PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 03-3977

KOS PHARMACEUTICALS, INC.,

Appellant

v.

ANDRX CORPORATION; ANDRX LABORATORIES, INC.

On Appeal from the United States District Court for the District of New Jersey
(District Court No. 03-cv-03714)
District Court Judge: Honorable Dennis M. Cavanaugh

Argued: March 9, 2004

Before: SLOVITER, NYGAARD, Circuit Judges, and OBERDORFER,* District Judge.

(Opinion Filed: May 24, 2004)

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OPINION OF THE COURT

OBERDORFER, Senior District Judge.

This is an appeal from the denial of preliminary relief in a trademark infringement action. Plaintiff-appellant Kos Pharmaceuticals, Inc. ("Kos") owns

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* The Honorable Louis F. Oberdorfer, Senior District Judge for the District of Columbia, sitting by designation.

the mark ADVICOR, which it uses in connection with cholesterol-altering drugs available by prescription. Kos sought a preliminary injunction preventing defendants-appellees Andrx Corporation and Andrx Laboratories, Inc. (collectively, "Andrx") from using the mark ALTOCOR in connection with sales of Andrx's own cholesterol-altering prescription drugs. The district court denied the requested relief, and this appeal followed. Because the denial of the preliminary injunction was premised on legal errors, we reverse. We remand the case to the district court with directions to enter a preliminary injunction on an expedited basis.

I. BACKGROUND

Unless otherwise noted, the following facts are undisputed. On October 3, 2000, Kos filed an application with the United States Patent and Trademark Office (the "PTO") to register ADVICOR as the mark for a new medication designed to improve cholesterol levels. This new drug combines 20 milligrams of lovastatin (which lowers LDL, or "bad" cholesterol) with varying strengths (500, 750, or 1000 milligrams) of an extended-release formulation of niacin (which increases HDL, or "good" cholesterol). Kos has been selling its proprietary extended-release form of niacin under the trade name Niaspan since 1997. In July 2001 Kos began advertising, and in December 2001 began selling, its new combination drug, Advicor.[1]

Shortly after Kos began marketing Advicor, it learned that Andrx planned to use the mark ALTOCOR for its own new anticholesterol medication, which would contain only a single active ingredient, an extended-release form of lovastatin, in varying strengths (10, 20, 40 or 60 milligrams). Andrx announced on January 31, 2002 that it had received preliminary marketing approval for Altocor from the United States Food and Drug Administration (the "FDA"). On February 5, 2002, the PTO published for opposition the ALTOCOR mark, which Andrx had applied to register in December 2000.

Kos tried to dissuade or otherwise prevent Andrx from using the ALTOCOR mark several times, both before and after Andrx began selling its new drug. On April 1, 2002, Kos wrote to Andrx that, in its view, the proposed use of the mark ALTOCOR "would constitute trademark infringement and unfair competition." JA at 273. It advised Andrx to "refrain from using ALTOCOR or any other mark which is likely to cause confusion with ADVICOR for pharmaceutical preparations." Id. Kos described its prior use of ADVICOR for its own cholesterol-altering medication and stated further that:

If Andrx were to use the

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[1] To distinguish the marks from the drugs they identify, we use all capital letters to refer to the marks, but capitalize only the first letter when referring to the drugs.

> mark ALTOCOR for [the described] pharmaceutical preparations, consumers and medical professionals would inevitably believe that Andrx's product originates with or is authorized by, sponsored by, or in some way connected with Kos and its ADVICOR pharmaceutical products. . . . The similarity between the marks and the goods may create confusion among health care practitioners in terms of both prescribing and dispensing, resulting in dangerous medication errors.

Id. at 272-73. A similar letter followed on April 15, 2002. Id. at 362. Andrx responded to neither letter.[2]

Kos also expressed its concerns about potential confusion to the FDA division responsible for reviewing proposed new drug names from a public health perspective, the Office of Drug Safety's Division of Medication Errors and Technical Support (the "Division of Medication Errors"). The Division of Medication Errors had preliminarily approved the name Altocor in November 2001.[3] At that time, the Division stated that the "name Advicor looks and sounds similar [to] Altocor," but concluded that the "difference in the written strengths" of the drugs reduced the risk of "error . . . between the two products." Id. at 269. After Kos learned of the preliminary approval, it sent a letter to the FDA, dated March 6, 2002, stating that it was "concerned that the similarity in the proprietary names of these two products may create confusion among health care practitioners in terms of both prescribing and dispensing these medications." Id. at 250.

In April 2002, the Division of Medication Errors reiterated its opinion that "the difference in the strengths (combination vs. single) will help ensure that medication errors do not occur between the two products." Id. at 261. At the same time, however, it concluded that "the name, Altocor, [is] no longer

[2] At oral argument, counsel for Andrx -- apparently and inexplicably unaware of these letters -- incorrectly stated that Kos did not inform Andrx directly of its view that Andrx's proposed mark was confusingly similar to its own before Altocor went to market.

[3] The Division of Medication Errors was then known as the Office of Post-Marketing Drug Risk Assessment. For ease of reference, we use the current name.

acceptable due to the potential for confusion with" a third, unrelated drug. Id. at 258. When Andrx objected to changing the name of its product, the Division of Medication Errors, while "not recommend[ing] the use of the proposed name, Altocor," gave conditional approval to using the name so long as Andrx "commit[ed] to submitting all potential and actual errors involving Altocor . . . [and] to changing the proprietary name, Altocor, if two or more reports of actual errors occur." Id. at 256.[4]

Kos next raised its concerns with the PTO. In May 2002, Kos filed an opposition to Andrx's application to register the mark ALTOCOR. Some discovery has been conducted in that proceeding, but no decision has been issued. According to the PTO docket, the opposition is suspended pending disposition of this civil litigation.

In July 2002, Andrx began marketing Altocor. Thereafter, Kos "advised Andrx of the growing number of instances of actual confusion" on multiple occasions. Id. at 75. For example, on January 10, 2003, Kos sent Andrx's counsel a chart "setting forth . . . occurrences of actual consumer confusion" reported to it. Id. at 368. On February 20, 2003, Kos sent an updated chart, entitled "Summary of Confusion Involving Advicor and Altocor," that listed 39 discrete instances of purported confusion. Id. at 304-08 (listing incidents between September 2, 2002 and February 12, 2003).

In the meantime, on December 5, 2002, Andrx filed with the FDA a "supplemental new drug application propos[ing] three alternate proprietary names" for Altocor. Id. at 380. On April 11, 2003, Andrx filed an application with the PTO to register the mark ALTOPREV. And Andrx's 2002 Annual Report, issued in the spring of 2003, stated:

> Andrx's application for a registered trademark for Altocor has been opposed by Kos Pharmaceuticals, who alleges that there is a likelihood of confusion between Kos' trademark, Advicor, and Altocor. Andrx has requested FDA guidance on other names, and may seek to change the name of Altocor.

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[4] The precise terms of the conditional FDA approval are in some dispute, but are only tangentially relevant to issues raised here. Andrx claims it needed to change its mark only if there were four actual errors the first year Altocor was sold, and then only if the errors were between Altocor and the unrelated drug about which the FDA expressed concern. JA at 345 (citing a letter Andrx sent the FDA shortly before the April 2002 Division of Medication Errors document was issued). In that letter, however, Andrx agreed to "submit all reports" of medication errors "related to Altocor" that it receives, not just those involving Altocor and one particular drug. Id. at 348.

Id. at 374. The FDA approved Andrx's supplemental application on August 20, 2003, stating that "the proprietary name, Altoprev, is acceptable." Id. at 380.[5]

By August 2003, Kos had spent more than $ 40 million on promotion and advertising, and Advicor had been prescribed more than 350,000 times, grossing approximately $ 70 million in sales. Andrx had spent more than $ 21 million on promotion and advertising, and Altocor had been prescribed more than 300,000 times, grossing more than $ 27 million.

On August 6, 2003, Kos filed a verified complaint, claiming that Andrx's use of the mark ALTOCOR on its anticholesterol drugs constituted trademark infringement and unfair competition under the federal Lanham Act, and under state and common law equivalents. Kos accompanied the complaint with the application for a preliminary injunction at issue here. Neither party requested an opportunity to adduce oral testimony on the application.

The documentary evidence before the district court included the following:

Evidence Regarding Actual Confusion

Kos submitted the Certification of its Vice President of Marketing, Aaron Berg, dated August 5, 2003 ("Berg Certification"),[6] which stated, inter alia, that Andrx's use of the mark ALTOCOR has caused confusion. Berg further stated that "over 60 instances of actual confusion between the two drugs have been documented and reported to [him] by [his] staff," including "six patients [who] received the wrong medication, either because they had been given a sample of one drug instead of the other, or because a pharmacist filled a prescription with the wrong drug." Id. at 69. Based on his "personal knowledge or [his] review of the business records of Kos," Berg described "representative . . . instances" of the incidents reported to him. Id. at 68, 71. These included, for example, doctors complaining to Kos representatives about the pricing or insurance coverage of Advicor, when their complaints were in fact about Altocor, as well as medical professionals identifying Altocor samples

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[5] Andrx claims that it no longer has FDA approval to use this name, but submitted no evidence to support that claim.

According to records available on the PTO website, a Notice of Allowance for the ALTOPREV mark was issued on February 24, 2004. We may take judicial notice of such public records. See, e.g., Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 954 n.27 (Fed. Cir. 1993); Standard Havens Prods., Inc. v. Gencor Indus., Inc., 897 F.2d 511, 514 n.3 (Fed. Cir. 1990).

[6] Andrx challenged the admissibility and probative value of the Berg Certification. JA at 41-44. The district court never ruled on Andrx's objection.

as Advicor samples, Altocor representatives as Advicor representatives, Altocor conferences as Advicor conferences, and vice versa.

Andrx submitted excerpts from Berg's deposition testimony, taken on June 12, 2003 in the PTO opposition proceeding. There, Berg said he had not had "direct contact" with the medical professionals involved in any of the reported incidents of confusion, but had learned of those incidents primarily through voice-mail or e-mail. Id. at 291. Andrx contrasted Berg's characterization of one incident -- where, Berg said, a patient whose "condition was improving . . . asked his cardiologist for more of the" Advicor his doctor had prescribed, but the "cardiologist refilled the prescription with Altocor," id. at 71 -- with the following more detailed description of the same incident, sent to Berg by e-mail:

> [A doctor] said that he had a patient that he had put on Advicor and when he went to his cardiologist, . . . he was due for a refill on Advicor. The patient returned . . . and [the doctor] notice[d] that the medicine listed was not Advicor, but Altocor! . . . [T]he patient told him that [the cardiologist] renewed his Rx. [The doctor] did not question [the cardiologist] directly . . . 'not my place to ? a cardiologist'. Up to that point, the patient had been doing well on the Advicor . . . no reason to change!

Id. at 340. Andrx also countered the Berg Certification with the declaration of its Vice President for Regulatory Affairs, Nicholas Farina, whose job requires him to report to the FDA "every incidence of actual confusion" involving Andrx in which "a product other than the one prescribed by a physician is dispensed by a pharmacist and the patient leaves the pharmacy." Id. at 345. Farina said no such incidents relating to Altocor had been reported to Andrx as of the date of his declaration, August 26, 2003. Id. at 346.

Medical Evidence

The parties submitted competing medical affidavits to support their respective views as to the nature and severity of potential consequences of mis-filled prescriptions.[7] Per Kos, niacin -- and thus Advicor, but not Altocor -- may cause serious injury, or even death, to patients with various conditions or sensitivities to the drug. Other, less serious, side effects of niacin may worry patients who have not been warned of those effects, and who may thus discontinue needed treatment. Patients who mistakenly receive Altocor rather

[7] Kos initially relied on the Berg Certification for these medical issues, but supplemented this -- at the hearing -- with a physician's certification. The district court's order, issued the day after the hearing, mentions only the initial certification.

than Advicor are also at risk, says Kos, since the conditions the niacin is meant to address will remain untreated. Andrx, on the other hand, claims that the "safety profile of both products is similar" and that there need not be "any unusual concern" about "harm to the public if the Andrx product is substituted for the KOS product." Id. at 226.

Evidence Regarding Adoption of Marks

The Berg Certification also addressed selection of the ADVICOR and ALTOCOR marks. Berg stated that Kos chose ADVICOR as "a fanciful, made-up name" that would be "an unusual, distinctive name to make the drug stand out to doctors as unique." Id. at 73. He asserted that a former Kos product manager, Charles Schneider, "who was actively participating in [Kos's] naming initiative" left Kos for Andrx during the "naming process." Id. at 73-74. Kos submitted an e-mail, sent to Schneider before his departure, that listed 42 possible names that it was considering, of which 12 -- including ADVICOR and AVICOR -- were "already picked" by it as possible names, and asked Schneider and one other Kos employee to select ten "back up names." Id. at 356-57. Berg said Andrx then applied to register "two closely similar trademarks: AVICOR and ALTOCOR" "[a]lmost immediately after" Schneider arrived there. Id. at 74. Andrx submitted a declaration from Schneider stating that he "was never involved with nor aware of the selection of the name ADVICOR," and that the "name ALTOCOR was one of many . . . generated by" an outside firm. Id. at 342.

Evidence Regarding Other Proceedings

Andrx submitted letters Kos sent the European Community Trademark Office in support of its application to register ADVICOR over the mark ACTIVOR, which was being used, not on prescription anticholesterol drugs, but rather on over-the-counter "stimulants and preparations used to build up vitality." Id. at 329, 333. Kos argued there, inter alia, that (1) the "opening syllable[s]" of the marks (AD v. AC) are "not identical," which is important "since attention to a polysyllabic word is normally focused on the beginning," id. at 328; (2) neither the middle (VI v. TI) nor final (COR v. VOR) syllables are identical; (3) the "suffix COR . . . is very common in the pharmaceutical Class 5 category," id. at 329; (4) the "functions [of the products] do not overlap," id.; (5) "there is little chance that any doctor would confuse a prescription cholesterol altering medication with an over the counter product," or that a "qualified pharmacist" would do so, id. at 333; and (6) "the channels of distribution, method of purchase and the targeted customer is different in relation to the two products," id.

On September 17, 2003, after hearing argument, the district court denied Kos's application for a preliminary injunction from the bench. The court issued a supplemental memorandum the following day that incorporated the "reasons . . . stated on the record during oral argument" and provided additional reasons for its decision. Id. at 13. The court held that Kos had not shown that it was likely to succeed on the merits, and found, based in large part on its negative assessment of Kos's likelihood of success, that Kos did not satisfy the other prerequisites for extraordinary relief. Kos filed this interlocutory appeal, and we granted Kos's request for an expedited appeal schedule.

II. LEGAL STANDARDS AND JURISDICTION

The test for preliminary relief is a familiar one. A party seeking a preliminary injunction must show: (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief. Allegheny Energy, Inc. v. DQE, Inc., 171 F.3d 153, 158 (3d Cir. 1999). Preliminary injunctive relief is "an extraordinary remedy" and "should be granted only in limited circumstances." American Tel. & Tel. Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1427 (3d Cir. 1994) (quotation omitted). "[O]ne of the goals of the preliminary injunction analysis is to maintain the status quo, defined as the last, peaceable, noncontested status of the parties." Opticians Ass'n of Am. v. Indep. Opticians of Am., 920 F.2d 187, 197 (3d Cir. 1990) (citation and quotation omitted); see also 5 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 30:50 (4th ed. 2003) ("The status quo to be preserved is not the

situation of contested rights . . . . In a trademark case, [it] is the situation prior to the time the junior user began use of its contested mark: the last peaceable, non-contested status.").

We review the denial of a preliminary injunction for "an abuse of discretion, an error of law, or a clear mistake in the consideration of proof." Winback, 42 F.3d at 1427 (quotation omitted). "[A]ny determination that is a prerequisite to the issuance of an injunction . . . is reviewed according to the standard applicable to that particular determination." Id. (second alteration in original, quotation omitted). "Thus, we exercise plenary review over the district court's conclusions of law and its application of law to the facts, but review its findings of fact for clear error, which occurs when we are left with a definite and firm conviction that a mistake has been committed." Duraco Prods., Inc. v. Joy Plastic Enters., Ltd., 40 F.3d 1431, 1438 (3d Cir. 1994) (citations and quotation omitted). "Despite oft repeated statements that the issuance of a preliminary injunction rests in the discretion of the trial judge[,] whose decisions will be reversed only for 'abuse,' a court of appeals must reverse if the district court has proceeded on the basis of an erroneous view of the applicable law." Apple Computer, Inc. v. Franklin Computer Corp., 714 F.2d 1240, 1242 (3d Cir. 1983) (quotation omitted).

The district court had original jurisdiction pursuant to 15 U.S.C. § 1121(a) and 28 U.S.C. § 1338, and we have jurisdiction over this interlocutory appeal pursuant to 15 U.S.C. § 1121(a) and 28 U.S.C. § 1292(a).

III. LIKELIHOOD OF SUCCESS ON THE MERITS

To prevail on a claim for trademark infringement or unfair competition under the Lanham Act, the owner of a valid and legally protectable mark, such as Kos, must show that a defendant's use of a similar mark for its goods "causes a likelihood of confusion." A & H Sportswear, Inc. v. Victoria's Secret Stores, Inc., 237 F.3d 198, 210 (3d Cir. 2000).[8] This Court has adopted a non-exhaustive list of factors to consider in evaluating likelihood of confusion, commonly referred to as the "Lapp factors." See Interpace Corp. v. Lapp, Inc., 721 F.2d 460, 463 (3d Cir. 1983). These factors were developed for cases involving non-competing products. Id. at

[8] See 15 U.S.C. § 1114(1)(a) (defining infringement as the unauthorized use of a "colorable imitation of a registered mark in connection with the sale, offering for sale, distribution or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive"); 15 U.S.C. § 1125(a)(1) (creating cause of action for use "in connection with any goods . . . [of] any word, term [or] name . . . likely to cause confusion, or to cause mistake, or to deceive as to . . . the origin, sponsorship, or approval of [those] goods . . . by another person").

462. Although we have held that courts "'need rarely look beyond the mark itself'" in cases involving competing goods, we recently recognized that "consideration of the Lapp factors . . . can be quite useful for determining likelihood of confusion even when the goods compete directly." A & H, 237 F.3d at 212 (quoting Lapp, 721 F.2d at 462). Because some of the initial Lapp factors were "not apposite for directly competing goods," we "adapted [them] to make them applicable whether the products directly compete or not." Id. at 212-13. As adapted, the factors are:

> (1) the degree of similarity between the owner's mark and the alleged infringing mark;
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> (2) the strength of the owner's mark;
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> (3) the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase;
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> (4) the length of time the defendant has used the mark without evidence of actual confusion arising;
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> (5) the intent of the defendant in adopting the mark;
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> (6) the evidence of actual confusion;
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> (7) whether the goods, competing or not competing, are marketed through the same channels of trade and advertised through the same media;
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> (8) the extent to which the targets of the parties' sales efforts are the same;
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> (9) the relationship of the goods in the minds of consumers, whether because of the near-identity of the products, the similarity of function, or other factors;
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> (10) other facts suggesting that the consuming public might expect the prior owner to manufacture both products, or expect the prior owner to manufacture a product in the defendant's market, or expect that the prior owner is likely to expand into the defendant's market.

Id. at 215. "None of these factors is determinative in the likelihood of confusion analysis and each factor must be weighed and balanced one against the other." Checkpoint Sys., Inc. v. Check Point Software Techs., Inc., 269 F.3d 270, 280 (3d Cir. 2001). Each factor is "weighed . . . separately," which "is not to say that all factors must be given equal weight." Fisons Horticulture, Inc. v. Vigoro Indus., Inc., 30 F.3d 466, 476 & n.11 (3d Cir. 1994). "[T]he different factors may properly be accorded different weights depending on the particular factual setting. A district court should utilize the

factors that seem appropriate to a given situation." A & H, 237 F.3d at 215. The Lapp factors are best understood as "tools to guide a qualitative decision." Id. at 216.

Here, the district court held that two of the factors -- strength of the owner's mark, and the extent to which the parties' sales efforts are the same -- favored Kos, but that "the remaining Lapp factors do not." JA at 10-11. The court found "[s]uccess on these two Lapp factors . . . insufficient to persuade [it] that confusion is likely to occur." Id. at 9. It further found that Kos "failed to convince [it] that the selective consumers in this case, physicians and pharmacists, will suffer from a likelihood of confusion." Id. at 9. The opinion analyzed only the two factors the court found weighed in Kos's favor. As to the remaining factors, the court said only that, "[a]fter carefully evaluating the Lapp test in its entirety, [it] concludes that there is no likelihood of confusion." Id. at 11.

We recognize that district courts must exercise their discretion on an expedited basis in deciding whether to grant preliminary relief. Although we ordinarily defer to that discretion, we cannot do so if it was exercised under a mistaken view of the law. Here, two fundamental errors of law taint the district court opinion: (1) the court used an overly narrow definition of confusion, in effect evaluating the likelihood of misdispensing rather than confusion; (2) the court did not properly analyze or weigh the Lapp factors.

First, the hearing transcript betrays a focus on whether prescriptions are likely to be mis-filled, to the apparent exclusion of all other types of confusion with which the Lanham Act is concerned. For example:

> MR. YOUNG [Counsel for Kos]: . . . The Lanham Act doesn't require misdispensing. What we have seen is, a lot of doctors are saying --
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> THE COURT: Yes, but misdispensing is the basis for confusion.
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> MR. YOUNG: That's powerful evidence of confusion. But what's also happening in the marketplace is, doctors are saying, Look, I'm not going to prescribe either drug because I can't keep them straight. . . .
>
> . . .
>
> THE COURT: Well, if that were the case, then I guess there's no concern about adverse health effects to the patient, because they're not getting the wrong drug; they're getting another drug that the doctor wants them to have.

JA at 52 (emphasis added). Similarly:

> MR. LITE [Counsel for Andrx]: . . . A prudent pharmacist cannot fill the wrong prescription. It's impossible to fill the wrong prescription.
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> THE COURT: That's my point: . . . that because of the types of dosages, if they have the wrong name, if they have a name with the wrong dosage, they wouldn't . . . be able to fill that prescription.
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> MR. LITE: That's absolutely correct, Your Honor.
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> THE COURT: So there can't be confusion, you're saying.
>
> MR. LITE: Well, I don't think there can be confusion. There can't, certainly, be confusion in the prescribing or dispensing of these drugs. . . .

Id. at 39-40. Much of the balance of the colloquy focused on the possibility, and potential danger, of misdispensing.[9] As

[9] The court's extensive focus on misdispensing may reflect consideration of Kos's "public interest" argument (that the chance of serious injury made preliminary relief essential) as well as a narrow view of the element of confusion. See, e.g., JA at 20:20; id. at 21:3-22; id. at 25:4-14, id. at 31:4-33:20; id. at 34:5-

noted above, the district court opinion incorporates the reasons articulated by the court at oral argument. These statements are thus a powerful indicator that the court's "likelihood of confusion" analysis rested substantially, if not entirely, on misdispensing as the confusion at issue. This is not the law. It is clear error to treat misdispensing as the only relevant Lanham Act confusion.

The Lanham Act defines trademark infringement as use of a mark so similar to that of a prior user as to be "likely to cause confusion, or to cause mistake, or to deceive." 15 U.S.C. § 1114(1). Likelihood of confusion under the Lanham Act is not limited to confusion of products, as in misdispensing. Confusion as to source is also actionable. See, e.g., Fisons, 30 F.3d at 472 ("[L]ikelihood of confusion . . . exists when the consumers viewing the mark would probably assume that the product . . . it represents is associated with the source of a different product . . . identified by a similar mark.") (quotation omitted). We recently described how the 1962 amendments to the Lanham Act broadened the scope of trademark protection beyond the traditional source-of-origin confusion. Checkpoint, 269 F.3d at 295 (citing deletion of the phrase "purchasers as to the source of origin of such goods or services" from the end of the former definition, which now reads "likely to cause confusion, or to cause mistake, or to deceive").

The Act is now broad enough to cover "the use of trademarks which are likely to cause confusion, mistake, or deception of any kind, not merely of purchasers nor simply as to source of origin." Syntex Labs., Inc. v. Norwich Pharmacal Co., 437 F.2d 566, 568 (2d Cir. 1971) (emphasis added); see, e.g., Checkpoint, 269 F.3d at 295 (overly narrow view of confusion "would undervalue the importance of a company's goodwill with its customers"); Morningside Group Ltd. v. Morningside Capital Group, L.L.C., 182 F.3d 133, 141 (2d Cir. 1999) (reversing due to lower court's use of "inordinately narrow definition of actual confusion" that ignored "actual confusion regarding affiliation or sponsorship"); Meridian Mutual Ins. Co. v. Meridian Insurance Group, Inc., 128 F.3d 1111, 1118 (7th Cir. 1997) (context of confusion "immaterial" because any injury to goodwill or loss of control over reputation is actionable); Champions Golf Club, Inc. v. Champions Golf Club, Inc., 78 F.3d 1111, 1119-20 (6th Cir. 1996) (relevant evidence of confusion goes beyond purchaser confusion and includes "confusion among nonpurchasers" in order to "protect the manufacturer's reputation"); Fuji Photo Film Co. v. Shinohara Shoji Kabushiki Kaisha, 754 F.2d 591, 596 (5th Cir. 1985) (actionable confusion includes any use "likely to confuse purchasers with respect to . . . [a product's] endorsement by . . ., or its connection with[,] the plaintiff").

Second, the district court failed to "employ all the relevant Lapp factors and weigh each factor to determine whether in

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13; id. at 35:4-36:20; id. at 37:19-40:15; id. at 42:10-18; id. at 48:16-52:25.

the totality of the circumstances marketplace confusion is likely." Checkpoint, 269 F.3d at 296 (emphasis added). Despite recognizing that "'each factor must be weighed and balanced,'" the court did not perform the requisite weighing and balancing on the record. JA at 8 (quoting Checkpoint, 269 F.3d at 280). The Lapp test is not a mechanistic one. It need not be "followed precisely so long as the relevant comparisons suggested by the test are made." A & H, 237 F.3d at 207. But if a district court finds "certain of the Lapp factors are inapplicable or unhelpful in a particular case," that court should "explain its choice not to employ those factors." Id. at 214 n.8. Here, the court analyzed only two of the ten Lapp factors -- both of which it found favored Kos. The court's conclusory statement that "the remaining Lapp factors do not [weigh in Petitioner's favor]," JA at 10-11, does not explain the basis for its holding as to each factor, whether it viewed each as neutral, irrelevant, or favorable to Andrx, or how it weighed and balanced the combined factors. The opinion thus does not make the "relevant comparisons" which the Lapp test identifies. Compare Fisons, 30 F.3d at 481 (reversing because "district court misapplied some [Lapp factors] and did not consider others") with A& H, 237 F.3d at 215-16 (affirming since "ostensibly missing Lapp factors appear to be incorporated into the District Court's test," which was "functionally similar to the Lapp test").[10]

When reviewing an order that does not adequately support the resolution of a motion for preliminary injunction, we may vacate and remand for additional findings or may "first look[] to see whether the record provides a sufficient basis to ascertain the legal and factual grounds for the grant or denial of the injunction." Bradley v. Pittsburgh Bd. of Educ., 910 F.2d 1172, 1178 (3d Cir. 1990). Although a district court's application of an incorrect legal standard "would normally result in a remand, we need not remand" if application of the correct standard could

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[10] The court's failure to explain its conclusions as to each Lapp factor also runs afoul of Rule 52(a), which requires courts to "set forth the findings of fact and conclusions of law which constitute the grounds" for "granting or refusing interlocutory injunctions." Fed. R. Civ. P. 52(a). "[F]air compliance with Rule 52(a)" is "of the highest importance to a proper review of the action of a court in granting or refusing a preliminary injunction." Mayo v. Lakeland Highlands Canning Co., 309 U.S. 310, 316 (1940). A district court's factual findings and legal conclusions must "explain the basis for" and "permit meaningful review of its ruling." Elliott v. Kiesewetter, 98 F.3d 47, 55 (3d Cir. 1996) (quotation omitted). "[T]he conclusions of law must carefully enunciate and explain the trial court's resolution of questions of law, so that the appellate court is able to conduct a just and orderly review of the rights of the parties." 9 James Wm. Moore et al., Moore's Federal Practice § 52.15[3] (3d ed. 2000).

support only one conclusion. Duraco Prods., Inc. v. Joy Plastic Enters., Ltd., 40 F.3d 1431, 1451 (3d Cir. 1994) (affirming denial of preliminary injunction where plaintiff could not demonstrate likelihood of success even "with the evidence viewed in the light most favorable to it"); see also Opticians, 920 F.2d at 198; Lapp, 721 F.2d at 460 (reversing and directing entry of judgment). Our holding in Opticians is instructive. There, we reversed due to legal error and went on to assess the likelihood of confusion, which the district court had not addressed. Id. at 194-95 ("Likelihood of confusion is a fact normally reviewable under the clearly erroneous standard. Our review, however, is plenary since there is no dispute as to the facts relevant to this issue."). Rather than remanding for the district court to exercise its discretion in the first instance, we determined that plaintiff had made all necessary showings on the undisputed facts of record and directed entry of a preliminary injunction. Id. at 196-98.

Here, we will review the findings and conclusions of the district court and the factual assertions and contentions of the parties in light of the controlling legal principles to see whether the facts and law compel a particular result. If so, it would be a waste of judicial resources to remand for reweighing.

A. The Individual Lapp Factors

1. Degree of Similarity of the Marks

"The single most important factor in determining likelihood of confusion is mark similarity." A & H, 237 F.3d at 216; see also id. at 214 ("[W]hen goods are directly competing, both precedent and common sense counsel that the similarity of the marks takes on great prominence."). Marks "are confusingly similar if ordinary consumers would likely conclude that [the two products] share a common source, affiliation, connection or sponsorship." Fisons, 30 F.3d at 477. The proper test is "not side-by-side comparison" but "whether the labels create the same overall impression when viewed separately." Id. (quotation and citation omitted). Courts should "compare the appearance, sound and meaning of the marks" in assessing their similarity. Checkpoint, 269 F.3d at 281 (quotation omitted). There is no simple rule as to when marks are too similar. "The degree of similarity . . . needed to prove likely confusion will vary with the difference in the goods . . . of the parties. Where the goods . . . are directly competitive, the degree of similarity required to prove a likelihood of confusion is less than in the case of dissimilar products." 3 McCarthy, supra, § 23:20.1.

The district court made no findings as to the degree of similarity of the ADVICOR and ALTOCOR marks; it merely concluded that this factor does not favor Kos.

The facts predicate to this analysis are manifest and undisputed. The facial similarity of the marks is apparent "on their face." Both are seven-letter, three-syllable words that begin and end with the same letters and the same sounds. The marks are also similar in that both are

"coined word[s], not found even in approximation in the English or any other familiar language." Telechron, Inc. v. Telicon Corp., 198 F.2d 903, 905 (3d Cir. 1952). "Fanciful marks are . . . given an expansive scope of judicial protection . . . as to more variations of format." 2 McCarthy, supra, § 11:6. Two names that look and sound similar will naturally seem even more similar where there are no differences in meaning to distinguish them. Nor can the similarity of coined marks be explained by, or ameliorated by virtue of, any relationship between the marks and the products identified. See, e.g., Telechron, 198 F.2d at 909 (Defendant "cannot claim that he is exercising the normal privilege of using ordinary language . . . [in] a case of a first coined word and a second coined word resembling it."); Lambert Pharmacal Co. v. Bolton Chem. Corp., 219 F. 325, 326 (S.D.N.Y. 1915) (Hand, J.) (One who has "adopt[ed a] . . . trade name, arbitrary in character, . . . has the right to insist that others in making up their arbitrary names should so certainly keep away from his customers as to raise no question.").

Andrx would differentiate the marks by distinguishing what it deems unimportant features (namely, "the first letter 'A' and the suffix 'COR'") from those that are "salient" (the "first syllables"). Appellees' Br. at 19-20. Andrx argues that the "first syllables (AD compared to AL) . . . create a completely different sight, sound and impression." Id. at 20 (emphasis added). But the proper legal test is not whether there is some confusing similarity between sub-parts of the marks; the overarching question is whether the marks, "viewed in their entirety," are confusingly similar. A & H, 237 F.3d at 216 (emphasis added). Cf. Fisons, 30 F.3d at 478 ("[T]he district court misapprehended the legal standard when it undertook a detailed analysis of the differences in the marks rather than focusing on the overall impression created by them.").

Andrx attempts to, but cannot, justify its approach by characterizing statements Kos made in European trademark proceedings as "admissions that directly contradict its position before this Court and the district court." Appellees' Br. at 10. The European proceeding involved different marks (ADVICOR v. ACTIVOR), different goods, and different legal standards than those at issue here. Kos's statements in those proceedings show that the material facts are not equivalent. For example, Kos distinguished Advicor from the over-the-counter "stimulants and preparations to build up vitality" at issue there by arguing, inter alia, that "their functions do not overlap," and that they have different "channels of distribution, method[s] of purchase and . . . targeted customer[s]." JA at 329, 333. More importantly, Kos's claims in those proceedings are all premised on European Community law. Trademark standards do not traverse international borders. "The concept of territoriality is basic to trademark law; trademark rights exist in each country solely according to that country's statutory scheme." Fuji Photo, 754 F.2d at 599 (finding it "error to admit evidence of the

parties' foreign trademark practices"); see also E. Remy Martin & Co. v. Shaw-Ross Int'l Imports, Inc., 756 F.2d 1525, 1531 (11th Cir. 1985) (district court erred in considering status of parties' marks in France; "Our concern must be the business and goodwill attached to United States trademarks, not French trademark rights under French law.") (quotation omitted); Vanity Fair Mills v. T. Eaton Co., 234 F.2d 633, 639 (2d Cir. 1956) ("[W]hen trade-mark rights within the United States are being litigated in an American court, the decisions of foreign courts concerning the respective trade-mark rights of the parties are irrelevant and inadmissible.").

Andrx also claims that "[t]he FDA and the USPTO have determined that the marks are not confusingly similar." Appellees' Br. at 19. But neither of those proceedings can supplant the required Lanham Act analysis. First, the FDA applies a standard different from the Lanham Act "likelihood of confusion" test at issue here. The FDA reviews proposed drug names "to predict potential confusion that may arise in the actual prescription process." 3 McCarthy, supra, § 19:149 (emphasis added); see also id. at § 19:150 (FDA "likelihood of confusion test [is] wholly distinct from the test employed by the PTO"). As discussed above, misdispensing is not the only type of confusion actionable under the Lanham Act. Indeed, to the extent that the FDA's proprietary name review is relevant here, the reviewing division's statement that the "name Advicor looks and sounds similar [to] Altocor" actually supports Kos's claim. See JA at 269.

Second, the PTO has not allowed Andrx to register the ALTOCOR mark. As stated above, Kos's opposition remains pending. Andrx's claim about a favorable PTO determination presumably rests on the examining attorney's decision approving publication of the ALTOCOR mark for opposition.[11] The record contains no information about the basis for the publication decision or about what information was before the examining attorney at that time. Thus, the record does not show that the PTO actually considered the registrability of ALTOCOR over ADVICOR, much less that it found the marks not to be confusingly similar. Cf. Marketing Displays, Inc. v. TrafFix Devices, Inc., 200 F.3d 929, 934 (6th Cir. 1999) (rejecting claim that registration of allegedly infringing mark creates inference that "the trademark examining attorney at the PTO actually examined the [earlier] mark and found that the [registered] mark

[11] We caution that Andrx's apparent shorthand characterization of this low-level decision as a PTO determination seems somewhat misleading, as do such statements as, for example, "the USPTO approved the mark." Appellees' Br. at 35. Publication of a mark is not equivalent to its allowance or registration; the PTO issues a Certificate of Registration only if "all oppositions filed" after publication are dismissed. 37 C.F.R. § 2.81. Reference to PTO action is more naturally understood as allowance (or denial) of an application rather than publication of a mark, especially where an opposition is filed.

did not infringe it"), rev'd on other grounds, 532 U.S. 23 (2001). Indeed, even where the record shows that an examining attorney has explicitly considered a prior mark, we have held that an "initial PTO determination . . . may be considered [but] need not be given weight when the PTO attorney did not review all the evidence available to the District Court." A & H, 237 F.3d at 221 (affirming decision that gave "no weight" to "low-level preliminary decision" even though examiner assessed likelihood of confusion with prior mark).

We hold that the district court clearly erred in failing to recognize that this factor weighs in Kos's favor. It does.

2. Strength of the Owner's Mark

The record supports the district court's finding that this factor weighs in favor of Kos. The court properly analyzed both the conceptual and commercial strength of the ADVICOR mark. Andrx argues that this factor does not favor Kos because ALTOCOR and ADVICOR are similarly distinctive and have similar strength in the marketplace. But the relative strength of the Andrx's mark is not relevant here. The second Lapp factor looks to "the strength of the owner's mark." Lapp, 721 F.2d at 463 (emphasis added). "Under the Lanham Act, stronger marks receive greater protection" because they "carry greater recognition, [so that] a similar mark is more likely to cause confusion." A & H, 237 F.3d at 222. It would not serve the purposes of the Lanham Act for trademark owners to receive less protection from strong infringing marks than weak ones. Indeed, it might be argued that a stronger junior mark is more likely to cause confusion, at least where, as here, both marks are being used in the same market.

3. Factors Indicative of the Care and Attention Expected of Consumers

The third Lapp factor weighs against finding a likelihood of confusion "[w]hen consumers exercise heightened care in evaluating the relevant products before making purchasing decisions." Checkpoint, 269 F.3d at 284. The district court held that Kos did not "convince [it] that the selective consumers in this case, physicians and pharmacists, will suffer from a likelihood of confusion." JA at 9. The opinion provided no basis for this conclusion, but did incorporate the "reasons . . . stated on the record during oral argument." Id. at 13. There, the judge stated that he thought the differences in the dosage of each drug made errors in filling prescriptions unlikely. E.g., id. at 49 ("[I]t seems to me because of the dosage that has to be made part of the prescription that the pharmacist would have to ignore some aspect of such a prescription to make a mistake."). The court did not analyze the likelihood of any type of confusion other than misdispensing.

The district court and the parties treated medical professionals, such as doctors, nurses and pharmacists, as the

relevant consumers.[12] These trained professionals may be expected to be knowledgeable about, and to exercise care in distinguishing between, medicines. We have emphasized a countervailing concern that weighs against allowing the expertise of physicians and pharmacists to trump other factors in assessing the likelihood of confusion in drug cases. "Prevention of confusion and mistakes in medicines is too vital to be trifled with" since "[c]onfusion in such products can have serious consequences for the patient." Morgenstern Chem. Co. v. G.D. Searle & Co., 253 F.2d 390, 393 (3d Cir. 1958) (quotation omitted). "[P]hysicians are not immune from confusion or mistake." Id. (quotation omitted); see also Syntex Labs., Inc. v. Norwich Pharmacal Co., 437 F.2d 566, 569 (2d Cir. 1971) (since confusion of prescription drugs "could result in physical harm to the consuming public," a "stricter standard in order to prevent likelihood of confusion seems desirable"). Other jurisdictions and authorities similarly recognize that "greater care should be taken to avoid confusion in connection with medications which affect the health of the patient." 3A Louis Altman, Callman on Unfair Competition, Trademarks & Monopolies § 21:10 & nn. 121-132 (4th ed. 2003) (collecting cases and authorities).

In assessing how customer sophistication should be weighed "[w]ith respect to pharmaceuticals," the "expertise of the physicians and pharmacists may be outweighed by" this need for heightened care. Id. at § 21:12 & n.24 (emphasis added). Where both professionals and the general public are relevant consumers, "the standard of care to be exercised . . . will be equal to that of the least sophisticated consumer in the class." Checkpoint, 269 F.3d at 285. In Morgenstern, we criticized the district court for weighing the "high standards of care" expected of "physicians and pharmacists" more heavily than the "obvious similarity in derivation, suggestiveness, spelling, and sound in careless pronunciation between [the marks] as applied to pills to be taken by

[12] We note that neither the parties nor the court below addressed the possible confusion of ultimate consumers. While doctors and pharmacists play a gate-keeping role between patients and prescription drugs, they are not the ultimate consumers. Patients are. Courts have noted that drugs are increasingly marketed directly to potential patients through, for example, "ask-your-doctor-about-Brand-X" style advertising. See, e.g., Puritan-Bennett Corp. v. Penox Techs. Inc., No. IP 02-0762-C, 2004 WL 866618, at * 4 (S.D. Ind. Mar. 2, 2004) (admitting evidence of patient confusion as to medical devices available only by prescription but advertised directly to patients because patients "are a part of, although not the entire, relevant market"); Upjohn Co. v. American Home Prods. Corp., No. 1:95CV237, 1996 WL 33322175, at *4 (W.D. Mich. Apr. 5, 1996) (patients are among relevant consumers for prescription drugs whose marketing targets them).

mouth for therapeutic purposes." 253 F.2d at 392. Recognizing that doctors and pharmacists "are carefully trained to detect differences in the characteristics of pharmaceutical products," we held that this "does not open the door to the adoption by manufacturers of medicines of trade-marks or names which would be confusingly similar to anyone not exercising such great care." Id. at 393 (emphasis added).[13] See also 3 McCarthy, supra, § 23:32 ("[I]t is proper to require a lesser quantum of proof of confusing similarity for drugs and medicinal preparations. . . . [For] prescription drugs, [this] rule . . . should control over the supposed 'sophistication' of physicians and pharmacists.") (emphasis added).

Andrx argues that confusion is even less likely here than in other cases involving medical professionals since prescriptions must reflect the different chemical composition of the drugs, with Advicor prescriptions specifying strengths of two active ingredients, and Altocor only one. Of course, this difference in prescribing is not relevant to the common practice of providing samples or to any type of confusion other than misdispensing. There is no reason to believe that medical expertise as to products will obviate confusion as to source or affiliation or other factors affecting goodwill. "It is well settled that expertise in the field of trademarks cannot

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[13] At oral argument, the question was raised whether Morgenstern creates a different standard for drug cases -- "possibility of confusion" rather than "likelihood of confusion" -- and, if so, whether it is good law. Compare Morgenstern, 253 F.2d at 394 ("If there is any possibility of . . . confusion in the case of medicines public policy requires that the use of the confusingly similar name be enjoined.") with A & H Sportswear, Inc. v. Victoria's Secret Stores, Inc., 166 F.3d 197, 205 (3d Cir. 1999) (en banc) ("[T]he appropriate standard for determining trademark infringement under the Lanham Act is the likelihood of confusion."). But cf. Morgenstern, 253 F.2d at 392 (test for infringement is whether marks are so similar "that ordinary purchasers, buying with ordinary caution, are likely to be misled") (quotation omitted, emphasis added).

We need not consider the applicability of the discredited "possibility of confusion" standard. Kos conceded at oral argument that the proper standard is "likelihood of confusion," relying on Morgenstern for the proposition that "the potential harm from a mistake warrants closer scrutiny" in such cases. Audio Tape of Oral Argument before Court of Appeals for the Third Circuit (Mar. 9, 2004) (on file with Court). Morgenstern's holding -- that drug manufacturers cannot use marks that would be confusingly similar to non-experts -- may be best understood as a warning that medical expertise is not enough, in and of itself, to lessen the likelihood of confusion in prescription drug cases.

be inferred from expertise in another area." Fuji Photo, 754 F.2d at 595 (collecting cases); see also Altman, supra, § 21:10 & n.139 ("[I]t has been held that the care with which consumers select a product does not impact the association they may make regarding sponsorship of another product or service; therefore even a high degree of care would have little effect on confusion of sponsorship."); cf. Sterling Drug Inc. v. Lincoln Labs., Inc., 322 F.2d 968, 971 (7th Cir. 1963) (that defendant's product requires prescription does not "eliminat[e] the likelihood of confusion as to source of origin" for medical products "designed to remedy the same condition in . . . [and] purchased and used by the same classes of persons"); Champions, 78 F.3d at 1121 (6th Cir. 1996) (sophistication of consumers, who exercise great care in joining golf club, does not preclude confusion "about affiliation between the two clubs").

The district court did not err in holding that this factor does not favor Kos. We conclude, however, that no reasonable factfinder could weigh it heavily for Andrx.

4/6. Length of Time Defendant's Mark Has Been Used Without Confusion / Evidence of Actual Confusion

Per the fourth Lapp factor, two parties' concurrent use of "similar marks for a sufficient period of time without evidence of consumer confusion about the source of the products" allows "an inference that future consumers will not be confused either." Fisons, 30 F.3d at 476. The sixth Lapp factor looks at evidence of actual confusion.

The district court recited Kos's claim that, in the thirteen months since ALTOCOR was first sold,[14] "at least six patients have received the wrong medication due to confusion between the drugs' names" and "over sixty instances of actual confusion [have been] reported to [Kos]." JA at 6. Yet the court conspicuously failed to analyze either Lapp factor concerned with actual confusion or to explain why these factors did not favor Kos in light of the incidents Kos identified.

a. Admissibility of Berg Certification

Before we reach the substantive issue of actual confusion, we must consider the evidentiary status of the Berg Certification on which Kos's claims about such confusion rest. Andrx challenges the admissibility and reliability of the Berg Certification, which it deems "self-serving, unreliable and uncorroborated hearsay" that "is an insufficient basis for the issuance of preliminary relief in a

[14] Compare Scott Paper Co. v. Scott's Liquid Gold, Inc., 589 F.2d 1225, 1230 (3d Cir. 1978) (citing "over forty years" of concurrent use "without any evidence of actual confusion" in finding no likelihood of confusion).

trademark matter." Appellees' Br. at 25.[15]

We have considered the possibility that the district court's conclusory finding as to these Lapp factors was based on its acceptance of the objections Andrx raised below to the Berg Certification. While it is implicit in the district court's holding that it found the Berg Certification insufficient to show actual confusion, nothing in the record suggests that it sustained Andrx's objections to the admissibility or credibility of the document itself. See, e.g., JA at 41. Indeed, in its opinion, the court twice took cognizance of the Certification with no indication that it viewed the document as inadmissible, inherently unreliable, or otherwise unworthy of consideration. Id. at 6, 12.

Nor do we agree with Andrx that the Berg Certification is an inadequate basis for preliminary relief because it contains multiple levels of hearsay and is not based solely on personal knowledge. It is well established that "a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." University of Texas v. Camenisch, 451 U.S. 390, 395 (1981). In keeping with this principle, many of our sister Circuits have recognized that "[a]ffidavits and other hearsay materials are often received in preliminary injunction proceedings." Asseo v. Pan Am. Grain Co., 805 F.2d 23, 26 (1st Cir. 1986); see also Ty, Inc. v. GMA Accessories, Inc., 132 F.3d 1167, 1171 (7th Cir. 1997) (citing Asseo); Levi Strauss & Co. v. Sunrise Int'l Trading, Inc., 51 F.3d 982, 985 (11th Cir. 1995) ("At the preliminary injunction stage, a district court may rely on affidavits and hearsay materials which would not be admissible evidence for a permanent injunction . . . ."); Sierra Club, Lone Star Chapter v. FDIC, 992 F.2d 545, 551 (5th Cir. 1993) (courts at preliminary injunction stage "may rely on otherwise inadmissible evidence, including hearsay"); Flynt Distrib. Co. v. Harvey, 734 F.2d 1389, 1394 (9th Cir. 1984) ("The urgency of obtaining a preliminary injunction . . . makes it difficult to obtain affidavits from persons who would be competent to testify at trial. The trial court may even give inadmissible evidence some weight . . . ."); cf. Heideman v. South Salt Lake City, 348 F.3d 1182, 1188 (10th Cir. 2003) ("The Federal Rules of Evidence do not apply to preliminary injunction hearings.").

These cases are consistent with the lack of any rule in the preliminary injunction context akin to the strict rules governing the form of affidavits that may be considered in summary judgment proceedings. Compare Fed. R. Civ. P. 56(e) (affidavits on summary judgment

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[15] Our holding in Versa Products. Co. v. Biford Co., 50 F.3d 189 (3d Cir. 1995) does not support Andrx's argument that "[such] double hearsay is an insufficient basis for . . . preliminary relief in a trademark matter." See Appellees' Br. at 25 (citing Versa Prods., 50 F.3d at 212). Versa Products was an appeal from a final judgment after a bench trial; its holding is not relevant in the preliminary injunction context.

"shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein") with Fed. R. Civ. P. 65 (no similar provision in rule governing preliminary injunctions). See also 11A Charles Alan Wright et al., Federal Practice & Procedure § 2949 (2d ed. 1995) ("[A] consideration of the different policies that underlie Rules 56 and 65 indicates [that the Rule 56(e) standard] should not be imposed on applications under the latter rule.").

District courts must exercise their discretion in "weighing all the attendant factors, including the need for expedition," to assess whether, and to what extent, affidavits or other hearsay materials are "appropriate given the character and objectives of the injunctive proceeding." Asseo, 805 F.2d at 26. The weight to which such materials are entitled may of course vary greatly depending on the facts and circumstances of a given case.[16] Under the circumstances here, we find that the district court's implicit admission of the Berg Certification for use at this preliminary stage was not clearly erroneous.

Moreover, we note that some of the evidence of actual confusion in the Berg Certification would be admissible even if compliance with the Federal Rules of Evidence or the strictures governing Rule 56(e) affidavits were required. The first level of hearsay analysis concerns the underlying statements said to show confusion. Such statements fall into two categories -- those exhibiting confusion and those proclaiming it. Statements of the first type (Dr. A[17] says "We have plenty of Advicor" but points to Altocor samples) are not hearsay because they are

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[16] We note that such assessments must be made in light of the rule that it may be improper to resolve a preliminary injunction motion on a paper record alone; where the motion turns on a disputed factual issue, an evidentiary hearing is ordinarily required. See, e.g., Sims v. Greene, 161 F.2d 87, 88 (3d Cir. 1947) (evidentiary hearing needed in light of conflicting claims in pleadings and affidavits). Neither party claims the district court erred here by not holding a hearing; indeed, neither party asked for a hearing.

[17] We note that one of Andrx's complaints is that the Berg Certification does not identify the doctors involved in each incident. This does not affect its admissibility. See Callahan v. A.E.V., Inc., 182 F.3d 237, 252 n.11 (3d Cir. 1999) ("In a practical sense, the[] identities [of the customers who made the statements at issue] are not important. The relevance of their statements depends only on the fact that they were the plaintiffs' customers . . . . Furthermore, we do not think that the admissibility of their statements under the Rule 803(3) hearsay exception depends on their being identified.").

not submitted for their truth; indeed, it is their falsity that shows the speaker's confusion. Statements of the second type (Dr. B says "I find these names confusing.") are admissible as "statement[s] of the declarant's then existing state of mind." Fed. R. Civ. P. 803(3). To the extent such statements address the speaker's plans (Dr. C says "Because these names are confusing, I will not prescribe either drug."), they create an inference "that the declarant acted in accord with that plan." See, e.g., United States v. Donley, 878 F.2d 735, 738 (3d Cir. 1989). The second level is the report of the marketing representative to Berg (Employee D: "Dr. A told me . . . ."). There is a factual dispute as to whether some, all, or none of these reports satisfy the "business records" exception to the hearsay rule. Even if the reports are not garden variety business records, however, Berg could attest to having received more than 60 reports of confusion in his official capacity. Berg's direct testimony that he received numerous and varied reports of alleged confusion is not hearsay but a factual claim that, as discussed below, has independent evidentiary significance tending to show actual confusion.

b. Probative Value of Berg Certification as to Actual Confusion

As Vice President of Marketing, Berg is responsible for Kos's "overall marketing strategy" and receives reports from "district managers who oversee the distribution of [Kos's] drugs . . . about significant issues occurring in the marketplace." JA at 68-69. He certified that his staff has reported more than 60 incidents of actual confusion to him. He describes a range of "representative . . . instances," including: medical professionals providing patients the wrong drug samples and, on one occasion, improperly filling a prescription; doctors complaining to Kos representatives about "Advicor," when their complaints really concerned Altocor; and medical professionals confusing Altocor samples with Advicor samples, Altocor representatives with Advicor representatives, or Altocor-sponsored events with Advicor-sponsored events. Id. at 69-71.

It may be that the Berg Certification is not competent proof or reliable evidence of any particular incident that it describes. However, as noted above, Berg is competent to attest that he received over 60 reports of alleged confusion, and his credibility as to this assertion has been tested by deposition in the PTO opposition proceedings. Moreover, the very number of reports Berg says he received, and the variety of sources and types of confusion reported, bolster the reliability of the reports as a whole. Courts are entitled to view such diverse reports of confusion as mutually reinforcing, particularly where, as here, the names and products are so similar as to make the reported confusion plausible. Indeed, the reverse may be true as well: here, for example, the 60 reported instances of confusion tend to confirm our determination that the names are confusingly similar.

Andrx argues that Kos cannot show trademark confusion because the 60 alleged incidents of confusion comprise too small a percentage of the approximately 350,000 Advicor prescriptions, or the approximately 650,000 combined prescriptions.[18] We have recognized, however, that evidence of actual confusion "is difficult to find . . . because many instances are unreported." Checkpoint, 269 F.3d at 291. Without knowing how many, or what percent of, incidents go unreported, anecdotal evidence of confusion cannot usefully be compared to the universe of potential incidents of confusion. The rarity of such evidence makes even a few incidents "highly probative of the likelihood of confusion." Id. (Because "reliable evidence of actual confusion is difficult to obtain in trademark and unfair competition cases, any such evidence is substantial evidence of likelihood of confusion.") (quotation omitted, emphasis added); see also Country Floors, Inc. v. Partnership of Gepner & Ford, 930 F.2d 1056, 1064 (3d Cir. 1991) (quoting cases holding that "very little proof of actual confusion would be necessary to prove likelihood of confusion") (emphasis added); cf. Sara Lee Corp. v. Kayser-Roth Corp., 81 F.3d 455, 466 (4th Cir. 1996) ("[W]e can but wonder how often the experiences related by the trial witnesses have been repeated -- but not reported -- in stores across the country.").

The Berg Certification provides more than enough evidence of actual confusion to support weighing the fourth and sixth Lapp factors in Kos's favor. Nonetheless, because there is room for differing views as to the weight to which the document is entitled, and because some of the underlying facts are disputed,[19] we decline to hold that the record evidence compels weighing these factors in Kos's favor as a matter of law. On the other hand, it would be clear error to weigh either factor against Kos on the present record.

5. Defendant's Intent in Adopting the Mark

"[E]vidence of intentional, willful and admitted adoption of a mark closely similar to the existing mark[] weighs strongly in favor of finding [a] likelihood of confusion." Checkpoint, 269 F.3d at 286 (quotation omitted). This inquiry

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[18] The district judge commented on these figures, but did not analyze them or otherwise indicate whether he saw them as legally or factually significant. See, e.g., JA at 19 ("So we're talking about something in the vicinity for both prescriptions of 650,000 drugs, of which you're aware of approximately 60 instances of confusion.").

[19] For example, Andrx claims that Berg's characterization of one incident as evincing confusion is belied by the e-mail describing that incident, which, Andrx claims, shows only that a cardiologist overrode the prescription choice made by a patient's non-specialist physician. See supra p. 6.

extends beyond asking whether a defendant purposely chose its mark to "promot[e] confusion and appropriat[e] the prior user's good will." Fisons, 30 F.3d at 479 (quotation omitted). The adequacy and care with which a defendant investigates and evaluates its proposed mark, and its knowledge of similar marks or allegations of potential confusion, are highly relevant. See, e.g., id. at 480 (directing district court to consider defendant's trademark search and investigation of similar marks to determine if it was "careless in its evaluation of the likelihood of confusion"); Lapp, 721 F.2d at 463 (relying on district court's finding that while defendant "may have acted innocently, [it] was careless in not conducting a thorough name search for American uses of the name"); Morgenstern, 253 F.2d at 394 (citing finding that defendant "trod a very narrow course when it adopted the name Mictine with full knowledge of the prior use of the name Micturin by the plaintiff"). A defendant that "persisted in its plan" to adopt a mark "after being warned of too close resemblance between" its proposed mark and plaintiff's mark is not "blameless[]." Telechron, Inc. v. Telicon Corp., 198 F.2d 903, 908 (3d Cir. 1952).

The district court did not analyze this factor on the record or make relevant factual findings. Kos argues that Andrx's intent to trade on Kos's goodwill may be inferred from Andrx's insistence on using this particular made-up (and meaningless) mark despite being warned of the likelihood of confusion before beginning to sell Altocor. Andrx responds that its allegedly infringing mark "was specifically considered by the USPTO, the FDA and a district court and found not to be confusingly similar." Appellees' Br. at 24.

As stated previously, Andrx is not entitled to rely on the PTO or FDA actions to justify its own. See supra pp. 16-17. Andrx's attempt to justify its conduct by reference to the district court decision is puzzling; that decision was obviously not issued when Andrx adopted the ALTOCOR mark. Andrx chose to use this mark with clear notice of Kos's objections and its successful prior use of the ADVICOR mark for similar goods. There was, in the words of Judge Learned Hand, "no reason whatever why [defendant] should have selected [an arbitrary, made-up trade-name] which bore so much resemblance to the plaintiff's." See Lambert Pharmacal Co. v. Bolton Chem. Corp., 219 F. 325, 326 (S.D.N.Y. 1915). Andrx's use of ALTOCOR for its anti-cholesterol drug was at least reckless, at worst a deliberate appropriation of the goodwill Kos had generated for its anti-cholesterol product, Advicor.

We therefore conclude that the district court clearly erred in failing to weigh this factor for Kos.[20]

[20] In view of this conclusion, it is unnecessary to address the factual dispute between the parties as to whether Andrx deliberately chose the ALTOCOR mark knowing Kos would be using ADVICOR for its own similar product in order to trade on the goodwill it expected Kos's new product to generate.

7. Whether Goods Are Marketed Through the Same Channels of Trade and Advertised in the Same Media

"[T]he greater the similarity in advertising and marketing campaigns, the greater the likelihood of confusion." Checkpoint, 269 F.3d at 288-89 (quotation omitted). This is a "fact intensive inquiry" that requires a court to examine the "media the parties use in marketing their products as well as the manner in which the parties use their sales forces to sell their products to consumers." Id. at 289. The district court did not address this factor directly, but implicitly found that it did not favor Kos. Nonetheless, the court's statement, when analyzing the eighth Lapp factor, that both parties' "sales representatives visit physicians with drug samples and related information" is relevant here, and supports weighing this factor in Kos's favor. JA at 10.

Andrx concedes that the "goods are marketed through the same channels," but argues that confusion is not likely since the "channels of trade and marketing efforts are directed to a very educated and highly sophisticated group." Appellees' Br. at 30. Andrx also claims that this factor favors it "because the products are not in direct competition" since each should be prescribed under somewhat different circumstances. Id.

The problem with Andrx's approach is that neither customer sophistication nor the relationship between the goods is relevant to determining whether the goods are "marketed through the same channels and advertised through the same media." Lapp, 721 F.2d at 463. There are other Lapp factors that take those issues into account. "[W]e [do] not discount the strength of plaintiff's case in one area because of weakness in another; we weigh[] each factor separately." Fisons, 30 F.3d at 476 (holding district court erred in "fail[ing] to count the similarities in channels of trade and target audience" for plaintiff due to district court's view that other Lapp factors weighed against plaintiff).

We find that the district court clearly erred in failing to recognize that this factor favors Kos. It does.

8. Extent to Which Targets of the Parties' Sales Efforts Are the Same

The record supports the district court's finding that this factor supports Kos because the "'parties target their sales efforts to the same consumers,'" namely, "physicians and pharmacists." JA at 10 (quoting Checkpoint, 269 F.3d at 289). Andrx again argues that "any potential confusion" is "obviate[d]" because the target audience is "a highly educated and sophisticated group." Appellees' Br. at 30. The district court properly rejected this argument, recognizing that it impermissibly conflated different Lapp factors. Cf. Fisons, 30 F.3d at 476.

9. Relationship of the Goods

"The closer the relationship between the products, . . . the greater the likelihood of confusion." Lapp, 721 F.2d at 462. The question is how similar, or

closely related, the products are. Fisons, 30 F.3d at 481 (describing cases where "the relationship of the products was close enough to lead to the likelihood of confusion" and "the goods were similar enough that a consumer could assume they were offered by the same source"). This factor focuses on the nature of the products themselves, asking whether it would be reasonable for consumers to associate them or see them as related. We have recognized that "the near-identity of the products" or their "similarity of function" are key to assessing whether consumers may see them as related. A & H, 237 F.3d at 215.

The district court did not analyze this factor. It did, however, make potentially relevant findings about similarities and differences in the usage and composition of the drugs. JA at 6 ("While both drugs are used to treat elevated cholesterol levels, their chemical compositions differ in such a way that there are different active ingredients, dosages, and side effects."). Andrx maintains that doctors will necessarily "distinguish the two products in their minds" because they will need to decide which to prescribe since Advicor, but not Altocor, contains niacin. Appellees' Br. at 30-31. Kos argues that the "differences in active ingredients," which make the drugs appropriate "for treatment of different types of patients with the same ailment[,] . . . do not negate a likelihood of confusion." Appellant's Br. at 25-26.

Goods need not be identical for this factor to support finding a likelihood of confusion. See, e.g., A & H, 237 F.3d at 224 (affirming holding that "product similarity factor favored [plaintiff]" where products were only "somewhat interchangeable" due to "slightly different functions"). The question is not whether it is possible to distinguish between the products but whether, and to what extent, the products seem related, "whether because of [their] near-identity, . . . or similarity of function, or other factors." Id. at 215; see also Fisons, 30 F.3d at 481 (equating factor with Sixth Circuit test for "Relatedness of the Goods"). Courts may consider here "whether buyers and users of each parties' goods are likely to encounter the goods of the other, creating an assumption of common source[,] affiliation or sponsorship." Checkpoint, 269 F.3d at 286.

Advicor and Altocor are both prescription drugs used to improve cholesterol levels. The products are of the same type and serve the same function in slightly different (but overlapping) ways that may be appropriate for slightly different (but overlapping) sets of patients. That doctors will need to decide which drug to prescribe does not mean they won't see the drugs as related or otherwise associate them. Indeed, it could be argued that the opposite is true, that is, that they will associate the products because they must consider both to decide which to prescribe. See, e.g., Syntex Labs., Inc. v. Norwich Pharmacal Co., 437 F.2d 566, 568-69 & n.1 (2d Cir. 1971) (affirming finding that drugs for "treatment of closely parallel and medically related conditions"

-- which had different compositions such that each was contraindicated for some patients who could take the other drug -- "are likely to be closely associated in the minds of those who prescribe and dispense them"); Sterling Drug Inc. v. Lincoln Labs., Inc., 322 F.2d 968, 971 (7th Cir. 1963) (confusion likely as to medicines "designed to remedy the same condition in [and] purchased and used by the same class of persons," even though products had different active ingredients, and were used and sold in different ways) (reversing and directing entry of permanent injunction); Ortho Pharm. Corp. v. American Cyanamid Co., 361 F. Supp. 1032, 1040 (D.N.J. 1973) (medical personnel likely to "mentally . . . associate" products even though unlikely to dispense one thinking it is the other).

Accordingly, we hold that the district court clearly erred in holding that this factor does not weigh in Kos's favor. It does.

10. Other Facts Suggesting the Public Might Expect the Prior Owner To Manufacture Both Products

In assessing this factor, courts may look at the nature of the products or the relevant market, the practices of other companies in the relevant fields, or any other circumstances that bear on whether consumers might reasonably expect both products to have the same source. This issue is highly context-dependent. See, e.g., Checkpoint, 269 F.3d at 291 (affirming finding that consumers were unlikely to expect plaintiff to "have the expertise" to enter defendant's field due to "highly specialized and technical nature" of defendant's products); Fisons, 30 F.3d at 480 (evidence that products "are closely related and are used together" and that "other companies market both products" supports finding that public might expect senior user to offer products of junior user); Lapp, 721 F.2d at 464 (close relationship between products that may be used together supports finding that "even sophisticated customers . . . would find it natural or likely" that plaintiff might offer product similar to defendant's); McNeil Labs., Inc. v. American Home Prods. Corp., 416 F. Supp. 804, 806-07 (D.N.J. 1976) (consumer might reasonably think TYLENOL manufacturer used EXTRANOL mark for extra-strength version of its drug); Ortho Pharm., 361 F. Supp. at 1040 (while purchasing agents are "likely to know that [drugs] are the products of two separate companies" since they typically order "face-to-face" with a sales representative, medical professionals will likely "associate with [defendant] the goodwill and the high reputation which [plaintiff] has acquired").

The district court did not discuss this factor, but held that it did not favor Kos.

In light of the close relationship between the drugs, customers could easily expect the maker of one to make the other. Cf. Checkpoint, 269 F.3d at 290 ("Evaluating this factor, courts look to evidence that . . . the products at issue are so closely related that the consuming public might find it natural for one

company to" sell both.). In addition, Kos argues that medical professionals might expect it to make a drug akin to Altocor in light of how well such a drug would fit into Kos's product line. Kos sells "two prescription drugs for the treatment of chronic . . . cholesterol disorders" -- Niaspan, which contains only niacin, and Advicor, which contains both lovastatin and niacin. JA at 69. A lovastatin-only anticholesterol drug could easily be a seen as a natural brand extension.

Andrx responds that doctors choose which drug to prescribe "based upon a patient's particular needs, not based upon who manufactures the drug." Appellees' Br. at 31. This response is wholly irrelevant to the question whether customers might expect Kos to offer a product like Altocor. Andrx's argument seems premised on the idea that goodwill is virtually irrelevant for prescription drugs. Andrx does not point to any evidence in support of such a novel position, which is counter to the purposes and assumptions of the Lanham Act.

Because Andrx has done nothing to rebut Kos's showing that customers could easily and naturally assume that Kos manufactures both products, we find that this factor favors Kos as a matter of law on the present record. The district court clearly erred in not weighing this factor for Kos.

B. Weighing the Lapp Factors

The most important factor -- mark similarity -- favors Kos. ADVICOR and ALTOCOR are similar in sound and appearance, and neither has any meaning that could distinguish between them or lead customers to associate them with distinct products. The ADVICOR mark is entitled to broad protection because it is a coined term and because it is a strong mark, both conceptually and commercially. The products in question are closely related and are marketed and sold to practically identical audiences in practically identical ways. These are products customers could easily expect to be manufactured by a single source. Also in Kos's favor is Andrx's deliberate decision to use a name dangerously close to that of a competing drug, with no apparent reason for choosing an arbitrary mark so similar to its competitor's and despite being warned of the confusing similarity. Accordingly, the first, second, fifth, seventh, eighth, ninth, and tenth Lapp factors unquestionably weigh in favor of Kos as a matter of law.

There is a factual dispute as to how Kos's evidence of actual confusion affects the analysis of the fourth and sixth Lapp factors. We conclude that while the evidence Kos submitted is undoubtedly sufficient to support weighing these factors in its favor, it is not so great as to compel that result. But the best Andrx could hope for on the present record is that these factors be found in equipoise; no reasonable factfinder could find that they weigh against finding a likelihood of confusion here. Only the third Lapp factor arguably weighs against finding a likelihood of confusion. It would, however, be clear error to allow this one factor to outweigh Kos's strong showing

on the key factor of mark similarity and on the remaining factors, particularly in light of our earlier discussion of the dangers of relying too heavily on medical sophistication in prescription drug cases.

We have carefully considered whether to direct the district court on remand to weigh the Lapp factors anew in light of the proper legal standards. On reflection, however, we conclude that doing so would serve no useful purpose. The undisputed facts weigh heavily in favor of Kos as a matter of law. Regardless of how the factual disputes might be resolved, any reasonable factfinder weighing the Lapp factors in accordance with the correct legal standards would hold that Kos is likely to succeed on the merits. Because the record could not support a contrary holding, a remand for reweighing would waste judicial resources and unnecessarily delay the proceedings further. Cf. Fisons, 30 F.3d at 482 (Garth, J., concurring in part and dissenting in part) ("I can see no purpose in remanding for retrial of Fisons' Lanham Act claims when it is so evident that the marks at issue here are confusingly similar."). Compare A & H, 237 F.3d at 238 (remanding where court could "not say as a matter of law that a different weighing of the factors could not have influenced the District Court to make a different finding of ultimate fact") with Tanimura & Antle, Inc. v. Packed Fresh Produce, Inc., 222 F.3d 132, 140 (3d Cir. 2000) (reversing and directing entry of preliminary injunction after finding "the four factors required to grant a preliminary injunction are apparent on the record before us").

IV. IRREPARABLE HARM

The district court held that Kos had not shown it would suffer irreparable harm absent an injunction because Kos's product had been on the market "less than two years." JA at 11. The court apparently deemed this an insufficient time in which to establish the goodwill needed to show such harm, as compared with the "over sixteen years" during which the goods were marketed in the case on which Kos relied. Id. (comparing Merrell-National Labs., Inc. v. Zenith Labs., Inc., 194 U.S.P.Q. 157, 161 (D.N.J. 1977)).

"Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of good will." Pappan Enters., Inc. v. Hardee's Food Sys., Inc., 143 F.3d 800, 805 (3d Cir. 1998). Lack of control over one's mark "creates the potential for damage to . . . reputation[, which] constitutes irreparable injury for the purpose of granting a preliminary injunction in a trademark case." Opticians Ass'n of Am. v. Indep. Opticians of Am., 920 F.2d 187, 196 (3d Cir. 1990). Thus, "trademark infringement amounts to irreparable injury as a matter of law." S & R Corp. v. Jiffy Lube Int'l, Inc., 968 F.2d 371, 378 (3d Cir. 1992); see also Times Mirror Magazines, Inc. v. Las Vegas Sports News, L.L.C., 212 F.3d 157, 169 (3d Cir. 2000) ("potential damage to . . . reputation or goodwill or likely confusion between parties' marks" is irreparable injury). "[O]nce the likelihood of confusion caused by trademark infringement has been established, the inescapable conclusion is that there was

also irreparable injury." Pappan, 143 F.3d at 805.

The district court's erroneous holding that Kos had not proven that it was likely to succeed on its trademark claims deprived Kos of the benefit of this rule. As we have already found that Kos has shown a likelihood of success, we hold it is entitled to a presumption that it will suffer irreparable harm absent an injunction.

We see nothing in the record that could overcome this presumption. Although we need not defer to the district court's holding since it was premised on an error of law, we have considered whether the length of time Advicor was marketed weakens Kos's showing of irreparable harm. We conclude that it does not. First, the district court's view that the relatively short time Advicor was on the market shows that Kos had not generated sufficient goodwill to suffer irreparable harm seems inconsistent with its holding that -- over the same time period -- Kos developed a "high level of commercial strength" based on sales grossing more than $ 70 million on more than 350,000 prescriptions. JA at 9. Second, we do not agree that a company's goodwill is less likely to be irreparably harmed if it has used its mark for only a short time. Indeed, it could be argued that irreparable harm is more likely where a "young" mark, rather than an old and well-established mark, is infringed. Most importantly, however, a company's right to control its own mark so it can avoid potential damage to its goodwill or possible confusion does not depend on the length of time it has been using that mark.

Nor can we accept Andrx's argument that Kos's delay -- filing suit after Altocor had been on the market for 13 months -- shows that Kos is not being irreparably harmed.[21] The claim that this delay bars preliminary relief is not consistent with the law of this Circuit or the facts of this case. The Third Circuit case Andrx cites for the proposition that "delay alone defeats Kos' assertions of irreparable harm" -- indeed, the only Third Circuit case Andrx relies on for this argument -- does not support its claim. Appellees' Br. at 32 (citing Times Mirror, 212 F.3d at 161). In that case, we considered -- and rejected -- the argument that a 15-month filing delay showed plaintiff's injury was "not immediate and irreparable," finding the argument unpersuasive since the "delay was

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[21] Andrx's other argument -- that Kos will suffer no irreparable harm because prescriptions will not be mis-filled, and, even if they are, there will be no "dire" medical consequences -- is clearly disposed of by our earlier holding that the Lanham Act covers likelihood of confusion of all types, and not just the likelihood that one product will be mistakenly substituted for another. Kos's loss of control over its mark is irreparable harm regardless of whether resulting confusion might lead to further injuries. Cf. Jiffy Lube, 968 F.2d at 378 (irrelevant whether "infringer is putting the mark to better use").

attributable to negotiations between the parties." Times Mirror, 212 F.3d at 169.

While Times Mirror may imply that inexcusable delay could defeat the presumption of irreparable harm in an appropriate case, it makes clear that the present case is not an appropriate one. Kos sought relief directly and through administrative proceedings from the time it learned of the proposed use of the ALTOCOR mark through the time it filed this suit. Andrx's conduct -- submitting alternate names to the FDA and the PTO, and stating in its 2002 Annual Report that Kos had opposed its application to register ALTOCOR and, in the next sentence, that it might "seek to change the name of Altocor," JA at 374[22] -- could reasonably be understood as a suggestion by Andrx that the matter might be resolved absent a lawsuit. Under these circumstances, no reasonable factfinder could find that Kos had waived its rights or conceded that it was not irreparably harmed by filing when it did.

Accordingly, we find that, given the undisputed facts of record, this factor weighs in favor of injunctive relief as a matter of law.

V. BALANCE OF HARDSHIPS

The district court held that "granting relief will result in greater harm to" Andrx than Kos would suffer absent an injunction. JA at 12. The court found that an injunction would "significantly affect" the "considerable time and expense" Andrx had spent "developing the market for [its] drug." Id. The court rejected Kos's argument that the harm to Andrx would be minimal since Andrx could continue to market its successful product, albeit under a different, non-infringing name. This claim failed, according to the district court, because "there is no trademark infringement." Id. We cannot base our analysis on, or defer to, the district court's balancing of the equities because that analysis is premised on holdings we have already found clearly erroneous, namely, that Kos has shown neither trademark infringement nor irreparable harm.

The question is whether, and to what "extent[,] . . . the defendants will suffer irreparable harm if the preliminary injunction is issued." Opticians, 920 F.2d

[22] At argument, Andrx's counsel represented that Andrx applied for alternate names "to be used only if" at least four incidents of actual confusion between Altocor and a third, unrelated drug were reported the first year Altocor was sold. Audio Tape of Oral Argument before Court of Appeals for the Third Circuit (Mar. 9, 2004) (on file with Court) (emphasis added). Andrx points to no record evidence that shows that possible confusion with a drug other than Advicor was its only concern in considering a name change, and this representation seems inconsistent with the juxtaposition of the Kos Opposition and the possible name change in the same paragraph of the 2002 Annual Report, with no mention of any other basis for the name change.

at 192. If temporary relief would irreparably harm an alleged infringer pending final disposition of the case, the court should "balanc[e] the hardships" to "ensure that the issuance of an injunction would not harm the infringer more than a denial would harm the mark's owner." Id. at 197. "Irreparable harm must be of a peculiar nature, so that compensation in money alone cannot atone for it." Pappan, 143 F.3d at 805 (quotation omitted). District courts should consider financial damages when establishing and setting the bond for an injunction, not when deciding whether to grant it. See Fed. R. Civ. P. 65(c) ("No . . . preliminary injunction shall issue except upon the giving of security by the applicant, in such sum as the court deems proper, for the payment of such costs and damages as may be incurred . . . by any party who is found to have been wrongfully enjoined.").

Andrx states that "if required to rename the product, [it will] incur significant time and expense in obtaining trademark clearance services, changing the labeling and product inserts, product re-launch advertising and the re-establishment of goodwill," and perhaps in "destroying inventory or recalling the products already distributed." Appellees' Br. at 35. Such costs, however, are compensable by money damages and thus do not constitute irreparable harm as a matter of law. "Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough." Sampson v. Murray, 415 U.S. 61, 90 (1974) (quoting Virginia Petroleum Jobbers Ass'n v. FPC, 259 F.2d 921, 925 (D.C. Cir. 1958)). The costs in time and money associated with adopting a new mark are not "injuries . . . that could not be remedied by money damages." Pappan, 143 F.3d at 805-6 ("significant financial injuries," including costs of replacing "several months worth of logoed product," do not constitute irreparable harm).

Andrx also argues that an injunction would "destroy the market" it has developed and would cause it to lose the goodwill associated with the ALTOCOR mark. Appellees' Br. at 34. Kos responds that this harm would be minimal since Andrx already has an alternate mark already in place. Appellant's Br. at 34. Although Andrx denies that it has an approved alternate name available,[23] its vague, unsubstantiated representation that the FDA approval is no longer valid cannot create a factual dispute in the face of record evidence that the FDA approved its use of the ALTOPREV mark and the judicially noticeable fact that the PTO has

[23] Nor is it clear that the alleged expiration of FDA approval would weigh in Andrx's favor. Even on Andrx's account, the lapse of approval is the consequence of Andrx's own actions in that approval supposedly expired "when we didn't use the name." See Audio Tape of Oral Argument before Court of Appeals for the Third Circuit (Mar. 9, 2004) (on file with Court). Moreover, Andrx has never alleged that there would be any barrier to its seeking reapproval of the mark if it has indeed elapsed.

issued a Notice of Allowance for this mark.[24]

Injury to goodwill does constitute irreparable harm. See, e.g., Opticians, 920 F.2d at 195. But, when the potential harm to each party is weighed, a party "can hardly claim to be harmed [where] it brought any and all difficulties occasioned by the issuance of an injunction upon itself." Id. at 197 (directing entry of preliminary injunction). We have often recognized that "the injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought that injury upon itself." Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578, 596 (3d Cir. 2002). Indeed, a different rule would allow "a knowing infringer [that] construct[s] its business around its infringement" to avoid an injunction by claiming it would have a "devastating effect" on that business, "a result we cannot condone." Apple Computer, Inc. v. Franklin Computer Corp., 714 F.2d 1240, 1255 (3d Cir. 1983). Andrx knew before its drug was first sold that Kos viewed ALTOCOR and ADVICOR as confusingly similar when used to identify competing prescription drugs for patients with high cholesterol. Andrx took a deliberate risk by proceeding despite being warned that its mark was dangerously close to that of a competing product, and is thus "not in position to urge its original blamelessness as a consideration which should be persuasive to a court of equity." Telechron, 198 F.2d at 908; see also Novartis, 290 F.3d at 596.

One other factor we have held weighs in the balance of hardships analysis is the "goal[] of the preliminary injunction analysis [of] maintain[ing] the status quo, defined as the last peaceable, noncontested status of the parties." Opticians, 920 F.2d at 197 (directing entry of injunction where such relief would restore status quo since defendant could not use mark "[b]efore this controversy began") (citation and quotation omitted). This factor favors Kos since it objected to Andrx's adoption of the ALTOCOR mark before Andrx had begun to use it in commerce.

We recently rejected an argument -- similar to one Andrx makes here -- that the harm a defendant would suffer if enjoined from selling its product under its current name "outweigh[ed] the potential harm to [its competitor] from losing market share if the injunction were not issued." Novartis, 290 F.3d at 596 (affirming preliminary injunction in false advertising case). We emphasized that the injunction did "not require [defendant] to abandon its product name forever[, but] only [to] cease shipping the [] product under that name until the end of the litigation on the merits." Id. at 597. The same is true here. We also stated that the defendant could still "ship[] the product currently in

[24] Our review of the record and the parties' arguments convinces us that the facts relevant to balancing the hardships are undisputed. Cf. Opticians, 920 F.2d at 197 (conducting own assessment of the balance of hardships where facts were not in dispute).

inventory under a different name [and] label" or ship that product without any such change if it were to prevail on the merits. Id. Again, the same is true here.[25] We note that Kos may be in an even stronger position than was the plaintiff in Novartis. The false advertising claim in Novartis was not based on any confusing similarity between the plaintiff's and defendant's marks; thus, the plaintiff there -- unlike Kos -- was not threatened with a likelihood of confusion or with loss of control over its own mark, which can lead to loss of reputation, loss of trade, and loss of goodwill. See Opticians, 920 F.2d at 195.

We have recognized that "[t]he more likely the plaintiff is to win, the less heavily need the balance of harms weigh in his favor." Novartis, 290 F.3d at 597. In light of Kos's strong showing of its likelihood of success, and the fact that Andrx accepted the risk of injury to its goodwill when it ignored Kos's claim of infringement, we hold that no reasonable factfinder could conclude that the irreparable harm Andrx might suffer pending resolution of this matter on the merits outweighs the irreparable harm that Kos would continue to suffer absent an injunction. Cf. Tenafly Eruv Ass'n, Inc. v. Borough of Tenafly, 309 F.3d 144, 178 (3d Cir. 2002) (assessing balance of hardships based on own "review of the record") (reversing and directing entry of injunction); Meridian Mutual Ins. Co. v. Meridian Insurance Group, Inc., 128 F.3d 1111, 1121 (7th Cir. 1997) ("Our examination of the record shows that . . . the harm to the plaintiff if no injunction is issued therefore outweighs any harm to the defendants if one is entered.") (reversing and directing entry of injunction); Jiffy Lube, 968 F.2d at 379 (balancing harms in first instance and holding that "self-inflicted harm" to alleged infringer "is far outweighed by the immeasurable damage done [plaintiff] by the infringement of its trademark," despite "sympathetic position" of defendant who would have to change name under which it was operating its business) (reversing and directing entry of injunction); Opticians, 920 F.2d at 197 (finding on undisputed facts that "grant of an injunction would impose no greater harm on [defendant] than would be imposed upon the [plaintiff] by the denial of an injunction") (reversing and directing entry of injunction).

Accordingly, we find that this factor weighs in favor of injunctive relief as a matter of law.

VI. PUBLIC INTEREST

The district court held that the "public interest does not favor" injunctive relief because Kos "failed to persuade [it] . . . that the public is at a serious health risk if this Court does not grant a

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[25] We note that the graphic Andrx submitted of its product does not show the ALTOCOR mark on the pills themselves. See Appellees' Br. at 28. Cf. Opticians, 920 F.2d at 197 (noting that defendant could continue to sell its product since the challenged mark was not placed on the "primary trade product" but on "promotional material").

permanent [sic] injunction." JA at 12.

Kos claims that the public interest "demands entry of a preliminary injunction" here because "[n]o public interest is greater than the public interest to preserve lives." Appellant's Br. at 35. Andrx responds that Kos's "self-serving, inflammatory rhetoric" is belied by the "neutral" conclusion of the FDA that it is unlikely that a patient will receive the wrong prescription. Appellees' Br. at 37. Andrx also argues that the public would be harmed by an injunction because those patients who depend on Altocor would be "deprive[d] . . . of a drug product that has been incorporated into their daily routine," and would suffer "unnecessary worry and anxiety when their prescriptions cannot be refilled and their doctors need to start them on a new drug regimen." Id. at 38.

These are not your usual Lanham Act public interest arguments. Indeed, neither the district court nor the parties even mentions the most basic public interest at stake in all Lanham Act cases: the interest in prevention of confusion, particularly as it affects the public interest in truth and accuracy. We have often recognized that "[p]ublic interest . . . in a trademark case . . . is most often a synonym for the right of the public not to be deceived or confused." Pappan, 143 F.3d at 807 (quoting Opticians, 920 F.2d at 197).

In light of our holding that "there is a likelihood of consumer confusion created by" the use of confusingly similar marks, "it follows that if such use continues, the public interest would be damaged. Conversely, a prohibition upon [defendant's] use of [its] mark[] would eliminate that confusion." Opticians, 920 F.2d at 198. Ordinarily, this might be the extent of the relevant analysis. Weighing the public interest in preliminary relief is often fairly routine. See American Tel. & Tel. Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1427 n.8 (3d Cir. 1994) ("As a practical matter, if a plaintiff demonstrates both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interest will favor the plaintiff.").

Here, however, we must confront the question whether the parties' claims as to specific harms to the public change the usual calculus.

We first consider Kos's claim that the interest in "preserv[ing] lives" requires injunctive relief. There is a factual dispute as to this issue. The parties submitted competing medical affidavits to support their respective views as to the nature and severity of the potential consequences of a mis-filled prescription.[26] Andrx also

[26] We note that the affidavit Andrx submitted focused on the potential harm of substituting Altocor for Advicor, while the more serious harms Kos identified are those that may occur in the reverse case, that is, when Advicor is substituted for Altocor. See supra p. 6. Although the Andrx affidavit cannot create a factual dispute as to the type of substitution it does not address, we hesitate to draw conclusions from the "undisputed" fact that serious harm may

disputed Kos's allegations as to the risks of misdispensing by arguing it is extremely unlikely that a pharmacist would improperly fill a prescription. The district court resolved this dispute in Andrx's favor, holding that Kos had not proven that the public would face a serious health risk absent an injunction. The colloquy at the hearing shows that the court was impressed by the FDA's statement that the "possibility of confusion was minimal," and was persuaded that "it would be difficult to imagine a situation" where the drugs would be confused "when a pharmacist is filling a prescription." JA at 25, 51. We note that, although the FDA's inquiry is not equivalent to the Lanham Act "likelihood of confusion" test, its review of proprietary drug names is relevant in assessing the health risks of mis-filled prescriptions. Indeed, the purpose of FDA review is "to predict potential confusion that may arise in the actual prescription process." 3 McCarthy, supra, § 19:149 (4th ed. 2003). We defer to the district court's resolution of this factual dispute because its finding is supported by the record and is thus not clearly erroneous.[27]

We must, however, distinguish between the court's finding that Kos did not establish a "serious health risk" and its conclusion that "[t]herefore, the public interest does not favor" injunctive relief. JA at 12 (emphasis added). While we defer to the former, the court's ultimate assessment of the public interest is clearly erroneous because it does not take into account the "right of the public not to be deceived or confused." Opticians, 920 F.2d at 197. As stated above, that right is implicated here.

The remaining question is whether this public interest is outweighed by the potential public harm of "depriv[ing]" patients of Altocor. Appellees' Br. at 38. Andrx claims that an injunction would mean that Altocor "prescriptions [could] not be refilled and . . . doctors [would] need to start [patients] on a new drug regimen." Id. The factual predicate for this claim seems to be the Declaration of Charles Schneider, which states that "[i]f Andrx is forced to suspend sales of ALTOCOR, [it] will suffer great economic harm by losing sales of an existing product and by a loss of good will with its

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result from substituting Advicor for Altocor. The most serious risks Kos identifies were mentioned for the first time in the affidavit Kos submitted at the hearing. See JA at 28-29. Since the district court ruled from the bench, Andrx had no chance to respond to these new claims and cannot be said to have conceded them.

[27] We do not suggest that the district court or the FDA (or, for that matter, this Court) is careless or insensitive to the potentially serious health risks of mis-filled prescriptions. Nonetheless, the recognition that the stakes are high does not mean that disputed claims about the possibility for such harm must be credited.

customers due to an interruption in the supply of an existing product." JA at 343.

Andrx's broad claims that it would have to "suspend" sales and "deprive" patients of Altocor ignore the fact that it is only the ALTOCOR mark and not the drug itself that an injunction should address. Andrx has provided no evidence to show that temporarily ceasing use of the ALTOCOR mark would cause "an interruption in the supply" of its extended-release lovastatin product. The record is bare of information as to how long it would take Andrx to provide new labels or label information for pharmacies to use when dispensing the drugs, to replace branded samples in physician's offices, to re-package its existing product as needed for pharmacies, or to take other necessary steps to suspend use of the mark ALTOCOR. Andrx has thus introduced no evidence from which a reasonable factfinder could find that the public would be harmed by the proposed injunction.

Accordingly, we find that this factor weighs in favor of injunctive relief as a matter of law.

VII.

In light of the foregoing analysis, we conclude that the district court clearly erred in denying Kos's motion for a preliminary injunction. We therefore reverse and remand with instructions that the district court fashion and enter, on an expedited basis, an order preliminarily enjoining Andrx from using the ALTOCOR mark in connection with the marketing and sale of its extended-release lovastatin medication.[28]

[28] We note that the district court will be setting such bond as it determines to be appropriate to secure payment to Andrx of any compensable money damages that it may incur prior to final disposition of this matter should it be determined that Andrx was erroneously enjoined. In determining the amount of such bond, the district court should, of course, take into account Andrx's ability to minimize the potential for such damages. See supra p. 61. To that end, the court may wish to shape the preliminary injunction, or set its effective date, to allow Andrx to take reasonable, expeditious steps to begin marketing its product under another name.