UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

NOVO NORDISK A/S,

Patent Owner.

Case No. IPR2023-00724

Patent No. 10,335,462

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,335,462

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1002	Prosecution history excerpts for U.S. Patent No. 10,335,462
1003	Declaration of John Bantle, MD
1004	CV of John Bantle, MD
1005	Declaration of William J. Jusko, Ph.D.
1006	CV of William J. Jusko, Ph.D.
1007	Declaration of Paul Dalby, Ph.D.
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I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc. ("Petitioner") petitions for *Inter Partes* Review of claims 1-10 of U.S. Patent No. 10,335,462 ("'462 patent") (Ex. 1001), assigned to Novo Nordisk A/S ("Patent Owner").

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 C.F.R. § 42.103, the fee set forth in § 42.15 (e) accompanies this Petition.

II. MANDATORY NOTICES

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 Pharmaceuticals Inc., Mylan Inc., and Viatris Inc.

B. Related Matters

In accordance with 37 C.F.R. § 42.8(b)(2), Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '462 patent. Petitioner is a defendant in the following consolidated litigation involving the '462 patent:

- *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-01040-CFC (D. Del.);
- *In re Ozempic (Semaglutide) Patent Litigation*, No. 22-md-3038-CFC (D. Del.); and
- *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00023 (N.D.W. Va.).

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In addition, the following litigations also involve the ’462 patent:

- *Novo Nordisk Inc. v. Aurobindo Pharma USA, Inc.*, No. 1:22-cv-00295 (D. Del.) (dismissed on March 28, 2022);
- *Novo Nordisk Inc. v. Rio Biopharmaceuticals, Inc*., No. 1:22-cv-00294 (D. Del.);
- *Novo Nordisk A/S v. Sun Pharm. Indus. Ltd*., No. 1:22-cv-00296 (D. Del.);
- *Novo Nordisk Inc. v. Zydus Worldwide DMCC*, No. 1:22-cv-00297 (D. Del.);
- *Novo Nordisk Inc. v. Dr. Reddy’s Laby’s Ltd*., No. 1:22-cv-00298 (D. Del.); and
- *Novo Nordisk Inc. v. Alvogen, Inc*., No. 1:22-cv-00299 (D. Del.).

Petitioner is not aware of any other pending litigation, or any pending proceedings in front of the Patent Trial and Appeal Board.

C. Identification of Counsel (37 C.F.R. § 42.8(b)(3))

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D. Service Information (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:

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Semaglutide-Ozempic@perkinscoie.com.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW

This Petition complies with all statutory requirements, as well as 37 C.F.R. §§ 42.104, 42.105, and 42.15, and should be accorded a filing date pursuant to 37 C.F.R. § 42.106. Petitioner's undersigned representative authorizes the Director

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to charge any required fees not submitted with this petition to Deposit Account 50-0065, charge number 136020-0073.0002.

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the ’462 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review on the grounds identified. Petitioner meets all requirements under 35 U.S.C. §§ 315(a)(1), 315(b), and 315(e)(1), and under 37 C.F.R. §§ 42.73(d)(1), 42.101, and 42.102.

B. 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 that the Board institute *inter partes* review on claims 1-10 of the ’462 patent and cancel them as unpatentable for anticipation and/or obviousness under 35 U.S.C. §§ 102 and 103:

Ground	Claims	Basis for Unpatentability
1	1-3	Anticipated by WO421
2	1-3	Anticipated by Lovshin
3	1-10	Obvious over WO421 considering the ’424 publication
4	1-10	Obvious over WO537 considering Lovshin
5	1-10	Obvious over NCT657 and NCT773 considering the ’424 publication

Petitioner’s statement of the reasons for the relief is set forth below. In support of these grounds for unpatentability, Petitioner submits the Declarations of Dr. John

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Bantle, Dr. William Jusko, and Dr. Paul Dalby and relies on the Exhibits identified in the concurrently filed Listing of Exhibits.

Statement of No Redundancy: This is the first petition for IPR of the '462 patent by Petitioner. The Grounds presented in this Petition have not previously been before the Board.

IV. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW

A petition for IPR 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 Petition clears that threshold. There is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims.

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Summary of the Argument

Glucagon-like peptide 1 ("GLP-1") is a well-known, naturally occurring protein hormone having 37 amino acid residues, with a short duration of action (lasting just minutes in the body before being broken down). By the 1980s, researchers had discovered GLP-1 played a significant role in moderating human blood glucose levels, but its short half-life made it impracticable as a treatment for diseases like diabetes caused by elevated blood glucose levels. But researchers also learned they could extend GLP-1's duration of action by optimizing its structure.

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The first-generation analogue—liraglutide—tweaked GLP-1 so that it would remain active for hours and therefore be a practicable diabetes treatment. Other GLP-1 analogues in the art followed the same strategy, i.e., using well-known techniques to design peptides more resistant to degradation in the body, thereby prolonging their actions.

A natural next step was for researchers to make additional tweaks to liraglutide's structure to further improve its half-life while maintaining its efficacy in treating diabetes, and they did that. POSAs knew this modified prior art compound as semaglutide. By the priority date, the prior art had already disclosed once-weekly administration of semaglutide with doses between 0.1 and 1.6 mg. And Phase I and II clinical trials were already reported at once-weekly doses in that same range. Thus, before the priority date, the prior art had already established semaglutide's utility as a once-weekly diabetes treatment and disclosed a finite range of efficacious doses to POSAs multiple times.

The '462 patent's claims are directed towards semaglutide administration in a 1.0 mg once-weekly dose to patients with type 2 diabetes. But, as outlined in Grounds 1 and 2, at the priority date, using semaglutide in a 1.0 mg once-weekly dose to treat patients with type 2 diabetes was disclosed in the art. A patent application from scientists at Boehringer Ingelheim, WO421, taught POSAs to administer semaglutide at once-weekly doses between 0.1 and 1.6 mg. Ex. 1011.

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Lovshin, an article by scientists at Mt. Sinai, likewise disclosed once-weekly doses of semaglutide between 0.1 and 1.6 mg. Ex. 1012. Both references also disclosed use of semaglutide in that dose range to treat diabetes. Thus, as outlined in Grounds 1 and 2, WO421 and Lovshin each anticipated claims 1-3. Claims 4-10 recite conventional excipients and properties of injectable formulations which were immediately obvious to POSAs and already disclosed in the art. These claims are also unpatentable.

Even if the claims are not found anticipated, however, there was ample reason for POSAs to select a 1.0 mg once-weekly dose from the narrow range disclosed in the art, making the challenged claims obvious, as outlined in Grounds 3-5. With the structure and function of semaglutide already well known, a POSA's remaining task was, at most, dose selection from a small and finite range already disclosed in the art (having a maximum of only 16 options). And at least three pieces of information would have motivated POSAs to choose that dosing regimen with a reasonable expectation of success. First, because semaglutide was known to be an even longer-lasting GLP-1 agonist than liraglutide, POSAs understood semaglutide would allow for once-weekly injections with a clinical effect like liraglutide, and that patients would prefer a once-weekly semaglutide injection versus a daily liraglutide injection. Second, the prior art, including Phase I and II clinical trials, patent applications, and scientific articles, further instructed POSAs to dose semaglutide at

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a once-weekly dose between 0.1 and 1.6 mg. Third, a POSA's understanding of the clinical trial process would have further directed POSAs to the claimed 1.0 mg once-weekly dose. This follows because POSAs would have known that all doses in the 0.1-1.6 mg range would have been expected to have some efficacy, and more importantly, the higher doses (e.g., 0.8 and 1.2 mg) administered in clinical trials like NCT773 and NCT657 were reasonably expected to succeed based on all the data and research that had come before. And there was nothing critical about a 1.0 mg dose.

So, for the reasons detailed and explained herein and in the accompanying declarations, claiming a 1.0 mg once-weekly dose of semaglutide to treat diabetes, as the '462 patent does, was obvious. Moreover, as will become evident, the Examiner materially erred in multiple ways in granting the '462 patent. Petitioner respectfully requests the Board to rectify that error by instituting this Petition for trial and ultimately declaring the challenged claims unpatentable.

B. Level of Ordinary Skill in the Art

A POSA has[1] (1) an M.D., Pharm.D., or Ph.D. in pharmacy, chemical engineering, bioengineering, chemistry, or related discipline; (2) at least two years

[1] All references herein to the knowledge or understanding of a POSA or their interpretation or understanding of a prior art reference are as of the earliest possible

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of experience in protein or peptide therapeutic development and/or manufacturing or diabetes treatments; and (3) experience with the development, design, manufacture, formulation, or administration of therapeutic agents, and the literature concerning protein or peptide formulation and design, or diabetes treatments.

Alternatively, a POSA would be (1) a highly-skilled scientist lacking an M.D., Pharm.D., or Ph.D., but would have (2) more than five years of experience in the area of protein or peptide therapeutic development and/or manufacturing or diabetes treatments; and/or (3) experience with the development, design, manufacture, or formulation of therapeutic agents, and the literature concerning protein or peptide formulation and design or diabetes treatments.

POSAs would have understood the prior art references referred to herein and would have the capability to draw inferences from them. To the extent necessary, a POSA may collaborate with one or more other skilled artisans for one or more aspects with which the other skilled artisan may have expertise, experience, and/or knowledge. Additionally, a POSA could have had a lower level of formal education than what is described here if the person has a higher degree of experience. In view

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priority date claimed on the face of the ’462 patent, July 1, 2012, unless stated otherwise.

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

C. The ’462 Patent

1. DISCLOSURE

The ’462 patent claims a method of treating type 2 diabetes comprising administering semaglutide. Ex. 1001, 35:40-36:53. The application that issued as the ’462 patent was filed on July 21, 2017, as a continuation of an application filed on June 21, 2013, and claims priority from two provisional applications filed on August 30, 2012, and October 1, 2012, and two foreign applications filed on October 1, 2012, and July 1, 2012. *Id.*, 1. For this Petition, Petitioner assumes the challenged claims are entitled to the earliest listed priority date of July 1, 2012.

The ’462 patent has ten claims. Claim 1 is the sole independent claim:

> A method for treating type 2 diabetes, comprising administering semaglutide once weekly in an amount of 1.0 mg to a subject in need thereof.

Id., 35:41-43. Claim 1 uses the open-phrase “comprising,” which means it covers *any* method of using semaglutide at a once-weekly dose of 1.0 mg, including methods wherein other medications are co-administered. Indeed, the specification expressly discloses that the claims cover combination therapy. Ex. 1001, 4:44-61.

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The dependent claims recite administration via parenteral administration or subcutaneous injection, and formulations with certain components. Ex. 1001, 35:45-36:53.

The ’462 patent’s “Example 1: The Glp-1 Peptide Semaglutide Provides Reduced HbA1c and Body Weight,” describes a 12-week study of once-weekly doses of semaglutide compared to placebo and open-label once-daily liraglutide. *Id.* 20:55-23:26. The once-weekly doses of semaglutide included 0.1, 0.2, 0.4, 0.8, and 1.6 mg (but not 1.0 mg), and the liraglutide doses administered once daily were 1.2 and 1.8 mg. *Id.*, 21:6-39. The specification concludes “semaglutide dose-dependently reduced HbA1c and body weight” (*id.*, 23:18-19) and “[t]he 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” (*id.*, 23:19-23).

While not titled an Example, the specification also contains a section titled “Pharmacological Methods,” describing five prophetic assays. *Id.*, 23:26-28:36. For these, the specification recites methods of determining certain pharmacologic properties but provides no results or data. *Id.*

2. PROSECUTION HISTORY

The application leading to the ’462 patent was filed with one independent claim:

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A method for

a) reduction of HbA1c;

b) treatment of type 2 diabetes, hyperglycemia, impaired glucose tolerance, or non-insulin dependent diabetes; or

c) 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;

ii) is administered in 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. 1002, 8.

The Examiner's sole set of rejections applied 35 U.S.C. § 112, § 102, and double patenting grounds to reject the then-pending claims. *Id.*, 309-18. The first § 102 rejection was based on NCT657,[2] a clinical trial disclosing semaglutide, in

[2] During prosecution, the Examiner cited a document from ClinicalTrials.gov, reinforcing the public availability of documents on that website. Ex. 1002, 312.

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view of Lau, a reference disclosing semaglutide's half-life and EC_{50} values. *Id.*, 312. The Examiner also rejected the claims as anticipated by references related to the GLP-1 agonist albiglutide, dulaglutide, and exenatide. *Id.*, 312-15.

The applicants amended claim 1 in response to these rejections to recite claim 1 as issued. *Id.*, 332. Following this amendment, the Examiner withdrew the rejections. *Id.*, 343-44. The notice of allowance stated:

> The '657 clinical trial compared semaglutide and liraglutide in treatment of type 2 diabetic patients. The semaglutide or liraglutide was used as [a]n add-on therapy to type 2 diabetic patients already taking metformin. Efficacy of treatment was further assessed by a reduction in HbA1c levels. Patients in the Arm Labels D and E of the clinical trial were administered 0.8 mg once weekly by subcutaneous injection. However, the reference does not teach or disclose a higher amount of 1 mg semaglutide.

Id., 344-45. The Examiner never applied any prior art reference that disclosed higher doses of semaglutide, including once-weekly 1.2 and 1.6 mg doses and ranges of once-weekly doses bracketing the claimed dose, to the claims. Indeed, other than NCT657, the Examiner never applied any of the other primary references identified in Grounds 1-5 herein.

Moreover, the document was submitted in an IDS (Ex. 1002, 324), demonstrating Patent Owner's acknowledgment that NCT657 is prior art.

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D. Claim Construction (37 C.F.R. §§ 42.100(b), 42.104(b)(3))

No claim term needs construction to resolve the issues presented in the Petition and all terms should be accorded their plain and ordinary meaning as would be understood by a POSA considering the intrinsic evidence. The preamble phrase "[a] method for treating type 2 diabetes" does merit brief discussion though.

Claim terms here are construed pursuant to the same standard as in a civil action. That is, in accordance with their ordinary and customary meaning, as understood by a POSA in view of the specification and prosecution history as of the effective filing date. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1321 (Fed. Cir. 2005) (en banc).

The plain and ordinary meaning of "[a] method for treating type 2 diabetes" is broad. Ex. 1003 ¶¶55-58; Ex. 1005 ¶¶56-60. Nothing in the specification or prosecution history suggests that phrase requires any degree of efficacy, e.g., a particular level of reduction in HbA_{1c}. The specification describes the terms "treatment" and "treating" as

> intended to include the full spectrum of treatments for a given condition from which the patient is suffering, such as administration of the active compound to alleviate the symptoms or complications; to delay the progression of the disease, disorder, or condition; to alleviate or relieve the symptoms and complications; and/or, to cure or eliminate the disease, disorder, or condition as well as to prevent the condition.

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Ex. 1001, 5:20-31. Accordingly, the plain and ordinary meaning of "[a] method for treating type 2 diabetes" would be understood by POSAs to broadly encompass administering semaglutide to alleviate or reduce symptoms and complications associated with type 2 diabetes or otherwise manage the disease. There is no requirement for any particular treatment effect.

E. Treating Diabetes with GLP-1 Agonists Was Well Known

1. DIABETES

Diabetes is a metabolic disorder in which an individual either fails to respond to insulin normally or produces insufficient insulin. Ex. 1003 ¶¶59-60; Ex. 1026. Because insulin regulates blood glucose, individuals with uncontrolled diabetes experience uncontrolled, and sometimes dangerously high, blood glucose levels. Ex. 1003 ¶¶59-60. Uncontrolled high blood glucose levels can impact many organ systems causing significant disease. Patients with type 2 (non-insulin dependent) diabetes have insulin resistance, causing ineffective insulin use, and abnormal insulin secretion. *Id.* ¶¶60-61.

2. GLP-1 AGONISTS WERE WELL KNOWN DIABETES TREATMENTS

While uncontrolled type 2 diabetes can lead to catastrophic outcomes, treatments have been available for decades. *Id.* ¶¶62-68; Ex. 1026. Insulin injections have been used since the 1920s. Ex. 1003 ¶¶62-68. Metformin has long been used

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to lower glucose production, repaglinide to stimulate insulin secretion, and pioglitazone to lower insulin resistance. *Id.* ¶¶65-67.

In the 1980s, researchers learned the body naturally synthesizes a peptide called glucagon-like peptide ("GLP-1"), and its naturally truncated form GLP-1(7-37). Ex. 1003 ¶64; Ex. 1005 ¶78; Ex. 1019; Ex. 1027; Ex. 1036. GLP-1(7-37) was found to stimulate insulin (which lowers blood glucose) and to inhibit glucagon (which raises blood glucose), lowering blood glucose levels via two complementary mechanisms. Ex. 1003 ¶64; Ex. 1005 ¶78. Given this, GLP-1 agonists—peptides that stimulate the GLP-1 receptor—were developed as a new class of medications to treat type 2 diabetes. Ex. 1003 ¶¶69-72; Ex. 1005 ¶¶78-81. The interest in, and concomitant research activities directed toward, GLP-1 agonists led to FDA approval of exenatide in 2005, a second formulation of exenatide in 2012, and liraglutide in 2010. Ex. 1003 ¶¶73-75, 87; Ex. 1005 ¶¶80-88; Exs. 1020-1021; Ex. 1039. While these were well-tolerated and sought-after medications, they had undesirable side effects like nausea and vomiting. Ex. 1003 ¶93; Ex. 1005 ¶81, 87. POSAs understood a longer half-life could lessen these side effects. Ex. 1003 ¶195; Ex. 1032, 4 ("Nausea may best be avoided by a long half-life because a long half-life gives the smallest needed excursions in plasma concentrations"), 323; Ex. 1005 ¶81. POSAs also understood a less-frequently-dosed GLP-1 agonist, compared to exenatide's twice-daily injections and liraglutide's once-daily injections, would be

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desirable and encourage patient compliance. Ex. 1003 ¶¶89, 323; Ex. 1005 ¶81. Thus, POSAs continued improving liraglutide and like analogues, seeking a longer half-life GLP-1 agonist, and naturally arrived at semaglutide, a longer-acting, once-weekly GLP-1 agonist. Ex. 1003 ¶¶80-94; Ex. 1005 ¶¶78-93.

3. POSAs Knew Semaglutide Was Being Used in Clinical Trials

Before the priority date, POSAs were aware of many publications disclosing semaglutide as a once-weekly injectable GLP-1 agonist for treating type 2 diabetes. Ex. 1003 ¶¶81-157; Ex. 1005 ¶¶94-102; Ex. 1011-1016; Ex. 1035. Publicly available patents and patent applications identified semaglutide as a once-weekly treatment for type 2 diabetes and disclosed how to formulate it for therapeutic use. Ex. 1003 ¶¶103-137; Ex. 1005 ¶¶94-102; Exs. 1015, 1025-1040, 64. POSAs further knew semaglutide was studied in both Phase I and II clinical trials. Ex. 1003 ¶¶85, 138-146, 305, 398; Ex. 1005 ¶¶94-102, 121-138; Exs. 1012-1014; Ex. 1035. Specifically, POSAs knew semaglutide was studied in three Phase I studies assessing pharmacokinetics and safety (NCT00813020, NCT00833716, and NCT00851773). Ex. 1003 ¶¶85, 398, 411; Ex. 1005 ¶¶94, 148. POSAs also knew that semaglutide was studied in a Phase II clinical trial ("NCT657") with a once-weekly dose of semaglutide ranging from 0.1-1.6 mg. Ex. 1003 ¶¶138-142; Ex. 1005 ¶¶94-97; Ex. 1013. Relatedly, POSAs would have been aware of a later Phase I trial

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("NCT773") with a once-weekly dose of semaglutide ranging from 0.1-1.2 mg. Ex. 1003 ¶¶143-146; Ex. 1005 ¶¶98-101; Ex. 1014.

The extensive use of semaglutide in prior art trials gave POSAs a wealth of knowledge related to semaglutide's expected efficacy treating type 2 diabetes. Ex. 1003 ¶¶80-94, 396-407; Ex. 1005 ¶¶89-102, 220-239. Indeed, POSAs would have known that to proceed with human trials, regulators would have required a significant amount of data to have been collected and provided to them, including preclinical testing such as receptor binding, and *in vitro* and *in vivo* pharmacodynamic and pharmacokinetic studies, including animal studies. Ex. 1003 ¶¶184, 330, 400; Ex. 1005 ¶¶65-74, 228-238. Moreover, before administration to humans, toxicology and long-term carcinogenicity testing must also have been performed. Ex. 1003 ¶400; Ex. 1005 ¶¶65-74. Thus, even absent published data from semaglutide's preclinical studies, POSAs would have known the preclinical data described above had been generated and thoroughly vetted by the trial sponsors and regulatory bodies. Ex. 1003 ¶¶400, 413; Ex. 1005 ¶¶65-74, 228-238.

Additionally, the disclosure of the dose amounts used in these trials would have been instructive to POSAs. Ex. 1003 ¶¶319-331; Ex. 1005 ¶¶223-238. POSAs would have understood that those doses would have been chosen carefully based on the data already collected. Ex. 1003 ¶¶319-331; Ex. 1005 ¶¶223-238. Indeed, under well-understood principles of clinical trial design, doses ranging from suboptimal to

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maximally effective would have been included in the trials. Ex. 1003 ¶¶256-265, 325, 330; Ex. 1005 ¶¶65-74, 223-238. Even without seeing results from the trial, POSAs would expect all doses administered in the trial to exhibit a degree of efficacy, and POSAs would certainly have expected the higher doses of semaglutide used would be effective. Ex. 1003 ¶¶262, 305; Ex. 1005 ¶¶65-74, 190, 223-238. As Dr. Jusko explains, POSAs would have expected the optimal dose in a Phase II trial to be nearer the higher end of the tested range. Ex. 1005 ¶¶68-74, 227-238. This expectation is bolstered by a POSA's knowledge of liraglutide's dose-response curve. POSAs knew that liraglutide had a smooth dose-response curve and would have expected semaglutide to have a similarly-shaped dose-response curve. Ex. 1003 ¶402; Ex. 1005 ¶¶68-74, 238. This would reinforce to POSAs that semaglutide doses at the higher end of the ranges in Phase I and II trials would be expected to be efficacious.

F. Scope and Content of the Prior Art

In addition to the prior art relied upon for Grounds 1-5, Petitioner relies on a POSA's knowledge, experience, and the available prior art contributing thereto. Ex. 1003 ¶¶26-28, 59-230; Ex. 1005 ¶¶28-33, 61-177; Ex. 1007 ¶¶24-28, 46-146. The expert declarations identify additional prior art explaining and confirming the bases of a POSA's knowledge. Ex. 1003 ¶¶158-230; Ex. 1005 ¶¶61-177; Ex. 1007 ¶¶110-146.

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1. **WO421**

WO421 is a published patent application submitted by researchers at Boehringer Ingelheim, different scientists than those identified on the ’462 patent, that disclosed a method of treating type 2 diabetes with semaglutide. Ex. 1003 ¶¶130-137; Ex. 1005 ¶¶106-111; Ex. 1011, 1, 65:27-31. While the claims generally relate to therapeutic use of a GLP-1 agonist alongside a DPP-4 inhibitor (*id.*, 62:1-65:31), the specification disclosed use of GLP-1 agonists as a separate therapy. *Id.*, 11:14-20. WO421 identified semaglutide as a GLP-1 agonist used to treat diabetes and disclosed it “is administered once weekly by subcutaneous injection (0.1-1.6 mg).” *Id.*, 34:20-22, 44:13.

WO421 was published on November 10, 2011, qualifying it as prior art at least under 35 U.S.C. § 102(a) as of that date. WO421 is also prior art under 35 U.S.C. § 102(e) as of May 5, 2010, the priority date of WO421 or, alternatively, May 5, 2011, the international filing date of WO421.[3]

[3] Should Patent Owner attempt to antedate any asserted prior art, Petitioner reserves the right to present an earlier priority date for it and to challenge any priority claim in the ’462 patent.

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2. LOVSHIN

Lovshin is an article that disclosed treating type 2 diabetes with semaglutide. Ex. 1003 ¶¶98-102; Ex. 1005 ¶¶112-120; Ex. 1012. Lovshin explained "[c]ontinuous, subcutaneous administration of native GLP-1 to patients with type 2 diabetes…lowers fasting and postprandial levels of glucose and HbA_{1c} effectively, and also results in weight loss." Ex. 1012, 1. Lovshin also confirmed that because native GLP-1 has a short half-life in the body, it was necessary to develop degradation-resistant GLP-1 agonists. *Id.*, 2. Lovshin identified "NN9535," disclosing that NN9535 (semaglutide)[4] treatment was being investigated at "0.1-1.6 mg once weekly" doses. *Id.* Additionally, Lovshin disclosed that NN9535 (semaglutide) was a long-acting GLP-1 agonist and one of the "multiple once-weekly GLP-1 therapies…under active clinical investigation in phase I–II studies." *Id.*, 5.

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[4] POSAs knew before the priority date that NN9535 was synonymous with semaglutide. Ex. 1060, 35:18 (equating the two). POSAs also knew the structure of semaglutide. Ex. 1015, 48:4-22 (disclosing semaglutide's structure and method of manufacture); Ex. 1057, 2:16-17 ("Semaglutide, a GLP-1 derivative for once weekly administration which is under development by Novo Nordisk A/S, is disclosed in Example 4 of WO 06/097537….").

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Lovshin was published in May 2009, more than one year before the ’462 patent’s earliest priority date, qualifying it as prior art at least under 35 U.S.C. § 102(b).

3. **NCT657**

NCT657 is a Phase II clinical trial that started in June 2008 and ended in February 2009. Ex. 1013, 15; Ex. 1003 ¶¶138-142; Ex. 1005 ¶¶121-125. The trial included arms A-F in which individuals were given once-weekly subcutaneous injections of semaglutide at 0.1, 0.2, 0.4, and 0.8 mg, and 0.8 and 1.6 mg with titration. Ex. 1013, 15-16.

NCT657 was published on ClinicalTrials.gov no later than February 6, 2009, as reflected in the “Last Updated”[5] field on the Wayback Machine[6] capture, more

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[5] “Last Updated” indicates the most recent date on which changes were made on ClinicalTrials.gov. Ex. 1086. This date on the face of the document indicates publication and demonstrates when the document was available on ClinicalTrials.gov. *Grünenthal GmbH v. Antecip Bioventures II LLC*, PGR2019-00003, 2020 WL 2203740, at *8 (PTAB May 5, 2020).

[6] Prior art obtained via the Wayback Machine® is *prima facie* evidence that the art was publicly accessible at the date and time provided in the time stamp. The burden then shifts to the patentee should they wish to challenge the authenticity, reliability,

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than one year before the ’462 patent’s earliest U.S. priority date, qualifying it as prior art at least under 35 U.S.C. 102(b). *Id.*, 19. NCT657, along with additional prior art versions of the same trial, was a document commonly reviewed by and publicly available to POSAs. Ex. 1003 ¶¶147-157; Ex. 1005 ¶¶121-125, 131-138.

4. **NCT773**

NCT773 is a Phase I clinical trial that started in February 2009 and ended in October 2009. Ex. 1014, 7; Ex. 1003 ¶¶143-146; Ex. 1005 ¶¶126-130. Several versions of NCT773 were published and publicly available on ClinicalTrials.gov. *Id.*, 7-9, 11-13; Ex. 1003 ¶143; Ex. 1005 ¶¶126-130, 131-138. A version last archived on September 11, 2009, and available as of August 26, 2009 (“2009 NCT773”), explained the trial included seven experimental arms where each respective arm included once-weekly subcutaneous injection of NN9535 for eight weeks at the following doses: (A) 0.1 mg, (B) 0.2 mg, (C) 0.4 mg, (D) 0.4 mg for 1 week, 0.8 mg for 7 weeks, (E) 0.8 mg, (F) 0.4 mg for 1 week, 0.8 mg for 1 week,

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or accessibility of such information. *See Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374-75 (Fed. Cir. 2021); MPEP § 2128(II)(E).

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1.6 mg for 6 weeks, and (G) 0.4 mg for 1 week, 0.8 mg for 1 week, followed by variable[7] once-weekly injections for 6 weeks. Ex. 1014, 11-13.

A later version last archived on October 22, 2011, and available as of July 15, 2010, ("NCT773") stated the trial included only five experimental arms, where each arm included once-weekly subcutaneous injections of NN9535 for eight weeks at the following doses: (A) 0.1 mg, (B) 0.2 mg, (C) 0.4 mg, (D) 0.4 mg for 1 week, 0.8 mg for 7 weeks, (F) 0.4 mg for 1 week, 0.8 mg for 1 week, 1.2 mg for 6 weeks. *Id.*, 7-9. Thus, POSAs would understand from these various disclosures that the sponsors removed the 1.6 mg arm from the final study design.

2009 NCT773 and NCT773 were published on ClinicalTrials.gov no later than August 26, 2009, and July 15, 2010, respectively, as reflected in the "Last Updated" field on the Wayback Machine® capture, each being more than one year before the '462 patent's earliest U.S. priority date, so they qualify as prior art at least under 35 U.S.C. § 102(b). Both versions of NCT773 were documents commonly reviewed by and publicly available to POSAs. Ex. 1003 ¶155; Ex. 1005 ¶¶126-130, 131-138.

[7] The variable dose in this later-dropped arm was determined based on safety and tolerability of previous dose steps. Ex. 1014, 11.

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5. **WO537**

WO537 is a published patent application that included claims disclosing semaglutide, injectable formulations of it, and its use to treat type 2 diabetes. Ex. 1015, 74, 76; Ex. 1007 ¶¶95-104. WO537 disclosed the structure of semaglutide in the specification and in claim 28. Ex. 1015, 48:4-8, 73:17-75:10. WO537 also taught that semaglutide could be used in pharmaceutical formulations combined with excipients such as "buffers, tonicity agents, preservatives, and the like." *Id.*, 3:6-8, 6:27-29, 32-35, 25:11-16. WO537 disclosed that semaglutide could be used to treat, prevent, or delay progression of type 2 diabetes. *Id.*, 23:24-24:3.

WO537 was published on September 21, 2006, more than one year before the '462 patent's earliest U.S. priority date, qualifying it as prior art at least under 35 U.S.C. § 102(b).

6. **'424 PUBLICATION**

The '424 publication is a published patent application disclosing "pharmaceutical formulations comprising a peptide and propylene glycol,…methods of preparing such formulations, and…uses of such formulations in the treatment of diseases and conditions for which use of the peptide contained in such formulations is indicated." Ex. 1016, Abstract; Ex. 1007 ¶¶77-85. The '424 publication specifically disclosed its formulations could be used with any peptide, including GLP-1 and derivatives and analogues thereof. Ex. 1016 [0038].

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The ’424 publication was published on January 11, 2007, more than one year before the ’462 patent’s earliest U.S. priority date, so it qualifies as prior art at least under 35 U.S.C. § 102(b).

7. PRIOR ART INFORMING A POSA’S GENERAL KNOWLEDGE.

Besides the prior art discussed above, Drs. Bantle, Jusko, and Dalby identify other prior art describing a POSA’s general knowledge at the priority date. Ex. 1003 ¶¶158-230; Ex. 1005 ¶¶61-177; Ex. 1007 ¶¶110-146. These references bolstered a POSA’s knowledge of the treatment of type 2 diabetes with semaglutide and formulation of it. Ex. 1003 ¶158; Ex. 1005 ¶¶61-177; Ex. 1007 ¶¶110-146.

G. WO421 Anticipated Claims 1-3

1. WO421 ANTICIPATED CLAIM 1

“To anticipate, a prior art reference must place the [invention] in the possession of the public.” *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc*., 471 F.3d 1369, 1375 (Fed. Cir. 2006). WO421 did exactly that for the method of claim 1. Claim 1 recites a method of treating type 2 diabetes comprising administration of a 1.0 mg once-weekly dose of semaglutide. Ex. 1001, 35:42-44. Each limitation of claim 1 was met by the embodiment disclosed in WO421’s specification and its claim 17. This is anticipation.

a. The preamble. WO421 expressly disclosed “a method for treating type 2 diabetes.” Ex. 1003 ¶¶233-234; Ex. 1005 ¶¶180-183. WO421 stated that it “relates to methods for treating and/or preventing metabolic diseases,

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especially type 2 diabetes." Ex. 1011, 2:4-5. The reference is replete with references to treating type 2 diabetes. Claim 17 recited the claimed treatment was "for use in the treatment of type 2 diabetes." *Id.* 62:24-29. WO421 left no doubt that the methods disclosed and claimed therein were methods of treating type 2 diabetes.

WO421's lack of data on the disclosed doses is of no moment. The prior art need not include definitive proof of efficacy to anticipate a claim. *See, e.g., Duke Univ. v. BioMarin Pharm. Inc*., 685 F. App'x 967, 973 (Fed. Cir. 2017) ("proof of efficacy or an actual reduction to practice…is not required for a reference to be an anticipation of…method of treatment claims"); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005) (same); *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc*., 246 F.3d 1368, 1379 (Fed. Cir. 2001) ("[A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to [a POSA]."). All that is required is an enabled disclosure of a method of treating, which WO421 contained.

b. Comprising administering semaglutide. WO421 unambiguously disclosed and claimed administering semaglutide.

WO421's specification disclosed a method of treating type 2 diabetes that comprised "administration of … a GLP-1 receptor agonist…[and] a DPP-4 inhibitor." Ex. 1011, 11:14-20. It further stated "[p]referred examples of GLP-1 receptor agonists…are…semaglutide." *Id.*, 34:20-22. Moreover, WO421 indicated

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its disclosure of combined administration includes administration of the semaglutide and DPP-4 inhibitors "simultaneously, ***separately***, sequentially or chronologically." *Id.*, 37:2-24 (emphasis added). POSAs would understand this to include administration of semaglutide alone, including as a separate course of treatment. Ex. 1003 ¶¶235-247; Ex. 1005 ¶¶184-188. That is made plain in WO421 itself based on the broad definition of combination therapy therein. Ex. 1011, 37:2-24. And it was well within the POSA's knowledge at the priority date. Ex. 1003 ¶¶235-247; Ex. 1005 ¶¶184-188. As described above, the prior art was replete with disclosures demonstrating GLP-1 agonists, such as semaglutide could be administered alone to treat type 2 diabetes. Ex. 1003 ¶¶69-94; Ex. 1005 ¶¶78-102.

In claim 17, WO421 recited the "semaglutide…for use in a method of treating type 2 diabetes…said method comprising administration (e.g., ***separate***, sequential or simultaneous administration) of [semaglutide] and a DPP-4 inhibitor." Ex. 1011, 65:26-31 (emphasis added). Claim 17 thus also specified administration of semaglutide as in claim 1. As in the specification, claim 17 allowed semaglutide to be administered "simultaneously, ***separately***, sequentially or chronologically." *Id.* (emphasis added).

While the specification and claim 17 of WO421 recited administration of semaglutide in combination with a DPP-4 inhibitor, claim 1 of the '462 patent encompassed such a method. Ex. 1003 ¶¶238-241; Ex. 1005 ¶¶184-188. Claim 1 of

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the ’462 patent recites the open-ended transition “comprising” (Ex. 1001, 35:42-44), meaning the claim is open and allows for other components. *Medichem*, 353 F.3d at 933 (holding “comprising” in a claim allows for additional method steps); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (same); *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1214 (Fed. Cir. 2008) (holding “comprising” means method steps are essential but other steps may be added). Claim 1 therefore allows for administration of additional therapeutics along with semaglutide. WO421 is an anticipatory disclosure of administration of semaglutide irrespective of its disclosure of co-administered medications. *See Invitrogen*, 327 F.3d at 1368; *see also In re Qapsule Techs., Inc.*, 759 F. App’x 975, 980 (Fed. Cir. 2019) (where claim language read “a synthetic capsule construct…comprising,” anticipation could not be defeated by showing prior art contained additional material in capsule beyond components described in the claim after “comprising”); Ex. 1011; Ex. 1003 ¶¶238-241; Ex. 1005 ¶¶184-188.

Thus, WO421’s specification and claim 17 expressly disclosed “administration of semaglutide.” Ex. 1003 ¶¶235-255; Ex. 1005 ¶¶184-188; *see also* Ex. 1001, 4:44-61, claim 11 (’462 patent stating invention includes use of semaglutide with other agents, including DPP-IV inhibitors).

c. Once weekly in an amount of 1.0 mg. The method disclosed in WO421’s specification taught the administration of semaglutide could be once-

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weekly in an amount of 1.0 mg. Ex. 1011, 44:14 ("[s]emaglutide is administered once weekly by subcutaneous injection (0.1 to 1.6 mg)"). WO421's disclosure of a narrow range of once-weekly doses anticipated the '462 patent's claim to a 1.0 mg once-weekly dose. *See Bristol-Myers*, 246 F.3d at 1380; *In re Petering*, 301 F.2d 676, 682 (CCPA 1962).

Anticipation is viewed from a POSA's perspective. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003) ("[T]he dispositive question regarding anticipation is whether [POSAs] would reasonably understand or infer from the prior art reference's teaching that every claim element was disclosed in that single reference." (cleaned up)). Here, POSAs would understand the 0.1-1.6 mg dose range in WO421 to be a disclosure of a discrete and limited class of doses a POSA can at once envisage. Where a genus is so limited that POSAs can "at once envisage each member of [a] limited class," a reference describing the genus anticipates every species within the genus. *Petering*, 301 F.2d at 681; *Bristol-Meyers*, 246 F.3d at 1380; *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) (affirming anticipation of claims for treating skin with fatty acid ester because prior art range of 0.01–20% by weight fatty acid ester "encompass[ed] and [did] not significantly deviate" from a claimed range of from about 0.025-5% by weight); *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir.

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2015) (affirming anticipation of claimed range of 0.05-0.5% by weight lubricant by prior art disclosing 0.1%-1% by weight). That is the case here.

The prior art range—0.1 to 1.6 mg—is a disclosure of a discrete number of doses. POSAs would view that range of doses as encompassing *at most* 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, and 1.6 mg—a group of just 16 doses. Ex. 1003 ¶¶256-260; Ex. 1005 ¶¶189-192; Ex. 1009; *see In re Copaxone Consol. Cases*, 906 F.3d 1013, 1026 (Fed. Cir. 2018) ("Although the universe of potential [drug] doses is theoretically unlimited, the universe of dosages in the prior art that had clinical support for being effective and safe consisted of only two doses: 20mg and 40mg. Even if there were multiple injection frequencies not yet tested in the prior art—1x, 2x, 3x a week etc.—these still represent a limited number of discrete permutations."). Prior art clinical trials for semaglutide adjusted doses in increments no less than 0.1 mg/dose. For example, 0.1 mg is the smallest dose administered in NCT657, which administered doses that doubled—e.g., 0.1, 0.2, 0.4, 0.8, and 1.6 mg. Ex. 1003 ¶¶256-260; Ex. 1005 ¶¶189-192; Ex. 1013, 7-8, 15-16. The prior art adjusted semaglutide doses in a minimum of 0.1 mg increments and offered no reason to believe any more precise dose was necessary. Ex. 1003 ¶¶256-260; Ex. 1005 ¶¶189-192; Ex. 1009. The liraglutide prior art disclosed dose adjustments in 0.6 mg increments. A POSA's knowledge that liraglutide was administered in large dosing increments of 0.6, 1.2, and 1.8 mg reinforced that

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POSAs would not expect dose adjustments smaller than 0.1 mg to be meaningful for semaglutide. Ex. 1003 ¶¶256-260; Ex. 1005 ¶¶189-192.

Moreover, there is nothing to suggest that a 1.0 mg dose is critical in any way. The disclosure of a range in the prior art is sufficient to anticipate a claim to a point within that range, where, as here, there is nothing to suggest the point claimed is "critical." *ClearValue, Inc. v. Pearl River Polymers, Inc*., 668 F.3d 1340, 1343-46 (Fed. Cir. 2012). The POSA would understand GLP-1 agonists have efficacy in treating diabetes across a wide range of doses. Ex. 1003 ¶262; Ex. 1005 ¶¶189-192. Clinical trials were already disclosed in the prior art with once-weekly doses ranging from 0.1-1.6 mg. Ex. 1003 ¶¶256-260; Ex. 1005 ¶¶189-192. As Dr. Jusko explains, POSAs would understand from these trials that there was a reasonable basis to believe semaglutide would have a treatment effect across that entire dose range. Ex. 1005 ¶190. And the '462 patent does nothing to demonstrate any criticality. *See* Ex. 1001. The data in the Figures demonstrate semaglutide causes a beneficial treatment effect—a reduction of HbA_{1c} or weight loss—across all tested doses, just as POSAs would have understood from the prior art. The lack of any criticality of the 1.0 mg dose reinforces that POSAs would immediately envisage a once-weekly 1.0 mg dose from the prior art. The decision in *ClearValue, Inc. v. Pearl River Polymers, Inc*., 668 F.3d 1340 (Fed. Cir. 2012), demonstrates that point. There, the challenged claim was directed to "[a] process for clarification of water of raw

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alkalinity less than or equal to 50 ppm." The patentee argued the prior art's disclosure of clarifying water with alkalinity of 150 ppm or less was too broad to anticipate a limitation of 50 ppm. But the patentee never asserted 50 ppm was "critical," or that the claimed method worked differently at other points within the prior art range. The prior art taught POSAs to clarify water with alkalinity of 150 ppm or less. Thus, in *ClearValue* prior art anticipated a claim to clarifying water with alkalinity of 50 ppm or less because 50 ppm was within the prior art range.

It is instructive to contrast *ClearValue* with the decision in *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006). In *Atofina*, the challenged patent claimed a method of synthesizing difluoromethane at a temperature between 330-450°C. The patent explained "only a narrow temperature range enables" the process to operate, and operating the reaction above or below the claimed range created problems as demonstrated by examples in the specification. During prosecution, the claimed temperature range was described as "critical." By contrast, prior art in *Atofina* disclosed a temperature range of 100-500°C. Nonetheless, the Federal Circuit found no anticipation because the broad prior art temperature range did not disclose every species within that genus where evidence established POSAs would have expected the synthesis process to operate differently outside the claimed "critical" range. Thus, the broader prior art range was insufficient to anticipate.

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The facts here are quite different. Patent Owner never suggested the 1.0 mg dose was critical or that other doses would not work to treat diabetes. To the contrary, the '462 patent's original claims recited a 0.7 mg dose, the specification discloses once-weekly doses between at least 0.8 mg to 1.6 mg would be effective, and the Figures establish semaglutide reduces blood glucose and causes weight loss at all administered doses (0.1, 0.2, 0.4, and 0.8 mg, and 0.8 and 1.6 mg with titration). Ex. 1001, 3:41-58, 16:58-17:38; Ex. 1002, 8.

WO421's claim 17 likewise anticipates the 1.0 mg dose limitation. Claim 17 recites administering semaglutide. POSAs would have understood, as guided by the specification, that the range disclosed for administration of semaglutide was 0.1-1.6 mg. For all the same reasons explained above, that range anticipates claim 1. Ex. 1003 ¶¶264-266; Ex. 1005 ¶¶189-192; *Bristol-Meyers*, 246 F.3d at 1380; *Perricone*, 432 F.3d at 1377; *Ineos*, 783 F.3d at 869; *Petering,* 301 F.2d at 681.

To a subject in need thereof. WO421 disclosed administering semaglutide "to a subject in need thereof." The specification specifically delineated that the therapies "may be used in [drug] naïve patients," or "patients with advanced or late-stage type 2 diabetes" or "patients ineligible for metformin" or "patients having…renal disease [or]…disfunction." Ex. 1011, 8:35-10:7. Thus, the specification identified a "subject in need" of treatment with the disclosed method, thereby anticipating claim 1 of the '462 patent. Ex. 1003 ¶¶267-268; Ex. 1005

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¶¶193-195; *see In re Montgomery*, 677 F.3d 1375, 1377-78 (Fed. Cir. 2012) (affirming description of clinical trial design anticipated patent claim, reasoning in part that recruiting "patients at high risk for cardiovascular events such as myocardial infarction and stroke" for a clinical trial of ramipril anticipated the limitation "administering, to a patient diagnosed as in need of [treatment or prevention of stroke or its recurrence]").

Moreover, claim 17 of WO421 disclosed "administration" as part of a "method of treating type 2 diabetes." Ex. 1011, 65:26-32. POSAs would have recognized this "administration" was necessarily to a subject in need of such treatment. Ex. 1003 ¶269; Ex. 1005 ¶¶193-195. Thus, claim 17 anticipated the limitation "to a subject in need thereof." Ex. 1003 ¶269; Ex. 1005 ¶¶193-195; *see Montgomery*, 677 F.3d at 1377-78.

2. WO421 ANTICIPATED CLAIMS 2-3

Claim 2 recites "the semaglutide is administered by parenteral administration" and claim 3 recites that "the solution is administered by subcutaneous injection." Ex. 1001, 35:45-48.

WO421 stated "[s]emaglutide is administered once weekly by subcutaneous injection." Ex. 1003 ¶¶270-286; Ex. 1005 ¶¶196-201; Ex. 1011, 36:23-37:5, 44:13. POSAs also understood the semaglutide in claim 17 would be administered by subcutaneous injection. *Id*. POSAs knew that a subcutaneous injection is a parenteral

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administration and necessarily a solution. Ex. 1003 ¶272; Ex. 1005 ¶200. WO421's specification and claim thus anticipated claims 2-3. Ex. 1003 ¶¶270-286; Ex. 1005 ¶¶196-201.

3. WO421 IS ENABLED

"The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102...differs from the enablement standard under section 112." *Rasmusson*, 413 F.3d at 1325. Enablement for anticipation requires only enablement of an embodiment that falls within the scope of the claim. *Chester v. Miller*, 906 F.2d 1574, 1577 (Fed. Cir. 1990). Enablement by a prior art patent is presumed. *See In re Antor Media Corp.*, 689 F.3d 1282, 1287 (Fed. Cir. 2012); *Impax Lab'ys, Inc. v. Aventis Pharms., Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008). Here, POSAs would have readily understood how to practice the methods recited and claimed in WO421. Ex. 1003 ¶¶130-137, 231-269; Ex. 1005 ¶¶180-195. WO421 explained semaglutide would be given to diabetic patients at a once-weekly dose between 0.1 and 1.6 mg, which included 1.0 mg. Nothing more is required for WO421 to be enabled for purposes of anticipation.

H. Lovshin Anticipated Claims 1-3

1. LOVSHIN ANTICIPATED CLAIM 1

Claim 1 was also anticipated by Lovshin. Lovshin expressly disclosed treating type 2 diabetes using semaglutide. Ex. 1012. Lovshin stated "[c]ontinuous, subcutaneous administration of native GLP-1 to patients with type 2

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diabetes…lowers fasting and postprandial levels of glucose and HbA_{1c} effectively, and also results in weight loss." *Id.,* 1. Lovshin identified "NN9535" which was known to POSAs as semaglutide, as a treatment being investigated at "0.1-1.6 mg once weekly." *Id*., 2 (Table 1). Lovshin further disclosed NN9535 (semaglutide) was a "long-acting GLP-1R agonist" "under active clinical investigation in phase I–II studies." *Id.*, 5.[8]

Accordingly, Lovshin expressly taught a method of treating type 2 diabetes with once-weekly administration of semaglutide to a subject in need thereof. Like WO421, Lovshin also taught semaglutide should be administered in a once-weekly dose of 1.0 mg. Lovshin's disclosure of a 0.1-1.6 mg once-weekly dose disclosed a 1.0 mg dose of semaglutide for the same reasons as did WO421. *See* Section V.G.1.

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[8] Teaching away is not relevant to anticipation. Thus, if Patent Owner were to contend Lovshin's statement that "few data are available on the structure or efficacy of these molecules" has any relevance, it does not. *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.,* 150 F.3d 1354, 1361 (Fed. Cir. 1998) ("whether a reference 'teaches away' from [an] invention is inapplicable to an anticipation analysis" (citation omitted)); *see also Perricone*, 432 F.3d at 1376.

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2. LOVSHIN ANTICIPATED CLAIMS 2-3

Lovshin also taught the once-weekly dose of semaglutide would be administered as a subcutaneous injection as recited in claim 2-3. Ex. 1012, 2 (Table 1). The POSA understood a subcutaneous injection was parenteral and necessarily a solution. Ex. 1003 ¶¶309-315; Ex. 1005 ¶¶214-219. Thus, Lovshin anticipated claims 2-3.

3. LOVSHIN IS ENABLED

Lovshin explained semaglutide would be given to diabetic patients at a once-weekly dose of 0.1-1.6 mg, which included 1.0 mg. Ex. 1012, 2. Nothing more is required.

I. Claims 1-10 Were Obvious

A patent claim is obvious "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103(a). "[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations." *Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737-38 (Fed. Cir. 2013); *see also Genentech, Inc. v. Hospira, Inc.*,

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946 F.3d 1333, 1341 (Fed. Cir. 2020). "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum, or workable ranges by routine experimentation." *Genentech*, 946 F.3d, 1341-42 (citations omitted).

1. POSAs Were Motivated to Pursue the Claimed Method

At the priority date, GLP-1 agonists were well-understood treatments for diabetes. Ex. 1003 ¶¶69-79. Liraglutide and exenatide, among others, were FDA-approved prior art GLP-1 agonists. POSAs, however, understood a need for improvement, including by reducing both the frequency of injection and gastrointestinal side effects, and POSAs further understood how a GLP-1 agonist with a longer half-life would address both issues. Ex. 1003 ¶¶319-328; Ex. 1005 ¶¶81, 224. The desire for less-frequently dosed and more tolerable GLP-1 agonists led to semaglutide, a prior art peptide with a structure known to provide a longer half-life than liraglutide. Ex. 1003 ¶323; Ex. 1005 ¶¶78-102.

WO421, Lovshin, and published clinical trials already taught once-weekly dosing of semaglutide at 0.1-1.6 mg to treat type 2 diabetes, giving POSAs a clear target for a likely efficacious dose, further motivating them to develop the claimed dosing regimen. POSAs would have also understood the doses undergoing expensive clinical trials would have already been subjected to extensive preclinical testing and scientific and regulatory scrutiny. Put another way, POSAs would have

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understood that for the studies to proceed in humans, there must have been data-supported scientific rationale for those doses being both safe and efficacious at the tested ranges. Accordingly, a POSA's sole and routine task was to evaluate the narrow and finite range of efficacious doses (16 options at most) in the prior art and to choose one. Doing so was not inventive.

2. POSAs Would Have Had a Reasonable Expectation of Success

POSAs would have also had a reasonable expectation that a once-weekly 1.0 mg dose of semaglutide would have been successful to treat diabetes. As discussed above, GLP-1 agonists, such as the closely related liraglutide, were known to be efficacious to treat type 2 diabetes. Ex. 1003 ¶¶62-79; Ex. 1005 ¶¶76-88, 223-239. POSAs would also have known that liraglutide, for example, provided a consistent dose-response profile for lower HbA_{1c}, a pattern POSAs would expect semaglutide to follow. Ex. 1003 ¶402; Ex. 1005 ¶¶85-88, 238.

With respect to semaglutide, WO421 taught semaglutide was to be given as a once-weekly subcutaneous injection in a range of 0.1-1.6 mg. Ex. 1003 ¶¶130-137, 256; Ex. 1005 ¶225; Ex. 1011, 44:13. Lovshin taught that same once-weekly dose range. Ex. 1003 ¶¶98-102, 298; Ex. 1005 ¶227; Ex. 1012, 2. NCT657 and NCT773 disclosed weekly dose ranges of 0.1-1.6 mg, and 0.1-1.2 mg, respectively, being tested in human clinical trials. Ex. 1003 ¶¶259, 401; Ex. 1005 ¶¶227-236; Ex. 1013, 15-16; Ex. 1014, 7. These prior art disclosures provided POSAs all they needed to

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expect success with a 1.0 mg once-weekly dose. Ex. 1003 ¶¶408-419; Ex. 1005 ¶¶221-239. POSAs would have been motivated to optimize the dose, a result-effective variable,[9] within the known range. Ex. 1003 ¶¶396-407; Ex. 1005 ¶¶223-239; *see also Mylan Pharms. Inc. v. Yeda Rsch. & Dev. Co.*, IPR2015-00830, Paper 85, 29 (PTAB Dec. 2, 2016) (finding reasonable expectation of success where POSA selected dose in dosing range known to be therapeutically effective).

The prior art clinical trials further bolstered a POSA's expectation of success with a 1.0 mg dose. The POSA would have understood—based on at least fundamental clinical trial design principles—that the upper-end of dose ranges tested in prior art semaglutide clinical trials were likely to be efficacious and successful methods of treating diabetes that best balanced efficacy and side effects. Ex. 1005 ¶¶226-238. As Dr. Jusko explains, and as shown in the figure below, Phase II studies typically investigate a range of doses predicted to be on the dose-response curve where lower doses are earlier on the curve and higher doses are further along on that

[9] A result-effective variable is one in which the variable achieves a result. *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012); *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018) (explaining POSAs are motivated to optimize a parameter that impacts the result). Here, the dose of semaglutide to be administered to patients is a result-effective variable.

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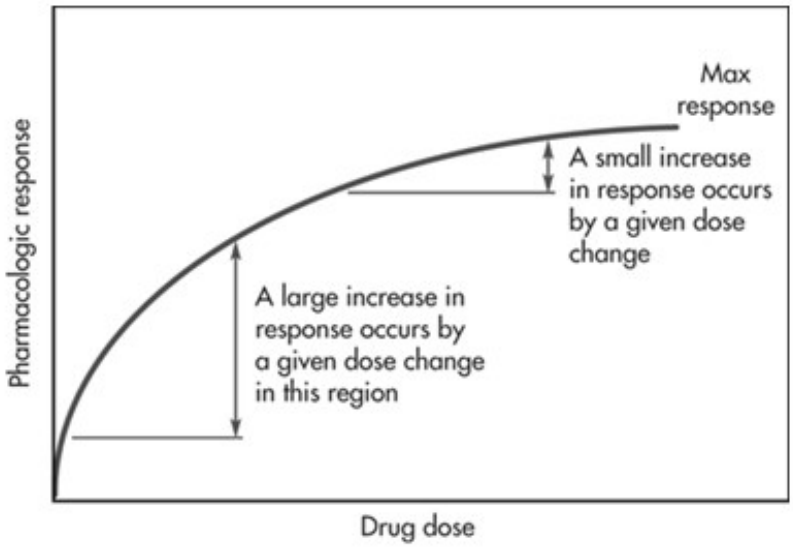
curve and nearer the plateau because they are nearing the maximum pharmacologic effect. Ex. 1045 at 82, Fig. 19-1; Ex. 1005 ¶¶68-74.



Accordingly, POSAs were directed towards the upper end of the prior art range, and therefore motivated to choose a 1.0 mg once-weekly dose. Ex. 1003 ¶¶305, 396-407; Ex. 1005 ¶¶65-74, 85-88, 226-238.

Obviousness requires only a reasonable expectation of success, i.e., no guarantee is required. The multiple disclosures demonstrating use of a finite range of doses in clinical trials would have given POSAs more than a reasonable expectation that a once-weekly 1.0 mg dose of semaglutide would be successful. Ex. 1003 ¶¶398-407; Ex. 1005 ¶¶233-238. POSAs knew that embarking on human clinical trials required a significant amount of preclinical data to have already been collected and analyzed, and the doses chosen for Phase I and II clinical trials in humans would include doses expected to work. Ex. 1003 ¶¶398-400; Ex. 1005 ¶¶65-

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74, 226-238. Otherwise, those trials would not have been ethical to pursue or allowed by regulations governing clinical trials because the interventions would not necessarily have been viewed as safe for use. Ex. 1003 ¶400; Ex. 1005 ¶¶65-74, 226-238.

Notably, the purpose of a Phase II study, like that disclosed in Lovshin and NCT657, would have been to determine the dose-response curve in humans. Ex. 1003 ¶399; Ex. 1005 ¶¶65-74, 227-238. Thus, the doses chosen for the study would include doses expected to be at each end of that dose-response curve. Ex. 1003 ¶¶325, 399; Ex. 1005 ¶¶65-74, 227-238. In particular, POSAs would have understood the doses at the upper end of the dosing range would be expected to treat type 2 diabetes. Ex. 1003 ¶¶325-330; Ex. 1005 ¶¶65-74, 227-238. POSAs would have also considered doses between 0.8 and 1.6 to be at the upper end of the dosing range where the dose-response curve plateaued, and maximum effect was achieved. Ex. 1003 ¶330; Ex. 1005 ¶¶65-74, 227-238.

Moreover, a POSA's expectation of success would have been bolstered by the fact that the ranges of semaglutide doses disclosed as being investigated was narrowed in later clinical trials. Ex. 1003 ¶¶401-18; Ex. 1005 ¶¶235-237. As explained above, NCT657 was the first clinical trial and studied a dose range from 0.1-1.6 mg. Ex. 1003 ¶¶138-142, 401; Ex. 1005 ¶¶235-237. The later NCT773 studied a dose range from 0.1-1.2 mg, thereby homing in on a dose closer to the

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claimed 1.0 mg, and providing an even narrower range of doses to be optimized. Ex. 1003 ¶¶143-146, 402; Ex. 1005 ¶¶94-102, 235-237. This dose range narrowing in the prior art would have further confirmed a POSA's reasonable expectation of success at 1.0 mg. Ex. 1003 ¶¶404-419; Ex. 1005 ¶¶94-102, 235-237.

3. CLAIMS 1-10 WERE OBVIOUS OVER WO421 CONSIDERING THE '424 PUBLICATION

a. Claim 1

As detailed above, POSAs were motivated to practice the claimed method of treating type 2 diabetes with a 1.0 mg once-weekly dose of semaglutide. Ex. 1003 ¶¶319-328; Ex. 1005 ¶¶220-239. That motivation would have led POSAs, based on the disclosure of WO421, to practice the claimed method with a reasonable expectation of success. Ex. 1003 ¶¶329-331; Ex. 1005 ¶¶220-239.

Indeed, as detailed above, WO421 anticipated claim 1. Ex. 1003 ¶¶231-269; Ex. 1005 ¶¶178-195. To the extent any differences between WO421 and claim 1 are found, the only possible one is claim 1's recitation of the 1.0 mg dose versus the narrow range of 0.1-1.6 mg disclosed in WO421. But selecting a 1.0 mg dose is merely a routine, non-patentable optimization of a result-effective variable disclosed within that narrow and finite prior art range. Ex. 1003 ¶¶323-328; Ex. 1005 ¶¶227-238; *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367-68 (Fed. Cir. 2007); *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1371 (Fed. Cir. 2006); *see also In re Luck*, 476 F.2d 650, 652-53 (CCPA 1973) (stating use of routine testing

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to identify optimum amounts lies within the ambit of a POSA). POSAs would have readily identified a 1.0 mg dose, particularly in view of the knowledge of GLP-1 agonists, particular teachings on semaglutide, and a POSA's understanding of semaglutide clinicals already in the art. Ex. 1003 ¶¶324-326; Ex. 1005 ¶¶85-88, 238.

Moreover, no trial-and-error procedures were necessary like they might have been in the absence of any guidance as to the dosage. *See Pfizer*, 480 F. 3d at 1367-68; *see also In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) (determining where in a disclosed set of percentage ranges the optimum combination of percentages lies is *prima facie* obvious); *In re Kulling*, 897 F.2d 1147, 1149 (Fed. Cir. 1990) (finding amount of chemical to be used was a matter of routine optimization known in the prior art and therefore obvious); *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) ("[I]t is not inventive to discover the optimum or workable ranges by routine experimentation." (citation omitted)); *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980) (same); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (same).

POSAs would have only needed to select the dose from the narrow and finite 0.1-1.2 mg or 1.6 mg range of once-weekly doses of semaglutide. Ex. 1003 ¶¶256-266, 325-326; Ex. 1005 ¶¶227-238. That would have been straightforward because POSAs understood how to evaluate the efficacy of a diabetes treatment, knew which side effects were implicated by GLP-1 agonists, and would have needed only to evaluate the effect of the treatment on patients using known parameters. The

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experimentation, if any, needed to arrive at the claimed "invention" was nothing more than routine application of well-known dose selection principles. Moreover, obviousness cannot be avoided simply by showing some degree of unpredictability in the art so long as there was a reasonable probability of success. *See In re Corkill*, 771 F.2d 1496, 1500 (Fed. Cir. 1985) (holding need for testing does not overcome prior art teaching that it will work); *see also Brown & Williamson Tobacco Corp. v. Philip Morris Inc.,* 229 F.3d 1120, 1125 (Fed. Cir. 2000) ("Obviousness does not require absolute predictability of success all that is required is a reasonable expectation of success." (cleaned up)); *Merck & Co. v. Biocraft Lab'ys, Inc.,* 874 F.2d 804, 809 (Fed. Cir. 1989) (same). Here, POSAs would have had every motivation to pursue a once-weekly 1.0 mg dose of semaglutide and would have expected it to work.

WO421 disclosed administering semaglutide in a range that encompassed the claimed dose. Ex. 1003 ¶¶256-260, 323; Ex. 1005 ¶¶224-226; Ex. 1011. While WO421 also encompassed combination therapy, it importantly disclosed and specifically contemplated administration of semaglutide alone. Further, claim 1 uses the open-ended transition "comprising," meaning administration of other agents with semaglutide is still within the claim's scope. *See Medichem,* 353 F.3d at 933.

Additionally, as detailed above, POSAs would have drawn certain conclusions about the dose range disclosed in WO421 from the clinical trials, and

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would have further expected doses at the upper end of that range to be most efficacious. Ex. 1003 ¶¶329-330; Ex. 1005 ¶¶227-238.

Finally, POSAs had to optimize only a single variable–dose size–from only 16 reasonably possible prior art options and with significant guidance pointing directly to 1.0 mg. Thus, the 1.0 mg once-weekly dose was, at least, obvious to try. Ex. 1003 ¶327; Ex. 1005 ¶233. The *Copaxone* decision is instructive. There, the Federal Circuit found claims to a less frequent dose of an injectable multiple sclerosis therapy obvious where there were "two critical variables, dose size and injection frequency, and the prior art provided clear direction as to choices likely to be successful in reducing adverse side effects and increasing patient adherence." 906 F.3d at 1025. Here, there was only one variable to optimize and clear guidance in the art, which makes the claims obvious.

b. **Claims 2-3**

Claims 2-3 are obvious for all the same reasons described above. *Supra* Section V.G.2 & V.H.2; Ex. 1003 ¶¶332-348; Ex. 1005 ¶¶240-245. Claims 2-3 were obvious for all the same reasons they are anticipated by WO421. Ex. 1003 ¶¶231-287; Ex. 1005 ¶¶196-201.

c. **Claims 4-10**

Claims 4-10 add limitations related to formulations of semaglutide. The additional limitations of claims 4-10 were obvious over WO421 considering the

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’424 publication. Ex. 1003 ¶¶317-352; Ex. 1005 ¶246. This is because POSAs were motivated to formulate semaglutide in each of the straightforward manners claims 4-10 recite, and POSAs would have had a reasonable expectation of success in doing so for each one. Ex. 1007 ¶¶147-224. The ’424 publication specifically described its disclosed formulations as suitable for any peptide, including GLP-1 and analogues thereof. Ex. 1016, [0038]. POSAs would look to the ’424 publication for formulations in which to administer semaglutide. Ex. 1007 ¶¶147-224.

Claim 4. Claim 4 recites administering semaglutide as “an isotonic aqueous solution comprising phosphate buffer at a pH in the range of 7.0-9.0.” The ’424 publication disclosed formulating peptides in isotonic aqueous solutions with a phosphate buffer as a preferred formulation and with a pH between 7.0 and 9.0. Ex. 1007 ¶¶191-196; Ex. 1016 [0003], [0180]-[0251]. For example, Examples 2-5 disclosed formulations with a phosphate buffer, a pH between 7.4 and 8.15, and isotonicity agents. Ex. 1016 [0180]-[0251]; *see also* Ex. 1007 ¶¶147-196. POSAs further understood a human’s physiological pH is around 7.4, making it desirable to have administered subcutaneous injections near that pH to avoid adverse reactions. Ex. 1007 ¶¶194-195.

Claim 8. Claim 8 recites administering semaglutide in a formulation wherein “the phosphate buffer is a sodium dihydrogen phosphate buffer.” The ’424 publication disclosed using sodium dihydrogen phosphate buffer in peptide

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formulations and identified it as "preferred." Ex. 1007 ¶211; Ex. 1016 [0180]-[0251].

Claim 9. Claim 9 recites administering semaglutide as a "subcutaneous injection in the form of an isotonic aqueous solution comprising at [sic] a sodium dihydrogen phosphate buffer at a pH in the range of 7.0-9.0, and wherein the solution further comprises propylene glycol and phenol." This claim is obvious for the same reason as claim 4. Ex. 1007 ¶¶191-196, 213-219. The '424 publication also taught propylene glycol and phenol would have stabilized the peptide formulation, and they were both preferred excipients, making it obvious to use these excipients in the formulation. Ex. 1007 ¶218; Ex. 1016 [0180]-[0251].

Claims 6 and 10. These claims recite administering semaglutide at a pH of 7.4. The '424 publication disclosed that formulations with a pH between 7.0 and 9.0, including specific formulations at pH 7.4, would minimize tissue damage and injection pain. Ex. 1007 ¶¶203, 222; Ex. 1016, [0180]-[0251]. POSAs understood a human's physiological pH is around 7.4, making it desirable to have administered subcutaneous injections near that pH to avoid adverse reactions. Ex. 1007 ¶¶173, 194, 201, 216, 220.

Claims 5 and 7. These claims recite administering semaglutide in a formulation that "comprises propylene glycol and phenol." The '424 publication also taught propylene glycol and phenol would have stabilized the peptide

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formulation and they were both preferred excipients. Ex. 1007 ¶¶199, 207; Ex. 1016 [0180]-[0251].

4. CLAIMS 1-10 WERE OBVIOUS OVER WO537 CONSIDERING LOVSHIN

a. Claim 1

As detailed above, POSAs would have been motivated to practice, and had a reasonable expectation of success in practicing, the claimed method of treating type 2 diabetes with a 1.0 mg once-weekly dose of semaglutide. *Supra* V.I.1-2.; Ex. 1003 ¶¶354-370; Ex. 1005 ¶¶247-267. That motivation would have led POSAs to combine the teachings of WO537 and Lovshin, making the '462 patent's claims obvious. Ex. 1003 ¶¶354-82; Ex. 1005 ¶¶247-267.

WO537 was a published patent application disclosing once-weekly administration of semaglutide to treat type 2 diabetes. Ex. 1003 ¶¶355-357; Ex. 1005 ¶¶116, 253; Ex. 1015. WO537 further described the tests the POSA should run to determine whether a GLP-1 agonist was suitable for once-weekly dosing. Ex. 1015, 60:24-61:29; Ex. 1003 ¶358. From WO537, POSAs would have concluded semaglutide was ready for dose optimization. Ex. 1003 ¶¶360-366; Ex. 1005 ¶¶252-255; Ex. 1015.

POSAs would have looked to Lovshin to determine that dose. Lovshin taught POSAs a narrow range of once-weekly doses of 0.1-1.6 mg of semaglutide were already being tested in clinical trials. Ex. 1003 ¶360; Ex. 1005 ¶¶252-255; Ex. 1012,

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2 (Table 1). As detailed above, that range already being used in clinical trials was more than enough to provide POSAs a reasonable expectation of success. *Supra* V.I.1-2; Ex. 1003 ¶¶367-369; Ex. 1005 ¶¶254-267. POSAs also knew the upper portion of the range was likely an effective dose, particularly given a POSA's knowledge of liraglutide's smooth dose-response curve. Ex. 1003 ¶369; Ex. 1005 ¶¶85-88, 254-267; *see also Valeant Pharms. Int'l, Inc. v. Mylan Pharms. Inc.*, 955 F.3d 25, 32 (Fed. Cir. 2020) (holding POSAs can expect similar compounds to have similar properties). Thus, POSAs would have looked to optimize the dose, a result-effective variable, including the claimed dose. Ex. 1003 ¶¶360-366, 370; Ex. 1005 ¶¶252-267. POSAs would have expected semaglutide to demonstrate a smooth sigmoidal dose-response curve, as was the case for liraglutide. This would direct the POSA to the higher end of dosing ranges used in Phase I and II studies and give the POSA a reasonable belief that doses at that higher end would be effective. Ex. 1003 ¶369; Ex. 1005 ¶¶68-74, 85-88, 254-267. While a dose need not be the "best" to be obvious, POSAs would have known that the optimal dose is often the smallest dose providing the near maximal treatment effect (i.e., the lowest dose near or on the plateau) because higher doses usually result in higher adverse event rates, which here would be expected near the upper end of the tested ranges.

In any event, as with WO421, the prior art left only one variable to optimize in a narrow and finite prior art range, meaning the claims here were at least obvious

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to try. *Copaxone*, 906 F.3d at 1025; *Pfizer*, 480 F.3d at 1365-66. That is particularly true given that the dosing options for POSAs to traverse were small and finite and the prior art had already winnowed down the doses to be tested to just a few.

POSAs were motivated with a reasonable expectation of success based on WO537 considering Lovshin to treat type 2 diabetes with 1.0 mg of semaglutide dosed once weekly, rendering claim 1 obvious. Ex. 1003 ¶¶354-370; Ex. 1005 ¶¶ 247-267.

b. **Claims 2-3**

Claim 2 recites "semaglutide is administered by parenteral administration" and claim 3 recites "the solution is administered by subcutaneous injection." WO537 disclosed "[p]arenteral administration [of semaglutide] may be performed by subcutaneous…injection by means of a syringe…." Ex. 1015, 35:15-16; Ex. 1003 ¶¶371-378; Ex. 1005 ¶¶268-273. POSAs also understood subcutaneous injections were necessarily solutions. Ex. 1003 ¶376; Ex. 1005 ¶272. Thus claims 2 and 3 were obvious.

a. **Claims 4-10**

Claims 4-10 each add limitations related to a pharmaceutical formulation of semaglutide. Each of the additional limitations of claims 4-10 were obvious over WO537 considering Lovshin at least because POSAs were motivated to administer semaglutide in the straightforward formulations claimed, and they had a reasonable

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expectation of success in doing so. Ex. 1003 ¶¶354-370, 380; Ex. 1005 ¶274; Ex. 1007 ¶¶225-287.

Claim 4. Claim 4 recites administering semaglutide in a formulation with an isotonic aqueous solution comprising phosphate buffer at a pH in the range of 7.0-9.0. WO537 taught formulating isotonic aqueous peptide solutions using a phosphate buffer, isotonicity agents, and with a pH in the claimed range. Ex. 1007 ¶¶254-259; Ex. 1015, 12:31 & 26:4-8.

Claim 8. POSAs were motivated to administer semaglutide in a formulation wherein "the phosphate buffer is a sodium dihydrogen phosphate buffer" and would have had a reasonable expectation in doing so. WO537 disclosed the use of a sodium dihydrogen phosphate buffer as an "exemplary" buffer. Ex. 1007 ¶¶272-275; Ex. 1015, 26:6.

Claim 9. POSAs were motivated to administer semaglutide as a "subcutaneous injection in the form of an isotonic aqueous solution comprising at a sodium dihydrogen phosphate buffer at a pH in the range of 7.0-9.0, and wherein the solution further comprises propylene glycol and phenol" and would have had a reasonable expectation in doing so. Ex. 1007 ¶¶225-253, 276-282. WO537 disclosed formulating GLP-1 agonists in an isotonic aqueous solution with a sodium dihydrogen phosphate buffer as an "exemplary" buffer and with a pH between 7.0

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and 9.0. Ex. 1007 ¶¶279-281; Ex. 1014. WO537 also taught that propylene glycol and phenol stabilized the formulation. Ex. 1007 ¶281; Ex. 1014.

Claims 6 and 10. POSAs were motivated to administer semaglutide as a formulation wherein the pH was 7.4 and would have had a reasonable expectation in doing so. Ex. 1007 ¶¶225-253. WO537 taught formulations with a pH between 7.0 and 9.0. Ex. 1007 ¶¶264-267, 283-86; Ex. 1015. POSAs also knew the physiological pH was around 7.4. Ex. 1007 ¶¶257, 264-67, 279, 283-86.

Claims 5 and 7. POSAs were motivated to administer semaglutide as a formulation that "comprises propylene glycol and phenol" and would have had a reasonable expectation in doing so. Ex. 1007 ¶¶225-53. WO537 taught that propylene glycol and phenol would stabilize the formulation. Ex. 1007 ¶¶262, 270; Ex. 1014.

5. CLAIMS 1-10 WERE OBVIOUS OVER NCT657, NCT773, AND THE '424 PUBLICATION.

a. Claim 1

As detailed above, POSAs were motivated and had a reasonable expectation of success in practicing the claimed method with a once-weekly 1.0 mg dose of semaglutide. Ex. 1003 ¶¶396-419; Ex. 1005 ¶¶275-294. That motivation would have led POSAs to combine the teachings of the NCT657 and NCT773 disclosures, in view of the '424 publication, making the '462 patent's claims obvious. Ex. 1003 ¶¶383-435; Ex. 1005 ¶¶275-294.

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As summarized below, NCT657 and NCT773 both disclosed semaglutide as a once-weekly treatment for type 2 diabetes in clinical trials where doses spanned between 0.1-1.6 mg in NCT657 and 0.1-1.2 mg in the later NCT773 trial. Ex. 1003 ¶¶140, 145, 398; Ex. 1005 ¶¶277-293; Ex. 1013, 15-16; Ex. 1014, 7. NCT657, which ended in February 2009, included arms A-F with once-weekly doses of semaglutide at 0.1, 0.2, 0.4, 0.8 mg, and 0.8 and 1.6 mg with titration. Ex. 1003 ¶401; Ex. 1005 ¶¶121-125, 280-293; Ex. 1013, 15-16. NCT773,[10] which ran from February 2009 to October 2009, included arms A-E with once-weekly subcutaneous injections of semaglutide for eight weeks at doses of: 0.1, 0.2, and 0.4 mg, 0.4 mg for 1 week and 0.8 mg for 7 weeks, and 0.4 mg for 1 week, 0.8 mg for 1 week and 1.2 mg for 6 weeks. Ex. 1003 ¶401; Ex. 1005 ¶¶126-130, 280-293; Ex. 1014, 7.

[10] An earlier version of NCT773 disclosed the following two dosing regimens not included in the final trial: 0.4 mg for 1 week, 0.8 mg for 1 week, and 1.6 mg for 6 weeks, and 0.4 mg for 1 week, 0.8 mg for 1 week, followed by variably dosed injections for 6 weeks. Ex. 1014, 11.

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	NCT657 (Ex. 1013)	NCT773 (Ex. 1014)
	Phase II	**Phase I**
Arm	**6/2008 - 2/2009**	**2/2009 - 10/2009**
A	0.1mg	0.1mg
B	0.2mg	0.2mg
C	0.4mg	0.4mg
D	0.8mg	0.4mg (1 week) 0.8mg (7 weeks)
E	0.8mg (with titration)	0.4mg (1 week) 0.8mg (1 week) 1.2mg (6 weeks)
F	1.6mg (with titration)	~~0.4mg (1 week) 0.8mg (1 week) 1.6mg (6 weeks)~~
G		~~0.4mg (1 week) 0.8mg (1 week) Variable mg (6 weeks)~~

As explained above, POSAs were aware of the required preclinical studies before these clinical trials could proceed in humans. *Supra* V.I.1-2; Ex. 1003 ¶400; Ex. 1005 ¶¶65-74, 280-293; Ex. 1013, 15-17; Ex. 1014, 7-9. POSAs would have also understood the higher doses, i.e., 0.8 and 1.6 mg doses in NCT657, and 0.8 and 1.2 mg doses in NCT772 would reasonably be expected to be on or near the plateau of a smooth dose-response curve based on the wealth of knowledge POSAs had concerning clinical trial design and their knowledge of the shape of the liraglutide dosing curve. *Supra* V.I.1-2; Ex. 1003 ¶¶402-406; Ex. 1005 ¶¶65-74, 85-88, 280-293. POSAs knew that liraglutide has a smooth dose-response curve, and would have expected semaglutide to have a similarly smooth dose-response curve, allowing

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them to expect that the higher doses in the Phase I and II trials would reasonably be likely to be efficacious. Ex. 1005 ¶¶68-74, 85-88, 280-293; *see also Valeant*, 955 F.3d at 32. While a dose need not be the "best" to be obvious, POSAs would have known that the optimal dose is often the smallest dose providing the near maximal treatment effect (i.e., the lowest dose near or on the plateau) because higher doses usually result in higher adverse event rates, which here would be expected near the upper end of the tested ranges. Ex. 1005 ¶¶68-74, 281-293.

POSAs would have also understood that the NCT773 trial occurred *after* the NCT657 trial, and the doses given in NCT773 were updated to *exclude* the 1.6 mg dose, and instead lowered the maximum dose to 1.2 mg. Ex. 1003 ¶¶401-402; Ex. 1005 ¶¶288-293; Ex. 1013, 15-17; Ex. 1014, 7-9. This data point would have provided POSAs additional reason to believe a 1.0 mg once-weekly dose would be efficacious. Ex. 1003 ¶¶404-405; Ex. 1005 ¶¶288-293; Ex. 1013, 16; Ex. 1014, 7. The 1.0 mg once-weekly dose is directly between 0.8 mg and 1.2 mg, the highest doses given in the follow-on NCT773 trial, providing POSAs with both motivation and a reasonable expectation of success. Ex. 1003 ¶¶404-406; Ex. 1005 ¶¶288-293.

In any event, as with the previous grounds, with only one variable to optimize in a narrow prior art range, the claims here were at least obvious to try. *Copaxone*, 906 F.3d at 1025.

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b. **Claims 2-3**

Claims 2-3 were obvious over NCT657 and NCT773 in view of the ’424 publication for the reasons already described. Ex. 1003 ¶¶420-431; Ex. 1005 ¶¶295-300. POSAs understood semaglutide was administered via subcutaneous injection, which is parenteral and necessarily a solution. Ex. 1003 ¶424; Ex. 1005 ¶299.

c. **Claims 4-10**

Claims 4-10 add only limitations related to the formulation, and were obvious over NCT657 and NCT773 in view of the ’424 publication for the same reasons that claims 4-10 were obvious over WO421 considering the ’424 publication. *Supra* Section V.I.3.c; Ex. 1005 ¶301; Ex. 1007 ¶¶147-224; Ex. 1016.

J. Secondary Considerations Fail to Overcome *Prima Facie* Obviousness

To overcome the wealth of evidence of obviousness, Patent Owner may attempt to rely on secondary considerations. While any would be insufficient, Petitioner nevertheless preliminarily addresses some of them, and reserves its right to fully respond in a reply to the extent Patent Owner raises any.

No unexpected results. Neither the ’462 patent nor its prosecution history disclose any unexpected results. This is because extensive prior art demonstrates nothing about the alleged invention was unexpected. Ex. 1003 ¶437; Ex. 1005 ¶303; Ex. 1007 ¶¶288-289.

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No industry skepticism or long-felt need. The prior art did not express any long-felt need or skepticism. Ex. 1003 ¶¶438-39; Ex. 1005 ¶¶304-305; Ex. 1007 ¶¶290-292. To the contrary, prior art encouraged using semaglutide in a 1.0 mg once-weekly dose.

VI. 35 U.S.C. § 325(d) PROVIDES NO BASIS TO DENY INSTITUTION

This Petition should be granted institution because it presents new art and arguments. Under § 325(d), the Board applies a two-part framework: "(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, 2020 WL 740292, at *3 (PTAB Feb. 13, 2020). The Board should consider *Becton Dickinson* factors (a), (b), and (d), as to the first question, and (c), (e), and (f), as to the second. *Id.* at *4.

Advanced Bionics Part One: This Petition presents both new art and arguments. The Examiner's single rejection—considering claims differing significantly from those that ultimately issued—never considered, let alone applied,

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WO421, WO537, the ’424 publication, NCT773 or Lovshin.[11] Ex. 1002, 308-18. And with respect to NCT657—the only primary reference the Examiner considered—the Examiner materially misapprehended it.

WO421 and Lovshin both disclosed ranges of once-weekly doses of 0.1-1.6 mg that encompass the 1.0 mg dose now claimed. Ex. 1011; Ex. 1012. NCT773 disclosed a clinical trial using once-weekly doses of semaglutide with a maximum dose of 1.2 mg. Ex. 1014. WO537 disclosed details regarding semaglutide and specified methods of using it more broadly than NCT657. Ex. 1015. And the ’424 publication disclosed formulation components not detailed in NCT657. *Compare* Ex. 1016 *with* Ex. 1013.

The Examiner’s single rejection of the claims concerning semaglutide focused on anticipation by NCT657[12] in view of post-priority date pharmacokinetic

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[11] While WO421 and WO537 are listed on an IDS in the prosecution history, neither was ever substantively discussed by the Examiner. Ex. 1002, 308-18, 323. The ’424 publication was never identified during prosecution. A related issued patent was listed on an IDS, but it was never discussed. And neither Lovshin nor NCT773 were cited or discussed during prosecution.

[12] The Examiner’s other anticipation rejection related to other GLP-1 peptides because the originally-filed claims covered other GLP-1 peptides. Ex. 1002, 8-9.

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parameters. Ex. 1002, 312. The Examiner never considered WO421 or Lovshin, let alone analyzed their disclosed range of doses as related to anticipation. Ex. 1002, 308-18. And obviousness was never addressed. The Examiner never substantively considered any of Petitioner's lead references. A rigorous examination it was not.

Advanced Bionics Part Two. To the extent the Board considers any condition of part one of the framework met, the Examiner erred in a manner material to the patentability of the challenged claims.

Failure to substantially address the issued claims. The Examiner's sole rejection addressed claims reciting "an about 0.7 mg weekly dose" that is "equivalent to semaglutide." The Examiner considered the claims broad enough to cover other GLP-1 peptides and to be anticipated by a 0.8 mg weekly dose. Ex. 1002, 312-15. The claims considered then were substantially different than the issued claims. Ex. 1002, 8-9, 332-33. However, the Examiner failed to issue a single office action on the issued claims. Ex. 1002, 332-33, 338-47. Given the myriad prior art describing semaglutide and the consistent range of doses being tested, that failure alone was material.

Failure to address any obviousness arguments. The Examiner's sole rejection was based on anticipation. Ex. 1002, 312-15. As detailed at length herein, the issued claims were obvious, yet the Examiner never addressed that issue. *Id*., 308-18. Given the prior art and arguments described herein, that failure was also material.

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Failure to substantively address WO421, the '424 publication, WO537, Lovshin or NCT773. The references in Grounds 1-5 in this Petition disclose prior art dose ranges (*see* WO421, Lovshin, and NCT773) never considered by the Examiner. As to WO421 and Lovshin, the claimed dose here falls within the range disclosed in those references, rendering the claims anticipated and obvious. Ex. 1003 ¶¶298-306; Ex. 1005 ¶¶178-199, 220-242. This differs from NCT657 which disclosed specific doses within that range, specifically 0.1, 0.2, 0.4, 0.8 and 1.6 mg doses. Ex. 1087. The Examiner never applied the 1.6 mg dose of semaglutide described in NCT657 to the amended claims or otherwise explained how the amended claims were patentable over disclosed dose ranges from 0.1-1.6 mg. The Examiner's failure to substantively address these multitude of dosing disclosures was material. NCT773 also disclosed a maximum dose of 1.2 mg of semaglutide dosed once-weekly. Ex. 1014, 7. The Examiner's failure to substantially address NCT773 was material. *See Adobe Inc. v. RAH Color Techs., LLC*, IPR2019-00646, 2019 WL 8106160, at *8 (PTAB Sept. 4, 2019) ("The fact that none of these references was the basis of rejection weighs strongly against exercising our discretion to deny institution....").

Moreover, WO537 disclosed once-weekly use of semaglutide to treat diabetes and formulation components of that treatment. Ex. 1015, 2:26-33, 25:11-29:11, 47:4-22 (semaglutide); Ex. 1003 ¶¶116-129; Ex. 1005 ¶¶116-120. WO537 thus

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demonstrates semaglutide was ready for use in patients, and it was material error for the Examiner not to substantially address WO537.

Finally, as to the dependent limitations, the ’424 publication provided all that was needed for POSAs to make the claimed formulation (Ex. 1016; Ex. 1007 ¶¶191-223), and thus it was material error for the Examiner to fail to substantially consider it as to claims 4-10.

Errors indicating the Examiner misunderstood NCT657. While the Examiner considered NCT657 in the sole Office Action and the Notice of Allowance (“NOA”), those documents contain clear errors indicating the Examiner misunderstood NCT657. In both documents, the Examiner stated “[t]he semaglutide or liraglutide was used as an add-therapy to type 2 diabetic patients already taking metformin.” Ex. 1002, 312, 344. While prior treatment with metformin was one inclusion criteria, patients whose diabetes were controlled with diet and exercise alone were also part of the trial, and NCT657 did not indicate that metformin was continued during the trial for those taking it previously. Ex. 1013, 15-16; Ex. 1003 ¶140. While the Examiner’s view on the impact of metformin on patentability is unclear, it is clear the Examiner misunderstood the central reference in the file history, again indicating material error in the ’462 patent’s grant.

Moreover, in the NOA, the Examiner stated patients were administered once-weekly semaglutide 0.8 mg, but “the reference does not teach or disclose a higher

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amount of 1 mg semaglutide." Ex. 1002, 345. The Examiner failed to recognize experimental arm F in NCT657 administered patients 1.6 mg semaglutide once weekly. *Compare* Ex. 1002, 344-45 *with* Ex. 1013, 16. It was therefore wrong for the Examiner to conclude NCT657 did not disclose administration of any dose of semaglutide higher than 0.8 mg. *Compare* Ex. 1002, 344-45, *with* Ex. 1013, 15-16. The Examiner's obvious error in failing to consider the full scope of the reference, e.g., failing to recognize the administration of a dose higher than the claimed dose at the time, was material to patentability because the Examiner issued the patent on the understanding "a" higher amount was not disclosed. *See, e.g.*, *ZTE (USA) Inc. v. Bell N. Rsch., LLC*, IPR2019-01365, 2020 WL 698725, at *4 (PTAB Feb. 11, 2020) ("We do not require the Petitioner to speculate from a silent record as to why the Examiner allowed the claims over [the prior art]. Rather, we are persuaded by Petitioner's evidence that Examiner overlooked the disclosure in [the prior art] of the limitations that the Examiner stated were missing from the prior art.").

Furthermore, even if NCT657 included metformin as a co-administrated therapy, the open-ended claims in the '462 patent allow for such therapies. The Examiner's conclusion that NCT657 was avoided simply because that prior art trial may have included co-administered metformin was plainly erroneous.

Any of these errors alone would have been material to patentability. However, when taken together, they demonstrate beyond a doubt that the Examiner made significant material errors during prosecution.

VII. 35 U.S.C. § 314(a) PROVIDES NO BASIS TO DENY INSTITUTION

The Board should likewise not exercise its discretion to deny institution under 35 U.S.C. § 314(a). Under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020), the Board considers several factors to determine whether to institute where there is parallel district court litigation. None of these factors support a discretionary denial of institution here.

Under the Director's *Interim Procedure For Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* ("Guidance"), compelling, meritorious challenges will be allowed to proceed even where district court litigation is proceeding in parallel. This Petition presents multiple grounds not considered during prosecution that render the asserted claims unpatentable. This Petition provides new evidence demonstrating the challenged claims never should have issued. This weighs in favor of institution.

Additionally, trial is not set in the Delaware litigation until September 30, 2024 (Ex. 1082), likely after a final written decision would be due. And because the district court trial will be a bench trial, a decision would not issue for at least several more months. *Id*. at 34. Petitioner's trial is likely to be even later. Petitioner will be

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remanded to the Northern District of West Virginia following the conclusion of Delaware MDL proceedings. Ex. 1083. No trial has been set in West Virginia. Thus, a final written decision should issue before a decision is expected to be issued by any district court. In addition, Petitioner stipulates that if the Board institutes, Petitioner will not pursue in the district court any instituted grounds against the originally-issued claims unless a change in law otherwise permits. This further weighs in favor of institution. *See Sand Revolution II, LLC v. Cont'l Intermodal Grp.*, IPR2019-01393, Paper 24, 12 (PTAB June 16, 2020).

VIII. CONCLUSION

Petitioner respectfully requests that the Board institute trial and find all claims of the '462 patent unpatentable.

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Respectfully submitted,
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Dated: March 16, 2023

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

This Petition complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1) because this Petition contains 13,899 words, as determined by the word-count function of Microsoft Word, excluding the parts of the Petition exempted by Rule (i.e., a table of contents, a table of authorities, mandatory notices under 37 C.F.R. § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing).

Dated: March 16, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: Petition for *Inter Partes* Review of U.S. Patent No. 10,335,462 including Exhibits 1001-1087 and Petitioner's power of attorney, by Federal Express Next Business Day Delivery on this day on the Patent Owner's correspondence address of record for the subject patent as follows:

Novo Nordisk Inc.
Intellectual Property Department
800 Scudders Mill Road
Plainsboro, NJ 08536

Courtesy copies of the Petition for *Inter Partes* Review of U.S. Patent No. 10,335,462, including Exhibits 1001-1087, have been sent by Federal Express Next Business Day Delivery on this day to Patent Owner's counsel of record in the matter identified in Section II.B of the Petition as follows:

Jeff Oelke
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