UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: RESPIMAT PHARMACEUTICALS ANTITRUST LITIGATION MDL No. 3154

TRANSFER ORDER

Before the Panel:* Plaintiff in the District of Massachusetts *Massachusetts Laborers' Health & Welfare Fund* action moves under 28 U.S.C. § 1407 to centralize this litigation in the District of Massachusetts. The litigation consists of two actions, as listed on Schedule A. Plaintiffs in the District of Connecticut *1199SEIU National Benefit Fund* action initially opposed centralization and, alternatively, requested centralization in the District of Connecticut; at oral argument, they stated that they now support centralization in the District of Connecticut or the District of Massachusetts. Defendants Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim International GmbH (together, Boehringer) oppose centralization but, if the Panel chooses to centralize the litigation, support centralization in the District of Massachusetts.

On the basis of the papers filed and the hearing session held, we find that these actions involve common questions of fact and that centralization in the District of Massachusetts will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. Plaintiffs are health and welfare funds that have paid for members to purchase Combivent Respimat and Spiriva Respimat.[1] The actions share common questions of fact arising from allegations that Boehringer has misused the provisions of the Hatch-Waxman Act to suppress generic competition in the market for Combivent Respimat and Spiriva Combivent products by improperly listing "device-only patents"—that is, patents that do not claim a drug as the invention—in the FDA's Orange Book.[2] Plaintiffs also allege that Boehringer delayed

* One or more Panel members who could be members of the putative classes in this litigation have renounced their participation in these classes and have participated in this decision.

[1] The Respimat is a metered-dose inhaler introduced by Boehringer in 2011 as an innovation on traditional L-shaped inhalers. Boehringer's Combivent Respimat and Spiriva Respimat dispense drugs that treat asthma and chronic obstructive pulmonary disease.

[2] The Hatch-Waxman Act was enacted to expedite the entry of generic drugs into the market, while providing protections for brand-name drug manufacturers against patent infringement by granting a near-automatic 30-month injunction when a generic drug manufacturer seeks approval from the U.S. Food and Drug Administration (FDA) to market proposed generic versions of drugs

(footnote continued . . .)

competition by bringing sham lawsuits against the first generic manufacturer to file an ANDA seeking approval to market generic versions of the products. Plaintiffs in both actions seek to represent a nationwide class of persons or entities that purchased or paid for Combivent Respimat, Spiriva Respimat, or generic equivalents thereof; plaintiffs in the District of Connecticut action also seek to represent multiple statewide classes of such persons or entities. Both actions will involve complex factual issues concerning the scope and validity of the patents at issue;[3] whether Boehringer improperly listed device-only patents for Combivent Respimat and Spiriva Respimat in the Orange Book; whether Boehringer's listings, if improper, were a good-faith attempt to comply with a clear regulatory mandate; and whether, in the absence of Boehringer's conduct, generic versions of Respimat products would have entered the market earlier. Plaintiffs in both actions bring antitrust, consumer protection, and unjust enrichment claims under the laws of multiple states, and a claim for injunctive relief under the Sherman Act.

Although there are only two related actions, the factual and legal issues will be complex and fact and expert discovery will be extensive, highly technical, and international in scope.[4] Since the first of these suits was filed, Boehringer has de-listed some or all of the patents at issue,[5] but

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covered by patents listed in the FDA's "Orange Book." The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), established a streamlined procedure for obtaining FDA approval of generic drugs, which allows a manufacturer to submit an abbreviated new drug application (ANDA) demonstrating that its proposed product is pharmaceutically equivalent and bioequivalent to an FDA-approved drug. 21 U.S.C. § 355(j)(2)(A)(i)-(iv). The ANDA must also include a certification, commonly referred to as a "paragraph IV certification," asserting that the proposed generic will not infringe any patents covering the brand name drug or that such patents are invalid. *Id.* § 355(j)(2)(A)(vii)(IV). Upon submitting an ANDA with a paragraph IV certification, the applicant must promptly notify the holder of the challenged patents that it has done so. The patent-holder then has 45 days to bring a patent infringement action and, if it does so, the FDA may not approve the ANDA drug for 30 months or until the patent at issue is held to be invalid or not infringed by the ANDA, if sooner. *See id.* § 355(j)(5)(B)(iii). To take advantage of the protections of the Hatch-Waxman Act, a brand-name manufacturer and patent holder must list its patents in the FDA's listing of *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book."

[3] The six patents at issue in both actions are: U.S. Patent No. 7,284,474; U.S. Patent No. 7,396,341; U.S. Patent No. 7,837,235; U.S. Patent No. 7,896,264; U.S. Patent No. 8,733,341; and U.S. Patent No. 9,027,967.

[4] Boehringer Ingelheim International GmbH is a German company.

[5] Boehringer de-listed the unexpired at-issue patents in March 2025, after rehearing was denied in *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898 (Fed. Cir. 2024). In *Teva*, the Federal Circuit held that a patent for an inhaler product was not

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the de-listing did not eliminate the issue of whether Boehringer previously had a good-faith basis for believing the patents were properly listed and to what extent the patents' listing deterred potential generic competitors from entering the market. In addition, while the actions do not involve claims of patent infringement or invalidity, they nonetheless may require claim construction proceedings. *See Teva*, 124 F.4th at 921 ("When determining what a patent claims for the purpose of the listing inquiry, we apply the rubric of claim construction."). Many issues, including class certification, will require extensive expert testimony and discovery. Because of such complexities, "the Panel has frequently centralized litigation comprised of only two Hatch-Waxman Act cases." *In re Nebivolol ('040) Patent Litig.*, 867 F. Supp. 2d 1354, 1355 & n.4 (J.P.M.L. 2012) (citing cases).

Boehringer opposes centralization, arguing that informal coordination of the two actions is practicable and stressing that it is willing to work cooperatively with plaintiffs. It argues that the same defendants are named in both actions and represented by the same counsel, and that both actions are at an early stage. While we applaud defendants' spirit of cooperation, given the complexity of these actions, we are persuaded that centralization is the surest means of serving the convenience of the parties and witnesses, ensuring efficient proceedings, and conserving judicial and party resources.[6]

The District of Massachusetts is an appropriate transferee district for this litigation. All parties support centralization there, in the first instance or in the alternative. The first-filed action is pending in the district and is somewhat more advanced than the District of Connecticut action, having produced a ruling on Boehringer's motion to dismiss. We assign the litigation to Judge Denise J. Casper, an experienced transferee judge who presides over the *Massachusetts Laborers* action. We are confident that she will steer this matter on an efficient and prudent course.

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properly listed in the Orange Book because it did not claim "at least what made the product approvable as a drug in the first place—its active ingredient." *Id.* at 911.

[6] Notably, in July 2024, Boehringer moved to transfer the District of Connecticut action to the District of Massachusetts under 28 U.S.C. § 1404, arguing that "allowing [the *1199SEIU* case] to proceed in a separate forum would waste judicial and party resources and raise the risk of inconsistent rulings."

IT IS THEREFORE ORDERED that the action listed on Schedule A and pending outside the District of Massachusetts is transferred to the District of Massachusetts and, with the consent of that court, assigned to the Honorable Denise J. Casper for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

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IN RE: RESPIMAT PHARMACEUTICALS ANTITRUST LITIGATION MDL No. 3154

SCHEDULE A

District of Connecticut

1199SEIU NATIONAL BENEFIT FUND, ET AL. v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL., C.A. No. 3:24-00783

District of Massachusetts

MASSACHUSETTS LABORERS' HEALTH & WELFARE FUND v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL., C.A. No. 1:24-10565