No. 2020-1545

United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICALS U.S.A., INC.,
PLAINTIFF-APPELLANT,
v.
ALKEM LABORATORIES LIMITED AND ASCEND LABORATORIES, LLC,
DEFENDANTS-APPELLEES.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
IN CASE NO. 20-00325-RGA, JUDGE RICHARD G. ANDREWS

BRIEF FOR HIKMA PHARMACEUTICALS USA, INC. AND HIKMA PHARMACEUTICALS INTERNATIONAL LIMITED AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL

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APRIL 3, 2020

CERTIFICATE OF INTEREST

Counsel for *Amici* Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Limited certify the following:

1. The full name of every party or *amicus* represented by me is:

Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Limited

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus* curiae represented by me are:

Hikma Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Eurohealth (U.S.A.), Inc., which is a wholly-owned subsidiary of Hikma UK Limited, which is a wholly-owned subsidiary of Hikma Holdings (UK) Limited, which is a wholly-owned subsidiary of Hikma Acquisitions (UK) Limited, which is a wholly-owned subsidiary of Hikma Pharmaceuticals PLC. Hikma Pharmaceuticals PLC is publicly listed. No other publicly held companies own 10% or more of the stock of Hikma Pharmaceuticals USA, Inc.

Hikma Pharmaceuticals International Limited is a wholly-owned subsidiary of Hikma UK Limited, which is a wholly-owned subsidiary of Hikma Holdings (UK) Limited, which is a wholly-owned subsidiary of Hikma Acquisitions (UK) Limited, which is a wholly-owned subsidiary of Hikma Pharmaceuticals PLC. Hikma Pharmaceuticals PLC is publicly listed. No other publicly held companies own 10% or more of the stock of Hikma Pharmaceuticals International Limited.

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 are:

Winston & Strawn LLP: Charles B. Klein and Dan H. Hoang

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:

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., No. 1:20-cv-00325-RGA (D. Del.)

Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc., No. 2020-1407 (Fed. Cir.)

Dated: APRIL 3, 2020

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION AND INTEREST OF *AMICI CURIAE*[1]

Amici Hikma Pharmaceuticals USA, Inc. (f/k/a West-Ward Pharmaceuticals Corp.) and Hikma Pharmaceuticals International Limited (together, "Hikma") are pharmaceutical companies dedicated to developing, manufacturing, and marketing a broad range of branded and non-branded generic pharmaceutical products across the world. In particular, Hikma developed a colchicine capsule product that was approved by the FDA in September 2014 for prophylaxis of gout flares in adults, which is presently marketed in the United States under the trade name Mitigare®. Hikma's Mitigare® product was the subject of a prior patent litigation brought by Appellant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") asserting infringement of some of the same patents—but not all—at issue in this appeal. *See Takeda Pharmaceuticals, U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA-SRF (D. Del.) (the "*West-Ward* Litigation").

Amici Hikma has a strong interest in this matter, because the present dispute between Takeda and Appellees Alkem Laboratories Limited and Ascend Laboratories LLC ("Alkem") regarding whether the launch of Alkem's generic colchicine product was authorized under their License Agreement turns on the impact of the holdings in the *West-Ward* Litigation.

[1] No part of this brief was authored by counsel for a party. Nor has any party or party's counsel, or any person or entity other than the *amici*, funded the preparation or submission of this brief.

The district court denied Takeda's motion for a temporary restraining order and a preliminary injunction against Alkem "[f]or the reasons stated in *Takeda v. Mylan*, No. 19-2216-RGA, D.I. 114 (D. Del.)." Appx1. As with its decision in the *Mylan* action, the district court committed legal error in concluding that the *West-Ward* Litigation triggered Section 1.2(d) of the License Agreement allowing Alkem to launch its generic colchicine product before the specified date-certain launch date. *See* Appx12-13. Section 1.2(d) of the License Agreement provides that Alkem may launch 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/or invalid, unpatentable, or unenforceable[.]

Appx83. For five of the eight asserted and adjudicated patents in the *West-Ward* Litigation, there was no such "holding that all unexpired claims . . . are either (i) not infringed, or (ii) any combination of not infringed and/or invalid, unpatentable, or unenforceable." *Id.* Instead, all asserted claims in those five adjudicated patents were dismissed with prejudice by a stipulation between Takeda and Hikma without any holding of non-infringement, invalidity, unpatentability, or unenforceability. Appx1342-1343; *see* Appx1340-1341. As such, for those five asserted and adjudicated patents, there was no holding adverse to Takeda that would have triggered the market-entry provision under Section 1.2(d).

Accordingly, Hikma submits this *amicus* brief in support of Takeda and urges this Court to reverse the district court's order denying Takeda's motion for a preliminary injunction.

BACKGROUND

Colchicine is an ancient drug that has been used for centuries as a prophylactic treatment for gout (a form of arthritis). Use of colchicine in the United States, in fact, pre-dated formal approval by FDA. In 2006, FDA launched an Unapproved Drug Initiative that required drugs grandfathered in by the Food, Drug, and Cosmetic Act—including colchicine—to be pulled from the market and go through the standard FDA approval process for new drugs.

In 2009, Takeda's predecessor company became the first company to obtain formal FDA approval for a colchicine *tablet* product, marketed as Colcrys®. On September 26, 2014, Hikma became the first company to receive FDA approval for a colchicine *capsule* product, marketed as Mitigare®.

Hikma's Mitigare® was not approved under an Abbreviated New Drug Application ("ANDA") as a generic of Colcrys®, but was instead approved pursuant to a separate 505(b)(2) New Drug Application ("NDA") under 21 U.S.C. § 355(b)(2). A 505(b)(2) NDA follows a different regulatory pathway than an ANDA, and does not require the product to have the same indications, labeling, or dosage form. Thus, while Colcrys® and Mitigare® have the same active ingredient

and dosage strength—thus competing with each other in the marketplace—they differ in dosage form (tablet vs. capsule) and have different prescription information. For example, as Takeda acknowledges, "[u]nlike Colcrys®, Mitigare® is not indicated for the treatment of gout flares or [familial Mediterranean fever]; it is indicated only for the prophylaxis of gout flares." Takeda Br., D.I. 35, at 8 (citing Appx1326).

On October 3, 2014, Takeda filed suit against Hikma in the *West-Ward* Litigation asserting patent infringement. No. 14-cv-1268-RGA-SRF, D.I. 1; *see also Takeda Pharms U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015). On December 15, 2016, Takeda served its Second Amended Complaint asserting two sets of patents against Hikma: five patents directed to drug-drug interactions ("the DDI patents"), and three patents directed to the treatment of acute gout flares ("the Acute Gout Flares patents"). *Id.*, D.I. 133. These eight patents consist of the full set of patents asserted by Takeda against Hikma.

On June 4, 2018, the district court entered a Stipulation and Order to Dismiss with prejudice the five DDI patents: U.S. Patent Nos. 7,964,648; 8,097,655; 8,440,722; 8,093,297; and 7,619,004. *Id.*, D.I. 377 (Appx1342-1343; *see* Appx1340-1341). Takeda and Hikma jointly stipulated to dismiss with prejudice all of their claims to the five DDI patents: (i) Takeda's Counts 2, 4-6, and 8 of its Second Amended Complaint claiming infringement of the five DDI patents, and (ii) Hikma's

Counts 3-4, 7-12, and 15-16 of its Answer and affirmative defenses for a declaratory judgment of noninfringement and invalidity of the same five DDI patents. *Id.* On December 12, 2018, the district court entered summary judgment of noninfringement for the remaining three Acute Gout Flares patents asserted by Takeda against Hikma. *Id.*, D.I. 415 (Appx1325-1339).

While the *West-Ward* Litigation was pending, on February 1, 2018, Takeda brought suit against Alkem for infringement of 17 patents—including the eight asserted against Hikma—based on Alkem's filing of its ANDA for FDA approval of its generic version of Colcrys®. *Takeda Pharms. U.S.A., Inc. v. Alkem Laboratories Limited*, No. 1:18-cv-189-RGA (D. Del.), D.I. 1. In May 2018, Takeda and Alkem settled their dispute for all 17 patents and entered into a License Agreement. Appx69-107.

Until late November 2019, the only FDA-approved colchicine products on the market included Takeda's Colcrys® and its authorized generic ("AG"), and Hikma's Mitigare® and its AG. In late November 2019, third-party Mylan launched its generic Colcrys® product before temporarily agreeing to stop further selling its product. Following Mylan's lead, Alkem launched its generic Colcrys® product in late February 2020 but was ordered by the district court to maintain the status quo until March 12, 2020. No. 20-325-RGA, D.I. 19, Order. After granting an interim injunction extending the district court's order to maintain the status quo, on March

23, 2020, this Court denied Takeda's motion for an injunction pending appeal and lifted the interim injunction. No. 2020-1545, D.I. 33, Order at 2.

ARGUMENT

Hikma's *amicus* brief addresses the first issue raised in Takeda's appeal to the district court's denial of a motion for preliminary injunction:

> Section 1.2(d) of the License Agreement at issue in this case permits Alkem to launch its generic Colcrys® product a specified time period "after the date of a Final Court Decision . . . holding that all unexpired claims of the Patents-in-Suit that were asserted and adjudicated against a Third Party are either (i) not infringed, or (ii) any combination of not infringed and/or invalid, unpatentable, or unenforceable[.]" The district court held that Takeda is unlikely to succeed in its argument that Alkem was not entitled to launch its generic product. Did the district court err in concluding that Section 1.2(d) was likely triggered by a court decision that: (A) held only three out of the eight asserted patents to be not infringed; and (B) reached no determination regarding noninfringement, invalidity, unpatentability, or unenforceability with respect to the remaining five patents?

Takeda Br., D.I. 35, at 1-2. Hikma respectfully submits that the district court erred.

In the *West-Ward* Litigation, the district court found that Hikma did not infringe any claim of the three "asserted and adjudicated" Acute Gout Flares patents. Appx1325-1339. But there was no holding of noninfringement, invalidity, unpatentability, or unenforceability for the five DDI patents that Takeda had asserted against Hikma. *Id.* Instead, the claims of the five asserted DDI patents had been dismissed with prejudice in a Stipulation and Order to Dismiss with no holding in favor of either party on the issue of infringement or non-infringement, validity or

invalidity, patentability or unpatentability, or enforceability or unenforceability. Appx1342-1343. As made clear by Rule 41(a) of the Federal Rules of Civil Procedure, once the asserted DDI patent claims were dismissed with prejudice, this "operate[d] as an *adjudication* on the merits." *See* Fed. R. Civ. P. 41(a)(1) (emphasis added).

The asserted claims of the five DDI patents were thus both "asserted and adjudicated," because they were dismissed with prejudice in the *West-Ward* Litigation. But there was no holding of noninfringement, invalidity, unpatentability, or unenforceability for any of those claims. Consequently, the *West-Ward* Litigation did not trigger provision 1.2(d) in Takeda's agreement with Alkem. This should end this case.

I. The five DDI patents were both asserted and adjudicated in the *West-Ward* Litigation.

In the *West-Ward* Litigation, the district court entered a Stipulation and Order to Dismiss with prejudice Takeda's patent infringement claims and Hikma's patent defenses to each of the five asserted DDI patents. Appx1342-1343. The dismissal order states that the stipulation dismissing the asserted claims of the DDI patents is "with prejudice" "pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii) of the Federal Rules of Civil Procedure." *Id.* As Takeda explained in its opening brief, because "those five patents were subject to a ***jointly agreed upon*** voluntary dismissal with prejudice," this is an "adjudication" for claim preclusion purposes. Takeda Br.,

D.I. 35, at 22 (citing *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1372-73 (Fed. Cir. 2013)) (emphasis in original). Thus, the five asserted DDI patents were adjudicated by the plain language of the Stipulation and Order to Dismiss. *See* Fed. R. Civ. P. 41(a)(1)(A)(ii). Under this scenario, Takeda is correct that "the voluntary dismissal did not trigger Section 1.2(d) [of the License Agreement], because Section 1.2(d) comes into play only when there is a 'holding' of noninfringement, invalidity, or unenforceability concerning 'all unexpired claims of the Licensed Patents,'" and "there was no such 'holding' for five of the eight asserted patents in the *West-Ward* Litigation." Takeda Br., D.I. 35, at 22-23.

Alkem agrees that this present appeal turns on whether those DDI patents asserted against Hikma were "adjudicated" under the "ordinary and usual meaning" of that term. Alkem Opp'n to Inj. Pending Appeal, D.I. 27, at 11-12.[2] Alkem, however, fails to apply that plain meaning of "adjudicated." Under Federal Circuit precedent, the dismissal with prejudice in the *West-Ward* Litigation "operates as an adjudication on the merits" between the parties for these asserted claims of the five DDI patents. *Qiang Wang v. Palo Alto Networks, Inc.*, 686 F. App'x 890, 893 (Fed.

[2] In opposing Hikma's motion for leave to file its *amici* brief in support of an injunction pending appeal, Alkem has further adopted Mylan's argument in the related *Mylan* appeal. Alkem Opp'n to *Amicus*, D.I. 29, at 1. In the related *Mylan* appeal, Mylan has also asserted that the "plain meaning" of "adjudicated" should govern the interpretation of Section 1.2(d) of the License Agreement. No. 20-1407, Mylan Opp'n to *Amicus*, D.I. 45-1, at 10.

Cir. 2017) ("Following the execution of the settlement agreement, counsel for the parties filed a joint stipulation of dismissal of all claims with prejudice, which 'operates as an adjudication on the merits.'") (citing Fed. R. Civ. P. 41(a)(1)); *see also Zenith Elecs. Corp. v. Exzec, Inc.*, No. 98-1288, 1998 WL 171429, at *1 (Fed. Cir. Mar. 27, 1998) ("Generally, a dismissal of a claim with prejudice pursuant to a negotiated settlement is an adverse adjudication on the merits of the claim."); *Ford-Clifton v. Dep't of Veterans Affairs*, 661 F.3d 655, 660 (Fed. Cir. 2011) ("It is widely agreed that an earlier dismissal based on a settlement agreement constitutes a final judgment on the merits in a *res judicata* analysis."); *Gambocz v. Yelencsics*, 468 F.2d 837, 840 (3d Cir. 1972) ("Dismissal with prejudice constitutes an adjudication of the merits as fully and completely as if the order had been entered after trial.").

Thus, the stipulation of dismissal itself along with Rule 41 establishes in no uncertain terms that the dismissal with prejudice of the infringement claims relating to the five DDI patents "operates as an *adjudication* on the merits." *See* Fed. R. Civ. P. 41(a)(1) (emphasis added).

II. The district court never held that any, much less all, of the asserted and adjudicated claims related to the five DDI Patents were not infringed, invalid, unpatentable, or unenforceable.

The Stipulation and Order to Dismiss purposefully did not include any finding that the five DDI patents were infringed/not infringed, valid/invalid, patentable/unpatentable, or enforceable/unenforceable, because Takeda and Hikma

had not reached any such agreement. As Takeda notes in its opening brief, "all parties to the *West-Ward* Litigation agreed that the issue of infringement (or noninfringement) of these five [DDI] patents would not be decided one way or the other." Takeda Br., D.I. 35, at 22. The parties also made no agreements regarding the validity, patentability, or enforceability of the five DDI patents. *Id.* Nor were such findings necessary to resolve Takeda and Hikma's dispute.

Hikma agrees with Takeda that a stipulation of dismissal with prejudice commonly serves to adjudicate a dispute between the parties, without deciding any substantive issues on the merits. *See Levi Strauss*, 719 F.3d at 1372-73 ("That judgment, while constituting an adjudication on the merits for *claim*-preclusion purposes, has no *issue*-preclusive effect. Being a voluntary dismissal, it did not depend on the 2009 findings that supported the reversed 2009 Judgment on Dilution; indeed, it did not decide any specific issue at all.") (emphasis in original); *see also* Takeda Br., D.I. 35, at 22.[3] Thus, the Stipulation and Order to Dismiss adjudicated

[3] *See also Arizona v. California*, 530 U.S. 392, 414 (2000) ("But settlements ordinarily occasion no *issue preclusion* (sometimes called collateral estoppel), unless it is clear, as it is not here, that the parties intend their agreement to have such an effect. 'In most circumstances, it is recognized that consent agreements ordinarily are intended to preclude any further litigation on the claim presented but are not intended to preclude further litigation on any of the issues presented.'") (emphasis in original); *Yong v. City of Providence*, 404 F.3d 4, 25 n.17 (1st Cir. 2005) ("While the voluntary dismissal surely had claim preclusive effect and barred any attempt to re-litigate the same claim against Solitro and Saraiva, . . . it did not have any issue preclusive effect on the factual question whether Solitro and Saraiva violated

the dispute between Takeda and Hikma regarding the five asserted DDI patents, without reaching any holding that the asserted claims in those patents were infringed, invalid, unpatentable, or unenforceable.

Therefore, for the reasons cited herein, Alkem did not have the right to launch its products, because there was no final court decision holding that all "asserted and adjudicated" claims of the licensed patents were either "(i) not infringed, or (ii) any combination of not infringed and/or invalid, unpatentable, or unenforceable[.]"

CONCLUSION

For these reasons, Hikma as *amici curiae* requests that this court reverse the district court and grant Takeda's motion for a preliminary injunction.

Cornel's constitutional rights because this issue was never actually litigated and decided.") (internal citations omitted); *Wilwording v. Swenson*, 502 F.2d 844, 848 (8th Cir. 1974) ("Nor does it appear that the petitioner's voluntary dismissal of these claims from the civil rights suit would bar a hearing on them now under the usual principles of collateral estoppel. It has long been recognized that dismissal at plaintiff's request, even if it is with prejudice, is insufficient to invoke the bar of collateral estoppel."); *Citibank, N.A. v. Data Lease Financial Corp.*, 904 F.2d 1498, 1504 (11th Cir. 1990) (because defendant "did not intend that the stipulated dismissal with prejudice would constitute a final judgment of a particular issue . . . those claims are not barred by collateral estoppel or issue preclusion," but that "does not eliminate the res judicata or claim preclusive effect in favor of" plaintiff); *InterDigital Tech. Corp. v. OKI Am., Inc.*, 866 F. Supp. 212, 214 (E.D. Pa. 1994) ("[A] dismissal with prejudice before an issue or claim [such as patent infringement] has been decided in an adversarial setting constitutes a final judgment barring relitigation for the purposes of claim preclusion but not for issue preclusion").

Respectfully submitted,

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APRIL 3, 2020

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Counsel for Amici Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals International Limited

April 3, 2020

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