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May 15, 2016 marked the 10th anniversary of the landmark eBay v. MercExchange decision, in which the United States Supreme Court held that permanent injunctions are not granted automatically in patent cases and that the traditional four-factor injunction test applies instead.¹ For the life sciences industry, where the cost of developing and bringing to market a new drug or biologic may exceed $2.5 billion and the cost of developing and bringing to market a new medical device may reach $1 billion, eBay poses a real threat to the incentive to invest if the market exclusivity of successful products is at risk.² With a decade of post-eBay case law to consider, we reflect on the impact the decision has had on the life sciences industry and the lessons learned along the way.

The eBay v. MercExchange Decision

Rejecting the “general rule” in patent cases “that a permanent injunction will issue once infringement and validity have been adjudged,”¹ the Supreme Court’s May 2006 decision in eBay Inc. v. MercExchange, L.L.C. required district courts to apply the familiar four-factor test in deciding whether to grant injunctive relief in patent cases.³ Under this test, to obtain a permanent injunction, a patentee must demonstrate (1) that it has suffered irreparable injury, (2) that monetary damages are inadequate, (3) that considering the balance of hardships, an injunction is warranted, and (4) that the public interest would not be disserved by a permanent injunction.⁴ The Supreme Court relied on 35 U.S.C. § 283, which “expressly provides that injunctions ‘may’ issue ‘in accordance with the principles of equity,’ ” even though in seemingly absolute terms 35 U.S.C. § 154(a) affords a patentee “the right to exclude others from making, using, offering for sale, or selling the invention.”⁵ The Court noted that this was consistent with the treatment of injunctions under the Copyright Act, which also provides that a court “may” enter an injunction even

³ eBay Inc., 547 U.S. at 391.
⁴ Id.
⁵ Id. at 392.
though the copyright owner is granted the right to exclude. Thus, as with the Copyright Act, “the creation of a right is distinct from the provision of remedies for the violation of that right.”

Although the district court in eBay purported to apply the proper test, the Supreme Court criticized the opinion for suggesting that in certain “‘broad classifications’ of cases—such as where a plaintiff is willing to license its patents or does not practice its patents—a patent holder would not suffer irreparable harm in the absence of an injunction.” The Court further noted that the Federal Circuit had swung the pendulum too far in the other direction by applying a standard under which permanent injunctions are entered automatically in patent cases except in “exceptional circumstances” and in “rare instances . . . to protect the public interest.” In rejecting “categorical” rules regarding grants or denials of permanent injunctions, the Court emphasized that district courts have “considerable discretion” in determining whether injunctive relief is appropriate. Thus, the injunction inquiry is fact-dependent, with few bright-line rules to be applied from case to case.

**Proving Irreparable Harm and Inadequacy of Monetary Damages post-eBay**

Because proving that monetary damages are inadequate often equates with establishing irreparable harm, these first two injunction factors are frequently analyzed together. An analysis of post-eBay case law reveals that the irreparable harm and inadequacy of monetary damages factors are most easily satisfied in cases involving direct competitors in a two-player market. This is because direct competition in a two-player market is most likely to create harm to the patentee that snowballs into tangible and intangible harms that are impossible to fully understand or quantify.

While “lost sales standing alone are insufficient to prove irreparable harm because they are presumed compensable through monetary damages,” they are a factor in the irreparable harm analysis when combined with other injuries. Lost sales mean lost customers and lost business opportunities that those customers could have provided, as well as lost market share and decreased revenue. Reduced revenue means less money available for employee attraction and retention and for research and development. For companies whose revenue streams, profitability, and continued research and development efforts depend on recouping costs through their commercially-successful products, a decreased revenue stream alone may cause irreparable harm. Moreover, where the patentee has to lower the price of its patented product due to the infringing competition (or risk harm to its goodwill and reputation), it would be nearly impossible to accurately calculate the actual economic loss through patent expiry. While high prices that follow from market exclusivity may harm the patentee’s reputation, competition may irreparably harm the patentee’s reputation as an innovator.

**Sanofi-Aventis Deutschland GmbH v. Glenmark Pharmaceuticals Inc., USA,** a patent dispute between two direct competitors, presents the quintessential fact pattern in which it should be relatively easy to establish irreparable harm and inadequacy of monetary damages. Sanofi-Aventis had market exclusivity for its patented Tarka® product until the defendants began marketing a generic version. The court noted that “Plaintiffs and Defendants are direct competitors in the Tarka market, prior to Defendants’ launch, Plaintiffs had 100% of the Tarka market; now every sale made by Defendants is a sale lost by Plaintiffs.” At the time of the litigation, Sanofi-Aventis had already lost two-thirds of its market share and expected to lose a total of 90% of the market to the generic competition. Moreover, Sanofi-Aventis had to reduce its price to compete with the infringing product and would not have been able to restore its price without hurting customer goodwill. Based on evidence of the loss of market share, price erosion, and the impact on the branded company’s customer goodwill, the court found that Sanofi-Aventis had demonstrated irreparable harm and inadequacy of monetary damages.

**Similarily, in Amgen, Inc. v. F. Hoffman-La Roche, Ltd.—**where the defendants intended to sell their infringing erythropoiesis-stimulating agent in direct competition with Amgen’s patented Epogen® product—the district court found that many of the same harms described in Sanofi-Aventis would occur if sales of the infringing product were not enjoined: “The vast majority of Roche sales would be to the exclusion of Amgen sales, resulting in lost profits, market share, and goodwill.” The court went on to recognize another potential harm in the absence of an injunction—that would-be infringers would be encouraged to try to gain market access and opportunities via infringing Amgen’s patents, which could result in “significant litigation expenses and uncertainty about the value of Amgen’s patents.” “[T]hese potentially immense and unquantifiable harms” demonstrated that denying an injunction would result in irreparable harm for which monetary damages are inadequate.

Many life sciences patent cases, especially in the biopharma sector, similarly involve disputes between direct competitors where the infringing product threatens to undercut the patentee’s market exclusivity and cause the irreparable harms discussed above. An injunction is necessary to prevent a loss of sales and market share and the intangible harms that could occur if the infringing product is not enjoined. However, even with help-

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6 Id. at 392-93.
7 Id. at 392.
8 Id.
9 Id. at 393-94.
10 Id. at 394.
11 See, e.g., Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc., 579 F. Supp. 2d 554, 558 (D. Del. 2008) (“Courts awarding permanent injunctions typically do so under circumstances where plaintiff practices its invention and is a direct market competitor.”).
ful facts, patentees now risk being denied an injunction if they do not substantiate their claims of future irreparable harm22 and inadequacy of monetary damages.23

Edwards LifeSciences, AG v. CoreValve, Inc., presents a cautionary tale with respect to a situation where the infringing product is already on the market. The parties were direct competitors in the market for heart valves and Edwards’ patent was found valid and willfully infringed.24 Yet, in denying a permanent injunction, the district court determined that Edwards had failed to demonstrate the necessary prospective irreparable harm. The evidence that Edwards proffered consisted of past harms—such as loss of first-mover advantage25 and market share—that would not be rectified by a permanent injunction.26 On appeal, the Federal Circuit criticized the district court’s analysis of irreparable harm, stating: “A patentee’s right to exclude is a fundamental tenet of patent law. . . . Absent adverse equitable considerations, the winner of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement.”27 The Federal Circuit went on to discuss the various injunction considerations and pointed out that ‘‘eBay did not hold that there is a presumption against exclusivity on successful patent infringement litigation.’’28 The denial of an injunction was therefore vacated and remanded “for consideration in light of ensuing events and any other relevant factors.”29

Edwards later obtained a preliminary injunction, after which the parties reached a global settlement and entered into a cross-license agreement.30 Nonetheless, the district court opinion highlights how important it is for the patentee to identify evidence of prospective harms, such as business plans projecting the need to lower prices, lost customers, or continued loss of market share absent an injunction.

In contrast to cases between direct competitors in a two-player market are cases involving a multi-player market, where it is more difficult to prove that infringing sales take any sales from the patentee (as opposed to other market players) or otherwise harm the patentee’s business. Similarly, the irreparable harm and inadequacy of monetary damages factors typically disfavor a permanent injunction where the patentee either does not practice the invention or is selling in a different market. These facts are less common, but not unheard of, in the life sciences industry.31

A patentee’s willingness to license its patents may also bear on whether monetary damages are an inadequate remedy.32 On the one hand, “a patent holder’s refusal to grant a license and its engagement in lengthy litigation to protect that business decision . . . weighs in favor of finding the remedy at law inadequate.”33 On the other hand, a patentee’s broad licensing of its patent rights, as in Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., is “inconsistent with [its] assertion that only enforcement of its rights to exclude” would adequately address its harm.34 However, the license of patent rights does not always weigh against an injunction. The patentee in Acumed LLC v. Stryker Corp, established irreparable harm and lack of adequate remedy at law even though it had licensed the patent-in-suit on two occasions, once in a settlement and once to a company that later became its competitor.35 In affirming the district court decision, the Federal Circuit noted that “[a]dding a new competitor to the market may create an irreparable harm that the prior licenses did not.”36 Thus, while licensing does not preclude a finding that monetary damages would be inadequate, the patentee must show why licensing does not defeat this factor.

The Continued Importance of the Public Interest Factor in Life Sciences Cases

The public interest factor has always been a hurdle for life sciences companies in obtaining permanent injunctions. The pertinent question is whether the

31 See, e.g., Advanced Cardiovascular Sys., 579 F. Supp. 2d at 558-60 (no irreparable harm where there were at least two other major competitors, patentee had regained nearly all market share lost to infringer, and there was no evidence of specific customers that patentee was likely to lose if an injunction was not imposed); Tyco Healthcare Group LP v. Applied Med. Res. Corp., No. 9:09-CV-176, D.N. 138, Order on Pending Post-Trial Mot. 5 (E.D. Tex. May 17, 2010) (no irreparable harm where the parties were no longer direct competitors because plaintiffs could not use the patented technology by virtue of an injunction in another case).

32 Acumed LLC v. Stryker Corp., 551 F.3d 1323, 1328 (Fed. Cir. 2008) (A patentee’s willingness to license its patent is “but one factor for the district court to consider.”).

33 Sanofi-Aventis, 821 F. Supp. 2d at 694 (internal quotation marks omitted).

34 712 F. Supp. 2d 1285, 1289 (M.D. Fl. 2010) (Johnson & Johnson offered to license or entered into licenses with three major domestic competitors and entered licenses with two foreign manufacturer).


36 Acumed LLC, 551 F.3d at 1329.
public interest would be “served” by an injunction, but whether it would “not be disserved”—a distinction of consequence. The patentee need not demonstrate that the public interest would benefit from an injunction, only that it would not be harmed.

While there is no clearly-defined rule dictating when an injunction would deserve the public interest and thus preclude a permanent injunction, it is well established that “the public interest in having access to generic drugs at reduced prices” is not enough to outweigh the “significant public interest in encouraging the massive investment in research and development that is required before a new drug can be brought to market.” Courts “have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the ‘encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.’” Favoring and incentivizing innovation seems especially appropriate when the competing products are essentially the same and serve the same patient population such that an injunction would not interfere with physician or patient choice.

However, even where the infringing product could potentially treat patients differently than the patented product, speculative harm to the public interest has been insufficient to outweigh the “public’s interest in robust patent rights that protect incentives for innovation.” In *Amgen Inc. v. F. Hoffman-La Roche*, the district court permanently enjoined the defendants’ infringing erythropoiesis-stimulating agent, even though “doctors and patients would probably benefit from additional choice.” The court found that public interest would not be disserved by an injunction where “there was no solid evidence that patients or the public coffers will suffer significant harm if the status quo is maintained.”

The public interest is most likely to trump irreparable harm and inadequacy of money damages where there are safety concerns or the possibility of treating a different or larger population of patients, or where the patent has already widely adopted the infringing product and an injunction would cause significant disruption to patient care.

In *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, for example, the district court evaluated the effect of enjoining the sale of the infringing Acuvue® Oasys contact lenses which were already being worn by approximately 5.5 million Americans. The court determined that the infringing lenses were the preferred choice by many eye care practitioners and that an injunction would have caused “substantive concerns” regarding “proper vision and eye care,” as well as disruption, confusion, and cost to patients who would have to be refitted to change brands. Because an injunction would “create consequential medical, practical and economic issues for large numbers of” users, the court found that an injunction would disserve the public interest. Similarly, the public interest factor outweighed irreparable harm and inadequacy of monetary damages in *Conceptus, Inc. v. Hologic, Inc.* where the infringing process—involving a sterilization product and process—was “not interchangeable” with the patentee’s product and process, and each had different side effects and safety issues. Finally, the district court in *Retractable Technologies Inc. v. Becton Dickinson & Co.* found that the public interest would be disserved by removing the infringing retractable syringe from the marketplace in light of evidence that the infringer’s syringes were different from the patented product and both could “be beneficial medical products for at least some applications.”

In contrast, “[n]umerous courts have granted permanent injunctions in cases involving medical devices where . . . there were alternative products already on the market or available to the infringer.” The key factor appears to be whether the infringing product provides an advantage over, or different qualities as compared with, the patentee’s product, as opposed to just providing choice and convenience. In *Smith & Nephew, Inc. v. Interlace Medical, Inc.*, the district court found that the public interest would not be disserved by granting an injunction because “anecdotal evidence about physician preference is not enough to prove an issue of patient safety.” Similarly, in *Alps South, LLC v. The Ohio Willow Wood Co.*, the district court found that the public’s interest in protecting the right of patent holders outweighed potential negative consequences to patients where there was no evidence of “substantial inconvenience, additional costs, or adverse consequences” even if patients needed to be refitted with a non-infringing product.

The courts increasingly are trying to find compromise positions to not disserv the public interest while minimizing the erosion of the patentee’s right to exclude. The injunction imposed in *B. Braun Melsungen AG v. TerumoMedical Corp.*, for example, tried to strike a balance by providing Terumo a fifteen month “sunset” period where it would be allowed to continue to sell the infringing product into a limited market segment while it developed and introduced a non-infringing catheter product before a complete injunction would be

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37 *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007) (internal quotation marks omitted) (permanently enjoining acts of infringement after Apotex launched generic version of Plavix® at risk where these “competing, important public interests in this litigation are either in equipoise or slightly favor Sanofi®”); *Sanofi-Aventis*, 821 F. Supp. 2d at 695-96.

38 *Sanofi-Synthelabo v. Apotex*, 470 F.3d 1368, 1383 (Fed. Cir. 2007) (citing *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985)).

39 *Amgen Inc.*, 581 F. Supp. 2d at 229.

40 Id.

41 Id. at 210.

42 *Johnson & Johnson Vision Care*, 712 F. Supp. 2d at 1290.
imposed.\textsuperscript{50} Other districts are granting injunctions, but
only as to new infringing products, so that products al-
ready on the market can be used without interruption.\textsuperscript{51}
Still other courts are granting and then staying the per-
manent injunction until the conclusion of any appeal or
reexamination period, to avoid impacting the public in-
terest in the interim.\textsuperscript{52}

\textbf{Where Are We Now?}

The more things change, the more they stay the
same. At least this is true for most life sciences cases in
a post-\textit{eBay} world. While many recent case law devel-
opments have tended to limit patentee rights and make
enforcement more difficult (\textit{e.g.}, the rising \textsection 101 and
\textsection 112 definiteness bars and the availability of new post-
grant procedures), \textit{eBay}’s requirement that courts apply
the traditional four-factor injunction standard for
patent cases has not drastically affected the ability of
life sciences companies to obtain injunctions after de-
terminations that their patents were infringed and not
invalid. Patentees do, however, have to make more of
an effort now than pre-\textit{eBay} to prove irreparable harm and
the inadequacy of monetary damages. For life sci-
ences companies where the value of market exclusivity
is paramount, these first two factors should be rela-
tively straight-forward to establish in most cases. How-
ever, they may be overcome by the public interest fac-
tor, which continues to be the most common barrier to
an injunction for life sciences companies. And where
market exclusivity is not of paramount value to the pat-
entee (as demonstrated through licensing practices), or
where the public interest would objectively be diserved
by an injunction, declining to seek a permanent injunc-
tion may save valuable time and resources while main-
taining credibility with the court and the public.

The last decade of patent injunction case law pro-
vides some lessons learned. A few key take-aways for
life sciences companies seeking to enforce their patent
rights include:

\begin{itemize}
  \item Consider the injunction case during pre-litigation
due diligence to decide whether an injunction
would be appropriate based on public interest im-
plications and also whether it is worth the neces-
sary time and resources to mount a fact-intensive
injunction case based on the likelihood an injunc-
tion would be granted;
  \item If the company decides to seek an injunction, start
marshaling the evidence early to be able to create
\end{itemize}

\begin{itemize}
  \item a sufficient record to establish that the \textit{eBay} fac-
tors favor an injunction and rebut any anticipated
arguments against an injunction;
  \item Especially if the infringing product is already on
the market, identify \textit{prospective} harms, such as
specific customers the patentee may lose to the
competitor, the company’s plans to reduce
prices to compete, and the quarter-over-quarter
loss of market share that will likely continue if
the infringing activity is not enjoined.
  \item To prove irreparable harm and inadequacy of
monetary damages:
    \begin{itemize}
      \item Build the story and evidence to show the impor-
tance of the right to exclude and market exclu-
sivity to the company’s business model, and the
parade of horrible harms that would occur if
forced to license valuable patent rights to a com-
petitor or other player in the market;
      \item Explain why existing license agreements, if any,
do not mandate a finding that monetary dam-
ages would be adequate; for example, because
the licenses were not to competitors, were to
small, non-threatening market players, or were
cross-licenses with other companies (even com-
petitors) where the value of the agreement ex-
ceeded the patent rights because they ended
lengthy, expensive litigation.
    \end{itemize}
  \item To prove an injunction would not disserve the
public interest:
    \begin{itemize}
      \item If possible, seek an injunction prior to the
launch of the infringing product to preclude a
public interest argument of physician or patient
preference for or reliance on the infringing
product, and also make the point that any al-
leged benefit to the public is mere speculation;
      \item If the infringing product has already launched,
marshaling evidence that it does not provide pa-
patients with any concrete medical or safety ben-
fits beyond the patented products already on
the market;
      \item Where the public interest factor may militate
against a complete injunction, be creative in fash-
ioning requested injunctive relief to minimize ef-
fect on public interest while preserving as much
market exclusivity as practical.
    \end{itemize}
\end{itemize}

In sum, while \textit{eBay} has not dramatically altered the
landscape for patent cases in the life sciences industry,
it has created some curves in the road to obtaining per-
manent injunctions—curves that can best be traversed
by understanding the trends in the post-\textit{eBay} case law
and preparing accordingly.

\textsuperscript{50} 778 F. Supp. 2d 506, 524 (D. Del. 2011).
\textsuperscript{51} See, \textit{e.g.}, \textit{Fresenius Med. Care Holdings}, 2008 BL 75933,
at *6-7.
\textsuperscript{52} See, \textit{e.g.}, \textit{Smith & Nephew}, 955 F. Supp. 2d at 80.