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*Approvals*

## Takeda, Colcrys Investors Appeal Ruling Upholding FDA's Approval of Competing Drug

Japanese drugmaker Takeda Pharmaceutical Co., which makes the gout drug Colcrys (colchicine), and Elliott Associates LP, which has a right to royalties from Takeda's Colcrys sales, are appealing a district court's ruling that upheld the Food and Drug Administration's approval of a competing gout treatment (*Takeda Pharm. U.S.A., Inc. v. Burwell*, D.C. Cir., Nos. 15-5021, 15-5022, *appeal docketed* 1/26/15; *Elliott Associates LP v. Burwell*, D.C. Cir., Nos. 15-5022, *appeal docketed* 1/26/15).

Both Takeda and Elliott Associates are appealing a Jan. 12 ruling from Judge Ketanji Brown Jackson of the U.S. District Court for the District of Columbia, unsealed Jan. 20, in which Jackson denied Takeda's request to overturn the agency's approval of West-Ward Pharmaceutical Corp. and Hikma Pharmaceuticals' (collectively Hikma) Mitigare 0.6 mg capsules for prophylaxis of gout flares in adults. The judge also granted summary judgment to the FDA in a related case against the agency filed by Elliott (D.D.C., No. 1:14-cv-01850-KBJ, 1/12/15).

While Mitigare is a capsule, Colcrys is in tablet form.

Takeda and Elliott each sued the FDA separately in federal district court, with each alleging that the FDA's September 2014 approval of Mitigare ''was unlawful, arbitrary and capricious'' partly because the agency didn't require Hikma/West-Ward to reference Takeda's own colchicine drug, Colcrys, in violation of agency procedure and, according to Elliott, in violation of the Federal Food, Drug, and Cosmetic Act (13 PLIR 61, 1/16/15).

But Jackson disagreed.

**"Based on the court's opinion, it is now clear that 505(b)(2) NDA filers can avoid the need to submit a Paragraph IV certification on Orange Book patents for another drug product so long as they do not need to identify the other product as a reference listed drug to support approval."**

—Steven H. Sklar, Leydig, Voit & Mayer

''[T]his Court discerns no basis in law or fact for Plaintiffs' insistence that FDA was legally required to force West-Ward to reference Colcrys and to certify to the Colcrys patents under the circumstances presented here,'' she said.

**Decision Could Affect Future 505(b)(2) Applications.** Some experts told Bloomberg BNA that the district court's decision, if it stands, may affect drug companies' willingness to engage in the 505(b)(2) drug approval process when dealing with older, grandfathered drugs like colchicine. Indeed, attorneys said the district court's decision that a patent certification to a previously approved application isn't necessarily required in the 505(b)(2) process could discourage companies from engaging in the drug approval process in the first place.

Takeda's notice of appeal to the U.S. Court of Appeals for the District of Columbia Circuit was docketed Jan. 26, as was Elliott'sappeal.

 ISSN 1542-9547

**Judge Rules for FDA.** In her 80-page opinion, unsealed Jan. 20, Jackson rejected arguments made by Takeda and Elliott.

''Plaintiffs are wrong to characterize FDA's actions with respect to Mitigare as unauthorized, unsafe, or unreasoned; to the contrary, it is clear on the record presented that FDA's approval of Mitigare was consistent with the FDCA, the regulations the agency has promulgated pursuant to the FDCA, the Citizen Petition Responses FDA has issued, and the policies and practices under which the agency operates,'' she wrote.

''Furthermore,'' the judge said, ''the record clearly reveals the reasonableness of FDA's expert determination that Mitigare is safe and effective as labeled, and it supports the agency's conclusion that Mitigare's labeling best reflects current scientific information regarding the risks and benefits of Mitigare—a conclusion that, in any event, is entitled to a high degree of deference.''

Accordingly, Jackson ruled against the plaintiffs and entered summary judgment as a matter of law in favor of the agency.

**505(b)(2) Pathway.** The new drug application for Mitigare was approved under Section 505(b)(2) of the FDCA. The 505(b)(2) process is an abbreviated pathway that allows the FDA to rely on data not developed by the applicant for approval of a new drug application.

''Based on the court's opinion, it is now clear that 505(b)(2) NDA filers can avoid the need to submit a Paragraph IV certification on Orange Book patents for another drug product so long as they do not need to identify the other product as a reference listed drug to support approval,'' attorney Steven H. Sklar, of Leydig, Voit & Mayer Ltd. in Chicago, told Bloomberg BNA Jan. 29. ''In other words, so long as a 505(b)(2) filer provides sufficient safety and efficacy data in its own application to support FDA approval, then the fact that FDA itself may go look to and even consider information on another drug product as part of the review does not create a requirement to submit a Paragraph IV certification.''

The Orange Book, formally titled Approved Drug Products with Therapeutic Equivalence Evaluations, lists patents submitted to the agency by branded drug companies as covering a branded drug or its use.

Judge Jackson, he said, ''clearly rejected Takeda's argument that the patent certification process is mandatory if FDA merely considers safety and efficacy information in its possession on another drug product. Because the 505(b)(2) NDA filer, Hikma/West-Ward, did not identify the other drug product as a reference listed drug, FDA did not violate any statutory or procedural requirement relating to patent certifications in approving Mitigare.''

Sklar added, ''Because Hikma/West-Ward were able to provide FDA sufficient data and other information to support approval of Mitigare without needing to identify Colcrys as a reference listed drug, then a certification to the Colcrys Orange Book patents was not necessary.''

But attorney Terry G. Mahn, with Fish & Richardson in Washington, told Bloomberg BNA Jan. 28 that Jackson's holding ''threatens to gut the patent certification provisions in the 505(b)(2) application approval process for certain drugs.''

''The whole idea behind the Hatch-Waxman 'right of reference' was to 'compensate' the brand in some way for the use of its proprietary information for the benefit of a third party. That compensation arrangement was the patent certification process,'' Mahn said.

''If FDA can use brand data 'already in its head' for the benefit of a third party without regard to the patent certification process, Hatch-Waxman's statutory balance starts to fall apart,'' he added.

**Patent Litigation Continuing.** Meanwhile, Takeda also is continuing with its patent infringement litigation against Hikma, which was filed in the U.S. District Court for the District of Delaware in 2014. On Jan. 9, the U.S. Court of Appeals for the Federal Circuit upheld a decision by the District of Delaware that affirmed the denial of Takeda's request for a preliminary injunction that would have prohibited the sale of Hikma's colchicine for gout ''during the pendency of Takeda's patent infringement litigation against Hikma.''

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—Terry G. Mahn, Fish & Richardson

Takeda said its Colcrys (colchicine, USP) is protected by patents that extend through 2028 and 2029. Meanwhile, London-based Hikma Jan. 12 said that it's preparing to distribute Mitigare.

In a separate announcement, Takeda Jan. 12 said that it reached an agreement with Prasco Laboratories, an Ohio-based company, for distribution of an authorized generic of Colcrys. The two companies said Colchicine Tablets, USP will be marketed under the Prasco label and will be widely available in U.S. pharmacies beginning in mid-January.

According to figures from IMS Health, sales of colchicine in the U.S. totaled about $688 million for the 12 months ended August 2014.

Susan M. Cook, Catherine E. Stetson and Jessica L. Ellsworth, of Hogan Lovells, in Washington, submitted the appeal on behalf of Takeda.

Matthew D. McGill, Lucas C. Townsend and Mithun Mansinghani, of Gibson Dunn & Crutcher LLP, in Washington, and Michael A. Sitzman, of Gibson Dunn & Crutcher LLP, in San Francisco, submitted the appeal on behalf of the Elliott plaintiffs.

Intervenor-defendant Hikma is represented by Winston & Strawn LLP and Goodwin Procter LLP.

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*The Jan. 12 opinion is at http://www.bloomberglaw.com/public/document/TAKEDA_PHARMACEUTICALS_USA_INC_TPUSA_v_BURWELL_et_al_Docket_No_11/2.*

*Takeda's notice of appeal is at http://www.bloomberglaw.com/public/document/Takeda_Pharmaceuticals_USA_et_al_v_Sylvia_Burwell_et_al_*

  PLIR ISSN 1542-9547

*Docket_No.*

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