

Assessing the Likelihood of a Preliminary Injunction in DCM Patent Litigation

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A preliminary injunction (PI) is an important remedy in patent infringement actions. For the patentee, it provides an opportunity to protect the market share a patented product has earned. For the accused infringer, it is a threat to a significant investment of time and resources into the development and launch of a new product. Consequently, this remedy is a frequent consideration in the drug, chemical and medical device (DCM) industry where the accused product (such as a generic drug) has the potential to cause tens of millions of dollars in lost revenue for the patentee. With such high stakes, it is beneficial for a patentee and accused infringer in the DCM industry, as a part of their due diligence, to assess the likelihood that a district court would impose a PI. Similarly, a company looking to develop and introduce a new product in the market should analyze the possibility of a PI as a part of its freedom to operate analysis.

This article will discuss how the PI win-rate has changed over the last 15 years, whether there is a difference in the success rate for DCM patents, and how district courts apply the famous four-factor test in DCM patent cases.

Preliminary Injunctions

Section 283 of 35 U.S.C. gives district courts the authority to "grant injunctions in accordance with the principles of equity." While it is not explicitly mentioned, the Federal Circuit has held that this "provision authorizes courts ... to grant preliminary injunctions." *High Tech Med. Instrumentation v. New Image Indus.*, 49 F.3d 1551, 1554 (Fed. Cir. 1995).

The purpose of a PI is "to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). A PI is considered an extraordinary remedy that is not routinely granted. *High Tech Medical*, 49 F.3d at 1554. The Supreme Court in *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 20 (2008), recently reaffirmed this principle and the need for district courts to apply the traditional four-factor test:

A plaintiff seeking a preliminary injunction must establish:

1. That he is likely to succeed on the merits;
2. That he is likely to suffer irreparable harm in the absence of preliminary relief;
3. That the balance of equities tips in his favor; and
4. That an injunction is in the public interest.

Obtaining PIs in Patent Cases

The success rate for obtaining PIs in patent cases over the last 15 years has been significantly influenced by the Supreme Court's decision in *eBay v. MercExchange*, 547 U.S. 388 (2006). Pre-*eBay*, the Federal Circuit applied an abbreviated standard that presumed irreparable harm "when a clear showing of patent validity and infringement has been made." *Amazon.com v. Barnesandnoble.com*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). In 2006, the Supreme Court took up this issue and rejected the Federal Circuit's presumption of irreparable harm. Instead, the Supreme Court emphasized the importance of applying the entire four-factor test "consistent with traditional principles of equity." *eBay*, 547 U.S. at 394. Subsequent to *eBay*, there were varying interpretations of the impact of *eBay* and whether *eBay* significantly increased the burden for a patent owner to obtain an injunction. The immediate effect of *eBay* can be observed by comparing the PI win rate before and after *eBay*. The attached table shows that from 1998 to 2005, the win rate was relatively consistent at or above 30 percent. After *eBay*, from 2007 to 2010, there was a larger volatility in the win rate from year to year. (The line graph is reproduced with permission from LegalMetric Inc.)

The volatility appears to have dissipated beginning in 2011, and there has been a steady increase in the PI win rate. One likely reason is that the Federal Circuit stepped in and explained the effect of *eBay* on a patentee obtaining an injunction. In *Robert Bosch v. Pylon Mfg. Corp.*, the Federal Circuit took the "opportunity to put the question to rest and confirm that *eBay* jettisoned the presumption of irreparable harm." 659 F.3d 1142, 1149 (Fed. Cir. 2011). However, the Federal Circuit advised that granting an injunction to a patent owner nevertheless is "consistent with traditional equitable principles" (*Id.* at 1148), and noted: "Although the Supreme Court disapproved of this court's absolute reliance on the patentee's right to exclude as a basis for our prior rule favoring injunctions, that does not mean that the nature of patent rights has no place in the appropriate equitable analysis." *Id.* at 1149.

Obtaining PI's in DCM Patent Cases

With respect to DCM patent cases, the success rate is much higher. A review of these cases from 2013 to 2016 reveals that the patentee prevailed approximately 45 percent of the time. The relatively higher rate of success in this field demonstrates why it is important, as a part of any litigation due diligence analysis, to assess the likelihood that a district court will impose a PI based on the four-factor test.

Courts determine that the patentee is likely to succeed on the merits when the patentee demonstrates that "it will likely prove infringement of one or more claims of the patents-in-suit" and "will also likely withstand the validity challenges presented by the accused infringer." *Amazon.com*, 239 F.3d at 1351. The district court is given broad discretion in this determination. *See Bio-Technology Gen. Corp. v. Genentech*, 80 F.3d 1553, 1558 (Fed. Cir. 1996). One exception, however, is claim construction, which is given de novo review by the Federal Circuit. *Pfizer v. Teva Pharm. USA*, 429 F.3d 1364, 1373 (Fed. Cir. 2005). If the Federal Circuit were to overturn a PI determination, it would likely be because the Federal Circuit found an error in the district court's claim construction.

With respect to irreparable harm, patentees in DCM patent cases typically prevail by presenting evidence of loss of market share, price erosion, loss of goodwill/customer relationships, damage to reputation, loss of business/research opportunities and employee layoffs. *See, e.g., Celsis In Vitro v. CellzDirect*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Sanofi-Synthelabo v. Apotex*, 470 F.3d 1368, 1381 (Fed. Cir. 2006). Other factors that may influence this analysis include whether the patentee delayed in seeking a PI, whether there are licensees in the market and patent term. One factor to be mindful of, however, is that the patentee must show "some causal nexus between [defendant's] infringement and the alleged harm to [plaintiff]." *Apple v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). If customers are buying the accused product "for reasons other than the patented feature," then the patentee has not been irreparably harmed by the infringement. *Id.*

When evaluating the balance of the hardships in DCM patent cases, courts typically weigh the patentee's irreparable harm, loss of value to the patent, whether the patentee is a relatively small business against the accused infringer's lost business opportunity, and whether the accused infringer is a relatively small business. *See, e.g., Pfizer*, 429 F.3d at 1380-81; *Everett Labs v. Breckenridge Pharm.*, 573 F.Supp.2d 855, 867-68 (D.N.J. 2008). Typically, the balance

of the hardships favors the patentee, especially when the accused infringer knows of the patent. However, some district courts recognize that both sides will be subject to hardships and treat this as a neutral factor.

When evaluating the public interest, courts typically weigh the interest in protecting the integrity of the patent system against getting new and affordable drugs or devices on the market. See, e.g., *Celsis*, 664 F.3d at 931-32; *Sanofi-Synthelabo*, 470 F.3d at 1383-84. Once again, the interest in protecting the patent system typically wins, especially when the patent owner and accused infringer are selling the same or substantially similar product. However, like balance of the hardships, some district courts recognize that the public has an interest associated with both parties and treat this as a neutral factor.

As noted above, district courts, applying these four factors, are more likely to grant PIs in DCM patent cases than in other patent cases. To the extent that a district court denies a PI in a patent case, it is most likely because the patentee failed to demonstrate a likelihood of success or irreparable harm. In 2013-2016, approximately one-third of denials were because the patentee did not demonstrate likelihood of success alone, and one-third were because the patentee didn't demonstrate irreparable harm alone. The remaining third were denied because the patentee failed on both fronts. While courts do make note of the balance of the hardships and public interest, ultimately, those factors alone did not carry the day in denying a PI.