

20-1407, -1417

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

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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

**CORRECTED BRIEF FOR DEFENDANT-APPELLEE
MYLAN PHARMACEUTICALS INC. IN OPPOSITION TO BRIEF
FOR HIKMA PHARMACEUTICALS USA, INC. AND
HIKMA PHARMACEUTICALS INTERNATIONAL LIMITED AS *AMICI CURIAE***

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April 3, 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)

MYLAN PHARMACEUTICALS INC.

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

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
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
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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc., No. 1:19-cv-02216-RGA (D. Del.)

March 4, 2020

Date

/s/ Michael S. Sommer

Signature of counsel

Michael S. Sommer

Printed name of counsel

Please Note: All questions must be answered

cc: _____

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Defendant-Appellee Mylan Pharmaceuticals Inc. (“MPI”) respectfully submits this response to non-parties Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Limited’s (collectively, “Hikma”) *amici curiae* brief. ECF No. 39-2 (“Hikma’s Br.”).¹

INTRODUCTION

This appeal concerns the meaning of a contractual provision contained within a confidential License Agreement between MPI and Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”). Hikma’s *amici* brief puts forward an interpretation of this contractual provision that neither party to the License Agreement accepts and that Takeda—the party Hikma purports to support through its *amici* brief—has explicitly and repeatedly rejected. The Court should decline to consider Hikma’s argument, which addresses an issue not disputed on appeal, and which constitutes an end-run around the rule that arguments not asserted in an appellant’s opening brief are waived and cannot be considered by the Court.

In the event the Court nonetheless considers Hikma’s argument – and it should not – Hikma’s proposed contract construction should be rejected. It is not surprising that the actual parties to the contract reject Hikma’s position: Hikma’s proposed interpretation bears no relation to the plain meaning of the relevant

¹ “ECF No.” refers to documents from this Court’s docket. “D.I.” refers to documents from the District Court’s docket.

contractual language and thus completely disregards the governing Delaware law on contract construction. Indeed, Hikma does not appear to be concerned with the contract at all, instead focusing its argument on how the relevant term might be construed for purposes of the Federal Rules of Civil Procedure and *res judicata* – an issue that is entirely beside the point.

Hikma is neither a party to the License Agreement, nor did it have any involvement in the negotiation or consummation of the License Agreement. As such, Hikma has no basis to tell the Court what the parties intended in their License Agreement, particularly because the self-serving interpretation urged by Hikma has been expressly disclaimed by the parties. Hikma’s argument should be rejected and its *amici* brief disregarded.

BACKGROUND

In its appeal, Takeda challenges the District Court’s denial of its Motion for Preliminary Injunction to enjoin sales of MPI’s colchicine product. *See* ECF No. 35. A key issue on appeal is the interpretation of a License Agreement that resolved a litigation in which Takeda alleged that MPI’s colchicine product infringed Takeda’s Colcrys® patents. *See* Appx18; Appx73-112. The License Agreement grants MPI a license to Takeda’s Colcrys® patents (the “Licensed Patents”) under specified terms and conditions. Appx88 § 1.1. Relevant to this

appeal is 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[.]

Id. § 1.2(d).²

At the time the parties entered into the License Agreement, Takeda was engaged in a lawsuit against Hikma, in which Takeda claimed that Hikma's Mitigare® product 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 [D.I. 43, Ex. B at 12-16]. Mitigare®, like Colcrys®, is a 0.6 mg colchicine product that is administered orally and that is indicated for the prevention of gout. *See* Appx1692, Appx1735 [D.I. 22, Ex. 2 at 1, Ex. 8 at 1].

Though at one point Takeda had asserted eight patents against Hikma, "[Takeda] voluntarily dismissed" five of those patents via a Stipulation of

² 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.

Dismissal, such that “only [three patents] remain[ed] at issue for the purposes of summary judgment.” Appx2357-2358 [D.I. 43, Ex. G at 1-2]; *see also* Appx2346-2347 ¶¶ 1-5 [D.I. 43, Ex. E ¶¶ 1-5] (“Stipulation of Dismissal”). Those three patents are “Licensed Patents” under the License Agreement between MPI and Takeda. *Compare* Appx2357-2358 [D.I. 43, Ex. G at 1-2] *with* Appx103 (“Licensed Patents” definition).

In a decision authored by Judge Andrews, in December 2018, the *West-Ward* court granted summary judgment in favor of Hikma, holding that Hikma did not infringe the three patents asserted by Takeda. Appx2358, Appx2361-2370 [D.I. 43, Ex. G at 2, 5-14]; Appx2372 [D.I. 43, Ex. H]. The same day, the court entered judgment in favor of Hikma and against Takeda to formalize its non-infringement adjudication. Appx2374 [D.I. 43, Ex. I] (“*West-Ward* Judgment”). Takeda did not appeal.

In October 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. Appx17-18. On December 2, 2019, over a month after MPI’s October notice, Takeda filed this action in the District Court alleging MPI’s breach of the License Agreement and patent infringement. Appx18. 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 colchicine product. Appx18.

On January 27, 2020, the District Court denied 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.

Takeda immediately filed this appeal. ECF No. 1.

ARGUMENT

I. THE COURT SHOULD NOT CONSIDER ARGUMENTS EXPRESSLY WAIVED BY TAKEDA AND ASSERTED ONLY IN HIKMA'S *AMICI* BRIEF

Hikma's *amici* brief improperly attempts to use the *amicus* process to put forward an argument that both parties have explicitly rejected and that is not in dispute on appeal. As described below, Hikma's *amici* brief urges this Court to find that the Stipulation of Dismissal "adjudicated" the five withdrawn patent claims, whereas *both* Takeda and MPI *agree* that the Stipulation of Dismissal did *not* "adjudicate" the five withdrawn claims for the purposes of Section 1.2(d) of the License Agreement. *See infra* pp. 7-9. The Court should reject Hikma's argument.

A. Hikma's Argument Has Been Disclaimed By The Parties And Waived By Takeda

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 themselves”); *N.J. Retail Merchants Ass’n v. Sidamon-Eristoff*, 669 F.3d 374, 382 n.2 (3d Cir. 2012) (“Although an amicus brief can be helpful in elaborating issues properly presented by the parties, it is normally not a method for injecting new issues into an appeal, at least in cases where the parties are competently represented by counsel.”) (citation omitted); *Resident Council of Allen Parkway Vill. v. U.S. Dep’t of Hous. & Urban Dev.*, 980 F.2d 1043, 1049 (5th Cir. 1993) (“We are constrained . . . by the rule that an amicus curiae generally cannot expand the scope of an appeal to implicate issues that have not been presented by the parties to the appeal.”).³

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.*

³ *See also Lane v. First Nat’l Bank of Bos.*, 871 F.2d 166, 175 (1st Cir. 1989) (“We know of no authority which allows an amicus to interject into a case issues which the litigants, whatever their reasons might be, have chosen to ignore.”); *United States v. Ne. Pharm. & Chem. Co.*, 810 F.2d 726, 732 n.3 (8th Cir. 1986) (“[A]micus[] cannot raise issues not raised by the parties.”).

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”).

Hikma’s *amici* brief does just that: It devotes itself entirely to the argument that the five patents voluntarily dismissed by Takeda in the Stipulation of Dismissal were “adjudicated.” Hikma’s Br. at 6-11. Both MPI and Takeda, however, have taken the contrary position, agreeing that those five patents were not adjudicated for the purposes of Section 1.2(d), such that the issue is not in dispute on appeal. In particular, Takeda – the party whom Hikma purports to support via its *amici* brief – has left no doubt that its position on appeal is that the five patents it voluntarily dismissed in the *West-Ward* Litigation in the Stipulation of Dismissal were not “adjudicated” under Section 1.2(d). *See* Takeda’s Br. (ECF No. 35) 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 Br. (Appx3758) [D.I. 122-1 at 3] (“[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) [ECF No. 21, Ex. A at 59:21-60:23] (“The patents were voluntarily dismissed, i.e., *they were never adjudicated....* There was no adjudication on those five patents.”) (emphasis added). This position, with which MPI concurred, was recognized and adopted by the District Court. *See* Appx19 (District Court order noting that “[a]ccording to Takeda, only three patents were ‘adjudicated’[.]”).

Takeda has given no indication that it intends to deviate from this position – to the contrary, Takeda has been steadfast in its interpretation including in this appeal. In any event, Takeda would be unable to change its position even if it wanted to. Having repeatedly admitted that the five withdrawn patents were not “adjudicated,” including in its opening brief on appeal, Takeda has waived any argument that the voluntary Stipulation of Dismissal “adjudicated” the five dismissed patents under Section 1.2(d). *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.”); *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”).

B. Hikma’s Attempt To Insert An Argument That Was Disclaimed By The Parties And Waived By Takeda Should Be Rejected

Hikma attempts to get around the parties’ rejection and Takeda’s waiver of Hikma’s proffered interpretation by claiming 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. (ECF No. 35) at 24. In making this argument, Takeda distinguished case law relied on by Hikma on the ground that this law finds “[a] voluntary dismissal with prejudice constitutes an adjudication ***solely for claim preclusion***[.]” *See id.* at 18 (emphasis added) (quoting *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 dismissal has the effect of an adjudication between the parties to the stipulation for the discrete purpose of future claim preclusion, such a stipulation does not

“adjudicate” claims for the purposes of Section 1.2(d) of the License Agreement. Indeed, the portion of Takeda’s opening brief quoted by Hikma confirms Takeda’s position that any effect a stipulation of dismissal might have for claim preclusion purposes is *irrelevant* to whether that stipulation “adjudicated” the subject patents under the License Agreement. *See* Hikma’s Br. at 10-11 (quoting Takeda’s Br. at 18-19 (“*[I]rrespective of whether the voluntary dismissal is regarded as an ‘adjudication’ for claim-preclusion purposes*, the voluntary dismissal did not trigger Section 1.2(d)[.]”) (emphasis added)).

No doubt recognizing that Takeda did not, in fact, offer Hikma’s interpretation as an “alternative ground for reversal,” Hikma maintains that the Court nonetheless “may accept *amici* Hikma’s interpretation of the contract” 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*, 930 F.2d 975 (2d Cir. 1991), 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[.]” *Id.* at 978. Although the appellee subsequently changed its position on appeal and 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, Takeda admitted that the five dismissed patents were

not “adjudicated” below, and the District Court expressly recognized and accepted Takeda’s position (with which MPI agreed) 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 because the District Court did not consider this argument in making its decision.

The other two cases cited by Hikma are likewise unavailing. In *United States v. Matthews*, 209 F.3d 338 (4th Cir. 2000), the appellate court did not decide the issue raised only by *amicus*, but rather merely commented in *dictum* that “Amici’s argument [was] ill-advised.” *Id.* at 344 n.3. 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*, 92 F.3d 329 (5th Cir. 1996), 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[.]” *Id.* at 334 n.8.

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). 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) (noting that the Court reviews “conclusions of law *de novo*” and finding that appellant “waived the right to argue” a contract construction based on the “plain language of the Contract” when the proffered “interpretation of the contract [was] different from and contrary to the one that [appellant] presented at trial”).

In sum, consideration of Hikma’s argument purportedly “in support of Takeda” – even though Takeda itself has both disclaimed and waived any such 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 that was not raised by the parties. For this reason alone, Hikma’s proffered interpretation of the License Agreement should be rejected.

II. THE PATENTS DISMISSED IN THE *WEST-WARD* LITIGATION WERE NOT “ADJUDICATED” UNDER SECTION 1.2(d) OF THE LICENSE AGREEMENT

Even if considered on the merits (which it should not be), Hikma’s argument on the meaning of “adjudicated” should be rejected. Under governing 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. *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006); *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, 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 – an outsider to the License Agreement motivated by its own business 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 the 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”).⁴

Hikma’s argument misses the point. The key issue before the Court on 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 have the effect of an adjudication between the parties for certain discrete purposes such as *res judicata*. Appx18 (“The critical issue here is whether Section

⁴ Notably, in making this argument, Hikma inaccurately represents that Federal Rule of Civil Procedure 41(a)(1)(A)(ii) provides that a voluntary stipulation of dismissal such as the one in the *West-Ward* Litigation “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 that is inapplicable to the Stipulation of Dismissal at issue here. *See* Fed. R. Civ. P. 41(a)(1)(B); Appx2346-2347 [D.I. 43, Ex. E].

1.2(d) of the License Agreement permits Mylan to launch its generic colchicine product.”). It goes without saying that something can operate as and have the effect of an adjudication for certain limited purposes without actually “adjudicat[ing]” claims as that term is commonly understood. Hikma thoroughly ignores this distinction.

When interpreted in accordance with its plain meaning – as governing Delaware law requires and as the District Court did (*see* Appx18-21) – it is clear that the five dismissed patents were not “adjudicated” for the purposes of Section 1.2(d). Delaware courts look to dictionaries for assistance in determining the plain and ordinary meaning of terms that are not defined in a contract. *Lorillard Tobacco Co.*, 903 A.2d at 738. Relevant dictionary definitions overwhelmingly make clear that the plain meaning of the License Agreement term “adjudicated” necessarily encompasses some form of judicial analysis and resolution. *See* BLACK’S LAW DICTIONARY (10th ed. 2014) (Appx2377) [D.I. 43, Ex. J] (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. 4, 2020) (Appx2381) [D.I. 43, Ex. K] (“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”).

The case of *Franklin v. Sessions*, 291 F. Supp. 3d 705 (W.D. Pa. 2017) is instructive. In that case, the court construed the word “adjudicated” in a statute. Recognizing that it is appropriate to “constru[e] statutory terms in accordance with their ordinary or natural meaning in the absence of a statutory definition,” the court consulted several dictionary definitions of the word “adjudicate” 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 did not involve contract interpretation (Hikma’s Br. at 9), Hikma does not dispute that the court was focused on determining the plain meaning of “adjudicated” – the precise issue on this appeal.

The construction of “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) [D.I. 43, Ex. J] (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) [D.I. 43, Ex. K] (defining “holding” as “a ruling of a court especially on an issue of law raised in a case”).

In stark contrast with the above, 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 adjudication 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 [D.I. 43, Ex. E ¶¶ 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.

Hikma’s *amici* brief also 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 from the litigation through filing of the Stipulation of Dismissal. *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 had “asserted” against Hikma and reclassified as ***un***asserted – indeed, that was the very purpose of the Stipulation of Dismissal. It makes no sense to find that by withdrawing patents – *i.e.*, by agreeing ***not*** to pursue them – Takeda is “assert[ing]” those very same patents. *See* BLACK’S LAW DICTIONARY (Appx2378) [D.I. 43, Ex. J] (“assert” means “[t]o invoke or enforce a legal right”); *see generally* ECF No. 21 at 11.

CONCLUSION

For the foregoing reasons, MPI respectfully requests that the Court disregard Hikma’s *amici* brief, which is exclusively devoted to an argument that has been waived and is not in dispute. To the extent the Court considers Hikma’s *amici* brief, MPI respectfully requests that it reject Hikma’s arguments and affirm the District Court’s order denying Takeda’s Motion for Preliminary Injunction.

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Respectfully Submitted,

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