear ruling from the Federal Circuit led to confusion among the district courts.\textsuperscript{83} Some courts continued to apply the presumption of harm noting the eBay only applied to permanent injunctions. Others ruled that eBay had eliminated the presumption.\textsuperscript{84} There is even an instance where a court ruled that eBay had eliminated the presumption but declined to apply the

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\textsuperscript{82} Amado v. Microsoft Corp., 517 F.3d 1353, 1359 n.1 (Fed. Cir. 2008) ("We find it unnecessary to reach this argument, however, because \textit{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."") (emphasis added).
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\textsuperscript{83} 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.").
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presumption only because the plaintiff failed to establish success on the merits.  

In 2011, the Federal Circuit finally announced that “eBay jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of [preliminary] injunctive relief.” However, in the absence of the presumption, courts can still reach similar results by examining the patent holder’s right to exclude. 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. This is in contrast to “non-traditional” cases like eBay where the patentee had not made a commercial use of the patent.

III. THE HATCH-WAXMAN ACT AND PHARMACEUTICAL PATENT ACTIONS

85 Klewin, supra note 21, at 2136 (citing Wireless TV Studios, Inc. v Digital Dispatch Systems, Inc., No. 07 CV 5103(RJD)(RER), 2008 WL 2474626, *3 (E.D.N.Y. June 19, 2008)).
87 Id.
88 Id. at 1150-51.
89 Id. at 1150 (citing eBay 547 U.S. at 396-97 (Kennedy, J., concurring)).
The Hatch-Waxman Act\textsuperscript{90} was enacted to achieve two competing goals: protecting pharmaceutical patent rights and encouraging competition from generic pharmaceutical makers.\textsuperscript{91} This section will describe historical background the Act, the provisions of the Act, and the process outlined in the Act for the approval of generic pharmaceuticals.

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.\textsuperscript{92} Before a new drug was permitted to enter the market the manufacturer must submit a new drug application


(“NDA”). The NDA contained scientific studies attesting to the drug’s safety.

The FDA maintained a policy that kept any unpublished information submitted with an NDA as confidential. 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 submittals. The FDA further reasoned that if the competing companies making identical or similar drugs would be less likely to invest in testing and safety practices if can demonstrate the safety of their own products through the research of another drug maker. The policies promulgated by the FDA at the time presented a barrier to generic makers.

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 requirements. Over time, drug makers were often required to run two clinical trials to in order to

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93 Id.
94 Id.
95 Id. at 587.
96 Id.
97 Id.
98 Id.
99 Id. at 588.
“demonstrat[e] statistically significant benefits for consumers.”\textsuperscript{100} Drug makers were often required to file for a patent before clinical trials.\textsuperscript{101} The new requirements burdened the drug makers with lengthy studies and trials which eroded the exclusivity periods of their patents.\textsuperscript{102}

In 1970 the FDA created the Abbreviated New Drug Application (“ANDA”), an approval process for generic drugs.\textsuperscript{103} 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.\textsuperscript{104} Despite streamlining the ANDA process even further in 1980, there were very little generic competition in the market.\textsuperscript{105}

There was great concern over the rise of prescription drug prices in the early 1980’s.\textsuperscript{106} Drug makers, without competition

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\item \textsuperscript{100} Id.
\item \textsuperscript{102} In some instances, drug makers lost “up to ten years” of exclusivity. Id.
\item \textsuperscript{103} Weiswasser, supra note 91 at 589.
\item \textsuperscript{104} Id.
\item \textsuperscript{105} Id. at 589-90.
\item \textsuperscript{106} Id. at 590.
\end{itemize}
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.107 The need to 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 innovator pharmaceutical firms to make the necessary investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”108

First, Congress incentivized innovator companies by creating a process that can extend patent exclusivity by up to five years.109 Secondly, a generic drug could gain approval before the patent’s expiration; enabling a generic maker to

107 Id.

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

109 Weiswasser, supra note 91, at 591.
release the product to market at the moment of expiration.\footnote{Clements, supra note 101, at 388.} 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.\footnote{Id.} The Act established a new ANDA process that also enabled generic makers to market versions of drugs approved after 1962.\footnote{Weiswasser, supra note, at 593.}

The Act also gives additional incentives for generic makers by granting a 180 day period of marketing exclusivity for the first generic maker that successfully challenges a patent.\footnote{Id. at 603.} 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.\footnote{Id.}

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, \textit{Approved Drug Products with Therapeutic Equivalence Evaluations},
more commonly known as the “Orange Book.” 115 Innovator companies enjoy a period of “data exclusivity” for five years in which a generic maker may not submit an ANDA. 116 After the data exclusivity period expires, generic drugs are approved provided that the generic is the “same and bioequivalent” to an approved patented drug. 117 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

(5) sample labeling. 118

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);

115 Id. at 595.


117 Id. at 594.

118 Id. at 595 (quoting 21 U.S.C. § 355(j)(2)(A)(vi)).
(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). 119

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. 120 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. 121 Further, 35 U.S.C. § 271(e)(2) provides that conduct pursuant to an ANDA submittal with the purpose of challenging a patent is considered infringement. 122

119 Id. at 600 (citing 21 U.S.C. § 355(j)(2)(A)(vii)).
120 Id.
121 Id.
122 35 U.S.C. § 271(e)(2); Clements, supra note 101, 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
The patent holder has forty-five days to file suit after being served notice that a Paragraph IV certification has been filed.\textsuperscript{123} 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.\textsuperscript{124} If the suit is filed within the forty-five day period, the FDA must stay the approval of the ANDA for thirty months.\textsuperscript{125} 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.\textsuperscript{126} The ANDA is approved upon a finding that the patent is not valid or infringed.\textsuperscript{127}

The FDA grants a thirty month stay only once.\textsuperscript{128} An applicant will not be granted an additional stay for any

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\textsuperscript{123} Weiswasser, supra note 101, at 600.  \\
\textsuperscript{124} Id. at 601.  \\
\textsuperscript{125} Id.  \\
\textsuperscript{126} Id.  \\
\textsuperscript{127} Id.  \\
\textsuperscript{128} Id. at 602.  
\end{flushright}
subsequent Paragraph IV certifications.\footnote{Id. at 603.} After the expiration of the stay, the innovator company may move for a preliminary injunction to enjoin the generic maker from releasing their product.

In the absence of a preliminary injunction, generic makers may attempt to release their product in an “at-risk launch.”\footnote{Joseph M. O’Malley, Jr. et al., Failure to Launch, INTELLECTUAL PROP. MAGAZINE at 30, 30 (April 2011) available at http://www.paulhastings.com/assets/publications/1877.pdf.} 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.\footnote{Id.} The threat of a large damage award, which can exceed the expected revenues of a generic drug, had kept at-risk launches at bay.\footnote{Id.} However, starting in 2007 generic makers have been more aggressive in releasing product before the conclusion of litigation.\footnote{Id.} Commentators have stressed the importance of preliminary

\footnote{Id.} \footnote{Id.} \footnote{Id.}
injunctions by noting that preliminary injunctions have only been granted in two instances following an at-risk launch.\textsuperscript{134}

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.\textsuperscript{135} Preliminary injunctions were granted in seven

\textsuperscript{134} Id. at 31.

instances.\textsuperscript{136} 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 second injunction factor.\textsuperscript{137}

\textit{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. The drug at issue was Boniva, a treatment for osteoporosis.\textsuperscript{138} 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 patents for the method of treatment.\textsuperscript{139} Roche sought to enjoin generic makers from releasing their versions of Boniva after the expiration of the ’814 patent in March, 2012.\textsuperscript{140}

\textsuperscript{136} Id.

\textsuperscript{137} See supra note 81.

\textsuperscript{138} 2012 WL 869572 at *1.


\textsuperscript{140} Roche, 2012 WL 869572 at *1.
The defendants in *Roche* mounted a vigorous challenge to the validity of the ‘957 and ‘634 patents.\(^\text{141}\) The defendants cited to numerous studies, reports, and patents dating back to the late 1990’s trying to establish that the industry was researching towards a weekly or monthly treatment for osteoporosis.\(^\text{142}\) The defendants argued that the ‘957 and ‘634 patents would have been obvious to a pharmaceutical researcher on account of the published studies.\(^\text{143}\) Moreover, Roche did not highlight “the ingenuity of the inventors,” which is unusual when defending patent validity.\(^\text{144}\)

The court concluded that Roche did not establish a likelihood of success on the merits and denied the motion for preliminary injunction.\(^\text{145}\) However, the court declined to consider the other factors on basis of Roche failing to establish the first factor.\(^\text{146}\) The court similarly considered

\(^{141}\) For the obviousness standard, see *supra* note 30.

\(^{142}\) *Roche*, 2012 WL 869572 at *3–6.

\(^{143}\) *Id.*

\(^{144}\) *Id.* at *8.*

\(^{145}\) *Id.* at *8–9.*

\(^{146}\) *Id.*
only first factor in two other instances where the plaintiff’s application for preliminary injunction was denied.\(^{147}\)

While seeking a preliminary injunction, innovator companies often argue that an entry of a generic competitor causes price erosion and loss of market share.\(^{148}\) This, in turn, causes job losses, reduction of research opportunities for newer drugs, and a loss of goodwill and brand equity.\(^{149}\)

The court in \textit{AstraZeneca v. Apotex, Inc.}, in concluding that AstraZeneca had shown sufficient evidence of irreparable harm, analyzed each of the plaintiff’s arguments in depth.\(^{150}\) First, the court concluded that the damages stemming from a loss of market share and price erosion are not irreparable because loss of sales and profits are generally calculable.\(^{151}\) Moreover,\(^{147}\) \textit{Sandoz}, 2010 WL 1957640, at *6; \textit{Tyco}, 2009 WL 2422382, at *7.

\(^{148}\) \textit{AstraZeneca}, 623 F.Supp.2d at 608.

\(^{149}\) \textit{Id.}

\(^{150}\) \textit{Id.} at 608-14.

\(^{151}\) 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
the resulting loss of research opportunity and funding is also calculable.\textsuperscript{152}

The court also found that Apotex’s at-risk launch could cause irreparable harm through personnel layoffs.\textsuperscript{153} The court agreed that layoffs, while commonplace in business, can cause a loss of morale and productivity that cannot be calculated.\textsuperscript{154} Finally, the court concluded an at-risk launch can cause market confusion.\textsuperscript{155} 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.”\textsuperscript{156} Loss of goodwill as an irreparable harm is a concept originally from trademark law that has been incorporated into patent law.\textsuperscript{157}

instance, lost future sales and licensing revenue constituted an irreparable harm. \textit{Id.} at 608-11.

\textsuperscript{152} \textit{Id.} at 613.

\textsuperscript{153} \textit{Id.} at 612.

\textsuperscript{154} \textit{Id.}

\textsuperscript{155} \textit{Id.} at 613.

\textsuperscript{156} \textit{Id.}

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.\(^{158}\) In other instances, the court has held that a potential loss of jobs is too speculative for irreparable harm at large companies, such as many of the innovator companies.\(^{159}\)

The varied case law on how courts have evaluated irreparable harm in Hatch-Waxman actions validates Professor Chisum’s observations on irreparable harm determinations.\(^{160}\) The following cases illustrate how the court usually finds irreparable harm where it also finds a likelihood success from the plaintiff.

In Novartis Corp. v. Teva Pharms., USA, the court made a preliminary finding that Novartis was unlikely to establish that Teva’s generic version of Lotrel infringed on Novartis’ patents.\(^{161}\) The court also found that Novartis failed to

\(^{158}\) Sanofi-Aventis, 2010 WL 2428561, at *17; Novartis I, 2007 WL 2669338, at *15.

\(^{159}\) See Novartis II, 2007 WL 1695689 at *28.

\(^{160}\) See supra notes 33-34, 147, 155-56 and accompanying text.

\(^{161}\) See Novartis II, 2007 WL 1695689 at *24.
establish Teva’s infringement under the doctrine of equivalents.\textsuperscript{162}

Novartis further argued that Teva’s at-risk launch of generic Lotrel would cause irreparable harm through “lost sales revenue, irreversible price erosion, lost business and growth prospects, and lost research opportunities.”\textsuperscript{163} The court said that economic loss estimates set forth by Novartis seemed to go against their arguments for irreparable harm.\textsuperscript{164} Further, the court posited that any potential economic damages are calculable and thus could “be repairable by money damages.”\textsuperscript{165} Thus, the irreparable harm determination in Novartis is consistent with the definition in Chisum’s treatise.\textsuperscript{166}

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 Labs., Ltd., a preliminary injunction

\textsuperscript{162} \textit{Id.} at *25.

\textsuperscript{163} \textit{Id.} at *26.

\textsuperscript{164} \textit{Id.} at *27.

\textsuperscript{165} \textit{Id.} (citing Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991)).

\textsuperscript{166} See, \textit{supra} note 33 and accompanying text.
was sought to enjoin the defendant from an at-risk launch\textsuperscript{167} of
generic fexofenadine.\textsuperscript{168} Unlike the Novartis court, the court in
Albany Molecular found that the plaintiff had demonstrated a
likelihood of success on the merits.\textsuperscript{169}

Like in Novartis, the plaintiff argued that an at-risk
launch would mean a loss of market share, permanent price
erosion and loss of brand equity.\textsuperscript{170} 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.\textsuperscript{171} 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

\textsuperscript{167} 2010 WL 2516465, at *1.
\textsuperscript{168} Fexofenadine is an allergy medication, notable brand names
include Allegra. NAT’L INST. OF HEALTH, Fexofenadine, MEDLINEPLUS
(last visited Feb. 25, 2013)
\textsuperscript{169} 2010 WL 2516465, at *9.
\textsuperscript{170} Id. at *11.
\textsuperscript{171} Id.
in Hatch-Waxman litigation.\textsuperscript{172} In that case, the court declined to issue a preliminary injunction.\textsuperscript{173}

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.\textsuperscript{174} Likewise, in those nine instances, the court also found that the plaintiff had also established irreparable harm.\textsuperscript{175} 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.\textsuperscript{176} Courts have refused to

\begin{itemize}
  \item \textsuperscript{172} Sanofi-Aventis, 2010 WL 2428561 at *17
  \item \textsuperscript{173} Id.
  \item \textsuperscript{174} Roche, 2010 WL 4687839 at *1; Corepharma, 2010 WL 1850200 at *5; AstraZeneca, 623 F.Supp.2d at 614; Ortho McNeil, 2009 WL 2182665 at *11; Eisai, 2008 WL 1722098 at *13; Everett, 573 F.Supp.2d at 871. See also Warner Chilcott, 451 Fed.Appx. at 938 (although the Federal Circuit reversed and vacated the injunction, the District of New Jersey analyzed all four factors in favor of the plaintiff).
  \item \textsuperscript{175} See id.
  \item \textsuperscript{176} Sanofi-Aventis, 2010 WL 2428561 at *17; Altana, 532 F.Supp.2d at 684; Novartis II, 2007 WL 1695689 at *28; Novartis I, 2007 WL 2669338 at *13. See also Graceway, 679 F.Supp.2d at 610 (due to
consider the remaining factors once the plaintiff fails to establish the first factor in some instances.\textsuperscript{177} When the courts consider all four factors, they have been consistent in determining a lack of irreparable harm when declining injunctive relief.

\textbf{V. 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.\textsuperscript{178} However, it seems that the presumption is alive and well in Hatch-Waxman actions, in practice if not in name.\textsuperscript{179} It is clear that likelihood of success on the merits influences the irreparable harm determination.\textsuperscript{180} 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.\textsuperscript{177} Apotex, 2012 WL 869572 at *9; Sandoz, 2010 WL 1967640 at *6; Tyco, 2009 WL 2422382 at *7

\textsuperscript{178} Everett Labs., 573 F.Supp.2d at 866.

\textsuperscript{179} See supra, Part IV.

\textsuperscript{180} See, supra notes 171-74 and accompanying text.
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.\textsuperscript{181} The patent at issue in Robert Bosch LLC v. Pylon Mfg. Corp. was for windshield wiper blades.\textsuperscript{182} 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.\textsuperscript{183} Pylon is company based in Florida that manufactures wiper blades under license from DuPont and Michelin.\textsuperscript{184} After obtaining a favorable judgment at the district


\textsuperscript{182} 659 F.3d at 1145.


court, Bosch unsuccessfully sought a permanent injunction against Pylon.\(^{185}\)

On appeal, the Federal Circuit examined the four injunction factors \textit{de novo}.\(^{186}\) 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 injunctive relief.”\(^{187}\)

The court noted that plaintiffs “can no longer rely on presumptions and other short-cuts to support a request for [injunctive relief].”\(^{188}\) However, the court also enunciated that “fundamental nature of patents as property rights [include] the

\(^{185}\) Bosch, 659 F.3d at 1145.

\(^{186}\) Id. at 1148 (The permanent injunction factors are: “(1) that it has suffered an \textit{irreparable injury}; (2) that remedies available at law, such a \textit{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.”) (emphasis added).

\(^{187}\) Id. at 1148-49.

\(^{188}\) Id. at 1149.
right to exclude.” 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. Applying the four factor analysis, the court found that Bosch had made a showing of irreparable by, among other things, establish that Pylon had taken market share through infringing product. In reversing the trial court’s decision, commentators have noted that the new standard may not be much different from the old. 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.


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 on online marketplace. MercExchange is

189 Id.

190 Id. at 1149-50.

191 Id. at 1154.

192 Rantanen, supra note 178.

considered a non-practicing entity ("NPE"), also pejoratively known as a patent troll.\footnote{Jones, supra note 64, at 1040.} Bosch, on the other hand, is a global manufacturer that spent approximately $5 billion in 2011 for research and development.\footnote{Bosch to Invest $10 million to Support Local Higher Education and Research Initiatives, ROBERT BOSCH, LLC, http://www.bosch-press.com/tbwebdb/bosch-usa/en-US/PressText.cfm?CFID=14076722&CFTOKEN=11bf1e9020f1e5e1-99191F5A-FF13-106E-B37674354D662767&Search=1&id=466 (last visited Mar 2, 2013).}

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.\footnote{Joe Mullin, How Newegg Crushed the "Shopping Cart" Patent and Saved Online Retail, ARS TECHNICA (Jan. 27 2013), http://arstechnica.com/tech-policy/2013/01/how-newegg-crushed-the-shopping-cart-patent-and-saved-online-retail/.} They do not manufacture products of any kind nor do they sell goods over the internet or otherwise.\footnote{Id.} Instead, Soverain is known for initiating patent infringement suits and obtaining generous
settlements and licensing agreements. Due to their litigious conduct, Soverain is widely known as a patent troll. In 2004, Soverain filed a patent infringement action against Amazon.com and The Gap alleging infringements of patents for online payment processing and shopping carts. Amazon.com later settled the case days within the start of trial for $40 million.

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

198 Id. (note that the term “patent troll” was used a total of five times in the article).


201 Id.
settlement or as leverage in licensing negotiations, especially in cases where the patent holder is an NPE.

C. Differences Between NPE’s 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. By the time Instagram was acquired by Facebook in 2012 it held around eight hundred patents. Industry experts have valuated the labor costs of developing an app similar to Instagram at under $200,000. Even considering costs for filing patents, it does

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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. 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 one thoroughly researched chemical. Further, the research behind pharmaceutical patents is also protected the Hatch-Waxman Act’s data exclusivity period. Thus, pharmaceutical patent infringement is almost always between two producing entities.

D. Moving Forward


205 See supra note 7 and accompanying text.


207 Id. See also, supra note 113 and accompanying text.
While the Federal Circuit has made clear in *Bosch* that the irreparable harm presumption is no more, courts have the latitude to conclude similarly as if the presumption still applied.\textsuperscript{208} Latitude is not 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 note, 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.\textsuperscript{209} However, the same cannot be said of other jurisdictions.

A lack of certainty can lead to forum shopping.\textsuperscript{210} Knowing that a patent infringement suit may take much longer than 30

\textsuperscript{208} See supra, Part V(a).

\textsuperscript{209} See supra Part IV.

\textsuperscript{210} See Ronald T Coleman 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
month stay, innovator companies will try to file suit in a jurisdiction where the first two preliminary injunction factors have not been decoupled. This problem can be solved by amending the Hatch-Waxman Act to give courts the power to apply the irreparable harm presumption. First, courts can apply tests or presumptions outside of the four factors with legislative authorization. Secondly, applying the irreparable harm presumption is consistent with the legislative aims of the Act by strengthening pharmaceutical patent 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

\[\text{a forum that has applied eBay and demands proof of irreparable harm.}\]

\[211 \text{ See id.}\]

\[212 \text{ See eBay, 547 U.S. at 391-92.}\]
fundamentally change the outcomes of preliminary injunction motions in Hatch-Waxman cases.