

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-00722
Patent 7,041,786 B2

Before TINA E. HULSE, CYNTHIA M. HARDMAN, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

DECISION

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

Granting Petitioner's Motion to Amend Real Party in Interest Statement
37 C.F.R. § 42.5

I. INTRODUCTION

Mylan Pharmaceuticals Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”), seeking *inter partes* review of claims 1–6 of U.S. Patent No. 7,041,786 B2 (Ex. 1001, “the ’786 patent”). Bausch Health Ireland Limited (“Patent Owner”) filed a Preliminary Response. Paper 11 (“Prelim. Resp.”).¹

In the Preliminary Response, Patent Owner argued that the Petition should be denied because it does not identify Viatris Inc. and Mylan Inc. as real parties in interest (“RPI”). *Id.* at 11–14. Patent Owner also requested that the Board exercise discretion to deny institution under 35 U.S.C. § 325(d) and challenged the merits of the grounds in the Petition. *See* Prelim. Resp. 26–62.

Petitioner subsequently filed amended mandatory notices. Paper 9. Patent Owner sought authorization to move to strike Paper 9 for failure to comply with 37 C.F.R. § 42.8(a)(3). Ex. 3001. Petitioner concurrently sought authorization to file a reply to the RPI and 35 U.S.C. § 325(d) arguments in the Preliminary Response. *Id.*

Following a conference call with the parties, we authorized Petitioner to file the requested reply and to include in that reply a motion to amend its mandatory notices to include the information in Paper 9. Paper 12, 3. We did not authorize Patent Owner to move to strike, but authorized Patent Owner to present its “opposition, if any, to Petitioner’s motion” in a sur-reply to

¹ Patent Owner has withdrawn certain arguments from its original Preliminary Response and, with our authorization, filed a redacted version of the Preliminary Response reflecting those changes. We cite the redacted version (Paper 11) herein.

Petitioner's reply. *Id.* Pursuant to our order, Petitioner filed a reply, which includes a motion to amend the RPI disclosure in its mandatory notices. Paper 13 ("Reply"). Patent Owner filed a sur-reply, which includes its opposition to Petitioner's motion. Paper 15 ("Sur-reply").

After considering the arguments and evidence presented at this stage of the proceeding, we are persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition and decline to exercise discretion to deny institution under 35 U.S.C. § 325(d). We also grant Petitioner's motion to amend its RPI disclosure while maintaining the original filing date of the Petition. In view of this amendment, Patent Owner's RPI arguments are moot. Accordingly, we institute *inter partes* review.

II. BACKGROUND

A. Real Parties in Interest

The RPI disclosure in the Petition ("original RPI disclosure") states that Petitioner "is a co-defendant with Mylan Laboratories Ltd., Agila Specialties Inc, Mylan API US LLC, Mylan Inc., and Viatriis Inc. in parallel litigation." Pet. 2. Petitioner subsequently sought to update that disclosure to indicate that "[a]dditionally, Viatriis Inc. and Mylan Inc. are parent companies of Mylan Pharmaceuticals Inc." Paper 9, 2 (emphasis omitted); *see also* Reply, 4–5 (moving to update original RPI disclosure). We address Petitioner's motion to update its RPI disclosure and Patent Owner's related RPI arguments below in § V.

Patent Owner identifies Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. as RPI. Paper 4, 2.

B. Related Matters

The parties identify the following related matters involving the '786 patent in which they are involved: *Bausch Health Ireland Ltd. v. Mylan Laboratories Ltd.*, 2:21-cv-573 (W.D. Pa.); 1:21-cv-00611 (D. Del.); 2:21-cv-10403 (D.N.J. – transferred to N.D. W.Va.); 1:22-cv-00020 (N.D. W.Va. – transferred from D.N.J.). Pet. 2–3; Paper 4, 2–3. In its updated notices, Petitioner additionally identifies the following matter as involving the '786 patent: *Bausch Health Ireland Ltd. v. MSN Labs.*, 2:21-cv-10057 (D.N.J.). Paper 9, 2.

C. The '786 Patent

The '786 patent issued on May 9, 2006 from a utility application filed on March 28, 2002, and claims priority to a provisional application filed on January 17, 2002. Ex. 1001, codes (22) (45) (60).

The '786 patent is titled “Guanylate Cyclase Receptor Agonists for the Treatment of Tissue Inflammation and Carcinogenesis.” Ex. 1001, code (54). According to the Specification,

[t]he present invention relates to the therapeutic use of guanylate cyclase receptor agonists as a means for enhancing the intracellular production of cGMP. The agonists may be used either alone or in combination with inhibitors of cGMP-specific phosphodiesterase to prevent or treat cancerous, pre-cancerous and metastatic growths, particularly in the gastrointestinal tract and lungs. In addition, the agonists may be used in the treatment of inflammatory disorders such as ulcerative colitis and asthma.

Id. at 1:14–23.

The Specification explains that “[u]roguanylin, guanylin and bacterial ST [i.e., heat-stable enterotoxin] peptides are structurally related peptides

that bind to a guanylate cyclase receptor and stimulate intracellular production of cyclic guanosine monophosphate (cGMP).” Ex. 1001, 1:26–30. “This results in the activation of the cystic fibrosis transmembrane conductance regulator (CFTR),” which in turn “leads to stimulation of sodium and water secretion into the intestinal lumen.” *Id.* at 1:30–36. “Therefore by serving as paracrine regulators of CFTR activity, cGMP receptor agonists,” such as uroguanylin, guanylin, and bacterial ST peptides, “regulate fluid and electrolyte transport in the GI tract.” *Id.* at 1:36–39.

“The present invention is based upon the development of new agonists of guanylate cyclase receptor” that “are analogs of uroguanylin.” Ex. 1001, 3:3–6. The Specification describes the sequence for its “most preferred” uroguanylin analog in SEQ ID NO:20, which is reproduced below.

Asn¹ Asp² Glu³ Cys⁴ Glu⁵ Leu⁶ Cys⁷ Val⁸ Asn⁹ Val¹⁰ Ala¹¹ Cys¹² Thr¹³ Gly¹⁴ Cys¹⁵ Leu¹⁶

Id. at 5:7–12. SEQ ID NO:20 provides the primary structure of a 16-amino acid long peptide. The sequence in SEQ ID NO:20 differs from that of the “Parent compound: uroguanylin” (shown in SEQ ID NO: 1) in that it has a “Glu³,” i.e., a glutamic acid (Glu) at position 3 in the peptide sequence, whereas human uroguanylin has an “Asp³,” i.e., an aspartic acid (Asp) at that position.² *See id.* at 11 (Table 2). This is the only difference between the

² Both parties use a superscript to denote the position of the residue in an amino acid sequence. *See, e.g.*, Pet. 1, 38; Prelim. Resp. 5, 7 (referring to “Glu³” and “Asp³”). In addition to Glu, other synonyms for glutamic acid appearing in the record include “glutamate” and the letter “E” from the single-letter code for amino acids. In addition to Asp, other synonyms for aspartic acid include “aspartate” and the letter “D.”

sequence in SEQ ID NO:20 and the naturally-occurring human uroguanylin sequence in SEQ ID NO:1. *Id.*; see also Ex. 1002 ¶¶ 24–25.

According to the Specification, the peptide of SEQ ID NO:20 has been found to have enhanced biological activity as an agonist of cGMP production due to its enhanced binding constant for the guanylate cyclase receptor, and is superior to uroguanylin with regard to temperature and protease stability and with regard to its biological activity at the physiologically favorable pH range (pH 6 to 7) in the large intestine.

Ex. 1001, 5:16–23.

D. Challenged Claims

The Petition challenges claims 1–6. Claims 1–3 and 6 are independent claims. They provide as follows:

1. A peptide consisting of the amino acid sequence of SEQ ID NO:20.
2. A composition in unit dose comprising a guanylate cyclase receptor agonist peptide consisting of the amino acid sequence of SEQ ID NO:20.
3. A composition in unit dose form comprising:
 - a) a guanylate cyclase receptor agonist peptide consisting of the amino acid sequence of SEQ ID NO: 20; and
 - b) at least one compound selected from the group consisting of: a cGMP-dependent phosphodiesterase inhibitor, an anti-inflammatory agent, an antiviral agent and an anticancer agent.
6. A peptide conjugate comprising polyethylene glycol (PEG) attached to a peptide consisting of the amino acid sequence SEQ ID NO:20.

Ex. 1001, 37:1–12, 38:7–9. Claims 4 and 5 additionally limit the compositions of either claim 2 or 3 to a “dose form . . . selected from the group consisting of a tablet, a capsule, a solution and an inhalation formulation” (claim 4) and to further comprise “one or more excipients” (claim 5). *Id.* at 38:1–6.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §³	Reference(s)/Basis
1	103	Currie ⁴ , Li ⁵
2, 4, 5	103	Currie, Li, Narayani ⁶
3–5	103	Currie, Li, Narayani, Campieri ⁷
6	103	Currie, Li, Ekwuribe ⁸

Petitioner also relies on the declaration of Blake R. Peterson, Ph.D. (Ex. 1002).

Before turning to our analysis of Petitioner’s grounds in § IV, we address Patent Owner’s arguments that, notwithstanding the merits of the

³ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), included revisions to 35 U.S.C. § 103 that became effective after the filing of the application that led to the ’786 patent. Therefore, we apply the pre-AIA version of 35 U.S.C. § 103.

⁴ U.S. Pat. 5,489,670, issued Feb. 6, 1996 (Ex. 1005) (“Currie”).

⁵ Zhiping Li et al., *Purification, cDNA Sequence, and Tissue Distribution of Rat Uroguanylin*, 68 *Regulatory Peptides* 45–56 (1997) (Ex. 1006) (“Li”).

⁶ R. Narayani et al., *Polymer-coated Gelatin Capsules as Oral Delivery Devices and their Gastrointestinal Tract Behavior in Humans*, 7 *J. Biomater. Sci. Polymer Edn.* 39–48 (1995) (Ex. 1007) (“Narayani”).

⁷ M. Campieri et al., *Oral Budesonide is as Effective as Oral Prednisolone in Active Crohn’s Disease*, 41 *Gut* 209–214 (1997) (Ex. 1008) (“Campieri”).

⁸ U.S. Pat. 5,359,030, issued Oct. 25, 1994 (Ex. 1009) (“Ekwuribe”).

Petition, the Board should exercise discretion to deny institution under 35 U.S.C. § 325(d).

III. DISCRETION UNDER 35 U.S.C. § 325(d)

Patent Owner argues that “Petitioner offers only one ground of unpatentability with respect to claim 1,” i.e., Ground 1 asserting that claim 1 is obviousness over Currie and Li, and that “Grounds 2-4 do not raise *any* additional argument regarding” the peptide of claim 1, which is also recited in the other independent claims. Prelim. Resp. 28 n.4. According to Patent Owner, Currie was considered by the Examiner and “[w]hile Li . . . was not itself of record, the art of record includes the same substantive teachings.” *Id.* at 5. Patent Owner contends “Petitioner makes no attempt to show any error by the Examiner” and thus urges that the Board “should exercise its discretion to deny institution under 35 U.S.C. § 325(d).” *Id.*

A. Legal Standard

Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office. The statute states, in pertinent part, “[i]n determining whether to institute . . . the Director may take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d).

The question of whether a petition presents art or arguments that are “the same or substantially the same” as art or arguments previously presented to the Office is a factual inquiry, which may be resolved by

reference to the factors set forth in *Becton, Dickinson*.⁹ The precedential section of that decision sets forth the following non-exclusive factors for consideration:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, 17–18.

*Advanced Bionics*¹⁰ sets out a two-part framework for analyzing these factors. In the first part, we consider factors (a), (b), and (d) to determine whether the art and arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, 8–10. “If, after review of factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office,” then we move on to the second part of the analysis

⁹ *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”).

¹⁰ *Advanced Bionics, LLC v. MED-EL Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 10 (Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

to determine “whether the petitioner has demonstrated a material error by the Office” in view of factors (c), (e), and (f). *Id.*

B. Advanced Bionics Part One

Starting with Ground 1, it is undisputed that Currie, but not Li, was cited and therefore considered during examination of the ’786 patent. *See* Pet. 56 (acknowledging that “Currie was cited”); Prelim. Resp. 5 (acknowledging Li “was not itself of record”).

Patent Owner contends Li contains substantially the same disclosure as two other references, Hidaka 1998 (Ex. 2008) and Hidaka 2000 (Ex. 2009), which were considered by the Examiner. Prelim. Resp. 32–36. According to Patent Owner, Hidaka 1998 discloses the sequence of human uroguanylin and Hidaka 2000 “compares uroguanylin and pro-uroguanylin’s sequences of human and mammals, explicitly disclosing rat uroguanylin’s sequence.” *Id.* at 32–34 (citing Ex. 2008, Fig. 1(b); Ex. 2009, Fig. 1). Patent Owner contends these disclosures are “substantively the same” as the disclosure Petitioner relies on from Li. *Id.* at 36.

We disagree with Patent Owner’s argument that Hidaka 1998 and Hidaka 2000 contain substantially the same disclosure as Li. The Petition relies on the sequence alignment in Li Figure 6(a), which compares the amino acid sequences of human and rat uroguanylin along with other uroguanylin and guanylin sequences and a ST sequence from *E. coli*. *See, e.g.*, Pet. 24–26, 33–34 (citing Ex. 1006, 52 (Fig. 6(a))). As Patent Owner points out, Hidaka 2000 also discloses a sequence alignment showing the sequences of human and rat uroguanylin. Prelim. Resp. 34 (citing Ex. 2009, Fig. 1). However, Li provides additional teachings analyzing the sequence

alignment in its Figure 6(a) to identify the residues that are of “particular interest” to the binding of the guanylin receptor (GCC). Ex. 1006, 54 (left column). Among the residues of “particular interest” that Li identifies are the Asp³ in human uroguanylin and the corresponding glutamic acid residue in rat uroguanylin. *Id.* Petitioner relies on these teachings in Li for its argument that it would have been obvious to make a “conservative substitution” of glutamic acid for the Asp³ in human uroguanylin, thereby arriving at the peptide of SEQ ID NO:20. *See* Pet. 26, 34–36.

Based on our review, there is no corollary in Hidaka 1998 or Hidaka 2000 to these additional teachings in Li, nor does Patent Owner identify such in its Preliminary Response. Thus, we agree with Petitioner that “Li is not cumulative” of the references that were before the Examiner. *See* Pet. 56; Reply 2–3 (urging that Li is not cumulative because it “shows the aspartic and glutamic acid residues in the second and third positions and identifies them as important for uroguanylin’s desirable activity level”).

In addition to the references cited in Ground 1, each of Petitioner’s Grounds 2–4 rely on additional references that were not considered by the Examiner. As Petitioner points out, “[n]one of Narayani, Campieri or Ekwuribe was ever considered during prosecution.” Pet. 56. Patent Owner does not dispute this, nor does Patent Owner identify references that were considered previously that it contends contain the same or substantially the same disclosure. *See* Prelim. Resp. 32–36.

For these reasons, we determine that, on the whole, the Petition does not present the same or substantially the same art or arguments as that previously presented to the Office. Because the first part of the *Advanced*

Bionics framework has not been met, we decline to exercise discretion to deny institution under 35 U.S.C. § 325(d).

IV. ANALYSIS OF THE ASSERTED GROUNDS

A. Legal Standards

Under pre-AIA § 103(a), a claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made.” 35 U.S.C. § 103(a) (2006); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

Relying on the testimony of its declarant, Dr. Peterson, Petitioner contends that as of January 17, 2002:

A skilled artisan would have been familiar with signaling peptides and their biochemistry, as the accompanying exhibits prove. The specification admits an artisan would also have known how to choose and prepare various dosage forms when it notes the use of known alternatives without further guidance on when and how to use them. A Ph.D. in peptide chemistry, protein engineering, or a related field, or alternatively, a master’s degree in one of these fields plus two to five years of experience in drug development would represent typical education and experience for a skilled artisan. EX1002, ¶¶40-

43. This individual would have worked in consultation with a team including, *e.g.*, a pharmaceutical chemist and/or a pharmacist familiar with formulating peptides for administration.

Pet. 13. Patent Owner does not presently challenge Petitioner’s description of a person of ordinary skill in the art (POSA). Prelim. Resp. 39.

At this stage in the proceeding, we find Petitioner’s description of the level of ordinary skill in the art to be sufficiently supported by the record. Accordingly, we apply this description in our analysis herein.

C. Claim Construction

Neither party identifies any claim term for construction. *See* Pet. 14 (“The claim terms do not require construction to apply the grounds.”); Prelim. Resp. 39 (“For purposes of this preliminary response only, Patent Owner does not challenge” the “construction positions proposed in the petition.”).

We agree that no formal claim construction is necessary at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (explaining that it is only necessary to “construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

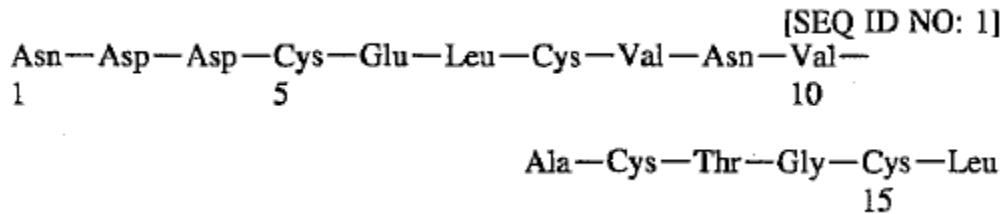
D. References Relied Upon

i. Currie

Currie is a United States Patent that was issued on February 6, 1996. Ex. 1005, code (45). Petitioner asserts that Currie qualifies as prior art under

35 U.S.C. § 102(b). Pet. 22. At this stage, Patent Owner does not dispute that Currie is prior art to the challenged claims.

Currie describes human uroguanylin. Ex. 1005, 1:47–63. Currie discloses the amino acid sequence for human uroguanylin in SEQ ID NO:1, which is reproduced below.



Id. at 1:50–55. The peptide shown in SEQ ID NO:1 of Currie is 16 amino acids long and has an Asp³.

Currie teaches that human uroguanylin “is an endogenous stimulator of intestinal guanylate cyclase” and “has been found to stimulate increases in cyclic GMP levels in a manner similar to guanylin and the STs.”¹¹ Ex. 1005, 2:6–8. Currie describes tests in which human uroguanylin “caused a concentration-dependent increase in T84 cell cyclic GMP” and “appeared to be more potent than human guanylin, but less potent than ST.” *Id.* at 6:11–14, Fig. 3A.¹² Currie also describes the results of a “competitive binding assay” showing “ST and human uroguanylin had similar affinities for the receptors on T84 cells and human guanylin had a much lower affinity.” *Id.* at 6:16–19, Fig. 3B. According to Currie these and other results described

¹¹ Currie explains that “STs” are a “family of heat stable enterotoxins” produced by *E. coli* and other bacteria “that activate intestinal guanylate cyclase” and “cause secretory diarrhea.” Ex. 1005, 1:31–39.

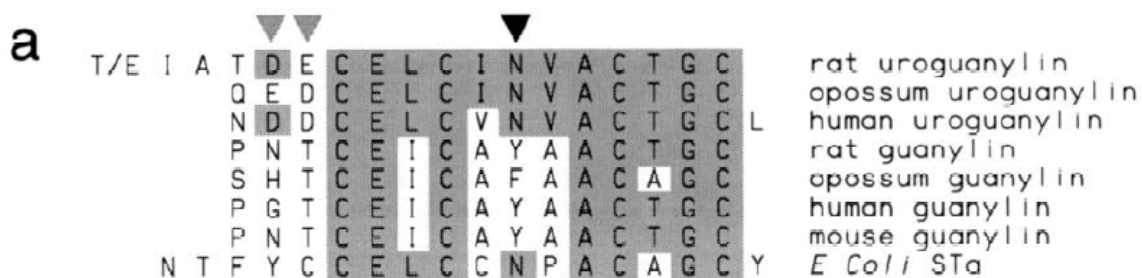
¹² Although it refers to “Fig. 4a” and “Fig. 4b,” the results Currie describes appear to be those shown in Figures 3A and 3B. *Compare* Ex. 1005, 6:11–22 *with id.*, Figs. 3A-B.

therein, suggest “human uroguanylin may . . . act as a laxative and be useful in patients suffering from constipation, e.g., cystic fibrosis patients who suffer from severe intestinal complications from constipation.” *Id.* at 2:20–24.

ii. Li

Li is an article from a scientific journal bearing a 1997 publication date. Ex. 1006, 45. Petitioner asserts that Li qualifies as prior art under 35 U.S.C. § 102(b). Pet. 24. At this stage, Patent Owner does not dispute that Li is prior art to the challenged claims.

Li describes the amino acid sequence for rat uroguanylin, explaining it has “high homology with uroguanylin” from humans and opossum uroguanylin. Ex. 1006, Abstr. Figure 6a of Li, reproduced below, is a sequence alignment comparing the amino acid sequences of uroguanylins, guanylins and ST from different species.



Id. at 52. Figure 6a shows the sequence for rat uroguanylin (first row) aligned with the sequences for opossum uroguanylin (second row) and human uroguanylin (third row) with shading added to indicate “amino acid identities.” *Id.* The alignment in Figure 6a shows that human and opossum

uroguanylin have an aspartic acid (D) residue at position 3,¹³ whereas rat uroguanylin has a glutamic acid (E) at the corresponding position. Figure 6a also depicts “stippled arrowheads,” i.e., gray triangles, above the residues at positions 2 and 3 and a “solid arrowhead,” i.e., a black triangle, above the residue at position 9. *See id.* at 54 (left column). Li explains that these “arrowheads denote structural features described in the text.”

Li teaches that

[t]he affinity of GCC [i.e., guanylate cyclase type C receptor] for uroguanylin (opossum or human) is about 10-fold higher than its affinity for guanylin (rat or human). Thus, features that are found in uroguanylin, but not in guanylin, offer information about structural elements that specify the strength of the ligand/receptor interaction. Of particular interest are two residues that are basic or uncharged in guanylin but acidic in uroguanylin (stippled arrowheads), and one residue that contains an aromatic ring in guanylin but an acidic amide in uroguanylin (solid arrowhead).

Ex. 1006, 54 (left column). Li explains that rat uroguanylin “follows the consensus sequence of uroguanylin rather than that of guanylin” at “[a]t all three positions” denoted by the arrowheads in Figure 6a “and thus we would expect its affinity to be comparable to that of opossum or human uroguanylin.” *Id.*

iii. Narayani

Narayani is an article from a scientific journal bearing a 1995 publication date. Ex. 1007, 39. Petitioner asserts that Narayani qualifies as

¹³ Here, we refer to the position numbers in human uroguanylin and the majority of the other sequences shown in Li Figure 6a.

prior art under 35 U.S.C. § 102(b). Pet. 26. At this stage, Patent Owner does not dispute that Narayani is prior art to the challenged claims.

Narayani describes tests of polymer-coated gelatin capsules. Ex. 1007, Abstr. Narayani explains that

[g]elatin capsules were coated with various concentrations of sodium alginate and cross-linked with appropriate concentrations of calcium chloride and tested *in vitro* for resistance to gastric and intestinal medium. Gelatin capsules coated with 20% w/v of the polymer which gave the most promising result *in vitro* were evaluated in human volunteers for their *in vivo* gastro intestinal tract behavior.

Narayani teaches that “the alginate coated gelatin capsules remained intact as long as they were retained in the stomach (up to 3 h) and then migrated to the ileocecal region of the intestine and disintegrated.” *Id.* According to Narayani,

[t]he results of this study clearly suggested that alginate-coated gelatin capsules are safe candidates as oral delivery devices to carry microspheres containing bioactive peptides and proteins and dump them selectively in the large intestine where thereapeutic action or drug absorption is desired. The polymer-coated gelatin capsules will facilitate the routine use of the oral route of delivery for protein and peptide drugs.

Id. at 47.

iv. Campieri

Campieri is an article from a scientific journal bearing a 1997 publication date. Ex. 1008, 209. Petitioner asserts that Campieri qualifies as prior art under 35 U.S.C. § 102(b). Pet. 27. At this stage, Patent Owner does not dispute that Campieri is prior art to the challenged claims.

Campieri describes a clinical study involving the oral administration of certain steroids, i.e., prednisolone and budesonide, to treat Crohn's disease. Ex. 1008, Abstr. Campieri teaches that budesonide in "controlled ileal release (CIR) capsules . . . administered at 9 mg daily or 4.5 mg twice daily, is comparable to prednisolone in inducing remission in active Crohn's disease." *Id.*

v. *Ekwuribe*

Ekwuribe is a United States Patent that issued on October 25, 1994. Ex. 1009, code (45). Petitioner asserts that Ekwuribe qualifies as prior art under 35 U.S.C. § 102(b). Pet. 28. At this stage, Patent Owner does not dispute that Ekwuribe is prior art to the challenged claims.

Ekwuribe discloses "[a] stabilized conjugated peptide complex comprising a peptide conjugatively coupled to a polymer including lipophilic and hydrophilic moieties." Ex. 1009, Abstr. Ekwuribe discloses examples that incorporate polyethylene glycol (PEG) into the polymer. *See id.* at 13:4-52. Ekwuribe teaches that "[t]he presence of these PEG residues will impart hydrophilic properties to the polymer and to the corresponding polymer-peptide conjugates." *Id.* at 12:41-43; 14:50-55.

E. Ground 1: Obviousness over Currie and Li

Petitioner contends that claim 1 would have been obvious over the combination of Currie and Li. *See* Pet. 32-39. Petitioner presents evidence and argument purporting to show that a peptide consisting of the amino acid sequence of SEQ ID. NO:20 would have been obvious over these references. *Id.*

Petitioner has demonstrated a reasonable likelihood that it will prevail

in showing that claim 1 is unpatentable. Based on the current record, Petitioner has shown that Currie teaches the amino acid sequence for human uroguanylin and that Currie identifies this peptide as a drug candidate for patients suffering from constipation. Ex. 1005, 1:50–55, 2:20–24. The only difference between SEQ ID. NO:20 in claim 1 and the sequence taught in Currie is the residue at position 3. In Currie’s sequence there is an Asp³, whereas SEQ ID NO:20 has a Glu³.

Based on the current record, Petitioner has demonstrated that a POSA would have been motivated to substitute glutamic acid for the Asp³ in Currie’s human uroguanylin sequence, thereby resulting in the peptide of claim 1. In particular, the Petition relies on Dr. Peterson’s testimony that: (1) aspartic acid and glutamic acid are structurally similar such that substituting glutamic acid for aspartic acid would have been regarded as a “conservative substitution,” which was a “primary strategy employed by protein engineers” (Ex. 1002 ¶¶ 73–75); (2) Li teaches that the presence of an acidic residue at position 3 in human uroguanylin is of “particular interest” to the ligand/receptor interaction and its sequence alignment shows that rat uroguanylin has a glutamic acid at the corresponding position, both of which would suggest substituting glutamic acid for the Asp³ in human uroguanylin (*id.* ¶¶ 137–152); (3) a POSA would have expected that the peptide resulting from this substitution “would be comparably more protonated than native human uroguanylin . . . in the large intestine and intestinal mucosa” and therefore it would have been reasonably expected to have “improved activity” as compared to the native human uroguanylin (*id.* ¶¶ 165–170); and (4) a POSA would have understood that another benefit of this substitution would be that it eliminates known sources of aspartimide

formation during synthesis (*id.* ¶¶ 175–179). *See* Pet. 34–39. On the current record, this evidence, which is largely unrebutted, is sufficient to show that a POSA would have been motivated to substitute glutamic acid for the Asp³ in human uroguanylin and would have had a reasonable expectation of success in doing so.

In its Preliminary Response, Patent Owner raises several arguments against the merits of Petitioner’s showing for Ground 1. *See* Prelim Resp. 38–46. Those arguments are unavailing on the current record for the reasons explained below.

First, Patent Owner argues that the Petition fails to perform a lead compound analysis to explain why a POSA would have started with human uroguanylin. *See* Prelim. Resp. 41–49. According to Patent Owner, Petitioner must establish “that a POSA would have chosen the Petitioner’s proposed lead sequence—here, human uroguanylin—over other prior art options.” *Id.* at 41 (citing *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010)). Patent Owner argues that Petitioner’s rationales for choosing uroguanylin are “conclusory” and “fall[] fatally short of the required analysis.” *Id.* at 41–42. According to Patent Owner, a POSA would not have selected uroguanylin as a lead compound because it “was known to have a characteristic—topo isomerisim—that causes it to be **unsuitable** for a therapeutic drug” and it was known that “heat-stable enterotoxins (ST)” were more potent than uroguanylin, which would have made STs “far more attractive as lead compounds.” *See id.* at 42–48.

On the current record, Patent Owner’s arguments are unavailing. As Patent Owner acknowledges, Petitioner has articulated reasoning to explain why a POSA would have selected human uroguanylin as a lead compound.

See Prelim. Resp. 41. In particular, Petitioner relies on the fact that based on its known activity, the prior art had already identified uroguanylin “as a good candidate for oral administration for delivery to the intestines to treat constipation.” Pet. 19 (citing Ex. 1002 ¶¶ 59–61, 82–86, 89–93, 107). As Dr. Peterson explains,

[k]nown uroguanylin signaling suggested the peptide as a treatment for constipation. Once uroguanylin binds intestinal guanylate cyclase, cyclic guanosine monophosphate (cGMP) builds up in the cell. This secondary messenger causes the cell, through a biochemical pathway, to secrete chloride and other anions. The increasing solute concentration in the intestinal lumen draws water into the lumen from the surrounding tissue. When too much water is drawn from the surrounding tissue into the intestinal lumen, the result is the disease commonly called diarrhea. Uroguanylin’s known agonist activity thus suggested its usefulness for treating constipation by increasing water content in the intestine.

Ex. 1002 ¶ 59 (citations omitted). Dr. Peterson further explains that STs were known to cause diarrhea and thus “[a]t least as early as 1993, treating constipation using a more controlled version of this pathway,” i.e., with a uroguanylin analog as opposed to one based on an ST, “had already been suggested.” *Id.* ¶ 60 (citing Ex. 1005, 2:20–25). Indeed, Currie expressly teaches that “human uroguanylin may . . . act as a laxative and be useful in patients suffering from constipation.”¹⁴ Ex. 1005, 2:20–25. Based on this

¹⁴ Patent Owner relies on the district court’s decision in *OSI Pharmaceuticals* to support its assertion that “[s]imply noting that a prior art reference identified uroguanylin as ‘preferred’ is insufficient to satisfy the lead compound analysis.” Prelim. Resp. 42 (citing *OSI Pharms., Inc. v. Mylan Pharms. Inc.*, 858 F.Supp.2d 341, 355–56 (D. Del. 2012)). There, the district court explained that the fact a compound was “one of thirteen” preferred compounds specifically claimed in a prior art patent application

evidence, we do not find Petitioner’s reasoning for selecting human uroguanylin as a lead compound to be overly conclusory such that it falls short of the showing required for institution.

Patent Owner’s argument that a POSA would not have selected human uroguanylin as a lead compound because STs presented more favorable candidates for drug development does not sufficiently undermine Petitioner’s showing on the current record. *See* Prelim. Resp. 43–49. Dr. Peterson’s testimony that STs were known to cause diarrhea, whereas human uroguanylin had been identified as a candidate for “treating constipation using a more controlled version” of the same biological pathway provides reasoning why a POSA would have selected uroguanylin as a lead compound even though STs were known to be more potent. Ex. 1002 ¶ 60. This testimony is currently unrebutted and Patent Owner will have the opportunity to address it more fully at trial. So too, the “topo isomerism” issue that Patent Owner identifies (*see* Prelim. Resp. 42) would benefit from further development at trial. We also note that our reviewing court has cautioned that it would be overly restrictive to view the “lead compound test” to require “that the prior art must point to only a single lead compound for further development.” *Altana Pharma AG. v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1008 (Fed. Cir. 2009). This suggests that the parties should

was not “dispositive . . . of the lead compound issue” because the party alleging obviousness had failed to point to “useful properties” that would have motivated a POSA to select that compound as a lead. *See OSI Pharms.*, 858 F.Supp.2d at 355–56. Here, however, Petitioner has identified useful properties it contends would have led a POSA to select human uroguanylin as a lead compound for developing a drug to treat constipation. The fact that Currie teaches human uroguanylin is useful for that purpose supports Petitioner’s allegation.

focus their arguments at trial on why or why not a POSA would have selected human uroguanylin for modification as opposed to merely attempting to show that there were other potential lead compounds known in the art.

Second, Patent Owner contends “the petition fails to provide a legally sufficient explanation as to why a POSA would have had a reason to substitute the aspartate at position 3 (‘Asp³’) of uroguanylin’s sequence with glutamate.” *See* Prelim. Resp. 49–53. More specifically, Patent Owner argues that “modifying the position 3 aspartate in uroguanylin’s sequence already had been demonstrated to **reduce** uroguanylin’s bioactivity.” *Id.* at 50–51. In support of this argument, Patent Owner cites references suggesting that deletion of Asp³ in uroguanylin reduced the activity of the resulting peptide as well as Li’s teaching that the acidic residues at “positions 2 and 3 of uroguanylin . . . are known to be **required** for uroguanylin’s improved activity as compared to guanylin.” *Id.* (quotations omitted). Thus, urges Patent Owner, “the very amino acid substitution that the petition suggests a POSA would have sought to employ with uroguanylin in fact would have been known to a POSA to have diminished uroguanylin’s bioactivity.” *Id.* at 52.

Patent Owner’s argument is unavailing on the current record. The Petition asserts that it would have been obvious to substitute glutamic acid for the Asp³ in human uroguanylin, thereby preserving the presence of a residue with an acidic side chain at that position. *See* Pet. 34–39. This “conservative substitution,” as the Petition refers to it, is consistent with Li’s teachings suggesting that the presence of an acidic residue at position 3 is important to the ligand/receptor interaction. *See* Ex. 1006, 54 (left column).

The other references Patent Owner cites suggest that *deleting* Asp³ along with other N-terminal residues in uroguanylin would have a deleterious effect on activity. *See* Prelim. Resp. 50–51 (citing Ex. 2020, 228; Ex. 1021, 2705, 2708–9; Ex. 2021, 7–8). But contrary to Patent Owner’s argument, deleting Asp³ is not the same as the substitution of Glu³ for Asp³ that Petitioner proposes. Accordingly, on the current record, Patent Owner’s argument does not undermine Petitioner’s articulated reasoning for modifying the references.

Third, Patent Owner asserts that the Petition’s reliance on the sequence for rat uroguanylin is driven by improper hindsight. *See* Prelim. Resp. 53–57. In particular, Patent Owner urges that Li’s Figure 6a shows that “the glutamate amino acid in rat uroguanylin is at ***position 6***, not position 3,” therefore “Petitioner and Dr. Peterson have relied upon a ***misalignment*** of the rat uroguanylin and human uroguanylin sequences.” *Id.* at 55.

This argument is also unavailing on the current record. As explained above, Figure 6a of Li discloses an alignment of different uroguanylin, guanylin and ST amino acid sequences. *Supra* § IV.D.ii. According to Li’s alignment, the Glu⁶ in rat uroguanylin corresponds to the Asp³ in the human uroguanylin sequence. Ex. 1006, 52 (Fig. 6a). Reproduced below is an annotated version of Li’s Figure 6(a), which Petitioner offers to illustrate this correspondence.

T/E	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	Sequence	
	T	D	E	C	E	L	C	I	N	V	A	C	T	G	C		rat uroguanylin	
	Q	E	D	C	E	L	C	I	N	V	A	C	T	G	C		opossum uroguanylin	
	N	D	D	C	E	L	C	V	N	V	A	C	T	G	C	L	human uroguanylin	
	P	N	T	C	E	I	C	A	Y	A	A	C	T	G	C		rat guanylin	
	S	H	T	C	E	I	C	A	F	A	A	C	A	G	C		opossum guanylin	
	P	G	T	C	E	I	C	A	Y	A	A	C	T	G	C		human guanylin	
	P	N	T	C	E	I	C	A	Y	A	A	C	T	G	C		mouse guanylin	
N	T	F	Y	C	C	E	L	C	C	N	P	A	C	A	G	C	Y	<i>E. coli</i> STa

Pet. 34. Petitioner’s annotations, which are supported by the testimony of Dr. Peterson, show that the Asp³ (red “D”) in the human uroguanylin sequence (yellow highlighted third row) corresponds to the glutamic acid residue (red “E”) in the rat uroguanylin sequence (yellow highlighted first row). *See* Ex. 1002 ¶ 145 (explaining that “the residues ‘of particular interest’” identified in Li “are those that are aligned with the second and third positions of the human uroguanylin sequence” and that the aspartic acid at position 3 in human uroguanylin “is instead a glutamic acid (E/Glu) in the aligned rat uroguanylin sequence”). To the extent Patent Owner believes that the sequences in Li’s Figure 6a are misaligned, it will need to present more than just attorney argument to overcome Petitioner’s showing and will have opportunity to do so in its subsequent papers at trial.

Fourth, Patent Owner argues that the Petition improperly focuses on replacing Asp³ while “ignor[ing] all the other differences between human uroguanylin and rat uroguanylin.” *See* Prelim. Resp. 56–59. Patent Owner argues that “unlike rat and opossum uroguanylin, human uroguanylin has a leucine residue at the C-terminus (‘Leu¹⁶’), which was known to play an important role in uroguanylin’s stability.” *Id.* at 56. Because the Petition does not consider this other difference when comparing the human and rat sequences, Patent Owner contends that Petitioner’s analysis is “predicated on impermissible hindsight.” *Id.* at 57.

This argument is also unavailing on the current record. The correspondence between the Asp³ in human uroguanylin and the glutamic acid residue in rat uroguanylin is only part of the reasoning Petitioner articulates to explain why a POSA would have been motivated to substitute glutamic acid for the Asp³ in human uroguanylin. *See* Pet. 34–39; *see also*, e.g., Ex. 1002 ¶ 123 (summarizing “three good reasons” a POSA would have had “to make [Glu³]-human uroguanylin with a reasonable degree of success”). Petitioner’s other reasoning includes that it would have the benefit of preserving the acidic residues that Li identifies as being of interest, while also resulting in a peptide that a POSA would expect to improve activity (*see* Pet. 36–37) and removing “problematic synthetic pairings” in the human uroguanylin sequence that encourage aspartimide formation (*see id.* at 37–38). On the current record, it does not seem that the additional benefits Petitioner identifies could be realized by modifying the Leu¹⁶ in human uroguanylin, which helps show why a POSA would have looked to modify other residues.¹⁵ Thus, viewed as a whole and on the current record, the reasoning articulated in the Petition is sufficient to explain why a POSA would have been motivated to focus on the substitution of glutamic acid for Asp³ that underlies Petitioner’s obviousness challenge.

Finally, Patent Owner’s related argument that the Petition “fails to consider alternative and additional modifications” to uroguanylin is likewise unavailing on the current record. *See* Prelim. Resp. 59–62. The Petition is premised on making a “conservative substitution,” i.e., a single substitution of one acidic residue for another based on Li’s teaching that the presence of

¹⁵ In any event, this issue would benefit from further development in the parties’ subsequent papers.

certain acidic residues in uroguanylin, as opposed to the basic or uncharged residues found at the corresponding positions in guanylin, is “[o]f particular interest.” Pet. 34 (quoting Ex. 1006, 54); *see also* Ex. 1002 ¶¶ 73–75 (explaining that “a primary strategy employed by protein engineers was making conservative substitutions” because “their impact on the structural and chemical properties of the protein may be similar enough to preserve functionality,” particularly where those “substitutions are found at a given position in natural homologs”). The Petition explains that of the “twenty proteogenic” amino acids only aspartic acid and glutamic acid are “negatively charged at neutral pH” and have “a carboxylic acid functional group” in their side chain. Pet. 15–17. Moreover, the Petition explains that the proposed substitution “would have been expected to result in a protonated glutamate at a higher pH (pKa =4.25 rather than aspartic acid’s 3.65) for better activity in the less acidic environment of the intestinal lumen further away from the stomach.” *Id.* at 36 (citing Ex. 1002 ¶¶ 61–65, 157–70; Ex. 1012, 118, Table 5-1). On the current record, this reasoning is sufficient to explain why a POSA would have been motivated to make only the particular substitution Petitioner proposes.¹⁶

¹⁶ Petitioner appears to acknowledge that according to its reasoning, Li also suggests a substitution of glutamic acid for Asp² resulting in [Glu²]-human uroguanylin, but argues that “the suggestion in the art to make [Glu³]-human uroguanylin is not undermined in any way by the possibility that a POSA could also make [Glu²]-human uroguanylin as an operable synthetic uroguanylin due to the ease with which both peptides could be synthesized and tested for activity.” Pet. 39. Patent Owner does not specifically respond to this argument in its Preliminary Response, but will have the opportunity to do so in its subsequent papers.

For these reasons, and based on the record at this stage of the proceeding, we determine that Petitioner has established a reasonable likelihood it will prevail in demonstrating that claim 1 would have been obvious over Currie and Li.

F. Grounds 2–4: Obviousness over Currie and Li in combination with other references

Grounds 2–4 rely on Petitioner’s showing for Ground 1 for the “peptide consisting of the amino acid sequence of SEQ ID NO:20” limitation recited in independent claims 2, 3, and 6. *See* Pet. 42, 46, 51–52 (referring back to Pet. § X (Ground 1)). That is, for each of these grounds, Petitioner asserts it would have been obvious to modify the human uroganylin sequence taught in Currie by substituting glutamic acid for Asp³ to arrive at the peptide of SEQ ID NO:20 based on the teachings in Li. *Id.* Petitioner then combines Currie and Li with one or more additional references, i.e., Narayani, Campieri, and/or Ekwuribe, to address the other limitations recited in claims 2–6. *Id.* at 40–44 (Ground 2), 45–47 (Ground 3), and 51–52 (Ground 4). Petitioner supports these assertions by articulating reasoning why, in its view, a POSA would have been motivated to make the combination and have a reasonable expectation of success in doing so. *See id.* at 44–45 (Ground 2), 47–50 (Ground 3), and 52–53 (Ground 4).

Patent Owner does not raise any separate argument regarding the merits of Grounds 2–4 in its Preliminary Response. Instead, Patent Owner argues “Grounds 2–4 do not need to be analyzed [in is Preliminary Response] because they cannot stand independently” from Ground 1. Prelim. Resp. 62. Thus, Patent Owner urges trial should not be instituted on Grounds 2–4 for the same reasons it argues for Ground 1. *See id.*

On the current record, we are persuaded that Petitioner’s showing for Grounds 2–4 is sufficient to meet the burden for institution of *inter partes* review for each of the claims challenged in these grounds. To the extent Patent Owner raises the same arguments for Grounds 2–4 that it does for Ground 1, we find those arguments unavailing on the current record as explained above. *See supra* § IV.E.

V. PETITIONER’S MOTION TO AMEND RPI DISCLOSURE

The original RPI disclosure in the Petition identifies Mylan Inc. and Viatris Inc. as “co-defendant[s]” with Petitioner in parallel litigation. Pet. 2. Patent Owner contends this is insufficient because “co-defendants in a related litigation, without more, are not considered RPIs,” whereas Mylan Inc. and Viatris Inc. are Petitioner’s “corporate parents.” Prelim. Resp. 3. Thus, Patent Owner urges that the original RPI disclosure does not go far enough to identify these entities as RPI. *See id.* at 11 (arguing that the Petition “does not state without qualification—or at all—that any of these entities is an RPI with the Petitioner”).

Petitioner disagrees with Patent Owner’s interpretation of its original RPI disclosure, urging that it “was a good faith attempt to identify all potential RPIs under 37 C.F.R. § 42.8, not any effort at intentional concealment.” Reply 4–5. Petitioner explains that it “updated its mandatory notices within 21 days of [Patent Owner] raising the issue, to confirm that [Petitioner] does not dispute the status of its parent companies.” *Id.* at 5; *see also* Paper 9, 2 (adding a sentence to Petitioner’s original RPI disclosure stating that Mylan Inc. and Viatris Inc. are parent companies of Petitioner). According to Petitioner, “[i]t is in the interests of justice to authorize

[Petitioner] to update its notices to remove any doubt that Viatris Inc. and Mylan Inc. are parent companies of [Petitioner] and are RPIs.” Reply 5.

Patent Owner opposes Petitioner’s motion to amend its mandatory notices. *See* Sur-reply 4–5. According to Patent Owner, Petitioner has not provided “any good reason” for its “belated admission” that Mylan Inc. and Viatris Inc. are RPI. *Id.* at 5. Patent Owner argues that “in the related district court case, [Petitioner] has vigorously tried, and succeeded, to obtain a dismissal of its parents from the lawsuit” and that its “failure to disclose its parents as RPIs here mirrors its attempts to dismiss them in the district court case.” *Id.* According to Patent Owner, these actions evidence Petitioner’s “intention ‘to gain some advantage’ of insulating its parents from the proceedings.” *Id.* (quoting *SharkNinja Operating LLC v. iRobot Corp.*, IPR2020-00734, Paper 11, 19 (PTAB Oct. 6, 2020) (precedential)).

Petitioner’s arguments are more persuasive. We see nothing here that suggests Petitioner sought to conceal its relationship to Mylan Inc. and Viatris Inc. Both entities are named in the original RPI disclosure. Pet. 2. And upon learning of Patent Owner’s RPI argument, Petitioner promptly sought to amend that disclosure to identify them as parent companies and avoid the dispute. Paper 9; *see also* Ex. 1056, 16:13–20 (Petitioner’s counsel representing that Petitioner does not dispute these entities are RPI). Contrary to Patent Owner’s argument, these facts do not evidence that Petitioner has sought to gain some advantage through its RPI disclosures. Indeed, there would seem to be no motive for Petitioner to try to “insulat[e] its parents,” as Patent Owner contends, because there is no allegation either entity was estopped or time-barred from seeking IPR as of the filing date of the

Petition.¹⁷ *See* Sur-reply 5. Accordingly, we accept Petitioner’s representation that it has acted in “good faith” to prepare and update its RPI disclosure and did not seek to intentionally conceal the status of Mylan Inc. and Viatris Inc. as RPI. Reply 5; *see also* Ex. 1056, 18:2–19:16.

We also agree with Petitioner that allowing Petitioner’s update while maintaining the original filing date of the Petition is in the interests of justice. The RPI disclosure in a Petition “serves to assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions.” *Adello Biologics LLC v. Amgen Inc.*, PGR2019-00001, Paper 11, 5–6 (PTAB Feb. 14, 2019) (precedential) (“*Adello*”) (quotation omitted); Patent Trial & Appeal Board Consolidated Trial Practice Guide November 2019 (“CTPG,” *available at* <https://www.uspto.gov/TrialPracticeGuideConsolidated>), 12. Because Mylan Inc. and Viatris Inc. were named in the original RPI disclosure, the Board was able to check for conflicts when the Petition was filed. Nor did Petitioner’s delay in identifying their corporate relatedness in this proceeding result in any undue prejudice to Patent Owner, as it appears that Patent Owner was already aware of that relationship. *See* Prelim. Resp. 13–14.

On the other hand, the result that Patent Owner seeks is the effective forfeiture of Petitioner’s IPR challenge. *See* Prelim. Resp. 14 (urging that

¹⁷ To the extent Patent Owner suggests that Petitioner’s actions in the parties’ district court litigation evidence that Petitioner sought to gain some improper advantage in its RPI disclosures here, we disagree. *See* Sur-reply 5. We are not sufficiently familiar with that litigation to draw any such conclusion and refuse to speculate regarding the motive for Petitioner’s strategies there.

“trial should not be instituted” because Mylan Inc. and Viatris Inc. were not identified as RPI in the Petition). But the Board’s precedential decision in *Adello* makes clear that “neither the statute nor the rule governing RPI disclosures is designed to award a patent owner such a windfall.” *Adello* at 3–4.

For these reasons, we exercise our discretion under 37 C.F.R. § 42.5(b) and (c)(3) and grant Petitioner’s motion, allowing it to update its RPI disclosure “while maintaining the original filing date of its Petition.” *See Adello* at 5. Petitioner has sufficiently identified Viatris Inc. and Mylan Inc. as RPI to this proceeding. *See* Paper 9, 2; Ex. 1056, 18:2–19:16; Reply 5. Thus, Patent Owner’s argument that institution should be denied because these entities have not been identified as RPI is moot.

VI. CONCLUSION

Based on the current record, we determine Petitioner has shown a reasonable likelihood that it will prevail in establishing that at least one claim of the ’786 patent is unpatentable. Accordingly, we institute review of all claims challenged on all of the grounds in the Petition. *See* CTPG 64.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim. Our view with regard to any conclusion reached in the foregoing analysis could change upon completion of the record.

VII. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 1–6 of the '786 patent based on the unpatentability challenges presented in the Petition;

FURTHER ORDERED that Petitioner's Motion to amend its mandatory notices is granted, Paper 9 will remain in the record, and the filing date of the Petition shall remain unchanged; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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