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Paper No. 10
Entered: October 4, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2023-00724
Patent 10,335,462 B2

Before JOHN G. NEW, SUSAN L. C. MITCHELL, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 1, "Pet."), seeking *inter partes* review of claims 1–10 U.S. Patent No. 10,335,462 B2 (Ex. 1001, "the '462 patent"). Novo Nordisk A/S ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

In its Preliminary Response, Patent Owner requests that the Board exercise its discretion to deny institution under 35 U.S.C. §§ 325(d) and 314(a). *See* Prelim. Resp. 59–67. Patent Owner also raises challenges to the merits of the grounds in the Petition. *Id.* at 14–59.

After considering the arguments and evidence presented at this stage of the proceeding, we are persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. *See* 35 U.S.C. § 314(a). We also decline to exercise our discretion to deny institution under 35 U.S.C. §§ 325(d) or 314(a). Accordingly, we institute *inter partes* review.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies Mylan Pharmaceuticals Inc., Mylan Inc., and Viatris Inc. as real parties in interest. *See* Pet. 1. Patent Owner identifies itself as the real party in interest, but also lists exclusive licensee Novo Nordisk Inc. *See* Paper 4, 1.

B. Related Matters

Petitioner and Patent Owner identify the following litigations as related matters, the first three of which involve Petitioner as a defendant. Pet. 1–2; Paper 4, 1–2.

1. *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-01040-CFC (D. Del.)
2. *In re Ozempic (Semaglutide) Patent Litigation*, No. 22-md-3038-CFC (D. Del.)
3. *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00023 (N.D.W. Va.)
4. *Novo Nordisk Inc. v. Aurobindo Pharma USA, Inc.*, No. 1:22-cv-00295 (D. Del.) (dismissed on March 28, 2022)
5. *Novo Nordisk Inc. v. Rio Biopharmaceuticals, Inc.*, No. 1:22-cv-00294 (D. Del.)
6. *Novo Nordisk A/S v. Sun Pharm. Indus. Ltd.*, No. 1:22-cv-00296 (D. Del.)
7. *Novo Nordisk Inc. v. Zydus Worldwide DMCC*, No. 1:22-cv-00297 (D. Del.)
8. *Novo Nordisk Inc. v. Dr. Reddy's Laby's Ltd.*, No. 1:22-cv-00298 (D. Del.)
9. *Novo Nordisk Inc. v. Alvogen, Inc.*, No. 1:22-cv-00299 (D. Del.)

C. The '462 Patent

The '462 patent issued on July 2, 2019, and is a continuation of an application filed June 21, 2013, now U.S. Patent No. 9,764,003, and claims priority from two provisional applications and two foreign applications, the

earliest of which was filed on July 1, 2012. Ex. 1001, codes (30), (45), (60), (63); 1:6–15.

The '462 patent relates to "use of long-acting GLP-1 peptides in certain dosage regimes for the treatment of type 2 diabetes, obesity, etc." Ex. 1001, Abstr. The '462 patent further describes one embodiment as follows:

> In one embodiment the invention relates to a method for a) reduction of HbA_{1c}; b) prevention or treatment of type 2 diabetes, hyperglycemia, impaired glucose tolerance, or non-insulin dependent diabetes; or c) prevention or treatment of obesity, reducing body weight and/or food intake, or inducing satiety; wherein said method comprises administration of a GLP-1 agonist to a subject in need thereof, wherein said GLP-1 agonist i) has a half-life of at least 72 hours, wherein said half-life optionally is determined by Assay (II); ii) is administered to an amount of at least 0.7 mg per week, such an amount equivalent to at least 0.7 mg semaglutide per week; and iii) is administered once weekly or less often.

Ex. 1001, 1:31–44.

The sole example provided in the '462 patent describes administering semaglutide, "a unique acylated GLP-1 peptide with a half-life of 160 hours," in order "to investigate HbA_{1c} dose-response of once-weekly doses of semaglutide (five dose-levels) in subjects with type 2 diabetes. Safety, tolerability and pharmacodynamics of semaglutide versus placebo and open-label once-daily liraglutide were also investigated." Ex. 1001, 20:66–21:5.

Figure 1 set forth below shows the change in HbA_{1c} from baseline at week 12 for Example 1. Ex. 1001, 22:5–7.

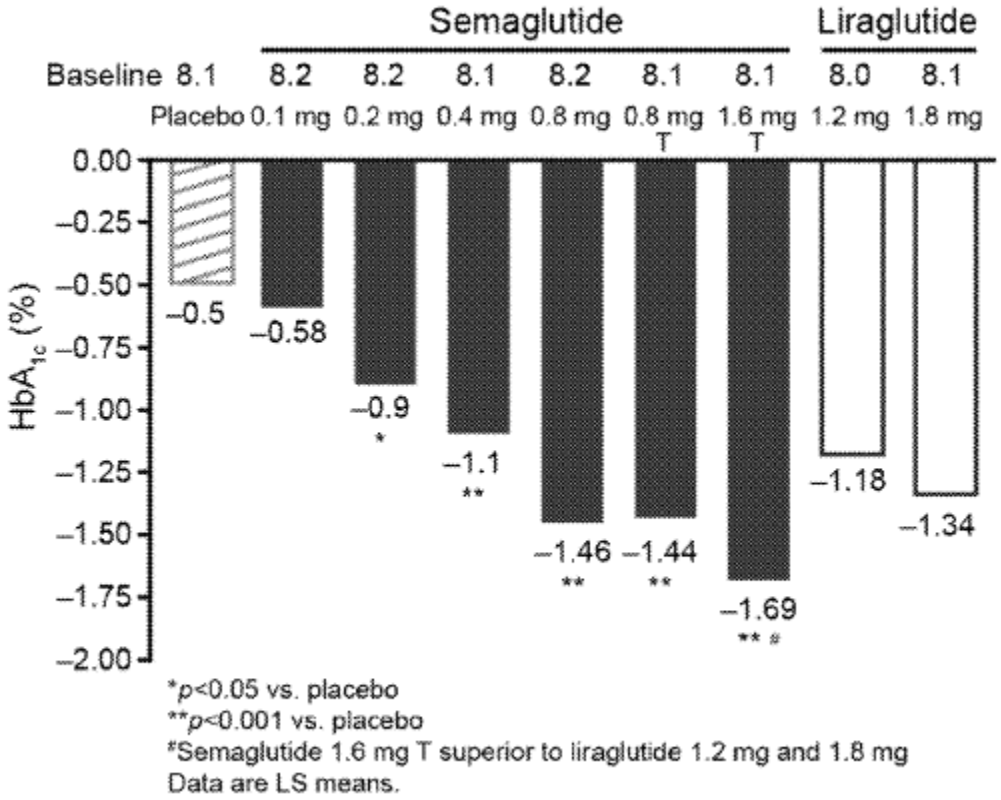

Fig. 1

The analysis of the results in Figure 1 set forth above shows "semaglutide (≥0.2 mg) dose-dependently reduced HbA_{1c} from baseline (FIG. 1), and increased the likelihood of achieving HbA_{1c}<7% (p<0.05 vs. placebo for doses ≥0.2 mg)." Ex. 1001, 22:2–5. The example also showed that "[b]ody weight was dose-dependently reduced from base-line by up to 4.8 kg vs. placebo 1.2 kg (p<0.1 for doses 13.8 mg).

The '462 patent concludes:

> Over 12 weeks, semaglutide dose-dependently reduced HbA_{1c} and body weight. The effect of semaglutide 0.4 mg on glycaemic control and body weight was comparable to that of liraglutide 1.2 mg, while semaglutide ≥0.8 mg appeared to bring more subjects to target and provided better weight loss than liraglutide 1.8 mg. No semaglutide safety concerns were

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