20-1407, -1417

United States Court of Appeals for the Federal Circuit

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

v.

MYLAN PHARMACEUTICALS INC.,
Defendant - Appellee.

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

BRIEF FOR PLAINTIFF-APPELLANT

Edgar H. Haug
Porter F. Fleming
Jonathan A. Herstoff
Camille Y. Turner
HAUG PARTNERS LLP
745 Fifth Avenue, 10th Floor
New York, New York 10151
(212) 588-0800
ehaug@haugpartners.com

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

February 19, 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.** Mylan Pharmaceuticals Inc.

Case No. 2020-1407

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, Drinker Biddle & Reath LLP
Thatcher Rahmeier, Drinker Biddle & Reath LLP
Nicholas Giove, Haug Partners 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 Pharmaceuticals Inc., No. 2020-1417 (Fed. Cir.)
Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc., No. 1:19-cv-02216-RGA (D. Del.)

2/19/2020
Date

/s/ Edgar H. Haug
Signature of counsel

Please Note: All questions must be answered

Edgar H. Haug
Printed name of counsel

cc: _____

Reset Fields

TABLE OF CONTENTS

CERTIFICATE OF INTEREST i

TABLE OF AUTHORITIES iv

STATEMENT OF RELATED CASES vii

JURISDICTIONAL STATEMENT 1

STATEMENT OF THE ISSUES 1

STATEMENT OF THE CASE 2

I. Colcrys® 2

II. Colcrys® Generic Patent Litigation and Settlements 3

III. Mitigare® 7

IV. Mylan's Early Launch of the Mylan ANDA Product 9

SUMMARY OF THE ARGUMENT 11

ARGUMENT 14

I. Legal Standards 14

II. The District Court Misinterpreted the Contract, and Under the Correct Interpretation Takeda Is Likely to Succeed on the Merits 15

A. Section 1.2(d) Is Triggered Only When There Is a Final Court Decision Holding *All Asserted* and Adjudicated Claims Not Infringed 15

1. The License Agreement Allows Mylan to Launch Before the Date-Certain Only Under Limited Circumstances 15

2. The Circumstances Allowing Mylan to Launch Under Section 1.2(d) Have Not Been Met 16

3. The Clear Intent of the Parties Was that the *West-Ward* Litigation Would Not Trigger Section 1.2(d) 19

B. The District Court's Decision Is Premised on Several Errors of Law 22

1. The District Court's Interpretation of Section 1.2(d) Gives No Meaning to the Terms "all" or "asserted" 22

2. The District Court Incorrectly Drew Parallels Between Section 1.2(d) and Other License Triggers Without Recognizing Key Distinctions 24

3. There Is Nothing in the Record that Supports the District Court's Assumption that Mylan Would Not Have Agreed to Section 1.2(d) Under Takeda's Interpretation 26

4. The District Court Erred in Determining that Takeda's Interpretation of Section 1.2(d) Would Render the Provision "practically useless" 30

III. The Remaining Preliminary-Injunction Factors Tip Decidedly in Takeda's Favor 34

A. Mylan'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 34

B. Even Apart from the Stipulation, the Remaining Factors Weigh Decisively in Takeda's Favor 36

CONCLUSION 40

TABLE OF AUTHORITIES

Cases

Apotex, Inc. v. Daiichi Sankyo, Inc.,
781 F.3d 1356 (Fed. Cir. 2015) 33

Aria Diagnostics, Inc. v. Sequenom, Inc.,
726 F.3d 1296 (Fed. Cir. 2013) 36

Bio-Rad Labs., Inc. v. 10X Genomics, Inc.,
No. 15-CV-152-RGA, 2019 WL 3322322
(D. Del. July 24, 2019) 38

Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.,
527 F.3d 1278 (Fed. Cir. 2008) 32

Cirrus Holding Co. v. Cirrus Indus., Inc.,
794 A.2d 1191 (Del. Ch. 2001) 35

Endo Pharm. Inc. v. Actavis, Inc.,
746 F.3d 1371 (Fed. Cir. 2014) 15

Endo Pharm. Inc. v. Mylan Techs. Inc.,
No. 11-220-GMS, 2013 WL 936452
(D. Del. Mar. 11, 2013) 27

GMG Capital Inv., LLC. v. Athenian Venture Partners I, L.P.,
36 A.3d 776 (Del. 2012) 21

Hemstreet v. Spiegel, Inc.,
851 F.2d 348 (Fed. Cir. 1988) 39

i4i Ltd. P'ship v. Microsoft Corp.,
598 F.3d 831 (Fed. Cir. 2010) 38

In re Cyclobenzaprine,
No. 09-2118-SLR, 2011 WL 1980610
(D. Del. May 20, 2011) 38

Kos Pharm., Inc. v. Andrx Corp.,
369 F.3d 700 (3d Cir. 2004) 37

Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.,
719 F.3d 1367 (Fed. Cir. 2013) 18

Osborn ex rel. Osborn v. Kemp,
991 A.2d 1153 (Del. 2010) 23

Sanofi-Aventis v. FDA,
725 F. Supp. 2d 92 (D.D.C. 2010) 28

Sanofi-Synthelabo v. Apotex, Inc.,
470 F.3d 1368 (Fed. Cir. 2006) 15, 39

Temsa Ulasim Araclari Sanayi Ve Ticaret A.S. v. CH Bus Sales, LLC, No. CV 18-698-RGA, 2018 WL 4179456
(D. Del. Aug. 31, 2018) 37

TP Group-CI, Inc. v. Vetecnik,
No. 16-623-RGA, 2016 WL 5864030 (D. Del. Oct. 6, 2016) 35, 39

Trebro Mfg. Inc. v. Firefly Equip., LLC,
748 F.3d 1159 (Fed. Cir. 2014) 15

Winter v. Natural Res. Def. Council, Inc.,
555 U.S. 7 (2008) 15

Statutes

21 U.S.C. § 355(j)(5)(B)(iii)(I) 26, 27

28 U.S.C. § 1292(a)(1) 1

28 U.S.C. § 1292(c)(1) 1

28 U.S.C. § 1331 1

28 U.S.C. § 1332 1

28 U.S.C. § 1338(a) 1

28 U.S.C. § 2107(a) 1

Rules

Fed. R. App. P. 4(a)(1) 1

Fed. R. Civ. P. 41(a)(1)(A)(i) 31

Fed. R. Civ. P. 41(a)(2) 32

STATEMENT OF RELATED CASES

Aside from the district-court proceedings that remain pending in this case, Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is unaware of any other related case pending before this or any other court that will directly affect or be affected by the decision in the pending 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 Defendant-Appellee Mylan Pharmaceuticals Inc. ("Mylan"). On January 27, 2020, the district court entered an order denying Takeda's motion for a preliminary injunction. Takeda timely filed a notice of appeal on January 27, 2020, and an amended notice of appeal on January 28, 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 Mylan to launch its generic colchicine 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 invalid or unenforceable[.]" The district court held that Takeda is unlikely to succeed in its argument that Mylan 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, 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 Mylan 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"). Appx2082(¶ 15); Appx1608. Colcrys® was the first pharmaceutical product approved by the United States Food and Drug Administration ("FDA") that contained colchicine

as the sole active ingredient. Appx2083(¶ 18). 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® Generic Patent Litigation and Settlements

Eleven generic manufacturers submitted Abbreviated New Drug Applications ("ANDAs") seeking to market generic versions of Colcrys®. Appx2093(¶¶ 60-61). Takeda sued each generic manufacturer for patent infringement and subsequently settled the respective litigation against each of these ANDA applicants. Appx2093(¶ 60). 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 Mylan—begins sales of its own generic version of Colcrys®. Appx2093(¶ 62).

The first ANDA was submitted by Par Pharmaceutical, Inc. ("Par"). Appx3410. Takeda sued Par for patent infringement on August

[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"). Appx2083-2088(¶¶ 24-41); Appx116-539.

30, 2013. Appx3410. 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 license to make and distribute Par's ANDA product. Appx3410. Pursuant to those agreements, Par launched its authorized generic Colcrys® product on July 1, 2018, and Takeda receives a percentage of the net profits. Appx3410-3411.

Amneal Pharmaceuticals LLC ("Amneal") and Watson Laboratories, Inc. ("Watson") also filed ANDAs and were subsequently sued for patent infringement by Takeda. Appx3411. Takeda reached settlements with Amneal and Watson, granting both Amneal and Watson non-exclusive 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. Appx3411.

Several months after the Par, Amneal, and Watson litigations were resolved, Takeda filed a complaint for patent infringement against Mylan based on Mylan's submission of ANDA No. 209470 ("the Mylan

ANDA"). *See* Appx2089-2090(¶¶ 45-49). Takeda asserted all of the Patents-in-Suit against Mylan. Appx2090(¶ 49).

In November 2017, Takeda and Mylan executed a settlement agreement ("Settlement Agreement") and an accompanying license agreement ("License Agreement"). Appx74; Appx87. The Settlement Agreement provided that Takeda and Mylan would stipulate to a dismissal of the pending lawsuit without prejudice. Appx75. The License Agreement granted Mylan a non-exclusive license to market the product that is the subject of the Mylan ANDA ("Mylan ANDA Product") in the United States upon the earliest of a number of "Generic Entry Dates." Appx88-90(§§ 1.1 and 1.2). Section 1.2(a) sets forth the first "Generic Entry Date"—a date-certain. Appx88(§ 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. Appx88-90(§§ 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. Appx88(§ 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 Mylan may launch the Mylan 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 invalid or unenforceable[.]

Appx88(§ 1.2(d)).

The License Agreement also contains provisions whereby Mylan admitted to the infringement, validity, and enforceability of all the Patents-in-Suit. Appx93-94(§ 1.8). In Section 1.8 of the License Agreement, Mylan acknowledges with respect to the Mylan 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 Mylan ANDA Product would infringe the Patents-in-Suit unless done pursuant to the License Agreement. Appx93-94(§ 1.8).

[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." Appx102.

Mylan additionally agrees that Takeda "shall be entitled to immediate injunctive relief to prevent Mylan from marketing the Mylan ANDA Product in breach of Sections 1.2 and 1.4 of this License Agreement," and acknowledges that "marketing the Mylan ANDA Product in breach of Section 1.2 of this License Agreement would cause Takeda irreparable harm." Appx94(§ 1.10); Appx3889-3890(91:21-92:1).

After executing the settlement, Takeda and Mylan filed a stipulation voluntarily dismissing the pending litigation. Appx4030-4031. On December 28, 2017, the district court so-ordered that stipulation. Appx4032-4033.

Takeda sued seven additional ANDA applicants for infringement of the Colcrys® Orange Book patents. Appx2093(¶¶ 60-61). Takeda settled all of these cases. Appx2093(¶ 60).

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* Appx3963(¶¶ 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. Appx3413. Further, Mitigare® is a capsule rather than a tablet like Colcrys®. Appx1735. And because Mitigare® is not AB-rated to Colcrys®, a prescription written for Colcrys® is not substitutable for Mitigare® at the pharmacy. Appx3413. The FDA approved Mitigare® in September 2014. Appx1750-1752. Hikma launched Mitigare® and an authorized generic Mitigare® product on October 1, 2014—more than two years before Takeda filed its complaint for patent infringement against Mylan. Appx1750-1752; Appx1755-1756.

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 Mylan. *See* Appx3955-3972.

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* Appx3973-4010. 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. Appx4011-4014. There was no holding of any kind by the district court with respect to any of those five patents. On December 12, 2018, the district court granted Hikma's motion for summary judgment of non-infringement with respect to the remaining three patents: U.S. Patent Nos. 7,964,647; 7,981,938; and 8,415,395. *See* Appx4015-4029.

IV. Mylan's Early Launch of the Mylan ANDA Product

Despite the agreed date-certain launch date in the License Agreement, Mylan, in a letter dated October 28, 2019, notified Takeda that it "intend[ed] to immediately start selling" the Mylan ANDA Product. Appx786. The next day, October 29, 2019, counsel for Takeda responded that Section 1.2(d) had not been triggered by the *West-Ward* Litigation, and provided a detailed explanation of its position. Appx788-789. Mylan did not substantively respond to Takeda's letter, but merely stated that it stood by its initial position. Appx792. Takeda responded again to Mylan on November 5, 2019. Appx794-795. On

November 26, 2019, Takeda received market intelligence that Mylan had shipped Mylan ANDA Product to a major wholesaler and that such product was en route to the wholesaler's distribution center(s). Appx2095(¶ 69). The National Drug Code Directory lists November 25, 2019, as the "Start Marketing Date" for the Mylan ANDA Product. Appx1763-1764. Takeda immediately brought the district-court action.

On January 27, 2020, the district court denied Takeda's motion for a preliminary injunction. *See* Appx16-22. Takeda filed a notice of appeal that same day. Appx3705-3706.[3] 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 pursuant to the cease and desist entered into between the parties) and to allow Takeda time to seek from this Court an injunction pending appeal. Appx22. 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* ECF No. 6-1. On January

[3] The district court later modified its decision to correct a typographical error. Takeda then filed an amended notice of appeal. *See* Appx3741-3742. As of February 19, 2020, the Court consolidated both appeals. ECF No. 33. ("ECF No." refers to documents from this Court's docket.)

29, 2020, this Court granted Takeda's request for an interim injunction. ECF No. 14.

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 district court incorrectly held that Mylan was likely entitled to launch based on Section 1.2(d) of the License Agreement, which provides that Mylan 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 invalid or unenforceable[.]

Appx88(§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).

The district court 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 Mylan 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 Mylan" 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." Appx21. 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 Mylan from marketing the Mylan ANDA Product in breach of . . . this License Agreement," and includes an express stipulation "that marketing the Mylan ANDA Product in breach of . . . this License Agreement would cause Takeda irreparable harm." Appx94(§ 1.10) (emphasis added). The district court's decision on irreparable harm is based primarily on its view that Mylan likely did not breach the License Agreement. Appx21-22. Accordingly, once the district court's erroneous legal conclusion that Mylan 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 Mylan 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, Mylan has acknowledged that an unauthorized sale of the Mylan ANDA Product would "infringe one or more of the claims of Licensed Patents." Appx93(§ 1.8(a)). Mylan further acknowledged that with respect the Mylan ANDA Product, the Licensed Patents "are valid and enforceable." Appx93(§ 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 Mylan to Launch Before the Date-Certain Only Under Limited Circumstances

Takeda agreed to grant Mylan a license to sell the Mylan ANDA Product prior to the expiration of the Patents-in-Suit in exchange for Mylan's agreement to respect Takeda's patents and defer its launch until Mylan's license becomes effective. Mylan'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 Mylan to launch prior to

the date-certain if, and only if, certain specific events occur (Sections 1.2(b)-(g)). Appx88-90(§§ 1.2(a)-(g)).

Read in context, it is clear that the foregoing triggering provisions were included in the License Agreement to allow Mylan to launch if there is a change in the status quo with respect to the colchicine market or with respect to the status of the Patents-in-Suit.

2. The Circumstances Allowing Mylan 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 non-infringed and invalid or unenforceable." Appx88(§ 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." Appx88(§ 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).[4]

[4] Hikma, the only other litigant, agrees with Takeda that these five patents were not subject to an adjudication of noninfringement, invalidity, or unenforceability. *See* Reply Brief For Hikma

The stipulated dismissal of five of the asserted patents is not a Final Court Decision of non-infringement, 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. 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. Accordingly, irrespective of whether the voluntary dismissal is regarded as an "adjudication" for claim-preclusion purposes, the voluntary dismissal did not trigger

---

Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Limited in Support of Motion for Leave to File Brief as Amici Curiae, ECF No. 30 at 4-5.

Section 1.2(d), since it was not a "holding that all unexpired claims of the Licensed Patents . . . are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable." Appx88(§ 1.2(d)). The failure of the stipulation to decide the issues of noninfringement, invalidity, and unenforceability for the 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)

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 Mylan on the market only if there was a change to the status quo either in the market or to the status of the Patents-in-Suit. When Mylan and Takeda settled their litigation, Mitigare® was already on the market. Thus, it defies common sense to suggest that Takeda and Mylan 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 Mylan's ANDA filing, could trigger Mylan's license. The district court's decision in the *West-Ward* Litigation holding only three of the Patents-in-Suit (that Mylan agreed were valid and enforceable, and infringed by the Mylan ANDA Product), to be not infringed by Mitigare® (neither a generic Colcrys® product nor AB-rated to Colcrys®) changed absolutely nothing. The colchicine market was not altered by the results of the *West-Ward* Litigation and the status of Patents-in-Suit—which Mylan admitted were (i) infringed by the Mylan 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 Mylan's license—does not impact Mylan'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-Mylan settlement was reached. At the time of the settlement with Mylan, Takeda had already settled with the Earlier Filers. "Par," "Watson," and "Amneal" are each defined terms in the License Agreement and are referenced throughout. Appx102; Appx105-106. For example, the Earlier Filers are explicitly excluded from the "Most

Favored Nation" provision ("MFN"). Appx91-92(§ 1.5). Mylan 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 Mylan. Appx91-92(§ 1.5).

The License Agreement contemplates that Mylan will be allowed to launch the Mylan 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 Mylan to enter the market with the Mylan 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)" (Appx19-20), 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.'" Appx19. Under the district court's interpretation, any Final Court Decision holding that the patents being adjudicated were not infringed, invalid, or unenforceable would trigger Mylan'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 the 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 renders the term "asserted" superfluous.

In contrast, Takeda's interpretation 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 (Appx19), 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 invalid 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. With respect to the remaining five patents, there was no adjudication at all—let alone an adjudication one way or the either regarding noninfringement, invalidity, or unenforceability. Therefore, Mylan'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,[5] purportedly evidencing the parties' intent that Section 1.2(d) was not to be limited to Generic Equivalents. Appx20. This point fails to recognize a key distinction between Section 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.

[5] "Generic Equivalent" is defined in the License Agreement as a AB-rated generic version of Colcrys® see further definition in Appx103.

Appx88-89(§§ 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 Mylan 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. Appx88-90(§§ 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 Mylan agreed are infringed, and valid and enforceable by the Mylan ANDA Product, were found not infringed, invalid, or unenforceable. In such circumstances, the parties agreed that Mylan 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, Mylan would not be permitted to enter the market. 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, Mylan 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 Mylan Would Not Have Agreed to Section 1.2(d) Under Takeda's Interpretation

The district court assumed, without basis, that Mylan 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) (Appx3940-3941). 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 decision

(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, 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 Mylan's license could be triggered by a third party that could not come to market because it is still subject to a 30-month, Takeda and Mylan agreed that ***all*** asserted patents must be adjudicated.

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

In addition to erroneously concluding that ***Mylan*** would not have agreed to Section 1.2(d) as interpreted by Takeda, the district court ignored that the interpretation advocated by Mylan (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, Mylan'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 Mylan's license, even though it will never be sold and never have any impact on the colchicine

market, is illogical. Mylan would have never 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 Mylan to launch based on circumstances that have no effect on the status quo, the colchicine 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." Appx21. Rather, it is the district court's interpretation that renders practically useless Mylan'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, because only that particular circumstance

would render inappropriate Mylan'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." Appx21. 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 Mylan'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, 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 Mylan." Appx21. 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. Mylan'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 Mylan 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. Appx21-22.

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

Appx94(§ 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) (Appx3953) (quoting *Cirrus Holding Co. v. Cirrus Indus., Inc.*, 794 A.2d 1191, 1209 (Del. Ch. 2001)). Section 1.10 of the License Agreement sets forth Mylan's unambiguous stipulation that the marketing of the Mylan 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 Mylan. Therefore, because Mylan has

breached the License Agreement, Takeda is entitled to a preliminary injunction.

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 Mylan 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. Mylan's sustained launch likely 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). For example, Par confirmed that it has already lost specific customers and sales—and Takeda by extension has already lost significant revenue—by virtue of Mylan diverting customers from Par's authorized generic product to the Mylan ANDA Product. Appx809.

With respect to balance of hardships, Takeda is merely seeking injunctive relief to maintain the status quo pending a determination by

the Court as to whether Mylan's license to sell the Mylan ANDA Product has become effective at this time. Here, the status quo is as it was prior to Mylan's very recent launch-at-risk activity, which Takeda objected to as soon as it learned that Mylan launched. *See Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 729 (3d Cir. 2004) (defining status quo as the "last peaceable, noncontested status of the parties" and finding that the balance-of-hardships factor weighed in favor of plaintiff because it objected to defendant's product before it entered commerce). As such, the balance of hardships favors maintaining the status quo. *See Temsa Ulasim Araclari Sanayi Ve Ticaret A.S. v. CH Bus Sales, LLC*, No. CV 18-698-RGA, 2018 WL 4179456, at *3 (D. Del. Aug. 31, 2018) (Appx3949) ("The balance of hardships favors an injunction because it would simply maintain the status quo.").

Maintaining the status quo by granting the injunctive relief sought herein will have little or no adverse effect on Mylan. At most, Mylan's revenues and profits from the Mylan ANDA Product would await the date-certain under Section 1.2(a) of the License Agreement. The market for the Mylan ANDA Product will not disappear or be materially changed. *In re Cyclobenzaprine*, No. 09-2118-SLR, 2011 U.S.

Dist. LEXIS 54062, at *10 (D. Del. May 20, 2011) (Appx3945) ("[T]here will always be a public that is willing to purchase a generic version of a branded drug."). For Mylan, as a large pharmaceutical company, generic Colcrys® would be only one more product in a broad product line. Mylan's product portfolio includes over 7,500 prescription generic, branded generic, brand-name drugs and over-the-counter remedies. Appx1769. Mylan also reported more than $11.4B in total revenues in 2018, with over $4B in gross profits. Appx1806. 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) (Appx3930) (citing *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862-63 (Fed. Cir. 2010)). Thus, the added revenue from the incremental sales of Mylan ANDA Product would be a very small percentage of Mylan's overall revenue and immaterial to Mylan. As such, the balance of hardships favors injunctive relief.

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

Mylan has acknowledged that the sale of the Mylan ANDA Product, "unless pursuant to the License granted by Takeda," would "infringe one or more of the claims of [Takeda's] Patents." Appx93(§ 1.8(a)). Mylan has further acknowledged that with respect to the Mylan ANDA Product, the Licensed Patents "are valid and enforceable." Appx93(§ 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 (Appx3953) ("The public interests at issue in this case are enforcing private contracts . . . .").

Mylan 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 Mylan'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: February 19, 2020

By: /s/ Edgar H. Haug

Edgar H. Haug
Porter F. Fleming
Jonathan A. Herstoff
Camille Y. Turner
HAUG PARTNERS LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800
ehaug@haugpartners.com

FORM 19. Certificate of Compliance With Rule 32(a)

Form 19
Rev. 12/16

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Federal Circuit Rule 32(a) or Federal Rule of Federal Circuit Rule 28.1.

☒ This brief contains [*state the number of*] 7,404 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f), or

☐ This brief uses a monospaced typeface and contains [*state the number of*] _____ lines of text, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Federal Circuit Rule 28.1 and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

☒ This brief has been prepared in a proportionally spaced typeface using

[*state name and version of word processing program*] Microsoft Word 2010 in

[*state font size and name of type style*] 14 point Century Schoolbook , or

☐ This brief has been prepared in a monospaced typeface using

[*state name and version of word processing program*] _____ with

[*state number of characters per inch and name of type style*] _____ .

_____

(Signature of Attorney)

/s/ Edgar H. Haug

(Name of Attorney)

Edgar H. Haug

(State whether representing appellant, appellee, etc.)

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

February 19, 2020

(Date)

Reset Fields

ADDENDUM

ADDENDUM TABLE OF CONTENTS

Page	**Document**
Appx16-Appx22	Memorandum Order (D.I. 114)

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