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

BRIEF FOR PLAINTIFF-APPELLANT

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March 27, 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

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

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.)

3/27/2020
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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STATEMENT OF RELATED CASES

Aside from the district court proceedings that remain pending in this case, *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 1:19-cv-02216-RGA (D. Del.), and *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 20-1407, -1417 (Fed. Cir.), 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.

JURISDICTIONAL STATEMENT

The district court exercised jurisdiction under 28 U.S.C. §§ 1331, 1332, and 1338(a). This Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1) and 1292(c)(1) because this appeal is from the district court's order denying Takeda's motion for a preliminary injunction against Defendants-Appellees Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively "Alkem"). On March 5, 2020, the district court entered an order denying Takeda's motion for a preliminary injunction. Takeda timely filed a notice of appeal on March 6, 2020. 28 U.S.C. § 2107(a); Fed. R. App. P. 4(a)(1).

STATEMENT OF THE ISSUES

1. Section 1.2(d) of the License Agreement at issue in this case permits Alkem to launch its generic Colcrys® product a specified time period "after the date of a Final Court Decision . . . holding that all unexpired claims of the Patents-in-Suit 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[.]" The district court held that Takeda is unlikely to succeed in its argument that Alkem was not entitled to launch its generic product. Did the district court err in concluding that Section

1.2(d) was likely triggered by a court decision that: (A) held only three out of the eight asserted patents to be not infringed; and (B) reached no determination regarding noninfringement, invalidity, unpatentability, or unenforceability with respect to the remaining five patents?

2. Based on the correct interpretation of the License Agreement, did the district court abuse its discretion in denying Takeda's motion for a preliminary injunction?

3. Based on the correct interpretation of the License Agreement, did the district court abuse its discretion in finding that there was no irreparable harm based on Section 1.10 of the License Agreement which provides that Takeda "shall be entitled to immediate injunctive relief" in the event of a breach, and that a breach by Alkem of the License Agreement, "would cause Takeda irreparable harm"?

STATEMENT OF THE CASE

I. Colcrys®

Takeda's product Colcrys® (colchicine, 0.6 mg tablets) is indicated for the prophylaxis and treatment of gout flares in adults and for familial Mediterranean fever ("FMF"). Appx1081(¶ 17); Appx571. Colcrys® was the first pharmaceutical product approved by the United States Food and Drug Administration ("FDA") that contained colchicine

as the sole active ingredient. Appx1082(¶ 20). Takeda owns all seventeen of the patents that are listed for Colcrys® in the Orange Book, with the last expiring in 2029.[1]

II. Colcrys® Hatch-Waxman Patent Litigation and Settlements

Eleven generic manufacturers submitted Abbreviated New Drug Applications ("ANDAs") seeking to market generic versions of Colcrys®. Appx1093(¶¶ 66-67). Takeda sued each generic manufacturer for patent infringement and subsequently settled the respective litigation against each of these ANDA applicants. Appx1093(¶ 66). Those settlements authorize the licensed generic-drug manufacturers to begin marketing their own generic versions of Colcrys® within the United States upon a date certain or shortly after an unlicensed competitor—such as Alkem—begins sales of its own generic version of Colcrys®. Appx1093(¶ 68).

[1] The Orange Book listed Takeda patents include U.S. Patent Nos. 7,906,519; 7,935,731; 8,093,298; 7,964,648; 8,093,297; 7,619,004; 7,601,758; 7,820,681; 7,915,269; 7,964,647; 7,981,938; 8,093,296; 8,097,655; 8,415,395; 8,415,396; 8,440,721; and 8,440,722 (collectively, the "Licensed Patents" or "Patents-in-Suit"). Appx1082-1087(¶¶ 26-43); Appx111-534.

The first ANDA was submitted by Par Pharmaceutical, Inc. ("Par"). Appx1166. Takeda sued Par for patent infringement on August 30, 2013. Appx1166. Then in November 2015, Takeda and Par entered into agreements that settled the litigation, granted Par a right to distribute an authorized generic version of Colcrys®, and granted Par a future license to make and distribute Par's ANDA product. Appx1166. Pursuant to those agreements, Par launched the authorized generic Colcrys® product on July 1, 2018, and Takeda receives a percentage of the net profits. Appx1166-1167.

Amneal Pharmaceuticals LLC ("Amneal") and Watson Laboratories, Inc. ("Watson") also filed ANDAs and were subsequently sued for patent infringement by Takeda. Appx1166. Takeda reached settlements with Amneal and Watson, granting both Amneal and Watson non-exclusive future licenses to market their respective ANDA products on a date certain with certain acceleratory provisions that allow for a possible earlier generic entry of their respective ANDA products. Appx1167.

Several months after the Par, Amneal, and Watson litigations were resolved, Takeda filed a complaint for patent infringement against

Alkem based on Alkem Laboratories Limited's submission of ANDA No. 211250 ("the Alkem ANDA"). *See* Appx1089-1090(¶¶ 53-56). Takeda asserted all of the Patents-in-Suit against Alkem. Appx1090(¶ 55).

In May 2018, Takeda and Alkem executed a settlement agreement ("Settlement Agreement") and an accompanying license agreement ("License Agreement"). Appx69-107. The Settlement Agreement provided that Takeda and Alkem would stipulate to a dismissal of the pending lawsuit without prejudice. Appx70-71. The License Agreement granted Alkem a non-exclusive future license to market the product that is the subject of the Alkem ANDA ("Alkem ANDA Product") in the United States upon the earliest of a number of "Generic Entry Dates." Appx83-85(§§ 1.1 and 1.2). Section 1.2(a) sets forth the first "Generic Entry Date"—a date-certain. Appx83(§ 1.2(a)). Sections 1.2(b)-(g) set forth accelerators that would permit early entry upon the occurrence of a narrow set of circumstances. Appx83-85(§§ 1.2(b)-(g)). For example, Section 1.2(c) sets forth a date that is a specified time period after Par, Watson, and/or Amneal ("Earlier Filers") are permitted to commercially sell their respective ANDA products pursuant to a license or other authorization by Takeda. Appx83(§ 1.2(c)).

The interpretation of Section 1.2(d) is the subject of the present dispute. Relevant here, Section 1.2(d) provides that Alkem may launch the Alkem ANDA Product on:

> The date that is [a specified time period] after the date of a Final Court Decision[2] (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 [.]

Appx83(§ 1.2(d)).

The License Agreement also contains provisions whereby Alkem admitted to the infringement, validity, and enforceability of all the Patents-in-Suit. Appx87-89(§ 1.8). In Section 1.8 of the License Agreement, Alkem acknowledges with respect to the Alkem ANDA Product that: (i) the seventeen Patents-in-Suit are valid and enforceable; and (ii) any manufacture, use, offer for sale, sale, or importation of the Alkem ANDA Product would infringe the Patents-in-

[2] "Final Court Decision" as defined in the License Agreement "means 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. For the avoidance of doubt, the decision of an appeals court is not final until entry by that court of the mandate." Appx97.

Suit unless done pursuant to the License Agreement. Appx87-89(§ 1.8). Alkem additionally agrees that Takeda "shall be entitled to immediate injunctive relief to prevent Alkem from marketing the Alkem ANDA Product in breach of Sections 1.2 and 1.4 of this License Agreement," and acknowledges that "marketing the Alkem ANDA Product in breach of Section 1.2 of this License Agreement would cause Takeda irreparable harm." Appx89(§ 1.10).

After executing the settlement, Takeda and Alkem filed a stipulation voluntarily dismissing the pending litigation. Appx1340-1341. On July 6, 2018, the district court so-ordered that stipulation. Appx1342-1343.

Takeda sued seven additional ANDA applicants for infringement of the Colcrys® Orange Book patents. Appx1093(¶¶ 66-67). Takeda settled all of these cases. Appx1093(¶ 66).

III. Mitigare®

Months before any ANDA for generic Colcrys® was filed, in October 2012, Hikma Pharmaceuticals LLC and West-Ward Pharmaceutical Corporation (collectively, "Hikma") submitted a 505(b)(2) NDA application to market a branded colchicine product

under the tradename Mitigare®. *See* Appx1273(¶¶ 24-25). Unlike Colcrys®, Mitigare® is not indicated for the treatment of gout flares or FMF; it is indicated only for the prophylaxis of gout flares. Appx1326. Further, Mitigare® is a capsule rather than a tablet like Colcrys®. *See* Appx1326. And because Mitigare® is not AB-rated to Colcrys®, a prescription written for Colcrys® is not substitutable for Mitigare® at the pharmacy. The FDA approved Mitigare® in September 2014. Appx1326. Hikma launched Mitigare® and an authorized generic Mitigare® product in October 2014—more than three years before Takeda initiated Hatch-Waxman litigation against Alkem. Appx1296 (¶ 44).

Two days after Mitigare®'s launch, Takeda filed a complaint for patent infringement against Hikma, alleging infringement of five patents (U.S. Patent Nos. 7,964,647; 7,964,648; 7,981,938; 8,097,655; and 8,440,722), a subset of the seventeen patents listed in the Orange Book for Colcrys® that were asserted against Alkem. *See* Appx1265-1282.

Takeda filed an amended complaint to add three additional patents (U.S. Patent Nos. 7,619,004; 8,093,297; and 8,415,395). *See*

Appx1283-1320. Following discovery, the parties jointly agreed to voluntarily dismiss with prejudice: (i) Takeda's claims concerning U.S. Patent Nos. 7,619,004; 7,964,648; 8,093,297; 8,097,655; and 8,440,722; and (ii) Hikma's defenses and counterclaims concerning noninfringement, invalidity, and unenforceability of the same patents. Appx1321-1324. There was no holding of any kind by the district court with respect to any of those five asserted patents. On December 12, 2018, the district court granted Hikma's motion for summary judgment of noninfringement with respect to the remaining three patents: U.S. Patent Nos. 7,964,647; 7,981,938; and 8,415,395. *See* Appx1325-1339.

IV. Alkem's Breach of License Agreement

On February 15, 2020, Takeda was informed by Mylan Pharmaceuticals Inc. ("Mylan") that Alkem "has introduced or intends imminently to introduce into the market a generic version of Colcrys® (colchicine) tablets." Appx742-743.

Takeda promptly reached out to Alkem's counsel, seeking assurances that no launch was imminent, and that Alkem had not engaged in any premature pre-marketing activities in violation of Section 1.4 of the License Agreement (e.g., manufacturing, importing, or

storing the Alkem ANDA Product). After several unreturned voicemails and e-mail correspondence, Alkem's counsel responded on February 20, 2020, that he was out of the country and would speak to Takeda on Monday, February 24, 2020. Appx745-746. Takeda promptly responded that it needed assurances that Alkem had not made commercial sales of its generic colchicine product. Appx745. Alkem then, on February 21, 2020, confirmed that it had not made any commercial sales. Appx745.

On February 25, 2020, Takeda spoke with Alkem's counsel (Ms. Teresa Summers), asking about: (1) Alkem's actions in the market to date; (2) any ongoing activities by Alkem concerning its generic Colcrys® product; (3) whether Alkem has plans to launch its product; and if so; (4) when Alkem is planning to initiate such a launch. Alkem's counsel disclaimed any knowledge of these issues, and stated that she would get back to Takeda with answers. Despite this representation, Alkem's counsel, on February 26, 2020, sent a brief e-mail saying that she did not "have anything further to add to the [phone] conversation" from February 25, 2020. Appx748-750. On February 27, 2020, Takeda sent a letter to Alkem's counsel, again reiterating the need for more

information regarding Alkem's market activities. Appx752-753. On February 28, 2020, Alkem's counsel responded with a terse letter that refused to provide any more information, but confirmed that Alkem still had not made a commercial sale of the Alkem ANDA Product. Appx755. On March 2, 2020, Takeda received notification from Par that Alkem had launched—or was going to launch within the next day—its generic Colcrys® product. Appx1225-1227. Takeda immediately brought the district-court action asserting breach of contract and patent infringement.

On March 5, 2020, the district court denied Takeda's motion for a preliminary injunction "[f]or the reasons stated in [the Mylan Case[3]]." Appx1. Takeda filed a notice of appeal the next day. Appx1044-1045. Although the district court declined to issue an injunction pending appeal, it ordered Alkem to maintain the status quo until March 12, 2020, (i.e., recall the Alkem ANDA Product that was in transit and refrain from selling or transferring any other Alkem ANDA Product)

[3] "Mylan Case" refers to *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 19-2216-RGA. Because the district court based its decision in the present case entirely on its decision in the Mylan Case (*see* Appx9-15), Takeda's arguments reference the district court's decision in the Mylan Case as being the basis for the district court's denial of a preliminary injunction here.

and to allow Takeda time to seek from this Court an injunction pending appeal. Appx1. The next day, March 6, 2020, Takeda filed its notice of appeal, an emergency motion for a temporary injunction pending appeal, and a motion for an interim injunction during the pendency of the temporary-injunction motion. Alkem Appeal[4], ECF No. 1; Alkem Appeal, ECF No. 2. On March 10, 2020, this Court granted Takeda's request for an interim injunction "to the extent that the district court's order that Alkem 'maintain the status quo' shall remain in effect through March 24, 2020" and set an expedited briefing schedule for Takeda's motion for an injunction pending appeal. Alkem Appeal, ECF No. 19.

On March 23, 2020, this Court denied an injunction pending appeal, "[w]ithout prejudicing the ultimate disposition of this case by a merits panel." Alkem Appeal, ECF No. 33 at 2. Judge Newman filed a dissenting opinion, analyzing the License Agreement and finding, on the record before her, "no support for the contract interpretation now offered by Mylan and Alkem." Alkem Appeal, ECF No. 33 at 5 (Newman, J., dissenting). In particular, Judge Newman concluded that

[4] "Alkem Appeal" refers to the docket in this present case (C.A. No. 20-1545).

"[t]he contracts strongly support Takeda's request for interim action to preserve the status quo." Alkem Appeal, ECF No. 33 at 5. Judge Newman observed that the License Agreement expressly stipulates that Takeda is entitled to immediate injunctive relief in the event of a breach and that "contractual stipulations as to irreparable harm alone suffice to establish that element for the purpose of issuing preliminary injunctive relief." Alkem Appeal, ECF No. 33 at 5 (Newman, J., dissenting) (quoting *Cirrus Holding Co. v. Cirrus Ind., Inc.*, 794 A.2d 1191, 1209 (Del. Ch. 2001)).

V. Pending Federal Circuit Appeal Regarding Mylan's Breach of the Mylan License Agreement

As this Court is aware (*see* Alkem Appeal, ECF No. 2 at 1-2), there is an ongoing litigation between Takeda and Mylan involving a license agreement very similar to the one at issue here. In that case, which involves another generic Colcrys® product, the district court denied Takeda's motion for a preliminary injunction filed against Mylan. Appx9-15. Takeda filed a notice of appeal that same day. Mylan Case, D.I. 115. Although the district court declined to issue an injunction pending appeal, it ordered Mylan to maintain the status quo until January 31, 2020 (i.e. refrain from selling the Mylan ANDA product

pursuant to the cease and desist entered into between the parties) and entered a temporary stay of its decision to allow Takeda to seek from this Court an injunction pending appeal. Appx15. The next day, January 28, 2020, Takeda filed two motions in this Court: (i) a motion for an injunction pending appeal, and (ii) a motion for an interim injunction while the motion for an injunction pending appeal is pending. *See Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 20-1407, ("Mylan Appeal") ECF No. 6-1. Then on January 29, 2020, this Court granted Takeda's request for an interim injunction entered against Mylan. *See* Mylan Appeal, ECF No. 14.

On March 23, 2020, this Court denied an injunction pending appeal, over the dissent of Judge Newman. Mylan Appeal, ECF No. 60.

SUMMARY OF THE ARGUMENT

The four preliminary-injunction factors tip heavily in Takeda's favor. By committing errors of law, the district court abused its discretion in denying Takeda's motion for a preliminary injunction.

The arguments that Takeda sets forth in the Mylan Appeal apply equally to the present appeal. The district court incorrectly held that Alkem was likely entitled to launch based on Section 1.2(d) of the

License Agreement, which provides that Alkem may launch its generic product on:

> [t]he 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/or invalid, unpatentable, or unenforceable[.]

Appx83(§ 1.2(d)). In particular, the district court incorrectly held that its summary-judgment decision in the *West-Ward* Litigation triggered Section 1.2(d).

The district court's decision ignores the language of Section 1.2(d), which requires that for ***all*** unexpired claims that were asserted against a third party, there needs to be a holding that those patent claims are not infringed, invalid, or unenforceable. Instead, the district court put forth an interpretation whereby a holding of noninfringement, invalidity, or unenforceability on only a subset of the patents asserted—without a decision one way or the other with respect to the remaining patents—triggers Section 1.2(d).

As in the Mylan Case, the district court in the present case erred as a matter of law in its interpretation of Section 1.2(d). *First*, the

district court's decision rewrites Section 1.2(d) by giving no meaning to the terms "*all* unexpired claims" and "asserted." *Second*, the district court improperly contrasted Section 1.2(d) with other license trigger provisions that included the term Generic Equivalent without consideration of the intent of the parties with respect to those provisions. *Third*, the district court assumed, without basis: (i) that Alkem would not have agreed to a narrow applicability of Section 1.2(d); and (ii) that Takeda would have agreed to the district court's overly broad application of Section 1.2(d). *Fourth*, the district court incorrectly assumed that the intent of Section 1.2(d) was to "open the door for [Alkem]" if Takeda attempted to assert the Patents-in-Suit against third parties and that therefore Takeda's interpretation would render Section 1.2(d) "practically useless" because "it is routine for asserted claims to be dropped." Appx14. The district court's analyses and conclusions miss the intended practical application of Section 1.2(d), which is written to be a very narrow exception to the anticipated, specified date-certain launch date.

With respect to irreparable harm, balance of hardships, and public interest, the License Agreement explicitly provides that Takeda "shall

be entitled to ***immediate injunctive relief*** to prevent Alkem from marketing the Alkem ANDA Product in breach of . . . this License Agreement," and includes an express stipulation "that marketing the Alkem ANDA Product in breach of . . . this License Agreement would cause Takeda irreparable harm." Appx89(§ 1.10) (emphasis added). The district court's decision on irreparable harm is based primarily on its view that Alkem likely did not breach the License Agreement. Appx14-15. Accordingly, once the district court's erroneous legal conclusion that Alkem likely did not breach the License Agreement is corrected, the License Agreement provides that the irreparable-harm, balance-of-hardships, and public-interest factors all favor Takeda. Additionally, even apart from the License Agreement's express stipulation that a breach by Alkem would entitle Takeda to immediate injunctive relief, the irreparable-harm, balance-of-hardships, and public-interest factors weigh decidedly in Takeda's favor. For instance, Alkem has acknowledged that an unauthorized sale of the Alkem ANDA Product would "infringe one or more of the claims of Licensed Patents." Appx87-88(§ 1.8(a)). Alkem further acknowledged that with

respect to the Alkem ANDA Product, the Licensed Patents "are valid and enforceable." Appx87-88(§ 1.8(a)).

For these reasons, Takeda is likely to succeed on the merits of its breach-of-contract and patent-infringement claims, and the additional preliminary-injunction factors overwhelmingly favor Takeda. Therefore, this Court should reverse the district court's denial of Takeda's motion for a preliminary injunction, and remand with instructions that the district court enter a preliminary injunction.

ARGUMENT

I. Legal Standards

"'A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.'" *Trebro Mfg. Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

While this Court reviews decisions to grant or deny a preliminary injunction for an abuse of discretion, this Court reviews underlying issues of law, such as interpretation of a contract, *de novo*. *See e.g.*,

Endo Pharm. Inc. v. Actavis, Inc., 746 F.3d 1371, 1373-74 (Fed. Cir. 2014) (citing *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006)).

II. The District Court Misinterpreted the Contract, and Under the Correct Interpretation Takeda Is Likely to Succeed on the Merits

A. Section 1.2(d) Is Triggered Only When There Is a Final Court Decision Holding *All Asserted* and Adjudicated Claims Not Infringed

1. The License Agreement Allows Alkem to Launch Before the Date-Certain Only Under Limited Circumstances

Takeda agreed to grant Alkem a license to sell the Alkem ANDA Product prior to the expiration of the Patents-in-Suit in exchange for Alkem's agreement to respect Takeda's patents and defer its launch until Alkem's license becomes effective. Alkem's license can become effective based on two types of triggers—(i) the date-certain (Section 1.2(a)); and (ii) conditional triggers that allow Alkem to launch prior to the date-certain if, and only if, certain specific events occur (Sections 1.2(b)-(g)). Appx83-85(§§ 1.2(a)-(g)).

Read in context, it is clear that the foregoing triggering provisions were included in the License Agreement to allow Alkem to launch if

there is a change in the status quo with respect to the Colcrys® market or with respect to the status of the Patents-in-Suit.

2. The Circumstances Allowing Alkem to Launch Under Section 1.2(d) Have Not Been Met

Section 1.2(d) requires a final decision holding that all of the unexpired claims of the Patents-in-Suit that were asserted and adjudicated are either (i) "not infringed" or (ii) "any combination of not infringed and/or invalid, unpatentable, or unenforceable." Appx83 (§ 1.2(d)). The *West-Ward* Litigation does not satisfy Section 1.2(d) because not all the claims that were asserted in that case were held to be not infringed or a combination of not infringed, invalid, or unenforceable by a Final Court Decision.

A Final Court Decision that can trigger Section 1.2(d) is limited in several respects, i.e., not all Final Court Decisions relating to Patents-in-Suit will trigger Section 1.2(d). The Final Court Decision must include a "holding" with regard to "all unexpired claims of the Licensed Patents that were asserted and adjudicated." Appx83(§ 1.2(d)). Additionally, with regard to all such asserted and adjudicated patent claims, the Final Court Decision must hold that all such claims are

either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable.

The summary-judgment decision in the *West-Ward* Litigation is not a Final Court Decision that meets the requirements of Section 1.2(d). In the *West-Ward* Litigation, of the eight Patents-in-Suit that "were asserted" by Takeda against Hikma, the court found that Hikma did not infringe ***only*** three of the asserted patents. Critically, for the five other patents there was no holding whatsoever; neither the summary-judgment decision nor any other decision reached any conclusion concerning noninfringement, invalidity, or unenforceability of those five asserted patents. Thus, the summary-judgment decision in the *West-Ward* Litigation is not a Final Court Decision holding *all* unexpired claims not infringed or a combination of not infringed, invalid, or unenforceable, as required by Section 1.2(d).[5]

[5] Hikma, the defendant in the *West-Ward* Litigation, agrees with Takeda that these five patents were not subject to an adjudication of noninfringement, invalidity, or unenforceability. *See* Alkem Appeal, ECF No. 30 at 4-5. Hikma moved to file an amicus brief in support of Takeda's emergency motion in the present case (Alkem Appeal, ECF No. 23-1 at 2-3). Hikma also moved for leave to file amicus curiae briefs in the Mylan Appeal, ECF Nos. 18 and 39. This Court granted Hikma leave to file an amicus brief in support of Takeda's emergency motion in the Mylan Appeal. Mylan Appeal, ECF No. 37. This Court

The stipulated dismissal of five of the asserted patents is not a Final Court Decision of noninfringement, invalidity, or unenforceability. Rather, those five patents were subject to a ***jointly agreed upon*** voluntary dismissal with prejudice. A voluntary dismissal with prejudice constitutes an adjudication solely for claim preclusion and not issue preclusion and "[does] not decide any specific issue at all." *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1372-73 (Fed. Cir. 2013). Indeed, that the stipulation failed to decide the issue of infringement or noninfringement is illustrated by the fact that the ***jointly agreed upon*** dismissal also included a dismissal—with prejudice—of all of Hikma's counterclaims and defenses of noninfringement, invalidity, and unenforceability. Appx1321-1324. Simply put, all parties to the *West-Ward* Litigation agreed that the issue of infringement (or noninfringement) of these five patents would not be decided one way or the other.

In sum, even assuming that the voluntary dismissal is regarded as an "adjudication" of some sort, the voluntary dismissal did not trigger

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granted Hikma leave to file an amicus brief in support of Takeda's appeal in the Mylan Appeal. Mylan Appeal, ECF No. 64. Hikma's other motion remains pending.

Section 1.2(d), because Section 1.2(d) comes into play only when there is a "holding" of noninfringement, invalidity, or unenforceability concerning "all unexpired claims of the Licensed Patents." Appx83(§ 1.2(d)). As explained in detail above, there was no such "holding" for five of the eight asserted patents in the *West-Ward* Litigation. The failure of the stipulation to decide the issues of noninfringement, invalidity, and unenforceability for these five patents conclusively establishes that the *West-Ward* Litigation did not trigger Section 1.2(d).

Because there was no Final Court Decision in the *West-Ward* Litigation holding *all* unexpired asserted claims not infringed, invalid, or unenforceable, the requirements of Section 1.2(d) have not been met.

3. The Clear Intent of the Parties Was that the *West-Ward* Litigation Would Not Trigger Section 1.2(d)

As Judge Newman noted, "'[w]hen interpreting a contract, the role of a court is to effectuate the parties' intent.'" Alkem Appeal, ECF No. 33 at 5 (Newman, J., dissenting) (quoting *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006)). While Section 1.2(d) does not expressly exclude a litigation that does not involve a generic Colcrys® product, it is clear that the license triggers, including Section 1.2(d), were intended 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. When Alkem and Takeda settled their litigation, Mitigare® was already on the market. Thus, it defies common sense to suggest that Takeda and Alkem expected or intended that the decision in the *West-Ward* Litigation, for a product that was already on the market and had been on the market even prior to Alkem's ANDA filing, could trigger Alkem's license. The district court's decision in the *West-Ward* Litigation holding only three of the Patents-in-Suit (that Alkem agreed were valid and enforceable, and infringed by the Alkem ANDA Product), to be not infringed by Mitigare® (which is neither a generic Colcrys® product nor AB-rated to Colcrys®) changed absolutely nothing. The Colcrys® market was not altered by the results of the *West-Ward* Litigation, and the status of Patents-in-Suit—which Alkem admitted were (i) infringed by the Alkem ANDA Product and (ii) valid and enforceable—remained unaffected.

The correct interpretation of Section 1.2(d)—where the *West-Ward* Litigation would not trigger Alkem's license—does not adversely impact Alkem's expected benefit under the License Agreement. Section 1.2(d) and the other license triggers need to be understood in the context in

which the Takeda-Alkem settlement was reached. At the time of the settlement with Alkem, Takeda had already settled with the Earlier Filers. "Par," "Watson," and "Amneal" are each defined terms in the License Agreement and are referenced throughout. Appx96; Appx99-100. For example, the Earlier Filers are explicitly excluded from the "Most Favored Nation" provision ("MFN"). Appx86-87(§ 1.5). Alkem specifically acknowledged those earlier settlements, and in the MFN provision acknowledged that the agreements with the Earlier Filers were on better terms than those granted to Alkem. Appx86-87(§ 1.5).

The License Agreement contemplates that Alkem will be allowed to launch the Alkem ANDA Product at a specified time period after the Earlier Filers launch their generic Colcrys® products, and contemporaneous with the launch of any generic filers other than the Earlier Filers. The district court's decision, if allowed to stand, would subvert the intent of the License Agreement by permitting Alkem to enter the market with the Alkem ANDA Product before the Earlier Filers. *See GMG Capital Inv., LLC. v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 779 (Del. 2012) ("The meaning inferred from a particular provision cannot control the meaning of the entire agreement

if such an inference conflicts with the agreement's overall scheme or plan.").

B. The District Court's Decision Is Premised on Several Errors of Law

1. The District Court's Interpretation of Section 1.2(d) Gives No Meaning to the Terms "all" or "asserted"

In concluding that "only [the three patents subject to the summary-judgment decision in the *West-Ward* Litigation] matter for purposes of Section 1.2(d)" (Appx12-13), the district court read out the requirement that Section 1.2(d) is triggered only when "all" asserted patents are adjudicated to be either not infringed or a combination of not infringed, invalid, or unenforceable. The district court's decision, while citing to the "asserted and adjudicated" language, effectively gives meaning only to "adjudicated." It fails to give meaning to the phase "asserted and adjudicated" and ignores the term "all." This is particularly disturbing in view of the district court's statement that "Section 1.2(d) applies to patent claims that were 'asserted and adjudicated[.]'" Appx12. Under the district court's interpretation, any Final Court Decision holding that the patents being adjudicated were not infringed, invalid, or unenforceable would trigger Alkem's license

under Section 1.2(d), regardless of whether there were other patents asserted in the litigation. As such, Section 1.2(d) would have the same meaning whether or not the terms "all" or "asserted" were in the provision. In so doing, the district court violated the fundamental principle that a court "will not read a contract to render a provision or term 'meaningless or illusory.'" *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citation omitted).

Under the district court's interpretation, regardless of what patents and claims are asserted in the litigation, the only thing that needs to be determined is whether any claims that were adjudicated in the underlying litigation were found not infringed, invalid, or unenforceable. What was actually asserted in the underlying litigation has no relevance according to the district court; this improperly renders the term "asserted" superfluous.

In contrast, the clear and unambiguous language of the Settlement Agreement requires looking at both what was asserted and what was adjudicated in the underlying litigation—requiring that all patents that were asserted in the underlying litigation must also be adjudicated as not infringed, invalid, or unenforceable. Takeda's

interpretation of Section 1.2(d) does not, as the district court implied (Appx12), change the phrase "asserted *and* adjudicated" to "asserted *or* adjudicated." Rather, Takeda's interpretation requires that all of the unexpired "asserted" claims must also be "adjudicated" to a "holding" of "(i) not infringed, or (ii) any combination of not infringed and/or invalid, unpatentable, or unenforceable" in order for Section 1.2(d) to be triggered. In the *West-Ward* Litigation, eight patents were asserted, but only three of the eight patents were adjudicated to a holding of noninfringement. With respect to the remaining five patents, there was no holding one way or the other regarding noninfringement, invalidity, or unenforceability. Therefore, Alkem's license was not triggered.

2. The District Court Incorrectly Drew Parallels Between Section 1.2(d) and Other License Triggers Without Recognizing Key Distinctions

The district court also based its decision on the fact that other trigger provisions, namely Sections 1.2(b) and 1.2(f), specifically mention Generic Equivalents,[6] purportedly evidencing the parties' intent that Section 1.2(d) was not to be limited to Generic Equivalents. Appx13. This point fails to recognize a key distinction between Section

[6] "Generic Equivalent" is defined in the License Agreement as a AB-rated generic version of Colcrys® see further definition in Appx97.

1.2(d) and those other triggers. In particular, Sections 1.2(b) and 1.2(f) address scenarios where products are actually coming to market. Appx83-84(§§ 1.2(b), 1.2(f)). In such circumstances, it makes sense that the applicability of those triggers is limited to Generic Equivalents, since the purpose of those provisions was to allow Alkem to: (i) enter the market if there was a change in the status quo with respect to its generic competitors; and (ii) launch if its competitors entered the market. In contrast, Sections 1.2(d) and 1.2(g), which both deal with Final Court Decisions, do not require a product to be coming on the market, because they serve a different purpose. Appx83-85(§§ 1.2(d), 1.2(g)). Those sections are intended instead to address circumstances where there was a change to the status quo with respect to the Patents-in-Suit such that the claims that Alkem agreed are infringed, and valid and enforceable by the Alkem ANDA Product, were found not infringed, invalid, or unenforceable. In such circumstances, the parties agreed that Alkem would be permitted to enter the market. However, if anything less than all of the asserted claims were adjudicated to be not infringed, invalid, or unenforceable, Alkem would not be permitted to enter the market by way of Section 1.2(d). Furthermore, because

Sections 1.2(d) and 1.2(g) do not address scenarios where a generic competitor is coming to market, the parties agreed to a narrow applicability of Section 1.2(d), which did not need to be further narrowed by including the term "Generic Equivalents." In the circumstance where a Final Court Decision led to generic competitors coming to market, Alkem was protected by other license triggers (e.g., Sections 1.2(b), 1.2(f)) and was therefore willing to agree to the narrow applicability of Section 1.2(d).

3. There Is Nothing in the Record that Supports the District Court's Assumption that Alkem Would Not Have Agreed to Section 1.2(d) Under Takeda's Interpretation

As in the Mylan Case, the district court assumed, without basis, that Alkem would not have agreed to a narrow applicability of Section 1.2(d). The corollary to that assumption, also without any basis, is that Takeda would have agreed to the district court's exceedingly broad interpretation of Section 1.2(d).

Contrary to the district court's conclusion, there are clear, concrete reasons why Section 1.2(d) was written to require that all claims that were asserted in the applicable litigation be adjudicated. For example, the Hatch-Waxman Act, in relevant part, permits a final

judgment to terminate the 30-month stay only if it includes 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). As such, if some of the patents asserted in the action were voluntarily dismissed from the action, there would be no substantive determination regarding such patents, because the district court would not have reached a conclusion concerning noninfringement, invalidity, or unenforceability. A voluntary dismissal of patents would not lift a 30-month stay. In contrast, a determination of noninfringement, invalidity, or unenforceability of all asserted patents—as required by Section 1.2(d)—would lift the 30-month stay.

Case law and FDA decisions—consistent with plain language of the Hatch-Waxman Act—have recognized that a 30-month stay does not end when a case is terminated without a substantive determination. For example, it was found that a 30-month stay was not extinguished when a patent-infringement complaint was dismissed without prejudice for lack of standing. *See Endo Pharm. Inc. v. Mylan Techs. Inc.*, No. 11-220-GMS, 2013 WL 936452, at *4-5 (D. Del. Mar. 11, 2013) (Appx1356-1357). In so finding, the court concluded that the explicit language of

§ 355(j)(5)(B)(iii)(I) precluded a holding that a 30-month stay could be terminated by a court decision that did not address the merits of the patent-infringement claim. Similarly, the FDA—in a 2015 memorandum decision (*see* Mylan Appeal, ECF No. 26-2)—concluded that a 30-month stay was not terminated where the patent-infringement suit was dismissed on jurisdictional grounds, without a substantive determination regarding patent infringement. *See also Sanofi-Aventis v. FDA*, 725 F. Supp. 2d 92, 98 (D.D.C. 2010) (finding that a 30-month stay is terminated by the entry of judgment by a district court).

Section 1.2(d) of the License Agreement requires a holding with respect to all of the asserted patents of noninfringement, invalidity, or unenforceability—a substantive determination under the Hatch-Waxman Act. In the absence of such a substantive determination, the 30-month stay would remain in force,[7] even if there were a final judgment holding less than all of the Orange Book listed patents to be not infringed. To avoid a scenario where Alkem's license could be triggered by a third party that could not come to market because it is

[7] Takeda and Alkem entered into the License Agreement less than six months into Alkem's 30-month stay.

still subject to a 30-month stay, Takeda and Alkem agreed that ***all*** asserted patents must be adjudicated.

Against this backdrop, it is entirely sensible to conclude—contrary to the district court—that Alkem agreed to Section 1.2(d), as interpreted by Takeda.

In addition to erroneously concluding that Alkem would not have agreed to Section 1.2(d) as interpreted by Takeda, the district court ignored that the interpretation advocated by Alkem (and accepted by the district court) results in a very broad applicability of Section 1.2(d), beyond anything that Takeda would have accepted. For example, if a generic-colchicine ANDA is filed seeking a dosing regimen identical to the regimen for Colcrys®, then Takeda, based on such information, can assert infringement of all seventeen Patents-in-Suit. The generic applicant could subsequently amend its label by changing the dosing regimen (possibly affecting FDA approvability) in an effort to avoid infringing some of the Patents-in-Suit. In view of such a change, Takeda and the generic applicant may come to an agreement stipulating to a dismissal of the no-longer-applicable Patents-in-Suit. If the remaining Patents-in-Suit are subsequently found not infringed in a

Final Court Decision, then according to the district court's interpretation, Alkem's license could be triggered by a generic product that is unable to obtain FDA approval. Such a scenario, where a non-approvable-generic product would trigger Alkem's license, even though it will never be sold and never have any impact on the generic Colcrys® market, is illogical. Alkem never would have demanded that such non-approved product is a trigger and that it be able to launch, nor would Takeda have agreed to give up its patent rights in such circumstance where there has been no change to the status quo. This scenario, as well as others, highlight the reason Takeda insisted on a narrow breadth for Section 1.2(d).

The district court fails to give any rationale for why Takeda would agree on a launch trigger that has such broad applicability and would allow Alkem to launch based on circumstances that have no effect on the status quo, the Colcrys® market, or the Patents-in-Suit.

4. The District Court Erred in Determining that Takeda's Interpretation of Section 1.2(d) Would Render the Provision "practically useless"

The district court wrongly found that Takeda's interpretation would render Section 1.2(d) "practically useless" because "it is routine

for asserted claims to be dropped." Appx14. Rather, it is the district court's interpretation that renders practically useless Alkem's admissions as to the infringement, validity, and enforceability of all the Patents-in-Suit in Section 1.8. Section 1.2(d) was drafted to address a very particular circumstance (i.e., a change to the generic Colcrys® market caused by a holding with respect to the Patents-in-Suit), because only that particular circumstance would call into question Alkem's admissions to validity and infringement of all the Patents-in-Suit.

In concluding otherwise, the district court rejected Takeda's interpretation of Section 1.2(d) because: (i) Takeda's reading "would make it trivially easy for Takeda to avoid triggering Section 1.2(d)" because Takeda could simply "assert all seventeen Colcrys patents against a third party, and then simply withdraw one patent (or one claim of one patent) early in litigation"; and (ii) "it is routine for asserted claims to be dropped throughout the course of patent litigation" and Takeda's reading would therefore render Section 1.2(d) "a practically useless provision." Appx14. This conclusion is erroneous.

The outcome of the *West-Ward* Litigation does not satisfy the requirements of Section 1.2(d) because the parties to that litigation ***jointly agreed*** to dismiss five of the patents, including Hikma's defenses and counterclaims. Absent Hikma's agreement to dismissal, all of the asserted patents in the *West-Ward* Litigation could have been adjudicated, potentially triggering Alkem's license under Section 1.2(d). *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). This is true because once an answer or summary-judgment motion has been filed, a plaintiff can obtain a voluntary dismissal only "on terms that the court considers proper." Fed. R. Civ. P. 41(a)(2). Moreover, where a defendant has pleaded a counterclaim prior to being served with a plaintiff's motion to dismiss, "the action may be dismissed over the defendant's objection only if the counterclaim can remain pending for independent adjudication." *Id.* Therefore, it was incorrect for the district court to assume that Takeda could unilaterally drop patents from a litigation or that a defendant would agree to a voluntary dismissal. In fact, the district court's suggestion that Takeda could unilaterally avoid the triggering of Section 1.2(d) is

contrary to this Court's precedent, which recognizes district courts' continuing ability to adjudicate issues of noninfringement, invalidity, and unenforceability where FDA issues are at play. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1296-97 (Fed. Cir. 2008) (concluding that a district court has jurisdiction over a generic company's request for declaratory judgment of noninfringement despite a unilateral covenant not to sue, where the judgment would eliminate barriers under the Hatch-Waxman Act); *see also Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1362-66 (Fed. Cir. 2015) (finding that there was standing for a generic company to seek a judgment of noninfringement even after the patent was statutorily disclaimed, where securing such a judgment was necessary to trigger a forfeiture provision under the Hatch-Waxman Act).

Accordingly, given the Federal Rules of Civil Procedure and this Court's precedent, the district court erred in assuming that Takeda can unilaterally drop patents or patent claims from a case.

The district court's reasoning also ignores that many ANDA applicants, as a condition to agreeing to remove a subset of patents from litigation, insist upon an affirmative judgment of noninfringement to

ensure that the dismissed patents do not remain barriers to the termination of the 30-month stay or to trigger a first-filer's 180-day exclusivity. Accordingly, because the License Agreement was entered into with Hatch-Waxman Act litigations firmly in mind, Takeda's interpretation is the proper reading of Section 1.2(d).

Contrary to the district court's conclusion, which mirrors its decision in the Mylan Case, Takeda's interpretation of Section 1.2(d) does not "mean, as a practical matter, attempts by Takeda to enforce its Colcrys patents would never risk a loss that could open the door for [Alkem]." Appx14. The district court's opinion assumes, without any factual basis, that Takeda would choose to stop asserting all the patents available to it to prevent a generic Colcrys® product from coming to the market in order to manipulate a result that would not trigger Section 1.2(d). Moreover, it also assumes—incorrectly—that defendants would routinely agree to a dismissal of a subset of claims without any substantive ruling on their defenses or counterclaims of noninfringement, invalidity, or unenforceability.

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

A. Alkem's Express Contractual Stipulation that Any Breach of the License Agreement Would Entitle Takeda to Immediate Injunctive Relief Demonstrates that the Remaining Factors Favor Takeda

Because of its erroneous conclusion that "it is unlikely that [Alkem] breached the Agreement," the district court failed to conclude, as required by Section 1.10, that the remaining factors governing injunctive relief weigh dispositively in Takeda's favor. Appx14-15. Section 1.10 provides as follows:

> 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 Alkem from marketing the Alkem ANDA Product in breach of Paragraphs 1.2 and 1.4 of this License Agreement. Alkem acknowledges that marketing the Alkem ANDA Product in breach of Paragraph 1.2 of this License Agreement **would cause Takeda irreparable harm**.

Appx89(§ 1.10) (emphasis added).

"Under Delaware law, 'contractual stipulations as to irreparable harm alone suffice to establish that element for the purpose of issuing preliminary injunctive relief.'" *TP Group-CI, Inc. v. Vetecnik*, No. 16-623-RGA, 2016 WL 5864030, at *2 (D. Del. Oct. 6, 2016) (Appx1368)

(quoting *Cirrus Holding Co.*, 794 A.2d at 1209); *see also* Alkem Appeal, ECF No. 33 at 5 (Newman, J., dissenting) (recognizing that the License Agreement "strongly support[s] Takeda's request for interim action to preserve the status quo"). Section 1.10 of the License Agreement sets forth Alkem's unambiguous stipulation that the marketing of the Alkem ANDA Product in breach of the License Agreement will irreparably harm Takeda and that Takeda is entitled to immediate injunctive relief.

Section 1.10 is decisive: Takeda is entitled to immediate injunctive relief in the event of a breach by Alkem. Therefore, because Alkem has breached the License Agreement, Takeda is entitled to a preliminary injunction. As Judge Newman recognized, "contractual stipulations as to irreparable harm alone suffice to establish that element for the purpose of issuing preliminary injunctive relief." Alkem Appeal, ECF No. 33 at 5 (quoting *Cirrus*, 794 A.2d at 1209).

B. Even Apart from the Stipulation, the Remaining Factors Weigh Decisively in Takeda's Favor

Even in the absence of Section 1.10, the remaining factors would weigh conclusively in Takeda's favor.

As to irreparable harm, each unauthorized sale by Alkem reduces the number of units and the price per unit of the branded and

authorized generic colchicine products that Takeda/Par are able to sell. A launch by Alkem will cause Takeda/Par to incur irreversible price erosion and long-term loss of market share, both of which are irreparable injuries. *See, e.g.*, *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) (recognizing that price erosion and loss of market share can be irreparable injuries).

Maintaining the status quo by granting the injunctive relief sought will have little or no adverse effect on Alkem. *First*, even Alkem admits it only had a single sale of the Alkem ANDA Product. Alkem Appeal, ECF No. 27 at 17 (referencing "***the sale***" it had to recall). *Second*, Alkem acknowledged it has only a "limited amount of inventory" remaining. Appx1238 (Tr. 9:13). When assessing the balance of hardships, it is appropriate for courts to consider "the parties' sizes, products, and revenue sources." *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, No. 15-CV-152-RGA, 2019 WL 3322322, at *3 (D. Del. July 24, 2019) (Appx1346) (citing *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862-63 (Fed. Cir. 2010)). Accordingly, any hardship to Alkem is minimal as revenue from such incremental sales would amount to a

very small percentage of Alkem's total revenue. Appx764 ("This year our revenues have crossed the US$ 1 billion mark[.]").

In contrast, the hardship to Takeda absent an injunction will be significant for denial of injunctive relief would pave the way for other generic competitors to come on the market. For instance, in the absence of injunctive relief against Alkem, other generic competitors with whom Takeda settled litigations would assert the right to launch their generic Colcrys® products in the face of Alkem's launch. Appx1241-1242 (Tr. 12:17-13:2).

Accordingly, balance of hardships favors Takeda here, as a preliminary injunction would maintain the status i.e., a colchicine market where no generic Colcrys® product was on the market. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (affirming the grant of a preliminary injunction where such an injunction would maintain the status quo). Takeda is merely seeking injunctive relief while the court determines whether Alkem's license to sell the Alkem ANDA Product has become effective at this time.

The public interests at issue in this case indisputably favor enforcing the parties' Settlement and License Agreement and Takeda's patent rights.

Alkem has acknowledged that the sale of the Alkem ANDA Product, "unless pursuant to the License granted by Takeda," would "infringe one or more of the claims of [Takeda's] Patents." Appx87-88 (§ 1.8(a)). Alkem has further acknowledged that with respect to the Alkem ANDA Product, the Licensed Patents "are valid and enforceable." Appx87-88(§ 1.8(a)). This Court has long recognized a strong public interest in enforcing valid patent rights. *See, e.g.*, *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) ("We have long acknowledged the importance of the patent system in encouraging innovation.").

This Court has also recognized the important public interest in enforcing private contracts, particularly settlement agreements. *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."); *TP Group-CI,* 2016 WL 5864030, at *3

(Appx1368) ("The public interests at issue in this case are enforcing private contracts . . . .").

Alkem cannot plausibly argue that any critical public interest favors allowing an admittedly infringing generic version of Takeda's Colcrys® to enter the market in breach of a settlement before the effective date of Alkem's license.

CONCLUSION

For at least the reasons expressed above, 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: March 27, 2020

By: /s/ Edgar H. Haug

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ADDENDUM

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC.,	:	
Plaintiff,	:	
v.	:	Civil Action No. 20-325-RGA
ALKEM LABORATORIES LIMITED, et al.,	:	
Defendants.	:	

ORDER

After consideration of the briefs (D.I. 7, 17) and discussion at a hearing on March 5, 2020, including acknowledgment of the related case, *Takeda v. Mylan*, Civ. Act. No. 19-2216-RGA (D. Del.), now on appeal to the Court of Appeals for the Federal Circuit, No. 20-1407,

IT IS HEREBY ORDERED this 5 day of March that:

1. For the reasons stated in *Takeda v. Mylan*, No. 19-2216-RGA, D.I. 114 (D. Del.)., the motion for a temporary restraining order and a preliminary injunction (D.I. 6) is DENIED.

2. As Plaintiff has indicated its intent to appeal this Order, and to seek immediate relief in the Court of Appeals, Defendants are ORDERED to maintain the status quo until the end of the day March 12, 2020. As stated at the hearing, the status quo 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.

Richard G. Andrews
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. MYLAN PHARMACEUTICALS, INC., Defendant.	Civil Action No. 19-2216-RGA

MEMORANDUM ORDER

Currently before the Court is Plaintiff Takeda Pharmaceuticals U.S.A., Inc.'s Motion for a Preliminary Injunction to prohibit Defendant Mylan Pharmaceuticals Inc. from launching a generic version of the drug Colcrys. (D.I. 12). The matter has been fully briefed. (D.I. 13, D.I. 91, D.I. 101). I heard oral argument on January 21, 2020. Because Plaintiff has failed to show it is likely to succeed on the merits or that it will suffer irreparable harm, the Motion is DENIED.

I. BACKGROUND

Colcrys, a branded version of the drug colchicine, is approved by the Food and Drug Administration (FDA) to treat and prevent gout flares and familial Mediterranean fever. (D.I. 15, Ex. 2). Takeda has seventeen patents listed for Colcrys in the FDA's "Orange Book." (D.I. 15, Ex. 4). In 2016, Mylan filed an Abbreviated New Drug Application (ANDA) with the FDA, seeking approval of a generic colchicine product. (D.I. 92, Meckstroth Decl., ¶ 6). Based on that filing, Takeda sued Mylan for infringement of its seventeen Colcrys patents. *Takeda*

Pharmaceuticals U.S.A., Inc.v. Mylan Pharmaceuticals Inc., No. 16-cv-987-RGA. The parties settled their lawsuit on November 7, 2017.

As part of that settlement, the parties signed a License Agreement, which allows Mylan to sell a generic colchicine product, but only after a specified date. (D.I. 15, Ex. 1, "Agreement.") Section 1.2 provides several situations, however, in which Mylan can launch its generic product before that date. Section 1.2(d) states that Mylan is entitled to launch a generic at:

> 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;

(*Id.*). 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." (*Id.*). The "Licensed Patents" include the seventeen Colcrys Orange Book patents Takeda had asserted against Mylan. (*Id.*). A "Third Party" is a "Person other than a Party or an Affiliate of a Party." (*Id.*).

According to Mylan, Section 1.2(d) was triggered by my decision in a separate case, *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA. In that litigation, Takeda asserted eight of its Colcrys patents against West-Ward, but, during summary judgment briefing, it indicated it was "willing" to dismiss five of them (No. 14-cv-1268-RGA, D.I. 361 at 1 n.2), which it did "with prejudice" a few weeks later. (*Id.*, D.I. 376). I granted summary judgment of non-infringement on the remaining three patents. 2018 WL 6521922 (D. Del. Dec. 12, 2018). There was no appeal.

On October 28, 2019, Mylan notified Takeda that it planned to "immediately start selling" a generic colchicine product "pursuant to the Parties' November 7, 2017 license

agreement (Section 1.2(d))." (D.I. 15, Ex. 11). Takeda sued Mylan on December 2, 2019 for patent infringement and breach of contract. (D.I. 2). Takeda filed this Motion for a Preliminary Injunction three days later, seeking to enjoin Mylan and anyone acting on Mylan's behalf from: "(1) commercially manufacturing, using, offering to sell, or selling within the United States its generic version of Takeda's oral single-active-ingredient colchicine brand drug Colcrys® (the 'Mylan ANDA Product'); (2) entering into and/or continuing discussions with current customers and potential customers regarding the availability of the Mylan ANDA Product; and (3) distributing or shipping the Mylan ANDA Product to customers." (D.I. 12). The parties agreed to a stipulation about further sales and distribution of the "Mylan ANDA Product" pending these proceedings. (D.I. 7 at 2).

II. LEGAL STANDARD

"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 v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "A preliminary injunction is an extraordinary remedy never awarded as of right." *Id.* at 24.

III. DISCUSSION

Takeda has failed to show it is likely to succeed on the merits. The critical issue here is whether Section 1.2(d) of the License Agreement permits Mylan to launch its generic colchicine product. The provision applies to a "Final Court Decision," which is defined as "a final judgment from which no appeal . . . has been or can be taken." In *West-Ward*, I granted summary judgment

for the defendant, and Takeda did not appeal within 30 days. That decision is therefore a final judgment, from which appeal is no longer possible. Fed. R. Civ. P. 4(a)(1)(A). It is undisputed that my summary judgment decision in *West-Ward* was a "Final Court Decision." It is also undisputed that Mylan has satisfied the provision's waiting period.

Section 1.2(d) applies if the "Final Court Decision" found the patents were "either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable." In *West-Ward,* I granted summary judgment because a reasonable jury could not have found that the defendant had induced infringement of the three Colcrys patents at issue. *West-Ward*, 2018 WL 6521922, at *6. Therefore, for purposes of Section 1.2(d), my *West-Ward* ruling was a "Final Court Decision" holding that those three patents were "not infringed." Takeda does not dispute this conclusion. (*See* D.I. 13 at 11-12).

Takeda argues nevertheless that the *West-Ward* decision did not trigger Section 1.2(d) because I only ruled on the three patents that were still at issue, and not on the other five that Takeda had dismissed with prejudice. (*Id.*). For Section 1.2(d) to apply, a court must find that "all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are" not infringed or invalid. According to Takeda, only three patents were "adjudicated," while a total of eight were "asserted." (D.I. 13 at 11.). Therefore, Takeda reasons, the summary judgment decision did not cover "all" unexpired claims of the Licensed Patents at issue. (*Id.*)

I do not think this is a correct reading of the Agreement. Section 1.2(d) applies to patent claims that were "asserted *and* adjudicated," not to patent claims that were "asserted *or* adjudicated." In *West-Ward*, claims from eight patents were "asserted," but claims from only three patents were "asserted and adjudicated." Thus, only those three patents matter for purposes

of Section 1.2(d). Of the three patents that were "asserted and adjudicated" in *West-Ward*, "all" of their unexpired claims were found not infringed. That decision thus triggered Section 1.2(d), which "entitle[s]" Mylan to launch a generic version of Colcrys. I conclude therefore that Takeda has not shown it is likely to succeed on the merits of its patent infringement or breach of contract claims.

Takeda argues that this reading of the Agreement conflicts with the intent of the parties. (D.I. 13 at 12-13). According to Takeda, the purpose of Section 1.2(d) was to ensure Mylan could enter the market if there was some change to the status quo that allowed the launch of other generic Colcrys products. (*Id.* at 12). Takeda asserts that Mitigare, the drug in dispute in *West-Ward*, is not a generic version of Colcrys, and therefore the parties did not envision that a judgment involving Mitigare could trigger Section 1.2(d). (*Id.*). Mylan notes that Mitigare, like Colcrys, is a 0.6 mg colchicine product. (D.I. 91 at 13). While it is undisputed that Mitigare is not a generic version of Colcrys, it does not follow that the language of the contract, as understood by an objective, reasonable third party, requires that Section 1.2(d) is limited to litigation over the possible introduction of generic Colcrys products. *See Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1267 (Del. 2017) ("[B]ecause Delaware adheres to an objective theory of contracts, the contract's construction should be that which would be understood by an objective, reasonable third party."). Section 1.2(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. The parties therefore clearly knew how to condition provisions of the contract on the launch of generic Colcrys products, but they chose not to condition Section 1.2(d) in such a way.

West-Ward is a "Third Party" for purposes of Section 1.2(d). The Agreement defines a "Third Party" as a "Person other than a Party or an Affiliate of a Party," i.e., Takeda or Mylan. Section 1.2(d) is therefore not limited to situations where Takeda has sued claiming that a generic version of Colcrys infringes some or all of the Licensed Patents. The "Third Party" does not have to be another generic drug competitor. Rather, the provision can be triggered by a Takeda lawsuit against any entity other than Mylan or its affiliates.

Takeda's interpretation would make it trivially easy for Takeda to avoid triggering Section 1.2(d). Takeda could assert all seventeen Colcrys patents against a third party, and then simply withdraw one patent (or one claim of one patent) early in litigation. But even aside from the possibility of such gamesmanship, it is routine for asserted claims to be dropped throughout the course of patent litigation. Takeda's reading of the provision would mean, as a practical matter, attempts by Takeda to enforce its Colcrys patents would never risk a loss that could open the door for Mylan. It seems unlikely that Mylan would have bargained for a practically useless provision. *See Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) ("We will not read a contract to render a provision or term meaningless or illusory.").

Takeda's primary argument for irreparable harm depends on its showing that it is likely to succeed on the merits. (D.I. 13 at 14). Specifically, Takeda cites Section 1.10 of the Agreement, which stipulates that a breach of the Agreement would cause irreparable harm. Because it is unlikely that Mylan breached the Agreement, however, this stipulation is unlikely to be effective. Without consideration of Section 1.10, I do not find that Takeda has shown it will suffer irreparable harm absent a preliminary injunction. Money damages would remedy any harm Takeda will suffer as a result of Mylan launching its product. *See Frank's GMC Truck Ctr., Inc. v.*

Gen. Motors Corp., 847 F.2d 100, 102 (3d Cir. 1988) ("The availability of adequate monetary damages belies a claim of irreparable injury."). I do not think calculating Takeda's damages would be any more difficult than in the usual patent case. Claims of price erosion are not compelling when it appears to be undisputed that that even if Mylan does not enter the market now, other generics will soon do so. By the time there would be any trial for damages, there will be plenty of actual data about how the market reacted to generic entry.

Because Takeda has failed to show that it is likely to succeed on the merits or that it will suffer irreparable harm, it is unnecessary to analyze the remaining factors of the preliminary injunction standard. "A movant must demonstrate both a likelihood of success on the merits and the probability of irreparable harm if relief is not granted. We cannot sustain a preliminary injunction where either or both of these prerequisites are absent." *Id.* (cleaned up).

IV. CONCLUSION

For these reasons, Plaintiff's Motion for a Preliminary Injunction is DENIED. For the same reasons that I do not grant the preliminary injunction, I do not grant any stay pending appeal, except that, in order to give Plaintiff an opportunity to seek immediate relief in the Court of Appeals, if it so chooses, Defendant is ORDERED to maintain the status quo until end of the day January 31, 2020.

IT IS SO ORDERED this 27 day of January, 2020.

United States District Judge

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Rev. 12/16

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Counsel for Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc.

March 27, 2020

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