

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII LLC
Petitioner

v.

POZEN INC.
Patent Owner

Case No. IPR2015-01344
Patent No. 8,858,996

PRELIMINARY PATENT OWNER RESPONSE

37 C.F.R. § 42.107

(REDACTED VERSION)

Mail Stop “PATENT BOARD”

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. BACKGROUND	3
III. LEVEL OF ORDINARY SKILL IN THE ART	6
IV. CLAIM INTERPRETATION	7
A. The Petition Incorrectly Interprets “Inhibited/Inhibits”	7
B. The Petition Incorrectly Interprets “Acid Inhibitor”	8
C. All Remaining Terms	12
V. THE BOARD SHOULD DENY CFAD’S PETITION BECAUSE IT FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD OF SUCCESS	12
A. Ground 1: Petitioner Has Not Established a Reasonable Likelihood that Claims 1-19 Are Obvious over Goldman in View of Remington in Further View of Lindberg	12
B. Ground 2: Petitioner Has Not Established a Reasonable Likelihood that Claims 1-19 Are Obvious over Gimet in view of Goldman and Lindberg	19
C. The Petition Fails To Demonstrate a Motivation To Combine or a Reasonable Expectation of Success	22
D. Ground 3: Petitioner Has Not Established a Reasonable Likelihood that Claims 1-19 Are Anticipated by Plachetka	29
1. The Claims of the ’996 Patent Are At Least Entitled to the Same Filing Date as the ’216 Application	30
a. The ’996 Patent Claims Provide For Coordinated Release of Esomeprazole and Naproxen	33

TABLE OF CONTENTS
(continued)

	Page
b. The '996 Patent Claims Are Adequately Described by the Specification of the '216 Application.....	35
c. Coatings that “Inhibit” Release Have Written Description Support in the '216 Application	36
2. The '216 Application Is Not Prior Art.....	38
E. Petitioner Fails to Offer Evidence Refuting Objective Indicia of Nonobviousness.....	38
1. Long Felt But Unresolved Need	43
2. Surprising and Unexpected Results	44
3. Licensing.....	46
4. Copying.....	46
VI. THE BOARD SHOULD DENY CFAD’S PETITION BECAUSE IT WAS FILED FOR AN IMPROPER PURPOSE.....	47
VII. CONCLUSION.....	54

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re Abbott Diabetes Care Inc.</i> , 696 F.3d 1142 (Fed. Cir. 2012)	11
<i>Ariad Pharm., Inc. v. Eli Lilly & Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc)	30
<i>Beckman Instruments, Inc. v. LKB Produkter AB</i> , 892 F.2d 1547 (Fed. Cir. 1989)	28
<i>Bumble Bee Foods, LLC v. Kowalski</i> , IPR2014-00224, Paper No. 18 (P.T.A.B. June 5, 2014)	20
<i>In re Chu</i> , 66 F.3d 292 (Fed. Cir. 1995)	30
<i>Cisco Sys., Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper No. 12 (P.T.A.B. Aug. 29, 2014)	40, 41, 42
<i>Coalition For Affordable Drugs V LLC v. Biogen IDEC Int’l GmbH</i> , IPR2015-01086, Paper No. 11 (P.T.A.B. July 3, 2015)	48
<i>Coalition For Affordable Drugs VI LLC v. Celgene Corp.</i> , IPR2015-01169, Paper No. 18 (P.T.A.B. Sept. 2, 2015)	52
<i>Consumer Watchdog v. Wis. Alumni Research Found.</i> , 753 F.3d 1258 (Fed. Cir. 2014)	49
<i>Crocs, Inc. v. Int’l Trade Comm’n</i> , 598 F.3d 1294 (Fed. Cir. 2010)	39
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.</i> , 676 F.3d 1063 (Fed. Cir. 2012)	40
<i>Eiselstein v. Frank</i> , 52 F.3d 1035 (Fed. Cir. 1995)	36

<i>Excelsior Med. Corp. v. Lake</i> , IPR2013-00494, Paper No. 10 (P.T.A.B. Feb. 6, 2014).....	17
<i>Fid. Nat’l Info. Servs., Inc. v. DataTreasury Corp.</i> , IPR2014-00489, Paper No. 9 (P.T.A.B. Aug. 13, 2014)	41, 42
<i>In re Haruna</i> , 249 F.3d 1327 (Fed. Cir. 2001)	28
<i>Heart Failure Techs., LLC v. Cardiokinetix, Inc.</i> , IPR2013-00183, Paper No. 12 (P.T.A.B. July 31, 2013)	20
<i>In re Huai-Hung Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	39, 40
<i>Hulu LLC v. Intertainer, Inc.</i> , IPR2014-01456, Paper No. 8 (P.T.A.B. Mar. 6, 2015)	16
<i>In re Kaslow</i> , 707 F.2d 1366 (Fed. Cir. 1983)	36
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	20
<i>McGinley v. Franklin Sports, Inc.</i> , 262 F.3d 1339 (Fed. Cir. 2001)	46
<i>Micron Tech., Inc. v. Bd. of Trs. of the Univ. of Ill.</i> , IPR2013-00005, Paper No. 54 (P.T.A.B. Mar. 10, 2014)	44
<i>Moses Lake Indus., Inc. v. Enthone, Inc.</i> , IPR2014-00243, Paper No. 6 (P.T.A.B. June 18, 2014)	20
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008)	39
<i>Panduit Corp. v. Dennison Mfg. Co.</i> , 810 F.2d 1561 (Fed. Cir. 1987)	38
<i>In re Payne</i> , 606 F.2d 303 (C.C.P.A. 1979)	28

<i>PowerOasis, Inc. v. T-Mobile USA, Inc.</i> , 522 F.3d 1299 (Fed. Cir. 2008)	30
<i>Prism Pharma Co. v. Choongwae Pharma Corp.</i> , IPR2014-00315, Paper No. 14 (P.T.A.B. July 8, 2014)	17
<i>Purdue Pharma LP v. Faulding Inc.</i> , 230 F.3d 1320 (Fed. Cir. 2000)	30
<i>In re Rouffet</i> , 149 F.3d 1350 (Fed. Cir. 1998)	46
<i>Santarus, Inc. v. Par Pharm., Inc.</i> , 694 F.3d 1344 (Fed. Cir. 2012)	25
<i>SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.</i> , 242 F.3d 1337 (Fed. Cir. 2001)	11
<i>Stratoflex, Inc. v. Aeroquip Corp.</i> , 713 F.2d 1530 (Fed. Cir. 1983)	39, 40
<i>Tec Air, Inc. v. Denso Mfg. Mich. Inc.</i> , 192 F.3d 1353 (Fed. Cir. 1999)	28
<i>Tronzo v. Biomet, Inc.</i> , 156 F.3d 1154 (Fed. Cir. 1998)	33
<i>TRW Auto. US LLC v. Magna Elecs. Inc.</i> , Nos. IPR2014-00293 & IPR 2014-00294, Paper No. 19 (P.T.A.B. July 1, 2014)	20
<i>Vas-Cath Inc. v. Mahurkar</i> , 935 F.2d 1555 (Fed. Cir. 1991)	30
<i>Zetec, Inc. v. Westinghouse Elec. Co.</i> , IPR2014-00384, Paper No. 10 (P.T.A.B. July 23, 2014)	49
Statutes	
35 U.S.C. § 112	30
35 U.S.C. § 120	30

35 U.S.C. § 311(a)	49, 53
35 U.S.C. § 313	1
35 U.S.C. § 314(a)	2, 49, 53
35 U.S.C. § 316(b)	49
35 U.S.C. § 325(d)	16, 17

Other Authorities

37 C.F.R. § 42.6(a)(3)	40
37 C.F.R. § 42.107	1
153 Cong. Rec. E774 (Apr. 18, 2007)	50
157 Cong. Rec. S5319-03 (Sept. 6, 2011)	50
157 Cong. Rec. S5411 (Sept. 8, 2011)	50
157 Cong. Rec. S952 (Feb. 28, 2011)	50
H.R. Rep. No. 112-98, pt. 1 (2011)	50
S. Rep. No. 110-259 (2008)	50

TABLE OF EXHIBITS

EX. NO.	DESCRIPTION
2001	License Agreement between Patent Owner Pozen Inc. and exclusive licensee Horizon Pharma, Inc.
2002	Norman & Hawkey, <i>What you need to know when you prescribe a proton pump inhibitor</i> , Frontline Gastroenterology, 1-7 (2011) (“Norman 2011”)
2003	Comprehensive Pharmacy Review, Chapter 17: Drug Metabolism, Prodrugs, and Pharmacogenetics, 398-420 (Leon Shargel et al. eds., 2010) (“Shargel 2010”)
2004	Cederberg et al., <i>Omeprazole: Pharmacokinetics and Metabolism in Man</i> , Scand. J. of Gastroenterology 24:33-40 (1989) (“Cederberg”)
2005	File History of U.S. Patent No. 6,926,907 (“the ’907 patent”)
2006	<i>New Oxford American Dictionary</i> , p. 894 (Oxford Univ. Press, 3rd ed. 2010)
2007	<i>The American Heritage College Dictionary</i> , p. 699 (Houghton Mifflin Co., 3rd ed. 1997)
2008	Wolfe et al., <i>Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs</i> , New England Journal of Medicine, 340(24):1888-99 (1999) (“Wolfe”)
2009	Stedman & Barclay, <i>Review article: comparison of the pharmacokinetics, acid suppression and efficacy of proton pump inhibitors</i> , Aliment Pharmacol. Ther. 14:963-78 (2000)
2010	Bell & Hunt, <i>Progress with Proton Pump Inhibition</i> , Yale J. Biology & Med., 65:649-57 (1992)
2011	Sachs et al., <i>Review article: the control of gastric acid and Helicobacter pylori eradication</i> , Aliment Pharmacol. Ther. 14:1383-401 (2000)
2012	Letter from Donna Griebel, Food and Drug Administration to Paul Ossi, Pozen, Inc. (Nov. 6, 2008)
2013	Segal, <i>Has Patent, Will Sue: An Alert to Corporate America</i> , N.Y. Times (July 13, 2013), available at http://www.nytimes.com/2013/07/14/business/has-patent-will-sue-an-alert-to-corporate-america.html?_r=1 (“NY Times”)

2014	Walker & Copeland, <i>New Hedge Fund Strategy: Dispute the Patent, Short the Stock</i> , Wall Street Journal (Apr. 7, 2015), available at http://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408 (“WSJ”)
2015	La Roche, <i>Kyle Bass’ war against the US pharmaceutical industry has officially begun</i> , Business Insider (Feb. 10, 2015), available at http://www.businessinsider.com/kyle-bass-files-first-ipr-petition-2015-2 (“Bus. Insider”)
2016	Hayman Capital Management, L.P., Form ADV Part 2A Brochure (June 1, 2015) (“ADV”)
2017	America Invents Act, 157 Cong. Rec. S5319-03 (2011)
2018	H.R. Rep. No. 112-98, pt. 1 (2011)
2019	157 Cong. Rec. S5402-43 (Sept. 8, 2011)
2020	153 Cong. Rec. E773-75 (Apr. 18, 2007)
2021	112 Cong. Rec. S936-53 (Feb. 28, 2011)
2022	S. Rep. No. 110-259 (2008)
2023	<i>Kyle Bass Continues Abuse of Patent Challenge System</i> , Biotechnology Industry Organization (Sept. 3, 2015), available at https://www.bio.org/media/press-release/kyle-bass-continues-abuse-patent-challenge-system (“Bio Statement 1”)
2024	Quinn, <i>Senator Coons – Patents are about the American Dream</i> , IPWatchdog.com (Mar. 5, 2015), available at http://www.ipwatchdog.com/2015/03/05/senator-coons-patents-are-about-the-american-dream/id=55442/ (“IPWatchdog”)
2025	<i>Bio Statement Following Kyle Bass’ IPR Petition</i> , Biotechnology Industry Organization (Feb. 11, 2015), available at https://www.bio.org/media/press-release/bio-statement-following-kyle-bass-ipr-petition-0 (“Bio Statement 2”)

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107, Horizon Pharmaceuticals, Inc. (“Horizon”) and Pozen Inc. (“Pozen”) (collectively, “Patent Owner”)¹ submit this Patent Owner’s Preliminary Response (“Preliminary Response”) to the Petition for *Inter Partes* Review (“Petition”) of claims 1-19 of U.S. Patent No. 8,858,996 (“the ’996 patent”), filed by Coalition for Affordable Drugs VII LLC (“CFAD” or “Petitioner”). This Response is timely under 35 U.S.C. § 313 and 37 C.F.R. § 42.107 and is filed within three months of the June 19, 2015 mailing date of the Notice of Filing Date Accorded to Petition (Paper No. 4).

I. INTRODUCTION

The Petition seeking *inter partes* review of the ’996 patent should be denied. The Petition fails to demonstrate a reasonable likelihood that any of the challenged claims are obvious. The Petition fails to provide any motivation to combine references with a reasonable expectation of success, and asserts substantially the same grounds of unpatentability that were asserted by the Examiner during prosecution and overcome by the Patent Owner. Significantly, the Petition fails to address the objective indicia of nonobviousness, even though hornbook law states

¹ As explained in Patent Owner’s Mandatory Notices, Paper No. 7, Pozen is the assignee of the ’996 patent and Horizon is its exclusive licensee.

that such evidence must *always* be considered and is often the most probative. The Petition also wrongly argues that a prior parent application constitutes anticipatory prior art.

In addition to the present petition, the Petitioner has filed three additional petitions targeting patents that, like the '996 Patent, cover Patent Owner's product, Vimovo.² These Petitions are among the 32 petitions for *inter partes* review filed by eleven related shell companies (Coalition For Affordable Drugs I-XI)³ against patents held by innovator pharmaceutical companies. The goal of filing these petitions is to manipulate the stock prices of the targeted pharmaceutical companies and generate profits for the Petitioner and his investors. This misuse of the *inter partes* review process should not be encouraged. In order to preserve the Office's resources and stem this abusive practice, the Board should exercise its discretion under 35 U.S.C. § 314(a) to deny institution of CFAD's Petition.

² IPR2015-01241; IPR2015-01680; IPR2015-01718.

³ Coalition for Affordable Drugs XII – XV have also been registered with the SEC, but as of the date of this Preliminary Response have not filed any petitions.

II. BACKGROUND

Non-steroidal anti-inflammatory drugs (“NSAIDs”) are valuable agents in the treatment of arthritis and other musculoskeletal disorders and are one of the most widely used classes of drugs in the United States. The use of NSAIDs, however, has been associated with mucosal injury to the upper gastrointestinal (GI) tract, including the development of peptic ulcer disease, upper gastrointestinal hemorrhage, and perforation. Vimovo® is a unique drug product specifically designed to reduce the potential for gastric mucosal tissue damage due to NSAID use. Vimovo consists of a delayed-release, enteric-coated NSAID core (naproxen) surrounded by an immediate-release acid inhibitor (esomeprazole magnesium). The acid inhibitor is released before the NSAID, allowing its gastroprotective effects to take hold before naproxen is released, thus reducing the potential for gastric damage.

The '996 patent is one of nine patents listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) that cover Vimovo.⁴ As described in more detail below, the '996 patent claims

⁴ Vimovo is also protected by U.S. Patent No. 6,926,907, at issue in IPR2015-01241 (filed by Petitioner); U.S. Patent No. 8,557,285, at issue in IPR2015-00802; U.S. Patent No. 8,852,636, at issue in IPR2015-1680 (filed by

pharmaceutical compositions that provide for coordinated release, “*i.e.*, for the sequential release of acid inhibitor followed by analgesic.” (Ex. 1001 at 6:27-30.) The pharmaceutical compositions include an immediate-release acid inhibitor, esomeprazole, and a delayed-release NSAID, naproxen, within a single oral dosage form that reduce the risk of GI injury arising from NSAID therapy. (*Id.* at 1:25-31.) The ’996 patent also claims methods of treating a patient for pain or inflammation with said pharmaceutical compositions.

Esomeprazole, the immediate-release acid inhibitor in Vimovo, is a proton pump inhibitor (“PPI”). In contrast to Vimovo’s immediate-release esomeprazole, it was—and remains—widely accepted that PPIs must be administered with an enteric coating to protect the drug from gastric acid degradation. (Norman 2011, Ex. 2002 at 1.) For example, in 2010, Petitioner’s declarant, Dr. Leon Shargel, wrote that “[e]nteric coated formulations can protect acid-sensitive drugs as they pass through the acidic environment of the stomach. . . . [O]meprazole [a PPI is an] example[] of acid-sensitive agents that are available as enteric-coated preparations.” (Shargel 2010, Ex. 2003 at 15.) While this enteric coating protects

Petitioner) and IPR2015-01774; U.S. Patent No. 8,945,621, at issue in IPR2015-01718 (filed by Petitioner) and U.S. Patent Nos. 5,714,504, 5,900,424, 6,369,085, 7,411,070, and 7,745,466.

acid-labile PPIs such as esomeprazole from acid degradation, it also reduces the PPI's rate of absorption into the systemic circulation. (Cederberg 1989, Ex. 2004 at 6-7.)

No prior art disclosed, taught, or suggested pharmaceutical compositions providing coordinated release of a delayed-release NSAID naproxen and an immediate-release acid inhibitor esomeprazole, as claimed in the '996 patent. Indeed, the '996 patent issued over several references cited by the Petitioner, including Goldman, Lindberg, and Plachetka. In the Notice of Allowance for the parent of the '996 patent, the Examiner correctly recognized that Goldman, was one of "the closest prior art [references] of record." (3/29/05 '907 Notice of Allowance, Ex. 2005 at 45.) Petitioner does not address why Goldman or any of the other references thoroughly considered by the Examiner warrants reconsideration by the Board now, other than to assert that the '996 patent "was not substantively examined." (Pet. at 8.) Petitioner's critique of the Patent Office is unwarranted and there is nothing in the '996 file history to suggest that it was not fully and properly examined prior to issuance. The Examiner correctly recognized that the '996 patent's claimed inventions are not taught or suggested by the prior art.

III. LEVEL OF ORDINARY SKILL IN THE ART

Patent Owner proposes the following definition of a person of ordinary skill in the art (“POSA”): “a person with at least a graduate degree in pharmacy, chemistry, chemical engineering, pharmaceuticals, or a comparable field, and some relevant pharmaceutical formulation work experience in industry.” While that definition is similar to the first definition provided by the Petitioner, *i.e.*, “a pharmacist, medical doctor, or pharmaceutical scientist having a doctor of medicine degree, a doctor of pharmacy degree, or a Ph.D. degree, or equivalent training or degree, and at least two years of practical experience or clinical research in pharmaceutical formulations,” (Pet. at 9 (citing Ex. 1003, ¶ 53)), the Petition’s definition of a POSA does not extend to a person having a graduate degree in chemistry or chemical engineering.

Petitioner’s alternative definition also misses the mark. Petitioner describes the “alternative” POSA as “a pharmacologist or pharmacokineticist having a Ph.D. degree or equivalent training or degree and at least two years of practical experience or clinical research in pharmacology or pharmacokinetics.” (*Id.*) The study of pharmacokinetics is concerned with drug absorption, bioavailability, distribution, metabolism, and excretion. The disciplines of pharmaceutical formulation and pharmacokinetics are not co-extensive and petitioner fails to

distinguish or explain how a POSA from either discipline would understand and interpret the prior art.

Patent Owner agrees with Petitioner that the definition of POSA should be considered at the time of the invention of the '996 Patent, June 1, 2001. (*Id.*)

IV. CLAIM INTERPRETATION

A. The Petition Incorrectly Interprets “Inhibited/Inhibits”

Patent Owner agrees with Petitioner that “inhibits” should be given its ordinary meaning, but disagrees with Petitioner’s definition of that plain meaning. The claims recite “inhibits” in the context of “release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher.” (Ex. 1001, Claim 1 at 21:33-35.) The ordinary meaning of “inhibits” applied within the context of the specification and claims is that the coating prevents, hinders, or restrains the release of NSAID. This ordinary meaning construction is derived directly from dictionary definitions. (Ex. 2006 at 3 (“hinder, restrain, or prevent (an action or process)”); Ex. 2007 at 3 (“[t]o hold back; restrain.”).)

Petitioner’s construction, which inserts the phrase “to slow down,” is imprecise because it implies a preexisting ongoing action that is being slowed down. The claims, however, refer to inhibiting release from the outset—*i.e.*, it is not a preexisting action that is being slowed down. In this context, the more appropriate ordinary meaning for “inhibits” is prevents, hinders, or restrains.

B. The Petition Incorrectly Interprets “Acid Inhibitor”

Although Petitioner does not identify the phrase “acid inhibitor” as a term for construction, Petitioner relies on an incorrect definition of “acid inhibitor” in Ground 2. “Acid inhibitor” is explicitly defined in the specification: “[t]he term ‘acid inhibitor’ refers to agents that inhibit gastric acid secretion and increase gastric pH.” (Ex. 1001 at 3:38-40.) In Ground 2, Petitioner mistakenly characterizes the prostaglandin misoprostol as an “acid inhibitor.” (Pet. at 28.) The broadest reasonable interpretation of “acid inhibitor” in light of the ’996 specification excludes prostaglandins. Expanding the scope to include prostaglandins, as suggested by Petitioner, is simply not supported by the specification or file history; such an interpretation would not be reasonable.

Petitioner provides no rationale why the express definition should be disregarded and provides no basis for its interpretation, other than citing to the Shargel Declaration, without any further explanation. The ’996 specification plainly distinguishes PPIs, describing them as “acid inhibitors,” from synthetic prostaglandins, describing them as “cytoprotective agents.” (*Compare* Ex. 1001 at 1:53-57 (“In general, more potent and longer lasting acid inhibitors, such as proton pump inhibitors, are thought to be more protective during chronic administration of NSAIDs than shorter acting agents, e.g., histamine H₂ receptor antagonists”)) *with id.* at 2:57-63 (“Other attempts to produce an NSAID therapy with less

gastrointestinal toxicity have involved the concomitant administration of a cytoprotective agent” including ArthrotecTM which “contains misoprostol (a cytoprotective prostaglandin) and the NSAID diclofenac.”).

Furthermore, the specification provides examples of acceptable acid inhibitors, listing specific PPIs. (Ex. 1001 at 3:40-62.) And as noted above, the specification distinguishes Arthrotec (a combination of misoprostol, a cytoprotective prostaglandin, and diclofenac, an NSAID) from the claimed invention. (Ex. 1001 at 2:57-63.)

The file history of the parent '907 patent also supports an interpretation of “acid inhibitor” that excludes prostaglandins. Specifically, during prosecution, an “attempt was made to restrict certain claims to either dosage forms containing H2 blockers or [PPIs].” (11/22/04 '907 Amendment and Response, Ex. 2005 at 62.) Furthermore, there is no evidence in the '907 file history that the Examiner ever considered synthetic prostaglandin art to be particularly relevant to the pending claims. The Examiner never rejected the pending claims of the '907 patent over any reference disclosing misoprostol or any other prostaglandin. Indeed, the Examiner characterized the closest prior art as Goldman and Depui, each of which relates to H1 or H2-blockers and PPIs, respectively. (3/29/05 '907 Notice of Allowance, Ex. 2005 at 45.)

To be sure, original claim 2 of the parent '907 patent, which depended from claim 1, recited that the “acid inhibitor is selected from: a proton pump inhibitor and an H2 blocker.” (5/31/02 '907 Claims, Ex. 2005 at 597.) From the doctrine of claim differentiation, it can be inferred that claim 1's recitation of “acid inhibitor” is thus broader in scope than a PPI and an H2 blocker. However, that doesn't necessitate that “acid inhibitor” include prostaglandins, which are cytoprotective agents and are clearly distinguished from “acid inhibitors.” Rather other known “acid inhibitors” include H1-blockers, as taught by, *e.g.*, Goldman, and muscarinic anticholinergic agents, such as mepenzolate bromide and glycopyrrolate, each of which, *inter alia*, reduce gastric acid secretion and are approved for the treatment of peptic ulcers, such as gastric ulcers and duodenal ulcers.

The only prostaglandin reference cited in the Petition, Gimet, does not describe the disclosed prostaglandin as an “acid inhibitor.” Instead, Gimet describes that the prostaglandin is administered “for its beneficial therapeutic value in preventing and or inhibiting the incidence of NSAID induced ulcers.” (Gimet, Ex. 1006 at 12:14-19.) Gimet's description of a prostaglandin is consistent with the description of prostaglandin in the '996 patent as a cytoprotective agent.

Given that the Board is required to apply the “broadest *reasonable* construction,” the Board should construe “acid inhibitor” consistent with the '996 specification to mean “an agent that inhibits gastric acid secretion and increases

gastric pH,” and excludes prostaglandins. *See In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1149 (Fed. Cir. 2012) (“Although the PTO emphasizes that it was required to give all claims their broadest reasonable construction, . . . this court has instructed that any such construction be consistent with the specification, and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.”) (internal citation omitted).

Further, to the extent that a prostaglandin may be considered an acid inhibitor, the patent has disclaimed formulations that combine an NSAID with a cytoprotective prostaglandin. As explained above, the specification of the patent distinguished the claimed invention from formulations such as Arthrotec that involve the concomitant administration of a prostaglandin with an NSAID. (Ex. 1001 at 2:57-63.) By distinguishing the invention from prior art use of prostaglandins, the patent has disclaimed these formulations and they do not fall within the scope of the claims. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (“Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.”).

C. All Remaining Terms

Patent Owner agrees that all remaining terms should be afforded their broadest reasonable construction, consistent with how the '996 specification would be interpreted by a POSA in June 2001.

V. THE BOARD SHOULD DENY CFAD'S PETITION BECAUSE IT FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD OF SUCCESS

Each of the proposed grounds in the Petition alleges that the challenged claims are unpatentable as obvious. As discussed below, each ground is legally deficient and should be denied.

A. Ground 1: Petitioner Has Not Established a Reasonable Likelihood that Claims 1-19 Are Obvious over Goldman in View of Remington in Further View of Lindberg

Petitioner cannot establish a reasonable likelihood that it would prevail on Ground 1. Ground 1 attempts to combine Goldman, which relates to H1 or H2-blockers and PPIs, with Remington, which describes pharmaceutical formulation techniques, in further view of Lindberg, which relates to enteric-coated, delayed-release esomeprazole.

With respect to the Goldman reference, Petitioner relies on substantially the same arguments that were made during prosecution of the application resulting in the parent '907 patent. Applicants cited the Goldman reference during the prosecution of the '907 patent as reference AB2 in an Information Disclosure

Statement filed on April 24, 2003. (4/24/03 '907 Information Disclosure Statement, Ex. 2005 at 554.) The Examiner initially rejected the then-pending claims as anticipated over Goldman because:

The [Goldman] reference clearly shows a pharmaceutical composition comprised of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID). The particular H2 blockers and proton pump inhibitors are the same as applicants'. The effective dosage amounts are the same as applicants'. The composition of Goldman would therefore inherently impart the same effects on the gastric ph as applicants'. Particular dosage forms including capsules are shown

(4/22/04 '907 Office Action Summary, Ex. 2005 at 96.) In response, Applicant argued that Goldman failed to teach the coordinated release of the active ingredients as claimed in the pending application:

All of Applicant's claims have requirements not only with respect to the type of active ingredients present in compositions or methods, but also with respect to the way in which the active ingredients are delivered in relation to one another. . . . [T]hese characteristics are not disclosed or suggested [by] Goldman. . . . By preventing NSAID from being released until the surrounding environment becomes more basic, the pharmaceutical composition defined in claim 1 provides for safer delivery.

(7/22/04 '907 Response to Office Action, Ex. 2005 at 86.) In the subsequent Office Action, the Examiner maintained the rejection because "[t]here is nothing in

claim 1 that enables the release that applicant is referring to. . . . Amending claim 1 to incorporate a polymer coating as set forth in claims 24 and 51-54 would be given favorable consideration in overcoming the prior art rejection.”⁵ (10/20/04 ’907 Office Action Summary, Ex. 2005 at 74.)

Applicant filed a Request for Continued Examination, and amended claims 1-3 and 12-20, among others “to comply with suggestions in the Office Action and to emphasize characteristics that Applicants believe are central to their invention:”

Amended claims require that NSAID be surrounded by a coating that prevents its release from the dosage form unless the pH of the surrounding medium is 3.5 or higher, and that at least a portion of the acid inhibitor in compositions is not surrounded by an enteric coating and is released regardless of whether the pH is above 3.5 or below 3.5. Amendments were introduced into claims 12-14 to indicate that that the recited tablet dosage forms contain a single core with NSAID that

⁵ Then-pending claim 51 recited:

The pharmaceutical composition of any one of claims 1-11, wherein said NSAID is surrounded by an enteric coating that does not dissolve until the pH of the surrounding medium is 3.5 or higher, and said acid inhibitor is either not surrounded by an enteric coating or it surrounded by an enteric coating that dissolves when the surrounding medium is at a pH below 3.5.

(10/17/03 ’907 Preliminary Amendment, Ex. 2005 at 123.)

is surrounded by the coating that prevents drug release and that acid inhibitor is in separate outer layers that are not enterically coated (claim 12). Other amendments indicate that the outer layers of the tablets do not contain NSAID (claim 13) and may be surrounded by a non-enteric film that allows for the release of acid inhibitor into a patient's stomach (claim 14). New claims 55-57 introduce these same requirements but refer back to claims 5-11 rather than to claim 1. The dependency of other claims was changed and an attempt was made to restrict certain claims to either dosage forms containing H2 blockers or proton pump inhibitors.

(11/22/04 '907 Amendment and Response, Ex. 2005 at 62.)

The Examiner allowed the amended claims, noting that Goldman failed to disclose the coordinated release element, which resulted in a safer delivery of the active agents. (3/29/05 '907 Notice of Allowance, Ex. 2005 at 45.)

In the Notice of Allowance for the '996 patent, the Examiner again emphasized the coordinated release aspect of the claimed inventions that are not taught by the prior art, including Goldman.

[T]he general state of the art is that solid oral dosage forms comprising proton pump inhibitors (PPIs) such as esomeprazole are enterically coated to prevent the acid sensitive PPI from being degraded by the acidic environment of the stomach before it can be absorbed. While some art teaches that enteric coatings need not be applied to dosage forms containing PPIs for oral administration like those of the instant claims, those prior art documents do not disclose a

combination dosage form as in the present claims of esomeprazole with naproxen. Prior art that discloses a combination of an NSAID such as naproxen enterically coat the naproxen and PPI portions of the dosage form. Compositions in which at least a portion of the esomeprazole is released regardless of the pH of the medium in combination with naproxen have been previously allowed (US 8,557,285). The instant claims are narrower, specifying dosages in milligrams or having a non-enteric film coat layer with esomeprazole that releases the esomeprazole to the stomach upon ingestion.

(7/24/14 Notice of Allowance, Ex. 1002 at 66.)

In response to the Examiner's statement of reasons for allowance, Applicant stated that "the identity of 'some art' referred to is not clear from the record, and the statement does not identify with particularity what art is being referenced. Moreover, Applicant is unaware of any prior art *'that teaches enteric coatings need not be applied to dosage forms containing PPIs for oral administration like those of the instant claims.'*" (9/9/14 Applicant's Response to Examiner's Statement of Reasons for Allowance, Ex. 1002 at 27) (emphasis in original omitted).)

Under 35 U.S.C. § 325(d), "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." The Board has exercised that authority to deny institution of an IPR based on art or arguments that were previously considered by an examiner during prosecution. *See, e.g., Hulu LLC v.*

Intertainer, Inc., IPR2014-01456, Paper No. 8 at 7-8 (P.T.A.B. Mar. 6, 2015); *Prism Pharma Co. v. Choongwae Pharma Corp.*, IPR2014-00315, Paper No. 14 at 12-13 (P.T.A.B. July 8, 2014); *Excelsior Med. Corp. v. Lake*, IPR2013-00494, Paper No. 10 at 20 (P.T.A.B. Feb. 6, 2014) (“The Board exercises its authority under 35 U.S.C. § 325(d) to deny this ground because the asserted prior art references and arguments were considered previously by the Office.”).

As the Examiner correctly concluded, Goldman does not disclose formulations with an immediate release acid inhibitor and a delayed release NSAID that would provide coordinated release. Nor does Goldman teach that coordinated release of an acid inhibitor with an NSAID is in any way desirable. Even if Goldman could be combined with Remington and Lindberg, the combination does not cure this deficiency.

Petitioner also fails to identify any specific passage in Remington supporting a motivation to combine the Goldman and Lindberg references. Petitioner makes a conclusory statement that Remington provides known techniques to prepare enteric and non-enteric coated tablets, but utterly fails to explain how a POSA would utilize Remington to modify either Goldman or Lindberg to arrive at the claimed inventions.

Significantly, both Lindberg and Remington teach away from the use of non-enteric coated esomeprazole. Lindberg teaches that esomeprazole must be enteric coated to protect it from the acidic environment of the stomach.

Granules and tablets [of esomeprazole] may be coated with an enteric coating which protects the active compound from acid catalyzed degradation as long as the dosage form remains in the stomach.

...

Soft gelatine capsules [of esomeprazole] may also be enteric-coated as described above.

...

[Hard gelatin] capsules [of esomeprazole] may be enteric-coated as described above.

(Lindberg, Ex. 1007 at 5:36-39, 5:48-50, 5:56-57.) Further, Example 13 of Lindberg describes how to prepare enteric coated tablets. (*Id.* at 12:12-43.)

Remington teaches that enteric coated tablet formulations are used with acid labile drug substances:

Enteric-Coated Tablets (ECT)-These are compressed tablets coated with substances that resist solution in gastric fluid but disintegrate in the intestine. Enteric coatings can be used for tablets containing drug substances which are inactivated or destroyed in the stomach, for those which irritate the mucosa, or as a means of delayed release of the medication.

(Remington, Ex. 1005 at 4.) As PPIs were well known in the art to be acid labile, Remington taught away from the use of a non-enteric coated PPI, such as esomeprazole.

The combination of Goldman, Lindberg and Remington does not teach coordinated release of an immediate-release esomeprazole with a delayed release naproxen. Petitioner has not carried its burden of establishing a reasonable expectation that it will succeed on any of its proposed Ground 1. Accordingly, this Ground should be denied in its entirety.

B. Ground 2: Petitioner Has Not Established a Reasonable Likelihood that Claims 1-19 Are Obvious over Gimet in view of Goldman and Lindberg

Ground 2 is based on a combination of Gimet, which relates to synthetic prostaglandins and more particularly, misoprostol, with Goldman and Lindberg, discussed above. Gimet describes a pharmaceutical composition comprising an NSAID core that may be enteric coated, surrounded by a layer of a synthetic prostaglandin, misoprostol. (Gimet, Ex. 1006 at 12:10-19.) Gimet does not state that the prostaglandin is capable of raising the gastric pH of a patient to at least 3.5. Furthermore, as explained above, “acid inhibitor” as understood in light of the specification of the ’996 patent excludes synthetic prostaglandins. Consequently, Gimet does not disclose a dosage form comprising an acid inhibitor in an amount effective to raise the gastric pH of a patient to at least 3.5.

In order to establish obviousness in view of the combination of Gimet, Goldman, and Lindberg, the Petition must set forth sufficiently articulated reasoning with rational underpinnings of why a person of ordinary skill in the art would have been motivated to combine the teachings of those references to derive the claimed subject matter and would have had a reasonable expectation of success in doing so. *Bumble Bee Foods, LLC v. Kowalski*, IPR2014-00224, Paper No. 18 at 25-26 (P.T.A.B. June 5, 2014). Petitions containing only general and conclusory statements regarding the reasons to combine or modify references have been denied by the Board. *See, e.g., Heart Failure Techs., LLC v. Cardiokinetix, Inc.*, IPR2013-00183, Paper No. 12 at 9 (P.T.A.B. July 31, 2013) (“Petitioner must show some *reason* why a person of ordinary skill in the art would have thought to combine *particular* available elements of knowledge, as evidenced by the prior art, to reach the claimed invention”) (emphasis in original); *TRW Auto. US LLC v. Magna Elecs. Inc.*, Nos. IPR2014-00293 & IPR 2014-00294, Paper No. 19 at 17 (P.T.A.B. July 1, 2014) (“[A]n analysis under 35 U.S.C. § 103(a) is objective and includes an explicit analysis requiring more than ‘mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007))); *Moses Lake Indus., Inc. v. Enthone, Inc.*, IPR2014-00243, Paper No. 6 at 20 (P.T.A.B. June 18, 2014) (“MLI must provide

more than conclusory expert testimony . . . and conclusory rationales to combine the teachings, to present a *prima facie* case of obviousness”) (emphasis in original).

Here, Petitioner alleges that both Gimet and Goldman are directed to pharmaceutical compositions comprising an NSAID and acid inhibitor, so a POSA would have considered their collective teachings. (Pet. at 28 (citing Ex. 1003, ¶¶ 236-237).) Even assuming that the synthetic prostaglandin of Gimet falls under the appropriate definition of “acid inhibitor,” this is still insufficient to support a finding of motivation to combine. Gimet and Goldman seek solutions to two entirely different problems. Gimet seeks a formulation that would reduce the gastric ulcers that are caused by chronic NSAID use. (Gimet, Ex. 1006 at 1:10–63.) By contrast, Goldman discloses a formulation that can be used to alleviate the discomfort associated with overindulgence of food and alcohol. (Goldman, Ex. 1004 at 1:10–16.) There is no teaching in Goldman that the disclosed formulations have any effect on NSAID-associated gastric ulcers. The Petition does not explain what properties the misoprostol of Gimet shares with the acid inhibitors of Goldman. The Petition provides no explanation as to why a POSA would formulate a PPI in an immediate release manner, *i.e.*, without an enteric coating. The Petition points to no evidence that the use of a non-enteric coated PPI would have been predicted to effectively raise gastric pH. Neither Gimet nor Goldman

disclose the coordinated release of an immediate-release acid inhibitor, as construed herein, with a delayed-release enteric coated NSAID. Further, Petitioner fails to identify any passage in Lindberg supporting a motivation to combine Gimet and Goldman.

As the foregoing demonstrates, the Petition cannot demonstrate a likelihood of success that the prior art combination of Gimet, Goldman, and Lindberg renders obvious the '996 patent because none of those references, either alone or in combination, provides any rationale for a unit dosage form with the specific structural features and functional properties that provide for coordinated delivery of an immediate-release esomeprazole and a delayed-release naproxen, as recited in the claims of the '996 patent. Ground 2 should be denied.

C. The Petition Fails To Demonstrate a Motivation To Combine or a Reasonable Expectation of Success

The Petition has not established a motivation to combine the references identified in Ground 1 and Ground 2, nor has it established an expectation of success in doing so. The claims of the '996 patent require a single dosage form that combines non-enteric coated esomeprazole with naproxen surrounded by a pH sensitive coating that inhibits its release. Together, these features result in coordinated (or sequential) release of the esomeprazole and naproxen. The references relied upon by Petitioner do not show a motivation to combine or an

expectation of success. Instead, these references and the prior art in general teach away from the construction of a dosage form combining non-enteric coated esomeprazole and naproxen surrounded by a pH sensitive coating in the claimed format to achieve coordinated release.

Dr. Shargel's declaration states that the prior art does not teach away from the use of uncoated PPIs. (Shargel Decl., Ex. 1003, ¶¶ 404-409.) This statement ignores the volumes of references teaching that PPIs are acid labile and must be protected from acidic environments, including a textbook Dr. Shargel, himself, authored and edited.

As Dr. Shargel's own pharmaceutical textbook, published in 2010, explains, the use of enteric coatings was, and still is, universally recognized in the art as the means for protecting PPIs in oral dosage forms from degradation by stomach acid. In his textbook, Dr. Shargel states, "Activation [of omeprazole] in the stomach prior to absorption can be prevented by the use of enteric-coated formulations." (Shargel 2010, Ex. 2003 at 17.) Dr. Shargel further states, "Enteric-coated formulations can protect acid-sensitive drugs as they pass through the acidic environment of the stomach. . . . [O]meprazole [is an] example[] of [an] acid-sensitive agent[] that [is] available as [an] enteric-coated preparation[]." (Shargel 2010, Ex. 2003 at 15.)

The need to enteric coat PPI formulations to protect the PPI from stomach acid was widely taught in the art as shown in the following exemplary listing of teachings:

[PPIs] are all acid-labile, so when administered orally ***they must be formulated in an enteric coating to protect them from rapid degradation in the stomach.*** They are rapidly absorbed in the duodenum.

(Stedman 2000, Ex. 2009 at 3 (emphasis added).)

As omeprazole is acid-labile, it is formulated as enteric-coated granules dispensed in a gelatine capsule. The granules release at an alkaline pH, allowing absorption of intact omeprazole into the circulation.

(Bell 1992, Ex. 2010 at 2 (emphasis added).)

All the proton pump inhibitors have a similar core structure, a substituted pyridyl methylsulfinyl benzimidazole. . . . ***As a class, these drugs are therefore acid-unstable, requiring protection against gastric acidity for oral formulation*** and requiring reconstitution for i.v. administration.

(Sachs 2000, Ex. 2011 at 5 (emphasis added).)

The Pilbrant reference, on which Dr. Shargel relies, also teaches away from using an uncoated esomeprazole. Pilbrant plainly states that an enteric coated solid dosage form “offers the best possibilities.” (Pilbrant, Ex. 1048 at 3.) Pilbrant

expressly “ruled out” the non-enteric coated solid dosage form for PPIs as an option after a pilot bioavailability study showed that more than half of a nonenteric coated dosage form is degraded in the stomach. (*Id.* at 2.) Pilbrant states that “a conventional, non-buffered, oral dosage form of omeprazole will have a low systemic bioavailability owing to preabsorption degradation of omeprazole in the stomach.” (*Id.* at 5.)

As Pilbrant expressly “ruled out” oral unit dosage forms with non-enteric coated PPIs as an option, it teaches away from using dosage forms containing non-enteric coated PPIs and demonstrates that a POSA would not have had a reasonable expectation of success with a dosage form utilizing a non-enteric coated PPI. Indeed, the Federal Circuit has evaluated the Pilbrant reference in a prior litigation involving PPI formulations and found that it “teaches away” from “conventional oral dosage forms such as tablets, capsules, or granules with non-enteric coated PPIs” and does not render them obvious. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1355 (Fed. Cir. 2012) (“Pilbrant explicitly ‘ruled out’ the third option—non-enteric coated conventional oral dosage forms such as tablets, capsules, or granules—because they degrade too quickly in the stomach to be absorbed in sufficient amounts to be effective. This disclosure would discourage a person of ordinary skill in the art from pursuing conventional oral dosage forms such as tablets, capsules, or granules with non-enteric coated PPIs,

and thus teaches away from such formulations. As a result, we hold that the district court erred by concluding that claims directed to such conventional dosage forms would have been obvious over Pilbrant”) (citation omitted).

In addition to Pilbrant, Dr. Shargel also cites to references by Clissold, Howden, Pritchard, and Tolman to argue that even if half of the PPI would be expected to degrade, a POSA would understand that remaining 50% of the PPI would be active and gradually increase its own bioavailability. (Shargel Decl., Ex. 1003, ¶¶ 400-403.) An examination of each of these references demonstrates the fallacy of Dr. Shargel’s argument.

First, Pilbrant states that the therapeutic effect of omeprazole on gastric acid secretion is a function of the AUC (area under the curve) of omeprazole in plasma. (Pilbrant, Ex. 1048 at 6.) This teaches away from a formulation in which nearly half of the dose is degraded in the stomach and does not reach circulation.

Clissold does not teach that a non-enteric coated, non-buffered omeprazole increases its own bioavailability because each successive dose increases pH and decreases degradation. Instead, Clissold notes that when omeprazole is administered daily in a buffered solution or in enteric-coated capsules for 5-7 days, the mean peak plasma concentration is elevated. Clissold then speculates a number of reasons why this could be the case; one, by improving its absorption through acid inhibition, and two, by saturation of enzymes responsible for the first-pass

metabolism of omeprazole. While Clissold does indicate that buffered, non-enteric coated omeprazole is absorbed more quickly, nowhere does Clissold suggest that quicker absorption would be desirable. Instead, Clissold notes the critical measurement for therapeutic purposes is AUC, and the amount of omeprazole in the plasma at any given point is irrelevant. (Clissold, Ex. 1047 at 22.)

Tolman describes a study comparing the pharmacokinetics of two different enteric-coated PPIs: omeprazole and lansoprazole. (Tolman, Ex. 1051 at 1.) While Tolman does show that levels of omeprazole in plasma were higher on the fifth day of daily administration of enteric-coated omeprazole than on the first, the study did not examine non-enteric coated omeprazole, nor suggest that with repeated dosing, non-enteric coated omeprazole would increase its own bioavailability.

Prichard does not teach that a non-enteric coated formulation of omeprazole would become therapeutically effective over time due to increased bioavailability. Instead, Prichard analyzed the pharmacokinetics of an enteric-coated dosage form of esomeprazole and did not consider whether a non-enteric coated dosage form would also show increased bioavailability over time. Nor did Prichard consider whether a non-enteric coated dosage form would become therapeutically viable due to increased bioavailability over time. In fact, Prichard teaches away from non-enteric-coated omeprazole by noting that “unprotected exposure to acidic gastric

contents results in inactivation of >50% of an oral dose.” (Prichard, Ex. 1050 at 1.)

Obviousness cannot be shown where “the art in any material respect taught away from the claimed invention.” *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (internal quotations and citation omitted). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant” *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999) (internal quotations and citation omitted).

Further, prior art as a whole must be enabling to support an obviousness determination. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989); *In re Payne*, 606 F.2d 303, 314 (C.C.P.A. 1979) (“References relied upon to support a rejection under 35 U.S.C. 103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public.”). Petitioner fails to provide any evidence that any of these references including Pilbrant, Clissold, Tolman, or Prichard would enable a POSA to make a dosage form containing a non-enteric coated PPI.

It should also be noted that FDA experts expressed doubt that Vimovo would provide a gastroprotective effect. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Petitioner's failure to address the voluminous number of references teaching that PPIs must be enteric coated and which negates any motivation to use a non-enterically coated form of a PPI, are incurable flaws in the Petition.

D. Ground 3: Petitioner Has Not Established a Reasonable Likelihood that Claims 1-19 Are Anticipated by Plachetka

In Ground 3, Petitioner asserts that the '996 claims are not supported by an earlier application, U.S. Patent Application No. 10/158,216 (the "'216 application" or "Plachetka publication"), and are therefore anticipated by the application.

Petitioner's argument is based on an improper, overly broad interpretation of the '996 Patent claims, but provides absolutely no analysis or support to justify such an interpretation. For the reasons set forth below, Ground 3 should be denied in its entirety.

1. The Claims of the '996 Patent Are At Least Entitled to the Same Filing Date as the '216 Application

Under 35 U.S.C. § 120, claims are granted the benefit of the filing date of an earlier-filed application unless the earlier application does not provide written description support for the later claims, as required by 35 U.S.C. § 112. *See* 35 U.S.C. § 120. *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995). The test for determining compliance with the written description requirement under 35 U.S.C. § 112, ¶ 1, is whether the original disclosure of the earlier-filed application reasonably would have conveyed to one with ordinary skill in the art that the inventor had possession the claimed subject matter at the time of the earlier-filed application. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). While the specification must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the claimed subject matter, as of the filing date of the earlier-filed application, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991), the specification need not contain precisely the same words as are found in the asserted claims. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008); *see also Purdue Pharma LP v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.”).

The '996 patent has priority to its provisional application 60/294,588 ("the '588 application"), filed on June 1, 2001, through non-provisional application 10/158,216 ("the '216 application") filed on May 31, 2002, published as 2003-0069255 ("the Plachetka publication") and issued as U.S. Patent No. 6,926,907 ("the '907 patent"), and continuation-in-part application 11/129,320 ("the '320 application"), issued as U.S. Patent No. 8,206,741 ("the '741 patent"). (Ex. 1001 at 1:7-21.) The '285 patent is a divisional of an abandoned application that was itself a divisional application of the '320 application. (*Id.*) Application 14/045,156 ("the '156 application") was filed as a continuation of application 13/215,855, and the application that ultimately issued as the '996 patent was filed as a continuation of the '156 application.

The relationship between the '588 application and the '996 patent is depicted below:



a. The '996 Patent Claims Provide For Coordinated Release of Esomeprazole and Naproxen

Petitioner suggests that under the broadest reasonable construction standard, the '996 Patent claims encompass esomeprazole/naproxen pharmaceutical compositions that do not have a coordinated or sequential release of the esomeprazole and naproxen. (Pet. at 50-51.) To satisfy the written description requirement, “the missing descriptive matter must necessarily be present in the [original] application’s specification such that one skilled in the art would recognize such a disclosure.” *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998). Petitioner utterly fails to provide any analysis as to how a POSA would understand the '216 application, and even fails to identify which claims it believes lack written description support.

Contrary to Petitioner’s unsupported assertion that none of the claims provides for coordinated release, claim 1 of the '996 patent recites a unit dosage form that provides for coordinated release of esomeprazole and naproxen. That coordinated release is a direct result of the claim limitations, which include “at least a portion of said esomeprazole is released regardless of pH of the medium,” and “release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher.” (Ex. 1001 at Claim 1.) The esomeprazole is immediately released in the stomach, regardless of pH. The release of the

naproxen is delayed until the pH of the surrounding medium is 3.5 or higher.

Claim 12, another independent claim, recites:

A pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising:

a core layer comprising naproxen, wherein said core layer has a coating that inhibits release of said naproxen from said core layer unless said dosage form is in a medium with a pH of 3.5 or higher; and

a layer comprising esomeprazole, wherein said layer is has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient.

(Ex. 1001 at Claim 12.) There is no question that the claim limitations provide for coordinated release with respect to the recited esomeprazole and naproxen elements.

Petitioner argues that because the phrase “coordinated release” is not expressly recited as a claim element, the claims are broad enough to cover unit dosage forms that do not exhibit a sequential release of esomeprazole and naproxen. (Pet. at 51.) Petitioner, however, fails to explain how a POSA, reading the claims in light of the specification, would understand that the claims are broad enough to cover uncoordinated release. As described above, the claims describe the initial, immediate release of esomeprazole, and the delayed release of naproxen. Petitioner also argues that because “a portion” of esomeprazole and

naproxen can be released simultaneously, there can be no coordinated release. (*Id.*) Petitioner cites no support in the specification or file history for this interpretation. Directly contrasting Petitioner's position, the Examiner specifically acknowledged that the "coordinated release" aspect of the claimed inventions allowed for "at least a portion of the esomeprazole" to be released immediately. (7/24/14 Notice of Allowance, Ex. 1002 at 66.)

b. The '996 Patent Claims Are Adequately Described by the Specification of the '216 Application

Petitioner also argues that because only a portion of naproxen is subject to an "inhibited" release, the claims of the '996 patent have no written description support in the '216 application. Again, the key inquiry is whether a POSA would recognize that the disclosure of the '216 application supports the claims of the '996 patent. Petitioner, however, provides absolutely no analysis or support for its argument, failing to explain how a POSA would view the '216 disclosure.

The '216 application describes unit dosage forms that combine: "a) an agent that actively raises intragastric pH to levels associated with less risk of NSAID-induced ulcers; and b) an NSAID that is specially formulated to be released in a coordinated way that minimizes the adverse effects of the NSAID on the gastroduodenal mucosa." (Ex. 1008 at [0010].) This is precisely what the '996 claims teach.

“In order to determine whether a prior application meets the ‘written description’ requirement with respect to later-filed claims, the prior application need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the earlier date the applicant had invented what is now claimed.” *Eiselstein v. Frank*, 52 F.3d 1035, 1038-39 (Fed. Cir. 1995); *see also In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983) (“The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.”). As described above, one of skill in the art would have recognized the disclosure of the ’216 patent fully supported the ’996 claims with respect to the release of naproxen.

c. Coatings that “Inhibit” Release Have Written Description Support in the ’216 Application

Relying on an incorrect construction of the term “inhibit,” Petitioner argues that the ’996 claims are broad enough to encompass enteric coatings that merely decrease the release rate of naproxen, rather than prevent the release of naproxen until a pH of 3.5 or higher is reached. (Pet. at 51.) As above, Petitioner provides no analysis, citations to evidence, or identification of specific claims at issue.

As discussed above in Section IV.A., the correct interpretation of “inhibit” is “prevents, hinders, or restrains.” A POSA would understand that the ’216 application plainly describes coatings that inhibit release of the naproxen.

A unit dosage form of the present invention preferably provides for coordinated drug release, in a way that elevates gastric pH and reduces the deleterious effects of the NSAID on the gastroduodenal mucosa, i.e., the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the GI tract has risen. In a preferred embodiment, the unit dosage form is a multilayer tablet, having an outer layer comprising the acid inhibitor and an inner core which comprises the NSAID. In the most preferred form, coordinated delivery is accomplished by having the inner core surrounded by a polymeric barrier coating that does not dissolve unless the surrounding medium is at a pH of at least 3.5, preferably at least 4 and more preferably, at least 5.

(Ex. 1008 at [0013].)

A coordinated delivery dosage may be used to provide fast release of an acid inhibitor, a proton pump inhibitor, omeprazole which raises the pH of the gastrointestinal tract to above 4, and the delayed release of a nonsteroidal anti-inflammatory drug, naproxen sodium. Omeprazole granules modify the pH of the stomach such that the drug readily dissolves and is absorbed in the stomach without significant degradation. The typical effective amount of omeprazole in the dosage form may vary from 5 mg to 50 mg. The release of naproxen sodium is delayed by enteric coating.

(Ex. 1008 at [0082].)

2. The '216 Application Is Not Prior Art

As discussed above, the claims of the '996 patent are adequately described by the specification of the parent '216 application. As of at least the filing date of the '216 Application, May 31, 2002, a POSA would understand that the inventor, Dr. Plachetka, was in possession of the inventions now claimed in the '996 patent. Thus the '216 Application cannot be §102(b) prior art. It is well settled that an applicant's own prior work will not anticipate his later invention unless that prior work constitutes a statutory bar under § 102(b). *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1581 n.47 (Fed. Cir. 1987).

As the foregoing demonstrates, the claims of the '996 patent are entitled to the priority provided by the disclosures in the '216 application. Petitioner therefore cannot demonstrate a likelihood of success that the '216 application anticipates the '996 patent because it does not constitute prior art. Ground 3 should be denied.

E. Petitioner Fails to Offer Evidence Refuting Objective Indicia of Nonobviousness

The basis for each of Petitioner's assertions of invalidity in Grounds 1 and 2 of its Petition is obviousness. It is longstanding law that an integral part of the obviousness analysis is the evaluation of objective indicia of non-obviousness, such as teaching away, long-felt need, and initial skepticism. "As [the Federal

Circuit] has repeatedly explained, this evidence is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness.” *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (internal citation omitted). “Secondary considerations can be the most probative evidence of non-obviousness in the record, and enables the . . . court to avert the trap of hindsight.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (internal quotations and citation omitted). Indeed, they are important enough that “when secondary considerations are present, though they are not always dispositive, it is error not to consider them.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Despite this unambiguous case law, the Petition contains one single sentence concerning secondary indicia of nonobviousness: “CFAD is unaware of any evidence of secondary considerations of nonobviousness in this case.” (Pet. at 60 (citing Ex. 1003, ¶ 26).) Contrary to its own assertion, Petitioner then cites to nine pages of Dr. Shargel’s declaration that discuss secondary factors. (*Id.* (citing Ex. 1003, ¶¶ 400-409).) Petitioner makes its citation to the declaration without any explanation, case law or argument. (*Id.*)

Petitioner’s single sentence is fatal to its petition for several reasons. First, it is clear that Petitioner was in fact aware of objective indicia of non-obviousness, as

is evidence from even a superficial review of the prosecution history and other documents submitted with the petition, which all specifically refer to objective indicia such as teaching away and initial skepticism. (7/24/14 Notice of Allowance, Ex. 1002 at 66.) Thus, Petitioner had an obligation to specifically address this evidence. *In re Huai-Hung Kao*, 639 F.3d at 1067; *see also Stratoflex, Inc.*, 713 F.2d at 1538. The burden of persuasion for secondary considerations remains with the patent challenger—not the patent owner—and the Petition contains no analysis of secondary considerations, therefore CFAD has not met this burden and its analysis is legally deficient. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079-80 (Fed. Cir. 2012). Petitioner’s assertion that it was “unaware” of any evidence is thus nothing more than a refusal to address this important evidence, and grounds for denial of the petition on this basis alone.

Second, while Petitioner’s single sentence cites to a Declaration, conclusory statements that are not otherwise supported in a petition are considered to be incorporated by reference. *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper No. 12 at 7-10 (P.T.A.B. Aug. 29, 2014). But arguments incorporated by reference are improper, and should not be considered by the Board. 37 C.F.R. § 42.6(a)(3); *Cisco Sys.*, Paper No. 12 at 10 (denying institution after refusing to consider arguments that were not made in the body of the petition,

but were instead incorporated by reference from portions of an expert declaration); *Fid. Nat'l Info. Servs., Inc. v. DataTreasury Corp.*, IPR2014-00489, Paper No. 9 at 9 (P.T.A.B. Aug. 13, 2014) (declining to consider information presented in a supporting declaration but not discussed sufficiently in a petition and denying institution of the petition).

In *Cisco Systems*, the Board explained:

One purpose of the prohibition against incorporation by reference is to eliminate abuses that arise from incorporation. Rules of Practice for Trials Before The Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions; Final Rule, 77 Fed. Reg. 48,612, 48,617 (Aug. 14, 2012); *see also DeSilva v. DiLeonardi*, 181 F.3d 865, 866-67 (7th Cir. 1999) (Incorporation “by reference amounts to a self-help increase in the length of the [] brief[,]” and “is a pointless imposition on the court’s time. A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.”). In the Petition before us, incorporation by reference of numerous arguments from Dr. Roy’s 250-page Declaration into the Petition serves to circumvent the page limits imposed on petitions for *inter partes* review, while imposing on our time by asking us to sift through over 250 pages of Dr. Roy’s Declaration (including numerous pages of claim charts) to locate the specific arguments corresponding to the numerous paragraphs cited to support Petitioner’s assertions. Accordingly, we will not consider arguments that are not made in the Petition, but are instead

incorporated by reference to the cited paragraphs and claims charts of Dr. Roy's Declaration.

Cisco Sys., Paper No. 12 at 10. Here, use of any of the cited material in Dr. Shargel's 200-page declaration would plainly serve to circumvent the page limit requirement of the Petition.

This is one example of Petitioner's improper attempt to incorporate the voluminous Shargel declaration by reference into the Petition. Dr. Shargel's declaration includes 104 pages of text and 79 pages of claim charts referencing 36 exhibits not cited in the Petition. Petitioner's reliance on arguments and evidence found only in the Shargel declaration is improper under 37 C.F.R. § 42.6(a)(3) and those arguments should not be considered. *See Fid. Nat'l Info. Servs., Inc. v. DataTreasury Corp.*, IPR2014-00489, Paper No. 9 at 9 (P.T.A.B. Aug. 13, 2014) (declining to consider information presented in a supporting declaration, but not discussed sufficiently in a petition because "among other reasons, doing so would permit the use of declarations to circumvent the page limits that apply to petitions. For the same reasons, our rules prohibit arguments made in a supporting document from being incorporated by reference into a petition.").

Third, even considering Dr. Shargel's declaration, Petitioner's arguments are deficient. Dr. Shargel's declaration only touches on teaching away, surprising results, and skepticism of experts. None of the opinions offered therein however is

persuasive evidence in contradiction to the substantial evidence of secondary considerations evident from the documents submitted with the petition itself—including long felt but unresolved need, surprising and unexpected results, skepticism of experts, licensing, and copying, as discussed below. A proper analysis of secondary factors is not achieved by *ignoring the known evidence supporting non-obviousness*.

1. Long Felt But Unresolved Need

It is undisputed that NSAID-induced gastropathology was a significant, unsolved problem at the time of the claimed inventions. For example, in 1999, it was conservatively estimated at least 103,000 people in the U.S. were hospitalized each year as a result of serious GI complications resulting from NSAID use. These hospitalizations were estimated to cost in excess of \$2 billion dollars annually. (Wolfe 1999, Ex. 2008 at 1.)

In 2001, companies such as AstraZeneca, Takeda, Wyeth, and others were actively trying to come up with an effective way to ameliorate GI damage associated with NSAID use. Given the magnitude of the NSAID market and the enormous size of the population suffering from NSAID-induced gastric pathology, it is telling that none of these companies ever thought to combine an immediate-release PPI, esomeprazole, with a delayed-release NSAID, naproxen, into a single dosage form.

2. Surprising and Unexpected Results

A comparison of the results of the claimed inventions of the '996 patent with the closest prior art demonstrates that the results are, in fact, surprising and unexpected. *Micron Tech., Inc. v. Bd. of Trs. of the Univ. of Ill.*, IPR2013-00005, Paper No. 54 at 19-20 (P.T.A.B. Mar. 10, 2014) (emphasizing the requirement of comparing allegedly unexpected results with the closest prior art to prove that the results truly were unexpected). The closest prior art, as identified by the Examiner during prosecution of the parent '907 patent, are Goldman and DePui. (3/29/05 '907 Notice of Allowance, Ex. 2005 at 45.)

The coordinated, immediate release of the esomeprazole, followed by the delayed release of the naproxen component after the pH is raised to 3.5 or above enables delivery of the active ingredients to provide a gastroprotective effect. Indeed, in the Notice of Allowance, the Examiner stated:

[T]he general state of the art is that solid oral dosage forms comprising proton pump inhibitors (PPIs) such as esomeprazole are enterically coated to prevent the acid sensitive PPI from being degraded by the acidic environment of the stomach before it can be absorbed. While some art teaches that enteric coatings need not be applied to dosage forms containing PPIs for oral administration like those of the instant claims, those prior art documents do not disclose a combination dosage form as in the present claims of esomeprazole with naproxen. Prior art that discloses a combination of an NSAID

such as naproxen enterically coat the naproxen and PPI portions of the dosage form. Compositions in which at least a portion of the esomeprazole is released regardless of the pH of the medium in combination with naproxen have been previously allowed (US 8,557,285). The instant claims are narrower, specifying dosages in milligrams or having a non-enteric film coat layer with esomeprazole that releases the esomeprazole to the stomach upon ingestion.

(7/24/14 Notice of Allowance, Ex. 1002 at 66.)

Dr. Shargel does not compare the results of the claimed invention with the any prior art, let alone the closest prior art, and is thus legally deficient for this additional reason. His declaration instead relies on the FDA's response to a Citizen Petition filed with the FDA as evidence that there are no surprising or unexpected results. (Shargel Decl., Ex. 1003, ¶¶ 406-407.)

The FDA made no determination on the patentability of Vimovo. Horizon petitioned the FDA to require ANDA applicants to include additional pharmacokinetic data to show that any generic product demonstrated the same coordinated release as Vimovo. (Ex. 1052 at 1-2.) The FDA responded that while it agreed that Vimovo demonstrated a gastroprotective effect, the clinical trial data submitted by Horizon with its petition did not provide enough data to support its request. (Ex. 1054 at 10-11.)

Dr. Shargel provided no analysis of unexpected results beyond his discussion of the Citizen Petition.

3. Licensing

The asserted patents were first licensed by AstraZeneca, who partnered with Patent Owner Pozen to commercialize Vimovo. Horizon now licenses the patents and partners with Patent Owner Pozen to commercialize and sell Vimovo. Dr. Shargel fails to address the significant industry licenses of the '996 patent.

Industry willingness to license the claimed inventions of the '996 patent provide additional evidence that the asserted claims are not obvious. *See In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (collecting cases). Industry respect for the '996 patent is one of the objective considerations of non-obviousness that protect against the prejudice of hindsight bias, which often overlooks that “[t]he genius of invention is often a combination of known elements which in hindsight seems preordained.” *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001).

4. Copying

Four different generic pharmaceutical companies have filed Abbreviated New Drug Applications (“ANDAs”) with the U.S. Food and Drug Administration (“FDA”) to market and sell generic copies of Vimovo, copying the invention

claimed in the '996 patent. The Petition and Dr. Shargel fail to address copying of the '996 patent.

When considered in total, these secondary considerations, including long felt but unresolved need, teaching away, surprising and unexpected results, skepticism of experts, licensing, and copying, are the most probative evidence that the inventions claimed in the '996 patent are nonobvious.

VI. THE BOARD SHOULD DENY CFAD'S PETITION BECAUSE IT WAS FILED FOR AN IMPROPER PURPOSE

This Petition is part of a strategy devised to misappropriate the IPR process to drive down the stock price of targeted companies in which Petitioner's fund hold short positions.⁶ (WSJ, Ex. 2014 at 1 ("A well-known hedge fund manager [Mr. Bass] is taking a novel approach to making money: filing and publicizing patent challenges against pharmaceutical companies while also betting against their shares.")) Mr. Bass publicly touted his investment strategy at an investment conference in January 2015. A news article from that conference reports that Mr. Bass stated, "We'll have a separate pharmacy vehicle. We've dedicated half of our

⁶ Mr. Bass is also paying Erich Spangenberg and his companies, IPNav and nXn, also named as real parties-in-interest, for consulting services related to this matter. Mr. Spangenberg is known as the king of patent trolls and has been involved in thousands of patent litigations. (NY Times, Ex. 2013.)

resources over the past six months to this.” (Bus. Insider, Ex. 2015 at 2.) He described his actions as a “short activist strategy.” (*Id.* at 1.) The Wall Street Journal investigated Mr. Bass’s new IPR strategy and reported:

Mr. Bass was pitching wealthy individuals and institutions to invest in a dedicated fund that would bet against, or short, the shares of companies whose patents Mr. Bass believed to be specious, and wager on rivals that could benefit. In particular, Mr. Bass was interested in older patents which he believed to be more vulnerable. The fund requires a minimum \$1 million investment, and Mr. Bass’s firm will keep 20% of all profits earned, according to a person familiar with the matter. The trades also will be part of Hayman Capital’s main fund.

(WSJ, Ex. 2014 at 4.)

Named RPI Hayman Capital Management L.P. admitted, in a June 1, 2015 Securities Exchange Commission (“SEC”) filing, that the “primary purpose” of at least two named RPI (Credes and Hayman Orange Fund SPC-Portfolio A) is to “generate superior risk-adjusted returns . . . through long or short position[s] . . . with regard to selected companies, primarily in the pharmaceuticals sector.” (Form ADV, Ex. 2016 at 5.) In a recent filing in another CFAD proceeding, it has not denied that it uses the *inter partes* review as part of a strategy to affect stock prices. *Coalition For Affordable Drugs V LLC v. Biogen IDEC Int’l GmbH*, IPR2015-01086, Paper No. 11 at 5-6 (P.T.A.B. July 3, 2015) (Petitioner’s Opposition to Patent Owner’s Motion for Additional Discovery).

The standard for institution of an *inter partes* review under 35 U.S.C. § 314(a) “is written in permissive terms Thus, Congress has given the Office discretion whether to institute a review or not institute a review.” *Zetec, Inc. v. Westinghouse Elec. Co.*, IPR2014-00384, Paper No. 10 at 5 (P.T.A.B. July 23, 2014). Congress also stated that, in prescribing regulations under 35 U.S.C. § 316, the Director shall consider the effect of any such regulation on things such as “the economy,” “the integrity of the patent system,” and “the ability of the Office to timely complete [IPR] proceedings” 35 U.S.C. § 316(b).

While 35 U.S.C. § 311(a) allows any third party to file a request for *inter partes* reexamination,⁷ there is no statutory guarantee of institution of the proceeding. There is simply no legal right conferred upon Petitioner by the AIA that mandates the PTAB to institute trial. *See Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1262 (Fed. Cir. 2014) (because Consumer Watchdog had no connection to patent-in-suit, the Board’s denial of its request for *inter partes* review “did not invade any legal right conferred upon Consumer Watchdog.”). Similar to Consumer Watchdog, Petitioner has no direct

⁷ 35 U.S.C. § 311(a) states, in part, “[s]ubject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an *inter partes* review of the patent.”

involvement in pharmaceutical research, development, or commercialization activities and does not compete with Patent Owner in the pharmaceutical marketplace. There is no indication that Petitioner has any connection to the '996 patent. Refusing to institute IPR proceedings here will not deny Petitioner anything to which it was entitled. *Id.*

Congress passed the AIA to crack down on patent “litigation abuses . . . that have done serious harm to American businesses.” (America Invents Act, 157 Cong. Rec. S5319-03 (Sept. 6, 2011), Ex. 2017.) The IPR process was included in the AIA to “provid[e] quick and cost effective alternatives to litigation[,] . . . not . . . [a] tool[] for harassment.” H.R. Rep. No. 112-98, pt. 1, at 48 (2011), (Ex. 2018 at 61); *see also* 157 Cong. Rec. S5411 (Sept. 8, 2011), (Ex. 2019 at 10); 153 Cong. Rec. E774 (Apr. 18, 2007), (Ex. 2020 at 2); 157 Cong. Rec. S952 (Feb. 28, 2011), (Ex. 2021 at 17). Congress felt that creating a second avenue to challenge the validity of patents only made sense “if such proceedings substitute for a phase of district-court litigation.” S. Rep. No. 110-259, at 66 (2008), (Ex. 2022 at 44). Petitioner is a nominal front for investors trying to profit by manipulating pharmaceutical company stocks. It does not compete against Patent Owner and does not manufacture, use, offer to sell, sell, or import any infringing products or components of any infringing products and does not actively induce anyone else to

infringe. Petitioner is plainly not using the IPR as an alternative to litigation, as Congress intended.

Not only does Petitioner lack a concrete interest in the patentability of the inventions claimed in the '996 patent, its purported altruistic interest in affordable medicine is blatantly misleading. For example, in the instant Petition, Mr. Bass and Petitioner fail to challenge all of the claims of the '996 patent. In the related petitions, Mr. Bass and Petitioner have failed to challenge all Orange Book-listed patents for Vimovo. In its 32 IPR attacks on innovator pharmaceutical companies, Mr. Bass and the Coalition hedge funds have failed to challenge all claims of all Orange Book-listed patents for all but *one* targeted drug.⁸

Without challenging all claims of all Orange Book-listed patents for a particular drug, there is no possibility of increased competition in the market. Mr. Bass claims that its IPR strategy “serves the socially valuable purpose of reducing

⁸ For example, Mr. Bass challenged only two of the seven Orange Book-listed patents for Biogen’s Tecfidera®. IPR2015-01136, IPR2015-01086. IPR2015-01136 was denied and IPR2015-01086 is pending. Mr. Bass challenged only one of four Orange Book-listed patents for Shire’s Gattex®. IPR2015-00990. Mr. Bass challenged only one of sixteen Orange Book-listed patents for Jazz Pharmaceutical’s Xyrem®. IPR2015-01018.

drug prices” *Coalition For Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01169, Paper No. 18 at 3 (P.T.A.B. Sept. 2, 2015) (Petitioner’s Response to Patent Owner’s Motion for Sanctions). However, attacking fewer than all claims of all Orange-Book listed patents will not reduce drug prices, as Mr. Bass surely knows. Generic pharmaceutical companies must successfully challenge all claims of all Orange Book-listed patents before entering the market, unless they wish to launch at risk of an infringement suit.

Mr. Bass’s abuse of the system is self-evident. For example, in February 2015, Mr. Bass filed two IPRs against Acorda Therapeutics, targeting two of the five Orange Book-listed patents covering Acorda’s, Ampyra®.⁹ The PTAB denied institution of those petitions on August 24, 2015. Within a week, Mr. Bass filed four new IPRs against Acorda, again targeting the two patents it previously targeted.

The fact that a hedge fund or others can file endless challenges to the same patents over and over again, forcing small companies like Acorda to divert their time, attention and limited resources to fighting these improper attacks rather than focusing on bringing new cures to patients, is outrageous and offensive. His abuse of this system highlights the need for reform. BIO again calls on the Patent and

⁹ IPR2015-00817; IPR2015-00720.

Trademark Office (PTO) and Congress to quickly take action to stop this abuse, which is threatening to undermine the medical innovation system in this country.”

(Bio Statement 1, Ex. 2023 at 1.)

This is plainly not what Congress intended when it enacted the AIA. U.S. Senator Chris Coons described Mr. Bass and Petitioner’s attack on pharmaceutical patents for financial gain as a “misuse of post grant proceedings” “not intended to increase competition but instead to scare away investment.” (IP Watchdog, Ex. 2024 at 2.) If Mr. Bass’s improper use of the IPR process is not checked, the value of pioneering drug companies will be damaged, resulting in a decline in drug development spending. (*See, e.g.*, Bio Statement 2, Ex. 2025 at 1.)

There can be no dispute that allowing hedge funds to use the IPR process to manipulate financial markets is inconsistent with Congressional intent, the directives given to the Office discussed above, and public policy favoring innovation. Instituting *inter partes* review here will only encourage more such filings, which will burden additional patent owners, their respective industries, and this Office.

The Board should exercise its discretion under § 314(a) and curb Petitioner’s improper use of the *inter partes* review process by refusing to institute this IPR.

VII. CONCLUSION

Patent Owner respectfully requests that the Board deny the Petition because (1) Petitioner has failed to meet its burden of establishing that it has a reasonable likelihood of success as to any of the challenged claims; and (2) the Petition was filed for an improper purpose. For at least these reasons, the Board should deny institution.

Date: September 18, 2015

Respectfully submitted,

/s/ Ricardo Rodriguez

Ricardo Rodriguez

Reg. No. 40,789

Counsel for Patent Owner

CERTIFICATION OF SERVICE UNDER 37 C.F.R. §§ 42.6(e), 42.105(a))

I, Ricardo Rodriguez, hereby certify that on this 18th day of September 2015, the foregoing Preliminary Patent Owner Response pursuant to 37 C.F.R. § 42.107 was served electronically via email on the following:

Amy E. LaValle
amy.lavalle@wickphillips.com

Jerry C. Harris, Jr.
jerry.harris@wickphillips.com

CFAD.IPRs@wickphillips.com

Wick Phillips Gould & Martin, LLP
3131 McKinney Avenue, Suite 100
Dallas, TX 75204

Date: September 18, 2015

BY: /s/ Ricardo Rodriguez

Ricardo Rodriguez

Reg. No. 40,789

Counsel for Patent Owner