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

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C. THE REFERENCES CITED BY DEFENDANTS

The references Defendants cite in their Contentions, either alone or in combination, do not render any of claims 1-10 of the ’462 patent invalid. While each of Defendants’ cited references is discussed below, some are not prior art and others are not relevant to the claimed inventions of the ’462 patent.

1. WO 2011/138421 (“WO ’421”)

International PCT Publication WO 2011/138421 (“WO ’421”), entitled “Combination Therapy” was published on November 10, 2011. Defendants identify WO ’421 as prior art, and also include it in combinations of prior art asserted against claims of the ’462 patent. Defendants allege that WO ’421 is prior art to the ’462 patent “under § 102(b).” Defendants’ Invalidity Contentions at 98. However, WO ’421 was not published more than one year before the ’462 patent’s foreign and U.S. provisional priority filings and was not published before the ’462 patent’s invention date; therefore, it is not prior art under 35 U.S.C. § 102(b). In any event, WO ’421 does

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4. Objective Indicia Support a Finding of Non-Obviousness

Objective indicia support a conclusion that the claims of the ’462 patent are non-obvious. First, as explained above, the determination that a 1.0 mg once weekly dose would be effective in treating type 2 diabetes was unexpected. A person of ordinary skill in the art would expect that a minimum therapeutically effective dose for semaglutide would be higher, including because the FDA-approved ***once daily*** dosage of liraglutide was 1.2-1.8 mg. Therefore, a person of ordinary skill would likely expect a weekly therapeutic dose for semaglutide to be greater than the daily dose of liraglutide. The data disclosed in the ’462 patent demonstrate the surprising result that a therapeutically effective once weekly dosage of semaglutide is actually ***lower*** than the approved daily liraglutide dose and achieved adequate reduction in HbA1c with substantial weight loss. Indeed, dosages of 0.8 mg once weekly and greater showed even better treatment of type 2 diabetes and weight loss than 1.2 and 1.6 mg once daily doses of liraglutide. Nothing in the prior art remotely suggested this would be so. Thus, it was unexpected that 1.0 mg of semaglutide once weekly would effectively treat type 2 diabetes.

The administration of 1.0 mg once weekly of semaglutide has been commercially successful, even beyond Novo Nordisk’s expectations, and at least six different generic companies are seeking to market generic versions of Ozempic®, which includes prescribing information encouraging doctors and patients to administer semaglutide in an amount of 1.0 mg once weekly. Copying is further objective indicia of nonobviousness.

The magnitude of weight loss seen with semaglutide in the claimed methods was particularly unexpected, in view of weight loss effects shown by other GLP-1 drugs, such as liraglutide. This finding led to semaglutide being approved by the FDA as an anti-obesity treatment, Wegovy®, in addition to its use as a diabetes treatment (i.e., Ozempic®). Semaglutide’s

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exceptional weight loss effects have received considerable praise and have helped satisfy a long-felt need for an improved anti-obesity therapeutic. The magnitude of these clinical anti-obesity benefits was first discovered by the inventor of the ’462 patent.

Defendants have not identified what they contend is the closest prior art to the asserted claims of the ’462 patent. Plaintiffs reserve their right to address unexpected results over such prior art upon identification by Defendants.

E. THE ASSERTED CLAIMS ARE ENABLED AND SUPPORTED BY SUFFICIENT WRITTEN DESCRIPTION

1. The Claims Are Not Invalid for Lack of Enablement

Defendants argue that the ’462 patent’s claims are invalid for lack of enablement because the specification “provides no support” for the claimed dosage of 1.0 mg semaglutide once weekly. Defendants’ Invalidity Contentions at 220. Defendants’ argument sounds in the written description requirement, not enablement. A specification need not “provide[ ] support” for the claimed dosage in the specification to meet the enablement requirement. Rather, the enablement requirement is satisfied if a skilled artisan is enabled to make and use the invention without undue experimentation. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003).

Defendants have not explained why a person of ordinary skill—with the benefit of the ’462 patent’s disclosure—would be unable to carry out a method of treating type 2 diabetes by administering (parenterally or subcutaneously) 1.0 mg semaglutide once weekly without undue experimentation. Accordingly, Defendants have not offered clear and convincing evidence of nonenablement of claims 1-3.

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