Trials@uspto.gov
571-272-7822

Paper 9
Entered: October 2, 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.

IPR2023-00722
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 Viatris 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.).

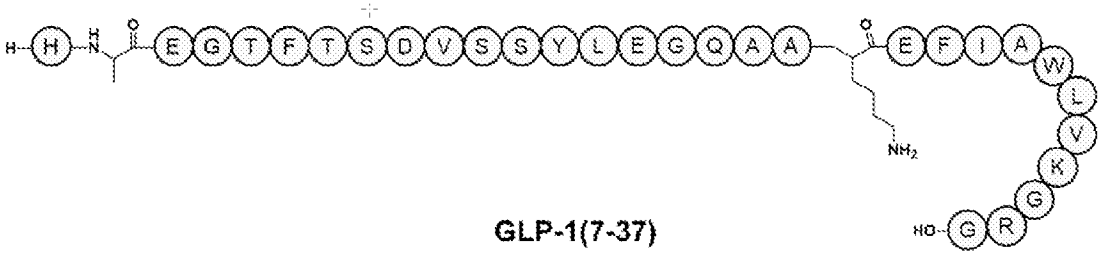
Pet. 2–3; Paper 4, 1–2.

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-1[2] 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.

Ex. 1011, 677.[3, 4] The structure of a naturally-occurring mature form is shown below.



GLP-1(7-37)

Pet. 18; Prelim. Resp. 7.[5] The above figure illustrates the structure of GLP-1(7–37) including the modifications to the alanine 7 and lysine 26.

In the body, GLP-1 is rapidly degraded by dipeptidyl aminopeptidase IV (DPP-IV), such that "the natural hormone is not very useful as a drug." Ex. 1011, 677. According to the '122 patent, the prior art discloses various "approaches . . . for modifying the structure of glucagon-like peptide 1 (GLP-1) compounds in order to provide a longer duration of action in vivo," but indicates that, because of the short half-lives, prior art GLP-1 compounds must be administered at least once daily. *See* Ex. 1001, 1:23–43.

The '122 patent discloses improved GLP-1 analogs intended to allow for reduced dosing frequency when treating type 2 diabetes. *Id.* at 1:52–2:7. In particular, the '122 patent describes GLP-1 analogs with modifications "of at least one non-proteogenic amino acid residue in positions 7 and/or 8 relative to the sequence GLP-1(7-37) (SEQ ID No. 1), which is acylated

---

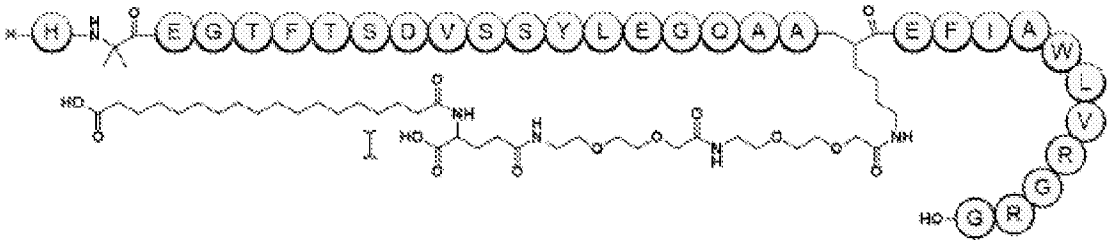
[3] L. B. Knudsen et al., *GLP-1 derivatives as novel compounds for the treatment of type 2 diabetes: selection of NN2211 for clinical development*, 26(7) DRUGS OF THE FUTURE 677–685 (2001). ("Knudsen 2001").

[4] We generally refer to the original page numbers of cited art rather than to the numbering assigned by the parties.

[5] Naturally occurring GLP-1 also occurs as an amide, GLP-1(7-36) amide. *See* Ex. 1011, 677.

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.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.