

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 13-2290

FERRING PHARMACEUTICALS, INC.,

Appellant

v.

WATSON PHARMACEUTICALS, INC.

On Appeal from the United States District Court
for the District of New Jersey
(No. 2-12-cv-05824-DMC-JAD)
District Judge: Honorable Dennis M. Cavanaugh

Argued: February 12, 2014

Before: CHAGARES, SHWARTZ, and ALDISERT, Circuit
Judges.

(Filed: August 26, 2014)

Arne M. Olson, Esq. (Argued)
Dennis H. Ma, Esq.
Brian R. Michalek, Esq.
Olson & Cepuritis
20 North Wacker Dr., 36th Floor
Chicago, IL 60606
Counsel for Appellant

David W. Phillips, Esq. (Argued)
Karol C. Walker, Esq.
LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard, 16th Floor

Newark, NJ 07102
Counsel for Appellee

David H. Bernstein, Esq.
Debevoise & Plimpton
919 Third Avenue
New York, NY 10022
Counsel for International Trademark
Association, Amicus Curiae

OPINION

CHAGARES, Circuit Judge.

Appellant Ferring Pharmaceuticals, Inc. appeals from a District Court order denying its motion for a preliminary injunction against appellee Watson Pharmaceuticals, Inc.¹ This appeal requires us to determine, inter alia, whether a party seeking a preliminary injunction pursuant to a Lanham Act claim is entitled to a presumption of irreparable harm. We conclude that, in light of the Supreme Court's decisions in eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006), and Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7 (2008), a party bringing a claim under the Lanham Act is not entitled to a presumption of irreparable harm when seeking a preliminary injunction and must demonstrate that irreparable harm is likely. We also conclude that the District Court did not err in finding that Ferring failed to demonstrate irreparable harm. We will, therefore, affirm the District Court's order.

I.

A.

¹ Watson Pharmaceuticals, Inc. is now known as Actavis, Inc. However, the parties refer to Watson in their briefs, and we will do so as well for ease of reference.

Ferring and Watson are pharmaceutical companies that market competing prescription progesterone products. Progesterone is a hormone that plays a key role in helping women become pregnant and maintain their pregnancies, specifically by preparing the uterine lining for the embryo and maintaining the lining to support the embryo during the early stages of pregnancy. Although women naturally produce progesterone, women seeking to become pregnant through assisted reproductive technology (“ART”) procedures, such as in vitro fertilization, generally require progesterone supplementation. Historically, women have received progesterone through intramuscular shots, which are not approved by the Food and Drug Administration (“FDA”) and which patients consider painful. Ferring and Watson each manufacture a product that administers progesterone to women through vaginal inserts rather than intramuscular shots. Ferring’s product, Endometrin, is delivered in capsule form and applied two or three times per day. Watson’s product, Crinone, is a gel delivered via applicator and is applied once daily. Endometrin and Crinone are currently the only two vaginal progesterone inserts for ART approved by the FDA.

Ferring’s claims arise out of two presentations made by Watson on September 11, 2012. On that date, Watson hosted and invited doctors and healthcare professionals to view two presentations about Crinone made by Dr. Kaylen M. Silverberg, a paid consultant. The presentations were streamed online at 7:30 p.m. and 9:00 p.m. throughout the United States and viewed by medical professionals in-person and over the Internet with a password. The webcasts were designed to encourage attendees to purchase Crinone and consisted of a series of PowerPoint slides prepared by Watson.

During the presentations, Dr. Silverberg made three statements with which Ferring takes issue: (1) he referenced a “Black Box” warning on Endometrin’s package insert; (2) he discussed a patient preference survey comparing Crinone and Endometrin; and (3) he mischaracterized the results of certain studies of Endometrin’s effectiveness in women over the age of thirty-five.

1.

First, during the 7:30 webcast, Dr. Silverberg stated that “if you read the package insert, for Endometrin there is a black box warning showing the efficacy has not been demonstrated with . . . patients 35 years of age and older.” Appendix (“App.”) 174-75. A Black Box warning is of special note in the medical community, as it signifies that medical studies indicate that the drug carries a significant risk of serious or life-threatening effects. See 21 C.F.R. § 201.57(c)(1) (providing that “[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box”). The package insert does state that “[e]fficacy in women 35 years of age and older has not been clearly established.” App. 6. However, that statement is not contained in a Black Box warning on the package insert. Watson admits that Dr. Silverberg’s statement was, therefore, made in error. Watson Br. 8.

Dr. Silverberg was alerted to the inaccuracy of his characterization of the statement as a Black Box warning after the 7:30 webcast, and the 9:00 webcast did not contain such a statement. Dr. Silverberg also certified to Ferring and to the District Court that he would not repeat this statement in the future.

2.

During the two presentations, Dr. Silverberg also told the audience that high percentages of women preferred Crinone to Endometrin. Specifically, during the 7:30 webcast, Dr. Silverberg stated:

When you look at Crinone compared to Endometrin, similar findings. 94 percent of patients thought that Crinone was easier to incorporate into their daily lifestyle, probably because it’s given once a day compared to three times a day for Endometrin, 82 percent thought that it was more convenient, or I’m sorry, that may be 88 percent, 94 percent thought that it

was more comfortable to use Crinone than the Endometrin.

App. 175. During the 9:00 webcast, Dr. Silverberg stated:

Now looking at Crinone compared to Endometrin, telephone survey, 94 percent of patients thought that Crinone was easier to incorporate into a daily lifestyle than the Endometrin given three times a day. 88 percent thought it was more convenient. 84 percent thought it was more comfortable to use.

App. 182-83.

The slide used by Dr. Silverberg during the presentations states that these percentages are based on a survey of women who used Crinone or Endometrin. The slide also states that the percentages are derived from a “tally of yes/no questions about whether CRINONE was easy to incorporate into a daily lifestyle, was convenient, and was comfortable to use.” App. 376. Thus, the text of the slide indicated that the survey was not actually a comparison of Crinone and Endometrin. Watson has admitted that Dr. Silverberg’s claims were false, because the figures cited were not based on a survey comparing patient preferences for Crinone and Endometrin.² Watson Br. 9-10. Dr. Silverberg certified to the District Court that he was aware of his mistake in misreading the survey results and will not repeat it in the future.

3.

Dr. Silverberg also made several statements regarding the efficacy of Crinone and Endometrin in women over thirty-five years of age. Dr. Silverberg stated that “if you read the package insert, for Endometrin there is a black box warning

² Watson asserts that other data from the survey did show that “patients preferred Crinone over Endometrin by a two-to-one margin” but acknowledges that “the figures were not identical to the ones Dr. Silverberg recited.” Watson Br. 10; App. 312.

showing the efficacy has not been demonstrated with . . . Endometrin for patients 35 years of age and older,” App. 174-75 (emphasis added), but Endometrin’s package insert actually states that “[e]fficacy in women 35 years of age and older has not been clearly established,” App. 6 (emphasis added).

In addition, Dr. Silverberg discussed studies performed by Schoolcraft WB, et al.,³ and Doody KJ, et al.,⁴ concerning the use of Crinone and Endometrin in women over thirty-five years of age. App. 191, 193-98. During the 7:30 webcast, Dr. Silverberg stated:

We know that efficacy has been established for Crinone in patients under the age of 35 as well as over the age of 35. Schoolcraft’s analysis of the Doody study and also our study found the exact same thing.

App. 176. During the 9:00 webcast, Dr. Silverberg stated:

The efficacy of Crinone, unlike the other products, has been established in women throughout the entire reproductive spectrum from 22 to 47, including women age 35 years of age and older. Schoolcraft’s study found that, our study found that.

App. 184. He also stated, during the same webcast:

Bill Schoolcraft has some published data showing that in fact that the efficacy of Endometrin given three times a day is not — it

³ See Schoolcraft WB, et al., Efficacy of a novel form of vaginal progesterone on continuing pregnancy rates in women undergoing IVF with elevated BMI and advanced age, 87 Fertility & Sterility S24 (2007).

⁴ See Doody KJ, et al., Endometrin for luteal phase support in a randomized, controlled, open-label, prospective in-vitro fertilization trial using a combination of Menopur and Bravelle for controlled ovarian hyperstimulation, 91 Fertility & Sterility 1012 (2009).

was not found to be efficacious for women over the age of 35.

App. 183.

The Schoolcraft study involved the administration of Endometrin twice or three times a day or Crinone to participants who were up to forty-two years old. The study lists the results for the participants who took Crinone, but the data analysis section and conclusion concern only Endometrin. The study concludes that “Endometrin was well tolerated and provided successful luteal support in poor-prognosis patients” such as “those older than 35.” App. 191. However, the study also includes a chart comparing the results for the participants taking Endometrin with the participants taking Crinone, and the chart indicates that Crinone has higher pregnancy rates than Endometrin for participants over the age of thirty-five.

The Doody study, structured similarly to the Schoolcraft study, directly compared Endometrin to Crinone and concludes that “[n]o clinically meaningful differences were observed across the three treatment groups in pregnancy rates or live birth rates,” and that “Endometrin provides a safe, well tolerated, and effective method for providing luteal phase support in women undergoing IVF.” App. 197.

Dr. Silverberg has certified that in future presentations concerning Crinone, he will make only specified statements as to the efficacy of Endometrin for women thirty-five years old or older in accordance with the statement contained on the product’s package insert.

B.

On September 17, 2012, Ferring filed a complaint pursuant to section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.*, and New Jersey common law, alleging, *inter alia*, that Watson’s statements at the presentations were false and misleading. On November 9, 2012, Ferring moved for a preliminary injunction to enjoin Watson from making further false statements and for corrective advertising.

The District Court denied Ferring's motion on April 4, 2013. Of particular note, the District Court found that Ferring was not entitled to a presumption of irreparable harm in seeking a preliminary injunction. Without this presumption, the District Court found that Ferring had failed to present sufficient evidence to demonstrate a likelihood of irreparable harm, and, accordingly, Ferring was not entitled to a preliminary injunction. The District Court also briefly addressed the likelihood of the success of Ferring's claims on the merits, noting that it was not clear, at the preliminary injunction stage, that Watson's allegedly false statements were "completely unsubstantiated" because Watson demonstrated that at least some support does exist to form the basis of the challenged statements. App. 14. However, the District Court stated that it did not need to make a determination as to the likelihood of success of Ferring's claims in light of Ferring's failure to demonstrate irreparable harm.

Ferring timely appealed.

II.

The District Court had jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1367, and this Court has jurisdiction pursuant to 28 U.S.C. § 1292.

We review the District Court's decision to grant or deny a preliminary injunction for abuse of discretion. Highmark, Inc. v. UPMC Health Plan, Inc., 276 F.3d 160, 170 (3d Cir. 2001). The District Court's findings of fact are reviewed for clear error and its conclusions of law are subject to plenary review. Id.⁵

⁵ Ferring argues, citing E.T. Browne Drug Co. v. Cococare Products, Inc., 538 F.3d 185, 196 (3d Cir. 2008), that where, as here, the district court did not conduct an evidentiary hearing in a Lanham Act case, the standard of review is plenary. However, E.T. Browne does not stand for that proposition. Rather, this Court in E.T. Browne observed that it was required to apply a plenary standard of review to a summary judgment ruling and distinguished this from a ruling

III.

Preliminary injunctive relief is an “extraordinary remedy, which should be granted only in limited circumstances.” Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578, 586 (3d Cir. 2002) (quotation marks omitted). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” Winter, 555 U.S. at 20. The “failure to establish any element . . . renders a preliminary injunction inappropriate.” NutraSweet Co. v. Vit-Mar Enters., Inc., 176 F.3d 151, 153 (3d Cir. 1999). The movant bears the burden of showing that these four factors weigh in favor of granting the injunction. See Opticians Ass’n of Am. v. Indep. Opticians of Am., 920 F.2d 187, 192 (3d Cir. 1990).

Ferring takes issue with the District Court’s analysis of the irreparable harm prong in deciding its motion for a preliminary injunction. It argues that irreparable harm can and should be presumed in Lanham Act comparative false advertising cases, and that the District Court erred in declining to afford Ferring that presumption and in denying it a preliminary injunction. Watson responds that: (1) this Court has never recognized such a presumption; (2) even if such a presumption once existed, it no longer does in light of the Supreme Court’s decisions in eBay, 547 U.S. 388, and Winter, 555 U.S. 7; and (3) without that presumption, Ferring failed to demonstrate a likelihood of irreparable harm. We address these contentions below.

A.

This Court has never held that a plaintiff seeking a preliminary injunction pursuant to a Lanham Act false advertising claim is entitled to a presumption of irreparable harm. However, prior to eBay, several of our sister courts

on a motion for a preliminary injunction (which, in that case, took place after a four-day evidentiary hearing), for which the weighing of evidence is reviewed for clear error. Id.

had applied a presumption of irreparable harm upon a showing of likelihood of success on the merits where a plaintiff seeks a preliminary injunction in a comparative false advertising case. See, e.g., Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1146 (9th Cir. 1997) (noting that for false comparative advertising claims, the Court of Appeals for the Ninth Circuit has held that “[p]ublication of deliberately false comparative claims gives rise to a presumption of actual deception and reliance” (quotation marks omitted)); Abbott Labs. v. Mead Johnson & Co., 971 F.2d 6, 16 (7th Cir. 1992) (referencing the “well-established presumption that injuries arising from Lanham Act violations are irreparable, even absent a showing of business loss”); McNeilab, Inc. v. Am. Home Prods. Corp., 848 F.2d 34, 38 (2d Cir. 1988) (affirming the district court’s presumption of irreparable harm from a finding of false or misleading advertising).

The Court of Appeals for the Second Circuit’s reasoning for applying this presumption in McNeilab is instructive. See 848 F.2d at 38. There, the court explained that

[a] misleading comparison to a specific competing product necessarily diminishes that product’s value in the minds of the consumer. By falsely implying that Advil is as safe as Tylenol in all respects, AHP deprived McNeil of a legitimate competitive advantage and reduced consumers’ incentive to select Tylenol rather than Advil. This is analogous to a Lanham Act trademark dispute. An infringing mark, by its nature, detracts from the value of the mark with which it is confused. In that context, we recently confirmed that irreparable harm will be presumed. Consequently, the district court did not err in presuming harm from a finding of false or misleading advertising.

Id. (citations omitted); see also Abbott Labs., 971 F.2d at 16 (“This presumption, it appears, is based upon the judgment that it is virtually impossible to ascertain the precise

economic consequences of intangible harms, such as damage to reputation and loss of goodwill, caused by such violations.”). The justification for applying this presumption, therefore, is twofold: (1) a misleading or false comparison to a specific competing product necessarily causes that product harm by diminishing its value in the mind of the consumer, similar to trademark infringement cases; and (2) the harm necessarily caused to reputation and goodwill is irreparable because it is virtually impossible to quantify in terms of monetary damages.

Although we have not applied a presumption of irreparable harm to a false advertising case, we have repeatedly held, prior to eBay and Winter, that a plaintiff alleging a Lanham Act trademark infringement claim is entitled to a presumption of harm when she demonstrates a likelihood of success on the merits.⁶ See Kos Pharm., Inc. v. Andrx Corp., 369 F.3d 700, 726 (3d Cir. 2004) (noting that “trademark infringement amounts to irreparable injury as a matter of law” (quotation marks omitted)); see also Opticians, 920 F.2d at 196. In Opticians, we concluded that trademark infringement constitutes a per se injury because it inhibits the owner’s “ability to control its own . . . marks, which in turn creates the potential for damage to its reputation. Potential damage to reputation constitutes irreparable injury for the purpose of granting a preliminary injunction in a trademark case.” 920 F.2d at 196; see also S & R Corp. v. Jiffy Lube Int’l, Inc., 968 F.2d 371, 378 (3d Cir. 1992) (noting that “[g]rounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill” and “trademark infringement amounts to irreparable injury as a matter of law”). Accordingly, prior to eBay and Winter, we applied a presumption of irreparable harm in Lanham Act trademark infringement cases in which a plaintiff sought a

⁶ Trademark infringement and false advertising claims both arise under section 43(a)(1) of the Lanham Act, see 15 U.S.C. § 1125(a), and courts often rely on trademark infringement precedent in deciding false advertising cases, as both types of cases address irreparable injuries in the form of reputational harm and loss of goodwill. See, e.g., McNeilab, 848 F.2d at 38 (analogizing false comparative advertising claims to trademark disputes with regard to the type of harm caused).

preliminary injunction, and our reasoning for doing so has been the basis for other courts' decisions in comparative false advertising cases: a false statement about a product in comparison to another creates the potential for damage to the product or brand's reputation, which constitutes irreparable injury that is difficult to quantify. See McNeilab, 848 F.2d at 38.

B.

The Supreme Court revisited the analytical framework governing injunctions in two significant cases from the last decade: eBay and Winter. The ramifications of these decisions have been considered by many of our sister Courts of Appeals.

eBay was a patent case in which MercExchange, holder of a business method patent for an electronic market, sued eBay and a subsidiary for patent infringement. See eBay, 547 U.S. at 390. A jury found that MercExchange's patent was valid and had been infringed, and that an award of damages was appropriate. Id. at 390-91. Following the verdict, the district court denied MercExchange's motion for permanent injunctive relief, "adopt[ing] certain expansive principles suggesting that injunctive relief could not issue in a broad swath of cases" and specifically "conclud[ing] that a 'plaintiff's willingness to license its patents' and 'its lack of commercial activity in practicing the patents' would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue." Id. at 393 (quoting MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 712 (E.D. Va. 2003)). The Court of Appeals for the Federal Circuit reversed, applying its "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." Id. at 391 (quoting MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1339 (Fed. Cir. 2005)). The Court of Appeals for the Federal Circuit cited Richardson v. Suzuki Motor Co. for this proposition, which arose out of the historical practice in the Federal Circuit that "[i]n matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement." Richardson, 868 F.2d 1226, 1247 (Fed. Cir. 1989) (quoting

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

The Supreme Court vacated the decision and remanded to the district court, holding that the Court of Appeals erred in applying a categorical rule that injunctions should issue upon a showing of valid patent infringement. eBay, 547 U.S. at 394. The Court held that a patent infringement plaintiff must fulfill the traditional requirements for a permanent injunction. Id. at 391. The Court observed that the Patent Act “expressly provides that injunctions may issue in accordance with the principles of equity,” and, accordingly, “a major departure from the long tradition of equity practice should not be lightly implied.” Id. at 391-92 (quotation marks omitted). The Court also noted that in copyright cases, it had “consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a copyright has been infringed.” Id. at 392-93 (citing cases).

The Court held that neither the district court nor the Court of Appeals “fairly applied these traditional equitable principles in deciding respondent’s motion for a permanent injunction,” because the district court applied a categorical rule in denying relief, while the Court of Appeals applied a categorical rule in granting injunctive relief. Id. at 393-94. Accordingly, the Court remanded to the district court, holding that “the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and . . . such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.” Id. at 394.⁷

⁷ Although the Court rejected the application of categorical rules that would eliminate the use of the traditional four-factor test, two concurrences, written by Chief Justice Roberts and Justice Kennedy, respectively, and separately joined by a total of seven Justices, suggested that such rules might survive as “lesson[s] of . . . historical practice” that might inform the district courts’ equitable discretion “when the circumstances of a case bear substantial parallels to litigation the courts have confronted before.” Id. at 395-97, (Kennedy,

Subsequently, in Winter, the Supreme Court addressed the standard for demonstrating irreparable harm in the preliminary injunction context. See 555 U.S. at 20-24. There, several environmental organizations sought a preliminary injunction against the Navy's use of sonar in training exercises, alleging that it would cause serious harm to various species of marine mammals. Id. at 13-14. The Court rejected the Court of Appeals for the Ninth Circuit's holding that "when a plaintiff demonstrates a strong likelihood of prevailing on the merits, a preliminary injunction may be entered based only on a 'possibility' of irreparable harm." Id. at 21. The Court "agree[d] with the Navy that the Ninth Circuit's 'possibility' standard is too lenient. [The Court's] frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is likely in the absence of an injunction." Id. at 22. The Court also noted that "[i]ssuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Id.

Several of our sister courts, although not this Court, have addressed the ramifications of these decisions for the irreparable harm prong of the preliminary injunctive relief analysis, uniformly holding that application of a presumption of irreparable harm is no longer permissible, for instance, in patent and copyright infringement cases.

In 2011, the Court of Appeals for the Federal Circuit held that, in patent cases, eBay "jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief." Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1149 (Fed. Cir. 2011). The court acknowledged that eBay "did not expressly address the presumption of irreparable harm." Id. at 1148. However, the court held that extension of the reasoning of eBay required elimination of the presumption, observing that "[i]n eBay, the Supreme Court made clear that 'broad classifications' and

J., concurring); see also id. at 394-95 (Roberts, C.J., concurring).

‘categorical rule[s]’ have no place in [the injunction] inquiry,” but rather “courts are to exercise their discretion in accordance with traditional principles of equity.” Id. (quoting eBay, 547 U.S. at 393-94).

The Courts of Appeals for the Second and Ninth Circuits have extended the eBay analysis to copyright cases. In Salinger v. Colting, a copyright case in which the plaintiff sought a preliminary injunction, the Court of Appeals for the Second Circuit held that eBay abrogated the presumption of irreparable harm in copyright cases. See 607 F.3d 68, 76-78 (2d Cir. 2010). The court began by observing that it had traditionally “presumed that a plaintiff likely to prevail on the merits of a copyright claim is also likely to suffer irreparable harm if an injunction does not issue.” Id. at 75. It then discussed the ways it had historically interpreted and applied the presumption: (1) as allowing a plaintiff likely to prevail on the merits to make a less “detailed showing of irreparable harm”; (2) “as though it applies automatically and is irrebuttable”; and (3) as rebuttable “where the plaintiff delayed in bringing the action seeking an injunction.” Id. However, the court observed that “[u]nder any of these articulations,” it had “nearly always issued injunctions in copyright cases as a matter of course upon a finding of likelihood of success on the merits.” Id. at 76.

The Salinger court held that the Supreme Court’s reasoning “applie[d] with equal force (a) to preliminary injunctions (b) that are issued for alleged copyright infringement.” Id. at 77. The court closely examined eBay, noting that “nothing in the text or the logic of eBay suggests that its rule is limited to patent cases. On the contrary, eBay strongly indicates that the traditional principles of equity it employed are the presumptive standard for injunctions in any context.” Id. at 77-78. The also court noted that this holding was consistent with the Supreme Court’s construction of the preliminary injunction standard in Winter. See id. at 79.

The Court of Appeals for the Ninth Circuit has also explicitly interpreted eBay to mean that the Supreme Court intended that the propriety of injunctive relief in copyright cases “be evaluated on a case-by-case basis in accord with traditional equitable principles and without the aid of

presumptions or a ‘thumb on the scale’ in favor of issuing such relief.” Perfect 10, Inc. v. Google, Inc., 653 F.3d 976, 980-81 (9th Cir. 2011) (quoting Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 157 (2010)).

C.

We now turn to the effect of eBay and Winter in Lanham Act cases. We hold that although eBay in particular arose in the patent context, its rationale is equally applicable in other contexts, including cases arising under the Lanham Act, for the reasons that follow.⁸

The Lanham Act’s injunctive relief provision is premised upon traditional principles of equity, like the Patent Act’s. Compare 15 U.S.C. § 1116(a) (Lanham Act) (“The several courts vested with jurisdiction of civil actions arising under this chapter shall have power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable” (emphasis added)), with 35 U.S.C. § 283 (Patent Act) (“The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” (emphasis added)). Accordingly, we should interpret this nearly identical wording in the same way. See N. Am. Med. Corp. v. Axiom Worldwide, Inc., 522 F.3d 1211, 1228 (11th Cir. 2008). Notably, the Court in eBay suggested that a “major departure from the long tradition of equity practice” should be permitted only to the extent that “Congress intended such a departure,” and the language of these two acts makes clear that Congress did not intend any such departure in these contexts. 547 U.S. at 391-92 (quotation marks omitted).

In addition, like the Court of Appeals for the Second Circuit, we believe the logic of eBay is not limited to patent cases but rather is widely applicable to various different types of cases. See Salinger, 607 F.3d at 78 n.7 (“[W]e see no

⁸ As will be discussed infra, Winter, by its terms, applies to the instant case, as it addressed the standard for preliminary injunctions generally. See 555 U.S. at 22.

reason that eBay would not apply with equal force to an injunction in any type of case.”). Indeed, the Supreme Court has applied the reasoning of eBay in a substantially distinct context. In Monsanto Co v. Geertson Seed Farms, a case involving violations of the National Environmental Policy Act of 1969 (“NEPA”), the Court rejected the Court of Appeals for the Ninth Circuit’s holding that “an injunction is the proper remedy for a NEPA violation except in unusual circumstances.” 561 U.S. at 157. Rather, the Court held that, in light of eBay and Winter, an injunction should issue “only if the traditional four-factor test is satisfied” and “[n]o . . . thumb on the scales is warranted.” Id.

Ferring argues that eBay does not apply to Lanham Act cases because it was decided in the patent context, which raises unique concerns not present in the Lanham Act context.⁹ See Ferring Br. 31-33. Among other things, Ferring notes that patents “have the attributes of personal property,” including “the right to exclude others from making, using, offering for sale, or selling the invention.” eBay, 547 U.S. at 392 (quoting 35 U.S.C. §§ 261, 154(a)(1)). By contrast, the Lanham Act creates no corresponding property right, especially with regard to false advertising claims. Lanham Act claims are also materially distinct from patent or copyright claims because, while injury arising from patent or copyright infringement can generally be measured in monetary terms by examining the “appropriation of a potential market for the patent invention or copyrighted work,” see David H. Bernstein & Andrew Gilden, No Trolls Barred: Trademark Injunctions After eBay, 99 Trademark Rep. 1037, 1055 (2009), injury to goodwill and reputation “is

⁹ In addition, although eBay addressed a permanent, rather than preliminary, injunction, this distinction is not significant. “The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success.” Amoco Prod. Co. v. Vill. of Gambell, Alaska, 480 U.S. 531, 546 n.12 (1987); see also Flexible Lifeline Sys. v. Precision Lift, Inc., 654 F.3d 989, 996 (9th Cir. 2011) (concluding that “eBay applies with equal force to preliminary injunction cases as it does to permanent injunction cases”).

real but difficult to measure in dollars and cents,” 5 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 30:47 (4th ed. 1996). See also Abbott Labs, 971 F.2d at 16 (noting that “it is virtually impossible to ascertain the precise economic consequences of intangible harms, such as damage to reputation and loss of goodwill, caused by [Lanham Act] violations”).

We are not persuaded by this argument. The rationale of the eBay decision was not that patent cases are somehow unique, but rather, as stated supra, that “the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.” eBay, 547 U.S. at 394. In addition, as noted supra, the Court in eBay suggested that a “major departure from the long tradition of equity practice” should be permitted only to the extent that “Congress intended such a departure.” 547 U.S. at 391-92. It follows that a court is not free to depart from traditional principles of equity merely because it believes such a departure would further a statute’s policy goals, such as, in the case of Lanham Act claims, compensating plaintiffs for harms that may be difficult to quantify. Rather, the text of the Lanham Act clearly evinces congressional intent to require courts to grant or deny injunctions according to traditional principles of equity. See 15 U.S.C § 1116(a).

Because a presumption of irreparable harm deviates from the traditional principles of equity, which require a movant to demonstrate irreparable harm, we hold that there is no presumption of irreparable harm afforded to parties seeking injunctive relief in Lanham Act cases. Consistent with our holding, the Court of Appeals for the Ninth Circuit recently extended the eBay analysis to a trademark infringement claim, holding that the likelihood of irreparable injury may no longer be presumed from a showing of likelihood of success on the merits. See Herb Reed Enters., LLC v. Fla. Entm’t Mgmt., Inc., 736 F.3d 1239, 1242 (9th Cir. 2013). The court noted that eBay and Winter “cast doubt on the validity of this court’s previous rule that the likelihood of ‘irreparable injury may be presumed from a showing of

likelihood of success on the merits of a trademark infringement claim.” Id. at 1248-49 (quoting Brookfield Commc’ns, Inc. v. W. Coast Entm’t Corp., 174 F.3d 1036, 1066 (9th Cir. 1999)). After summarizing the holdings of eBay and Winter, the court noted that following those cases, it “held that likely irreparable harm must be demonstrated to obtain a preliminary injunction in a copyright infringement case and that actual irreparable harm must be demonstrated to obtain a permanent injunction in a trademark infringement action.” Id. at 1249 (citing Flexible Lifeline Sys. v. Precision Lift, Inc., 654 F.3d 989, 998 (9th Cir. 2011) and Reno Air Racing Ass’n, Inc. v. McCord, 452 F.3d 1126, 1137-38 (9th Cir. 2006)). The court concluded that its “imposition of the irreparable harm requirement for a permanent injunction in a trademark case applies with equal force in the preliminary injunction context” and held that “the eBay principle — that a plaintiff must establish irreparable harm — applies to a preliminary injunction in a trademark infringement case.” Id. We agree with the holding and rationale of the Herb Reed court.¹⁰

¹⁰ Several other Courts of Appeals have held that the reasoning of eBay applies to the Lanham Act context and have acknowledged that eBay may call the use of a presumption of irreparable harm into doubt, although they have explicitly declined to decide the issue. See, e.g., Swarovski Aktiengesellschaft v. Bldg. No. 19, Inc., 704 F.3d 44, 53-55 (1st Cir. 2013) (noting that “we have so far declined to address whether eBay’s bar on ‘general’ or ‘categorical’ rules includes the presumption of irreparable harm in trademark disputes” and declining to decide the issue because the plaintiff failed to demonstrate a likelihood of success on the merits); Paulsson Geophysical Servs., Inc. v. Sigmar, 529 F.3d 303, 313 (5th Cir. 2008) (acknowledging that “whether a court may presume irreparable injury upon finding a likelihood of confusion in a trademark case” was “a difficult question considering the Supreme Court’s opinion in eBay,” but declining to answer because the facts of the case supported a finding of a substantial threat of irreparable injury if an injunction was not issued); Axiom Worldwide, 522 F.3d at 1226-28 (observing that “a strong case can be made that eBay’s holding necessarily extends to the grant of preliminary injunctions under the Lanham Act,” but “declin[ing] to

The Court's decision in Winter, requiring that a plaintiff demonstrate a likelihood, rather than a possibility, of irreparable harm, further supports our conclusion.¹¹ As the Court of Appeals for the Ninth Circuit has observed, if requiring a plaintiff to "demonstrate at least a possibility of irreparable harm[] is 'too lenient,' then surely a standard which presumes irreparable harm without requiring any showing at all is also 'too lenient.'" Flexible Lifeline, 654 F.3d at 997. Rather, injunctive relief is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter, 555 U.S. at 22 (emphasis added). Presuming irreparable harm would relieve the plaintiff of her burden to make such a showing.

address whether [a presumption of irreparable harm] is the equivalent of the categorical rules rejected by the Court in eBay").

¹¹ We note that before Winter, we had not treated the preliminary injunction irreparable harm requirement in a uniform manner, at times requiring a showing of a "possibility," "probability," or "potential" for irreparable harm. See, e.g., Presbytery of N.J. of Orthodox Presbyterian Church v. Florio, 40 F.3d 1454, 1458 (3d Cir. 1994) (holding that the plaintiff "failed to demonstrate the possibility of immediate and irreparable harm"); Furlong v. Gudknecht, 808 F.2d 233, 234 (3d Cir. 1986) (noting that the district court considered, inter alia, the "potential for irreparable injury absent temporary relief" in determining whether to grant a preliminary injunction); United Tel. Workers, AFL-CIO v. W. Union Corp., 771 F.2d 699, 703 (3d Cir. 1985) ("In deciding whether to provide preliminary relief, the district court must consider the probability of irreparable injury to the moving party in the absence of such relief"); United States v. Price, 688 F.2d 204, 211 (3d Cir. 1982) (noting that the "factors which guide the exercise of the courts' equitable discretion" in granting or denying a request for preliminary injunctive relief include "the probability of irreparable injury to the moving party in the absence of relief"). However, in light of Winter, parties seeking a preliminary injunction are now required to demonstrate that "irreparable injury is likely in the absence of an injunction." Winter, 555 U.S. at 22.

In addition, “Winter tells us that, at minimum, we must consider whether irreparable injury is likely in the absence of an injunction, we must balance the competing claims of injury, and we must pay particular regard for the public consequences in employing the extraordinary remedy of injunction.” Salinger, 607 F.3d at 79 (quotation marks omitted). A presumption of irreparable harm that functions as an automatic or general grant of an injunction is inconsistent with these principles of equity. See id.; see also Munaf v. Green, 553 U.S. 674, 689-90 (2008) (noting that an injunction is an “extraordinary and drastic remedy” that “is never awarded as of right” (quotation marks omitted)).

For these reasons, we hold that a party seeking a preliminary injunction in a Lanham Act case is not entitled to a presumption of irreparable harm but rather is required to demonstrate that she is likely to suffer irreparable harm if an injunction is not granted.

D.

Although we agree with the District Court that Ferring was not entitled to a presumption of irreparable harm, we must also review the District Court’s finding that Ferring failed to make a showing of likelihood of irreparable harm without the presumption.

In evaluating whether Ferring demonstrated that it would suffer real, irreparable harm in the absence of an injunction, the District Court noted that Dr. Silverberg agreed he misstated the Black Box warning in the first webcast, but removed the statement during the second webcast, and certified to the District Court that he will never make that statement in the future. App. 12, 237. The District Court also found it significant that Dr. Silverberg certified that, at the request of Watson, in future presentations concerning Crinone, he will make only specified statements as to the efficacy of Endometrin for women thirty-five years of age or older, all in accordance with Endometrin’s package insert. App. 12, 240. The District Court noted that there was no showing that the allegedly false information contained in the webcasts is still available online to be accessed by consumers. App. 12. For these reasons, the District Court found that

Ferring did not produce evidence sufficient to prove that it was harmed, or that the harm was irreparable and could only be cured by a preliminary injunction. App. 12.

Ferring disputes the District Court's finding, arguing that it did in fact present evidence of irreparable harm in the form of a declaration by Dr. Angeline N. Beltsos (the "Beltsos Declaration"), a licensed reproductive endocrinologist. App. 144-48. The declaration stated, inter alia, that: (1) Dr. Beltsos and other doctors would be less likely to prescribe a drug if they believed it contained a Black Box warning; (2) Dr. Beltsos and other doctors would be less likely to prescribe a drug if patients in the marketplace generally preferred another drug; and (3) Dr. Beltsos and other doctors would be less likely to prescribe a drug if it was not effective for a particular age group. App. 146-47.

Ferring also argues that the District Court erred in failing to analyze the specific harm caused by Watson's claims regarding the superiority of Crinone over Endometrin in patient preference surveys. Ferring asserts that this is particularly unjust because Watson is still making these statements, as evidenced by the Declaration of Lynne Amato, Watson's Vice President of Global Brand Marketing, submitted on December 3, 2012, stating that Watson's slide presentation now has a "correct slide stating that the survey was of women who had used both Crinone and Endometrin." App. 303.¹²

We hold that the District Court did not clearly err in finding that Ferring failed to demonstrate irreparable harm. We, like the District Court, find it significant that Dr.

¹² As evidence that Watson claims to have stopped making these allegedly false statements but actually continues to do so, Ferring states that one of Watson's sales representatives has already been caught making an allegedly false statement regarding Endometrin's efficacy in women over thirty-five years old in a note. App. 140-43. However, the note at issue was written on November 7, 2012, before Ferring even filed for a preliminary injunction and almost a month before Dr. Silverberg's certification to the court. See App. 141. Accordingly, this is not a persuasive argument.

Silverberg has certified to the court that he will not make the Black Box statement in the future, and it was removed from the 9:00 webcast. App. 12, 237. Dr. Silverberg also certified that he will make age efficacy statements about Endometrin only in accordance with the product's package insert. App. 240. We see no evidence that the allegedly false statements are still available to consumers. Although Ferring argues that only Dr. Silverberg, and not Watson itself, has promised not to make these offending statements in the future, Ferring has adduced no evidence that there is any risk that any Watson representative will make such statements, especially in light of the fact that Watson has conceded that certain of these statements were inaccurate, and that all of the statements at issue here were made by Dr. Silverberg. See App. 6-8.

We also hold that the Beltsos Declaration does not sufficiently demonstrate irreparable harm such that the District Court's finding was clear error.¹³ The Beltsos Declaration is speculative, containing statements by Dr. Beltsos that the considerations of whether drugs are preferred by certain patients or are considered effective for a particular age group "may influence" her decision and the decisions of other doctors as to which drugs they prescribe. App. 146-48. Dr. Beltsos stated that she and other doctors "would be less likely" to prescribe the non-effective and non-preferred drugs, but this too is speculation, as she does not assert that she or

¹³ Ferring argues that the District Court erred in failing to consider the Beltsos Declaration in its irreparable harm analysis. We acknowledge that it would have been preferable for the District Court to have explicitly referenced the Beltsos Declaration in its decision, especially with regard to Ferring's request for corrective advertising. But we observe that Ferring did not raise, before this Court, any arguments specifically referencing its request for corrective advertising. In any event, "[a] party seeking a mandatory preliminary injunction that will alter the status quo bears a particularly heavy burden in demonstrating its necessity." Acierno v. New Castle Cnty., 40 F.3d 645, 653 (3d Cir. 1994). In light of this heavy burden, and the fact that the harm described in the Beltsos Declaration is purely speculative, we hold that the District Court's alleged failure to consider the Declaration was, at most, harmless error.

any other doctors have prescribed Endometrin less frequently in light of the allegedly false statements made by Dr. Silverberg. App. 146-48.

Ferring also argues that a Lanham Act defendant cannot automatically moot a case simply by ending its infringing conduct, but rather must irrefutably demonstrate that the offending conduct has been totally reformed, and this burden is a “heavy” one. Ferring Br. 38-39 (citing authority). However, whether a case should be dismissed on mootness grounds is a materially distinct inquiry from a determination as to whether a plaintiff has demonstrated irreparable harm. Whether a defendant’s conduct has ceased is certainly a relevant consideration in making the latter determination, and the District Court did not err in considering and crediting Dr. Silverberg’s certifications that the allegedly false statements would not be repeated.

Accordingly, we hold that the District Court did not clearly err in finding that Ferring failed to demonstrate that it would likely suffer irreparable harm in the absence of preliminary injunctive relief. Absent a showing of irreparable harm, a plaintiff is not entitled to injunctive relief, even if the other three elements are found. See NutraSweet, 176 F.3d at 153.

IV.

For the foregoing reasons, we hold that the District Court did not abuse its discretion in denying Ferring’s motion for a preliminary injunction. We will, therefore, affirm the District Court’s order.