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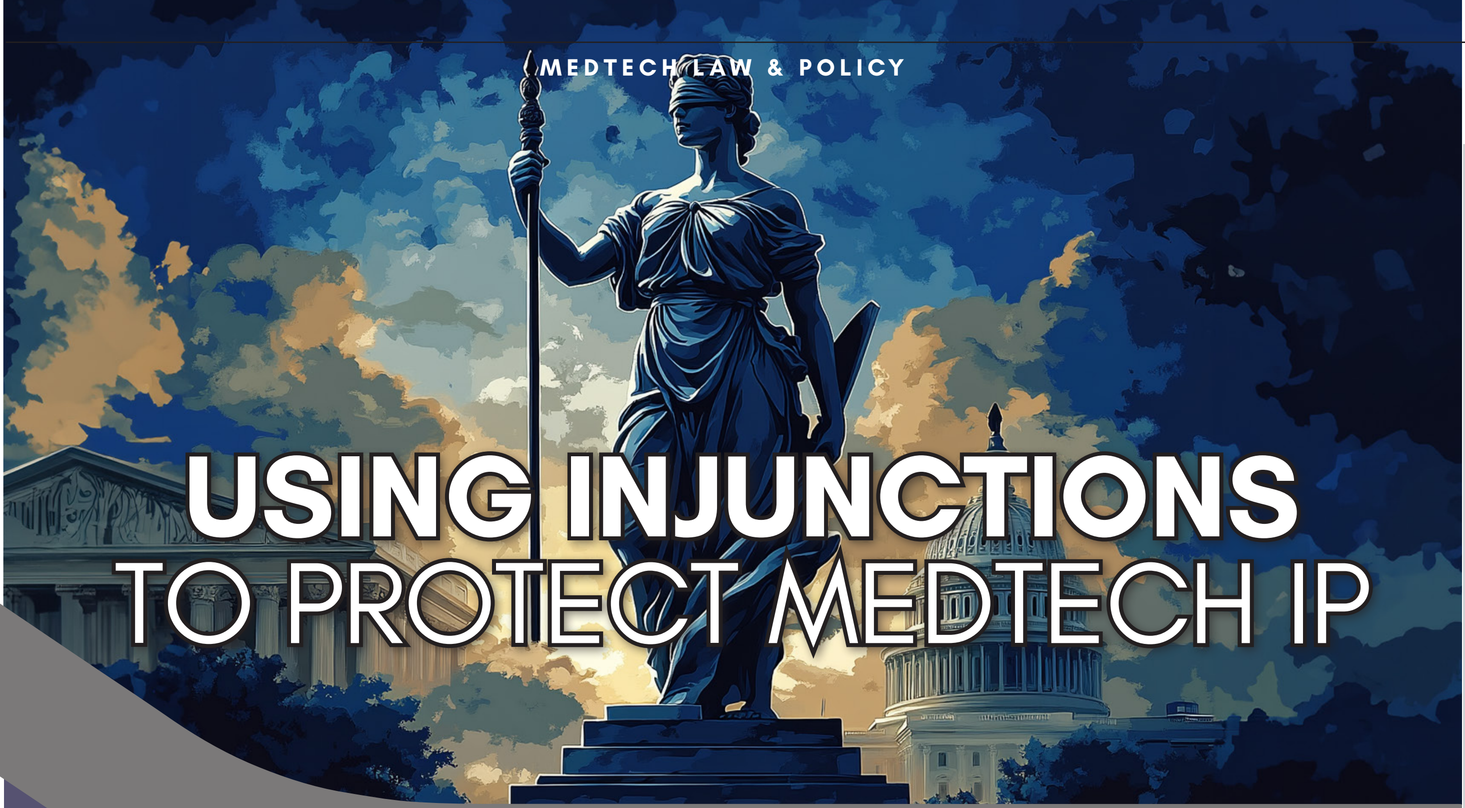

USING INJUNCTIONS TO PROTECT MEDTECH IP

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Permanent injunctions can be a powerful tool in protecting medical device patents. Two experienced IP counselors outline the standards that product companies need to meet to invoke this approach.

Medical device companies face increasing scrutiny on how patents will affect their business. Investors, boards of directors, and strategic partners may ask if competitor patents will prevent market entry—or whether the company's patents can block infringing products. To respond to such scrutiny, companies must understand and assess infringement remedies. These remedies can compensate for past patent infringement, and they can even prevent future sales of infringing products through a court-ordered injunction.

Historically, obtaining a permanent injunction was automatic if infringement was found, as the patent statute emphasizes that exclusion is a fundamental aspect of patent rights. Outcomes from motions for permanent injunctions in patent cases from 2008 to present are summarized as an example (*see Figure 1*).

The figure illustrates that patent owners across all sectors secured permanent injunctions in approximately 86% of cases. The last analysis of injunctions in the medical device area occurred in 2013. It revealed that medical device companies outperformed other sectors, securing permanent injunctions in 80% of cases that went to trial. This success rate, which is 10% higher than many other sectors, demonstrates the potential of medical device companies to obtain permanent injunctions in patent cases (see *MobiHealthNews*, March 22, 2013). However, the total number of patent cases each year, including those that do not go to trial, ranges from 2,300 to 7,000. Accordingly, only about 1% of total patent cases result in a permanent injunction.

Our analysis of medical device companies' post-trial motions for permanent injunctions decided since 2010 revealed that these companies secured permanent injunctions in about 76% of cases. This finding underscores the importance of careful consideration of potential outcomes in advance. While the scope of the patent owner's right to exclude future conduct is nuanced, exclusion remains integral to the patent grant. These nuances pose challenges for medical device patent owners and technology developers, making it crucial for companies to navigate them with foresight and strategic planning.

The Supreme Court has identified four equitable factors for judges to consider when evaluating the appropriateness of a permanent injunction: (1) whether the patent holder would suffer irreparable harm without such relief; (2) whether monetary damages or other legal remedies are sufficient to compensate for the infringement; (3) whether granting a permanent injunction would impose greater hardship on the infringer than on the patent owner; and (4) whether such relief would serve the public interest. Below we discuss how courts have dealt with each of these factors when determining whether to grant a permanent injunction.

1 Whether the patent holder will suffer irreparable harm

To establish irreparable harm, the patent holder must demonstrate that the infringer's actions have caused harm, and establish a link between the infringement and the harm. This connection can be established by showing that consumers purchased the accused product specifically for its patented features. It is not necessary to prove that the patented features were the sole cause of downstream sales. Evidence showing a loss of market share, price erosion, damage to goodwill, damage to reputation, and missed business opportunities are also considered grounds for establishing irreparable harm, as the following examples illustrate.

Loss of Market Share: In a case regarding retractable syringes, the patent holder was losing market share to the competitor while the market was growing. (*Retractable Techs. Inc. v. Becton, Dickinson & Co.*, No. 2:07-CV-250 (E.D. Tex. May 19, 2010)). The patent holder company was small in size, and retractable syringes were its main product. The court relied on all these facts in finding the harm of infringement was irreparable.

In another case, the patent owner successfully argued that the parties were the only two players in the orthopedic pulsed lavage market. (*Stryker Corp. v. Zimmer Inc.*, No. 1:10-CV-1223 (W.D. Mich. Aug. 7, 2013)). This highly concentrated market was also found to cause irreparable harm.

Loss of Goodwill and Damage to Reputation: In a case regarding hydradermabrasion systems, a court found loss of goodwill and damage to reputation from customer complaints regarding the competitor's product—which they believed to be the patent holder's product. (*Edge Sys. LLC v. Aguila*, No. 1:14-cv-24517 (S.D. Fla. May 9, 2016)).

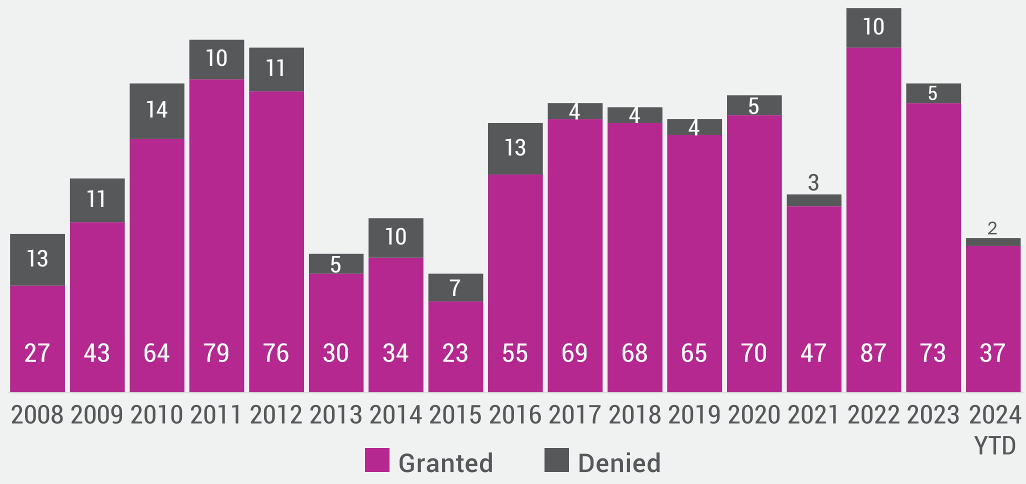
2 Whether other remedies available at law, such as monetary damages, are adequate to compensate for the infringement

Many courts struggle to determine the adequacy of monetary damages because it is inherently challenging to quantify harm from loss of market share, brand recognition, and customer goodwill. In many cases, courts rely on the existence of direct competition between the patent owner and competitor to suggest monetary damages would be inadequate. Some courts reason that because a direct competitor's sale could take *market share* in this case, the effect would be more harmful than merely the loss of the particular sales.

In other instances, courts consider whether the infringer would be unable to pay the requisite monetary damages. If the monetary damages cannot be paid, then the monetary damages are clearly not adequate compensation.

Figure 1

Permanent Injunction Outcomes, 2008-2024



Source: Docketfinder.com

For example, in a case about competitors in the tourniquet space, the accused infringer had filed for bankruptcy and the bankruptcy plan contemplated paying creditors through continued infringement. (*Composite Res. Inc. v. Recon Med. LLC*, No. 2:17-cv-01755 (D. Nev. Jan. 6, 2022)). In light of this, the court found there was no adequate remedy besides a permanent injunction.

On the other hand, where the patentee had previously demonstrated a willingness to accept an ongoing royalty, or where the patent holder had previously licensed the patent to competitors, courts can find that monetary damages are an adequate remedy, and a permanent injunction is not required.

3 Whether the balance of hardships favors injunctive relief

When determining the relative effect on the parties of granting or denying an injunction, courts consider the parties' respective sizes, products, and revenue sources. Courts may consider both past harm and potential future harm when attempting to balance the hardships.

On the patentee side, courts often weigh the time, capital, and other resources the patent holder expended to develop, promote, and sell its patented products against the loss of income to the infringer. The infringer's hardship sometimes can outweigh any harm to the patentee where there is no evidence of continuing infringement, and where imposing an injunction would require the accused infringer to spend a substantial amount of money in redesigning all its marketing materials and packaging. (*KFx Med. Corp. v. Arthrex Inc.*, No. 11-cv-1698 (S.D. Cal. Feb. 18, 2014)).

In a case on surgical endoscopic cutting devices, a court found that the balance of hardships weighed against a permanent injunction where there was no evidence that the infringement was willful, the asserted claims were subject to ongoing Patent Office reexaminations, and an injunction would cause the accused infringer to lose a large investment and lay off a significant number of employees. (*Smith & Nephew Inc. v. Interlace Med. Inc.*, No. 1:20-cv-10951 (D. Mass. June 27, 2013)).

4 Whether the public interest will be harmed by injunctive relief

The public interest generally favors upholding patent rights. In contrast, inconvenience to an infringer's customers or end users does not generally tilt the public interest analysis in favor of the infringer. But exceptions can arise for critical medical technologies. Specifically, courts have found that the public interest would be harmed if an injunction had the potential to interrupt the public availability of important medical technology, such as syringes, drugs, etc. But even if a technology is critical, some courts have found that the public interest still will not be harmed where the patentee can supply the market sufficiently.

In a case about a contact lens design, the public interest favored keeping the infringing contact lens on the market to prevent disruption, confusion, and cost to patients. (*Johnson & Johnson Vision Care Inc. v. CIBA Vision Corp.*, No. 3:05-cv-135 (M.D. Fla. Aug. 10, 2010)). The court found that the patent holder's lenses may not fit all patients and rejected the argument that patients could just wear glasses instead.

Some courts have found that the public interest favors the infringer when healthcare providers and patients benefit substantially from having both the patent holder's and infringer's products available in the market. Some consideration can also be given to the fact that doctors preferred the infringing product over the patent holder's device.

In a case on vascular closure devices, the court weighed the accused product's improved, extravascular, and newer technology against preserving the integrity of the patent system. (*St. Jude Med. Inc. v. Access Closure Inc.*, No. 08-CV-4101 (W.D. Ark. June 4, 2012)). Here, both parties presented doctor declarations stating they preferred one device over the other. Overall, the court found that even with the accused product enjoined, doctors would still be able to treat patients having punctures in their arteries, and that an injunction would not harm the public interest.

In conclusion, medical device companies should understand the equitable factors underlying patent injunctions. Permanent injunctions serve as a potent tool for protecting intellectual property, provided that patentees demonstrate diligent enforcement and adherence to the principles guiding equitable relief.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