UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: OZEMPIC (SEMAGLUTIDE) PATENT LITIGATION

MDL No. 3038

TRANSFER ORDER

Before the Panel:* Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, Novo Nordisk) move under 28 U.S.C. § 1407 to centralize this litigation in the District of Delaware. This litigation consists of six actions, five in the District of Delaware and one in the Northern District of West Virginia, as listed on Schedule A. The defendant in the West Virginia action, Mylan Pharmaceuticals Inc., opposes centralization. Alternatively, it suggests the Northern District of West Virginia as the transferee district. No other defendant responded to the motion.

Novo Nordisk filed these actions after the various generic drug manufacturer defendants submitted Abbreviated New Drug Applications (ANDAs) seeking approval by the U.S. Food and Drug Administration (FDA) to make and sell generic versions of Ozempic (semaglutide), which is prescribed for the treatment of type 2 diabetes and for long-term weight management. The actions on the motion are a series of Hatch-Waxman[1] patent infringement lawsuits, in which the plaintiffs allege that each defendant has infringed one or more claims of between two and eighteen

* Judge Roger T. Benitez did not participate in the decision of this matter.

[1] Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"), Congress established an incentive for companies to bring generic versions of branded drugs to market faster than they otherwise might by granting the first company to file an ANDA an "exclusivity period" of 180 days, during which the FDA may not approve for sale any competing generic version of the drug. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063–65 (D.C. Cir. 1998). Submitting an ANDA with a "paragraph IV certification"—stating that the patents listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) as covering the previously approved drug are invalid or will not be infringed by the generic drug—constitutes a statutory act of infringement that creates subject-matter jurisdiction for a district court to resolve any disputes regarding patent infringement or validity before the generic drug is sold. *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–78 (1990). If the patentholder initiates an infringement action against the ANDA filer within 45 days of receipt of the paragraph IV certification, then the FDA may not approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

U.S. patents covering Ozempic[2] by filing an ANDA seeking FDA approval to market generic versions of Ozempic in the United States.

On the basis of the papers filed and the hearing session held, we find that the actions listed on Schedule A involve common questions of fact, and that centralization in the District of Delaware will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions involve substantially similar claims that defendants infringed two or more of the Ozempic patents. While the patents asserted in each action vary somewhat, there is significant overlap. Two patents—No. 9,132,239, entitled "Dial-Down Mechanism for Wind-Up Pen" and No. 10,335,462, entitled "Use of Long-Acting GLP-1 Peptides"—are asserted in all six actions. Another eight patents are asserted in multiple actions pending in both of the involved districts. Centralization is warranted to eliminate duplicative discovery; prevent inconsistent pretrial rulings (particularly with respect to claim construction and issues of patent validity); and conserve the resources of the parties, their counsel, and the judiciary.

We have centralized similar patent litigations, citing "the complexity of the allegations and regulatory framework governing Hatch-Waxman cases, as well as the need for swift progress in litigation involving the potential entry of generic drugs into the market." *See In re Kerydin (Tavaborole) Topical Solution 5% Patent Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019); *see also In re Xarelto (Rivaroxaban) ('310) Patent Litig.*, MDL No. 3017, 2021 WL 5872990, at *2 (J.P.M.L. Dec. 10, 2021); *In re Entresto (Sacubitril/Valsartan) Patent Litig.*, 437 F. Supp. 3d 1372, 1373 (J.P.M.L. 2020); *In re Palbociclib Patent Litig.*, 396 F. Supp. 3d 1360, 1361–62 (J.P.M.L. 2019). Mylan argues that, unlike these prior patent litigations (each of which involved, as here, one or more Delaware actions and a single action against Mylan filed in West Virginia), the West Virginia action here involves eight unique patents, containing a total of 125 unique claims, not at issue in the Delaware actions. Mylan also stresses that most of the patents asserted against it relate to the injection pen for delivering the medication, rather than the formulation and use of semaglutide.

This argument is not persuasive. To begin, counsel for plaintiffs stated at oral argument that they have agreed to withdraw claims as to eleven device patents in the West Virginia action. Thus, while the West Virginia action at present involves eight unique patents, this may be a temporary distinction. Further, many of the "non-common" patents asserted in the West Virginia action derive from the same patent family as patents asserted in the Delaware actions, and thus are likely to share similar terms and claims. *Compare, e.g.*, U.S. Patent No. 8,129,343 (asserted in four actions and relating to "[p]rotracted GLP-1 compounds and therapeutic uses thereof), *with* U.S. Patent No. 8,536,122 (asserted in the West Virginia action, a continuation of the application that led to the '343 patent). In any event, the West Virginia action also involves ten patents that *are* asserted in the Delaware actions. "Transfer under Section 1407 does not require a complete identity, or even majority, of common factual issues as a prerequisite to transfer." *In re Ameriquest Mortg. Co. Mortg. Lending Practices Litig.*, 408 F. Supp. 2d 1354, 1355 (J.P.M.L. 2005). That some of these patents relate to the injection device, as opposed to semaglutide itself, is irrelevant to this analysis.

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[2] The patents at issue include U.S. Patent Nos. 8,114,833; 8,129,343; 8,536,122; 8,684,969; 8,920,383; 9,108,002; 9,132,239; 9,457,154; RE46,463; 9,616,180; 9,687,611; 9,775,953; 9,861,757; 10,220,155; 10,335,462; 10,357,616; 10,376,652; and 11,097,063.

Mylan also contends that centralization would interfere with its right to litigate the action in a proper forum. This argument is not well taken—under 28 U.S.C. § 1407, this Panel is authorized to select the appropriate venue for coordinated or consolidate pretrial proceedings of actions involving common factual questions. Moreover, "the transferee judge has all the jurisdiction and powers over pretrial proceedings in the actions transferred to him that the transferor judge would have had in the absence of transfer." *In re Delta Dental Antitrust Litig.*, 509 F. Supp. 3d 1377, 1379 (J.P.M.L. 2020) (quoting *In re FMC Corp. Patent Litig.*, 422 F. Supp. 1163, 1165 (J.P.M.L. 1976) (internal citations omitted)).

The District of Delaware is an appropriate transferee district for this litigation. Five of the six actions on the motion are pending in this district. Additionally, several patent infringement actions involving Saxenda (liraglutide), a related drug marketed by Novo Nordisk that uses the same injection device, are pending in the District of Delaware. One of these actions, *Novo Nordisk Inc. v. Teva Pharms., Inc.*, C.A. No. 1:21-01782 (D. Del.), involves fifteen of the eighteen patents at issue in the Ozempic litigation. Centralization in this district thus offers the potential for realizing substantial efficiencies. We assign this litigation to the Honorable Colm F. Connolly, who is well-versed in complex patent litigation and who presides over both the Ozempic and Saxenda actions. We are confident that Judge Connolly will steer this litigation on a prudent and expeditious course.[3]

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

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

Nathaniel M. Gorton
David C. Norton
Madeline Cox Arleo

Matthew F. Kennelly
Dale A. Kimball

[3] Mylan contends that centralization in Delaware will not yield efficiencies because that court does not permit summary judgment motions in Hatch-Waxman litigation. Given the District of Delaware's extensive experience with such litigation and the time constraints imposed by the Hatch-Waxman process, we decline Mylan's invitation to second guess the efficiency of that court's case management practices. Mylan may take up this issue with the transferee court.

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SCHEDULE A

District of Delaware

NOVO NORDISK INC., ET AL. v. RIO BIOPHARMACEUTICALS, INC., ET AL., C.A. No. 1:22–00294
NOVO NORDISK A/S, ET AL. v. SUN PHARMACEUTICAL INDUSTRIES LTD., ET AL., C.A. No. 1:22–00296
NOVO NORDISK INC., ET AL. v. ZYDUS WORLDWIDE DMCC, ET AL., C.A. No. 1:22–00297
NOVO NORDISK INC., ET AL. v. DR. REDDY'S LABORATORIES LTD., ET AL., C.A. No. 1:22–00298
NOVO NORDISK INC., ET AL. v. ALVOGEN, INC., C.A. No. 1:22–00299

Northern District of West Virginia

NOVO NORDISK INC., ET AL. v. MYLAN PHARMACEUTICALS, INC., C.A. No. 1:22–00023