2020-1545

United States Court of Appeals for the Federal Circuit

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

v.

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

Appeal from the United States District Court for the District of Delaware
in Case No. 1:20-cv-00325-RGA, Judge Richard G. Andrews

REPLY BRIEF FOR PLAINTIFF-APPELLANT

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April 24, 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. 2020-1545

CERTIFICATE OF INTEREST

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

Takeda Pharmaceuticals U.S.A., Inc.

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
Takeda Pharmaceuticals U.S.A., Inc.	None	Takeda Pharmaceutical Company Limited; Takeda Pharmaceutical International AG

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:

Francis DiGiovanni, Faegre Drinker Biddle & Reath LLP
Thatcher Rahmeier, Faegre Drinker Biddle & Reath LLP

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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.)

4/24/2020
Date

/s/ Edgar H. Haug
Signature of counsel

Please Note: All questions must be answered

Edgar H. Haug
Printed name of counsel

cc: _____

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INTRODUCTION

Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively "Alkem") filed an Opposition Brief ("Opp." or "Opposition Brief") (ECF No.[1] 49) to Takeda Pharmaceuticals U.S.A., Inc.'s ("Takeda") Opening Appeal Brief ("Op. Br.") (ECF No. 35), which only confirms that the district court abused its discretion in denying a preliminary injunction. *First*, Alkem does not deny that the summary-judgment decision in *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA (D. Del. Oct. 3, 2014) (the "*West-Ward* Litigation") adjudicated noninfringement with respect to only three of the eight patents asserted in that litigation. *Second*, Alkem ignores that all claims, counterclaims, and defenses for the remaining five asserted patents were dismissed with prejudice, including the defenses and counterclaims of Hikma Pharmaceuticals LLC and West-Ward Pharmaceutical Corporation (collectively "Hikma") with respect to noninfringement, invalidity, unpatentability, and unenforceability. Accordingly, Alkem does not dispute that for these five patents, which were asserted in the *West-Ward* Litigation, there was no "holding" on

[1] Unless otherwise indicated, "ECF" refers to documents in the present appeal.

the issues of noninfringement, invalidity, unpatentability, or unenforceability, as required by Section 1.2(d). *Third*, Alkem's arguments are directly contrary to the text of Section 1.2(d), which requires an adjudication of ***all*** asserted claims. Alkem's interpretation is especially untenable, given that the purpose of the accelerators in the License Agreement is to allow early entry upon a change to the status quo in the colchicine market.

Alkem's license was not triggered by the *West-Ward* Litigation. Therefore, Alkem has breached the License Agreement and willfully infringed the Patents-in-Suit. The district court erred in finding otherwise. Takeda is likely to succeed in this appeal.

Alkem does not deny that Section 1.10 of the License Agreement expressly provides that a breach of the agreement entitles Takeda "to immediate injunctive relief to prevent Alkem from marketing the Alkem ANDA Product in breach of Paragraphs 1.2 and 1.4 of this License Agreement." This provision is dispositive of the remaining factors to consider in deciding whether to grant a preliminary injunction. Even without such a provision, as discussed below, the balance of hardships strongly favors Takeda because a preliminary

injunction would maintain the status quo in the colchicine market, and the public interest favors enforcement of valid patent rights.

Because all of the factors tip decidedly in Takeda's favor, the district court abused its discretion in denying Takeda's motion for a preliminary injunction. Therefore, the district court's order denying a preliminary injunction should be reversed, and the case should be remanded with instructions that a preliminary injunction be entered.

ARGUMENT

I. Takeda Is Likely to Succeed Because Alkem's Proposed Interpretation of Section 1.2(d) Is Contrary to the Plain Meaning of the License Agreement and Ignores the Context Under Which the License Agreement Was Entered

A. The Unambiguous Language of Section 1.2(d) Supports Takeda's Interpretation that the *West-Ward* Litigation Was Not a Triggering Event Under Section 1.2(d)

The *West-Ward* Litigation was not a triggering event as required by Section 1.2(d). Alkem reads Section 1.2(d) of the License Agreement to be triggered even if a Final Court Decision does not adjudicate **all** claims of the Licensed Patents asserted in the *West-Ward* Litigation. Alkem's interpretation of Section 1.2(d) of the License Agreement is simply incorrect. Alkem's interpretation requires that Section 1.2(d) be

read as applying to only to those Licensed Patents that were "asserted" at the time of adjudication. Opp. at 14.

Alkem's interpretation also ignores that Section 1.2(d) refers to "**all** unexpired claims." Appx83(§ 1.2(d)) (emphasis added). Under Alkem's flawed interpretation, Alkem considers only "three patents that were 'asserted and adjudicated' were determined to be 'not infringed[.]'" Opp. at 15. In other words, Alkem simply chooses to ignore the five other patents that were asserted in the *West-Ward* Litigation and removed from the case without any holding of noninfringement, invalidity, unpatentability, and unenforceability as required by Section 1.2(d).[2] Because the Rule 41 dismissal provided no "holding" whatsoever with respect to the five asserted patents, and certainly no holding that any of those five patents were (i) not infringed, or (ii) any combination of not infringed and/or invalid, unpatentable, or unenforceable as required by Section 1.2(d), the *West-Ward* Litigation

[2] Contrary to Alkem's statements (*see* Opp. at 14), ***both parties*** in the *West-Ward* Litigation ***jointly agreed*** to a stipulated dismissal of the five patents, as well as Hikma's defenses and counterclaims. It was not, as Alkem seems to suggest, the result of unilateral action brought by Takeda. *See* Fed. R. Civ. P. 41(a)(1)(A)(i) (providing that a unilateral, voluntary dismissal is not available after the filing of an answer or summary-judgment motion); *see also* Op. Br. at 36.

cannot be a "Final Court Decision" triggering Section 1.2(d). As this Court recently held, a voluntary dismissal under Rule 41(a)(1)(A)(i) does not result in a "final court decision." *O.F. Mossberg & Sons, Inc. v. Timney Triggers, LLC*, ---F.3d---, No. 2019-1134, 2020 WL 1845302, at *3 (Fed. Cir. Apr. 13, 2020). That case confirms the correctness of Takeda's argument that the *West-Ward* Litigation did not trigger Section 1.2(d) of the License Agreement, because the Rule 41 dismissal was entered without an adjudication—one way or the other—on noninfringement, invalidity, unpatentability, or unenforceability.

In *O.F. Mossberg*, the patentee filed a notice of voluntary dismissal without prejudice under Rule 41, and the accused infringer moved for attorney fees, claiming "prevailing party" status. *O.F. Mossberg*, 2020 WL 1845302, at *1. Rejecting the claim that a Rule 41 voluntary dismissal (and the district court's order memorializing it) rendered the accused infringer a "prevailing party," this Court concluded that dismissal under Rule 41 does not constitute "a final decision at all." *O.F. Mossberg*, 2020 WL 1845302, at *2-3. In so concluding, the Court recognized that "[a] properly filed Rule 41(a)(1)(A)(i) voluntary dismissal becomes effective immediately upon

plaintiff's filing of the notice of dismissal[,]" and therefore does not constitute a "final court decision." *O.F. Mossberg,* 2020 WL 1845302, at *3.

Similarly here, the Rule 41 dismissal of five patents in the *West-Ward* Litigation (*see* Appx1321-1324) did not adjudicate—one way or the other—the issues of infringement, validity, patentability, or enforceability of those five patents. As in *O.F. Mossberg*, the Rule 41 dismissal was not "a court decision with the necessary judicial *imprimatur*." *O.F. Mossberg,* 2020 WL 1845302, at *1. Accordingly, because not all of the "asserted" patents were "adjudicated" to be invalid, unpatentable, unenforceable, or not infringed, the *West-Ward* Litigation lacks the type of "Final Court Decision" that would trigger Section 1.2(d) of the License Agreement.

Moreover, the mere fact that the five patents asserted in the *West-Ward* Litigation were dismissed prior to the end of the litigation does not negate that these patents "were asserted" and were a subset of the Licensed Patents. Alkem's argument to the contrary hinges on its belief that in order to be "asserted," all claims of a patent must be pressed against a third party through the end of the litigation. Had the parties

intended for that to be the case, Section 1.2(d) would have been drafted to say so explicitly.

Unable to refute that its interpretation of Section 1.2(d) renders the term "asserted" superfluous, Alkem claims, without support, that "Takeda could unilaterally withdraw claims from the litigation at any time[]" and thus avoid triggering Section 1.2(d). Opp. at 16 (emphasis omitted). Alkem is incorrect. Alkem fails to appreciate that (i) pursuant to Fed. R. Civ. P. 41(a)(1)(A)(i) a unilateral, voluntary dismissal is not available after the filing of an answer or summary-judgment motion, and (ii) Section 1.2(d) can be triggered by the dismissal of claims if the parties stipulate that such claims were indeed invalid, unpatentable, unenforceable, and/or not infringed. *See* Op. Br. § II.B.4.

Alkem relies on its misguided example that Section 1.2(d) would not apply to a declaratory-judgment action because "a generic could bring a declaratory judgment action, in which claims would be adjudicated but not asserted." Opp. at 16. However, Section 1.2(d) *does* apply in instances of declaratory-judgment actions provided Takeda denies the allegations of noninfringement, invalidity, unpatentability,

or unenforceability—i.e., "assertions" of the patents that are subject to the declaratory-judgment action. Alkem's interpretation of Section 1.2(d) produces an absurd result whereby (i) a declaratory-judgment action (by Alkem or a third party) that finds *all* of the Licensed Patents to be not infringed *would not* trigger Section 1.2(d) because the Licensed Patents were not "asserted," whereas (ii) an infringement action (brought by Takeda) that finds *only some* of the Licensed Patents to be not infringed—with no finding one way or the other with respect to the remaining asserted patents—*would* trigger Section 1.2(d). Alkem's interpretation is untenable.

In contrast to Alkem's atextual interpretation of Section 1.2(d), Takeda's interpretation gives meaning to both "asserted" and "adjudicated." The term "asserted" defines the claims that need to be considered, and the term "adjudicated" makes clear that those claims that were "asserted" need to be adjudicated. As Alkem admits, the claims of five of the patents that were "asserted" in the *West-Ward* Litigation were never adjudicated. Appx1059. As such, because "all" of the claims of the Licensed Patents that were "asserted" were not "adjudicated," and there was no corresponding holding of

noninfringement, invalidity, unpatentability, or unenforceability, Section 1.2(d) was not triggered.

B. Takeda's Interpretation Is Consistent with the Parties' Objective Intent, Whereas Alkem's Interpretation Is Not

Under Delaware law it is unequivocal that "[w]hen 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). Indeed, when interpreting a contract, courts "will give priority to the parties' intentions as reflected in the four corners of the agreement[.]" *GMG Capital Inv., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 779 (Del. 2012). As Takeda explained in detail (*see* Op. Br. at 23-26), the four corners of the License Agreement make clear that where a court's findings of noninfringement, invalidity, unpatentability, or unenforceability are limited to only a subset of asserted patents, Section 1.2(d) will not be triggered.

In response, Alkem wrongly characterizes Takeda as "ask[ing] this Court to inject a requirement that the 'litigation' referenced in Section 1.2(d) be a litigation concerning generic Colcrys® products, not Mitigare®." Opp. at 16. To the contrary, Takeda merely pointed out

that at the time the parties negotiated and entered into the License Agreement, Mitigare®—the product at issue in the *West-Ward* Litigation—had already been on the market. *See* Op. Br. at 23-24. Accordingly, it makes no sense to conclude that the parties intended the *West-Ward* Litigation to trigger Alkem's license when such a decision would have no effect on the colchicine market.

Moreover, Takeda has consistently maintained that the outcome of the *West-Ward* Litigation does not trigger Section 1.2(d) because it failed to satisfy Section 1.2(d)'s requirements. The *West-Ward* Litigation would have triggered Alkem's license had there been a Final Court Decision holding all eight asserted patents to be not infringed, invalid, or unenforceable, even though the product in the *West-Ward* Litigation was not a Generic Equivalent.

The License Agreement's license accelerators (*see, e.g.*, Appx83(§ 1.2(b)); Appx84(§ 1.2(f))) clearly focus on the occurrence of certain limited events regarding generic Colcrys® products. Therefore, it makes sense to interpret Section 1.2(d) narrowly, instead of giving Section 1.2(d) the expansive effect that Alkem is advocating.

Alkem also wrongly denies that the License Agreement, including its Most Favored Nation ("MFN") provision (Appx86-87(§ 1.5)), acknowledges that certain "Earlier Filers" were permitted earlier entry dates than Alkem. Opp. at 18. Rather, Alkem contends that "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." Opp. at 18. However, Alkem is categorically wrong. Alkem's License Agreement unequivocally demonstrates that the Earlier Filers bargained for superior rights. For example, Section 1.5 unambiguously provides that the terms in Alkem's License Agreement shall be "equivalent to or better than the terms being offered to any Third Party (other than Generic Entry Dates offered to [certain Earlier Filers])[.]" Appx86-87(§ 1.5). That proviso would be unnecessary if Alkem were being offered the same entry date as those Earlier Filers. Accordingly, the MFN provision objectively shows the parties' overarching intent that Alkem would launch ***after*** the Earlier Filers, and certainly not ***before*** the Earlier Filers as Alkem seeks to do.

C. Alkem's Proposed Interpretation Would Lead to Absurd Results

Alkem still points to no reason why Takeda would have agreed to the exceedingly broad interpretation of Section 1.2(d) that the district court adopted. *See* Op. Br. at 16, 30. As an initial matter, Alkem improperly purports to incorporate by reference portions of Mylan's appeal brief. Opp. at 19 (citing Mylan Appeal[3], ECF No. 47 at 26-41). As detailed below, this incorporation by reference violates the Federal Rules of Appellate Procedure and this Court's precedent, and the Court therefore should strike it. Additionally, with little analysis, Alkem dismisses the absurd results that would flow from Alkem's interpretation as "improbable", "inapplicable, unavailing, and facts that are contrary to Hatch-Waxman litigation." Opp. at 18. Alkem is incorrect, as discussed in further detail below.

1. This Court Should Strike Alkem's Improper Incorporation of Mylan's Brief

Alkem's incorporation by reference to Mylan's brief is improper, and the Court should strike it. *See* Opp. at 19 (incorporating by reference Mylan Appeal, ECF No. 47 at 26-41). The Federal Rules of

[3] "Mylan Appeal" refers to the docket in C.A. No. 20-1407.

Appellate Procedure "authorize[] incorporation of co-party briefing only in the case of consolidated appeals[,]" and "incorporation of co-party briefing is only allowed in consolidated cases as explained in Fed. R. App. P. 28(i)[.]" *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 910 (Fed. Cir. 2014) (citing Fed. R. App. P. 28(i)). This appeal has not been consolidated with the Mylan Appeal. Rather, the two appeals are merely "considered companion cases and assigned to the same merits panel for oral argument." ECF No. 44; Mylan Appeal, ECF No. 80. As this Court has recognized, treating two appeals as companion cases is not the same as consolidating them. *See, e.g.*, *Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1461 n.1. (Fed. Cir. 1998) (recognizing that where the Court "declined to consolidate" several appeals but instead treated them as "companion cases[,]" "a separate disposition [would] issue in each appeal."); *King v. Dep't of Health & Human Servs.*, 133 F.3d 1450, 1451 n.1 (Fed. Cir. 1998) ("We have decided not to consolidate these appeals but will treat them as companion cases."); *see also McLaughlin v. U.S. Postal Serv.*, 34 F.3d 1078, 1994 WL 416969, at *1 (Fed. Cir. 1994) (unpublished) ("While the cases concern the same factual circumstances, the cases involve two separate actions, two

separate Board decisions, and two different respondents. Thus, we deem it appropriate to treat the cases as companion cases rather than to consolidate them.").

Accordingly, because Alkem's incorporation by reference violates Federal Rule of Appellate Procedure 28(i) and this Court's case law, Takeda respectfully requests that this Court: (i) strike it; and (ii) find that Alkem waived the right to make the arguments that it makes only via incorporation by reference. Alternatively, should the Court decline to strike this material or find waiver by Alkem, Takeda respectfully directs the Court to pages 10-22 of its reply brief in the Mylan Appeal (Mylan Appeal, ECF No. 54 at 10-22), in which Takeda responds in detail to Mylan's arguments that Alkem purports to incorporate by reference.

2. The Plain Language of the Hatch-Waxman Act Confirms the Absurd Results that Would Result from Alkem's Overly Broad Interpretation of Section 1.2(d)

Alkem wrongly denies that Takeda's interpretation—i.e., that Section 1.2(d) is triggered only when there has been an adjudication of noninfringement, invalidity, unpatentability, or unenforceability with respect to ***all*** of the patents that were asserted in the litigation—is

most sensible given that the 30-month stay is lifted only by a judgment that applies to all claims. Opp. at 18-19. In particular, Alkem claims that "the Hatch-Waxman Act permits the lifting of a 30-month stay . . . where some patents are voluntarily dismissed and others are subject to the final judgement of non-infringement." Opp. at 18-19. Not so.

The Hatch-Waxman Act provides (in relevant part) that a 30-month stay can be terminated before the 30-month period runs only if there is a "***substantive determination*** that there is no cause of action for patent infringement." 21 U.S.C. § 355(j)(5)(B)(iii)(I) (emphasis added). Alkem does not—and cannot—dispute that under this plain language, five of the eight patents that were asserted in the *West-Ward* Litigation were not subject to a "substantive determination" that Takeda lacked a cause of action for patent infringement," and therefore were not "adjudicated" to be invalid, unenforceable, or not infringed. *See* Appx83(§ 1.2(d)).[4] Indeed, as this Court has recognized, a Rule 41

[4] Takeda's opening brief (Op. Br. at 31-32) analyzes decisions from courts and the FDA demonstrating that a 30-month stay cannot be terminated in the absence of a substantive determination of noninfringement, invalidity, or unenforceability. Alkem's brief offers no response.

dismissal is not "a court decision with the necessary judicial *imprimatur*." *O.F. Mossberg*, 2020 WL 1845302, at *1.

A stipulated Rule 41 dismissal of the type that occurred in the *West-Ward* Litigation is not a "substantive determination that there is no cause of action for patent infringement" because it does not conclude—one way or the other—whether the five patents were infringed, invalid or unenforceable. This point is underscored by the fact that not only were Takeda's patent-infringement claims dismissed with prejudice, but Hikma's counterclaims and defenses of noninfringement, invalidity, and unenforceability, were also dismissed with prejudice. Appx1321-1324. Simply put, the stipulated Rule 41 dismissal in the *West-Ward* Litigation lacks "the necessary judicial *imprimatur*" (*O.F. Mossberg*, 2020 WL 1845302, at *1) to be a "substantive determination that there is no cause of action for patent infringement[.]" 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Alkem's sole basis for claiming that the Hatch-Waxman Act permits a 30-month stay to be lifted when only a subset of the asserted patents are adjudged to be invalid, unenforceable, or not infringed, is a citation—without further analysis—to 21 C.F.R. § 314.107(b)(3)(viii)

("Rule 107(b)(3)(viii)"). Opp. at 18-19. Alkem's citation is misplaced. If Rule 107(b)(3)(viii) purports to permit termination of a 30-month stay "where some patents are voluntarily dismissed and others are subject to the final judgement of non-infringement" (Opp. at 18-19) then Rule 107(b)(3)(viii) is flatly inconsistent with the Hatch-Waxman Act, and therefore invalid.

The statute makes clear that there must be a "substantive determination that there is no cause of action for patent infringement" in order to terminate a 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii)(I). During the notice-and-comment period for Rule 107(b)(3)(viii), one comment correctly pointed out that the Rule "should be withdrawn because the statute does not specify that an order of dismissal without a finding of infringement will terminate a 30-month stay." 81 Fed. Reg. 69580, 69627 comment 58 (Oct. 6, 2016). In response, the FDA made no attempt to square Rule 107(b)(3)(viii) with the plain language of the statute. *Id.* Because Rule 107(b)(3)(viii) conflicts with the statute, it is invalid. *See Teva Pharm. U.S.A., Inc. v. Sebelius*, 595 F.3d 1303, 1315-18 (D.C. Cir. 2010) (invalidating an FDA regulation that was inconsistent with the plain language of 21 U.S.C. § 355(j)); *see also*

Facebook, Inc. v. Windy City Innovations, LLC, 953 F.3d 1313, 1328-29 (Fed. Cir. 2020) (invalidating the USPTO's interpretation of the IPR statute where the USPTO's interpretation conflicted with the statute's plain language); *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1361 (Fed. Cir. 2019) (invalidating USPTO regulations that were inconsistent with the patent statute).

Alkem claims that the 30-month stay is not explicitly mentioned in the License Agreement. Opp. at 18. But Alkem ignores that the Hatch-Waxman Act is referenced repeatedly in the License Agreement. Appx82; Appx85(§ 1.2(g)); Appx86-87(§§ 1.5 and 1.7); Appx97. It therefore makes sense to interpret the License Agreement against the backdrop of the Hatch-Waxman Act. *See Chi. Bridge & Iron Co. N.V. v. Westinghouse Elec. Co. LLC*, 166 A.3d 912, 913-14 (Del. 2017) ("In giving sensible life to a real-world contract, courts must read the specific provisions of the contract in light of the entire contract.").

In sum, five of the eight asserted patents in the *West-Ward* Litigation were never subject to any type of determination (substantive or otherwise) that Takeda's allegations of patent infringement lacked merit. Accordingly, as per § 355(j)(5)(B)(iii)(I), a stipulation of

dismissal—in the absence of a substantive determination of noninfringement, invalidity, or unenforceability—would not terminate Alkem's 30-month stay. The accelerator provisions of Section 1.2 were intended to operate only in the event of a material change to the status quo in the colchicine market. It is therefore entirely sensible to interpret Section 1.2(d) to be triggered only by an event that mirrors the type of occurrence that would lift a 30-month stay.

3. Alkem's Failure to Respond Substantively to the "amended label hypothetical" Further Demonstrates that Alkem's Interpretation of Section 1.2(d) Is Untenable

Alkem's brief offers no substantive response to Takeda's argument that Alkem's overly broad interpretation of Section 1.2(d) leads to absurd results. In particular, Alkem's brief does not address the fact that under its interpretation, a third party could trigger Alkem's license simply by: (i) seeking FDA approval for a dosing regimen identical to that of Colcrys® and then being sued by Takeda for infringement of all of the Patents-in-Suit; (ii) amending its label to carve out certain indications, resulting in Takeda having to drop certain patents from the suit; and (iii) obtaining a judgment of noninfringement with respect to the remaining patents. Rather, Alkem simply refers back to its

argument that the text of Section 1.2(d) supports Alkem's interpretation. Opp. at 19 (citing Opp. § II.A). As explained in detail (*see supra* § I.A-C), Alkem's textual arguments are unsupported. In any event, contracts should not be read "to reach an absurd, unfounded result." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010).

II. Takeda Will Suffer Irreparable Harm Absent a Preliminary Injunction

Section 1.10 of the License Agreement provides that Takeda "shall be entitled to immediate injunctive relief to prevent Alkem from marketing the Alkem ANDA Product in breach of Paragraphs 1.2 and 1.4 of this License Agreement." Appx89. However, Alkem now denies that Takeda would suffer irreparable harm. Opp. at 21. Because Section 1.10 is clear and unambiguous, this Court should reject Alkem's attempt to contradict the License Agreement. This Court should also reject Alkem's attempt to distance itself from the agreed-upon language of the License Agreement.

Alkem mischaracterizes the district court as holding that "any harm suffered by Takeda is fully compensable by monetary damages and therefore not irreparable." Opp. at 21. To the contrary, the district court simply concluded that "[w]ithout consideration of Section

1.10 [of the License Agreement], I do not find that Takeda has shown it will suffer irreparable harm absent a preliminary injunction." Appx14. The district court reached this conclusion only because it found that it was "unlikely that [Alkem] breached the Agreement." *Id.* The district court in no way discounted the irreparable harm that Takeda would suffer if Alkem breached the License Agreement. *See id.* Nor could it, given the unequivocal nature of Section 1.10.

Alkem further contends that Takeda would not suffer irreparable harm because "the parties willingly entered into a license agreement[.]" Opp. at 21. This argument is misplaced. Indeed, this Court has upheld the grant of a preliminary injunction against a generic pharmaceutical company—including a finding of irreparable harm—even when a brand pharmaceutical company had already licensed the patents to two other generic competitors. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008). Moreover, in vacating the denial of a permanent injunction, this Court recently clarified that "[i]rreparable 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' . . . ." *Texas 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)); *see also Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1329 (Fed. Cir. 2008) (affirming the grant of a permanent injunction even where patent owner had granted licenses to other entities, because "[a]dding a new [direct] competitor to the market may create an irreparable harm that the prior licenses did not.").

Alkem's suggestion that monetary damages would be sufficient to remedy Takeda's harm (Opp. at 21) is especially untenable given that Alkem alleges its own irreparable harm (to reputation in the marketplace, loss of goodwill, and loss of brand loyalty) associated with an inability to sell its colchicine product. Opp. at 21-22. Simply put, if the harm to Alkem is deemed irreparable, then surely it cannot be correct to dismiss—as "fully compensable by monetary damages and therefore not irreparable" (Opp. at 21)—Takeda's loss of reputation in the marketplace, loss of goodwill, and loss of brand loyalty.

III. The Remaining Preliminary-Injunction Factors Weigh in Takeda's Favor

Section 1.8 and Section 1.10 of the License Agreement bar Alkem's arguments (Opp. at 21-22) that the balance of hardships and the public

interest favor Alkem, just as they bar Alkem's attempt to deny irreparable harm. Because Alkem agreed that a breach of the License Agreement would constitute "infringe[ment of] one or more of the claims of [Takeda's] Patents" and "entitle[] [Takeda] to immediate injunctive relief," Alkem cannot now argue against the issuance of an injunction in the event of a breach by Alkem. Appx87-89; *see also* ECF No. 32 at 5 (Newman, J., dissenting) (recognizing that a contractual stipulation as to irreparable harm is binding on the parties, and suffices to establish irreparable harm for the purpose of securing injunctive relief).

As discussed previously, the balance of hardships favors maintaining the status quo. *See Abbott Labs.*, 544 F.3d at 1362 (affirming the grant of a preliminary injunction where such an injunction would maintain the status quo). Alkem's only response is a conclusory statement that "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." Opp. at 21. However, as with Alkem's attempt to deny irreparable harm, Alkem's argument cannot be squared with the Section 1.10 of the License

Agreement, in which Alkem agrees that a breach will "entitle[] [Takeda] to immediate injunctive relief." Appx89.

Finally, Alkem claims that the public interest favors Alkem, because denial of injunctive relief "would permit Alkem to introduce its generic colchicine product, which would increase generic competition and promote more affordable pricing in the colchicine market." Opp. at 22. But as with Alkem's attempts to rebut irreparable harm and balance of hardships, this argument is squarely foreclosed by Section 1.10 of the License Agreement, in which Alkem agrees that Takeda "shall be entitled to immediate injunctive relief" in the event of a breach. Appx89. In any event, the public interest favors Takeda because there is a strong public interest in enforcing valid patent rights. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383-84 (Fed. Cir. 2006). There is also an important public interest in enforcing private settlement agreements. *See Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988); *see also TP Group-CI, Inc. v. Vetecnik*, No. 16-623-RGA, 2016 WL 5864030, at *3 (D. Del. Oct. 6, 2016) (Appx1368).

For all these reasons, the balance of hardships and public interest favor Takeda.

CONCLUSION

For at least the reasons expressed above and in Takeda's opening brief, this Court should reverse the district court's denial of a preliminary injunction, and remand with instructions that a preliminary injunction be issued.

Respectfully submitted,

Takeda Pharmaceuticals U.S.A., Inc.

Dated: April 24, 2020

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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