

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

NOVO NORDISK A/S,  
Patent Owner.

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IPR2023-00722  
Patent 8,536,122 B2

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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).<sup>1</sup>

### 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.

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<sup>1</sup> 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.

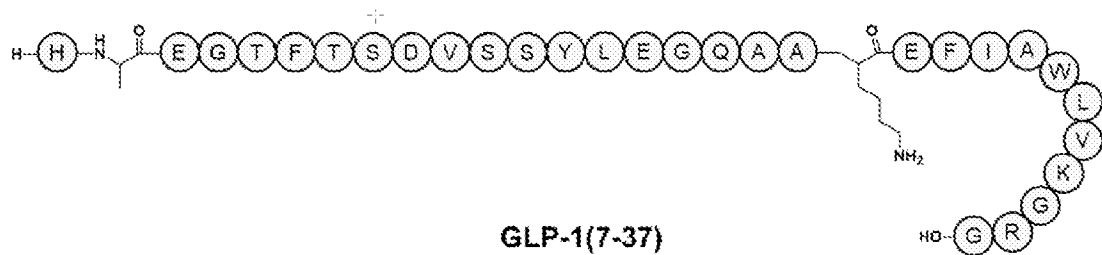
## C. The ’122 Patent and Relevant Background

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<sup>2</sup> 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,

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<sup>2</sup> 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.<sup>3, 4</sup> The structure of a naturally-occurring mature form is shown below.



Pet. 18; Prelim. Resp. 7.<sup>5</sup> 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

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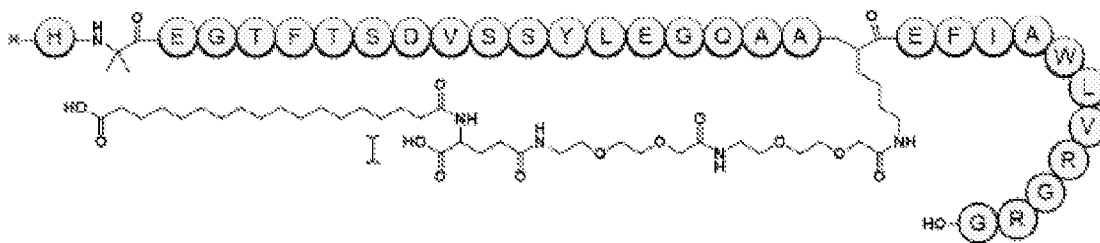
<sup>3</sup> L. B. Knudsen et al., *GLP-1 derivatives as novel compounds for the treatment of type 2 diabetes: selection of NN2211 for clinical development*, 26(7) DRUGS OF THE FUTURE 677–685 (2001). (“Knudsen 2001”).

<sup>4</sup> We generally refer to the original page numbers of cited art rather than to the numbering assigned by the parties.

<sup>5</sup> 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- $\epsilon^{26}$ -[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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