Appeal Nos. 2020-1407, -1417

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff-Appellant,

—v.—

MYLAN PHARMACEUTICALS INC.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
JUDGE RICHARD G. ANDREWS
1:19-CV-02216-RGA

BRIEF FOR DEFENDANT-APPELLEE

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March 11, 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. 20-1407, -1417

CERTIFICATE OF INTEREST

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

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
MYLAN PHARMACEUTICALS INC.	None	Mylan Pharmaceuticals Inc. is a
		wholly owned subsidiary of
		Mylan Inc., which is indirectly
		wholly owned by Mylan N.V.

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:

Stu Williams, Wilson Sonsini Goodrich & Rosati, P.C.
David S. Steuer, Wilson Sonsini Goodrich & Rosati, P.C.
Nicole W. Stafford, Wilson Sonsini Goodrich & Rosati, P.C.
Paul C. Gross, Wilson Sonsini Goodrich & Rosati, P.C.
Kenneth Laurence Dorsney, Morris James 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. 1:19-cv-02216-RGA (D. Del.)

Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Laboratories Ltd., et al., No. 1:20-cv-00325-RGA (D. Del.)

Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Laboratories Ltd., et al., No. 20-1545 (Fed. Cir.)

March 11, 2020
Date

/s/ Michael S. Sommer
Signature of counsel

Please Note: All questions must be answered

Michael S. Sommer
Printed name of counsel

cc: _____

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITES

Page(s)

CASES

STATUTES AND REGULATIONS

RULES

OTHER AUTHORITIES

STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, Defendant-Appellee Mylan Pharmaceuticals Inc. ("MPI") states that no appeal from the same trial court action was previously before this or any other appellate court and aside from the District Court proceedings that remain pending in this case, *Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Laboratories Ltd., et al.*, No. 1:20-cv-00325-RGA (D. Del.), and *Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Laboratories Ltd., et al.*, No. 20-1545 (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.

INTRODUCTION

This Court should affirm the District Court's order ("Order") denying Takeda Pharmaceuticals U.S.A., Inc.'s ("Takeda") Motion for Preliminary Injunction ("Motion"). Takeda fails to identify any error in the District Court's reasoning, let alone show that the District Court abused its discretion in denying Takeda the extraordinary relief of a preliminary injunction. Nor could Takeda, as each of the four preliminary injunction factors supports the denial of Takeda's Motion.

Takeda is unlikely to succeed on the merits because MPI was permitted to launch its colchicine product under Section 1.2(d) of the parties' License Agreement, which accelerates MPI's authorized launch date based on a "Final Court Decision" holding that "all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party" were "not infringed." The District Court properly held that the court's decision in the *West-Ward* Litigation met the requirements of Section 1.2(d) and thus triggered MPI's launch rights.

In an effort to deprive MPI of these rights, Takeda attempts to rewrite the License Agreement. Specifically, Takeda seeks to alter the language of Section 1.2(d) to require that "all unexpired claims of the Licensed Patents that were asserted at any point ~~and adjudicated~~ against a Third Party supplier, distributor, or manufacturer of a Generic Equivalent" must be found "not infringed." Takeda

identifies no legal authority supporting its self-serving rewrite, and the District Court was correct in rejecting this interpretation in favor of the License Agreement's clear and unambiguous language.

Unable to rely on the plain language of Section 1.2(d), Takeda resorts to focusing on its own subjective intent. Yet Takeda's primary intent argument supports MPI's position. Takeda asserts that it intended Section 1.2(d) to be triggered only "where there was a change to the status quo with respect to the Patents-in-Suit[.]" That is exactly what happened in the *West-Ward* Litigation. In that case, the court (in a decision authored by Judge Andrews) held that the three Licensed Patents asserted by Takeda and adjudicated by the court were not infringed, thus changing the status quo with respect to those Licensed Patents.

While Takeda's failure to show likelihood of success on the merits is dispositive of this appeal, the District Court was also correct in holding that Takeda failed to demonstrate it would suffer irreparable harm because money damages would remedy any harm that Takeda might suffer in the absence of a preliminary injunction. This is particularly so given that "if [MPI] does not enter the market now, other generics will soon do so." Takeda's failure to demonstrate irreparable harm provides another, independent basis to affirm the District Court's Order.

The remaining two factors – balance of hardships and public interest – also weigh in MPI's favor. If MPI is enjoined, it will lose the extremely valuable position of being the first generic colchicine product on the market (other than the Mitigare® and Colcrys® authorized generics) – all while the market endures material changes to MPI's significant disadvantage. Finally, the public interest in increased competition and more affordable pricing supports having MPI's product on the market.

COUNTERSTATEMENT OF THE ISSUES PRESENTED

1. Whether the District Court committed reversible error by holding that the plain language of Section 1.2(d) of the parties' License Agreement – which permits MPI to launch its generic colchicine product "after the date of a Final Court Decision…holding that all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable" – permitted MPI to launch its colchicine product based on a "Final Court Decision" issued in an action filed by Takeda against a Third Party holding that all of Takeda's unexpired patent claims that were both "asserted and adjudicated against [the] Third Party" were "not infringed."

2. Whether the District Court committed reversible error by holding that "an objective, reasonable third party" would not agree with Takeda that Section

1.2(d) of the License Agreement is "limited to litigation over the possible introduction of generic Colcrys products" where Section 1.2(d) is not expressly limited to and "makes no mention of generic Colcrys products," and where other provisions of the License Agreement include limiting language demonstrating the parties "knew how to condition provisions of the contract on the launch of generic Colcrys products" but chose not to in Section 1.2(d).

3. Whether the District Court abused its discretion in finding that Takeda will not suffer irreparable harm absent entry of a preliminary injunction, and that any harm Takeda may suffer is fully compensable with monetary damages.

4. Whether the District Court abused its discretion in denying Takeda's motion for a preliminary injunction when Takeda "failed to show it is likely to succeed on the merits or that it will suffer irreparable harm[.]"

COUNTERSTATEMENT OF THE CASE

A. MPI and Takeda Execute the License Agreement

In 2016, MPI submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") pertaining to MPI's generic version of Takeda's branded Colcrys®, colchicine in 0.6 mg tablets. Appx40(¶ 45), Appx2302(¶ 6). Takeda subsequently sued MPI in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:16-cv-00987-RGA (D. Del.) ("*MPI* Litigation"), alleging that MPI infringed patents listed in the Orange Book

as covering Takeda's Colcrys® ("Licensed Patents"). Appx41(¶ 49), Appx2317. Takeda and MPI ultimately resolved the litigation through a Settlement Agreement and License Agreement, effective November 7, 2017, and Takeda dismissed its lawsuit. Appx41(¶ 51), Appx74-112.

B. The License Agreement Authorizes MPI's Colchicine Product Launch

The License Agreement grants MPI "a fully paid-up, royalty-free, irrevocable, non-exclusive license under the Licensed Patents[.]" Appx88(§ 1.1). Section 1.2 of the License Agreement provides that "[MPI] shall be entitled to make, use, import, market, offer for sale, sell, and distribute the Mylan ANDA Product [(i.e., MPI's generic colchicine product)] during the period beginning on the first to occur of the following [dates] (each, a 'Generic Entry Date') and continuing until the expiration of the last to expire of the Licensed Patents[.]" Appx88(§ 1.2). One such "Generic Entry Date" is set forth in Section 1.2(d), which provides that MPI shall be entitled to market and distribute its generic colchicine product on:

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

Appx88(§ 1.2(d)).[1]

The License Agreement contains an integration clause providing that the License Agreement and Settlement Agreement "constitute the entire agreement between the Parties relating to the subject matter hereof[.]" Appx98(§ 7).

C. The *West-Ward* Litigation and Resulting Judgment

At the time of the *MPI* Litigation, Takeda was also pursuing claims against Hikma Americas Inc. and Hikma Pharmaceuticals PLC (collectively "Hikma"), alleging that Hikma's Mitigare® colchicine products infringed certain of Takeda's Colcrys® patents. *See Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, No. 1:14-cv-01268-RGA-SRF (D. Del.) (Andrews, J.) ("*West-Ward* Litigation"); Appx2320-2324.

Mitigare®, like Colcrys®, is a 0.6 mg colchicine product that is administered orally. *Compare* Appx719 *with* Appx763. Both drugs received FDA approval – through 505(b)(2) NDAs – based in part on data developed from the drug Col-Probenecid (*compare* Appx3042 and Appx3046 *with* Appx3062), and both drugs are indicated for the prevention of gout. *Compare* Appx719 *with* Appx763. Takeda has acknowledged that Colcrys® and Mitigare® compete in the

[1] The License Agreement defines "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," while "Third Party" is defined as "a Person other than a Party or an Affiliate of a Party." Appx102, Appx105.

same market. In support of its ultimately unsuccessful motion for preliminary injunction against Hikma, Takeda argued that "Hikma's release of a colchicine product…would have a devastating and permanent effect on Takeda's sales of Colcrys®." *West-Ward* Litigation, D.I. 6 at 18;[2] *see also Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, 72 F. Supp. 3d 539 (D. Del. 2014) (denying preliminary injunction). Takeda explained that "care providers customarily write Colcrys® prescriptions using the generic term 'colchicine,' [so] pharmacies will fill such prescriptions with a lower cost Mitigare™ or an authorized generic version thereof." *West-Ward* Litigation, D.I. 6 at 17. Takeda further argued that "there is a high likelihood that virtually all prescribers who are not already writing prescriptions for the generic active ingredient, 'colchicine,' would begin doing so once Hikma['s] authorized generic product became available." *Id*.

Though at one point Takeda had asserted eight patents against Hikma in the *West-Ward* Litigation, "[Takeda] voluntarily dismissed" five of those patents via a stipulation of dismissal, such that "only [three patents] remain[ed] at issue for the purposes of summary judgment." Appx2357-2358; *see also* Appx2346-2348(¶¶ 1-5) ("Stipulation of Dismissal"). The Stipulation of Dismissal was executed by the

[2] "D.I." refers to documents from a district court's docket. "ECF No." refers to documents from this Court's docket.

parties to the *West-Ward* Litigation and filed pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii). Appx2346-2348. The three patents that were not voluntarily dismissed by Takeda are "Licensed Patents" under the License Agreement. *Compare* Appx2358 *with* Appx103.

In December 2018, in a decision and order authored by Judge Andrews, the *West-Ward* court granted summary judgment in favor of Hikma, holding that Hikma did not infringe the three Colcrys® patents asserted by Takeda. Appx2358, Appx2361-2370, Appx2372. The same day, the court entered judgment in favor of Hikma and against Takeda to formalize this non-infringement adjudication. Appx2374 ("*West-Ward* Judgment"). Takeda did not appeal the *West-Ward* Judgment and does not dispute that the *West-Ward* Judgment constitutes a "Final Court Decision" as defined in the License Agreement. Appx19; *see also* 28 U.S.C. § 2107(a) (requiring notice of appeal to be filed within 30 days after the entry of judgment).

D. MPI's Launch of its Colchicine Product Pursuant to Section 1.2(d) of the License Agreement

On October 28, 2019, MPI advised Takeda that, based on the *West-Ward* Judgment, MPI planned to "immediately start selling" its generic colchicine product pursuant to Section 1.2(d) of the License Agreement. Appx786 (setting forth MPI's position that the "judgment of non-infringement in favor of West Ward Pharmaceutical Corp. et al.," which "Takeda did not appeal," triggered

Section 1.2(d)). Takeda did not take any legal action in response to MPI's notice. To the contrary, in a November 5, 2019 letter, Takeda's counsel stated that "Takeda has not indicated that it will file a complaint against [MPI] prior to [MPI]'s breach of the License Agreement." Appx794 (emphasis in original). By late November, Takeda still had not taken any legal action, and MPI subsequently launched its colchicine product on or about November 25, 2019. *See* Appx44-45(¶ 64).

On December 2, 2019, over a month after receiving MPI's October letter, Takeda filed this action alleging breach of contract and patent infringement. Appx30-72. Takeda subsequently filed a Motion for Preliminary Injunction seeking to enjoin MPI from commercially manufacturing, offering to sell, or selling within the United States its generic colchicine product. Appx640-645.

E. The District Court's Order

On January 27, 2020, after full briefing and oral argument, the District Court issued an Order denying Takeda's Motion for Preliminary Injunction. Appx16-22. The District Court held that Takeda "failed to show it is likely to succeed on the merits or that it will suffer irreparable harm[.]" Appx16. With respect to the merits, the District Court held that under the clear and unambiguous language of the License Agreement, the *West-Ward* Judgment "triggered Section 1.2(d), which 'entitle[s]' [MPI] to launch a generic version of Colcrys." Appx18-20.

Specifically, the District Court held that only three patents were ***both*** "asserted and adjudicated" in the *West-Ward* Litigation, and all of these patents were held to be "not infringed." Appx19-20. With respect to the five patents that Takeda had voluntarily dismissed, because these patents were not both "asserted and adjudicated" they were irrelevant for the purposes of Section 1.2(d). *Id*.

In reaching this holding, the District Court rejected Takeda's interpretation of Section 1.2(d) as requiring that all the patents asserted by Takeda at any point in the litigation must be adjudicated in order to trigger acceleration. Appx19-21. The District Court also rejected Takeda's argument that Section 1.2(d) is limited to Final Court Decisions in cases involving generic Colcrys® products only. Appx20-21.

Regarding irreparable harm, the District Court held that the contractual "stipulation" relied on by Takeda, reflected in Section 1.10 of the License Agreement, was unlikely to apply given that Takeda had not demonstrated it was likely to succeed on the merits of its breach of contract claim. Appx21. The District Court further held that Takeda did not demonstrate irreparable harm because "[m]oney damages would remedy any harm Takeda will suffer as a result of [MPI] launching its product," especially because "it appears to be undisputed that…even if [MPI] does not enter the market now, other generics will soon do so." Appx21-22. The District Court denied a stay pending appeal, though it

ordered MPI to "maintain the status quo until end of the day January 31, 2020." Appx22.

Takeda immediately filed an appeal, as well as an Emergency Motion for an Injunction Pending Appeal. ECF Nos. 1, 6. In a short order issued the day after Takeda filed its Emergency Motion for Injunction Pending Appeal, and without making any findings on the relevant issues, this Court extended the District Court's "status quo" order pending the Court's consideration of Takeda's Emergency Motion, which was set on a highly expedited briefing schedule. *See* ECF Nos. 6, 14. Takeda's Emergency Motion, which has been fully briefed since February 7, 2020, remains pending, and MPI remains bound by the Court's temporary interim injunction dated January 29, 2020.

SUMMARY OF ARGUMENT

The District Court did not abuse its discretion in denying Takeda the extraordinary relief of a preliminary injunction. Takeda fails to demonstrate that any of the four factors necessary to establish such extraordinary relief weigh in its favor.

As the District Court correctly held, Takeda is unlikely to succeed on the merits because Section 1.2(d) of the License Agreement – in clear and unambiguous language – accelerates MPI's license to market its colchicine product based on the issuance of a "Final Court Decision" holding that all of the "Licensed

Patents" that were "asserted and adjudicated" against a "Third Party" are not infringed.

On December 12, 2018, a Third Party – Hikma – obtained just that: a final court decision holding that the only Licensed Patents that Takeda chose to assert against Hikma – namely, the three Licensed Patents that Takeda had not voluntarily withdrawn after Hikma's summary judgment motion was filed – were not infringed. The District Court correctly found that this event triggered Section 1.2(d), clearing the way for MPI to launch its colchicine product. Takeda, however, refuses to acknowledge MPI's bargained-for rights under the License Agreement, and instead asks this Court to rewrite Section 1.2(d) to exclude the *West-Ward* Judgment. Takeda's arguments are contrary to the clear and unambiguous language of the License Agreement and should be rejected.

While Takeda's failure to show likelihood of success on the merits is dispositive of this appeal, Takeda also has failed to demonstrate that it will suffer irreparable harm absent an injunction – yet another reason to affirm the District Court's Order. Takeda's irreparable harm argument relies almost entirely on a provision of the License Agreement, Section 1.10, that is inapplicable where, as here, MPI's launch of its colchicine product was in full compliance with the License Agreement. To the extent Takeda does reference purported harms, the District Court rightly held that these alleged harms are readily addressed through

monetary damages should Takeda ultimately prevail on the merits (which it will not).

The remaining two factors – balance of hardships and the public interest – also weigh in favor of MPI and against Takeda's request for a preliminary injunction. If prevented from exercising its rights under the License Agreement, MPI will lose not only sales, but the extremely valuable position of being the first generic colchicine product on the market (other than the Mitigare® and Colcrys® authorized generics). This harm will be exacerbated by the substantial changes to the colchicine market that are likely to occur during the pendency of any injunction. Finally, the public interest in generic competition for this important medicine would be impaired by the grant of any injunction.

ARGUMENT

I. LEGAL STANDARD

As the District Court rightly acknowledged, "[a] preliminary injunction is an extraordinary remedy never awarded as of right." Appx18 (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)). 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.'" Appx18 (quoting *Winter*, 555 U.S. at 20). The District Court correctly found that Takeda failed to make this required showing. *See* Appx16, Appx18.

It is well-settled that "[a]n appellant carries a heavier burden when seeking to reverse the denial of a preliminary injunction than seeking to reverse the grant of a preliminary injunction." *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). "When a preliminary injunction is denied, the movant…must show not only that one or more of the factors relied on by the district court was clearly erroneous, but also that a denial of the preliminary relief sought would amount to an abuse of the court's discretion upon reversal of an erroneous finding." *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992).[3]

[3] Though MPI does not dispute the portions of the standard of review set forth in Takeda's brief, Takeda failed to acknowledge that a preliminary injunction is an extraordinary remedy and that appellant faces a heavier burden when seeking to reverse the denial of a preliminary injunction. *See* ECF No. 35 ("Takeda's Br.") at 15.

II. TAKEDA HAS NOT SHOWN IT IS LIKELY TO SUCCEED ON THE MERITS

The District Court was correct:

> 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) [of the License Agreement], which "entitle[s]" [MPI] 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.

Appx20. Takeda has not shown any reason to disturb the District Court's holding. Because Takeda cannot show a likelihood of success on the merits, this Court should affirm District Court's Order. *See Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988) (court "cannot sustain a preliminary injunction" where likelihood of success on the merits is not shown) (citation omitted); *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 141 (3d Cir. 2019) (Appx4062-4063) (holding that "[b]ecause a failure to establish a likelihood of success is fatal to obtaining a preliminary injunction, the District Court appropriately denied [appellant's] motion") (citation omitted).

A. The District Court Correctly Applied Delaware Contract Law by Enforcing Section 1.2(d) As Drafted

The District Court correctly applied Delaware principles of contract interpretation in construing the License Agreement. *See* Appx18-21; *see also* Appx97(§ 5) (License Agreement is governed by Delaware law).

In interpreting the License Agreement, this Court – like the District Court – is "constrained by a combination of the parties' words and the plain meaning of those words[.]" *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006); *see also Paul v. Deloitte & Touche, LLP*, 974 A.2d 140, 145 (Del. 2009) (courts "start by looking to the four corners of the contract"). The Court must analyze the language as it "would be understood by an objective, reasonable third party." *Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1267 (Del. 2017) (citation omitted). "[W]hen two sophisticated parties bargain at arm's length and enter into a contract," as is the case here, "the presumption is even stronger that the contract's language should guide the Court's interpretation." *JFE Steel Corp. v. ICI Ams., Inc.*, 797 F. Supp. 2d 452, 469 (D. Del. 2011).

Here, the parties agree that the language of Section 1.2(d) is clear and unambiguous. *See* Appx3815:11-3816:23. As such, the contract language "should be given its ordinary and usual meaning"; otherwise there is a risk of "creat[ing] a new contract with rights, liabilities and duties to which the parties had not assented." *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1195-96 (Del. 1992) (citation omitted); *see also Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159-60 (Del. 2010) (where a contract is "clear and unambiguous," courts must "give effect to the plain-meaning of the contract's

terms and provisions"). Moreover, "[i]f a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract, or to create an ambiguity." *Exelon*, 176 A.3d at 1267 (citation omitted); Appx3816:6-9 (acknowledgement by Takeda that the court should not consider extrinsic or parole evidence).

B. The District Court Correctly Found That the *West-Ward* Judgment Triggered Section 1.2(d) and Permitted MPI's Launch

Section 1.2(d) of the License Agreement permits MPI to launch its colchicine product where a "Final Court Decision" is issued holding that all unexpired claims of the Licensed Patents that were "asserted and adjudicated against a Third Party" are "not infringed." Appx88(§ 1.2(d)). The *West-Ward* Judgment was such a "Final Court Decision." As the *West-Ward* court recognized, because Takeda voluntarily dismissed five of the eight patents after the filing of Hikma's summary judgment motion, "only [three patents] remain[ed] at issue for the purposes of summary judgment." Appx2358. The *West-Ward* court adjudicated all three of those patents as not infringed and entered judgment accordingly. Appx2361-2370, Appx2372, Appx2374. Because the *West-Ward* Judgment constituted a "Final Court Decision" holding that all of the Licensed Patents that were ***both*** asserted against Hikma ***and*** adjudicated by the Court were

found to be "not infringed," Section 1.2(d) applies.[4]

In this appeal, Takeda expressly concedes that the five patents it voluntarily dismissed in the *West-Ward* Litigation were not "adjudicated" under Section 1.2(d). *See* Takeda's Br. at 24 ("In the *West-Ward* Litigation, …***only three of the eight patents were adjudicated***. With respect to the remaining five patents, ***there was no adjudication at all***[.]") (emphasis added); Takeda's Reply ISO Mot. for Inj. Pending Appeal (ECF No. 26-1) at 5 (stating that "***Takeda has consistently argued*** to the district court…as well as to this Court…that only three of the eight patents in the *West-Ward* Litigation were 'adjudicated' and ***that the remaining five patents were not 'adjudicated***'") (emphasis added); *see also* Takeda's Mot. for Inj. Pending Appeal (ECF No. 6) at 17 (contending that the voluntarily dismissed patents were not "adjudicated").

Takeda's position on appeal is consistent with its position before the District Court. *See* Takeda's Reply ISO Mot. (Appx3195) ("[T]he claims of five of the patents that were 'asserted' in the *West-Ward* Litigation ***were not adjudicated***.") (emphasis added); Argument Transcript (Appx3857:21-3858:23) ("The patents were voluntarily dismissed, i.e., ***they were never adjudicated***…. There was no adjudication on those five patents.") (emphasis added); *see also* Appx19 (District

[4] Takeda does not dispute that the *West-Ward* Judgment is a "Final Court Decision," or that the "waiting period" set forth in Section 1.2(d) elapsed prior to MPI's launch. Appx19.

Court order noting that "[a]ccording to Takeda, only three patents were 'adjudicated'").

Takeda's concession that the five voluntarily dismissed patents were not "adjudicated" under Section 1.2(d) is both binding and dispositive. It is binding because, having repeatedly admitted these withdrawn patents were not "adjudicated" under Section 1.2(d), including in its opening brief on appeal, Takeda has waived any argument to the contrary. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006) ("Our law is well established that arguments not raised in the opening brief are waived."); *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1375 n.4 (Fed. Cir. 2005) (declining to address arguments not raised in opening brief); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (appellant "waived its argument…by failing to raise it in its opening brief"). And the admission is dispositive because it necessarily leads to the conclusion that the only three Licensed Patents that were ***both*** asserted ***and*** adjudicated in the *West-Ward* Litigation were held to be "not infringed" in a "Final Court Decision." *See* Takeda's Br. at 9 (acknowledging that the *West-Ward* Judgment found the three Licensed Patents that were addressed by the court to be not infringed). In such circumstances, the clear and unambiguous language of Section 1.2(d) permits MPI

to launch its colchicine product. For this reason alone, Takeda cannot prevail on the merits.[5]

Takeda's position further fails because the five patents Takeda voluntarily dismissed from the *West-Ward* Litigation were not "asserted" against Hikma under Section 1.2(d) because Takeda made the affirmative decision to withdraw these patents from the litigation. *See* Appx88(§ 1.2(d)) (taking into account only those patents that were ***both*** "asserted and adjudicated"). Immediately upon filing of the Stipulation of Dismissal, the subject patents were removed from among those that Takeda "asserted" against Hikma and reclassified as ***un***asserted patents – indeed, that was the very purpose of the stipulation. *See AbbVie Inc. v. Hospira, Inc.*, 71 F. Supp. 3d 477, 480 n.2 & 482 (D. Del. 2014) (noting that plaintiff "is no longer asserting" several patents "as the result of two stipulations of dismissal," and excluding dismissed patents from list of "Asserted Claims").

It makes no sense to find that by withdrawing patents – i.e., by agreeing ***not*** to pursue them – Takeda was "assert[ing]" those very same patents. *See Edwards Lifesciences AG v. CoreValve, Inc.*, No. C.A. No. 08-91-GMS, 2010 WL

[5] Remarkably, although both Takeda and MPI – the only two parties to the License Agreement – agree that the five voluntarily dismissed patents in the *West-Ward* Litigation were not "adjudicated" under Section 1.2(d), *Amici* Hikma improperly argues otherwise. *See* ECF No. 39-2. Hikma's argument is addressed below.

11483203, at *2 n.4 (D. Del. Feb. 26, 2010) (Appx4067) ("The parties agreed at the pre-trial conference that the '614 patent should be dismissed from the case….To date, the parties have not filed a stipulation of dismissal, but the court relies on the parties' representations that the '614 patent is no longer being asserted in this case."). To hold otherwise would be to construe the term "asserted" in a manner inconsistent with its plain meaning, something Delaware law does not permit. *See* BLACK'S LAW DICTIONARY (10th ed. 2014) (Appx2378) ("assert" means "[t]o invoke or enforce a legal right" and "[t]o state positively"); *Lorillard Tobacco Co.*, 903 A.2d at 738 (Delaware courts look to dictionaries for assistance in determining the plain and ordinary meaning of terms that are not defined in a contract); *see also Rhone-Poulenc*, 616 A.2d at 1195 (court should apply the "ordinary and usual meaning" of contract terms).

Since the five patents Takeda voluntarily dismissed from the *West-Ward* Litigation were neither "asserted" nor "adjudicated" for the purposes of Section 1.2(d), it necessarily follows that the *West-Ward* Judgment held that "all unexpired claims of the Licensed Patents ***that were asserted and adjudicated*** against a Third Party" were "not infringed," thus triggering MPI's launch rights under Section 1.2(d) of the License Agreement. *See* Appx88(§ 1.2(d)) (emphasis added), Appx18-20.

C. Takeda's Proffered Construction of Section 1.2(d) Is Contrary To the Plain Language of the License Agreement

As it did before the District Court, on appeal, Takeda argues that Section 1.2(d) is triggered only where all of the Licensed Patent claims that were asserted at any time in a litigation against a Third Party were ultimately held to be not infringed (or any combination of not infringed, unenforceable, and/or invalid). Takeda's Br. at 11, 16, 19; Appx3816:20-23, Appx3840:18-20, Appx3757-3758. The District Court correctly rejected this argument. Appx19-20. Nothing in the language of Section 1.2(d) suggests – let alone requires – that all Licensed Patents asserted during the course of the litigation must ultimately be adjudicated as non-infringing, invalid, and/or unenforceable in order for the provision to apply. Instead, by its plain language, Section 1.2(d) takes into account only those patents "that were 'asserted ***and*** adjudicated'" against the Third Party. Appx19 (emphasis in original). If a patent was not ***both*** asserted ***and*** adjudicated, it is irrelevant for the purposes of Section 1.2(d). *Id*.

Unable to support its own position through the language of Section 1.2(d), Takeda attacks the District Court's construction as purportedly rendering the terms "all" and "asserted" superfluous. Takeda is wrong. Although Takeda argues that the District Court effectively reads the word "asserted" out of Section 1.2(d) since any patent claims that were "adjudicated" necessarily will have been "asserted," Takeda ignores that the plain language of Section 1.2(d) requires the unexpired

patent claims be asserted "***against a Third Party***" in order for the provision to apply. Appx88(§ 1.2(d)) (emphasis added). As the District Court explained, and as Takeda acknowledged, there exist situations in which a patent may be "adjudicated" by the Court, but not "asserted…against a Third Party" as required by Section 1.2(d). Appx3844:2-3845:2 ("THE COURT: …a generic [could] bring a declaratory judgment [action] against a brand [name] company…would that be a scenario where the asserted and the adjudicated would not be exactly the same? [Takeda's Counsel]: It could be.").

Similarly without merit is Takeda's suggestion that the District Court ignored the word "all" in Section 1.2(d). *See* Takeda's Br. at 22-24. To the contrary, the District Court expressly noted that Section 1.2(d) applies only when "'***all*** unexpired claims of the Licensed Patents that were asserted and adjudicated'" are found "not infringed or invalid." Appx19-20 (quoting Appx88(§ 1.2(d)) (emphasis added). That is precisely what occurred in the *West-Ward* Litigation – ***all*** of the Licensed Patents that were both asserted and adjudicated were held not infringed. *Id*. By contrast, had the *West-Ward* court held that only one of the three "asserted and adjudicated" patents was not infringed, while holding that the other two patents were infringed, Section 1.2(d) would not have been triggered. Appx88(§ 1.2(d)).

Notably, it is Takeda's interpretation of the License Agreement – not MPI's

– that renders contract language superfluous. Takeda's interpretation of Section 1.2(d) provides that the provision is only triggered where there is a Final Court Decision "holding *all* unexpired asserted claims not infringed, invalid or unenforceable." Takeda's Br. at 19 (emphasis in original); *see also id*. at 16 ("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…."). By taking into account all claims that were "asserted" in the litigation, rather than only those claims that were both "asserted and adjudicated," Takeda improperly rewrites the provision to strike the words "and adjudicated" from the License Agreement. In so doing, Takeda expands the scope of the claims to be considered for the purposes of Section 1.2(d), thereby reducing the likelihood that the provision will be triggered. Such a rewrite should be rejected. *See Osborn*, 991 A.2d at 1159 (citation omitted) (court "will not read a contract to render a provision or term 'meaningless or illusory'"); *see also United States v. Geiser*, 527 F.3d 288, 298-99 (3d Cir. 2008) (interpreting the word "and" in a statute to require an applicant "meet two sets of requirements" because "[t]he usual meaning of the word 'and'...is conjunctive") (citation omitted).

Indeed, Takeda itself concedes that its construction is contrary to the plain language of Section 1.2(d), openly admitting that the provision is triggered where the Final Court Decision "includes a 'holding' with regard to 'all unexpired claims

of the Licensed Patents ***that were asserted and adjudicated***." Takeda's Br. at 16-17 (emphasis added); *id*. at 17 ("Additionally, ***with regard to all such asserted and adjudicated patent claims***, the Final Court Decision must hold that all such claims are" not infringed, invalid and/or unenforceable) (emphasis added). Because Takeda's interpretation disregards the clear and unambiguous language of Section 1.2(d) in favor of a self-serving rewrite, it was properly rejected by the District Court.

D. The District Court Correctly Rejected Takeda's Argument That the Parties Did Not Intend the *West-Ward* Litigation to Trigger Section 1.2(d)

In an attempt to justify its interpretation of Section 1.2(d) despite the provision's plain language to the contrary, Takeda argues that the parties' purported "intent" in agreeing to Section 1.2(d) was that MPI would only be able to launch its colchicine product upon a "change to the status quo either in the market or to the status of the Patents-in-Suit," and that the *West-Ward* Judgment accomplished neither. Takeda's Br. at 19. These arguments are unavailing.

1. The District Court Was Correct That Section 1.2(d) Is Not Limited to Litigation over Generic Colcrys® Equivalents

Takeda admits that "Section 1.2(d) does not expressly exclude a litigation that does not involve a generic Colcrys® product[.]" Takeda's Br. at 19; *see also* ECF No. 6 at 14 (conceding that Section 1.2(d) does not "expressly exclude the *West-Ward* Litigation or any other litigation that does not involve a generic

Colcrys® product"). Takeda nonetheless suggests that the parties intended for Section 1.2(d) to be limited to litigation involving "Generic Equivalents"[6] to Colcrys® and thus to exclude the *West-Ward* Litigation, which related to the colchicine product Mitigare® and its authorized generic. Takeda's Br. at 19-20, 24-16. Takeda's argument is contrary to the clear language of the License Agreement and thus cannot stand. *See Lorillard Tobacco Co.*, 903 A.2d at 739 (in interpreting a contract, the court is "constrained by a combination of the parties' words and the plain meaning of those words").

As the District Court recognized, and as Takeda concedes (*see* Takeda's Br. at 19; ECF No. 6 at 14), "Section 1.2(d) makes no mention of generic Colcrys products." Appx20. This omission is especially telling given that Takeda and MPI are both sophisticated pharmaceutical companies that knew how to include limiting language and did so in other subsections of Section 1.2. *See* Appx20; *JFE Steel Corp.*, 797 F. Supp. 2d at 469 (presumption that "contract's language should guide the Court's interpretation" is stronger when sophisticated parties enter into a contract).

For example, Section 1.2(b) authorizes MPI to launch its colchicine product based on "a first commercial sale of a ***Generic Equivalent***…permitted or

[6] The License Agreement defines "Generic Equivalent" as an AB-rated generic version of Colcrys®. Appx103.

authorized…by Takeda," and Section 1.2(f) authorizes MPI to launch based on the date that a third party launches a "***Generic Equivalent***" at risk. Appx88-89 (emphasis added); *see also id*.(§ 1.2(e)) (authorizing MPI to launch based on the date "***Authorized Generic Products***[7] are simultaneously sold by two (2) or more parties") (emphasis added). Thus, although the parties "clearly knew how to condition provisions of the contract on the launch of generic Colcrys products, …they chose not to condition Section 1.2(d) in such way." Appx20; *see also Unwired Planet, Inc. v. Microsoft Corp.*, 193 F. Supp. 3d 336, 343 (D. Del. 2016) (declining to accept defendant's limited reading of contract where "Microsoft did not limit the scope of the patents although it clearly knew how"); *Oxbow Carbon & Minerals Holdings, Inc. v. Crestview-Oxbow Acquisition, LLC.*, 202 A.3d 482, 507 (Del. 2019) (court "should be most chary about implying a contractual protection when the contract could easily have been drafted to expressly provide for it") (citation omitted).

Takeda claims that the District Court erred by drawing "parallels" between Section 1.2(d) and the other subsections of Section 1.2 because Section 1.2(d) relates to changes in the Licensed Patents, while the other cited subsections relate

[7] "Authorized Generic Product" is defined in the License Agreement as "a generic version of Colcrys that is marketed, distributed, or sold in the Territory pursuant to the Takeda NDA(s), and any supplements or amendments thereto." Appx102.

to changes in the generic market. Takeda's Br. at 24-25. Rather than support Takeda's position, however, Takeda's argument explains why the parties intentionally chose ***not*** to limit Section 1.2(d) to "Generic Equivalents"; namely, because unlike some other Section 1.2 subsections, Section 1.2(d) is focused on patents, not products. *Id*. (Takeda acknowledging that Sections 1.2(b) and 1.2(f) "address scenarios where products are actually coming to market" ***and thus are "limited to Generic Equivalents***," while "***[i]n contrast***, Sections 1.2(d) and 1.2(g)…do not require a product to be coming on the market" but rather "are intended instead to address circumstances where there was a change to the status quo with respect to the Patents-in-Suit") (emphasis added).

Furthermore, the District Court did not simply rely on these "parallels." Instead, the District Court recognized that the plain language of Section 1.2(d) is not limited to claims against suppliers of generic Colcrys® products, but rather refers generally to claims asserted by Takeda "against a Third Party," where "Third Party" is defined broadly "as a 'Person other than a Party or an Affiliate of a Party[.]" Appx21. As the District Court rightly noted, "[t]he 'Third Party' [against whom the litigation is brought] ***does not have to be another generic drug competitor***." *Id.* (emphasis added).

The District Court's reasoning was sound. Takeda and MPI could have limited Section 1.2(d) to Final Court Decisions issued in cases involving a Generic

Equivalent. The parties did not do so. *See* Appx20. Takeda's post-facto attempt to insert such a limitation into the License Agreement should be rejected. *See Nw. Nat'l Ins. Co. v. Esmark, Inc.*, 672 A.2d 41, 44 (Del. 1996) (rejecting proffered contract interpretation "because it adds a limitation not found in the contract language"); *Cipla Ltd.*, 778 F. App'x at 140 (Appx4062) ("Delaware law holds sophisticated parties…to the bargain they actually struck, rather than the one in hindsight they realize they should have made."); *Aspen Advisors LLC v. United Artists Theatre Co.*, 843 A.2d 697, 707 (Del. Ch. 2004) (to read a contract contrary to its express terms "would be to grant the plaintiffs, by judicial fiat, contractual protections that they failed to secure for themselves at the bargaining table"), *aff'd*, 861 A.2d 1251 (Del. 2004).

2. Takeda's Argument That the *West-Ward* Judgment Cannot Trigger Section 1.2(d) Because It Failed to Sufficiently Alter the "Status Quo" Is Meritless

Takeda next argues that the *West-Ward* Judgment does not trigger acceleration because Section 1.2(d) was "intended to allow [MPI] 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." Takeda's Br. at 19. This argument should be rejected. To start, no such "status quo" language exists in the contract, and MPI disputes that the License Agreement requires anything other than what is provided for by its plain language. *See supra* Section II.A. In any event, the *West-Ward* Judgment

did change the "status quo" – including as specifically contemplated by Section 1.2(d) – and Takeda's arguments to the contrary are without merit.

First, Takeda's contention that "it defies common sense" for Section 1.2(d) to be triggered by "a product that was already on the market," as Mitigare® was, misses the point. Takeda's Br. at 19-20. As Takeda itself admits, Section 1.2(d) was intended "to address circumstances where there was a change to the status quo with respect to the Patents-in-Suit," ***not*** where there was a change to the market due to product entry, such as a Third Party's product launch. *Id*. at 24-25. Thus, whether Mitigare® was on the market at the time of the License Agreement is irrelevant; all that matters is whether a Final Court Decision was issued holding that all Licensed Patents that were "asserted and adjudicated" against the Third Party were not infringed.[8]

Second, contrary to Takeda's contention (*see* Takeda's Br. at 20), the *West-Ward* Judgment ***did*** change the status quo with respect to the Patents-in-Suit so as to trigger Section 1.2(d). The court in the *West-Ward* Litigation held that the three Licensed Patents asserted by Takeda against Hikma were not infringed by Mitigare® and its authorized generic – both competitors in the colchicine market. Appx2358, Appx2361-2370, Appx2372. Takeda provides no credible explanation

[8] In any event, during the pendency of the *West-Ward* Litigation and at the time the parties entered into the License Agreement, Mitigare® was on the market at-risk.

as to why its inability to enforce three Licensed Patents against existing market competitors – as well as potential future competitors marketing generic Mitigare® products – is an insufficient change in the "status quo" to trigger Section 1.2(d).

Although Takeda vaguely suggests that every single one of the Licensed Patents would need to be held "not infringed" for a Final Court Decision to trigger Section 1.2(d), *see* Takeda's Br. at 20, 25, nothing in the language of Section 1.2(d) supports this requirement. Instead, Section 1.2(d) considers only those Licensed Patents "that were asserted and adjudicated against a Third Party[.]" Appx88(§ 1.2(d)). Even Takeda's own proffered construction of Section 1.2(d) – flawed as it is – acknowledges that the relevant patent claims for the purposes of the provision are those that Takeda "asserted" against the Third Party, not all Licensed Patents generally. *See* Takeda's Br. at 16 (arguing that "[t]he *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"); *Id*. at 26 (arguing that "Section 1.2(d) was written to require that all claims ***that were asserted in the applicable litigation*** be adjudicated") (emphasis added).

Nor can Takeda support its theory through reliance on Section 1.8 of the License Agreement. According to Takeda, Section 1.8 constitutes an admission by MPI that its colchicine product infringed "all" the Licensed Patents – such that MPI should be permitted to launch only where all of these patents are found not

infringed. *See* Takeda's Br. at 30; *see also id*. at 20, 25. Takeda misrepresents Section 1.8 of the License Agreement. Section 1.8 merely acknowledges that MPI's colchicine product "would infringe ***one or more of the claims of the Licensed Patents***[.]" Appx93(§ 1.8(a)) (emphasis added). It does not admit that MPI's colchicine product infringes "***all*** the Patents-in-Suit," as Takeda maintains. Takeda's Br. at 30. Moreover, Section 1.8 contains an express carve-out for conduct by MPI "pursuant to the License granted by Takeda hereunder" (Appx93(§ 1.8(a))), making clear that MPI's launch pursuant to Section 1.2(d) does not constitute infringement regardless of any admissions in Section 1.8.

Finally, construing Section 1.2(d) as drafted – that is, as taking into account only those patent claims that were asserted by Takeda and adjudicated by the Court, rather than all Licensed Patents generally – makes particular sense in the context of patent litigation, where Courts routinely require plaintiffs to limit the asserted claims because they are overlapping and/or duplicative. *See In re Katz Interactive Cell Processing Patent Litig.*, 639 F.3d 1303, 1312 (Fed. Cir. 2011) (affirming district court decision to limit the number of asserted claims "[b]ased on its initial determination that the asserted patents contained many duplicative claims"); *Masimo Corp. v. Philips Elecs. N.A. Corp.*, 918 F. Supp. 2d 277, 284-85 (D. Del. 2013) (ordering reduction in asserted claims based in part on "the related subject matter of the patents, the genealogy of the asserted patents and the

relationship among them"); *see also* Appx3835:21-3836:14 ("THE COURT: . . . Have you ever gone to trial or even summary judgment on every single asserted claim?...[Takeda's Counsel]:…[Y]ou're exactly right that in this day and age and even before Your Honor where there are multiple patents being asserted and multiple claims that the courts do encourage the parties to reduce the number of claims.").

3. Takeda's Argument That the Parties Intended MPI to Enter the Market After the Earlier Filers Has No Bearing on Section 1.2(d)

Takeda asserts that construing Section 1.2(d) to permit the *West-Ward* Judgment to trigger MPI's launch rights would "subvert the intent of the License Agreement by permitting [MPI] to enter the market…before the Earlier Filers."[9] Takeda's Br. at 21. Takeda is wrong for at least two reasons.

First, Takeda fails to demonstrate that the parties intended MPI to enter the market only after the "Earlier Filers" entered with their own colchicine products. Although Takeda argues that the License Agreement's "Most Favored Nation" provision "acknowledge[s] that [Takeda's] agreements with the Earlier Filers were on better terms than those granted to [MPI]" (*id*. at 20-21), that is not accurate. Instead, the provision merely carves out the Earlier Filers, such that their terms are

[9] Takeda uses the term "Earlier Filers" to refer to the three parties that settled litigation with Takeda regarding the Licensed Patents prior to the License Agreement. Takeda's Br. at 5, 20.

irrelevant to Takeda's "Most Favored Nation" obligations to MPI with respect to Generic Entry Dates. *See* Appx91-92(§ 1.5). Nor does Section 1.2(c) guarantee that MPI will enter the market after the Earlier Filers – an argument Takeda presented to the District Court but appears to have abandoned on appeal. *See* Appx658; *see also* Takeda's Br. at 5. Section 1.2(c) merely sets forth one potential basis for acceleration; it is not to the exclusion of the other potential bases for acceleration set forth in Section 1.2, which may result in an earlier Generic Entry Date.

Second, even if the parties had intended the Earlier Filers to enter the market before MPI in any and all circumstances (as Takeda maintains), absolutely nothing in MPI's and the District Court's construction of Section 1.2(d) precludes this from happening. To the contrary, whereas Section 1.2(d) requires MPI to wait a specified time period after the Final Court Decision before launching, presumably Takeda's agreements with the Earlier Filers do not require such a waiting period prior to launch.[10]

[10] To the extent the License Agreement contravenes some obligation of Takeda toward one or more of the Earlier Filers, surely that is not a basis to strip MPI of its bargained-for rights.

E. Takeda's Remaining Contract Interpretation Arguments Are Unavailing

1. Takeda Cannot Rewrite the Contract by Arguing It Would Not Have Accepted the Plain Meaning of Section 1.2(d) Based on Flawed Hypotheticals

In attempting to support its construction of Section 1.2(d) as requiring "that ***all*** asserted patents must be adjudicated" (Takeda's Br. at 28 (emphasis in original)), Takeda relies on two implausible Hatch-Waxman Act hypothetical situations nowhere referenced in the License Agreement. *See* Takeda's Br. at 26-30. Neither of Takeda's hypotheticals warrants overriding the clear language of Section 1.2(d).

a. The 30-Month Stay Hypothetical

Takeda's first hypothetical assumes a scenario where Takeda asserts Licensed Patents against a Third Party that is subject to a 30-month stay under the Hatch-Waxman Act, and where certain of these patents are voluntarily dismissed while the remaining patents are held to have been "not infringed." Takeda's Br. at 26-28. Takeda argues that under MPI's proffered interpretation of Section 1.2(d), this scenario would result in a situation where the non-infringement decision would trigger MPI's launch rights, while the Third Party would continue to be subject to a 30-month stay due to the voluntary dismissal. This hypothetical is unavailing.

First, Takeda's suggestion that the parties crafted Section 1.2(d) to prevent the above scenario is baseless. As discussed above, Section 1.2(d) is not limited to

Hatch-Waxman litigations, which necessarily involve "Generic Equivalents." *See supra* Section II.D.1. Nor does Section 1.2(d) mention a 30-month stay – let alone render acceleration contingent on such a stay applying to the Third Party and subsequently being lifted. Appx88(§ 1.2(d)). Indeed, as Takeda admits, the License Agreement does not reference the 30-month stay at all. *See* Appx3896:15-19 (acknowledging that "the words 30 month[s] are not [in the License Agreement]"). Under such circumstances, it would be entirely inappropriate to limit Section 1.2(d) based on a hypothetical specific to a situation where the Hatch-Waxman Act and associated 30-month stay apply.

Second, Takeda's argument with respect to this hypothetical is premised on the incorrect assumption that the 30-month stay can be lifted only by a final judgment that includes a "substantive determination that there is no cause of action for patent infringement." Takeda's Br. at 26 (citation omitted). This is contrary to the implementing regulations to the Hatch-Waxman Act, which Takeda conceded permit lifting the stay upon the voluntary dismissal of some patents and the entry of final judgment of non-infringement as to the remaining patents. *See* Appx3839:1-3840:12; *see also* 21 CFR § 314.107(b)(3)(viii) (authorizing the FDA to lift the 30-month stay when "the court(s) enter(s) an order of dismissal, with or without prejudice, without a finding of infringement"); 80 Fed. Reg. 6802, 6864 (Feb. 6, 2015) ("We are proposing to add § 314.107(b)(3)(viii) to ***codify FDA's***

policy that court entry of an order of dismissal, with or without prejudice…will terminate the 30-month period…if such order does not state a finding of patent infringement.") (emphasis added). Indeed, the FDA has lifted the stay upon voluntary dismissal of some patents and a finding of non-infringement with respect to others. *See, e.g.*, Letter from Dep't of Health & Human Servs. to Anchen Pharm. Inc. (Dec. 14, 2006), at 2, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/077284s000ltr.pdf (FDA lifting 30-month stay upon voluntary dismissal of some patents and non-infringement adjudication of others); Stipulated Dismissal of Claims, *Biovail Labs. Inc. v. Anchen Pharm. Inc.*, No. 8:04-cv-01468-JVS-RC (C.D. Cal. Feb. 3, 2006), D.I. 47.

The authorities relied upon by Takeda are inapposite. *See* Takeda's Br. at 27-28. In *Endo Pharm.*, the district court determined *sua sponte* that its order dismissing plaintiff's complaint without prejudice for lack of standing would not have terminated the 30-month stay. *See Endo Pharm. Inc. v. Mylan Techs. Inc.*, C.A. No. 11-220-GMS, 2013 WL 936452, at *5 (D. Del. Mar. 11, 2013) (Appx3940-3941). There was no stipulation of dismissal with prejudice followed by a final judgment of non-infringement on the remaining patents, as Takeda's hypothetical assumes. Moreover, the litigation in *Endo Pharmaceuticals* continued

after the Rule 12(b)(6) dismissal because the district court permitted the plaintiff to amend its complaint and correct the defect. *Id.* at *2 (Appx3938-3939).[11]

Nor does the FDA decision cited by Takeda (ECF No. 26-2) help its cause. *See* Takeda's Br. at 27-28. This decision, too, does not involve a stipulation of dismissal with prejudice, but rather it involves a subsequently-vacated dismissal for lack of personal jurisdiction. ECF No. 26-2 at 6. The FDA found that "because the Delaware district court ultimately determined that its dismissal was not proper…and the original infringement action…remains pending, Congress' intent is served by considering the stay to be in effect." *Id.* at 6-7. Those circumstances are not present here. Finally, in rendering its decision, the FDA expressly acknowledged that its "general policy has been that a court entry of an order of dismissal, with or without prejudice, of patent infringement litigation…will terminate the 30-month period if the order does not state a finding of patent infringement." *Id*. at 6.

b. The Amended Label Hypothetical

Takeda's second hypothetical fares no better. Takeda's Br. at 29-30. This hypothetical envisions a scenario where a Third Party files a generic colchicine

[11] Takeda also cites *Sanofi-Aventis v. Food and Drug Administration*, 725 F. Supp. 2d 92, 98-99 (D.D.C. 2010) for the irrelevant proposition that the 30-month stay is terminated by the entry of a judgment by a district court even if the judgment is vacated on appeal.

ANDA seeking a dosing regimen identical to the regimen for Colcrys®, in response to which Takeda files a lawsuit asserting infringement of all of the Licensed Patents. The Third Party then amends its label to "carve out" one or more of the Colcrys® indications, prompting Takeda to voluntarily dismiss certain of the Licensed Patents while continuing to pursue others. According to Takeda, should the Third Party obtain a holding of non-infringement on the remaining patents, this theoretically could result in a situation where MPI's license is triggered under Section 1.2(d), but the Third Party cannot launch due to a failure to obtain FDA approval for its amended label.

This hypothetical, too, is fatally flawed. ***First***, Takeda's key concern with this hypothetical scenario – that it could lead to a situation "where a non-approvable-generic product would trigger [MPI]'s license, even though it will never be sold and never have any impact on the colchicine market" (Takeda's Br. at 29-30) – is a red herring. As Takeda has conceded, Section 1.2(d) is triggered based upon a change relating to Licensed Patents – not a change in the colchicine market. *See id*. at 25. For this reason, whether the Third Party's product is ever sold on the market is irrelevant to MPI's rights under Section 1.2(d).

Second, nothing in this scenario requires Takeda to voluntarily withdraw Licensed Patents. Instead, Takeda could continue to assert the Licensed Patents, as it did in its litigation against the Earlier Filers. That is the very purpose of Section

1.2(d) – to allow Takeda to assert the Licensed Patents that it deems appropriate to protect its monopoly.

Third, Takeda is incorrect in assuming that the hypothetical Third Party generic product would not be approvable by the FDA. The Hatch-Waxman Act expressly contemplates that an ANDA applicant may "carve out" an approved indication of the branded drug (i.e., Colcrys®). *See* 21 U.S.C. § 355(j)(2)(A)(viii). The FDA will approve the generic ANDA for the remaining indication or indications, provided there are no other patents that are held to cover the remaining indications, and the other requirements for FDA approvability have been satisfied.

In sum, none of Takeda's faulty, after-the-fact hypotheticals warrant deviating from the plain language of Section 1.2(d).

2. The District Court Did Not Err in Finding That Takeda's Interpretation Renders Section 1.2(d) Meaningless

The District Court was correct: Takeda's proffered interpretation of Section 1.2(d) would render the provision meaningless by "mak[ing] 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." Appx21. Indeed, because "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 [MPI]." *Id*.

Takeda's attempt to contradict these findings fails. ***First***, Takeda argues that its proffered construction would not permit it to circumvent Section 1.2(d) because Takeda purportedly cannot "unilaterally drop patents from a litigation" without a defendant's consent. Takeda's Br. at 31-32. But Takeda offers no explanation as to why a defendant would not consent to dismissal with prejudice of patent claims asserted against it pursuant to an agreed-upon stipulation between the parties, as Hikma did in the *West-Ward* Litigation. Moreover, Takeda does not dispute that it could drop a patent without defendant's consent prior to defendant filing an answer or summary judgment motion (*see* Fed. R. Civ. P. 41(a)(1)(A)(i)), or with a court order. *See* Fed. R. Civ. P. 41(a)(2); *see also* Takeda's Br. at 31-32. Although Takeda suggests that such unilateral dismissal may not dispose of a declaratory judgment claim asserted by defendant, such a claim would not be "asserted" by Takeda "against a Third Party" and thus is irrelevant to Section 1.2(d). *See* Appx88(§ 1.2(d)), Appx3844:2-3845:2. Finally, Takeda does not dispute that nothing would prevent it from unilaterally dropping a specific claim of a patent (rather than the entire patent), which in itself would render Section 1.2(d) as interpreted by Takeda meaningless. Appx21.

Second, Takeda incorrectly argues that even if the Third Party defendant

consented to Takeda dismissing certain patent claims, the Third Party would 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" under the Hatch-Waxman Act. Takeda's Br. at 33. As discussed above, a judgment of non-infringement is not required to terminate the 30-month stay. *See supra* pp. 37-38. Moreover, the notion that a Third Party would insist on an affirmative judgment "to trigger a first-filer's 180-day exclusivity" prior to agreeing that Takeda may dismiss a Licensed Patent is contradicted by stipulations of dismissal in Takeda's actions against the Earlier Filers, none of which incorporated such a judgment.[12] *See Takeda Pharm. U.S.A., Inc. v. Par Pharm. Cos. Inc.*, No. 1:13-cv-01524-SLR (D. Del. Jan. 8, 2016), D.I. 240; *Takeda Pharm. U.S.A., Inc. v. Watson Labs. Inc.*, No. 1:14-cv-00268-SLR (D. Del. Feb. 26, 2016), D.I. 189; *Takeda Pharm. U.S.A. Inc. v. Amneal Pharm. LLC*, No. 1:13-cv-01729-SLR (D. Del. May 2, 2016), D.I. 204. In addition, Takeda's argument is disingenuous because by the time the License Agreement was executed, Takeda had already entered an agreement with Par under which Par would distribute an authorized generic Colcrys®, which in turn would trigger Par's 180-day exclusivity period. *See* Appx1117-1118(¶¶4-7), Appx2843-2844(¶¶4-7).

[12] While Par, as the "first filer," may have wanted to hold off on triggering its 180-day exclusivity period, the same cannot be said for the other two Earlier Filers.

Thus, had a Third Party insisted on an affirmative judgment to trigger Par's 180-day exclusivity, Takeda was positioned to explain that this should not be a concern (and, in fact, that exclusivity was triggered in July 2018). In any event, Section 1.2(d) is not limited to Hatch-Waxman litigations and ANDA applicants, rendering this argument another red herring. *See supra* Section II.D.1 & pp. 36-37.

Third, Takeda wrongly contends that it is not routine for parties to drop asserted claims throughout the course of a patent litigation. Takeda's Br. at 31. As this Court has explained, "[c]laims and defendants frequently are dropped and amended during the course of a lawsuit," and "sound judicial policy encourages a narrowing of issues." *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 694 (Fed. Cir. 2001); *see also Chrimar Holding Co., LLC v. ALE USA Inc.*, 732 F. App'x 876, 891 (Fed. Cir. 2018), *as amended* (June 1, 2018) (Appx4057) (holding that the district court did not abuse its discretion by finding that the defendant's decision to drop defenses and counterclaims late in the litigation "fell within the range of ordinary practices involving the narrowing of claims for trial"). This is especially true in complex patent litigation, where "it is often helpful to allow parties … to narrow the scope of their dispute by dropping certain patent claims from the action." *Twin Rivers Eng'g, Inc. v. Fieldpiece Instruments, Inc.*, No. 2:16-cv-04502-MLH (MRWx), 2018 WL 6038277, at *12 (C.D. Cal. Apr. 24, 2018) (Appx4106). Indeed, as noted above, courts routinely require plaintiffs to

limit the asserted claims where they are overlapping and duplicative. *See supra* pp. 33-34.

Fourth, Takeda's suggestion that the District Court was relying on an assessment of MPI's subjective intent is baseless. The District Court was clear it was interpreting the License Agreement as it "would be understood by ***an objective, reasonable third party***." Appx20 (emphasis added) (quoting *Exelon*, 176 A.3d at 1267). The Court's statement that "[i]t seems unlikely that [MPI] would have bargained for a practically useless provision" was merely assuming that MPI would act as "an objective, reasonable third party." *See* Appx20-21. It was also applying the fundamental principle of contract interpretation that courts "will not read a contract to render a provision or term meaningless or illusory." Appx21 (quoting *Osborn*, 991 A.2d at 1159-60).

Because Section 1.2(d) clearly and unambiguously permits MPI to launch its colchicine product, Takeda has failed to demonstrate a likelihood of success on the merits. This alone warrants affirmance of the District Court's Order.

III. TAKEDA FAILED TO DEMONSTRATE IRREPARABLE HARM

The District Court was correct: Takeda failed to demonstrate irreparable harm. Appx21-22. Takeda hinges its irreparable harm argument almost entirely on a provision of the License Agreement providing that marketing MPI's colchicine product "in breach of Paragraph 1.2…would cause Takeda irreparable

harm." Appx94(§ 1.10), Appx21-22; *see also* Takeda's Br. at 34-36. But Takeda fails to demonstrate a breach of the License Agreement by MPI, rendering Section 1.10 inapplicable. *See supra* Section II; Appx94(§ 1.10); *see also* Appx21.[13]

Without an enforceable stipulation upon which to rely, Takeda did not and cannot prove irreparable harm. Though Takeda suggests that MPI's launch "likely will cause Takeda/Par to incur irreversible price erosion and long-term loss of market share," Takeda offers no evidence to support this assertion. Takeda's Br. at 36. Instead, all Takeda offers is a single email indicating loss of a single customer of Par's authorized generic – hardly indicative of "irreversible price erosion and long-term loss of market share[.]" *See* Appx665 n.3, Appx808-809; *see also Marxe v. Jackson*, 833 F.2d 1121, 1127 (3d Cir. 1987) (failure to produce affirmative evidence indicating movant "will be irreparably harmed" requires denial of preliminary relief).

Moreover, as the District Court correctly held, "[m]oney damages would remedy any harm Takeda will suffer as a result of [MPI] launching its product." Appx21-22 (citing *Frank's GMC Truck Ctr.*, 847 F.2d at 102); *see also Baxalta*

[13] Even when such a provision is applicable, courts have conducted an independent analysis of irreparable harm. *See Cabela's LLC v. Highby*, 362 F. Supp. 3d 208, 224 (D. Del. 2019) (noting "most federal courts do not consider a contractual stipulation dispositive for purposes of showing irreparable harm"); *Hadeed v. Advanced Vascular Res. of Johnstown, LLC*, No. 3:15-cv-22, 2016 WL 7176658, at *4 (W.D. Pa. Dec. 8, 2016) (Appx4074) (noting Delaware courts do not necessarily regard contractual irreparable harm provisions as dispositive).

Inc. v. Genentech, Inc., C.A. No. 17-509-TBD, 2018 WL 3742610, at *10 (D. Del. Aug. 7, 2018) (Appx4042) (preliminary injunction denied where movant "has not shown that the loss of sales and market share it will experience could not be compensated by money damages").

This is particularly so because, independent of any launch by MPI under Section 1.2(d), other generic Colcrys® competitors are likely to enter the market without challenge from Takeda long before any damages trial in this action.[14] The default Generic Entry Date in MPI's own License Agreement almost certainly will arrive before any damages trial in this action would occur (*see* Appx88(§ 1.2(a))), and there is no basis to believe that manufacturers who settled with Takeda after MPI have materially later default Generic Entry Dates. *See* Appx44(¶ 62) (alleging that its settlements with generic Colcrys® manufacturers each provide a default "Generic Entry Date" guaranteeing access to the market "upon a date certain"). Moreover, Takeda has repeatedly contended that the "Earlier Filers" have the right to enter the generic Colcrys® market before MPI, further confirming that there will be generic Colcrys® competition well in advance of any permanent injunction and damages trial in this action. *See* Takeda's Br. at 21; Appx663.

[14] To be clear, MPI maintains that no such damages trial will ever take place since Takeda cannot prevail on liability.

Accordingly, the District Court was correct that "calculating Takeda's damages [will not] be any more difficult than in the usual patent case," particularly "when it appears to be undisputed that even if [MPI] 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." Appx21-22; *see also Baxalta*, 2018 WL 3742610, at *11 (Appx4042) ("[T]his is not a case where a jury would be tasked with calculating speculative damages for an ongoing loss of market share that cannot be recouped. [Movant] will almost certainly lose market share in the near future after patent expiration, and it can be compensated for any lost sales that occur in the intervening period before patent expiration.").[15]

Finally, the fact that Takeda has engaged in a practice of granting licenses under the Licensed Patents demonstrates that should a violation of Takeda's patent rights be found (which it will not be), any associated harm can be addressed with monetary damages. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (offering to license the patent "suggests that any injury suffered by [the patentee] would be compensable in damages").

[15] Takeda has not disputed that MPI would be able to satisfy any adverse judgment. *See* Appx2306(¶¶ 26-27).

Because Takeda's harms are fully compensable, Takeda fails to demonstrate irreparable harm.

IV. THE REMAINING FACTORS WEIGH IN MPI'S FAVOR

Although this Court (like the District Court) need not consider the remaining two factors, they weigh strongly in favor of denying Takeda's Motion.

A. The Balance of Hardships Favors MPI

In assessing this factor, the Court "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief[.]" *Winter*, 555 U.S. at 24 (citation omitted). The harm to MPI if a preliminary injunction were granted strongly outweighs any harm to Takeda should a preliminary injunction be denied. As an initial matter, Takeda's weak showing of likelihood of success in itself tips the balance of hardships toward MPI. *See Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990).

Moreover, while any harm Takeda may suffer in the absence of an injunction is fully compensable, *see supra* pp. 46-48, an injunction will cause MPI to lose the extremely valuable position of being the first generic colchicine product on the market (other than Mitigare® and Colcrys® authorized generics). Appx2303-2304(¶¶ 12, 15-17). As one of the first generic colchicine product suppliers on the market, MPI would be able to reap attendant benefits in market share, goodwill, and brand loyalty. *Id*.(¶ 16). Loss of this critical advantage will

result in the immediate decline of MPI's market share and decreased product sales over the life of MPI's colchicine product, as well as commensurate harms to MPI's brand, including loss of customer goodwill and diminished reputation. Appx2304(¶ 17). Such harms have been recognized as irreparable. *See Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 211 (3d Cir. 2014) ("[H]arm…caused to reputation and goodwill is irreparable because it is virtually impossible to quantify in terms of monetary damages."); *Gucci Am., Inc. v. Daffy's, Inc.*, 354 F.3d 228, 237 (3d Cir. 2003) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill.") (citation omitted).

Although Takeda asserts that the market for MPI's colchicine product "will not disappear or be materially changed" while an injunction is in effect (Takeda's Br. at 37), that is simply wrong. An injunction would provide Takeda and third parties the opportunity to take advantage of MPI's absence from the market while the litigation is pending. Appx2304(¶ 18). For example, Takeda could renegotiate settlement agreements with competitors it views as less viable than MPI (to MPI's disadvantage), or Takeda, Par, and/or Hikma could flood the market with their own colchicine products – as could other third parties, who no doubt would use the time to put themselves in a position to launch their colchicine products as soon as they

are able.[16] *Id*. In addition, as discussed above, other generic Colcrys® competitors are nearly certain to have default Generic Entry Dates that permit them to enter the market during the pendency of any injunction (*see supra* p. 47), rendering Takeda's claim that the market will not "materially change[]" inexplicable. Constraining MPI while Takeda, Par, Hikma, and other colchicine manufacturers are permitted to distribute their products or otherwise take advantage of MPI's absence is both harmful to MPI and the height of unfairness.

Finally, although Takeda claims that MPI's generic colchicine "would be a very small percentage of [MPI's] overall revenue and immaterial to [MPI]" (Takeda's Br. at 38), Takeda fails to analyze the ***comparative*** harm to MPI from the loss of sales of its generic colchicine product as compared to the potential loss Takeda may face. *See Winter*, 555 U.S. at 24. Takeda's argument – which omits reference to Takeda's own portfolio and revenue – is irrelevant. For all these reasons, the balance of hardships factor favors MPI.

B. The Public Interest Favors MPI

Courts "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 555 U.S. at 24 (citation omitted). The public would be adversely affected should Takeda's

[16] Alkem Laboratories is one example of this. *See Takeda Pharm. U.S.A., Inc. v. Alkem Labs. Ltd.*, No. 1:20-cv-00325-RGA (D. Del. filed Mar. 3, 2020).

requested injunction be granted. Colchicine is a critical medicine for the millions of Americans suffering from gout. Appx2395. The re-introduction of MPI's colchicine product will increase competition in the market, leading to more affordable pricing, and making the product more readily available to patients. Appx2306(¶¶ 24-25); *see also Genentech, Inc. v. Amgen Inc.*, Civ. No. 18-924-CFC, 2019 WL 3290167, at *3 n.7 (D. Del. July 18, 2019) (Appx4070) ("For pharmaceutical drugs that prolong and save lives, there is a critical public interest in affordable access to those drugs."), *aff'd*, No. 2019-2156, 2020 WL 1081707 (Fed. Cir. Mar. 6, 2020).

Moreover, the public interest in "enforcement of valid patent rights, and protection of the attendant incentive to invest large sums of money in research and development of new medicines" has already been satisfied here. *See Noven Pharm., Inc. v. Mylan Techs. Inc.*, C.A. No. 17-1777-LPS, 2018 WL 4052418, at *5 (D. Del. Aug. 20, 2018) (Appx4092). Takeda has enjoyed a substantial period of exclusivity and has significantly profited from its patent rights. *See* Appx2398. Takeda enjoyed this exclusivity even though "healthcare professionals…have questioned the value of the research that allowed Takeda to obtain exclusivity in the first instance." Appx2398-2399 ("[I]t is important to recognize that the standard of care was evolving toward the use of low-dose colchicine [before Takeda's study].") (citation omitted).

V. HIKMA'S ARGUMENT IN ITS PROPOSED *AMICI* BRIEF SHOULD BE REJECTED[17]

A. Hikma's Argument Was Expressly Disclaimed and Waived by Takeda and Thus Should Not Be Considered by the Court

Hikma's *amici* brief asks this Court to find that the Stipulation of Dismissal "adjudicated" the five withdrawn patent claims – even though Takeda and MPI ***agree*** that the Stipulation of Dismissal did ***not*** "adjudicate" these claims for the purposes of Section 1.2(d). *See supra* pp. 19-20. The Court should reject Hikma's attempt to put forward an argument that both parties have rejected and that is not in dispute on appeal.

Appellate courts have consistently held that an *amicus* "may not raise additional issues or arguments not raised by the parties" themselves. *Self-Ins. Inst. of Am., Inc. v. Snyder*, 827 F.3d 549, 560 (6th Cir. 2016) (citation omitted); *see also United States v. Ackerman*, 831 F.3d 1292, 1299 (10th Cir. 2016) (functions of *amici* briefs "don't include presenting arguments forgone by the parties"); *N.J. Retail Merchants Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 382 n.2 (3d Cir. 2012) (*amicus* brief "is normally not a method for injecting new issues into an appeal") (citation omitted); *Resident Council of Allen Parkway Vill. v. U.S. Dep't of Hous.*

[17] The Court has yet to rule on Hikma's Motion for Leave to File an Amici Brief, which MPI has opposed. Thus, out of an abundance of caution, MPI addresses Hikma's argument herein. Should the Court deny Hikma's Motion for Leave, the Court may disregard this portion of MPI's brief.

& Urban Dev., 980 F.2d 1043, 1049 (5th Cir. 1993) ("[A]n amicus curiae generally cannot expand the scope of an appeal to implicate issues that have not been presented by the parties to the appeal.").

Consequently, appellate courts "routinely decline[] to consider arguments presented only in an amicus brief[.]" *Ackerman*, 831 F.3d at 1299; *see also Self-Ins. Inst. of Am.*, 827 F.3d at 560 ("To the extent that the amicus raises issues or makes arguments that exceed those properly raised by the parties, we may not consider such issues.") (citation omitted); *World Wide St. Preachers Fellowship v. Town of Columbia*, 591 F.3d 747, 752 n.3 (5th Cir. 2009) ("[W]e will not consider the arguments raised only by the amicus curiae."); *Narragansett Indian Tribe v. Nat'l Indian Gaming Comm'n*, 158 F.3d 1335, 1338 (D.C. Cir. 1998) (refusing to consider arguments raised by *amicus* "[b]ecause we ordinarily do not entertain arguments not raised by parties").

Here, Hikma's *amici* brief is devoted entirely to the argument that the five patents voluntarily withdrawn by Takeda in the Stipulation of Dismissal were "adjudicated." ECF No. 39-2 ("Hikma's Br.") at 6-11. Yet both MPI and Takeda have taken the contrary position, ***agreeing*** that those five patents were ***not*** adjudicated for the purposes of Section 1.2(d). In particular, Takeda – the party Hikma purports to support – has left no doubt that its position is that the five patents addressed in the Stipulation of Dismissal were not "adjudicated" under

Section 1.2(d). *See supra* pp. 19-21. Having repeatedly admitted that the five withdrawn patents were not "adjudicated" under Section 1.2(d), including in this appeal, Takeda has waived any argument to the contrary. *See supra* p. 20.

Despite the above, Hikma claims that its position "comports with Takeda's alternative ground for reversal[.]" Hikma's Br. at 10. Hikma is wrong. Takeda's opening brief does not offer an "alternative" position on whether the Stipulation of Dismissal constitutes an adjudication of the withdrawn patents for the purposes of Section 1.2(d). To the contrary, Takeda is absolutely clear: "In the *West-Ward* Litigation,…***only three of the eight patents were adjudicated***. With respect to the remaining five patents, ***there was no adjudication at all***[.]" Takeda's Br. at 24 (emphasis added). In making this argument, Takeda distinguished the same authority relied on by Hikma on the ground that this authority finds "[a] voluntary dismissal with prejudice constitutes an adjudication ***solely for claim preclusion***[.]" *See id*. at 18 (emphasis added) (citing *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1372-73 (Fed. Cir. 2013)). In other words, Takeda recognized that regardless of whether a stipulation of voluntary dismissal has the effect of an adjudication between the parties to the stipulation for the discrete purpose of claim preclusion, such a stipulation does not "adjudicate" claims for the purposes of Section 1.2(d) of the License Agreement.

Even if not offered by Takeda, Hikma suggests that the Court nonetheless may accept Hikma's interpretation as an "alternative to Takeda's primary argument." Hikma's Br. at 10 n.3. The authorities relied on by Hikma for this proposition – set forth only in a footnote – are inapposite. *Id*. For example, in *Samuels, Kramer & Co. v. CIR*, the lower court relied on the appellee's argument to conclude "that the Tax Court is a 'Court of Law' within the meaning of the Appointments Clause[.]" 930 F.2d 975, 978 (2d Cir. 1991). Although the appellee subsequently changed its position on appeal such that only the *amicus* asserted this argument, *id*. at 986 n.9, the appellate court necessarily had to address the argument to affirm or reverse the lower court's decision. *Id*. at 994. Here, by contrast, Takeda admitted that the five dismissed patents were not "adjudicated" below, and the District Court accepted Takeda's position in denying the preliminary injunction. *See* Appx19. Accordingly, this Court need not consider Hikma's argument when deciding whether to affirm or reverse the District Court's Order.

The other cases cited by Hikma are likewise unavailing. In *United States v. Matthews*, the court did not decide the issue raised only by *amicus*, but rather merely commented in *dictum* that "Amici's argument [was] ill-advised." 209 F.3d 338, 344 n.3 (4th Cir. 2000). Further, the appellant in *Matthews* did not repeatedly and expressly reject the argument urged by *amici*, including in its briefs on appeal

(as Takeda does here). Rather, the appellant "clarified at oral argument that he does not" make the same claim as *amici*. *Id*. *Bridges v. City of Bossier* similarly did not involve a situation where the appellant directly contradicted the argument raised by *amicus*, but rather the *amicus* presented a "variation on [appellant's] legal argument[.]" 92 F.3d 329, 334 n.8 (5th Cir. 1996).

Hikma's final argument that "this Court reviews issues of law…*de novo*" (Hikma's Br. at 10 n.3) is irrelevant. The "standard of review is wholly separate from whether a party has adequately preserved an issue for review on appeal." *Meineke Car Care Ctrs., Inc. v. RLB Holdings, LLC*, 423 F. App'x 274, 279 n.6 (4th Cir. 2011) (Appx4088). A party can waive an argument even if the argument is legal in nature. *See id.* (holding that "the failure of a party at trial to raise a certain interpretation of a[] contract results in a waiver of that argument on appeal" even though "appellate review of a district court's interpretation of a contract is *de novo*") (citation omitted); *Prusky v. Prudential Ins. Co. of Am*., 44 F. App'x 545, 547-48 (3d Cir. 2002) (Appx4096-4097) (finding that appellant "waived the right to argue" a contract construction when the proffered "interpretation of the contract [was] different from and contrary to the one that [appellant] presented at trial").

Consideration of Hikma's argument would be tantamount to permitting an end-run around the rules that arguments not raised in an opening brief are waived,

and that *amici* should not be allowed to insert into the appeal an issue not raised by the parties. Accordingly, Hikma's interpretation should be disregarded.

B. The Patents Dismissed in the *West-Ward* Litigation Were Not "Adjudicated" Under Section 1.2(d)

Even if considered on the merits, Hikma's argument on the meaning of "adjudicated" should be rejected. Under Delaware law, the Court is "constrained by a combination of the parties' words and the plain meaning of those words" in interpreting the License Agreement. *See supra* pp. 17-18. Moreover, courts should reject arguments from outsiders to the contract that urge an interpretation different than that agreed by the contracting parties. *See, e.g.*, *James v. Zurich-Am. Ins. Co. of Ill.*, 203 F.3d 250, 255 (3d Cir. 2000) (explaining that where "both parties to the contract say that the provision means 'X,' while a stranger to the contract . . . says it means 'Y,'" the "construction given to that provision by the parties to the contract controls its terms"); *Hilco Capital, LP v. Fed. Ins. Co.*, 978 A.2d 174, 179 (Del. 2009) ("The intent of the contracting parties, not outsiders, controls the construction of the agreement.").

Hikma – a non-party to the License Agreement motivated by its self-interest in excluding MPI from the colchicine market (*see* Hikma's Br. at 3) – disregards these standards, urging an interpretation that was rejected by the parties and that does not address the plain meaning of the License Agreement. In fact, Hikma does not address whether the five dismissed patents were "adjudicated" for the purposes

of Section 1.2(d) at all. Instead, Hikma focuses on the irrelevant question of whether the Stipulation of Dismissal "operates as an adjudication" between the parties to that stipulation under the Federal Rules of Civil Procedure and for *res judicata* purposes. *See* Hikma's Br. at 8 (citing cases for the proposition that a stipulation of dismissal may create the effect of an "adjudication" between the parties to the stipulation for discrete purposes such as claim preclusion); *id*. at 9 (claiming that "the answer lies in the [S]tipulation of [D]ismissal itself along with Rule 41").

Hikma misses the point. The key issue before the Court in this appeal is whether the clear and unambiguous language of Section 1.2(d) permits MPI to launch its colchicine product – not whether the Stipulation of Dismissal may "operate as an adjudication" between the parties to the stipulation for certain discrete purposes such as *res judicata*. *See* Hikma's Br. at 8-9. Clearly, something can have the effect of an adjudication for certain limited purposes without actually "adjudicat[ing]" claims as that term is commonly understood. Hikma ignores this distinction.

Construing "adjudicated" (the actual contract term) in accordance with its plain meaning, it is clear that the five dismissed patents were not "adjudicated" for the purposes of Section 1.2(d). Relevant dictionary definitions overwhelmingly confirm that the plain meaning of "adjudicated" necessarily encompasses some

form of judicial analysis and resolution. *See* BLACK'S LAW DICTIONARY (10th ed. 2014) (Appx2377) (defining "adjudicate" as "[t]o rule on judicially" and "adjudge"); MERRIAM-WEBSTER DICTIONARY (Online Version), https://www.merriam-webster.com/dictionary/adjudicate (last visited Mar. 10, 2020) (Appx2381) ("adjudicate" defined as "to make an official decision about who is right in (a dispute)," "to settle judicially," and "to act as judge"); THE OXFORD ENGLISH DICTIONARY (2d ed. 1991) (defining "adjudicate" as "[t]o adjudge; to award; to give something controverted to one of the litigants, by a sentence or decision," "[t]o try and determine judicially; to pronounce by sentence of court," and "[t]o sit in judgment and pronounce sentence; to act as a judge, or court of judgment"); *see also Lorillard Tobacco Co.*, 903 A.2d at 738 (Delaware courts look to dictionaries in determining the plain meaning of undefined contract terms).

Franklin v. Sessions, 291 F. Supp. 3d 705 (W.D. Pa. 2017), is instructive. There, the court consulted dictionary definitions and found that "[t]he plain meaning of 'adjudicated' connotes the involvement of a judicial decision-maker, the resolution of a dispute after consideration of argument by the parties involved, and a deliberative proceeding with some form of due process." *Id.* at 715 & n.9. Though Hikma attempts to distinguish this case by asserting that it involved statutory rather than contract interpretation (Hikma's Br. at 9), Hikma does not

dispute that the court was focused on determining the plain meaning of "adjudicated." *Id*. at 715 (finding it is appropriate to "construe [undefined] statutory terms in accordance with their ordinary or natural meaning"). Interpreting the plain meaning of Section 1.2(d) is the precise issue on this appeal.

Interpreting "adjudicated" as involving a judicial ruling is also consistent with other language in Section 1.2(d), which contemplates a judicial decision encompassing "holding[s]" on substantive issues such as those enumerated in the provision. *See* BLACK'S LAW DICTIONARY (Appx2379) (defining "holding" as "[a] court's determination of a matter of law pivotal to its decision" and "[a] ruling on evidence or other questions presented at trial"); MERRIAM-WEBSTER DICTIONARY (Online Version), https://www.merriam-webster.com/dictionary/holding (Appx2382) (defining "holding" as "a ruling of a court especially on an issue of law raised in a case").

By contrast, a stipulation of dismissal under Federal Rule of Civil Procedure 41(a)(1)(A)(ii) – the provision invoked in the *West-Ward* Litigation – is self-executing; it involves no judicial ruling or determination whatsoever. *See State Nat'l Ins. Co. v. Cty. of Camden*, 824 F.3d 399, 406-07 (3d Cir. 2016) ("Every court to have considered the nature of a voluntary stipulation of dismissal under Rule 41(a)(1)(A)(ii) has come to the conclusion that it is immediately self-executing. No separate entry or order is required to effectuate the dismissal.");

Fed. R. Civ. P. 41(a)(1)(A) (setting forth mechanism for "Voluntary Dismissal…Without a Court Order"). This is consistent with the text of the Stipulation of Dismissal, which simply provides for dismissal of the covered claims and associated defenses. *See* Appx2346-2347(¶¶ 1-5). Even Hikma concedes that the Stipulation of Dismissal did not "decid[e] any substantive issues on the merits." Hikma's Br. at 11-12.

Notably, in urging this Court to disregard the plain meaning of the License Agreement, Hikma's *amici* brief inaccurately represents that Federal Rule of Civil Procedure 41(a)(1)(A)(ii) provides that a stipulation of dismissal "operates as an adjudication on the merits." Hikma's Br. at 9. In fact, that language does not appear in the cited subsection, but rather appears in a sentence of Rule 41 inapplicable here. *See* Fed. R. Civ. P. 41(a)(1)(B); Appx2346-2347. In any event, as noted above, whether the Stipulation of Dismissal "operates as an adjudication" under Federal Rule of Civil Procedure 41 for the purposes of *res judicata* is irrelevant to how the term "adjudicated" as used in Section 1.2(d) should be interpreted.

Finally, Hikma's *amici* brief ignores that regardless of whether the five dismissed patents were adjudicated – and they were not – the patents were not "asserted" as required by Section 1.2(d) because Takeda made the affirmative

decision to withdraw these patents through filing of the Stipulation of Dismissal. *See supra* pp. 21-22.

CONCLUSION

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

Dated: March 11, 2020

Respectfully Submitted,

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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(Date)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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