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. 1:20-cv-00325-RGA, Judge Richard G. Andrews

BRIEF FOR PLAINTIFF-APPELLANT

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March 27, 2020

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Takeda Pharmaceuticals U.S.A., Inc. **v.** Alkem Laboratories Ltd. and Ascend Laboratories, LLC

Case No. 2020-1545

CERTIFICATE OF INTEREST

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

Takeda Pharmaceuticals U.S.A., Inc.

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

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Takeda Pharmaceuticals U.S.A., Inc.	None	Takeda Pharmaceutical Company Limited; Takeda Pharmaceutical International AG

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

Francis DiGiovanni, Faegre Drinker Biddle & Reath LLP
Thatcher Rahmeier, Faegre Drinker Biddle & Reath LLP

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 Pharm. Inc., No. 2020-1407 and 2020-1417 (Fed. Cir.)
Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharm. Inc., No. 1:19-cv-02216-RGA (D. Del.)
Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Labs. Ltd. et al., No. 20-325-RGA (D. Del.)

3/27/2020
Date

/s/ Edgar H. Haug
Signature of counsel

Please Note: All questions must be answered

Edgar H. Haug
Printed name of counsel

cc: _____

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STATEMENT OF RELATED CASES

Aside from the district court proceedings that remain pending in this case, *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 1:19-cv-02216-RGA (D. Del.), and *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 20-1407, -1417 (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.

JURISDICTIONAL STATEMENT

The district court exercised jurisdiction under 28 U.S.C. §§ 1331, 1332, and 1338(a). This Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1) and 1292(c)(1) because this appeal is from the district court's order denying Takeda's motion for a preliminary injunction against Defendants-Appellees Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively "Alkem"). On March 5, 2020, the district court entered an order denying Takeda's motion for a preliminary injunction. Takeda timely filed a notice of appeal on March 6, 2020. 28 U.S.C. § 2107(a); Fed. R. App. P. 4(a)(1).

STATEMENT OF THE ISSUES

1. Section 1.2(d) of the License Agreement at issue in this case permits 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?

2. Based on the correct interpretation of the License Agreement, did the district court abuse its discretion in denying Takeda's motion for a preliminary injunction?

3. Based on the correct interpretation of the License Agreement, did the district court abuse its discretion in finding that there was no irreparable harm based on Section 1.10 of the License Agreement which provides that Takeda "shall be entitled to immediate injunctive relief" in the event of a breach, and that a breach by Alkem of the License Agreement, "would cause Takeda irreparable harm"?

STATEMENT OF THE CASE

I. Colcrys®

Takeda's product Colcrys® (colchicine, 0.6 mg tablets) is indicated for the prophylaxis and treatment of gout flares in adults and for familial Mediterranean fever ("FMF"). Appx1081(¶ 17); Appx571. Colcrys® was the first pharmaceutical product approved by the United States Food and Drug Administration ("FDA") that contained colchicine

The balance of this brief has been omitted for this sample.

For a complete version of this brief, please contact our office.

Thank you.