I. INTRODUCTION

~~Mylan Institutional~~**Fresenius Kabi USA,** LLC ("Petitioner") petitions for *Inter Partes* Review **("IPR")** of claims 1-31 of U.S. Patent ~~No.~~ 8,114,833 ("~~the~~ '833 patent") (Ex. 1001), ~~which is~~ assigned to Novo Nordisk A/S ("Patent Owner"), under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 and seeks a determination that all claims ~~(1-31)~~ of the '833 patent be canceled as unpatentable.

II. MANDATORY NOTICES

This Petition is filed in accordance with 37 C.F.R. § 42.106(a). Filed herewith is a power of attorney and exhibit list per § 42.10(b) and § 42.63(e). ~~Pursuant to~~ 37**Petitioner authorizes the U.S. Patent & Trademark Office to charge Deposit Account No. 506989 for any necessary fees.**

A. Real Parties-In-Interest – 37 C.F.R. § ~~42.103, the fee set forth in § 42.15(e) accompanies this Petition~~42.8(b)(1).

~~A. Real Parties-In-Interest~~

In accordance with 37 C.F.R. § 42.8(b)(1), ~~the real parties-in-interest for Petitioner are Mylan Institutional LLC, Mylan Inc., and Mylan N.V~~**and in abundance of caution, Fresenius Kabi, LLC may be a real party-in-interest**.

B. Related Matters – 37 C.F.R. § 42.8(b)(2).

In accordance with 37 C.F.R. § 42.8(b)(2), Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '833 patent.

~~Petitioner is the defendant in the following litigation involving the '833 patent:~~

~~*Novo Nordisk Inc. v. Mylan Institutional LLC*, C.A. No. 19-cv-01551-CMC (D. Del.).~~

The '833 patent is the subject of the following litigations: *Novo Nordisk Inc. et al v. Sandoz Inc.*, Case No. 1:20-cv-00747 (D. Del.) ("Sandoz Litigation"), *Novo Nordisk Inc. et al v. Teva Pharmaceuticals, Inc. et al*, Case No. 1:21-cv-

Case No. 1:21-cv-01783 (D. Del.). Trial is scheduled in the Sandoz litigation to begin in April 2022. No schedule has been entered in the other litigations.

The '833 patent was the subject of two Inter Partes Review proceedings: *Mylan Institutional LLC v. Novo Nordisk A/S*, IPR2020-00324, and *Pfizer Inc. v. Novo Nordisk A/S*, IPR2020-01252. These petitions were instituted and joined, but both settled before issuance of a Final Written Decision. This petition presents the same grounds of unpatentability as IPR2020-00324 and IPR2020-01252.

Petitioner is not aware of any other ~~pending litigation, or any pending~~judicial or administrative matter that would affect or be affected by a decision in this IPR.

~~proceedings in front of the Patent Trial and Appeal Board.~~

A patent application in the same patent family is pending as U.S. Patent Application No. 16/~~260,204~~910,945, filed on ~~Jan. 29~~June 24, ~~2019~~2020.

C. ~~Identification of~~Lead and Backup Counsel ~~(~~ 37 C.F.R. § 42.8(b)(3)~~)~~

Petitioner designates the following lead and backup counsel:

Lead Counsel	~~Back Up~~*Back-up Counsel*
~~Brandon M. White~~Linnea Cipriano (Reg. No. ~~52,354)Perkins Coie LLP~~67,729) ~~700 Thirteenth Street, N.W. Suite 600~~ ~~Washington, D.C. 20005~~ Goodwin Procter LLP 620 Eighth Avenue New York, NY 10018 ~~Telephone~~Phone: (~~202~~212) ~~654-6206~~813-8800 Fax: (212) 355-3333 ~~Facsimile: (202) 654-9681~~ ~~BMWhite@perkinscoie.com~~lcipriano@~~goodwinlaw.com~~	~~Lara Dueppen (Reg. No. 65,002)~~ ~~Perkins Coie LLP~~ ~~1888 Century Park EastSuite 1700~~ ~~Los Angeles, CA 90067~~ ~~Telephone: (310) 788-3349~~ Daryl Wiesen (*pro hac vice* application to be filed) Goodwin Procter LLP 100 Northern Avenue Boston, MA 02210 Phone: (617) 570-1000 Fax: (617) 523-1231 ~~Facsimile: (310) 788-3399~~ ~~LDueppen@perkinscoie.com~~dwiesen@

~~D. Service Information~~

D. Service Information – 37 C.F.R. § 42.8(b)(4)

Pursuant to 37 C.F.R. § 42.8(b)(4), Petitioner respectfully requests that all correspondence be directed to lead counsel and back-up counsel at the contact information provided above. Petitioner consents to electronic service by e-mail at the following email addresses:

~~White-ptab@perkinscoie.com; Dueppen-ptab@perkinscoie.com; and Liraglutide@perkinscoie.com.~~

lcipriano@goodwinlaw.com

dwiesen@goodwinlaw.com

III. ~~III.~~ GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '833 patent is available for ~~*inter partes* review~~IPR and that Petitioner is not barred or estopped from requesting ~~*inter partes* review~~IPR on the grounds identified herein.

IV. ~~IV.~~ IDENTIFICATION OF CHALLENGE AND STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.22(a) and 37 C.F.R. § 42.104(b), Petitioner requests *inter partes* review and cancellation of claims 1-31 on the following grounds:

Ground 1: Claims 1-15 of the '833 patent were anticipated by Flink (Ex. 1004).

Ground 2: Claims 1-15 of the '833 patent would have been obvious over Flink (Ex. 1004).

Ground 3: Claims 1-31 of the '833 patent would have been obvious over Flink
(Ex. 1004) in view Betz (Ex. 1005).

Petitioner's statement of the reasons for the relief is set forth below. In support of these grounds for unpatentability, Petitioner submits the declaration of Laird Forrest, Ph.D.~~, and relies on the Exhibits identified in the concurrently-filed Listing of Exhibits~~ **(Ex. 1002).**

~~Statement of No Redundancy: This is the first petition for *inter partes* review of the '833 patent by Petitioner. Grounds 1-3 presented in this Petition have not previously been before the Board.~~

V. ~~V.~~ THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW

~~A petition for *inter partes* review must demonstrate a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). This~~ **As explained in detail herein, this** Petition clears ~~that~~**the** threshold~~. There~~ **for institution because there** is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. **35 U.S.C. § 314(a).**

VI. STATEMENT OF REASONS FOR THE RELIEF REQUESTED.

A. Summary of the Argument

The challenged claims relate to a formulation containing a glucagon-like peptide 1 ("GLP-1") agonist, a standard buffer to stabilize the pH of the formulation, and a common tonicity agent. This same formulation was, however, already

disclosed in the prior art, including in the Flink reference relied on here. The claims offer nothing new over the prior art, rendering them unpatentable.

B. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA")~~[1]~~[1] would have had (1) a Pharm. D., or a Ph.D. in pharmacy, chemical engineering, bioengineering, chemistry, or related discipline; (2) at least two years of experience in the area of protein or peptide therapeutic development and/or manufacturing; and (3) experience with the development, design, manufacture, or formulation of therapeutic agents, and the literature concerning protein or peptide formulation and design. Ex. 1002, ¶¶26-27.

~~[1] All references herein to the knowledge or understanding of a POSA or a POSA's interpretation or understanding of a prior art reference are as of the earliest possible priority date claimed on the face of the '833 patent, November 20, 2003, unless specifically stated otherwise.~~

In view of the relatively high level of skill and the clear teachings in the prior art, the level of skill of the POSA is not dispositive of any issue raised in this Petition.

C. The '833 Patent and Its Prosecution

1. ~~THE~~The '833 ~~PATENT DISCLOSURES~~Patent Disclosures

[1] All references herein to the knowledge or understanding of a POSA or a POSA's interpretation or understanding of a prior art reference are as of the earliest possible priority date claimed on the face of the '833 patent, November 20, 2003, unless specifically stated otherwise.

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.