ORAL ARGUMENT HELD ON 4/15/2016
No. 15-5021 (consolidated with No. 15-5022)

IN THE
United States Court of Appeals for the District of Columbia Circuit

TAKEDA PHARMACEUTICALS U.S.A., INC.,
Plaintiff-Appellant,
v.
SYLVIA MATHEWS BURWELL, IN HER OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *ET AL.*,
Defendants-Appellees,
and
HIKMA PHARMACEUTICALS PLC, *ET AL.*,
Intervenor-Appellees.

On Appeal from the
United States District Court for the District of Columbia
Case No. 1:14-cv-1668 (Hon. Ketanji Brown Jackson)

APPELLANT TAKEDA PHARMACEUTICALS U.S.A., INC.'S PARTIAL JOINDER IN PETITION FOR REHEARING AND/OR REHEARING *EN BANC*

Catherine E. Stetson
Counsel of Record
Jessica L. Ellsworth
Susan M. Cook
Morgan L. Goodspeed
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
cate.stetson@hoganlovells.com
Counsel for Appellant Takeda Pharmaceuticals U.S.A., Inc.

August 29, 2016

Appellant Takeda Pharmaceuticals U.S.A., Inc. joins in part the petition for rehearing and/or rehearing en banc filed today by Appellants Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P ("Elliott").

On July 15, 2016, a panel of this Court dismissed this appeal (in part, and as relevant for these purposes) as moot. A1. It held that a recent decision by the District Court for the District of Delaware—which held that Appellee Hikma Pharmaceuticals PLC had not infringed certain of Takeda's patents—rendered moot this Administrative Procedure Act challenge. A2-3; *see Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-1268, 2016 WL 2904593 (D. Del. May 18, 2016). The panel relied on 21 U.S.C. § 355(c)(3)(C)(i)(I), which provides that FDA's approval of a drug "shall be made effective on . . . the date on which the court enters judgment reflecting the decision" that the relevant patents are invalid or not infringed. A2.

In the Delaware proceedings on which this Court relied, Takeda has filed a motion to alter or amend the judgment under Federal Rule of Civil Procedure 59(e). *See* Mot. for Leave to Amend, *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-1268 (D. Del. June 3, 2016), ECF No. 124. That motion remains pending. A decision by the Delaware district court to amend its judgment and reopen the patent case may call into question this Court's mootness determination. *See* Elliott Pet. for Reh'g 12-14.

This Court has not expressly addressed the possibility that the judgment in the Delaware proceedings could be reopened. And the parties have not fully briefed the statutory question that would follow: whether an approval under 21 U.S.C. § 355(c)(3)(C)(i)(I) remains in effect if *the district court itself* withdraws an initial erroneous judgment of non-infringement. Given that unresolved issue, Takeda joins Elliott's petition for rehearing and/or rehearing en banc.

In the alternative, Takeda respectfully requests that this Court withhold its mandate until the Delaware district court acts on the pending Rule 59(e) motion. If the Delaware district court grants Takeda's pending motion, the Court may find it appropriate to request supplemental briefing about the effect of that decision on this case, before issuing its mandate.

Dated: August 29, 2016

Respectfully submitted,

/s/ Catherine E. Stetson
Catherine E. Stetson
Jessica L. Ellsworth
Susan M. Cook
Morgan L. Goodspeed
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
cate.stetson@hoganlovells.com
jessica.ellsworth@hoganlovells.com
susan.cook@hoganlovells.com
morgan.goodspeed@hoganlovells.com

Counsel for Appellant Takeda Pharmaceuticals U.S.A., Inc.

ADDENDUM

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 15-5021 **September Term, 2015**

FILED ON: JULY 15, 2016

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

ELLIOTT ASSOCIATES, L.P., ET AL.,
APPELLEES

v.

SYLVIA MATHEWS BURWELL, IN HER OFFICIAL CAPACITY AS SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Consolidated with 15-5022

Appeals from the United States District Court
for the District of Columbia
(No. 1:14-cv-01668)
(No. 1:14-cv-01850)

Before: KAVANAUGH and WILKINS, *Circuit Judges*, and SILBERMAN, *Senior Circuit Judge*.

J U D G M E N T

This appeal was considered on the record from the United States District Court for the District of Columbia and on the briefs and oral arguments of the parties. The Court has afforded the issues full consideration and has determined that they do not warrant a published opinion. *See* D.C. Cir. R. 36(d). It is

ORDERED and **ADJUDGED** that the portion of the appeal seeking review of FDA's decision to approve Mitigare without Hikma's certifying to the Colcrys patents be **DISMISSED AS MOOT** and that this portion of the judgment of the District Court be **VACATED**. It is

FURTHER ORDERED and **ADJUDGED** that the portion of the judgment of the District Court regarding Takeda's challenge to FDA's approval of the Mitigare label be **AFFIRMED**.

In 2009, the Food and Drug Administration approved Colcrys, a drug for the prevention and treatment of acute gout flares. Five years later, FDA approved a new drug – Mitigare – also for the prevention of gout flares.

When an applicant seeks FDA approval for a new drug under the Food, Drug, and Cosmetic Act, the applicant must generally certify to any patents "relied upon by the applicant for approval of the application." 21 U.S.C. § 355(b)(2). One such certification is called a Paragraph IV certification. A Paragraph IV certification is generally used when an applicant seeks to market a new drug that is essentially identical to a previously approved drug and the applicant claims that the patent for the previously approved drug "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(b)(2)(A)(iv). As relevant here, an applicant filing a Paragraph IV certification must also notify the owner of the patents for the previously approved drug. *Id.* § 355(b)(3).

Once the applicant has made the Paragraph IV certification, FDA's "approval shall be made effective immediately." *Id.* § 355(c)(3)(C). If, however, the patent owner brings an infringement action against the applicant within 45 days of receiving notice, then FDA must stay its approval for up to 30 months or until specified events happen in the patent litigation. *See id.* Of relevance here, if a district court decides "that the patent is invalid or not infringed," then FDA "approval shall be made effective on the date on which the court enters judgment reflecting the decision." *Id.* § 355(c)(3)(C)(i)(I). For present purposes, the most important point is this: If a patent infringement action is brought, then FDA approval of the application must be made effective on the date of any district court judgment concluding that the patent is not infringed.

When Hikma Pharmaceuticals applied for FDA approval of Mitigare, Hikma did not certify to the Colcrys patents. As a result, Colcrys's manufacturer – Takeda Pharmaceuticals – was not able to obtain a 30-month stay of FDA's approval of Mitigare. When Takeda discovered that FDA had approved Mitigare, Takeda sued Hikma for patent infringement in the U.S. District Court for the District of Delaware. The District Court of Delaware recently found no infringement of Takeda's patents and dismissed Takeda's infringement suit. *See Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, Civ. No. 14-1268-SLR (May 18, 2016).

Meanwhile, Takeda also sued FDA in the U.S. District Court for the District of Columbia, alleging that the agency had acted arbitrarily and capriciously for purposes of the Administrative Procedure Act. The D.C. District Court consolidated Takeda's suit with a similar suit brought by Elliott Associates, a hedge fund with rights to a percentage of royalties from the domestic sale of Colcrys. First, Takeda and Elliott claimed that Hikma should have certified to the Colcrys patents under Paragraph IV and that FDA should not have approved Hikma's application without that certification. Second, Takeda also alleged that FDA had impermissibly departed from agency precedent in approving the Mitigare label.

We conclude that the first issue – whether Hikma should have certified to the Colcrys patents under Paragraph IV – is moot because the underlying issue of infringement has already been resolved in Hikma's favor by the District Court of Delaware. "A case is moot if events have so transpired that the decision will neither presently affect the parties' rights nor have a more-than-speculative chance

of affecting them in the future." *Pharmachemie B.V. v. Barr Laboratories, Inc.*, 276 F.3d 627, 631 (D.C. Cir. 2002) (internal quotation marks omitted). Here, even if we were to hold that Hikma should have certified to Takeda's patents, that decision would at most entitle Takeda to a stay of FDA's approval of Mitigare pending a district court decision on the patent infringement suit. But there has already been a district court judgment on the patent infringement suit, so Takeda would not receive any stay of FDA's approval of Mitigare. Without the possibility of such a stay, Takeda's and Elliott's claims about Hikma's failure to certify to the Colcrys patents are academic and moot. *Cf. id.*

Takeda and Elliott offer three other primary reasons why the certification issue is not moot. *First*, Takeda and Elliott argue that Hikma should be made to go through the motions of re-applying to FDA for approval of Mitigare. But given the District Court of Delaware's decision, forcing Hikma to reapply would provide no meaningful redress to Takeda and Elliott. *Second*, Takeda also refers to the bond it posted in the District Court of Delaware. But that is an issue for the District Court of Delaware to resolve, as explained more fully below. *Third*, Elliott (but importantly not Takeda) argues that the District Court of Delaware did not purport to adjudicate all of the patents that Hikma was allegedly obligated to certify to. So, Elliott contends, Takeda could still sue Hikma for infringement and obtain the 30-month stay. But the reason that the District Court of Delaware did not adjudicate all of the patents is because Takeda did not sue Hikma based on all of the patents. That no doubt is why Takeda has not joined Elliott in advancing this argument as a basis for rejecting mootness. In short, Elliott's argument is unavailing.

We have carefully considered all of the arguments about mootness. We conclude that Takeda and Elliott's challenge to FDA's decision to approve Mitigare without Hikma's certifying to the Colcrys patents is moot. To state the obvious, if FDA ever concludes that Mitigare is no longer safe and effective, FDA has an array of statutory and regulatory tools to pull it off the market. *See* 21 U.S.C. § 355(e). But the dispute over whether Hikma should have certified to the Colcrys patents under Paragraph IV is moot.

In so ruling, we emphasize that our decision should have no impact on the District Court of Delaware's ruling on the Rule 65 bond issue. In particular, the District Court of Delaware may independently decide whether Hikma should have certified under Paragraph IV to the Colcrys patents, as well as whether and how the answer to that question should affect the District Court's resolution of the Rule 65 bond issue. In that regard, we note that the District Court of Delaware's initial ruling on the TRO stated that "Hikma has effectively side-stepped" the Paragraph IV certification process "in an effort to get its generic product to market without appropriate legal underpinnings." Memorandum Order at 6, *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, No. 14-1268 (D. Del. Oct. 9, 2014). The District Court of Delaware factored that point into its analysis of the balance of hardships and the public interest, and the court may do so again if it believes doing so would be relevant to resolution of the Rule 65 bond issue.

Apart from its claim about Hikma's failure to certify, Takeda also argues that the Mitigare label impermissibly omits critical safety information. That claim is not moot, but we disagree on the merits with Takeda. When FDA makes scientific judgments, this Court owes the agency the "most deferential" review. *Baltimore Gas & Electric Co. v. Natural Resources Defense Council,*

Inc., 462 U.S. 87, 103 (1983). Here, FDA affirmatively chose to depart from some past statements it had made about the labeling of products for the prevention and treatment of acute gout flares. As the record makes clear, the agency "employed its scientific expertise to reach" each of those decisions. *Takeda Pharmaceuticals, U.S.A., Inc. v. Burwell*, 78 F. Supp. 3d. 65, 107 (D.D.C. 2015). FDA then adequately explained those decisions through "various memos detailing its considerations and conclusions." *Id.* As the District Court concluded, "Takeda has not established that the APA requires anything more." *Id.*

In sum, we dismiss as moot the portion of the appeal seeking review of FDA's decision to approve Mitigare without Hikma's certifying to the Colcrys patents, and we affirm the judgment of the District Court with respect to Takeda's challenge to FDA's approval of the Mitigare label.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. R. 41.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Ken Meadows
Deputy Clerk

CERTIFICATE OF PARTIES & DISCLOSURE STATEMENT

Pursuant to Circuit Rules 35 and 28.1(a)(1), the undersigned counsel for Appellant Takeda Pharmaceuticals U.S.A., Inc. submits this Certificate of Parties and Disclosure Statement.

Plaintiffs in the court below and Appellants in this Court are Takeda Pharmaceuticals U.S.A., Inc.; Elliott Associates, L.P.; Elliott International, L.P.; and Knollwood Investments, L.P. Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, the undersigned counsel further submits that:

Appellant Takeda Pharmaceuticals U.S.A., Inc. is a pharmaceutical company that sells a patented colchicine product, Colcrys®. Takeda Pharmaceuticals U.S.A, Inc. is a wholly owned subsidiary of Takeda America Holdings, Inc., which is in turn a wholly owned subsidiary of Takeda Pharmaceutical Company Limited. Takeda Pharmaceutical Company Limited is a publicly traded company listed on the Tokyo Stock Exchange.

Defendants in the court below and Appellees in this Court are Sylvia Mathews Burwell, in her official capacity as Secretary, U.S. Department of Health and Human Services; and Margaret A. Hamburg, in her official capacity as Commissioner of Food and Drugs, Food and Drug Administration.

Intervenor-Defendants in the court below and Appellees in this Court are Hikma Pharmaceuticals PLC and West-Ward Pharmaceutical Corp.

Amicus in this court is the Pharmaceutical Research and Manufacturers of America.

/s/ Catherine E. Stetson
Catherine E. Stetson

Counsel for Appellant Takeda Pharmaceuticals U.S.A., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2016, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson

Counsel for Appellant Takeda Pharmaceuticals U.S.A., Inc.