

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: OZEMPIC (SEMAGLUTIDE)
PATENT LITIGATION

)
) MDL No. 22-MD-3038 (CFC)
) **ANDA CASE**
)

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

RIO BIOPHARMACEUTICALS INC., et al.,

Defendants.

)
) C.A. No. 22-cv-294 (CFC)
) **CONSOLIDATED**
) **ANDA CASE**
)
)
)

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

)
) C.A. No. 22-1040 (CFC)
) **ANDA CASE**
)
)
)

**NOVO NORDISK’S INITIAL RESPONSES TO DEFENDANTS’ INITIAL
INVALIDITY CONTENTIONS REGARDING U.S. PATENT NOS. 8,129,343; 8,536,122;
8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462**

skill in the art, and therefore claims 2, 3, 5, and 6 are nonobvious. In addition, the prior art taught away from using GLP-1 analogs in pharmaceutical compositions or diabetes treatments because of their short half-life and duration of action, potential for side effects, and the existence of other more promising approaches. *See supra*, § III.A. In fact, no GLP-1 receptor agonist had been approved by the FDA as of the priority date, and no GLP-1 analog approach had been confirmed to be successful. *See supra*, § III.A.4. For at least these additional reasons, the pharmaceutical compositions and methods of treatment of claims 2, 3, 5, and 6 are therefore not obvious in view of the prior art.

5. Objective Indicia Support a Finding of Non-Obviousness

Objective indicia evidence further supports nonobviousness of the '343 patent. First, as explained above, there was a significant, long-felt need in the prior art for improved type 2 diabetes therapies. *See supra*, § III.A. Semaglutide has satisfied that long-felt need, as evidenced at least by the widespread adoption of Ozempic[®] by doctors and patients. This has led to tremendous commercial success in the marketplace, even beyond Novo Nordisk's expectations. Ozempic[®] has experienced sales well over \$3B in the United States alone, prompting at least six generic manufacturers to copy and seek FDA approval to sell generic versions of Ozempic[®]. *See, e.g.*, Novo Nordisk, Appendix 6 to Form 6-K (2021) (showing U.S. sales of Ozempic[®] of nearly \$3.3 billion in 2021). Ozempic[®] achieved this enormous commercial success despite entering a crowded and highly competitive marketplace and has in fact expanded the market for GLP-1 therapeutics, including by offering an alternative to historically-used oral therapies despite being an injectable product. Semaglutide has also received praise in the field for its efficacy as a type 2 diabetes treatment, as well as for its efficacy in treating obesity, for which it is FDA-approved under a separate trade name, Wegovy[®].

There was skepticism in the diabetes marketplace and even at Novo Nordisk as semaglutide was developed that it could successfully treat type 2 diabetes as a once weekly drug and that it could provide superior A1c reduction as well as weight loss benefits over existing once-daily injectables. There was also skepticism that semaglutide (or any chronic use peptide) would be plausible as an oral diabetes agent but in 2019, Rybelsus[®] (semaglutide tablets) became the first oral dosage form peptide approved by the FDA.

Semaglutide has many unexpected favorable properties that have contributed to its extensive use as a therapeutic agent. These properties include unexpectedly improved efficacy in treating diabetes; unexpectedly improved weight loss; unexpectedly improved cardiovascular benefits, and a dramatically and unexpectedly improved half-life. Indeed, semaglutide was the first GLP-1 peptide discovered with a sufficiently long half-life for once-weekly use, despite skepticism from those in the field that once-weekly GLP-1 was a viable approach. Additionally, semaglutide is orally bioavailable and has become the first FDA-approved oral peptide therapy for diabetes (under the trade name Rybelsus[®]).

Defendants have not identified what they contend is the closest prior art to the asserted claims of the '343 patent. Plaintiffs reserve their right to address unexpected results over such prior art upon identification by Defendants.

E. THE ASSERTED CLAIMS ARE NOT INVALID UNDER § 112

1. The Asserted Claims Are Definite

Defendants cannot meet their burden to prove by clear and convincing evidence that any of the asserted claims of the '343 patent is invalid for indefiniteness.

First, Defendants contend that Claims 1–3 are invalid because the term “the amino acid sequence” lacks antecedent basis. Defendants’ Invalidity Contentions at 141. Thus, Defendants