

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK, INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS
INC.,

Defendant.

Civil Action No. 23-101-CFC
ANDA CASE

Travis J. Murray and Brian P. Egan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; Nicholas P. Groombridge, Josephine Young, Peter H. Sandel, Jenny C. Wu, Daniel J. Klein, Naz E. Wehrli, Joshua D. Reich, and Scott Miller, GROOMBRIDGE, WU, BAUGHMAN & STONE LLP, New York, New York; Philip S. May, GROOMBRIDGE, WU, BAUGHMAN & STONE LLP, Washington, D.C.

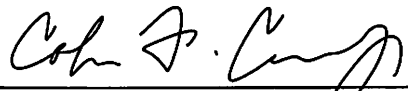
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Counsel for Defendant

MEMORANDUM OPINION

July 22, 2025
Wilmington, Delaware



COLM F. CONNOLLY
CHIEF JUDGE

Plaintiffs Novo Nordisk, Inc. and Novo Nordisk A/S (collectively, Novo) manufacture and sell WEGOVY®, a prescription injection belonging to the GLP-1 receptor agonist drug class that dispenses the active ingredient semaglutide. Novo has sued Defendant Mylan Pharmaceuticals Inc. (Mylan) pursuant to the Hatch-Waxman Act, codified in part at 21 U.S.C. § 355(j), for infringement of five patents, one of which is U.S. Patent No. 9,764,003 (the #003 patent). Novo alleges that the five asserted patents cover WEGOVY® and the generic version of WEGOVY® that Mylan has asked the Food and Drug Administration (FDA) to approve for manufacture and sale. Novo has either listed or intends to list the asserted patents in the FDA's Orange Book.¹ And it alleges in the Complaint that

¹ As the Federal Circuit explained in *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, 124 F.4th 898, 902–03 (Fed. Cir. 2024):

When a generic drugmaker applies to market a drug using the same active ingredient as a branded drug, the Food and Drug Administration (“FDA”) cannot approve the generic company’s application if the generic company’s drug would infringe the brand-name manufacturer’s patent. The FDA checks for whether the generic company’s drug would infringe by looking at which patents the brand-name manufacturer listed in a publication called the Orange Book. If the brand-name manufacturer lists a non-expired patent that the brand-name manufacturer purports

Mylan's submission to the FDA of an Abbreviated New Drug Application (ANDA) for approval to market its generic version of WEGOVY® constitutes infringement of the asserted patents pursuant to § 271(e)(2)(A) of the Patent Act, 35 U.S.C. § 100, *et seq.* See D.I. 1 ¶ 25.

“Section 271(e)(2)(A) defines the filing of an ANDA [for a generic drug covered by a patent listed in the Orange Book] as an act of infringement.” *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012). That definition “create[s] case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity” of such patents. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). “[A] district court’s inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit, *viz.*, whether the patent in question is ‘invalid or *will not be infringed* by the manufacture, use, or sale of the drug for which the [ANDA] is submitted.’” *Id.* (emphasis and alteration in the original) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

claims its drug, the FDA will not approve the generic company’s application. Instead, simply by listing a patent as claiming a drug, the brand-name manufacturer can make the FDA withhold approval of the generic company’s application for thirty months.

Pending before me is Mylan's motion pursuant to Federal Rule of Civil Procedure 12(c) for an order of judgment on the pleadings that it does not infringe the #003 patent. D.I. 160. A court may grant a Rule 12(c) motion only where "the movant clearly establishes that no material issue of fact remains to be resolved and that [the movant] is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (quotation marks and citation omitted). In evaluating a Rule 12(c) motion, I may only consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents integral to or explicitly relied upon in the pleadings, *Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019); and I must accept as true all well-pleaded allegations in the non-movant's pleadings and draw all reasonable inferences in the non-movant's favor, *Zimmerman v. Corbett*, 873 F.3d 414, 417–18 (3d Cir. 2017).

I.

Mylan argues first that because the asserted claims of the #003 patent are method-of-treatment claims and Mylan is a pharmaceutical company that does not treat or administer drugs to patients, Mylan cannot directly infringe the asserted claims under 35 U.S.C. § 271(a) as a matter of law. D.I. 161 at 12. (Section 271(a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States

any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a).) Novo counters that this argument “do[es] not require the Court’s action” because Novo “has not alleged *Mylan* directly infringes the [#]003 Patent,” but rather has “allege[d] ‘use’ of [Mylan’s] ANDA Product by ‘*physicians, prescribers, and/or patients*’ directly infringes [the #003 patent] as a necessary predicate for Mylan’s indirect infringement.” D.I. 168 at 20 (emphasis in the original) (quoting D.I. 1 ¶¶ 165–66, 169). This representation by Novo is consistent with the Complaint’s factual allegations, none of which individually or collectively imply in any way that Mylan itself would directly infringe the #003 patent were it to market its ANDA product. But Novo makes the conclusory legal allegation in paragraph 45 of the Complaint that “Defendants”—i.e., Mylan and now-dismissed Defendant Viatrix, Inc.—“will infringe one or more claims of the Asserted Patents under 35 U.S.C. § 271(a)” D.I. 1 ¶ 45. And it states in paragraph 173 of the Complaint that it “seeks an order declaring that Defendants will infringe at least claim 1 of the [#]003 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Defendants’ ANDA Product before the expiration of the [#]003 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).” D.I. 1 ¶ 173. Accordingly, it seems to me that court action *is* required, and I will grant the motion as unopposed insofar as it seeks a judgment of no direct infringement by Mylan.

II.

I will similarly grant as unopposed Mylan's motion insofar as it seeks a judgment of no contributory infringement of the #003 patent by Mylan. Mylan argued in its opening brief filed in support of its motion that Novo cannot state a claim for contributory infringement of the #003 patent under § 271(c).

D.I. 161 at 20. (Section 271(c) provides that "[w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(c).) In its answering brief, Novo stated that it had "proposed to Mylan that the parties stipulate to entry of partial judgment of no contributory infringement of the [#]003 Patent." D.I. 168 at 21. Mylan's reply to the proposal is that it is "entitled to judgment, whether stipulated or decided." D.I. 187 at 10. I will therefore enter a stipulated judgment of no contributory infringement of the #003 patent by Mylan.

III.

Mylan next argues that it is entitled to a judgment of no induced infringement of the #003 patent based on my construction of the term “administered without another therapeutic agent” in claim 1 of the patent. Claim 1, from which all the other claims in the patent depend, reads:

A method for reducing body weight, comprising administering semaglutide once weekly in an amount of at least 0.7 mg and up to 1.6 mg to a subject in need thereof, wherein said semaglutide is *administered without another therapeutic agent*.

#003 patent at claim 1 (D.I. 1-1 at 169) (emphasis added). I construed the term “administered without another therapeutic agent” to mean “administered without another therapeutic agent as part of the method for reducing body weight, or for treating the conditions of diabetes or hypertension.” D.I. 126 at 8.

Under § 271(b) of the Patent Act, “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). “To prove inducement of infringement, . . . the patentee must show that the accused inducer took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement.” *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 904 (Fed. Cir. 2014). When, as in this case, the FDA has yet to approve the accused generic drug for manufacture and sale, the issue of induced infringement turns on the contents of the proposed label for the drug submitted to

the FDA, as that label will guide physicians' and patients' use of the drug if it were to receive FDA approval and enter the market. *See Grunenthal GmbH v. Alkem Lab'ys. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019). Since the #003 patent claims methods of treatment, "[t]he pertinent question is whether the proposed label instructs users [of Mylan's generic semaglutide product] to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

Mylan argues that its proposed label does not instruct users to administer its semaglutide product without another therapeutic agent as part of a method for reducing body weight or for treating the conditions of diabetes or hypertension, and that therefore it cannot as a matter of law infringe claim 1 of the #003 patent. I agree. Although Mylan's label instructs that its semaglutide product "should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist," D.I. 162 at 4, the label does not state, imply, or suggest in any way that Mylan's semaglutide product should be administered without any other therapeutic agent to reduce weight loss or to treat diabetes or hypertension. To the contrary, the label makes clear that Mylan expects that physicians will at times administer its semaglutide with therapeutic agents other than semaglutide-containing products and GLP-1 receptor agonists as part of a method for reducing body weight or for treating the conditions of diabetes or hypertension. Specifically, the proposed label states that "[t]he safety and efficacy of

coadministration with other products for weight loss have not been established,” D.I. 162 at 4 (emphasis added); that semaglutide “delays gastric emptying [that] [m]ay impact absorption of *concomitantly administered oral medications*,” D.I. 162 at 4 (emphasis added); that “[h]ypotension and orthostatic hypotension were more frequently seen in adult patients *on concomitant antihypertensive therapy*,” D.I. 162 at 15 (emphasis added); and that “[p]atients with type 2 diabetes mellitus taking semaglutide *in combination with an insulin secretagogue . . . or insulin* may have an increased risk of hypoglycemia,” D.I. 162 at 10 (emphasis added). Most notably, the label also instructs physicians to “consider *reducing* [(i.e., not eliminating)] the dose of *concomitantly administered insulin secretagogue . . . or insulin* to reduce the risk of hypoglycemia.” D.I. 162 at 10 (emphasis added). (“Hypoglycemia is a condition in which [a patient’s] blood sugar (glucose) level is lower than the standard range” and “is often related to diabetes treatment.” *Hypoglycemia*, Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/hypoglycemia/symptoms-causes/syc-20373685> [<https://perma.cc/E4EH-C8T4>] (last visited July 22, 2025)). It is undisputed that insulin secretagogue and insulin are therapeutic agents.)

Novo contends that Mylan’s intent to induce physicians and patients to use its semaglutide product without another therapeutic agent for reducing body weight or for treating diabetes or hypertension can be inferred from the proposed label’s

“multiple warnings against co-administration regarding the real risks of interference with oral medications, hypoglycemia, and hypotension all across the label.” D.I. 168 at 18. But the fact that the label expressly instructs physicians and patients not to coadminister Mylan’s product with other semaglutide-containing products or GLP-1 receptor agonists but contains no such directive for other therapeutic agents that the label implicitly acknowledges will be coadministered with semaglutide makes clear that Mylan did not intend to preclude the coadministration of those other agents with its semaglutide product. Any doubt on that score is resolved by the label’s advice to physicians to “reduc[e]”—not to eliminate or to avoid—“the dose of concomitantly administered insulin secretagogue . . . or insulin to reduce the risk of hypoglycemia.” D.I. 162 at 10.

Novo also argues that Mylan’s proposed label “directs that semaglutide be used for reducing body weight without another therapeutic agent by instructing that semaglutide be administered to patients with obesity or overweight—including those without any comorbid conditions—with diet and exercise *alone*.” D.I. 168 at 17–18 (emphasis added); *see also* D.I. 168 at 14 (stating that “[t]he only recommended concomitant therapy for both sub-populations is diet and exercise”). But the proposed label simply states that Mylan’s semaglutide product is “indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in” adult patients who are either (1) obese or

(2) overweight with at least one weight-related comorbid condition. D.I. 162 at 4.

The label does not state or imply that a reduced-calorie diet and exercise are the only forms of therapy that can be coadministered with Mylan's semaglutide product.

Novo insists that because the proposed label does not require patients to receive other treatment beyond a reduced-calorie diet and physical activity, "physicians will inevitably prescribe Mylan's ANDA Product without another therapeutic agent as part of a method for reducing body weight, or for treating the conditions of diabetes or hypertension as [my] construction requires." D.I. 168 at 14 (internal quotation marks and citation removed). But whether physicians will inevitably prescribe Mylan's product without another therapeutic agent is irrelevant. And that is the case even if Mylan expects, suspects, or hopes that physicians will inevitably do so. *See HZNP Meds. LLC v. Actavis Lab'ys. UT, Inc.*, 940 F.3d 680, 701 (Fed. Cir. 2019) ("To prove inducement, a plaintiff must present evidence of active steps taken to encourage direct infringement; mere knowledge about a [method's] characteristics or that it may be put to infringing uses is not enough."). The dispositive question is whether Mylan's proposed label *encourages* physicians and patients not to use any other therapeutic agent when administering its semaglutide product to reduce a patient's body weight or to treat diabetes or hypertension. And, as noted above, the proposed label does not state or

imply that Mylan's semaglutide product should not be coadministered with a therapeutic agent other than other semaglutide-containing products and other GLP-1 receptor agonists, and it makes clear that Mylan expects that physicians will administer its semaglutide product with another therapeutic agent when treating diabetes or hypertension or to reduce a patient's weight.

Finally, Novo argues that Mylan's motion "should be denied in view of material factual issues that would need to be resolved, including any expert physician testimony on what the label encourages." D.I. 168 at 19. Novo, however, does not identify any specific factual issues that need to be resolved for me to decide the pending motion, and it does not explain why expert testimony is necessary to interpret the label or apply my claim construction. Novo cites *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, 104 F.4th 1370 (Fed. Cir. 2024) for the proposition that "[j]ust recently, the Federal Circuit re-confirmed the importance of additional fact development [and] revers[ed] a district court's dismissal of an induced infringement case at the pleading stage." D.I. 168 at 19. But the Federal Circuit in *Amarin* emphasized that the case before it, unlike this action, was "not a Hatch-Waxman case arising under 35 U.S.C. § 271(e)(2)(A)" and "not a traditional 'ANDA case' in which the patent owner seeks to establish that *if* a generic manufacturer's drug is put on the market, it would infringe the asserted patent." 104 F.4th at 1376 (emphasis in the original). The ANDA at issue

in *Amarin* had already been approved by the FDA and the accused infringer had already launched its generic product. *Id.* And thus, “the allegations of the complaint [in *Amarin*] transform[ed] th[at] case from a pre-approval, label-only induced infringement claim to one where the alleged infringement [wa]s based on the generic manufacturer’s . . . label as well as its public statements and marketing of its already-approved generic product.” *Id.* at 1377 (emphasis omitted). This case, by contrast, is a pre-approval, label-only, traditional ANDA case that arises under § 271(e)(2)(A). *Amarin*’s holdings and reasoning are therefore inapposite.

Because Mylan’s proposed label does not encourage, promote, or recommend that physicians and patients not coadminister Mylan’s semaglutide product with other semaglutide-containing products or GLP-1 receptor agonists to reduce a patient’s body weight and because the proposed label does not encourage, promote, or recommend that physicians and patients not coadminister Mylan’s semaglutide product with another therapeutic agent to treat diabetes or hypertension, Mylan does not induce infringement of the “administered without another therapeutic agent” limitation of claim 1 of the #003 patent. Because the accused product must meet all the limitations of an asserted claim to infringe that claim, *TEK Global, S.R.L. v. Sealant Systems International, Inc.*, 920 F.3d 777, 788 (Fed. Cir. 2019), Mylan’s ANDA product does not infringe claim 1. And because all the other claims of the #003 patent depend from claim 1, Mylan is

entitled to a judgment of no induced infringement of the #003 patent as a matter of law. I will therefore grant the motion insofar as it seeks that judgment.²

IV.

For the reasons discussed above, I will grant Mylan's Rule 12(c) motion (D.I. 160) and enter a judgment of no direct, contributory, and induced infringement of the #003 patent under § 271(e)(2)(A) in Mylan's favor.³

The Court will issue an Order consistent with this Memorandum Opinion.

² Mylan also argued in its briefing that it is entitled to a judgment of no induced infringement of the #003 patent because its proposed label does not induce physicians or patients to "administer[]semaglutide once weekly in an amount of at least 0.7 mg and up to 1.6 mg," as required by claim 1. D.I. 161 at 18–19 (internal quotation marks omitted). In light of my finding that the proposed label does not induce physicians or patients to practice claim 1's "administered without another therapeutic agent" limitation, I need not address this argument.

³ In its opening brief filed in support of its motion, Mylan stated that "[i]f Novo argues" that § 271(e)(2)(A) creates a separate cause of action that does not require a showing of direct, induced, or contributory infringement, "that claim fails." D.I. 161 at 21–22. In its opposition brief, Novo stated that it "has not alleged infringement under § 271(e)(2)(A) as a free-standing act of liability," and that it "ultimately alleges infringement as 'determined by traditional patent infringement analysis, just the same as it is in other infringement suits.'" D.I. 168 at 21 (quoting *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003)). Since Novo sought in its Complaint "an adjudication that Defendants have infringed one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A)," D.I. 1 at 45, I will enter a judgment that states that Mylan has not infringed the #003 patent "under 35 U.S.C. § 271(e)(2)(A)."