IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| NOVO NORDISK INC. and NOVO NORDISK A/S,<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN PHARMACEUTICALS INC.,<br><br>Defendant. | Civ. No. 23-cv-00101-CFC<br>**ANDA CASE** |

**MEMORANDUM ORDER**

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively Novo Nordisk) market Wegovy®, a drug product approved by the U.S. Food and Drug Administration (FDA) to treat obesity and the reference product for the abbreviated new drug application filed by Defendant Mylan Pharmaceuticals, Inc. that led to this patent infringement litigation. Pending before me is the construction of two terms in claim 1 of the asserted U.S. Patent No. 9,764,003 (the #003 patent).

The active ingredient in Wegovy® is a GLP-1 receptor agonist called semaglutide. Claim 1 of the #003 patent 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 35:31–35 (emphasis added).

The first disputed term is "in an amount of at least 0.7 mg and up to 1.6 mg." Both parties ask me to give the term its plain and ordinary meaning. They dispute, however what that meaning is. Novo Nordisk proposes that I construe the term to mean "in doses greater than or equal to 0.7 mg and less than or equal to 1.6 mg," D.I. 63 at 41, and argues that under this construction the claimed method allows for administrations of semaglutide in amounts less than 0.7 mg and above 1.6 mg. Mylan argues that the claimed method does not allow for administrations of semaglutide in doses less than 0.7 mg or above 1.6 mg, and its asks that I construe the term to mean "only in doses greater than or equal to 0.7 mg and less than or equal to 1.6 mg." D.I. 63 at 41.

Novo Nordisk argues that "[i]t is black letter law that '[t]he transition "comprising" in a method claim indicates that the claim is open-ended and allows for additional steps,' even where such steps are unclaimed." D.I. 63 at 42 (quoting *Invitrogen Corp. v. Biocrest Mfg. L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (second alteration in the original)). Novo Nordisk "is correct that, generally, the use of the transitional phrase 'comprising' does not exclude additional, unrecited steps." *Bd. of Regents of the Univ. of Texas Sys. v. BENQ Am. Corp.*, 533 F.3d 1362, 1372 (Fed. Cir. 2008) (citing *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337,

1343 (Fed. Cir. 2007)). But "[t]he presumption raised by the term 'comprising' does not reach into each of the [] steps to render every word and phrase therein open-ended—especially where . . . the patentee has narrowly defined the claim term it [] seeks to have broadened." *Dippin' Dots*, 476 F.3d at 1343. Thus, a patentee "cannot rely on the word 'comprising' to broaden the scope of a claim phrase that was limited during prosecution so as to gain allowance of the patent." *Univ. of Texas*, 533. F.3d at 1373.

In this case, during its prosecution of the #003 patent, Novo Nordisk expressly capped the dosage of the method in claim 1 at 1.6 mg in order to obtain the patent. On September 22, 2016, the United States Patent & Trademark Office (PTO) rejected Novo Nordisk's application for a previous version of claim 1 (at the time designated claim 13) as indefinite because the proposed claim did not have an upper dosage limit:

> Claims 13, 16, 20, 21, 23, 28, and 29 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. **This is a new rejection necessitated upon further consideration the claims and potential claim scope.**
>
> Claim 13 (and dependent claims 16, 20, 21, 23, 28, and 29) are drawn to a method for treating obesity, comprising administering semaglutide once weekly in *an*

> *amount of at least 0.7 mg* to a subject in need thereof, wherein said semaglutide is administered alone or in combination with an antiobesity agent.
>
> The metes and bounds of the claim are deemed to be indefinite because there is no upper limit in the claims. Accordingly, the claim is interpreted as a method of administering semaglutide once weekly in an amount of at least 0.7 mg which without an upper limit, further includes an amount that is broadly interpreted as up to an infinite amount (0.7 mg - infinite amount). Claim clarification is required.

D.I. 64-7 at 4 (bold and italicized font in the original). In response to this rejection, Novo Nordisk added the words "and up to 1.6 mg" to then-claim 13. D.I. 64-8 at 2. Based on that change (and others), the PTO issued claim 13 as claim 1 of the #003 patent.

Having narrowed claim 1 with an upper dosage limit to gain allowance of the claim, Novo Nordisk cannot rely on the word "comprising" to broaden the scope of the claim to recapture what it expressly and unambiguously relinquished. *Univ. of Texas*, 533. F.3d at 1373. Thus, I agree with Mylan that claim 1 does not allow for administrations of semaglutide in doses greater than 1.6 mg. Mylan, however, does not identify anything in the prosecution history of the #003 patent that suggests, let alone clearly shows, that Novo Nordisk disclaimed dosage amounts below 0.7 mg to obtain issuance of claim 1. For that reason, I cannot agree that claim 1 does not allow for dosage amounts below 0.7 mg.

Accordingly, I will construe "in an amount of at least 0.7 mg and up to 1.6 mg" to mean "in doses greater than or equal to 0.7 mg and never to exceed 1.6 mg." This construction is also consistent with the fact that the patent's written description discloses a dosage amount of less than 0.7 mg, *see, e.g.*, #003 patent at 21:15–17; 22:12–55, but does not disclose any dosage amount above 1.6 mg.

The second disputed term is "administered without another therapeutic agent." Here again, both parties say I should give the term its plain and ordinary meaning but they disagree about what that meaning is. "Therapeutic agent" is not defined in the patent, and neither claim 1 nor any other claim makes clear what is the universe of therapeutic agents covered by "another therapeutic agent" in claim 1. Novo Nordisk asks me to construe "administered without another therapeutic agent" to mean "without coadministration of another medicament intended to reduce body weight." Mylan originally sought the construction "without coadministration of another medicament," but at the December 13, 2023 claim construction hearing, it said that it was not seeking to exclude the coadministration of all other medicaments but only those medicaments implicated by the patent's written description and the discussion of the Madsbad et al. reference in the #003 patent's prosecution history. *See* D.I. 76 at 27:10–15. Having become convinced during oral argument that the term "additional

therapeutic agents" contemplated only additional agents that treat a specific subset of conditions, I asked the parties for additional briefing to help me determine those conditions. The parties filed supplemental letters on December 15, 2023. D.I. 77; D.I. 78.

Having considered the parties' positions and studied the patent and its prosecution history, I will construe 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." I will do so for two reasons.

First, the patent's written description provides that:

> [i]n one embodiment the GLP-1 agonist is administered with another therapeutic agent. Administration with another therapeutic agent may be carried out as administration of the GLP-1 agonist and the other therapeutic agent within the same therapeutic window (e.g. within a period of two weeks, a period of one week, or in a 96, 72, or 48 hour period, etc.). The treatment with a GLP-1 agonist according to the present invention may be combined with *one or more additional therapeutic agents, e.g. selected from antidiabetic agents, anti obesity agents, appetite regulating agents, antihypertensive agents, agents for the treatment and/or prevention of complications resulting from or associated with diabetes and agents for the treatment and/or prevention of complications and disorders resulting from or associated with obesity*; examples of these therapeutic agents are: sulphonylureas, thiazolidinediones, biguanides, meglitinides, glucosidase inhibitors,

> glucagon antagonists, and DPP-IV (dipeptidyl peptidase-IV) inhibitors.

#003 Patent at 4:35–52 (emphasis added). It is clear from this passage that Novo Nordisk understood when it applied for the #003 patent that "another therapeutic agent" included at a minimum agents used to treat diabetes, obesity, and hypertension.

Second, during the prosecution of the patent, Novo Nordisk added "administered without another therapeutic agent" to overcome the patent examiner's rejection of the then-pending claim 13 (now claim 1) as unpatentable on obviousness grounds because of an article authored by Madsbad and others. The examiner had stated in her rejection that "Madsbad teaches the advantages of using a combination of a GLP-1 receptor and metformin for not only treating type 2 diabetes, but also treating the obesity that is associated with type 2 diabetes . . . ." D.I. 64-7 at 9. In its response to the rejection, Novo Nordisk added "administered without another therapeutic agent" and stated:

> Although Madsbad discusses GLP-1 receptor agonists, such discussion is focused on using such agonists <u>in combination</u> with metformin. Indeed, the Office Action specifically cites Madsbad for teaching that "because of the complementary effects of metformin and a GLP-1 receptor agonist on weight and the low risk of hypoglycaemia with this combination, the most optimal approach for GLP-1 receptor agonist treatment may be ***in combination*** with metformin as agent number 2 in the

> treatment algorithm." Office Action at page 11 (emphasis added). Thus, Madsbad does not teach or suggest, as presently claimed, methods for treating obesity by administering semaglutide ***without another therapeutic agent***.

D.I. 64-8 at 4 (underline and italicized font in the original). This statement makes clear that Novo Nordisk intended "another therapeutic agent" to cover at the very least agents used to treat diabetes and obesity.

NOW THEREFORE, at Wilmington on this Twenty-fifth day of March in 2024, it is HEREBY ORDERED that the Court adopts the following claim construction with respect to the asserted claims of U.S. Patent No. 9,764,003:

| Term | Construction |
|---|---|
| "in an amount of at least 0.7 mg and up to 1.6 mg" (Claims 1, 2, 5, and 6) | "in doses greater than or equal to 0.7 mg and never to exceed 1.6 mg" |
| "administered without another therapeutic agent" (Claims 1, 2, 5, and 6) | "administered without another therapeutic agent as part of the method for reducing body weight, or for treating the conditions of diabetes or hypertension." |

CHIEF JUDGE