United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICALS U.S.A., INC.,
Plaintiff-Appellant

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellee

2020-1407, 2020-1417

Appeals from the United States District Court for the District of Delaware in No. 1:19-cv-02216-RGA, Judge Richard G. Andrews.

Decided: July 31, 2020

PORTER F. FLEMING, Haug Partners LLP, New York, NY, argued for plaintiff-appellant. Also represented by EDGAR HAUG, JONATHAN HERSTOFF, CAMILLE YVETTE TURNER.

MICHAEL S. SOMMER, Wilson, Sonsini, Goodrich & Rosati, PC, New York, NY, argued for defendant-appellee. Also represented by JESSICA MARGOLIS, SHERYL SHAPIRO BASSIN, STU A. WILLIAMS; SHYAMKRISHNA PALAIYANUR, Perkins Coie LLP, Austin, TX.

CHARLES B. KLEIN, Winston & Strawn LLP,

Washington, DC, for amici curiae Hikma Pharmaceuticals International Limited, Hikma Pharmaceuticals USA, Inc. Also represented by DAN HOANG, Chicago, IL.

Before PROST, *Chief Judge*, NEWMAN and HUGHES, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* PROST.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

PROST, *Chief Judge*.

Takeda Pharmaceuticals U.S.A., Inc. appeals the decision of the United States District Court for the District of Delaware denying a preliminary injunction based on the court's conclusion that Takeda failed to show that it was likely to succeed on the merits or that it would be irreparably harmed absent a preliminary injunction. For the reasons described below, we affirm.

I. BACKGROUND

A

In 2016, Takeda sued Mylan Pharmaceuticals Inc. for patent infringement based on Mylan's recently submitted Abbreviated New Drug Application ("ANDA") for a generic version of Takeda's Colcrys® product, which is a branded version of the drug colchicine. Takeda alleged that Mylan infringed seventeen patents listed in the Food and Drug Administration's Orange Book as covering Colcrys® ("Licensed Patents"). *See Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 1:16-cv-987-RGA (D. Del.). The parties ultimately resolved the litigation through a Settlement

Agreement and License Agreement, effective November 7, 2017 ("License Agreement").[1]

The License Agreement allows Mylan to sell a generic colchicine product on a specified date, or in the event of certain circumstances defined in Section 1.2, on an earlier date. Relevant to this appeal, Section 1.2(d) of the License Agreement defines one such circumstance, providing that Mylan is entitled to launch a generic product on:

> The date that is [a specified time period] after the date of a Final Court Decision (as defined in Exhibit A) holding that all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable[.]

J.A. 88. Exhibit A defines a "Final Court Decision" as "the entry by a federal court of a final judgment from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) had been or can be taken." J.A. 102. The "Licensed Patents" include the seventeen Colcrys® Orange-Book listed patents that Takeda asserted against Mylan. J.A. 103. A "Third Party" is broadly defined as a "Person other than a Party or an Affiliate of a Party." J.A. 105.

According to Section 1.10 of the License Agreement, if Mylan breaches Section 1.2, the parties stipulate that such breach "would cause Takeda irreparable harm." J.A. 94. Section 5 of the License Agreement further provides that

---

[1] Takeda entered a similar settlement and license agreement with Alkem Laboratories Limited based on Alkem's ANDA for its generic Colcrys® product. That agreement is the subject of a separate appeal, which is resolved in a concurrently issued opinion. *See Takeda Pharm. U.S.A., Inc. v. Alkem Labs. Ltd.*, No. 20-1545 (Fed. Cir.).

the agreement "shall be governed and interpreted in accordance with the laws of the State of Delaware." J.A. 97.

B

Concurrent with its litigation against Mylan, Takeda also pursued patent infringement claims against Hikma Americas Inc. and Hikma Pharmaceuticals PLC (collectively "Hikma") based on Hikma's colchicine product Mitigare®. *See Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 1:14-cv-1268-RGA-SRF (D. Del.) ("West-Ward Litigation"). Unlike Mylan's generic product, but like Takeda's branded Colcrys®, Hikma received approval to market Mitigare® through a § 505(b)(2) New Drug Application. Both Colcrys® and Mitigare® are 0.6 mg colchicine products that are administered orally, and both are indicated for the prevention of gout. *Compare* J.A. 719, *with* J.A. 763.

Initially, Takeda asserted eight of the Licensed Patents against Hikma in the West-Ward Litigation. But after the parties voluntarily dismissed with prejudice five of those patents according to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), only three patents remained at issue in the case. Ultimately, in December 2018, the district court granted summary judgment in favor of Hikma, holding that Hikma did not infringe any asserted claim of the three remaining Licensed Patents. *See Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-1268-RGA-SRF, 2018 WL 6521922 (D. Del. Dec. 12, 2018). The court entered its final judgment of noninfringement the same day. Takeda did not appeal.

C

In October 2019, Mylan notified Takeda that it planned to "immediately start selling" a generic colchicine product pursuant to Section 1.2(d) of the License Agreement. J.A. 786. Mylan asserted that the provision had been triggered by a "judgment of noninfringement in favor of West

Ward Pharmaceutical Corp. et al.," which "Takeda did not appeal." *Id.* On November 5, 2019, Takeda responded with a letter, which declined to indicate whether Takeda would pursue legal action against Mylan prior to breach of the License Agreement. *See* J.A. 794. Mylan subsequently launched its generic Colcrys® product on or about November 25, 2019.

Shortly after Mylan launched its product, on December 2, 2019, Takeda filed a complaint in the United States District Court for the District of Delaware, alleging breach of contract and patent infringement. Several days later, Takeda filed a motion for preliminary injunction, seeking to enjoin Mylan from commercially manufacturing, offering to sell, or selling its generic colchicine product within the United States. To avoid an additional emergency motion for a temporary restraining order, the parties stipulated that pending the district court's resolution of Takeda's request for a preliminary injunction, Mylan would suspend further sales and distribution of its generic Colcrys® product.

After full briefing and oral argument, the district court issued an order denying Takeda's motion for preliminary injunction. *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 19-2216-RGA, 2020 WL 419488 (D. Del. Jan. 27, 2020) ("*Order*"). The district court held that Takeda "failed to show it is likely to succeed on the merits or that it will suffer irreparable harm." *Id.* at *1.

With respect to Takeda's likelihood of success on the merits, the district court agreed with Mylan that Section 1.2(d) was triggered by the West-Ward Litigation, and therefore that the License Agreement permits Mylan to launch its generic colchicine product. *Id.* at *2. The court explained that according to Section 1.2(d), the West-Ward Litigation had resulted in a "Final Court Decision" that found all asserted claims of the three patents at issue "not infringed." *Id.* The court rejected Takeda's argument that

Section 1.2(d) was not triggered because "the district court had only ruled on the three patents that were still at issue, and not the other five that Takeda had dismissed with prejudice." *Id.* Looking to the language of Section 1.2(d), the court stated that the License Agreement applies to patent claims that were "asserted *and* adjudicated," not to patent claims that were "asserted *or* adjudicated." *Id.* (emphases in original). Thus, according to the district court, only the unexpired claims of the three patents that were asserted and resulted in a final decision bore any relevance to Section 1.2(d). *Id.* Furthermore, the district court noted that, as a practical matter, Takeda's proposed interpretation would prevent Mylan from ever relying on the clause to enter the market because Takeda could always "withdraw one patent (or one claim on one patent)," whether through gamesmanship or through the normal course of litigation, to avoid triggering Section 1.2(d). *Id.* at *3.

The district court also rejected Takeda's argument that the parties only intended for Section 1.2(d) to permit Mylan's entrance into the market upon a change in the status quo of other generic Colcrys® products, not different products like Mitigare®. *See id.* The district court disagreed because an objective, reasonable third party would not read Section 1.2(d) to be limited to generic equivalents of Colcrys® to the exclusion of § 505(b)(2) products like Mitigare®. *See id.* The district court found this to be particularly true in the context of the License Agreement, where Sections 1.2(b), (e), and (f) included express references to a "Generic Equivalent" or "Authorized Generic Products" of Colcrys®, showing the parties knew how to limit provisions of the contract to generic Colcrys® products. *Id.*

As to irreparable harm, the district court found that Takeda had not shown that it would suffer irreparable harm without a preliminary injunction. *Id.* at *3. To prove irreparable harm before the district court, Takeda primarily relied on the stipulation of irreparable harm in Section 1.10 of the License Agreement. *See id.* But because

Takeda had not demonstrated that it was likely to show that Mylan had breached the License Agreement, the district court found that Section 1.10's stipulation did not apply. Without the stipulation, the court found that "[m]oney damages would remedy any harm Takeda" would suffer as a result of Mylan launching its generic product. *Id.* Having found that Takeda is unlikely to succeed on the merits and that it would not suffer irreparable harm, the district court denied Takeda's request for a preliminary injunction. *Id.*

The district court also denied Takeda's request for a stay pending appeal but ordered that the parties maintain the "status quo" until the end of day on January 31, 2020 to give Takeda "an opportunity to seek immediate relief in the Court of Appeals." *Id.* Takeda filed its notice of appeal the same day as the court's order, and Takeda's notice was docketed with this court the following day on January 28, 2020.

Together with its notice of appeal, Takeda filed an emergency motion requesting an injunction pending appeal, and requesting an interim injunction pending the resolution of its motion. On January 29, 2020, we granted Takeda's motion for an interim injunction "to the extent the district court's order that Mylan 'maintain the status quo' shall remain in effect" pending our consideration of Takeda's request for an injunction pending appeal." Order, No. 20-1407 (Fed. Cir. Jan. 29, 2020), ECF No. 14 at 2. Following briefing by both parties, on March 23, 2020, we denied Takeda's request for an injunction pending appeal. Mylan subsequently re-launched its generic Colcrys® product.

We now consider the merits of Takeda's appeal. We have jurisdiction pursuant to 28 U.S.C. § 1292(c)(1).

II. DISCUSSION

Takeda appeals the district court's denial of its preliminary injunction request. Because we agree that Takeda is unlikely to succeed on the merits and has not shown that it will be irreparably harmed in the absence of an injunction, we affirm.

A

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). We review a district court's determination to grant or deny a preliminary injunction for abuse of discretion, and we review the court's findings of fact for clear error. *Abbott Labs. v. Andrx Pharm., Inc.,* 452 F.3d 1331, 1334 (Fed. Cir. 2006). "To the extent the court's decision is based upon an issue of law, we review that issue de novo." *Endo Pharm. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1374 (Fed. Cir. 2014).

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter*, 555 U.S. at 20; *see also Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375–76 (Fed. Cir. 2009).

B

We first consider whether the district court correctly determined that Takeda is unlikely to succeed on the merits. Because we agree with the district court that the final judgment in the West-Ward Litigation likely triggers Section 1.2(d) of the License Agreement, permitting Mylan to market its generic colchicine product, we likewise agree that Takeda is unlikely to succeed on the merits.

Contract interpretation is a question of law. *See Endo Pharm.*, 746 F.3d at 1374. Because "[g]eneral contract interpretation is not within the exclusive jurisdiction of the Federal Circuit," *Texas Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1329 (Fed. Cir. 2000), and because "[t]he interpretation of private contracts is ordinarily a question of state law," *Volt Info. Scis., Inc. v. Brd. of Trs. of Leland Stanford Junior Univ.*, 489 U.S. 468, 474 (1989), in this case, we apply Delaware law to interpret the License Agreement. Furthermore, the governing law clause of the License Agreement states that it will be governed by Delaware law. J.A. 97.

"Delaware adheres to an objective theory of contracts," and therefore the "contract's construction should be that which would be understood by an objective, reasonable third party." *Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1267 (Del. 2017) (internal citations omitted). "If a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract, or to create an ambiguity." *Id.*

On appeal, Takeda argues that the district court erred in determining that it is unlikely to succeed because the district court misinterpreted the License Agreement. Specifically, Takeda argues that the district court ignored the term "all" in Section 1.2(d), and by giving effect only to the word "adjudicated," the court "read out the requirement that Section 1.2(d) is triggered only when 'all' asserted patents are adjudicated." Appellant's Br. 22. Takeda therefore argues that the West-Ward Litigation—which did not include a holding of noninfringement, invalidity, or unenforceability for five of the Licensed Patents—does not trigger Section 1.2(d) because "not *all* the claims that were *asserted* in that case were held to be not infringed . . . by a Final Court Decision." Appellant's Br. 16 (emphases added); *see also id.* at 22–23. Takeda further argues that the district court's interpretation of the License Agreement

is counter to the parties' intent to limit Section 1.2(d) to changes in status quo with respect to generic colchicine products, which do not include Hikma's Mitigare® product at the center of the West-Ward Litigation. Appellant's Br. 19–21.

The plain language of Section 1.2(d), however, does not support Takeda's interpretation. *See Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159–60 (Del. 2010) ("When the contract is clear and unambiguous, we will give effect to the plain-meaning of the contract's terms and provisions."). Section 1.2(d) clearly states that Mylan may launch its generic colchicine product following "a Final Court Decision . . . holding that *all unexpired claims* of the Licensed Patents *that were asserted and adjudicated* against a Third Party are . . . not infringed." J.A. 88 (emphases added). Section 1.2(d) does not require, as Takeda suggests, a Final Court Decision for all claims that have merely been asserted during the course of the litigation. Instead, the plain language of the clause requires a Final Court Decision for all claims that are both asserted *and* adjudicated. *See United States v. Geiser*, 527 F.3d 288, 298-99 (3d Cir. 2008) (interpreting the word "and" in a statute to require an applicant "meet two sets of requirements" because "[t]he usual meaning of the word 'and'. . . is conjunctive" (citation omitted)).

We reject Takeda's interpretation because it would render meaningless the "adjudication" requirement in Section 1.2(d). *See Osborn*, 991 A.2d at 1159 ("We will not read a contract to render a provision or term 'meaningless or illusory.'" (citation omitted)). According to Takeda, we need only determine whether the claim was asserted to determine whether a claim must be included in the Final Court Decision required for Section 1.2(d) to apply. But as the district court recognized, reading the License Agreement in this way leads to the absurd result that Takeda could prevent Mylan from ever relying on the clause by simply asserting and then withdrawing a claim from a proceeding.

See Order at *3. We decline to allow for such gamesmanship, particularly where doing so would be contrary to the plain language of the License Agreement.

Takeda's arguments in support of its interpretation are unpersuasive. Takeda argues that reading Section 1.2(d) to require that claims are both asserted and adjudicated renders superfluous the terms "all" and "asserted," and gives effect only to the term "adjudicated" because all adjudicated claims must have been asserted. Takeda is wrong. Takeda ignores that Section 1.2(d) requires that the claims be "asserted and adjudicated *against a Third Party*." J.A. 88 (emphasis added). To be sure, not all adjudicated claims have necessarily been asserted against a third party.[2] The plain language of Section 1.2(d) thus requires that "all" claims relevant to the clause meet two conditions: namely "all" claims must be "asserted and adjudicated." A claim that was asserted but not adjudicated, or adjudicated but not asserted, is not relevant to Section 1.2(d).

Takeda additionally argues that the parties intended Section 1.2 of the License Agreement to permit Mylan to enter the market with its generic Colcrys® product either on a particular date or at an earlier date if there was a change in the status quo of either the market or the Licensed Patents. Takeda's argument fails for at least two reasons. First, and critically, the parties' "intent" to limit Mylan's market entrance under Section 1.2(d) based on changes in the generic Colcrys® market is absent from the language of the provision and would not be understood by an objective, reasonable third party. *See Exelon Generation*, 176 A.3d at 1267. Section 1.2(d) makes no mention of

---

[2] For example, as Takeda acknowledged during oral argument, claims may be adjudicated but not asserted against a Third Party through a declaratory judgment action. Oral Arg. at 10:19–56, No. 20-1407 (Fed. Cir. June 8, 2020), http://www.cafc.uscourts.gov/node/26299.

generic Colcrys® products. Nor is Section 1.2(d) otherwise limited to court proceedings related to particular types of products. Indeed, Takeda admits that Section 1.2(d) "does not expressly exclude a litigation that does not involve a generic Colcrys® product." Appellant's Br. 19. For these reasons, it would be improper to import such a limitation into the License Agreement. *See Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006) (Though "the role of a court is to effectuate the parties' intent" when interpreting a contract, in so doing, the court is "constrained by a combination of the parties' words and the plain meaning of those words.").

Second, while Takeda asks us to consider the context in which the parties entered the License Agreement, such context fails to support Takeda's interpretation. Takeda argues that the parties included Section 1.2(d) specifically to address a change in the status quo of the Licensed Patents, since other clauses, including Sections 1.2(b) and 1.2(f), were intended to address the change in status quo of the generic colchicine market. *See* Appellant's Br. 25. Takeda thus asserts that Section 1.2(d) does not include any reference to "Generic Equivalents" like Sections 1.2(b) and 1.2(f) because it serves a different purpose.[3] *See id.* Takeda's argument fails. Not only does Takeda's argument show, as the district court recognized, that the parties knew how to limit Mylan's market entry based on the

---

[3] The License Agreement defines "Generic Equivalent" to mean "a pharmaceutical product that has received FDA approval for marketing in the Territory pursuant to an ANDA approved pursuant to 21 U.S.C. § 355(G) or an application under 21 U.S.C. § 355(b)(2), each as an AB-rated generic version of the Colcrys product for which Colcrys is the Reference Listed Drug and which is covered by the Takeda NDAs, but excluding any Authorized Generic Product." J.A. 104.

product at issue, *see Order* at *3, but it also confirms that the parties did not intend to so limit Section 1.2(d). Furthermore, the West-Ward Litigation, which resulted in a change in the status quo of three Licensed Patents, is exactly a circumstance Takeda asserts Section 1.2(d) was intended to cover. Accordingly, even to the extent it is proper to allow the subjective intent of the parties to control our interpretation of the License Agreement, Takeda has not shown that the parties intended to exclude the West-Ward Litigation from Section 1.2(d).[4]

When the License Agreement is correctly construed, there can be no dispute that the final judgment in the West-Ward Litigation triggered Section 1.2(d). During the course of the West-Ward Litigation, Takeda asserted eight Licensed Patents against Hikma, a Third Party. Of the eight asserted patents, the parties agree that five Licensed Patents were not adjudicated because the parties stipulated to the voluntarily dismissal of those patents. Indeed, Takeda has repeatedly and unequivocally stated that the

---

[4] We observe that the West-Ward Litigation was pending at the time the parties entered the License Agreement. There is no question therefore that Takeda knew litigation related to the Licensed Patents may involve a product that is not a generic Colcrys® product. To the extent Takeda intended to exclude the West-Ward Litigation from the License Agreement, Takeda was free to express that intent in the agreement. We cannot rewrite the License Agreement because Takeda failed to communicate its intent. *See Exelon Generation*, 176 A.3d at 1267; *Lorillard Tobacco*, 903 A.2d at 739; *see also JFE Steel Corp. v. ICI Ams., Inc.*, 797 F.Supp. 2d 452, 469 (D. Del. 2011) ("[W]hen two sophisticated parties bargain at arm's length and enter into a contract, the presumption is even stronger that the contract's language should guide the Court's interpretation.").

five voluntarily dismissed patents were not adjudicated. Appellant's Br. 24 ("With respect to the remaining five patents, there was no adjudication at all. . . ."); Appellant's Reply Br. 7 ("[T]he claims of five of the patents that were 'asserted' in the West-Ward Litigation were never adjudicated."); *see also*, *e.g.*, Appellant's Br. 18–19, 25; Appellant's Reply Br. 1, 8–9; J.A. 3195, 3857–58.[5] The parties further agree that all unexpired claims of the remaining three Licensed Patents were adjudicated when the district

---

[5] We note that Takeda switched course at oral argument, suggesting that it had argued that the five patents voluntarily dismissed from the West-Ward Litigation were "adjudicated" according to Section 1.2(d) of the License Agreement. *See, e.g.*, Oral Arg. at 4:40–5:05. Takeda's assertions at oral argument are clearly contradicted by the record, and its new interpretation of the License Agreement is waived. *See Prism Techs. LLC v. Spring Spectrum L.P.*, 849 F.3d 1360, 1373 n.5 (Fed. Cir. 2017); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006). But even had Takeda properly preserved this argument, we would not be persuaded by it. The plain language of Section 1.2(d)—which describes a "holding" resulting from a Final Court Decision—contemplates an adjudication that is a substantive decision resolving an issue of infringement, validity, or enforceability of the Licensed Patents. Section 1.2(d) includes no suggestion that an asserted patent is adjudicated through a self-executing, voluntary dismissal according to Federal Rule of Civil Procedure 41(a)(1)(A), which does not resolve any issue on the merits. To be sure, "[a] stipulated dismissal with prejudice . . . ordinarily should not itself count as the actual adjudication of any issue." *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1373 (Fed. Cir. 2013) (quoting 18A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 4435 (2d ed. 2002)).

court entered summary judgment of noninfringement for those claims. *See* Appellant's Br. 24; Appellee's Br. 18–19. Takeda did not appeal the court's noninfringement decision. Thus, the West-Ward Litigation triggers Section 1.2(d) because all unexpired claims of the three Licensed Patents that were "asserted and adjudicated" against a Third Party were held to be not infringed in a Final Court Decision.[6]

Accordingly, we agree with the district court that Takeda is unlikely to succeed on the merits.

C

We now turn to consider whether the district court correctly determined that Takeda failed to show that it will be irreparably harmed without a preliminary injunction. As it did before the district court, Takeda primarily relies on Section 1.10 of the License Agreement to prove irreparable harm. By its terms, Section 1.10 only offers Takeda a basis

---

[6] While the parties agreed during briefing that the five voluntarily dismissed patents in the West-Ward Litigation were not "adjudicated," we recognize that amici curiae Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Ltd. ("amici"), who are not parties to the License Agreement, argue that those five patents were "adjudicated." *See generally* Brief for Hikma Pharm. USA, Inc. and Hikma Pharm. Int'l Ltd. as Amici Curiae Supporting Appellants, No. 20-1407 (Fed. Cir. Mar. 26, 2020), ECF No. 67. Amici argue that the West-Ward Litigation does not trigger Section 1.2(d) because only three of the eight "asserted and adjudicated" Licensed Patents were held to be not infringed, invalid, or unenforceable. *Id.* We are not persuaded by this argument, *see supra* § II(B) n.5, and in any case, decline to adopt an interpretation of the License Agreement that was not briefed by any party to it.

for establishing irreparable harm in the event Mylan breached Section 1.2. J.A. 94; *see also* Oral Arg. at 17:32–18:03 (Takeda's counsel agreeing that Section 1.10 is predicated on a breach in the License Agreement). Because we conclude that it is unlikely Takeda can show that Mylan breached the License Agreement, *see supra* § II(B), we further conclude that Section 1.10 is not useful for establishing irreparable harm in this case.[7]

Without the stipulation of irreparable harm, Takeda makes no credible assertion that it cannot be compensated by monetary damages. Takeda states generally that each sale by Mylan reduces the units sold by Takeda and that Mylan's sustained launch "likely will cause" Takeda to incur irreversible price erosion and long-term loss of market share. Appellant's Br. 36. Though we have recognized that price erosion and loss of market share may in some cases be irreparable injuries, *see Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013), a bare assertion of irreparable harm is never sufficient to prove such harm or justify the "extraordinary remedy" of a preliminary injunction, *see Winter*, 555 U.S. at 24.[8] *See also Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847

---

[7] Because we conclude that it is unlikely that Mylan breached the License Agreement, and therefore conclude that the stipulation of irreparable harm according to Section 1.10 is not applicable in this case, we need not consider the significance of the stipulation to the irreparable harm analysis.

[8] We recognize that Takeda cited one email showing that a single customer had switched from purchasing Par Pharmaceutical's authorized generic product to Mylan's generic product. *See* Appellant's Br. 36 (citing J.A. 809). This email, standing alone, offers no probative evidence that Takeda would be irreparably harmed and says nothing at all about Takeda's price erosion or change in market share.

F.2d 100, 102–03 (3rd Cir. 1988) ("The availability of adequate monetary damages belies a claim of irreparable injury. . . . [S]ince Frank's GMC has failed to articulate and adduce proof of actual or imminent harm which cannot otherwise be compensated by money damages, it has failed to sustain its substantial burden of showing irreparable harm"). Takeda's nonspecific and unsupported assertion that Mylan's sales "likely will cause" irreparable harm falls far short of establishing that irreparable harm has occurred, or will likely occur, absent a preliminary injunction.

Accordingly, we agree with the district court that Takeda has not shown that it would be irreparably harmed absent a preliminary injunction.

D

Because we agree with the district court that Takeda failed to show that it is likely to succeed on the merits or that it would be irreparably harmed absent a preliminary injunction, we conclude that the district court did not abuse its discretion in denying Takeda's request for a preliminary injunction.

CONCLUSION

We have considered Takeda's remaining arguments and find them unpersuasive. For the foregoing reasons, the district court's denial of Takeda's request for a preliminary injunction is affirmed.

AFFIRMED

United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICALS U.S.A., INC.,
Plaintiff-Appellant

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellee

2020-1407, 2020-1417

Appeals from the United States District Court for the District of Delaware in No. 1:19-cv-02216-RGA, Judge Richard G. Andrews.

NEWMAN, *Circuit Judge*, dissenting.

This appeal is from the district court's denial of injunctive relief, despite the explicitly agreed provision for an immediate injunction on breach of the License Agreement. I respectfully dissent, for judicial refusal to enforce settlement terms violates fundamental principles of contract law and commerce, and negates the strong public policy favoring settlement of litigation on agreed terms.

The settlement agreement provides for an immediate injunction

Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") and Mylan Pharmaceuticals Inc. ("Mylan") settled the infringement suit that arose from Mylan's Abbreviated New Drug

Application ("ANDA") for FDA approval of the generic equivalent to Takeda's Colcrys® product (colchicine 0.6 mg tablets) for treatment of gout flares and familial Mediterranean fever. Mylan states that its generic counterpart is the "AB grade" equivalent of Colcrys®.

The infringement settlement included the grant of licenses to Takeda's seventeen patents on the production, formulation, and use of colchicine, as listed in the FDA's Orange Book; the last of the Takeda patents expires in 2029. The License Agreement grants Mylan the licensed entry of its generic Colcrys® counterpart on a specified date, with provision for earlier entry on occurrence of any of several accelerating events defined in the License Agreement. The License Agreement states that breach by Mylan constitutes irreparable harm and is subject to immediate injunction. The Settlement Agreement and incorporated License Agreement were executed on November 7, 2017.

On November 25, 2019, Mylan launched its generic counterpart to Colcrys®, stating that an accelerating event had occurred. Takeda immediately filed this suit for infringement and breach of contract, and moved the district court to enter the agreed injunction. The district court granted a brief stay, and passed the issue to the Federal Circuit. We granted a brief stay, but on March 23, 2020, this court lifted the stay, although the proposed hearing had not yet occurred. Mylan then launched its generic counterpart.

We heard argument on the requested injunction on June 8, 2020, and my colleagues now hold that the accelerating event cited by Mylan had indeed occurred. I cannot agree, for the cited event relates to a different product of a different provider having a different FDA approval for different uses, and is not a generic counterpart of Colcrys®. That product (brand name Mitigare®) and the then ongoing litigation is not mentioned in the License Agreement as possibly providing an accelerating event. Mitigare® had

been FDA-approved and marketed since 2014, Takeda had been in litigation concerning Mitigare® since 2014, and this court in that litigation held in 2015 that Takeda was not likely to succeed in establishing infringement—as was duly confirmed.[1] The termination of those proceedings cannot reasonably be deemed an accelerating event for Mylan's generic Colcrys® entry.

In contrast, in the case at hand, Mylan had conceded infringement and validity, and as a condition of the settlement and the license-assured generic entry, Mylan had agreed that irreparable harm would result from breach of specified agreement provisions, and that specific enforcement is appropriate, as set forth in ¶ 1.10 of the License Agreement:

> 1.10. Specific Enforcement. Takeda shall be entitled to specific enforcement of the terms and conditions set forth in Paragraphs 1.2 and 1.4 of this License Agreement, and shall be entitled to immediate injunctive relief to prevent Mylan from marketing the Mylan ANDA product in breach of Paragraphs 1.2 and 1.4 of this License Agreement. Mylan acknowledges that marketing the Mylan ANDA Product in breach of Paragraph 1.2 of this License Agreement would cause Takeda irreparable harm.

---

[1] *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 72 F. Supp. 3d 539, 549 (D. Del. 2014) (denying preliminary injunction); *id.*, 785 F.3d 625, 630–34 (Fed. Cir. 2015) (affirming that Takeda is not likely to succeed on its infringement claim); *id.*, No. 14-1268-RGA-SRF (D. Del. June 4, 2018) (Dkt. No. 377) (dismissal with prejudice of five unadjudicated patents); *id.*, No. 14-1268-RGA-SRF, 2018 WL 6521922 (D. Del. Dec. 12, 2018) (judgment of non-infringement of three patents).

License Agreement at 8. This enforcement provision embodies the parties' agreement concerning the balance of harms. Takeda points out that if it were to turn out that the requested injunction were wrongfully granted, Mylan could be made whole by the injunction bond required by Fed. R. Civ. P. 65(c); whereas if the injunction were wrongfully denied Takeda could not be made whole from the market impact of Mylan's entry. *See Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304–05 (Fed. Cir. 2013) (price erosion and loss of market share can be irreparable injuries). Thus Takeda argues that "[t]he balance of hardships favors an injunction because it would simply maintain the status quo." Takeda Br. 37 (quoting *Temsa Ulasim Araclari Sanayi Ve Ticaret A.S. v. CH Bus Sales, LLC*, No. CV 18-698-RGA, 2018 WL 4179456, at *3 (D. Del. Aug. 31, 2018)).

Takeda points out that Mylan agreed that the Mylan ANDA Product would "infringe one or more of the claims of the Licensed Patents" and that the Licensed Patents are "valid and enforceable." License Agreement at 7 (¶ 1.8(a)). The License Agreement's provision for injunctive relief was a negotiated condition of the settlement, balancing Takeda's relinquishing of Hatch-Waxman benefits, *see* 21 U.S.C. § 355(j)(5)(B)(iii).

Delaware precedent is clear that "contractual stipulations as to irreparable harm alone suffice to establish that element for the purpose of issuing preliminary injunctive relief." *Cirrus Holding. Co. v. Cirrus Indus., Inc.*, 794 A.2d 1191, 1209 (Del. Ch. 2001). *See also TP Group-CI, Inc. v. Vetecnik*, No. CV 16-00623-RGA, 2016 WL 5864030, at *2 (D. Del. Oct. 6, 2016) (granting preliminary injunction where "Defendant agreed to 'a remedy of . . . injunctive or other relief in order to enforce or prevent any violations' of the restrictive covenants") (ellipsis in original).

This court has previously recognized that the Supreme Court has ruled that: "Irreparable harm, not adequately

compensable at law, may exist even if there is evidence that, for example, the patent owner is 'willing[] to license its patent'." *Tex. Advanced Optoelectronic Sols., Inc. v. Renesas Elecs., Am., Inc.*, 895 F.3d 1304, 1331 (Fed. Cir. 2018) (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006)) (alteration in original); *see also Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060, 1066 (Fed. Cir. 2016) (holding that because "[t]he parties stipulated that [plaintiff] will be irreparably harmed if [defendant] enters the market," the courts should "grant [] a preliminary injunction without addressing [preliminary-injunction] factors").

In refusing to enforce this agreed condition of the settlement, the court negates both judicial and public interest. *See Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988) ("The law strongly favors settlement of litigation, and there is a compelling public interest and policy in upholding and enforcing settlement agreements voluntarily entered into.").

The court also negates the public interest in upholding the integrity of contracts. *See TP Group-CI*, 2016 WL 5864030, at *3 ("The public interests at issue in this case are enforcing private contracts."). And the court departs from its role in achieving stability through judicial process.

The accelerating condition in ¶ 1.2(d) is not met by the Mitigare® litigation

The License Agreement specifies events that could accelerate the fixed date of licensed entry of Mylan's generic counterpart of Colcrys®. These events all concern other providers of generic Colcrys®, licensed and unlicensed. Mylan states that ¶ 1.2(d) authorizes the Mylan launch in November 2019:

> 1.2. Generic Entry Dates. Mylan shall be entitled to make, use, import, market, offer for sale, sell, and distribute the Mylan ANDA Product during the period beginning on the first to occur of the

> following (each, a "***Generic Entry Date***") and continuing until the expiration of the last to expire of the Licensed Patents:
>
> * * *
>
> (d) The date that is [confidential] after the date of a Final Court Decision (as defined in Exhibit A) holding that all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable.

License Agreement at 2 (confidential matter omitted) (emphasis in original).

Mylan states that the conditions of ¶ 1.2(d) were met by litigation between Takeda and West-Ward Pharmaceutical Corp. on a different colchicine product, Mitigare®. As observed *ante*, Mitigare® had been marketed since 2014, with FDA approval based on a different NDA from a different producer, for different uses than Colcrys®. It is undisputed that Mitigare® is not deemed an FDA equivalent of Colcrys®. And although Takeda had attempted to assert a few of its colchicine patents against Mitigare®, the attempt had failed. *See* n.1, *ante*.

Nonetheless, my colleagues now hold that Takeda's unsuccessful litigation against Mitigare® was an accelerating event to enable Mylan to market its generic counterpart of Colcrys®. This is not a reasonable interpretation of ¶ 1.2(d). Takeda points out that the litigation on Mitigare® had been proceeding since 2014, yet is not mentioned in the Settlement and License Agreements as an accelerating event for Mylan's generic counterpart of Colcrys®.

Courts "should be most chary about implying a contractual protection when the contract could easily have been drafted to expressly provide for it." *Oxbow Carbon &*

Minerals Holdings, Inc. v. Crestview-Oxbow Acquisition, LLC, 202 A.3d 482, 507 (Del. 2019). Takeda cannot reasonably be assumed to have intended to tie entry of the Mylan generic to the Mitigare® litigation, for rulings adverse to Takeda had occurred in 2015, before the Colcrys® litigation against Mylan had begun.

"When interpreting a contract, the role of [the] court is to effectuate the parties' intent." *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006). It is not reasonable to hold that Takeda would have agreed to the spin that my colleagues place on ¶ 1.2(d). My colleagues' interpretation of the Settlement and License Agreements to authorize Mylan's generic launch based on ¶ 1.2(d), accompanied by judicial withholding of the contracted remedy for agreed irreparable harm, are not appropriate. I respectfully dissent.