

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

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MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

AMYLIN PHARMACEUTICALS, INC.,

Plaintiff - Appellant,

v.

ELI LILLY AND COMPANY,

Defendant - Appellee.

No. 11-55939

D.C. No. 3:11-cv-01061-JLS-NLS

MEMORANDUM*

Appeal from the United States District Court
for the Southern District of California
Janis L. Sammartino, District Judge, Presiding

Argued and Submitted October 11, 2011
Pasadena, California

Before: FERNANDEZ and CALLAHAN, Circuit Judges, and TIMLIN, Senior
District Judge.**

In 2002, Plaintiff-Appellant Amylin Pharmaceuticals, Inc. (“Amylin”),
formed an alliance with Defendant-Appellee Eli Lilly and Co. (“Lilly”) to jointly
market Amylin’s diabetes drug, exenatide. In 2005, Amylin received approval
from the FDA to market exenatide as Byetta, and Amylin and Lilly began

* This disposition is not appropriate for publication and is not precedent
except as provided by 9th Cir. R. 36-3.

promoting Byetta pursuant to their agreement. In 2011, Lilly announced that it was entering into another alliance with Boehringer Ingelheim GmbH (“BI”), to market BI’s diabetes drug, Tradjenta. Amylin demanded that Lilly use a separate sales force to market Tradjenta rather than the sales force that was privy to years of Amylin’s confidential marketing strategies and materials. Lilly refused. Amylin sued, requesting the district court enter a temporary restraining order (“TRO”) and preliminary injunction. The district court initially granted the TRO, but after briefing and a hearing, vacated the TRO and denied the injunction. The district court held that Amylin had not shown a likelihood of irreparable harm absent the injunction. Amylin has appealed.

A district court’s decision denying preliminary injunctive relief is subject to limited review. *Harris v. Bd. of Supervisors, Los Angeles Cnty.*, 366 F.3d 754, 760 (9th Cir. 2004) (review “limited and deferential”). We may reverse only if the district court abused its discretion or based its decision on an erroneous legal standard or on clearly erroneous findings of fact. *FTC v. Enforma Natural Prods.*, 362 F.3d 1204, 1211-12 (9th Cir. 2004). A district court’s conclusions of law are reviewed de novo. *Husain v. Olympic Airways*, 316 F.3d 829, 835 (9th Cir. 2002), *aff’d* 540 U.S. 644 (2004).

We recently clarified our “two-part test used to determine whether a district court has abused its discretion. First, we ‘determine de novo whether the trial court identified the correct legal rule to apply to the relief requested.’” *Cal. Pharmacists Ass’n v. Maxwell-Jolly*, 596 F.3d 1098, 1104 (9th Cir. 2010), *cert. granted in part on other grounds by Maxwell-Jolly v. Cal. Pharmacists Ass’n, Inc.*, 131 S. Ct. 992 (2011), (quoting *United States v. Hinkson*, 585 F.3d 1247, 1262 (9th Cir. 2009) (en banc)). Second, if the district court got the law right, we then “determine whether the trial court’s application of the correct legal standard was (1) ‘illogical,’ (2) ‘implausible,’ or (3) without ‘support in inferences that may be drawn from the facts in the record.’” *Hinkson*, 585 F.3d at 1262 (quoting *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 577 (1985)).

Here, the district court got the law right. It identified the correct legal rule in its TRO and expressly incorporated that standard in its order denying the preliminary injunction. Specifically, the district court, citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008), held that “[a] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.”

The district court correctly noted that all four factors of this four-factor test must be satisfied.

The remaining question is whether the district court's application of this four-factor test was "illogical," "implausible," or without "support in inferences that may be drawn from the facts in the record." *Hinkson*, 585 F.3d at 1262. We determine that the district court's application of the test was sound.

Amylin claims that it will lose sales to Tradjenta due to Lilly's representatives possessing Amylin's sales strategies for Byetta. Even assuming this is true, however, lost profits due to lost sales generally constitutes the type of harm that is fully compensable through money damages and therefore does not support injunctive relief. *Maxwell-Jolly*, 563 F.3d at 851. Amylin, as the party seeking injunctive relief, has the burden of making a "clear showing" that it is entitled to injunctive relief, which includes demonstrating a likelihood of irreparable harm. *Winter*, 555 U.S. at 22.

Lilly presented expert testimony and opinion that any damages Amylin might experience in the form of lost sales or lost customers could be calculated through the use of commonly-used, standard economic analyses. Amylin did not proffer any evidence that seriously refutes Lilly's expert's conclusion. Lilly's expert's qualifications and experience are unchallenged, and the expert declares

that he has wide experience calculating these types of damages in similar cases.

The district court did not abuse its discretion in relying on the expert's conclusion.

Amylin also argues that the loss of goodwill and customers it will suffer constitutes irreparable harm sufficient to justify injunctive relief. Loss of goodwill is an injury that can be considered irreparable, and thus may support injunctive relief. *See, e.g., Stuhlberg Int'l Sales Co., Inc. v. John D. Brush & Co., Inc.*, 240 F.3d 832, 841 (9th Cir. 2001) ("Evidence of threatened loss of prospective customers or goodwill certainly supports a finding of the possibility of irreparable harm."); *see also Rent-A-Center, Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991) (same).

The district court found that Amylin's claim that it would lose goodwill was speculative. Amylin supports its claim primarily with the declarations of its own President, Vice President and Senior Marketing Director. Amylin alleges that Lilly will "falsely describ[e] the nature, characteristics and attributes of exenatide," and that "[t]hese false descriptions will irreparably harm Amylin's reputation, sales and goodwill." However, FDA regulations prohibit such false descriptions, and as the district court noted, "Amylin has offered no concrete evidence that Lilly's sales representatives would risk FDA sanctions to maximize the sales of Tradjenta."

Amylin also contends that Lilly will no longer vigorously promote Byetta in favor of Tradjenta. However, Amylin offered only the unsubstantiated declaration of its Vice President to support this claim. Lilly has a 50% interest in the sales of each medication. Amylin has not established any motive Lilly's sales representative might have to favor Tradjenta over Byetta. Given the conflicting evidence, the district court concluded it could not find "that Amylin is likely to lose prospective customers and goodwill simply because Lilly's sales representatives will sell Byetta and Tradjenta from the 'same bag.'" This finding is not clearly erroneous.

Amylin also argues that the loss of sales of its yet-to-be-released drug Bydureon also establishes irreparable injury. Amylin alleges these damages would be difficult, if not impossible, to calculate because, unlike Byetta, there is no established sales history for Bydureon. To support injunctive relief, harm must not only be irreparable, it must be imminent; establishing a threat of irreparable harm in the indefinite future is not enough. Rather, "a plaintiff must *demonstrate* immediate threatened injury as a prerequisite to preliminary injunctive relief." *Caribbean Marine Servs. Co., Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988) (emphasis original).

Amylin admits that Bydureon has not yet been approved by the FDA, and asserts that it *expects* that Bydureon will be approved sometime within the next year. Because Amylin's injury regarding Bydureon sales is not imminent, but rather may occur at some indefinite time in the future, the injury does not support injunctive relief.

In sum, the district court identified the correct legal rule to apply in this preliminary injunction case, and its application of the facts to the rule was not "illogical," "implausible," or without "support in inferences that may be drawn from the facts in the record." *Hinkson*, 585 F.3d at 1262. Amylin failed to show that the alleged loss of sales would be irreparable, or that the alleged harm to marketing Bydureon is imminent. Because Amylin has failed to carry its burden of showing a likelihood of irreparable harm, we need not address the remaining factors necessary for injunctive relief. The district court's denial of preliminary injunctive relief is **AFFIRMED**.