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Paper [number]
Date:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COLLEGIUM PHARMACEUTICAL, INC.,
Petitioner,

v.

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P.,
AND THE P.F. LABORATORIES INC.,
Patent Owners.

Case PGR2018-00048
Patent 9,693,961 B2

Before CHRISTOPHER G. PAULRAJ, KRISTI L. R. SAWERT, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

NEWMAN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)
Denying Patent Owner's Motion to Exclude
37 C.F.R. § 42.64(c), 42.61(a)

I. INTRODUCTION

A. Background and Summary

Collegium Pharmaceutical, Inc., ("Petitioner") filed an Amended Petition for Post-Grant Review (Paper 4, "Pet.") requesting post-grant review of claims 1–17 of U.S. Patent No. 9,693,961 B2 (Ex. 1001, "the '961 patent"). Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories Inc. (collectively, "Patent Owner") filed a Preliminary Response (Paper 13). We determined, based on the information presented in the Petition and Preliminary Response, that the '961 patent was eligible for post-grant review, and that the challenged claims were more likely than not unpatentable at least based on Petitioner's challenge under 35 U.S.C. § 112 for a lack of written description support and under 35 U.S.C. § 102 as anticipated by U.S. Pat. App. 2011/0142943 ("the '943 Publication") (Ex. 1046). Paper 18, 20 ("Institution Decision" or "Inst. Dec."). Pursuant to 35 U.S.C. § 324, the Board instituted trial on October 4, 2018, of all challenged claims on all grounds. *Id*.

Following institution, Patent Owner filed a Response to the Petition (Paper 23, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 26, "Reply"), and Patent Owner filed a Sur-reply (Paper 32, "Sur-reply"). Both Petitioner and Patent Owner filed Objections to Post-Institution Evidence (Papers 24 and 28), and Patent Owner filed a Motion to Exclude Petitioner's evidence (Paper 35). Petitioner filed an Opposition (Paper 37), and Patent Owner filed a Reply (Paper 40). An oral hearing was held on July 10, 2019, and a transcript has been entered into the record (Paper 56, "Tr.").

Patent Owner filed a Notice of Bankruptcy Filing and Imposition of Automatic Stay on September 24, 2019 (Paper 43). We extended the time period for issuance of our Final Written Decision for good cause (Papers 44 and 45). As described in our concurrent Decision Denying Patent Owner's Motion to Terminate (Paper 57), the bankruptcy stay was lifted on September 2, 2020, and the parties subsequently briefed the issue of whether we retained authority to issue our Final Written Decision in this case even though the statutory time period has passed. In that Decision, we determine that we have the authority to issue our Final Written Decision under the circumstances of this proceeding. Paper 57, 28.

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a). Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–17 of the '961 patent are unpatentable. We deny Patent Owner's Motion to Exclude.

B. Real Parties-in-Interest

Petitioner states that the real party-in-interest for Petitioner is Collegium Pharmaceutical, Inc. Pet. 4.

Patent Owner states that the real parties-in-interest for Patent Owner are Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. Paper 5.

C. Related Matters

Patent Owner has asserted the '961 patent against Petitioner in a civil action in the United States District Court for the District of Massachusetts, captioned as *Purdue Pharma L.P. et al. v. Collegium Pharmaceutical, Inc.*, 1-17-cv-11814 (D. Mass., filed Sept. 21, 2017). Pet. 4. That litigation was

consolidated for case management and discovery purposes with prior pending litigation, captioned as *Purdue Pharma L.P. et al. v. Collegium Pharmaceutical, Inc.*, 1-15-cv-13099 (D. Mass., filed Aug. 6, 2015). *Id.*

Other members of the '961 patent's family have also been involved in litigation. The '961 patent claims priority to the same non-provisional application, No. 10/214,412 ("the '412 application"), as U.S. Patent Nos. 8,337,888 (the "'888 patent"); 9,060,976 (the "'976 patent"); and 9,034,376 (the "'376 patent"). Some of the '888 patent's claims were previously found invalid for obviousness and indefiniteness. *See In re OxyContin Antitrust Litig.*, No. 04-Md-1603, 2015 U.S. Dist. LEXIS 45967, at *53 (S.D.N.Y. Apr 8, 2015), *aff'd*, No. 2015-1654 (Fed. Cir. Apr. 8, 2016).

Additionally, both the '976 patent and the '376 patent have previously been the subject of *inter partes* review proceedings, IPR2016-01027; IPR2016-01028, IPR2016-01412, and IPR2016-01413, which resulted in final written decisions and Federal Circuit affirmances determining that the challenged claims of those patents were unpatentable. In particular, claim 1 of the '976 patent was determined unpatentable for obviousness. *See Amneal Pharms., LLC v. Purdue Pharma L.P.*, IPR2016-01027 (PTAB Nov. 8, 2017) (Paper 48), *aff'd*, No. 2018-1285 (Fed. Cir. Apr. 4, 2019); *Amneal Pharms., LLC v. Purdue Pharma L.P.*, IPR2016-01028 (PTAB Nov. 8, 2017) (Paper 47), *aff'd*, No. 2018-1286 (Fed. Cir. Apr. 4, 2019). Claims 1–13 and 16–19 of the '376 patent were also determined unpatentable for obviousness. *See Amneal Pharms., LLC v. Purdue Pharma L.P.*, IPR2016-01412 (PTAB Feb. 8, 2018) (Paper 39), *aff'd*, *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918 (Fed. Cir. Apr. 17, 2019); *Amneal Pharms., LLC v. Purdue Pharma L.P.*, IPR2016-01413 (PTAB Jan. 17, 2018) (Paper 37),

aff'd, *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918 (Fed. Cir. Apr. 17, 2019).

D. The '961 Patent (Ex. 1001)

The '961 patent, titled "Pharmaceutical Formulation Containing Gelling Agent," relates generally to controlled release oral dosage forms subject to less parenteral, intranasal, or oral abuse than other dosage forms. *See*, *e.g.*, Ex. 1001, code (54) Abstract; 2:31–55. The '961 patent issued from Application No. 15/015,722, filed February 4, 2016, and claims priority through a series of continuations to Provisional Application No. 60/310,534 (Ex. 1005), filed August 6, 2001.[1] Ex. 1001, codes (60), (63).

The controlled release oral dosage forms of the '961 patent comprise a therapeutically effective amount of an opioid analgesic—a drug that is susceptible to abuse—together with one or more pharmaceutically acceptable excipients, including a gelling agent in an amount effective to impart a viscosity unsuitable for administration via parenteral and nasal routes when the dosage is crushed and mixed with an aqueous liquid. *Id.* at 2:31–3:26.

The Specification explains that "[o]pioid analgesics are sometimes the subject of abuse," and oral opioid formulations are often abused by extracting the opioid from the dosage form and injecting it, or by crushing the dosage form and administering it orally or nasally. *Id.* at 1:26–40. As recognized in the patent, the prior art describes dosage forms that combine opioid antagonists with opioid agonists to deter parenteral abuse of opioid agonists. *Id.* at 1:42–2:12. The prior art further describes narcotic drug

[1] We refer herein to the chain of applications to which the '961 patent claims priority as the "Priority Applications."

addiction therapies "formulated to prevent injection abuse through concentration of the active component in aqueous solution by incorporating in a solid dosage or tablet form of such drug an ingestible solid having thickening properties which cause rapid increase in viscosity upon concentration of an aqueous solution thereof." *Id.* at 2:13–20. In spite of the advancements discussed in the prior art, "there still exists a need for a safe and effective treatment of pain with opioid analgesic dosage forms which are less subject to abuse than current therapies." *Id.* at 2:22–24.

The '961 patent purports to address this need by providing oral dosage forms of an opioid analgesic subject to less parenteral abuse, less intranasal abuse, less oral abuse, and less diversion than other dosage forms. The '961 patent also describes a method of treating pain with such abuse deterrent dosage forms and a method of manufacturing such dosage forms. *Id.* at 2:31–51. The oral dosage form includes at least one "aversive agent," defined as a bittering agent, an irritant, a gelling agent, or combinations thereof, which makes the drug less attractive to a potential abuser. *Id.* at 2:52–3:50, 4:27–29. In addition, the dosage form is resistant to tampering through means of "crushing, shearing, grinding, chewing, dissolution in a solvent, heating, (e.g., greater than about 45° C), or any combination thereof" to prevent the opioid agonist [in the inventive dosage form] from being inappropriately used such as administration by an alternate route, e.g., parenterally. *Id.* at 4:30–40.

E. Illustrative Claim

Petitioner challenges claims 1–17 of the '961 patent, of which claims 1 and 16 are the only independent claims. Claim 1 recites:

> 1. A method of preparing an abuse deterrent controlled release dosage form comprising:

> combining oxycodone or a pharmaceutically acceptable salt thereof as active agent, polyglycolyzed glycerides, a C_{12} to C_{40} fatty acid or a mixture thereof, carnauba wax and beeswax, to form a homogenous mixture, wherein the oxycodone or pharmaceutically acceptable salt thereof is the sole active agent in the dosage form;
> preparing particles from the homogenous mixture; and containing the particles in a capsule;
> the abuse deterrent dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient, and
> the abuse deterrent dosage form being abuse deterrent when subjected to tampering comprising heating at a temperature greater than about 45° C.

Ex. 1001, 41:37–52. Dependent claims 2–15 further set forth components or other requirements for the particles, the oxycodone or pharmaceutically acceptable salt thereof, the fatty acid, the method of combining the materials in the homogenous mixture, the composition of the homogenous mixture, and size of the particles. *Id.* at 42:1–31. Independent claim 16 is similar to claim 1, except it requires the abuse deterrent dosage form to "hav[e] a viscosity of about 10 cP or more when subjected to tampering comprising heating at a temperature greater than about 45° C." *Id.* at 42:32–49. Claim 17 depends from claim 16 and recites a particle diameter of "from about 0.1 mm to about 2.5 mm." *Id.* at 42:50–51.

F. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–17 ("the challenged claims") of the '961 patent would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–17	112(a)	Written Description
1–17	112(a)	Enablement
1–17	112(b)	Definiteness
1–17	102(a)	U.S. Pat. App. 2011/0142943 ("the '943 Publication") (Ex. 1046)

Pet. 3, 6.

In support of its challenges, Petitioner relies upon declarations submitted by its expert, Walter G. Chambliss, Ph.D. Ex. 1002; Ex. 1087. In support of its Response, Patent Owner relies upon a declaration submitted by its expert, Panayiotis P. Constantinides, Ph.D. Ex. 2030.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner proposes that a person of ordinary skill in the art ("POSA") would have possessed "a degree in one or more fields of medicine, chemical engineering, chemistry, pharmaceutical science, and/or pharmacology and a number of years of industry training or experience in one or more of those fields." Pet. 21 (citing Ex. 1002 ¶ 82). Petitioner further proposes that "[i]f the degree is a Ph.D[.], then the required industry experience need not be significant, e.g., two years or more, but if the technical degree is a B.S. or M.S., then the industry experience would be more significant, e.g., five years or more." *Id.* We preliminarily adopted Petitioner's definition of a POSA's

skill level in our Institution Decision as it was undisputed at the time and consistent with the evidence of record. Inst. Dec. 7–8.

Neither Patent Owner nor Petitioner addresses the level of ordinary skill in the art in the post-institution briefing. We continue to adopt Petitioner's proposed skill level for a POSA herein and have also taken into account the level of skill reflected in the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Applying this level of skill, we find that Dr. Chambliss and Dr. Constantinides are qualified to provide opinions as to the perspective and knowledge of a POSA. *See* Ex. 1002 ¶¶ 81–83; Ex. 2030 ¶¶ 58–63.

B. Claim Construction

Petitioner proposes a construction of "abuse deterrent dosage form" as a "dosage form that is subject to less parenteral, intranasal, or oral abuse than other dosage forms." Pet. 17 (citing Ex. 1002 ¶¶ 71–80). Patent Owner argues we need not construe this term because, even if the term is construed more broadly than Petitioner itself proposes, the additional claim elements in the challenged claims "provide insight as to the abuse deterrence contemplated." PO Resp. 20. Patent Owner further argues that a "POSA would understand that the '961 patent claims methods of making formulations with features/ingredients that are designed to reduce the potential of abuse as compared to hypothetical formulations lacking such features/ingredients." *Id*.

We agree with Patent Owner that the challenged claims recite methods of making formulations using recited features and ingredients. In addition, as we stated in our Decision on Institution, "[t]he claims define abuse deterrence in terms of when the dosage form is 'subjected to

t[a]mpering comprising heating at a temperature greater than about 45° C.'" Inst. Dec. 19 (quoting Ex. 1001, 41:50–52). Additionally, the claims and specification identify specific ingredients that can purportedly help achieve this abuse deterrence functionality. *Id.* Given these conclusions, further construction of "abuse deterrent," which both parties generally agree relates to methods of making the drug dosage form less likely to be abused, is not necessary to resolve the issues before us.

C. Patent Owner's Motion to Exclude

Patent Owner moves to exclude certain evidence pursuant to Federal Rules of Evidence 402, 403, 702, 703, and 37 C.F.R. § 42.64(c). Paper 35. Specifically, Patent Owner moves to exclude paragraphs 22–25 of the supplemental Declaration of Petitioner's expert, Dr. Walter G. Chambliss (Ex. 1087, hereafter "Supplemental Chambliss Decl.") and Petitioner's Exhibits 1073, 1074, 1075, 1082, 1083, 1084, 1085, 1086, 1088, and 1090. Paper 35, 1. Patent Owner timely objected to Petitioner's evidence (Paper 28) and later preserved these objections through this motion to exclude challenging the testimony and exhibits.

Patent Owner argues that paragraphs 22–25 of the Supplemental Chambliss Declaration should be excluded because they present "factually and scientifically unsupported opinions that PGGs [polyglycolized glycerides] are not gelling agents." Paper 35, 1. Patent Owner argues that Dr. Chambliss "cites no evidence" to support these opinions, which are "contradicted by prior art that describes PGGs as excipients with gelling properties." *Id.*

Patent Owner argues that Dr. Chambliss' testimony that "'PGGs are not gelling agents' and that 'PGGs were not a well-characterized or

commonly used excipient'" is based on the lack of a listing for PGGs in the Handbook of Pharmaceutical Excipients and because "he was unaware of 'any literature describing PGGs as a gelling agent in a pharmaceutical composition.'" *Id.* at 5. Patent Owner argues that literature describing PGGs as a gelling agent pre-dating the '961 priority date was presented to Dr. Chambliss at his deposition, but Dr. Chambliss "refused to accept the straightforward teaching of the prior art." *Id.* at 6. Patent Owner concludes that because Dr. Chambliss' testimony is unsupported evidence without basis and "is not the product of reliable principles and methods, it should be excluded under FRE 702/703 and 37 C.F.R. § 42.65(a)," and also under FRE 402 for lack of relevance and [FRE] 403 because "its probative value is substantially outweighed by its risk of unfair prejudice and confusing the issues." *Id.* at 7.

Petitioner opposes the motion (Paper 37), and argues that Dr. Chambliss' testimony that the skilled artisan would not have believed PGGs were gelling agents as of the priority date was supported by lack of disclosure to this effect in the Priority Applications or the relevant literature, the lack of mention of this property in the commonly used Handbook of Pharmaceutical Excipients (which Petitioner explains Patent Owner's own expert relied upon as a seminal source for such information; *see* Paper 37, 5–6 n.4), and a monograph for PGGs published after the priority date that excludes gelling agent from the list of functional characteristics. *Id.* at 4–5. Petitioner notes that this lack of information supporting PGGs as gelling agents formed the substance of its examination of Patent Owner's expert, Dr. Constantinides, on this issue, and that Dr. Constantinides had not identified literature to contradict Dr. Chambliss' position. *Id.* at 8–9.

Patent Owner responds that Dr. Chambliss' testimony is explained by his impermissibly narrow definition of "gelling agent," which ignores the '961 patent's explicit definition. Paper 40, 1–2. Patent Owner argues that this narrow definition is the reason Dr. Chambliss argues that the literature Petitioner provided fails to identify that PGGs are gelling agents. *Id.*

With regard to Petitioner's Exhibits 1073, 1074, 1075, 1082, 1083, 1084, 1085, 1086, 1088, and 1090, Patent Owner seeks to exclude these exhibits because although they were submitted with Dr. Chambliss' Supplemental Declaration (Ex. 1087), the exhibits were not cited or discussed in any of Petitioner's papers. Paper 35, 7. Patent Owner challenges these exhibits under FRE 401/402/403 and 37 C.F.R. § 42.6(a)(3) as improper attempts to incorporate evidence that was not relied upon. *Id.* at 7–8.

Petitioner responds that the challenged exhibits are relevant because they "disclosed the underlying facts and data that support [Dr. Chambliss'] well-reasoned and detailed analysis of PGGs." Paper 37, 11. Petitioner cites the Board's holding in *Nevro Corp. v. Bos. Sci. Neuromodulation Corp.*, IPR2017-01812, Paper 79 at 24 (PTAB Feb. 1, 2019), in which the Board declined to exclude exhibits not discussed in the papers where the declarants relied upon the exhibits in forming their opinions. Paper 37, 1–12. Patent Owner does not respond to this point.

We are not persuaded that exclusion of the cited portions of Dr. Chambliss' testimony or Exhibits 1073, 1074, 1075, 1082, 1083, 1084, 1085, 1086, 1088, and 1090 is warranted. While the parties disagree on the merits of Dr. Chambliss' testimony as to whether PGGs were known to be gelling agents by persons of ordinary skill in the art at the time of the

Priority Applications, Patent Owner does not persuade us that Dr. Chambliss fails to support his testimony with any reasonable logical or scientific basis. The exhibits that Patent Owner seeks to exclude, which include a patent, technical references, and a journal article, are relevant to the inquiry Dr. Chambliss performed in forming his opinion. We therefore do not see a basis for exclusion under FRE 702/703 or 37 C.F.R. § 42.64(c). Moreover, we find this evidence both admissible and relevant as it concerns a fundamental issue for our patentability analysis. Thus, we decline to exclude the evidence under FRE 401 or 402.

With regard to exclusion under Rule 403, we note that the application of Rule 403 to non-jury trials has been questioned. *See, e.g.*, *Schultz v. Butcher*, 24 F.3d 626, 632 (4th Cir. 1994) ("[I]n the context of a bench trial, evidence should not be excluded under 403 on the ground that it is unfairly prejudicial."); *Gulf States Utilities Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir. 1981) ("[E]xclusion of this [relevant] evidence under Rule 403's weighing of probative value against prejudice was improper" and is a "useless procedure" because "[t]his portion of Rule 403 has no logical application to bench trials"). It has been recognized that in a non-jury trial, such as in trial proceedings before the Board, the risk that a decision by the trier of fact will be unfairly affected by the admission of improper evidence is far less than in a jury trial. *See E.E.O.C. v. Farmer Bros. Co.*, 31 F.3d 891, 898 (9th Cir. 1994).

As the factfinders, we are able to consider the evidence offered by Petitioner and Patent Owner, in light of the parties' arguments, and give it the appropriate weight, without risk of unfair prejudice. *See* Wright & Miller, 22A Fed. Prac. & Proc. Evid. § 5213 (2d ed.) ("In bench trials . . . ,

appellate courts have said that exclusion of evidence on grounds of 'prejudice' makes little sense because the judge has to see the putatively prejudicial evidence in order to rule."); *see also Schultz*, 24 F.3d at 632 (court should not exclude evidence under Rule 403 in non-jury trial on grounds of unfair prejudice).

The weight of Patent Owner's arguments, including those made in these Motions to Exclude, will be considered in our evaluation of the complete record of evidence. *See Corning, Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) (quoting *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941) ("One who is capable of ruling accurately upon the admissibility of evidence is equally capable of sifting it accurately after it has been received.")). The Motion to Exclude is denied.

D. Written Description and Post-Grant Review Eligibility

Petitioner contends that claims 1–17 of the '961 patent are eligible for post-grant review because the claimed invention lacks written description support in any of the priority applications. Petitioner relies upon the same arguments as a basis for its unpatentability arguments in this proceeding. Pet. 67–68 (incorporating reasoning set forth in Petition at 26–40 regarding PGR eligibility of the '961 patent). Accordingly, we address these issues together. We focus our discussion on claim 1.

The parties agree that the specification of the '961 patent has substantially the same disclosures as the specification of the Priority Applications, including the '534 Provisional Application to which the '961 patent claims priority. *See, e.g.*, Pet. 22–23; PO Resp. 19 n.4. Below we revisit the issue of whether the '961 patent is eligible for post-grant review,

and conclude that it is eligible because the disclosures in the Priority Applications do not sufficiently provide written description support for the claimed invention. We conclude that Petitioner has demonstrated by a preponderance of the evidence that the challenged claims are unpatentable for lack of written description support for the same reasons.

1. Legal Standards

Post-grant reviews are available only for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"). AIA § 6(f)(2)(A); *see Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 13 at 15 (PTAB, Sept. 2, 2016). These patents issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. AIA § 3(n)(1). Because the AIA was enacted on September 16, 2011, post-grant reviews are available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013, or later. *See also* 37 C.F.R. § 42.204(a) (requiring that "petitioner . . . certify that the patent for which review is sought is available for post-grant review"). Petitioner bears the burden of proving by a preponderance of the evidence that the '961 patent is eligible for post-grant review. *U.S. Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019 at 9–10 (PTAB Dec. 28, 2016) (Paper 54).

The effective filing date for a patent on an invention is "the filing date of the earliest application for which the . . . application is entitled, as to such invention, to a right of priority under section 119, 365(a), 365(b), 386(a), or

386(b) or to the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c)." 35 U.S.C. § 100(i)(1)(B) (2018). In the event that the application is not entitled to any earlier filing date or right of priority, the effective filing date is "the actual filing date of the . . . application for the patent containing a claim to the invention." 35 U.S.C. § 100(i)(1)(A).

A patent claim is entitled to the benefit of an earlier filing date if the priority application discloses the claimed invention in manner sufficient to satisfy the written description and enablement requirements of 35 U.S.C. § 112.

The test for written description support is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" based on an "objective inquiry into the four corners of the specification." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). If this test fails, the application is not entitled to the benefit of the earlier filing date.

The written description requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 928 (Fed. Cir. 2004). The specification does not have to provide exact or verbatim textual support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). The Federal Circuit has clarified that

> [a]lthough [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she]

> invented what is claimed . . . . The test for sufficiency of support . . . is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citations omitted, all but first alterations in original). Moreover, "the written description requirement does not demand either examples or an actual reduction to practice." *Ariad Pharms., Inc.*, 598 F.3d at 1352. "[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). Furthermore, "[a] specification may . . . contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses." *Id.* (second alteration in original).

Finally, the written description inquiry is a question of fact, is context specific, and must be determined on a case-by-case basis. *Ariad Pharms., Inc.*, 598 F.3d at 1351 (citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985); *Capon v. Eshar*, 418 F.3d 1349 (Fed. Cir. 2005), 418 F.3d at 1357–1358); *see also Vas-Cath*, 935 F.2d at 1562 ("Precisely *how* close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis." (quoting *In re Smith*, 258 F.2d 1389, 1395 (CCPA 1972))). "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharms., Inc.*, 598 F.3d at 1351 (citing *Capon*, 418 F.3d at 1357–1358). Factors used to evaluate the sufficiency of a disclosure include 1) "the existing knowledge in the

particular field"; 2) "the extent and content of the prior art"; 3) "the maturity of the science or technology"; and 4) "the predictability of the aspect at issue" (the "*Ariad* factors"). *Id.* (citing *Capon*, 418 F.3d at 1359).

2. Whether "Transitional" Continuation Patents May Be PGR-Eligible

The '961 patent issued on July 4, 2017, from U.S. Application Ser. No. 15/015,722 (the "'722 application"), filed on February 4, 2016. Ex. 1001, codes (45), (21), (22). The '722 application, through a series of continuation applications, claims benefit of priority of U.S. Provisional Application No. 60/310,534 (the "'534 Provisional Application", Ex. 1005), filed on August 6, 2001. Ex. 1001, code (60). Because it was filed after March 16, 2013, the '722 application is an AIA (first-inventor-to-file) application; but the '534 Provisional Application and other non-provisional applications with the same disclosures filed before that date are pre-AIA (first-to-invent) applications. As such, the '961 patent is eligible for post-grant review only if it is not entitled to claim priority to the earlier Priority Applications.

In its Response to the Petition, Patent Owner contends that "transitional"[2] continuation patents such as the '961 patent are not PGR-eligible. PO Resp. 22–23. Patent Owner relies upon the legislative record of the AIA as indicating that "continuations of first-to-invent applications that do not introduce new matter will remain subject to first-to-invent rules." *Id.* at 22–23 (citing 157 CONG. REC. S1373 (Mar. 8, 2011)). Patent Owner contends that the '961 patent does "not introduce new matter" because it has

[2] A "transitional" patent is a patent that issued after the effective date of the AIA, but was filed as a continuation application that claims priority to an application that was filed prior to the effective date of the AIA.

the same disclosures as at least the earliest non-provisional priority application, the '412 application, filed in 2002. *Id.* at 23.

We are unpersuaded by this argument. The Board's practice of considering PGR-eligible those patents that lack adequate support under § 112 for the claimed invention in pre-AIA priority applications is based on the statutory language, which provides that the "effective filing date" of a claimed invention in a patent shall be either the "actual filing date of the patent" or "the filing date of the earliest application for which the patent . . . is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c)." 35 U.S.C. § 100(i)(1). To be entitled to the benefit of an earlier filing date as a continuation application under § 120, that earlier-filed application must have disclosed the invention "in the manner provided by section 112(a) (other than the requirement to disclose the best mode)." 35 U.S.C. § 120. Section 112(a), of course, requires that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains." 35 U.S.C. § 112(a). As we noted in our Institution Decision, a patent claiming the benefit of priority of an application filed before March 16, 2013, must have written description support for the claimed invention in the earlier-filed application in order to avoid PGR-eligibility. Inst. Dec. 8–10. The Federal Circuit confirmed this reasoning in *Team Worldwide Corp. v. Intex Recreation Corp.*, No. 2020-1975, 2021 WL 4130634 (Fed. Cir. Sept. 9, 2021), wherein the petitioner filed a post-grant review against a patent that had been filed after the effective date of the AIA, but claimed priority to a

pre-AIA application. *Id.* at *1. The Board found the challenged claims eligible for post-grant review because the pre-AIA application to which patent owner claimed priority did not contain sufficient written description support for the claims, and further found the claims unpatentable as indefinite. *Id.* at *1, 3. On review, the Federal Circuit affirmed both the subject patent's eligibility for post-grant review and the finding that the claims were indefinite. *Id.* at *8.

Accordingly, we determine that the '961 patent may be PGR-eligible if the Priority Applications lack adequate written description support for the challenged claims. The mere fact that the '961 patent does "not introduce new matter" as compared to the Priority Applications is not sufficient to take it out of the realm of PGR-eligibility. We, thus, turn to our analysis of whether the Priority Applications provide adequate written description support for the challenged claims.

3. Whether the Priority Applications Provide Written Description Support for the Claimed Invention

Petitioner asserts that the '961 patent is PGR-eligible because the challenged claims are not entitled to an effective filing date earlier than the February 4, 2016, filing date of the '722 application, which issued as the '961 patent. Pet. 24–40. Petitioner contends that the Priority Applications do not provide written description support for the full scope of the challenged claims. *Id.* at 24–25. Petitioner raises two separate written description arguments as the basis for its contention that the '961 patent is PGR-eligible. First, Petitioner contends that the inventors were not in possession of the full scope of "abuse deterrent dosage forms" recited in the challenged claims. *Id.* at 26, 28–33. Second, Petitioner contends that the claimed dosage form is the result of impermissible "picking and choosing"

from the specifications of the Priority Applications. *Id.* at 26, 33–40; Reply 4. As it is dispositive to our conclusion of PGR-eligibility, we focus our analysis on this second, "picking and choosing" written description argument. We focus our discussion on claim 1, which shares common elements with all challenged claims.

a) Petitioner's arguments for lack of written description support

Petitioner argues that the '534 Provisional application contains insufficient support for the challenged claims. Pet. 28–39. Petitioner argues that the components of the abuse deterrent dosage forms recited in the claims—oxycodone, PGGs, C_{12}–C_{40} fatty acids, carnauba wax, and beeswax (the "Claimed Pharmaceutical Ingredients")—are not described together as a combination anywhere in the disclosure, or even as a combination of any subset of these ingredients. *Id.* at 34.

Petitioner adds that even if the claimed combination had been shown in some form, the '534 Provisional application does not support the conclusion that the inventors possessed a method of preparing "the full scope of the Claimed Pharmaceutical Ingredients, including: (i) oxycodone and all pharmaceutically acceptable salts thereof, (ii) all grades of PGG, (iii) all C_{12}-C_{40} fatty acids or a mixture thereof, (iv) carnauba wax, and (v) beeswax." *Id.* (citing Ex. 1002 ¶¶ 104, 105). Petitioner argues that there is no teaching or example in the '534 Provisional application to demonstrate that the inventors knew how to prepare a capsule dosage form containing these ingredients in combination, and that the examples focused on other pharmaceutical ingredients with the exception of oxycodone hydrochloride. *Id.* at 34–35 (citing Ex. 1002 ¶¶ 106, 107). Petitioner argues that the '534 Provisional application mentions PGG "only once in the '534 Provisional, as

an optional surfactant, and does not teach the grade or amount of PGG to be used," nor does it disclose any C_{12}-C_{40} fatty acid by name and "fails to recite any amount of C_{12}-C_{40} fatty acid(s), carnauba wax, or beeswax to be used." *Id.* at 35 (citing Ex. 1002 ¶¶ 108–111).

Petitioner argues that these references lack any teaching of grade, type, or amount of any component notwithstanding that the various physiochemical properties of the claimed ingredients can influence the functional behavior of the dosage form. *Id.* at 34–37 (citing Ex. 1002, ¶¶ 41–49, 112–114); Reply 4. Petitioner notes that the '534 Provisional application likewise lacks any process instructions regarding how to prepare a homogenous mixture of the claimed ingredients and how to make particles from that mixture, despite that "a POSA would look for these disclosures in the '534 Provisional application given that the claimed pharmaceutical excipients have varied physiochemical properties" that may affect the release of the oxycodone from the dosage form, directly impacting the deterrence and thus whether the dosage form would meet the functional claim limitations. Pet. 35–36. In addition, Petitioner argues, the '534 Provisional application "provides no example of any dosage form, let alone one comprising the Claimed Pharmaceutical Ingredients, that is abuse deterrent when exposed to tampering at a temperature greater than about 45º C." *Id.* at 36–37. Absent these teachings or examples, Petitioner concludes that the '534 Provisional lacked adequate description of the subject matter of the challenged claims at the time of the claimed invention, and thus the '961 patent is not entitled to claim priority to the '534 Provisional application. *Id.* at 38–39.

With regard to the PGG component, Petitioner argues that "the disclosure of 'hydrophobic binder materials … including but not limited to fatty acid esters, [and] fatty acid glycerides'" does not teach PGGs for three reasons. Reply 5 (citing Ex. 1001, 16:22–29) (alterations in original). First, Petitioner argues the Priority Applications' discussion of binders "does not list or reference PGGs," but PGGs are referenced in a "laundry list of optional surfactants" found in a different part of the specification. *Id.* at 6. From this, Petitioner concludes, "the inventors knew how to reference a PGG when desired, and the different language used in the binder section of the Priority Applications [which excludes PGGs] should be accorded a different meaning." *Id.* Second, the Priority Applications' discussion of binders "does not disclose the constituent parts of a PGG" and "only discloses the genus of 'fatty acid esters'" rather than "the required PGG species: PEG fatty acid esters." *Id.* (citing Ex. 1087 ¶¶ 31–33) (emphasis omitted). Third, the Priority Applications' discussion of binders "exclusively describes hydrophobic excipients" and does not disclose the constituent parts that constitute a PGG because "[a]s agreed by both experts, the 'PEG fatty acid ester will always be the hydrophilic constituent of the PGG.'" *Id.* at 6–7 (citing Ex. 1081, 31:13–16, 144:25–145:5) (emphasis omitted).

Petitioner argues that the Priority Applications' discussion of the "melt extruded matrix" never discloses or recites PGGs and a POSA would have had to impermissibly pick and choose from the Priority Applications' teachings to conclude that PGGs are surfactants that can be used as gelling agents. *Id.* at 7–10. Petitioner contends that there is no evidence that supports the use of PGGs as gelling agents. *Id.* (citing Ex. 1087 ¶ 22).

According to Petitioner, the Priority Applications do contain a list of gelling agents, but the list does not include PGGs and "merely states that some surfactants can act as a gelling agent." *Id.* at 9 (citing Ex. 1001, 6:64–7:13; Ex. 1081, 79:15–18, 135:9–12; Ex. 1087 ¶ 23). Petitioner further explains that "as of the Purported Priority Date[3] (and still today) the art does not describe PGGs as gelling agents, and thus a POSA would not recognize the Priority Applications as disclosing PGGs as a preferred gelling agent." *Id.* (citing Ex. 1087 ¶ 24). Petitioner contends that "Dr. Constantinides admits he did not 'cite any literature in [his] supplemental declaration for the fact that a PGG can be a gelling agent'" and he "has never used a PGG as a gelling agent, nor has he heard of others doing so." *Id.* at 9–10 (citing Ex. 1081 (second Constantinides deposition), 75:7–15, 187:12–15; Ex. 1091, 28:20–23, 37:7–9 (first Constantinides deposition)).

Petitioner provides additional evidence that PGGs were not included in the Handbook of Pharmaceutical Excipients ("HPE") and were not included in the IIG FDA-maintained list of pharmaceutical excipients as of the Purported Priority Date. *Id.* (citing Ex. 1081, 82:7–11; Ex. 2007; Ex. 1087 ¶¶ 24–25). According to Petitioner, PGGs were later added to the HPE "with the following non-abuse deterrent functions: dissolution enhancer, emulsifying agent, penetration enhancer, solubilizing agent, surfactant, sustained-release agent," but not as gelling agents. *Id.* (citing Ex. 1081, 105:25–106:9, 109:19–112:2; Ex. 1078 at 558).

[3] Petitioner uses "Purported Priority Date" to refer to Patent Owner's claim that the '961 patent claims priority to the filing date of the '534 Provisional. Pet. 18.

b) Substantial Similarity of Priority Applications to '961 Patent Specification

Petitioner argues that the specifications of the non-provisional patent applications to which the '961 patent claims priority are substantially similar to the specification of the '534 Provisional application. Pet. 39. Dr. Chambliss testifies that the specifications are substantially similar, with a primary difference being that the definition of "aversive agent" in the '534 Provisional includes dye, which is excluded from the other applications. Ex. 1002 ¶ 89. The challenged claims do not recite dye; therefore, we conclude that for the purposes of the issues before us, the specifications are substantially similar.

Petitioner argues that because the applications are substantially similar, no related application in the chain provides written description support for the full scope of the challenged claims, meaning that the effective filing date of the '961 patent is the '722 application filing date, February 4, 2016. *Id.* at 37–39 (citing Ex. 1002 ¶¶ 115, 116).

Patent Owner does not contest the substantial similarity of the specification of the '534 Provisional application and the specifications of the remaining priority applications. *See generally* PO Resp.; Sur-reply.

Because the specifications and original claims are substantially similar to each other, the issue of whether the Priority Applications provide sufficient written description support for the challenged claims (i.e., whether the '961 patent is PGR-eligible) is congruent with whether the '961 patent provides sufficient written description for those claims. Petitioner asserts that the challenged claims are unpatentable for lack of written description support for the same reasons that the related applications "fail to convey to a POSA that the inventors were in possession of the full scope of the

Challenged Claims." Pet. 67–68. Petitioner relies on its arguments made with regard to '961 patent's eligibility for post-grant review. *Id.* at 67. Thus, we proceed to address Patent Owner's responses to this challenge.

c) Patent Owner's arguments regarding written description

Patent Owner argues that the written description requirement is satisfied because each of the claimed ingredients is explicitly identified in the specification and "[t]here can be no argument that the disclosure of PGGs provides the structural features common to members of this subgenus." PO Resp. 26. Patent Owner provides the following table as the "clearest evidence" for where the claimed ingredients are disclosed in the specification:

Claim 1	Specification, 17:64–18:2[4]
A method of preparing an abuse deterrent controlled release dosage form comprising: combining	"The preparation of a suitable melt extruded matrix according to the present invention may, for example, include the steps of blending
oxycodone or a pharmaceutically acceptable salt thereof as active agent,	the **opioid analgesic**
polyglycolyzed glycerides,	and at least one **aversive agent**
A C_{12} to C_{40} fatty acid or a mixture thereof, carnauba wax and beeswax, to form a homogenous mixture,	together with **a sustained release material and preferably a binder material** to obtain a homogenous mixture."

Id. at 27. Patent Owner relies upon the foregoing statement from the "Matrix Formulations" section of the specification as a roadmap that

[4] Patent Owner's citations are to the column and line numbers of the '961 patent (Ex. 1001), which has the substantially same disclosure as the specifications of the Priority Applications. We also cite to the patent for ease of reference.

allegedly leads to the combination of claimed ingredients disclosed in other portions of the specification. *Id.* at 26–27 (citing Ex. 2030 ¶ 78).

Patent Owner contends that the specification identifies oxycodone as a preferred opioid analgesic. *Id.* at 28–29 (citing Ex. 1001, 8:49–51; Ex. 1005, 12; Ex. 1006 ¶ 57 (US 2003/0068375 A1, a Priority Application)). In particular, Patent Owner points to the statement that "[i]n certain preferred embodiments, the opioid agonist is oxycodone or hydrocodone." Ex. 1001, 8:49–51. Patent Owner also contends that the specification provides support for the requirement in certain dependent claims reciting an oxycodone base (claims 3, 7, 11, 16) or an organic acid salt of oxycodone (claim 2). PO Resp. 28. With respect to those claim requirements, Patent Owner points to the specification's disclosure that the "opioid agonists useful in the present invention include, but are not limited to, . . . oxycodone . . . , mixtures of any of the foregoing, salts of any of the foregoing, and the like." *Id.* at 29 (citing Ex. 1001, 8:20–40; Ex. 1005, 12; Ex. 1006 ¶ 56) (alterations in original). Patent Owner also points to the specification's disclosure that "[t]he invention disclosed herein is meant to encompass the use of any pharmaceutically acceptable salts thereof of the disclosed opioid analgesic," including "organic acid salts such as formate, acetate, trifluoroacetate, maleate, tartrate and the like." *Id.* (citing Ex. 1001, 30:27–42; Ex. 1005, 42–43; Ex. 1006 ¶ 184) (emphasis omitted).

Patent Owner contends that the Priority Applications teach a POSA to design a melt-extruded matrix formulation for oxycodone by starting with the "selection of the claimed sustained release and binder materials (*i.e.*, a C_{12} to C_{40} fatty acid, carnauba wax and beeswax)" and then "look to the teachings of the Priority Applications to select an aversive agent that was

compatible with those sustained release materials." *Id.* at 28 (citing Ex. 1001, 8:49–51, 15:28–23:51; Ex. 1005, 12, 21–33; Ex. 1006 ¶¶ 57, 95–146; Ex. 2030 ¶ 80).

Patent Owner further contends that the combination of C_{12} to C_{40} fatty acid, carnauba wax, and beeswax are described as preferred sustained release and binder materials in the Matrix Formulations section. In particular, Patent Owner points to the specification's disclosure that

> The matrix may also include a binder. . . . If an additional hydrophobic binder is included, it is preferably selected from natural and synthetic waxes, ***fatty acids***, fatty alcohols, and mixtures of the same. Examples include ***beeswax***, ***carnauba wax***, ***stearic acid*** and stearyl alcohol. . . . In certain preferred embodiments, a ***combination*** of two or more hydrophobic binder materials are included in the matrix formulation.

Id. at 30 (citing Ex. 1001, 15:64–16:8; Ex. 1005, 22; Ex. 1006 ¶¶ 97–98) (alterations in original). Patent Owner further notes that in the very next paragraph, the specification states that "***[p]referred*** hydrophobic binder materials . . . include digestible, long chain (C_8-C_{50}, ***especially C_{12}-C_{40}***) substituted or unsubstituted hydrocarbons, such as ***fatty acids***." *Id.* at 31 (citing Ex. 1001, 16:9–13; Ex. 1005, 22; Ex. 1006 ¶ 99) (alteration in original).

Patent Owner states that "the Priority Applications in combination with the knowledge of a person of ordinary skill would lead to the use of a surfactant" and "a POSA would have been directed to the use of PGGs in this combination because of its ability to act[] as both an aversive agent and a surfactant." *Id.* at 28. Patent Owner argues that these teachings provide a "clear path to the claimed combination of ingredients." *Id.*

Patent Owner contends that the specification would have led a POSA to use PGGs as aversive agents in hydrophobic melt-extruded formulations.

To reach this conclusion, Patent Owner starts with the specification's definition of "aversive agents," which includes gelling agents. *Id.* at 31 (citing Ex. 1001, 4:26–29, 6:64–66; Ex. 1005, 5, 10; Ex. 1006 ¶¶ 30, 49). Patent Owner then relies upon the fact that the specification lists "surfactants" among the possible gelling agents, and later in the disclosure lists PGGs among the possible surfactants that may be used. *Id.* (citing Ex. 1001, 6:64–7:11, 28:36–41; Ex. 1005, 10, 40; Ex. 1006 ¶¶ 49, 173). Patent Owner argues that "[a] POSA would recognize PGGs as a preferred aversive agent" because the "Priority Applications' definition of 'aversive agents' explicitly includes 'gelling agents' and those applications describe 'embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent . . . .'" *Id.* at 31 (citations omitted) (citing Ex. 1001, 4:26–29, 6:64–66; Ex. 1005, 5, 10; Ex. 1006 ¶¶ 30, 49).

In addition to the foregoing, Patent Owner contends that the specification discloses the claimed excipients in a single sentence:

> In certain embodiments, the hydrophobic binder materials may comprise natural or synthetic ***waxes***, fatty alcohols (such as lauryl, myristyl, stearyl, cetyl or preferably cetostearyl alcohol), ***fatty acids***, including but not limited to ***fatty acid esters, fatty acid glycerides*** (mono-, di-, and tri-glycerides), hydrogenated fats, hydrocarbons, normal waxes, ***stearic acid***, stearyl alcohol and hydrophobic and hydrophilic materials having hydrocarbon backbones.

Id. at 33–34 (citing Ex. 1001, 16:22–29; Ex. 1005, 23; Ex. 1006 ¶ 100). Patent Owner contends that the disclosure to use fatty acid esters and fatty acid glycerides in a matrix containing carnauba wax, beeswax and fatty acids would clearly point to PGG as the gelling agent surfactant. *Id.* at 33 (citing Ex. 2030 ¶ 87). Additionally, Patent Owner asserts that PGGs are mixtures of fatty acid esters with fatty acid glycerides, which consist of both

hydrophobic and hydrophilic components. *Id.* at 34 (citing Ex. 2029, 130:11–13 (Chambliss deposition); Ex. 2030 ¶ 91).

Patent Owner argues that "PGGs are mixtures of PEG fatty acid esters ('PEGEs') and glycerol fatty acid esters ('fatty acid glycerides')" and that "the specification discloses that 'the hydrophobic binder material may comprise … hydrophobic and hydrophilic materials, having hydrocarbon backbones,'" immediately after "the disclosure of 'fatty acid esters' and 'fatty acid glycerides' in the binder section of column 16." Sur-reply 10 (citing Ex. 2030 ¶ 91; Ex. 1001, 16:28–29; Ex. 2029, 130:11–13) (emphasis omitted, alteration in original). According to Patent Owner, PGGs act as solubilizers and help a formulation accommodate a broader range of poorly water-soluble drugs because PGGs have both hydrophobic and hydrophilic components. *Id.* at 10–11 (citing Ex. 2030 ¶ 91). So, Patent Owner concludes, "PGG's ability to add both hydrophobic and hydrophilic characteristics to the matrix would lead a POSA to select PGGs." *Id.*

In addition to the explicit disclosures in the specification, Patent Owner asserts that a POSA would have recognized that commercially available PGGs, in particular, Gelucire® 44/14 and 50/13, were consistently used in the melt extrusion/melt granulation preparation techniques disclosed in the "Matrix Formulations" section. PO Resp. at 32 (citing Ex. 1001, 17:42–43; Ex. 1005, 24; Ex. 1006 ¶ 110; Ex. 2030 ¶ 87). Patent Owner also contends that the beneficial ability of PGGs to add both hydrophobic and hydrophilic characteristics to the matrix would lead a POSA to select PGGs in the claimed combination. *Id.* at 34–35 (citing Ex. 2030 ¶ 91). Additionally, according to Patent Owner, a POSA would have recognized that the commercially available PGGs mentioned above are solid at ambient

and physiological temperature, and thereby provide both abuse-deterrent properties and function as excellent surfactants/emulsifying agents. *Id*. at 35 (citing Ex. 2030 ¶¶ 92–93). Patent Owner contends that, because PGGs can function in the dual role of a binder and surfactant, a POSA would have viewed PGGs as a primary candidate for the "fatty acid esters"/"fatty acid glycerides" category of binders, as PGGs would have satisfied multiple functional goals of the claimed waxy matrix abuse dosage form. *Id.* at 36 (citing Ex. 2030 ¶ 94). Patent Owner further notes that the specification teaches that "surfactants" may be among the gelling agents used to deter abuse, and that PGGs are specifically identified as an exemplary surfactant. *Id*. at 37–38 (citing Ex. 1001, 7:11–12, 28:36–41; Ex. 1005, 10, 40; Ex. 1006 ¶¶ 49, 89, 173). Patent Owner alleges that "[t]hese needs for the claimed matrix would have been blaze marks to use PGG." *Id.* at 36.

Patent Owner disputes Petitioner's argument that PGGs are not gelling agents and contends that the argument "has no scientific basis and is contradicted by the prior art." Sur-reply 7. Patent Owner further contends that Dr. Chambliss failed to present "explanation or evidence to refute the disclosures in the specification and prior art explicitly demonstrating that PGGs were known as gelling agents at the time of the invention." *Id.* at 7–8. In support of this argument, Patent Owner cites to disclosures discussing Gelucire's gelling abilities from various references that were presented to Dr. Chambliss, which Patent Owner contends he failed to refute. *Id.* (citing Ex. 2034, 56; Ex. 2037, 367; Ex. 2036, 385; Ex. 2035, 5:49–57).

d) Analysis

After reviewing the briefing and evidence of record developed in this proceeding, we are persuaded that Petitioner has demonstrated by a preponderance of the evidence that the Priority Applications lack written description support for the claimed invention. We find that the specification fails to reasonably convey that the inventors had possession of an abuse-deterrent controlled release dosage form that included all the Claimed Pharmaceutical Ingredients—in particular PGGs—and also satisfied the claimed functionality of a) "providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient" and b) "being abuse deterrent when subjected to tampering comprising heating at a temperature greater than about 45°C."

We acknowledge that, as Patent Owner argues, the case law does not mandate that a specification include an example with a particular set of claimed elements to satisfy the written description requirement. *See* PO Resp. 12–13 (citing *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015)). We also recognize, as described above and as Petitioner acknowledges (Pet. 34), that the Claimed Pharmaceutical Ingredients are mentioned at various points in the specification:

- "Oxycodone or a pharmaceutically acceptable salt thereof" is identified in the specification as one of the preferred embodiments of an "opioid analgesic." *See, e.g.*, Ex. 1001, 8:49–51. In particular, the specification states: "[t]he opioid agonists useful in the present invention include, but are not limited to . . . oxycodone . . . . In certain preferred embodiments, the opioid agonist is oxycodone or hydrocodone." *Id.* at 8:20–51; *see also id.* at 31:5–6. Oxycodone's chemical structure, commercial

availability, and envisioned doses are described in the specification at 9:36–10:9. *See also id.* at 30:27–42 (organic acid salts).

- C_{12}–C_{40} fatty acids, carnauba wax, and beeswax are specifically identified as additional hydrophobic binder materials that "preferably contribute[] to the sustained release of the opioid analgesic or pharmaceutically acceptable salt thereof from the sustained-release matrix." *Id.* at 15:65–67. The specification states that if additional hydrophobic binder material is included,

  > it is preferably selected from natural and synthetic waxes, fatty acids, fatty alcohols, and mixtures of the same. Examples include beeswax, carnauba wax . . . In certain preferred embodiments, a combination of two or more hydrophobic binder materials are included in the matrix formulations. Preferred hydrophobic binder materials which may be used in accordance with the present invention include digestible, long chain (C_8-C_{50}, especially C_{12}-C_{40}).

  Id. at 16:1–12.

- PGGs are disclosed for use as a surfactant: "Surfactants useful in accordance with the present invention, include for example . . . polyglycolyzed glycerides." *Id.* at 28:35–41. The specification also discloses that "surfactants" and "mixed surfactant/wetting agent systems" are amongst the gelling agents that can comprise an aversive agent. *Id.* at 6:64–7:11.

The specification also discloses methods of creating drug abuse deterrence to preclude tampering and that the dosage form provides a therapeutic effect for at least about 12 hours when orally administered to a human patient. Ex. 1001, 1:1–2, 4:30–40 (disclosing tampering methods to access the opioid), code (57).

Notwithstanding these individual teachings, we find that the specification fails to demonstrate that the inventors of the '961 patent possessed a dosage form comprising a combination of the recited components that also satisfied the recited functionality. We are persuaded that the specification fails to provide sufficient guidance that would have led the POSA to create the recited dosage form. *See Fujikawan* 93 F.3d at 1571; *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967). Rather, "one is left to select[] from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made." *Ruschig*, 379 F.2d at 995.

The written description issue presented in this case is similar to that addressed in *Novozymes A/S v. DuPont Nutrition Bioscis, APS*, 723 F.3d 1336 (Fed. Cir. 2013). There, the Federal Circuit considered whether a priority application provided written description support for a claim reciting alpha-amylase enzymes with three features: (1) a parent sequence having at least 90% homology with BSG alpha-amylase; (2) an amino acid substitution at position serene 239; and (3) increased thermostability at 90°C, pH 4.5, and 5 ppm calcium. *Id.* at 1348. The court noted that although "each of those individual limitations is expressly stated in the disclosure of the [priority] application . . . , [the] application . . . contains no disclosure of any variant that actually satisfies the claims, nor is there anything to suggest that [patent owner] actually possessed such a variant at the time of filing." *Id.* In other words, while the "application provides formal textual support for each individual limitation recited in the claims of the [patent-in-question], it nowhere describes the actual functioning

thermostable alpha-amylase variants that those limitations together define." *Id.* at 1349. The Federal Circuit further provided: "[t]aking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches the [priority] application in vain for the disclosure of even a single species that falls within the claims or for any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." *Id.* When "viewing the matter from the proper vantage point of 'one with no foreknowledge of the specific compound,'" the court found that the particular variants claimed in the patent lacked meaningful written description support in the priority application. *Id.* (citing *Ruschig*, 379 F.2d at 995).

The cases Patent Owner cites in response, *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005) and *Snitzer v. Etzel*, 465 F.2d 899 (CCPA 1972), are unavailing. Patent Owner claims that the cases Petitioner cites, including *Novozymes*, are distinguishable because, in those cases, the specifications "did not specifically identify the claimed embodiments." PO Resp. 15–16. Patent Owner cites *Snitzer's* holding that "the literal description of a species provides the requisite legal foundation for claiming that species" as support for its disclosure of PGGs as gelling agents. *Id.* Patent Owner cites *Perricone* as distinguishing a specific disclosure of a claim element within a list from a disclosure of a genus encompassing a claimed subgenus. *Id.* at 16.

Neither of these cases applies here. *Snitzer* is distinguishable because the subject compound, ybetterium, was clearly disclosed for the claimed purpose in a small list of fourteen components. *Snitzer*, 59 CCPA at 1243.

In addition, *Snitzer's* claim did not involve use of a combination of components used for their specific characteristics, as is the case here.

In *Perricone*, the court examined whether the inclusion of an ingredient could "anticipate because it appears without special emphasis in a longer list" and concluded that its presence in the list was sufficient for the purposes of anticipation. *Perricone*, 432 F.3d at 1376. There is no dispute between the parties that PGGs are disclosed in the '961 patent; rather, the question is whether PGGs are adequately disclosed as a gelling agent that could be used in the claimed dosage form, and whether that use was ascertainable by a POSA upon reading the specification. *Perricone's* holding does not apply.

Like the court in *Novozymes*, we find that, without the benefit of hindsight, a POSA would not have been guided by the disclosure of the '961 specification towards combining the individual teachings scattered throughout the specification to arrive the claimed abuse deterrent dosage form. We have considered, but do not agree with, Patent Owner's arguments to the contrary.

Patent Owner asks us to start with the Matrix Formulations section of the specification as the "roadmap" for the claimed invention. PO Resp. 27 (citing Ex. 1001, 17:64–18:2). Even assuming that a POSA would have focused on that section as the starting point, the path to the claimed invention from there is not so clear. The cited sentence broadly mentions "blending the opioid analgesic and at least one aversive agent, together with a sustained release material and preferably a binder material to obtain a homogenous mixture." Ex. 1001, 17:64–18:2.

We are unpersuaded by Patent Owner's contention (e.g., PO Resp. 28) that the specification demonstrates that PGGs would have been considered an "aversive agent" that could be used with the other Claimed Pharmaceutical Ingredients in the dosage form. In support, Patent Owner points out that a) the specification defines "aversive agents" to include a "gelling agent" (Ex. 1001, 4:27–29); b) the specification lists "surfactants" among the gelling agents that may be used (*id.* at 6:64–7:13), and c) the specification lists "polyglycolyzed glycerides" (PGGs) among the "[s]urfactants useful in accordance with the present invention" (*id.* at 28:35–58). Although we agree that the specification discloses that an aversive can be a "gelling agent," we do not agree with Patent Owner that the specification contemplates or adequately discloses that PGGs can be used as a gelling agent in the claimed dosage form. Instead, the specification recites PGGs only once, in a paragraph beginning with "[i]n certain embodiments of the dosage forms of the present invention may also include a surfactant." *Id.* at 28:35–36. Those surfactants, however, are generically described as "for example, ionic and nonionic surfactants or wetting agents commonly used in the formulation of pharmaceuticals"—not as aversive agents. *Id.* at 28:37–39.

Thus, to arrive at Patent Owner's preferred conclusion, a POSA would have had to first choose "gelling agents" from a list of "aversive agents," then choose "surfactants" from a laundry list of over thirty-five potential gelling agents, and then further choose PGGs from another laundry list—approximately 20 columns later—of over forty-five potential surfactants, none of which are described or contemplated as "aversive agents." We acknowledge Dr. Chambliss' testimony that PGGs offer beneficial

characteristics within a formulation by acting as a solubilizer due to their hydrophobic and hydrophilic components, and that a POSA wanting these characteristics would be led to select PGGs. Ex. 2030 ¶ 91. But in the absence of guidance in the specification to instruct a POSA that PGGs could be used in a formulation of the recited claims for this purpose, we do not find its placement in a laundry list of potential components sufficiently points to the use of PGGs as part of the claimed formulation as an aversive agent.

We are likewise unpersuaded by Patent Owner's assertion that a POSA would have selected PGGs for the abuse deterrent dosage form because they satisfy "several goals . . . for the claimed waxy matrix abuse deterrent dosage form: (1) gelling; (2) improve drug release; and (3) improve processing of API. These needs for the claimed matrix would have been blaze marks to use PGG." PO Resp. 36 (citing Ex. 2030 ¶ 94). The cited testimony by Dr. Constantinides cites no supporting evidence in the '961 patent or the prior art for this statement aside from an admission by Dr. Chambliss that "PGG also acts as an emulsifying agent 'that holds the oil and water together to make an emulsion.'" Ex. 2030 ¶ 94. Dr. Chambliss' statement does not support Dr. Constantinides' assertion that the ultimate drive to select PGGs was based on its satisfaction of (1) gelling, (2) improved drug release, and (3) improved processing of API. Therefore, Dr. Constantinides' testimony on this point is unsupported and entitled to little weight. *See Rohm and Haas Co. v. Brotech Corp*., 127 F.3d 1089, 1092, (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness). Moreover, Dr. Constantinides' testimony does not give

us reason to conclude that the '961 patent reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

Indeed, the Federal Circuit affirmed the Board's finding that claims in a related patent[5] reciting polyethylene oxide ("PEO") and hydroxypropylmethyl-cellulose ("HPMC") did not find written description support in the same laundry list of gelling agents relied upon by Patent Owner in this case. *Purdue Pharma L.P.*, 767 F. App'x at 924 (nonprecedential). The court found that "PEO and HPMC are merely two of many undifferentiated compounds that fall within the genus of gelling agents." *Id.* The court explained, "the language 'mixtures thereof' suggests the possibility of combining two or more of the listed gelling agents. Without more, however, that language fails to highlight any preference for how many and which gelling agents to combine." *Id.* "The additional references to PEO and HPMC throughout the provisional application do not constitute 'blaze marks' that indicate or direct that a particular combination should be made 'rather than any of the many others which could also be made.'" *Id.* at 925. As such, the court found that the claimed invention in that case did not have written description support to support a claim of priority to the '534 Provisional Application.

[5] Claims 1–13 and 16–19 of related U.S. Pat. No. 9,034,376 were found unpatentable for obviousness, affirming the Board's same finding. *See Amneal Pharms., LLC v. Purdue Pharma L.P.*, IPR2016-01412 (PTAB Feb. 8, 2018) (Paper 39), *aff'd*, *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918 (Fed. Cir. Apr. 17, 2019); *Amneal Pharms., LLC v. Purdue Pharma L.P.*, IPR2016-01413 (PTAB Jan. 17, 2018) (Paper 37), *aff'd*, *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918 (Fed. Cir. 2019).

The same is true here. The challenged claims ask a POSA to make a combination not taught, described, or even forecast in the specification. Patent Owner engages in hindsight reconstruction, rather than describing the alleged invention as required by 35 U.S.C. § 112(a).

In summary, we conclude that the challenged claims do not have sufficient written description support in any of the Priority Applications, and can claim priority only to the '722 application that led to the '961 patent. Because the '722 application was filed after March 16, 2013, the '961 patent claims are eligible for post-grant review. Further, because the specifications are substantially similar, the specification of the '961 patent likewise fails to provide adequate written description support for the challenged claims.

E. Enablement

1. Legal standard

Section 112(a) states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112(a). "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Trustees of Boston University v. Everlight Electronics Co., Ltd.*, 896 F.3d 1357, 1362 (Fed. Cir. 2018) (bracketing in original; internal quotations omitted). That is, "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill [in the art] how to make and how to use the invention as broadly as it is claimed." *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991). "That some experimentation is necessary does

not preclude enablement; the amount of experimentation, however, must not be unduly extensive." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F. 2d 1569, 1576 (Fed. Cir. 1984) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983)).

2. Analysis

Petitioner argues that the Priority Applications[6] do not enable the full scope of the '961 patent's claims. Pet. 40–66; 68–69; Reply 18–26. Petitioner contends that the challenged claims are "extraordinarily broad" because "they do not limit the identity of the specific ingredients in the broadly claimed classes, nor the relative amounts, nor any limitation on how to achieve the Functional Claim Limitations." Pet. 42 (citing Ex. 1002 ¶¶ 118–133). Petitioner argues that the scope of the challenged claims would cover: (1) "any 'oxycodone or pharmaceutically acceptable salt thereof'" of "any amount"; (2) any amount and any chemical composition of a single grade, or combination of grades, of PGG; (3) any amount, chemical composition, or combination of C_{12}-C_{40} fatty acids; and (4) any amount of carnauba wax or beeswax. *Id.* at 43–44 (citing Ex. 1002 ¶¶ 40–49, 119, 122, 123, 125).

Petitioner argues that the challenged claims recite "an abuse deterrent dosage form" but provide "no specific structures or mechanisms to limit or guide how the abuse-deterrent property should be achieved" and provide that the temperatures for tampering are nearly limitless (i.e., any temperature greater than about 45 C). *Id.* at 44–45 (citing Ex. 1002 ¶¶ 128–129).

[6] Because the applications are substantially similar, we interpret Petitioner's arguments about the '534 provisional application to apply equally to the '961 specification ('722 provisional application).

Petitioner additionally argues that the claims do not recite a method for preparing the dosage form, but require it to be homogenous and the preparation process to result in particles that can be combined by melting, with dependent claims reciting certain particle size ranges. *Id.* at 45 (citing Ex. 1002 ¶ 130).

Petitioner argues that the '534 Provisional Application does not provide any working examples of formulations within the scope of the challenged claims and "a POSA's formulation efforts would be an entirely *de novo* effort, as opposed to routine experimentation" because "the claimed art—pharmaceutical sciences—is inherently unpredictable, especially with regard to whether any combination of Claimed Pharmaceutical Ingredients will satisfy the Functional Claim Limitations." Pet. 42 (citing Ex. 1002 ¶¶ 156–190); Reply 23–26. Petitioner argues that the '534 Provisional Application – which lacks a working embodiment of the claimed invention that was tampered by heating to above about 45º C – "does not provide a POSA with direction or guidance concerning how to make the claimed subject matter." Pet. 46–47. Instead, Petitioner argues, the specification states that the methods and ingredients can be used by, e.g., "any of the procedures well-known to those skilled in the art of pharmaceutical formulation." *Id.* at 47–50 (citing Ex. 1002 ¶¶ 134–153).

Petitioner alleges that the art is unpredictable, and that "without first formulating and then testing, a POSA would not know" how to identify properties of the ingredients to use or how to achieve formulations that meet the claim limitations. *Id.* at 50–51 (citing Ex. 1002 ¶¶ 156–159). Petitioner identifies evidence submitted by Patent Owner during prosecution reflecting Patent Owner's difficulty experienced when substituting types of

oxycodone. *Id.* Petitioner alleges that this difficulty shows the unpredictability of formulating the claimed oral dosage form. *Id.* at 53–54 (citing Ex. 1032; Ex. 1002 ¶¶ 159–168). Petitioner further claims that the lack of information about how to manufacture the claimed dosage form, the varying effects of the method of manufacture and form of each individual component, and the "near infinite number of combinations of the Claimed Pharmaceutical Ingredients that fall within the Challenged Claims" are all factors that would make creating the dosage form more difficult. *Id.* at 55–56 (citing Ex. 1002 ¶¶ 169–175). Petitioner alleges that because the specification and the prior art were devoid of guidance, the POSA would have needed to experiment to determine the parameters needed to create a dosage form that met the claimed limitations, and "a minimum of 1200 hours of experimentation, over an 8-month period, to enable the full scope of the narrowest claims of the '961 patent." *Id.* at 57–63 (citing Ex. 1002 ¶¶ 176–193).

According to Petitioner,

> A POSA confronted with the Related Applications is presented with (i) broad claims that encompass nearly an infinite number of potential claimed embodiments, (ii) no working Examples, (iii) minimal or no guidance concerning how to select the identity or amount of the Claimed Pharmaceutical Ingredients found in the many laundry lists of ingredient in the specifications, and (iv) given the unpredictable nature of the art, numerous inoperative formulations that fail to satisfy the Functional Claim Limitations.

Id. at 40 (citing Ex. 1002 ¶¶ 118–193); Reply 18.

Patent Owner argues that the challenged claims are adequately enabled, that Petitioner ignores the POSA's existing knowledge, and that "[a] POSA reading the '534 specification would have much more guidance

than Collegium contends." PO Resp. 42. According to Patent Owner, the specification teaches a POSA how to use the claimed method and states that the claimed dosage form can be made by "any of the procedures well-known to those skilled in the art of pharmaceutical formulation" so long as the method prepares particles from a homogenous mixture. *Id.* (citing Ex. 1002 ¶ 141; Ex. 2030 ¶ 104). Patent Owner further argues that melt-granulation and melt-extrusion methods of manufacturing sustained-release dosage forms in connection with matrix formulations are identified in detail in the specification and were known in the art, so "[n]o further explanation would be needed for a POSA to understand how to use them to manufacture multiparticulates and make a solid oral dosage form." *Id.* at 42–43 (citing Ex. 2030 ¶¶ 104, 105; Ex. 1001, 17:15–19:10, 19:54–20:45; Ex. 1005, 24–26, 27–29; Ex. 1006 ¶¶ 105–120, 125–129).

Patent Owner identifies purported errors in Dr. Chambliss' testimony about the POSA's knowledge (*see id.* at 44–45), and additionally contends that Dr. Chambliss overcounted the possible combinations of ingredients that could meet the claim limitations. *Id.* at 44–48. For example, Patent Owner argues that in choosing an oxycodone active pharmaceutical ingredient ("API"), "a POSA would first have focused on APIs that are specifically identified in the specification: oxycodone base and the hydrochloride and sulfate salts" and "given the other claimed ingredients, namely, the hydrophobic waxes and hydrophobic fatty acid, a POSA would [] first have a more hydrophobic API—thus, oxycodone base." *Id.* at 44 (citing Ex. 2030 ¶ 108; Ex. 1001, 30:27–37; Ex. 1005, 44–45; Ex. 1006 ¶ 184). Patent Owner also contends that "the range of extended-release oxycodone dosage strengths on the market as of August 2001 was narrow,

i.e., four strengths between 10 and 80 mg" and once a POSA achieved success with one strength, she "would expect to be able to formulate additional strengths without undue experimentation." *Id.* at 45–46 (citing Ex. 2030 ¶ 112; Ex. 1031; Ex. 2013). Patent Owner makes similar observations with regard to PGGs, C_{12}–C_{40} fatty acids, waxes, abuse-deterrent dosage forms, and process elements. *Id.* at 46–54.

In further support of its argument that the specification fully enables the '961 patent's claims, Patent Owner discusses the *Wands* factors. *Id.* at 55–63 (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). According to Patent Owner, a "POSA is knowledgeable, and the supposed deficiencies of the specification identified by Collegium are within the scope of the POSA's knowledge" because "a POSA would have known which ingredients within the claims to try, as well as how to combine those ingredients with melt granulation or melt extrusion." *Id.* at 55 (citing Ex. 2030 ¶ 125). Patent Owner further explains the steps a POSA would have taken to reach the claimed dosage forms and argues that the specification provides a POSA with ample guidance to practice those steps. *Id.* at 55–56 (citing Ex. 2030 ¶ 126). Patent Owner contends that working examples are not required for the claims to be enabled, and the "detailed disclosure" in the specification is sufficient without working examples. *Id.* (citing *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 (Fed. Cir. 2006)). Patent Owner also argues that Petitioner does not identify any inoperative embodiments, and the art is not so unpredictable because "a POSA would have understood that a more hydrophobic API (e.g., oxycodone base) would dissolve better in the hydrophobic excipients of the '961 claims (waxes, fatty

acid) than a hydrophilic API (e.g., oxycodone hydrochloride) and would have started with the base for that reason." *Id.* at 58–59 (citing Ex. 2030 ¶¶ 130–131). Finally, Patent Owner states that the quantity of experimentation estimated by Petitioner, "at least 1200 man-hours over at least an 8-month period," is not undue experimentation because "a POSA would know what experiments to carry out, such that experimentation would be routine." *Id.* at 62–63 (citing Ex. 1002 ¶ 193; Ex. 2030 ¶ 140).

Petitioner responds that the evidence does not show the entire scope of the '961 patent claims are enabled, and that enabling some of the claimed embodiments is insufficient. Reply 19–20. Petitioner claims that Patent Owner and its expert did not address additional components of the composition—fatty acids and PGGs—that were known as of the priority date but that were not examined by the expert's testimony in forming his opinion that the specification enables the claims. *Id.* (citing Ex. 1002 ¶ 183; Ex. 2030 ¶ 113; Ex. 1081, 47:11–24, 175:3–13, 176:3–12). Petitioner argues "at a minimum, the record evidence contains twenty different PGGs with varying physical-chemical properties" and that Patent Owner's expert "mistakenly believes that [the patent] need only enable PGGs that are solid at room temperature and were used in previously-approved FDA products." *Id.* at 21 (citing Ex. 1087 ¶ 37; Ex. 2030 ¶¶ 20, 113, 123; Ex. 1081, 61:2–64:9).

Petitioner argues that a POSA would not know "without first formulating and then testing," whether a given combination would satisfy the claim limitations. *Id.* at 22. Petitioner argues that Patent Owner's expert ignores clear evidence of the unpredictability in formulating mixtures that meet the claim limitations by mistakenly construing a "homogenous

mixture" to mean that the components must exist in a single phase rather than the commonly accepted understanding, "a mixture where the ingredients are uniformly distributed and need not form a single phase." *Id.* at 22–24 (citing Ex. 1032; Ex. 1081, 166:7–167:23; Ex. 1087 ¶¶ 8–20). Petitioner argues that, even under the incorrect definition, the art is still unpredictable because Patent Owner's expert conceded that "[i]t might not be possible" for a POSA to make a formulation according to the claims using the only oxycodone form used in the examples. *Id.* at 24 (citing Ex. 1082, 179:17–182:13). Petitioner cites Patent Owner's statements to our appellate court that, at the time of the invention, the process of making a formulation by hot-melt extrusion was new, not well understood, and fraught with potential problems. *Id.* at 25 (citing Ex. 1080 at 15–16, 39). Petitioner argues these problems are even more unpredictable when making a single-phase composition, and when adding a gelling agent, despite that guidance to overcome these problems is not provided in the specification. *Id.* at 25–26 (citing Ex. 1087 ¶ 41; Ex. 1081, 158:15–159:5; Ex. 1081, 159:20–160:22, 177:9–13; Ex. 1040, 41[7]; Ex. 1002 ¶ 190).

Patent Owner replies that enabling the full scope of the '961 patent's claims does not require that the specification enable a POSA to make a formulation using every possible variant. Sur-reply 12. Patent Owner claims the skilled artisan would know "which PGGs to use to achieve solid, controlled release, abuse-deterrent dosage forms." *Id.* at 13 (citing Ex. 2030 ¶¶ 87, 92–94, 125). Patent Owner argues that a skilled artisan "would naturally include PGGs that were FDA approved, commonly used with the

[7] Petitioner cited Ex. 1040, 41, which we interpreted by context to mean Ex. 1080, 41.

melt extrusion/granulation process, and solid at room temperature." *Id.* Patent Owner argues that Petitioner's case fails because it has "presented no evidence that practicing the claimed invention would require undue experimentation using the processes disclosed in the specification, such as melt extrusion and granulation." *Id.* at 14–15.

After reviewing the full record of evidence, and considering the relevant *Wands* factors in light of the evidence and prior art teachings relied upon by the parties and the relevant case law, we conclude that Petitioner has not shown that the '961 patent fails to enable the challenged claims. "Although there is often significant overlap" between the enablement and written description requirements, "they are nonetheless independent of each other." *Univ. of Rochester*, 358 F.3d at 921. An "invention may be enabled even though it has not been described." *Id.* Such is the situation here. While we conclude that one skilled in the art would have been able to make and use the full scope of the challenged claims through routine experimentation, we find, as discussed above, that Patent Owner did not describe the invention of the claims sufficiently to show it had possession of the claimed genus of PGGs as aversive agents. *See, e.g.*, *Noelle v. Lederman*, 355 F.3d 1343, 1348 (Fed. Cir. 2004) (the "invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*").

The question for our analysis is whether, should the POSA have selected to make the dosage forms recited in the challenged claims, including PGGs, using the teachings in the specification combined with the POSA's own knowledge and information available in the prior art at the time of the invention, would the POSA have been able to do so without undue experimentation? The burden of persuasion on this issue rests on the

Petitioner. And although Petitioner has shown that experimentation required to practice the full scope of the claimed invention might have been extensive, Petitioner fails to show that the evidence supports the conclusion that the amount of experimentation would not have been routine for this art. *See, e.g., Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("test [for undue experimentation] is not merely quantitative . . . if it is merely routine"). A "patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

In making these findings, we are informed by our appellate court's decision in *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961 (Fed. Cir. 2014). The court in *Pfizer* found that claims construed to cover "all compositions of 3–isobutylGABA, without limitation as to isomeric form" were enabled by a specification that did not "disclose the required starting materials, reaction conditions, and other working examples" and indicated that teachings in the prior art could be used to inform the process. *Id.* at 966. Here, we are persuaded that the prior art and the specification provide sufficient guidance, including examples, to assist one of skill in the art with formulating a dosage form that meets the limitations of the challenged claims once the desired combination of components was envisioned. In this regard, we are persuaded by Patent Owner's expert testimony and supporting evidence of the guidance provided. *See* Ex. 2030 ¶¶ 104, 105; Ex. 1001, 17:15–19:10, 19:54–20:45; Ex. 1005, 24–26, 27–29; Ex. 1006 ¶¶ 105–120, 125–131. Specifically, Dr. Constantinides explains that the methods disclosed in the '961 patent for making the dosage form, require a homogenous mixture to be made. Ex. 2030 ¶ 104. For this reason, the

POSA would eliminate methods not including forming a homogenous mixture, leaving granulation methods and melt-extrusion methods known in the art. *Id.* Dr. Constantinides continues that, despite that the methods are known, the '961 patent "provides detailed procedures for manufacturing particles via melt granulation and melt extrusion" and "provides a detailed discussion of preparing [extended release] melt-extruded matrix multiparticulates and the equipment for doing so, and containing those particles in a capsule." *Id.* ¶ 105.

Petitioner has not shown that the skilled artisan would have been unable to make the claimed dosage forms using the knowledge of the prior art and guidance of the examples. Though no specific example in the specification shows how to make a dosage form using the claimed components, the specification does identify some of the components—oxycodone, C_{12} to C_{40} fatty acids, carnauba wax, and beeswax—as useful in a manner consistent with their use in the claims and provides detailed methods for their use. *See, e.g.*, Ex. 1001, 17:64–18:2; Ex. 1002 ¶¶ 104, 105. With regard to these components, while Petitioner has provided testimonial evidence that compositions made in the instructed manner with such components can be difficult to formulate, the only evidence Petitioner provides to demonstrate difficulty in creating such formulations pertained to the oxycodone component. Pet. 53–55 (citing Ex. 1032).

Petitioner's discussion of Exhibit 1032 is persuasive as to the point that oxycodone or its salts can present challenges in formulating a homogenous mixture,[8] and that Patent Owner used this evidence to argue the

[8] We acknowledge Petitioner's argument that the parties' definitions of "homogenous phase" differ, and that a single phase may behave differently

novelty of the claimed invention to the Patent Office. *Id.* But this difficulty alone is insufficient to persuade us that the skilled artisan would have been unable to make the formulations described by the challenged claims based on the teachings of the specification combined with knowledge from the prior art. This analysis equally applies to Petitioner's argument that additional oxycodone APIs and abuse deterrent dosage forms have increased as of the effective filing date (*id.* at 68), because any additional testing required to use such forms has not been shown to be beyond the knowledge and capability of the skilled artisan. Moreover, enablement is determined as of the patent's effective filing date, not as of the time of the inquiry. *See, e.g., Plant Genetic Sys., N.V. v. DeKalb Genetics Corp*., 315 F.3d 1335, 1339 (Fed. Cir. 2003).

Similarly, we are not persuaded that it was necessary for the specification to include an example dosage form that was abuse deterrent when subjected to a temperature greater than "about 45 degrees" to enable claims to dosage forms that are abuse deterrent under the claimed tampering conditions. In this regard, we are persuaded by Patent Owner's argument as supported by Dr. Constantinides that the specification discloses gelling agents that will achieve sufficient viscosity (e.g., at least about 10 cP) when heated to greater than about 45° C, such that the components of a tampered dosage form would become gel-like and thus less able to be absorbed for abuse purposes. PO Resp. 75–77 (citing Ex. 1006 ¶¶ 23, 31, 50, 51); Ex.

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from the remainder of the mixture. Reply 22–24. We are not persuaded that this issue is dispositive because, for the dosage form to function as claimed, the particles must contain all components extracted as particles from the homogenous mixture, and Petitioner has provided no evidence showing impossibility in this regard. Ex. 1001, 41:37–52.

2030 ¶ 135. These gelling agents are disclosed in the specification for use in a manner consistent with their established use in matrix formulations, which use Dr. Constantinides has testified would have been understood by one of ordinary skill in the art. Ex. 2030 ¶¶ 36–39. Petitioner has provided no persuasive evidence to show that such use of these gelling agents would require undue experimentation, requires additional guidance, or is otherwise unpredictable. *See In re Wands*, 858 F.2d at 737 (enumerating factors to be considered in determining whether a disclosure would require undue experimentation).

With regard to the PGG component, we are persuaded by the testimony of Dr. Constantinides (Ex. 2030 ¶¶ 87, 92–94, 125) that a POSA "would have known that Gelucire® 44/14 and 50/13 can improve drug solubility and dissolution for solid dispersions prepared with melt granulation and melt extrusion." *Id.* ¶ 87 (citing Ex. 2027, 237; Ex. 2028, 1663). The prior art cited by Dr. Constantinides is evidence that skilled artisans at the time of the invention knew how to make solid dispersions by melt-granulation or melt-extrusion using PGGs to improve drug solubility. *Id.* While experimentation would have been necessary, we are not persuaded on this record that it would have been unduly burdensome. Rather, we are persuaded by Dr. Constantinides' testimony that the skilled artisan would have been guided to select an oxycodone active pharmaceutical ingredient based on those exemplified in the specification, and would have selected an oxycodone base due to the hydrophobic nature of the other ingredients. *Id.* ¶¶ 108, 130–131. The artisan would likewise have used dosage strengths reflecting those in use on the market, e.g., 10–80 mg, and would have formulated desired dosage forms in different strengths

using lessons learned with the first dosage forms. *Id.* ¶ 112. In the same manner, the artisan would have known how to experiment with various PGGs that were commercially available, including ones not in solid phase at room temperature, and fatty acids, to make new formulations within the scope of the claims.[9] Petitioner provides no evidence to suggest that experimentation in this manner would not have been successful, given the guidance in the specification and the prior art. We conclude that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims are not enabled.

F. Indefiniteness

1. Legal Standard

In this post grant review proceeding, we apply the test for indefiniteness approved by the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). *See* Memorandum on Approach to Indefiniteness Under 35 U.S.C. § 112 in AIA Post-Grant Proceedings (Jan. 6, 2021), 5 ("The office now clarifies that the Board shall follow *Nautilus* in AIA post-grant proceedings."), available at https://www.uspto.gov/sites/default/files/documents/IndefinitenessMemo.pdf. Under *Nautilus*, a claim of a patent challenged for indefiniteness is unpatentable for indefiniteness if the claim, read in light of the patent specification and the prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. *Nautilus*, 572 U.S. at 901.

[9] Our finding in this regard does not undermine our determination in our written description analysis above that the specification itself fails to adequately describe the use of PGGs as a gelling agent in the claimed formulation.

2. Analysis

Petitioner argues that the '961 patent's claims are unpatentable as indefinite because they "recite a result—an 'abuse deterrent dosage form'—without claiming either the process or pharmaceutical ingredients that result in the 'abuse deterrent dosage form.'" Pet. 69–70 (citing *Forest Labs., Inc. v. Teva Pharm. USA, Inc.*, 716 F. App'x 987, 996 (Fed. Cir. 2017) (Lourie, concurring)). Petitioner did not develop this argument further over the course of the proceeding.

As noted in our Institution Decision and by Petitioner in its Reply, Patent Owner does not address Petitioner's arguments in either its Preliminary Response or its Patent Owner Response. Inst. Dec. 19–20; Reply 27. According to Patent Owner, "[i]t is [] unnecessary to address Collegium's alternative grounds of invalidity (indefiniteness and anticipation), which are relevant only if Collegium succeeds in demonstrating that the claims lack written description or enablement." PO Resp. 23.

Because the parties' arguments and evidence regarding Petitioner's indefiniteness challenge did not change after institution, we remain unpersuaded that the claims are indefinite. We stand by our discussion in the Institution Decision in which we found that "[t]he claims define abuse deterrence in terms of when the dosage form is 'subjected to tempering comprising heating at a temperature greater than about 45° C'" and found that "the claims and specification identify specific ingredients that can help achieve this abuse deterrence functionality." Inst. Dec. 19 (citing Ex. 1001, 41:50–52). As in the Institution Decision, we find the claim limitations here to be distinguishable from the claims at issue in *Forest Labs*, which were

construed to require human study comparisons and found indefinite because the evidence did not establish the particular studies used to make such comparisons. *See id.* (citing 716 F. App'x at 994–95). Thus, we determine that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims are unpatentable as indefinite.

G. Anticipation Based on the '943 Publication

1. Legal Standard

A patent claim is invalid for anticipation under 35 U.S.C. § 102 when a prior art reference describes "each and every claim limitation and enable[s] one of skill in the art to practice an embodiment of the claimed invention without undue experimentation." *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012) (quoting *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1341 (Fed. Cir. 2011)).

2. The '943 Publication

The '943 Publication is a United States patent application assigned to Petitioner. Ex. 1046, code (73). The '943 Publication published on June 16, 2011. *Id.* at code (43). As discussed above, we conclude the '961 patent is not entitled to claim the benefit of an earlier priority date due to a lack of written description support in the Priority Applications, and has a priority date of February 4, 2016. *See supra at* Section II.D(3). Hence, the '943 Publication qualifies as prior art to the '961 patent under at least AIA § 102(a).

The '943 Publication describes "[a]n abuse-deterrent pharmaceutical composition and methods of making and using thereof." Ex. 1046 ¶ 16. An object of the disclosed invention is "to provide a pharmaceutical composition (e.g., a multiparticulate composition) that reduces the potential

for improper administration of drugs without the addition of aversive agents or antagonists, which have the potential to cause harm to legitimate patients." *Id.* ¶ 15. Disclosed compositions "can be used to reduce the likelihood of improper administration of drugs, especially drugs prone to abuse such as oxycodone." *Id.* ¶ 16. Extended release dosage forms containing narcotic analgesics and other drugs available at the time the '943 Publication was filed were "subject to misuse, in part, because mechanical destruction of the dosage form exposes the encapsulated drug and allows for rapid dissolution of the drug into aqueous media." *Id.* ¶ 30.

The '943 Publication discloses that a narcotic analgesic rapidly dissolves into aqueous media as a result of three properties: "(1) the high water solubility of the drug salt form; (2) the lack of protection offered by the hydrophilic and/or water soluble excipients in the formulation; and (3) the ease with which the surface area of the formulation is increased by simple chewing or crushing." *Id.* To modify these properties and achieve the object of the invention, the '943 Publication teaches that the drug's solubility can be modified by forming an ionic interaction between a drug molecule and a charged lipophilic compound, such as a C_5–C_{30} lipophilic acid or amine such as stearic acid. *Id.* ¶ 48.

The '943 Publication additionally teaches that the drug may be "formulated with one or more excipients to form muliparticulates" which may then be used to create a "solid dispersion" which is a system "having small particles of drug . . . of one phase dispersed in another phase." *Id.* ¶¶ 55, 57. A solid dispersion can be created by dispersing the drug in fine particles with excipient(s) or "partially dissolving the drug in molten excipient(s) or partially dissolving the drug with the excipient(s) in a mutual

solvent (e.g., methylene choloride [sic]) during the formulation of the multiparticulates." *Id.* ¶ 59. "Preferred excipients . . . either dissolve slowly in water or are insoluble in water" and include waxes, such as beeswax and carnauba wax. *Id.* ¶ 60.

"[T]he dissolution behavior or the physical and/or chemical stability of the formulation" may also be changed by incorporating one or more substances into the formulation, such as pharmaceutically acceptable surfactants, specifically "[m]ixtures of mono-, di- and tri-glycerides and mono- and di-fatty acid esters of polyethylene glycol, available under the trade name such as GELUCIRE® or Myrj®." *Id.* ¶¶ 61–62.

According to the '943 Publication, "[t]he pharmaceutical composition, when administered orally, results in a desired drug release profile. The release profile provides a therapeutic effect for an extended period of time, typically from 6 to 24 hours, preferably from 12 to 24 hours" and "release[s] only a fraction of the total drug load in simulated stomach conditions when crushed." *Id.* ¶¶ 21, 129. Example 2 of the '943 Publication shows that warming of multiparticulate formations prepared according to the disclosure as compared to OxyContin tablets reduced the percentage of drug that was released from crushing, functioning as a tampering deterrent. *Id.* ¶ 128.

3. Analysis

Petitioner contends that claims 1–17 are anticipated by the '943 Publication. Pet. 70–84. Petitioner provides a claim chart detailing how each limitation of the challenged claims is allegedly taught by the '943 Publication. *Id.* at 72–74, 80–84.

As noted in our Institution Decision and by Petitioner in its Reply, Patent Owner does not address Petitioner's arguments in either its

Preliminary Response or its Patent Owner Response. Inst. Dec. 19–20; Reply 27. According to Patent Owner, "[i]t is [] unnecessary to address Collegium's alternative grounds of invalidity (indefiniteness and anticipation), which are relevant only if Collegium succeeds in demonstrating that the claims lack written description or enablement." PO Resp. 23.

In our Institution Decision, we found that Petitioner demonstrated a reasonable likelihood of prevailing with respect to at least one claim based on its anticipation challenge. Inst. Dec. 20. We have revisited the analysis set forth in our Institution Decision and considered the question of patentability anew in view of all the evidence and arguments presented in this proceeding. Based on the record developed during this proceeding, including the claim charts in the Petition on pages 72–74, 80–84, as supported by the testimony of Dr. Chambliss (Ex. 1002 ¶¶ 213–227), we conclude that Petitioner has shown by a preponderance of the evidence that the '943 Publication anticipates claims 1–17.

III. CONCLUSION[10]

After reviewing the entire record and weighing the evidence offered by both parties, we determine that Petitioner has shown by a preponderance

[10] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

of the evidence that claims 1–17 of the '961 patent are unpatentable as lacking adequate written description support under 35 U.S.C. § 112(a) and as anticipated by the disclosure of the '943 Publication. We conclude that Petitioner has not shown by a preponderance of the evidence that claims 1–17 of the '961 patent are unpatentable as indefinite or nonenabled.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–17 of U.S. Patent No. 9,693,961 B2 have been shown to be unpatentable;

FURTHER ORDERED that, with respect to Paper 35, Patent Owner's Motion to Exclude Evidence (Paper 35); and paragraphs 22–25 of the supplemental Declaration of Petitioner's expert, Dr. Chambliss (Ex. 1087) is denied; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims	**35 U.S.C. §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not shown Unpatentable**
1–17	112(a)	Written Description	1–17	
1–17	112(a)	Enablement		1–17
1–17	112(b)	Indefiniteness		1–17
1–17	102(a)	'943 Publication	1–17	
Overall Outcome			1–17	

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