

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2023-00722
Patent 8,536,122 B2

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

POLLOCK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, Mylan Pharmaceuticals Inc., filed a Petition for *inter partes* review of claims 1, 2, 4–11, 13, and 15 of U.S. Patent No. 8,536,122 B2 (Ex. 1001, “the ’122 patent”). Paper 1 (“Pet.”). Patent Owner, Novo Nordisk A/S, timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7, “Reply”); Patent Owner filed a responsive Sur-Reply (Paper 8, “Sur-reply”).

For the reasons provided below, we determine Petitioner has not satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has not demonstrated a reasonable likelihood that at least one claim of the ’122 patent is unpatentable, we do not institute an *inter partes* review on the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”); *see also* Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018).¹

A. Real Parties in Interest

Petitioner identifies Mylan Pharmaceuticals Inc., Mylan Inc., and Viartis Inc. as the real parties-in-interest. Pet. 2. Patent Owner identifies Novo Nordisk A/S and Novo Nordisk Inc. as real parties-in-interest. Paper 4, 1.

¹ Available at <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial> (“Guidance”).

B. Related Matters

In addition to the current matter, Petitioner challenges claims 1–6 of U.S. Patent No. 8,129,343 B2 (Ex. 1002, “the ’343 patent”) in IPR2023-00723. The ’122 patent is a continuation of application No. 11/908,834 that issued as the ’343 patent.

According to the parties, the ’122 patent is at issue in the following pending actions involving the parties, among other litigations:

Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc., No. 22-cv-01040-CFC (D. Del.);

Novo Nordisk Inc. v. Viatris Inc., No. 1:23-cv-00013-TSK (N.D. W. Va.);

Novo Nordisk Inc. v. Viatris Inc., No. 1:23-cv-00101-CFC (D. Del); and

In re: Ozempic (Semaglutide) Patent Litig., No. 22-md-3038-CFC (D. Del.).

Pet. 2–3; Paper 4, 1–2.

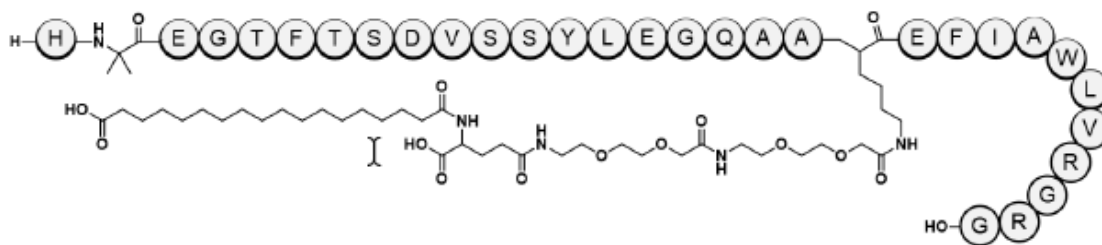
C. The ’122 Patent and Relevant Background

The ’122 patent, titled “Acylated GLP-1 Compounds,” is directed to modified analogs of glucagon-like peptide 1 (GLP-1). Ex. 1001, code (54), 1:59–2:7. GLP-1² is a naturally-occurring insulinotropic peptide hormone derived from a 37-amino acid precursor by the enzymatic removal of amino acids 1–6 and modification of amino acids 8 and 26. *See, e.g., id.* at 3:27–30,

² Although the unprocessed peptide is sometimes referred to as GLP-1 (*see* Pet. 17–18), we generally understand the term to refer to a processed form. *See, e.g.,* Ex. 1002, 3:27–30. For additional specificity, GLP-1 peptides may be identified with reference to its amino acid sequence as compared to the 37 amino acid precursor form. For example, GLP-1(1–37) may refer to the full-length parent molecule, and GLP-1(7–37) to a post-cleavage form in which amino acids 1–6 have been removed. *See* Prelim. Resp. 6, n.3.

with a moiety to the lysine residue in position 26,” and wherein the moiety includes at least two acidic groups. *Id.* at 1:57–63, 4:4–16, Ex. 1011, 677. The non-proteogenic amino acid residue in positions 7 and/or 8 protects the modified compounds from DPP-IV degradation as compared to native GLP-1. *See* Ex. 1002, 4:4–19; 6:18–25. The acylated GLP-1 analog binds to albumin and the GLP-1 receptor simultaneously. *Id.* at 5:4–6. Specifically, the acylated GLP-1 analog is acylated “with a lipophilic albumin binding moiety containing at least two free acidic chemical groups attached via a non-natural amino acid linker to the lysine residue in position 26.” *Id.* at 6:11–14.

The '122 patent discloses a number of specific compounds, including semaglutide, N- ϵ^{26} -[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib8,Arg34]GLP-1-(7-37)peptide. *Id.* at 57:1–58:37 (Example 4); Ex. 1020 ¶ 100. The structure of semaglutide may also be illustrated as:



Ex. 1020 ¶ 100.

D. Relevant Prosecution History

The '122 patent was filed as Application No. 13/412,283 and claims priority as a continuation of Application no. 11/908,834, having a filing date of March 20, 2006, that issued as the '343 patent. Accordingly, we discuss the prosecution history both the '343 and '122 patents below.

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