

No. 2020-1407

United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICALS U.S.A., INC.,
PLAINTIFF-APPELLANT,
v.
MYLAN PHARMACEUTICALS INC.,
DEFENDANT-APPELLEE.

*APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
IN CASE NO. 19-2216-RGA, JUDGE RICHARD G. ANDREWS*

**BRIEF FOR HIKMA PHARMACEUTICALS USA, INC. AND HIKMA
PHARMACEUTICALS INTERNATIONAL LIMITED AS AMICI CURIAE
SUPPORTING PLAINTIFF-APPELLANT'S MOTION FOR AN INJUNCTION
PENDING APPEAL**

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February 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.).

Dated: FEBRUARY 3, 2020

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INTRODUCTION AND INTEREST OF AMICI CURIAE¹

Amici Hikma Pharmaceuticals USA, Inc. (f/k/a West-Ward Pharmaceuticals Corp.) and Hikma Pharmaceuticals International Limited (together, “Hikma”) support the emergency motion of Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) for an injunction pending appeal.

Amici Hikma has a strong interest in this matter, because the present dispute between Takeda and Mylan Pharmaceuticals Inc. (“Mylan”) turns on the holding in a prior patent litigation between Takeda and amici Hikma involving Hikma’s Mitigare® colchicine capsule product. *See Takeda Pharmaceuticals, U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA-SRF (the “*West-Ward Litigation*”). Specifically, Mylan asserts that it may launch its competing colchicine product into the marketplace, pursuant to Section 1.2(d) of its license agreement with Takeda, if there was a final court decision in the *West-Ward Litigation* “holding that all unexpired claims of the Licensed Patents that were asserted and adjudicated” are “either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable[.]” *See* D.I. 7, § 1.2(d).

Hikma submits this memorandum to provide the Court with a perspective on the *West-Ward Litigation*—and, in particular, to clarify that there were no such

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.

“holding[s]” for five of the eight asserted and adjudicated patents in the *West-Ward* Litigation. All asserted claims in those five adjudicated patents were dismissed with prejudice by a stipulation without any holding of non-infringement, invalidity, or unenforceability.

BACKGROUND

In 2009, Takeda’s predecessor company became the first company to obtain formal FDA approval for a colchicine tablet product, a 0.6 mg colchicine tablet marketed as Colcrys®. On September 26, 2014, Hikma became the first company to receive FDA approval for a colchicine *capsule* product with its 0.6 mg colchicine capsule marketed as Mitigare®. Hikma’s Mitigare® was not approved under an Abbreviated New Drug Application (“ANDA”) as a generic of Colcrys®, but instead approved pursuant to a 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 it 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.

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. 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. While the *West-Ward* Litigation was pending, in November 2017, Takeda and Mylan settled their dispute and entered into a License Agreement. No. 2020-1407, D.I. 7. Subsequently, on June 4, 2018, the district court entered a Stipulation and Order to Dismiss with prejudice the five DDI patents. No. 14-cv-1268-RGA-SRF, D.I. 377 (Ex. A). On December 12, 2018, the district court entered summary judgment of noninfringement for the remaining three patents asserted by Takeda against Hikma. *Id.*, D.I. 415.

Until late November 2019, the only FDA approved colchicine products on the market included Takeda’s Colcrycs® and its authorized generic (“AG”), and Hikma’s Mitigare® and its AG. In late November 2019, Mylan launched its generic Colcrycs® product before temporarily agreeing to stop further selling its product.

ARGUMENT

The issue in this case addresses whether all of the patent claims that were “asserted and adjudicated” in the *West-Ward* Litigation were held to be not infringed, invalid, or unenforceable. The answer is no. In fact, only three out of the eight total patents “asserted” were “adjudicated” to be not infringed on summary judgment. The claims of the five DDI patents were “asserted and adjudicated,”

because they were dismissed with prejudice, but there was no holding of noninfringement, invalidity, or unenforceability. Thus, the *West-Ward* Litigation did not trigger provision 1.2(d) in Takeda's agreement with Mylan. This should end this case.

Contrary to Mylan's assertion, there was no "holding that [the five DDI patents] that were asserted and adjudicated against [Hikma] are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable[.]" No. 2020-1407, D.I. 7. During the *West-Ward* Litigation, on June 4, 2018, the District Court entered a Stipulation and Order to Dismiss the five asserted DDI patents: U.S. Patent Nos. 7,964,648; 8,097,655; 8,440,722; 8,093,297; and 7,619,004. No. 14-cv-1268-RGA-SRF, D.I. 377. 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.*

First, the five DDI patents were asserted and adjudicated. The dismissal with prejudice "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. 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.”).

Second, this adjudication included no holding of noninfringement, invalidity, or unenforceability. The Stipulation and Order to Dismiss purposefully did not include any finding that the five DDI patents were infringed/not infringed, valid/invalid, or enforceable/unenforceable, as Takeda and Hikma had not reached any agreement on those terms. 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.” D.I. 6, Takeda Br. at 14. The parties also made no agreements regarding the validity or

enforceability of the five DDI patents. *Id.* Nor were such findings necessary to resolve Takeda and Hikma's dispute.

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 & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1372-73 (Fed. Cir. 2013) ("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).² Thus, the Stipulation and Order to Dismiss adjudicated the dispute

² *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 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

between Takeda and Hikma regarding the five asserted DDI patents, without reaching any holding that the asserted claims in those patents were infringed, invalid, or unenforceable.³

Therefore, for the reasons cited herein, Mylan 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 invalid or unenforceable[.]”

CONCLUSION

For these reasons, Hikma as *amici curiae* requests that this court grant Takeda’s motion for an injunction pending appeal.

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”).

³ In its ruling, the District Court suggested that this interpretation “would make it trivially easy for Takeda to avoid triggering Section 1.2(d).” No. 2020-1407, D.I. 6-2, Memorandum Order at 6. This result, however, is consistent with the plain language of the License Agreement, and both Mylan and Takeda were aware of, for example, the specific nature of the “holding” necessary in the Agreement to trigger this exception to their agreed upon date. *Cf.*, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (requiring for purposes of forfeiture provisions of the Hatch-Waxman Act “a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed”).

Respectfully submitted,

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FEBRUARY 3, 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on February 3, 2020
by:

- U.S. Mail
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- Hand
- Electronic Means (by E-mail or CM/ECF)

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/s/ Charles B. Klein

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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February 3, 2020

(Date)

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Exhibit A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

Plaintiff,

v.

WEST-WARD PHARMACEUTICAL
CORPORATION, HIKMA AMERICAS INC., and
HIKMA PHARMACEUTICALS PLC,

Defendants.

Civil Action No. 14-cv-1268-RGA-SRF

STIPULATION AND ~~PROPOSED~~ ORDER TO DISMISS “DDI PATENTS”

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) and Defendants West-Ward Pharmaceutical Corporation, Hikma Americas Inc., and Hikma Pharmaceuticals PLC, Inc. (collectively, “Hikma”), by and through their counsel of record, hereby stipulate pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii) of the Federal Rules of Civil Procedure to the following dismissals of certain claims and defenses set forth in Plaintiff’s Second Amended Complaint for Patent Infringement (“Takeda’s Second Amended Complaint”), D.I. 133, and Defendants’ Answer, Affirmative Defenses and Counterclaims to Plaintiff’s Second Amended Complaint for Patent Infringement (“Hikma’s Answer”), D.I. 135, pending in the above-captioned matter:

1. Count 2 of Takeda’s Second Amended Complaint, claiming inducement of infringement by Hikma of United States Patent Number 7,964,648 (“the ’648 Patent”), is dismissed with prejudice.

2. Count 4 of Takeda's Second Amended Complaint, claiming inducement of infringement by Hikma of United States Patent Number 8,097,655 ("the '655 Patent"), is dismissed with prejudice.

3. Count 5 of Takeda's Second Amended Complaint, claiming inducement of infringement by Hikma of United States Patent Number 8,440,722 ("the '722 Patent"), is dismissed with prejudice.

4. Count 6 of Takeda's Second Amended Complaint, claiming inducement of infringement by Hikma of United States Patent Number 8,093,297 ("the '297 Patent"), is dismissed with prejudice.

5. Count 8 of Takeda's Second Amended Complaint, claiming inducement of infringement by Hikma of United States Patent Number 7,619,004 ("the '004 patent"), is dismissed with prejudice.

6. Count 3 of Hikma's Answer, for a declaratory judgment of noninfringement of the '648 patent, is dismissed with prejudice.

7. Count 4 of Hikma's Answer, for a declaratory judgment of invalidity of the '648 patent, is dismissed with prejudice.

8. Count 7 of Hikma's Answer, for a declaratory judgment of noninfringement of the '655 patent, is dismissed with prejudice.

9. Count 8 of Hikma's Answer, for a declaratory judgment of invalidity of the '655 patent, is dismissed with prejudice.

10. Count 9 of Hikma's Answer, for a declaratory judgment of noninfringement of the '722 patent, is dismissed with prejudice.

11. Count 10 of Hikma's Answer, for a declaratory judgment of invalidity of the '722 patent, is dismissed with prejudice.

12. Count 11 of Hikma's Answer, for a declaratory judgment of noninfringement of the '297 patent, is dismissed with prejudice.

13. Count 12 of Hikma's Answer, for a declaratory judgment of invalidity of the '297 patent, is dismissed with prejudice.

14. Count 15 of Hikma's Answer, for a declaratory judgment of noninfringement of the '004 patent, is dismissed with prejudice.

15. Count 16 of Hikma's Answer, for a declaratory judgment of invalidity of the '004 patent, is dismissed with prejudice.

16. Hikma's affirmative defenses relating to the non-infringement, invalidity, or enforceability of the '648 Patent, the '655 Patent, the '722 Patent, the '297 Patent, and the '004 Patent (collectively, the "DDI Patents") are dismissed with prejudice.

17. Each party shall bear its own costs and attorney's fees as to the dismissed claims set forth herein.

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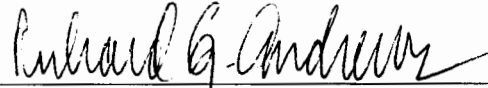
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Dated: June 4, 2018

SO ORDERED this 4 day of June 2018.



UNITED STATES DISTRICT JUDGE