Appeal No. 2020-1545

United States Court of Appeals for the Federal Circuit

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

v.

ALKEM LABORATORIES LIMITED., ASCEND LABORATORIES LLC,
Defendants - Appellees

Appeal from the United States District Court for the District of Delaware in Civil Action No. 20-00325-RGA, Judge Richard G. Andrews

CORRECTED BRIEF FOR DEFENDANTS-APPELLEES

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April 20, 2020

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Takeda Pharmaceuticals U.S.A., Inc. **v.** Alkem Laboratories Ltd. and Ascend Laboratories, LLC

Case No. 20-1545

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ■ (appellee) ☐ (amicus) ☐ (name of party)

Alkem Laboratories Ltd.

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Alkem Laboratories Ltd.	Alkem Laboratories Ltd.	None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

Adam Wyatt Poff: Young, Conway, Stargatt & Taylor LLP
Samantha G. Wilson: Young, Conway, Stargatt & Taylor LLP

FORM 9. Certificate of Interest **Form 9**
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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharm. Inc., No. 2020-1407 and 2020-1417 (Fed. Cir.)
Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharm. Inc., No. 1:19-cv-02216-RGA (D. Del.)
Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Labs. Ltd. et al., No. 20-325-RGA (D. Del.)

3/9/2020
Date

/s/A.Neal Seth
Signature of counsel

Please Note: All questions must be answered

A. Neal Seth
Printed name of counsel

cc: Counsel of Record

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ■ (appellee) ☐ (amicus) ☐ (name of party)

Ascend Laboratories, LLC

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Ascend Laboratories, LLC	Ascend Laboratories, LLC	Alkem Laboratories Ltd.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

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/s/A.Neal Seth
Signature of counsel

Please Note: All questions must be answered

A. Neal Seth
Printed name of counsel

cc: Counsel of Record

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, Defendants-Appellees Alkem Laboratories, Ltd. and Ascend Laboratories LLC (collectively "Alkem") state that no appeal from the same trial court action was previously before this or any other appellate court. The district court proceedings that remain pending in this case, as well as those that remain pending in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals U.S.A., Inc.*, No. 1:19-CV-02216-RGA (D. Del.), and together with the consolidated appeals in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals U.S.A., Inc.*, Nos. 2020-1407, -1417 (Fed. Cir.) that this Court designated as companion cases to the instant appeal are pending in this Court and directly affect or be directly affected by the Federal Circuit's decision in this appeal. Aside from these cases, there are no other cases pending in any court or agency that will directly affect or be directly affected by the Federal Circuit's decision in this appeal.

INTRODUCTION

The district court correctly denied Takeda's motion for preliminary injunction and temporary restraining order "[f]or the reasons stated in *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.,* No. 19-cv-2216-RGA, D.I. 114 (D. Del.)." *Takeda Pharms. U.S.A., Inc. v. Alkem Laboratories, et. al.*, No. 20-cv-00325-RGA (D. Del. 2020) (the "*Alkem* Litigation"); Appx1.[1] This ruling was not an abuse of discretion. Rather, it was firmly rooted in the relevant law and amply supported by the clear and unambiguous language of the License Agreement at issue. For the reasons expressed herein, as well as those expressed by Mylan in its response brief filed in the companion *Mylan* Appeal, Alkem respectfully submits that the district court's order should be affirmed.

The underlying dispute in both cases centers around whether Alkem's launch of a generic version of Colcrys® breached the parties' License Agreement. The district court correctly concluded that Takeda was not likely to succeed on the merits in proving that Alkem was in breach because a prior litigation triggered Section 1.2(d) of the License Agreement, permitting Alkem to lawfully launch its approved generic product. The district court also correctly concluded that Takeda would not

[1] Takeda's brief on appeal advances arguments that are identical in substance to those Takeda asserts in the companion case, *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, No. 20-1407, -1417 (Fed. Cir.) (the "*Mylan* Appeal").

suffer irreparable harm because money damages would sufficiently remedy any harm Takeda may suffer.

COUNTERSTATEMENT OF THE ISSUES

1. Whether the district court abused its discretion in finding that Takeda was unlikely to succeed on the merits with respect to its argument that Alkem breached the License Agreement?

2. Whether the district court abused its discretion in finding that Takeda will not suffer irreparable harm absent entry of a preliminary injunction, and that any harm Takeda may suffer is compensable with monetary damages?

3. Whether the district court abused its discretion in denying Takeda's Motion?

COUNTERSTATEMENT OF THE CASE

Takeda first sued Alkem in District Court on February 1, 2018, alleging infringement of seventeen patents that purportedly cover Takeda's Colcrys® and that are listed in the Orange Book for Colcrys® based on Alkem's submission of ANDA No. 211250 (the "Alkem ANDA"). Appx1090. Takeda also filed similar lawsuits against various other generic colchicine ANDA applicants, including, among others, Mylan Pharmaceuticals Inc. ("Mylan"). Appx1093; *see also Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, No. 16-cv-987, 2017 WL 991449 (D. Del.). In due course, Takeda and the various generic colchicine ANDA applicants,

including Mylan, settled the lawsuits by way of Settlement and License Agreements. Appx1093. In May 2018, Takeda and Alkem also settled their litigation through a Settlement Agreement and a License Agreement (the "License Agreement"). *See* Appx69-107.

The License Agreement permits Alkem to sell a generic colchicine product on a certain specified date, or under several circumstances that the parties agreed allow for an earlier launch date. Appx83. Relevant here is Section 1.2(d) of the License Agreement. This provision states that Alkem may launch at:

> The date that is [a specified number of] days 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/or invalid, unpatentable, or unenforceable.

Id. (Appx83). 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) has been or can be taken." Appx97. "Third Party" is a "Person other than a Party or an Affiliate of a Party." Appx99.

Notably, the parties do not dispute that Section 1.2(d) in the License Agreement is nearly identical to the same provision in a license agreement entered

into between Takeda and Mylan.[2] This provision was litigated in the *Mylan* Litigation and interpreted by the District Court for the District of Delaware in *Takeda Pharms. U.S.A., Inc., v. Mylan Pharms., Inc.*, No. 19-cv-2216, 2020 WL 419488 (D. Del. Jan. 27, 2020) (the "*Mylan* Judgment"), after Mylan launched at risk and Takeda filed a complaint and a motion for preliminary injunction against Mylan that is substantially similar to the motion it filed against Alkem in the same district court.

By way of background, on October 28, 2019, Mylan notified Takeda that it planned to "immediately start selling" a generic colchicine product pursuant to Section 1.2(d) of the parties' license agreement. *Mylan* Appeal, ECF 47 pp. 9-10. Shortly thereafter, Mylan commercially launched its generic colchicine tablets. *Id.* p. 10. Takeda and Mylan subsequently reached an agreement whereby Mylan agreed to cease any further commercial sales. *See* Appx1230-1254. On December 2, 2019, Takeda filed a complaint against Mylan in the district court, alleging, among other things, breach of the parties' settlement and license agreement and, on December 5th, Takeda filed an Emergency Motion for a Preliminary Injunction. *Mylan* Appeal, ECF 47, p. 10.

[2] While the settlement and license agreements between Takeda and Mylan are confidential, it is clear from public filings that the relevant provisions of Section 1.2 are substantially equivalent to those of the Takeda-Alkem Agreement, analyzed herein.

Before the district court, as in this Court, Mylan's position is that Section l.2(d) of the license agreement was triggered by the Court's decision in *Takeda Pharms., U.S.A., Inc. v. West-Ward Pharms. Corp.*, No. 14-cv-1268, 2018 WL 6521922 (D. Del. Dec. 12, 2018) (the "*West-Ward* Judgment"). In that case, Takeda asserted eight of its patents related to Colcrys® against West-Ward, alleging patent infringement by West-Ward's drug known as Mitigare®. Like Colcrys®, Mitigare® is a 0.6 mg colchicine product. *Mylan* Appeal, ECF 47, p. 7. Moreover, the patents Takeda asserted in the *West-Ward* Litigation overlapped with those asserted in the infringement actions Takeda brought against Mylan and Alkem in district court. In the *West-Ward* Litigation, Takeda eventually dismissed five of the asserted patents with prejudice. *Mylan* Appeal, ECF 47, p. 8. The Court granted summary judgment of non-infringement on the remaining three patents, all of which were also asserted by Takeda against Mylan and Alkem and are included as "Licensed Patents" in the License Agreement. *West-Ward* Judgment at *7. Neither Takeda nor West-Ward appealed the judgment and it therefore became final. 28 U.S.C. § 2107(a). Thus, according to Mylan, the West-Ward Judgment constituted a "Final Court Decision" 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," triggering Section 1.2(d).

Takeda did not dispute that the *West-Ward* Judgment was a "Final Court Decision," but argued below, as it does here, that the decision did not trigger Section 1.2(d) because the Court only ruled on the three patents that were still at issue, and not on the other five that Takeda dismissed with prejudice. Takeda Br. pp. 26-28. Takeda also argued below and again here that the *West-Ward* decision should not trigger Section 1.2(d) because such a reading would conflict with the intent of the parties. *Id.* pp. 23-26. Apparently Takeda contends that, because Mitigare® is not a generic version of Colcrys®, the parties did not intend that a judgment involving Mitigare® could trigger Section 1.2(d).

The district court heard oral argument in the *Mylan* Appeal on January 21, 2020. Appx9. On January 27, 2020, the district court issued an order denying Takeda's motion for preliminary injunction. Appx9-15. The district court first observed that Section 1.2(d) applies to patent claims that were "asserted *and* adjudicated," not to patent claims that were "asserted *or* adjudicated." Appx4. The district court noted that, in the *West-Ward Litigation*, three of eight patents were "asserted and adjudicated." *Id.* Thus, those were the only patents that mattered for purposes of determining whether a "Final Court Decision" found them to be "either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable" pursuant to Section 1.2(d). Appx4-5. Because the other five patents were only "asserted," and not "asserted and adjudicated," they were irrelevant to the

analysis as to whether the *West-Ward* decision triggered Section 1.2(d). *Id.* The district court also expressed concern that Takeda's reading of Section 1.2(d) could lead to gamesmanship, whereby Takeda could assert all seventeen Colcrys® patents against a third party, and then simply withdraw one patent or one patent claim early in litigation and noted that it is common for asserted claims to be dropped as litigation progresses. Appx6.

Next, the district court rejected Takeda's argument that the *West-Ward* decision should not trigger Section 1.2(d) because that case did not involve a generic version of Colcrys®. Appx5-6. The district court instead found that construing Section 1.2(d) as limited to litigation over the possible introduction of generic Colcrys® products would be contrary to the plain language of the agreement. *Id.* The district court observed that Section l.2(d) makes no mention of generic Colcrys® products. By contrast, Sections 1.2(b) and 1.2(f) refer to the sale of a "Generic Equivalent" of Colcrys®, and Section 1.2(e) refers to the sale of "Authorized Generic Products" of Colcrys®. *Id.* Section 1.2(d), on the other hand, is not conditioned in such a way. The district court further noted that its interpretation of Section 1.2(d) is consistent with the definition of a "Third Party," which does not have to be another generic drug competitor. *Id.* Similarly, the definition of "Final Court Decision" is not limited to a final decision concerning generic Colcrys® and Takeda did not dispute that the *West-Ward* Judgment was a "Final Court Decision."

Appx4. For these reasons, the district court held that Takeda did not prove that it was likely to succeed on the merits because it is unlikely that Mylan breached the Takeda-Mylan Agreement.

Turning next to the irreparable harm prong of the injunction analysis, the district court determined Takeda failed to show irreparable harm because any harm it would suffer in the absence of an injunction would be fully compensable by money damages. Appx6-7. The district court rejected Takeda's argument that Section 1.10 of the License Agreement, which stipulates that a breach of the Agreement would cause irreparable harm, means that irreparable harm should be presumed. The district court reasoned that, because it is unlikely that Mylan breached the License Agreement at all, it is similarly not likely that the stipulation set forth in Section 1.10 would be effective. *Id*. Having failed to carry its burden under either of the foregoing prongs, the court denied Takeda's motion for preliminary injunction.

On March 3, 2020, Takeda filed its Complaint against Alkem in District Court, alleging that Alkem breached its License Agreement with Takeda. Appx1078-1119. On the same day, Takeda filed its Emergency Motion for a Temporary Restraining Order and a Preliminary Injunction (the "District Court Motion") seeking to enjoin Alkem from commercially manufacturing, offering to sell, or selling within the United States its generic colchicine product. Appx1160-1179. The district court ordered Alkem to respond to the District Court Motion just

one day later, on March 4, 2020, which Alkem did. Appx1054-1070. The district court ordered the parties to appear for argument in court the next day, on March 5, 2020, and, shortly after argument, the district court issued an order denying the District Court Motion for the reasons articulated by the court in *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.,* No. 19-cv-2216, ECF No. 114 (D. Del.). Appx1. The district court also ordered that Alkem maintain a "status quo" that "includes recalling the ANDA product that is represented to be currently en route to a customer, and not selling or transferring any other inventory of the ANDA product," even though Alkem never agreed to cease commercial sales unlike Mylan had in its case. *Id.*

Shortly thereafter, Takeda filed a notice of appeal and Emergency Motions for an Injunction Pending Appeal and to Expedite the Briefing Schedule. ECF Nos. 1, 2, 17. On March 23, 2020, this Court denied Takeda's Motion for an injunction pending appeal. ECF No. 33. The Motion Panel majority found that Takeda did not show that an injunction pending appeal was warranted. *Id.*, p. 2. Judge Newman dissented. *Id.*, pp. 4-6. Also, on March 23, 2020, this Court entered an expedited briefing schedule that was agreed upon by the parties. *Id.*, p. 2. On April 10, 2020, this Court designated this appeal and the *Mylan* Appeal as companion cases. ECF No. 44.

SUMMARY OF THE ARGUMENT

For the reasons that follow, Takeda has failed to prove that any of the four factors required to warrant injunctive relief are met. First, Takeda is not likely to succeed on the merits in demonstrating that Alkem breached the License Agreement because, under the clear and unambiguous language of the Agreement, the *West-Ward* Judgment triggered Section 1.2(d) thereby permitting Alkem to launch its generic Colcrys® product. Second, Takeda cannot show that it will suffer irreparable harm absent a preliminary injunction because monetary damages would suffice and, because Alkem acted in full compliance with the License Agreement, Section 1.10 of the License Agreement is not enforceable. Factors three and four also favor Alkem. Alkem will suffer hardship if precluded from product sales while being in full compliance with the terms of the License Agreement. And the public interest favors competition in the pharmaceutical market and the price reductions that generic competition facilitates.

Applying deference to the district court under the applicable abuse of discretion standard, this Court should affirm the district court's well-reasoned order denying Takeda the extraordinary relief of a preliminary injunction.

ARGUMENT

I. LEGAL STANDARDS

Injunctive relief is an extraordinary remedy and is issued cautiously and sparingly. *Weinberger v. Romero-Barcelo,* 456 U.S. 305, 312-313 (1982). Four factors must be considered when deciding whether to grant a preliminary injunction: (1) whether the movant has a strong likelihood of success on the merits; (2) whether there is a threat of irreparable harm to the movant; (3) whether others will suffer substantial harm as a result of the injunction, should it issue; and (4) whether the public interest will be served by the injunction. *Winter v. Nat'l Res. Def. Council, Inc.,* 555 U.S. 7, 20 (2008). "Although the factors are not applied mechanically, a movant must establish the existence of both of the first two factors to be entitled to a preliminary injunction." *Altana Pharma AG. v. Teva Pharms. USA Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). "An appellant carries a heavier burden when seeking to reverse the denial of a preliminary injunction than seeking to reverse the grant of a preliminary injunction." *Id.*. "The standard for obtaining a temporary restraining order is the same as the standard for a preliminary injunction." *Olde Discount Corp. v. Tupman*, 805 F. Supp. 1130, 1135 (D. Del. 1992) (citing Fed. R. Civ. P. 65(b)).

"General 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). The Supreme Court has held that "the interpretation of

private contracts is ordinarily a question of state law," in this case Delaware. *Volt Info. Scis., Inc. v. Bd. of Trs. of Leland Stanford Junior Univ*., 489 U.S. 468, 474, (1989). Furthermore, the governing law clause of the License Agreement at issue states that it is governed by Delaware law. Appx92.

A district court's determination to grant or deny a preliminary injunction is reviewed for abuse of discretion and findings of fact for clear error. *Abbott Labs. v. Andrx Pharms., Inc.,* 452 F.3d 1331, 1334 (Fed. Cir. 2006). Takeda carries a heavy burden in seeking to reverse the denial of a preliminary injunction. *New England Braiding Co., Inc. v. A.W. Chesterton Co.,* 970 F.2d 878, 882 (Fed. Cir. 1992) ("When a preliminary injunction is denied, the movant . . . must show not only that one or more of the factors relied on by the district court was clearly erroneous, but also that a denial of the preliminary relief sought would amount to an abuse of the court's discretion upon reversal of an erroneous finding."). "To the extent the court's decision is based upon an issue of law, [this Court] review[s] that issue de novo." *Sanofi–Synthelabo v. Apotex, Inc.,* 470 F.3d 1368, 1374 (Fed. Cir. 2006).

II. AS IN *MYLAN*, TAKEDA HAS NOT SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS

A. The *West-Ward* Judgment Triggered Section 1.2(d)

As the district court found, Takeda cannot show irreparable harm or a likelihood of success on the merits for the same reasons articulated by that court in the *Mylan* Litigation and summarized above. Specifically, the *West-Ward* Judgment

triggered Section 1.2(d) and therefore Alkem would not be in breach of the License Agreement. Section 1.2(d) requires (1) a ***Final Court Decision***; and (2) a holding that all unexpired claims of the Licensed Patents that were ***asserted and adjudicated*** against a Third Party are not infringed and/or invalid, unpatentable, or unenforceable. Appx83. In *West-Ward*, there were only three patents that were "asserted and adjudicated," and they were determined to be "not infringed." After the time for appeal elapsed, that judgment became final and Takeda does not dispute that the judgment in *West-Ward* is a "final judgment."

Takeda does not dispute that the five patents it withdrew from the *West-Ward* Litigation were not "adjudicated." Takeda Br. p. 28 ("In the *West-Ward* Litigation . . . only three of the eight patents were adjudicated to a holding of noninfringement."); Takeda Reply ISO Mot. for Inj. Pending Appeal (ECF No. 28-1) pp. 3, 5, 6 (repeatedly conceding that the five patents Takeda withdrew from the *West-Ward* Litigation were not adjudicated).

Despite acknowledging that the five patents it withdrew from litigation were not "adjudicated," Takeda nonetheless argues that Section 1.2(d) was not triggered because those patents were "asserted" and one point in time. Takeda apparently interprets Section 1.2(d) such that, if any claims are withdrawn from the litigation, Section 1.2(d) cannot be triggered. But the language of the contract is clear and unambiguous, requiring 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/or invalid, unpatentable, or unenforceable." Appx83 (emphasis added). In *West-Ward*, all three patents that were "asserted and adjudicated" were determined to be "not infringed," triggering Section 1.2(d).

Takeda appears to be asking this Court to change "asserted and adjudicated" to "asserted or adjudicated." Because the License Agreement is clear and unambiguous, it should not be rewritten at Takeda's whim and arising from facts related to extrinsic events transpiring years after Takeda negotiated and willingly entered into it to change "and" to "or." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159-60 (Del. 2010) (where a contract is "clear and unambiguous," courts must "give effect to the plain-meaning of the contract's terms and provisions"); *Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1267 (Del. 2017) ("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.").

Moreover, Takeda's interpretation would give it a unilateral right to avoid triggering Section 1.2(d) simply by withdrawing claims from the litigation at any point it believed its litigation positions may be weak. Parties routinely drop claims as the case progresses. District courts also occasionally order parties to narrow the asserted claims as trial approaches in order to streamline the issues for the jury.

Conversely, there may be instances when a generic could bring a declaratory judgment action, in which claims would be adjudicated but not asserted. While Takeda argues that, in certain circumstances, it would need a defendant's consent to drop patents from a litigation, Takeda offers no reason why a defendant would withhold such consent and, in any event, Takeda could unilaterally withdraw ***claims*** from the litigation at any time.

B. The District Court Correctly Rejected Takeda's Attempts to Re-Write the Language of Section 1.2(d) to Pertain Only to Litigation Concerning Generic Colcrys®

Takeda next contends that, as presently written, Section 1.2(d) does not properly reflect what it now claims is the "intent of the parties," and proposes an interpretation that would re-write the clear and unambiguous language of the contract. Takeda Br. 23-25. Takeda asks this Court to inject a requirement that the "litigation" referenced in Section 1.2(d) be a litigation concerning generic Colcrys® products, not Mitigare®. But no such requirement is warranted. Before the district court, Takeda did not dispute that the language of Section 1.2(d) is clear and unambiguous, and Takeda does not advance any such argument here. Accordingly, Section 1.2(d) "should be given its ordinary and usual meaning"; otherwise there is a risk of "creat[ing] a new contract with rights, liabilities and duties to which the parties had not assented." *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins.*

Co., 616 A.2d 1192, 1195-96 (Del. 1992) (citation omitted). In any event, Mitigare®, like Colcrys®, is a 0.6 mg colchicine product.

Moreover, as the district court observed and as noted above, Section 1.2(d) makes no mention of generic Colcrys® products. Appx13. Other sections, however, do. For example, Sections 1.2(b) and 1.2(f) refer to the sale of a "Generic Equivalent" of Colcrys®, and Section 1.2(e) refers to the sale of "Authorized Generic Products" of Colcrys®. *Id.* Thus, had Takeda chosen to limit Section 1.2(d) to a litigation concerning Colcrys®, it knew how to do so but chose not to.

Takeda's brief is riddled with statements that underscore the fallacy of Takeda's intent argument. For example, Takeda contends that the purported intent of the parties was "to allow Alkem on the market only if there was a change to the status quo either in the Colcrys® market or to the status of the Patents-in-Suit." Takeda Br. at 23-24. This is precisely what the *West-Ward* Litigation did. Takeda chose to assert the same patents against both West-Ward and Alkem where both cases involved 0.6 mg colchicine products. The final decision in the *West-Ward* Litigation case found three of those patents to be not infringed, thus changing the status quo in the 0.6 mg colchicine product market and to the status of the Patents-in-Suit.

C. Takeda's Remaining Arguments Lack Merit

Takeda advances a few remaining arguments that are based on speculation and inapposite hypotheticals which lack merit. For example, Takeda speculates that the district court's interpretation of Section 1.2(d) may contravene agreements Takeda reached with certain Earlier Filers, who purportedly are on better terms than those granted to Alkem. Takeda Br. pp. 24-25. Regardless as to whether the Earlier Filers may have superior terms, their mere existence should not subvert Alkem's bargained-for rights. Further, whether or not Takeda's agreement with Alkem interferes with any of the purportedly superior rights Takeda granted to the Earlier Filers is uncertain, unproven, not supported by any evidence, and not before this Court in this appeal.

Takeda's 30-month stay and amended label hypotheticals (Takeda Br. pp. 30-34) are improbable and assume scenarios that are inapplicable, unavailing, and facts that are contrary to Hatch-Waxman litigation. The 30-month stay hypothetical, which imagines a scenario where Alkem's ability to launch under Section 1.2(d) would interfere with rights of a Third Party subject to a 30-month stay, is flawed and baseless. Section 1.2(d) does not mention any such stay or make Alkem's ability to launch contingent upon any 30-month stay applying to a third party being lifted. Further, the Hatch-Waxman Act permits the lifting of a 30-month stay in precisely the scenario Takeda presupposes, *i.e.*, where some patents are voluntarily dismissed

and others are subject to the final judgement of non-infringement. 21 C.F.R. § 314.107(b)(3)(viii).

Similarly, the amended label hypothetical, which assumes that a third party alters a dosing regimen or otherwise designs around the asserted claims may prompt Takeda to withdraw those claims, fails for the same reasons articulated in Section II.A., above. Takeda could withdraw claims for any reason at any time, but Section 1.2(d) of the License Agreement would be triggered so long as there was a final decision "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/or invalid, unpatentable, or unenforceable." Appx83.

In any event, the district court carefully considered Takeda's arguments below in the *Mylan* Litigation and, as Mylan points out in its appeal brief, correctly rejected them. *See Mylan* appeal, ECF No. 47 pp. 26-41. For these reasons and as articulated by the district court in the *Mylan* Judgment and by Mylan on appeal (*Mylan* appeal, ECF No. 47), Takeda's arguments that Section 1.2(d) was not triggered are unavailing and are unlikely to prevail.

III. TAKEDA WILL NOT SUFFER IRREPERABLE HARM

Takeda fails to demonstrate it would suffer irreparable harm in the absence of an injunction for at least two reasons. First, Takeda asserts that, because the License

Agreement contains a provision (Section 1.10) stating that any breach of the agreement will irreparably harm Takeda, Takeda is presumptively entitled to injunctive relief. Takeda Br. p. 39. Because, for the reasons above, Takeda is unlikely to prevail on the issue of breach, it necessarily follows that Section 1.10 is likewise unlikely to apply.

The case cited by Takeda in support of its argument that "contractual stipulations as to irreparable harm alone suffice to establish that element for the purpose of issuing preliminary injunctive relief" (Takeda Br. p. 39 (citing *TP Group-CI, Inc. v. Vetecnik*, No. 16-cv-623-RGA, 2016 WL 5864030, at *2 (D. Del. Oct. 6, 2016)) is inapposite because, in that case, the court granted injunctive relief where it determined that the plaintiff ***was*** likely to succeed on the merits.[3] While courts may recognize such contractual stipulations as a general principle, these stipulations are routinely held to be not enforceable absent a showing of likelihood of success on the merits, which Takeda has failed to do. Such stipulations are, after all, premised on a breach of the agreement and in the absence of such breach, the requisite antecedent basis does not exist.

[3] The case quoted by the *TP Group-CI* court as well as the case cited by the dissent in this Court's denial of Takeda's motion for injunction pending appeal, Alkem Appeal, ECF No. 33 at 5, also do not support Takeda's argument. In those cases, while the courts recognized as a general principle that contractual stipulations as to irreparable harm may suffice to establish irreparable harm, they ***declined*** to issue injunctive relief because, as here, the plaintiff failed to show a likelihood of success on the merits.

Second, as the district court found in *Mylan* (Appx9-10), and as evidenced by the fact that the parties willingly entered into a license agreement, any harm suffered by Takeda is fully compensable by monetary damages and therefore not irreparable. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (offer of a patent license "suggests that any injury suffered by [the patentee] would be compensable in damages").

IV. THE REMAINING FACTORS FAVOR ALKEM

A. The Balance of Hardships Favors Alkem

Takeda's inability to show likelihood of success tips the balance of hardships toward Alkem. *See Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990) ("[W]eak showing of likelihood of success tips the balance of hardships toward" non-movant). Moreover, the harm to Alkem if a preliminary injunction were granted outweighs any harm to Takeda which, as explained above, is fully compensable by money damages. Alkem should remain free to sell its generic product to its customers, maintain its reputation in the marketplace, and enjoy the goodwill and brand loyalty it has worked hard to achieve. *See Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 211 (3d Cir. 2014) ("[H]arm . . . caused to reputation and goodwill is irreparable because it is virtually impossible to quantify in terms of monetary damages."); *Gucci Am., Inc. v. Daffy's, Inc.*, 354 F.3d 228, 237

(3d Cir. 2003) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill.") (citation omitted).

B. The Denial of Injunctive Relief That Would Delay Generic Drug Entry Is In the Public Interest

The public interest is best served by affirming the district court and holding Takeda to the bargain it struck in the License Agreement. Pursuant to the License Agreement, Alkem has a clear and unambiguous right to sell its generic colchicine product in the wake of the *Mylan* and *West-Ward* Judgments. Moreover, denial of injunctive relief favors the public interest because it would permit Alkem to introduce its generic colchicine product, which would increase generic competition and promote more affordable pricing in the colchicine market. *Genentech Inc. v. Amgen Inc.*, No. 18-cv-924, 2019 WL 3290167 (D. Del. July 18, 2019) at *3 n.7 ("For pharmaceutical drugs that prolong and save lives, there is a critical public interest in affordable access to those drugs.")

CONCLUSION

For all of the foregoing reasons, Alkem respectfully requests that the Court affirm the District Court's denial of Takeda's Motion for a Preliminary Injunction.

Respectfully Submitted,

April 20, 2020

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