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