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571-272-7822

Paper 49
Entered: June 2, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A. and DR. REDDY'S LABORATORIES, INC.,
Petitioners,

v.

INDIVIOR UK LIMITED,
Patent Owner.

IPR2019-00329
Patent 9,687,454 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and RICHARD J. SMITH, *Administrative Patent Judges.*

SMITH, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. ("Petitioners") filed a Petition to institute an *inter partes* review of claims 1–5 and 7–14 ("the challenged claims") of U.S. Patent No. 9,687,454 B2 (the "'454 patent"). Paper 1 ("Pet.").

On June 3, 2019, we entered our Decision on Institution (Paper 21, "Inst. Dec." or "Institution Decision") instituting *inter partes* review of all challenged claims under the only asserted ground. Inst. Dec. 28. Patent Owner filed a Response (Paper 33, "PO Resp."), Petitioner filed a Reply (Paper 42, "Reply"), and Patent Owner filed a Sur-reply (Paper 45, "Sur-reply").[1]

Petitioners and Patent Owner requested an oral hearing. Papers 43, 44. An oral hearing was held on March 3, 2020, and a transcript of that hearing has been entered into the record. Paper 48 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioners have demonstrated by a preponderance of the evidence that claims 1–5, 7, and 9–14 of the '454 patent are unpatentable, but have not demonstrated by a preponderance of the evidence that claim 8 of the '454 patent is unpatentable.

[1] Petitioners and Patent Owner filed objections to the other party's evidence, but did not file motions to exclude to preserve any objection. Papers 23, 24, 35; 37 C.F.R. § 42.64(c).

A. Real Parties-in-Interest

Petitioners identify the real parties-in-interest as Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. Pet. 42.

Patent Owner identifies Indivior UK Limited and Indivior Inc. as the real parties-in-interest. Paper 4, 1.

B. Related Matters

Petitioners and Patent Owner indicate that the '454 patent is involved in litigation in the District of New Jersey in three separate actions: *Indivior Inc. v. Dr. Reddy's Laboratories S.A.*, No. 2:17-cv-07111 (D.N.J.) (Consolidated); *Indivior Inc. v. Alvogen Pine Brook, Inc.*, No. 2:17-cv-07106 (D.N.J.) (Consolidated); and *Indivior Inc. v. Teva Pharmaceuticals USA, Inc.*, 2:17-cv-07115 (D.N.J.) (Consolidated). Paper 3, 2; Paper 4, 1. According to the parties, the '454 patent is also involved in litigation in the District of Delaware in *Indivior Inc. v. Actavis Laboratories UT, Inc.*, No. 1:18-cv-00499 (D. Del.). Paper 3, 2; Paper 4, 1.

Petitioners state that the '454 patent is commonly owned with, shares the same specification as, and is a direct descendant of, U.S. Patent No. 8,475,832 ("the '832 patent"). Paper 3, 2. According to Petitioners, claims of the '832 patent were previously found invalid by the District of Delaware in *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Labs., Inc.*, No. CV 13-1674-RGA, 2016 WL 3186659, at *1 (D. Del. June 3, 2016) (Ex. 1006, "the Delaware Opinion"). *Id.* at 2–3. Petitioners state that aspects of that decision that do not involve the '832 patent are currently on appeal in: *Indivior Inc. v. Dr. Reddy's Laboratories, S.A.*, No. 17-2587 (Fed. Cir.); *Indivior Inc. v. Actavis Laboratories UT, Inc.*, No. 18-1405 (Fed. Cir.); and *Indivior Inc. v. Alvogen Pine Brook LLC*, No. 18-1949 (Fed. Cir.). *Id.* at 3.

Patent Owner states that the '454 patent descends from the '832 patent, and that claims 15–19 of the '832 patent were canceled on June 30, 2015, in Case No. IPR2014-00325. *BioDelivery Sciences Int'l Inc. v. RB Pharm. Ltd*, IPR2014-00325, slip op. at 47 (Paper 43) (PTAB June 30, 2015). Paper 4, 1. Patent Owner indicates that decision was affirmed by the Federal Circuit. *RB Pharm. Ltd. v. BioDelivery Sciences Int'l, Inc.*, 667 Fed. Appx. 997 (Fed. Cir. 2016). *Id.* Patent Owner also states that the Delaware district court separately found that certain asserted claims of the '832 patent, including claims 15–19, were invalid. *Id.* at 1–2 (citing the Delaware Opinion); Ex. 1006.

The parties also identify U.S. Patent Application Serial No. 15/483,769, filed on April 10, 2017, that claims the benefit of the '454 patent, and Petitioners' filing of a second petition for *inter partes* review of the '454 patent in Case No. IPR2019-00328.[2] Paper 3, 3; Paper 4, 1.

C. The '454 Patent

The '454 patent "relat[es] to films containing therapeutic actives . . . [and] more particularly relates to self-supporting film dosage forms which provide a therapeutically effective dosage, essentially matching that of currently-marketed tablets containing the same active." Ex. 1001, 1:20–25. The '454 patent states that "[s]uch compositions are particularly useful for treating narcotic dependence while providing sufficient buccal adhesion of the dosage form." *Id.* at 1:25–27.

[2] Institution of a trial based on that second petition was denied on June 3, 2019. *See Dr. Reddy's Labs. S.A. v. Indivior UK Ltd.*, IPR2019-00328, Paper 21 at 21 (PTAB June 3, 2019).

The '454 patent explains that "[c]urrently, treatment of opioid dependence is aided by administration of Suboxone®, which is an orally dissolvable tablet. This tablet . . . provides a combination of buprenorphine (an opioid agonist) and naloxone (an opioid antagonist)." *Id.* at 4:67–5:4. However, the '454 patent states that tablet forms have the potential for abuse and, in some instances, "the patient who has been provided the drug may store the tablet in his mouth without swallowing the tablet, then later extract the agonist from tablet and inject the drug into an individual's body." *Id.* at 2:1–5.

The '454 patent further states that "the invention relates to the treatment of opioid dependence in an individual, while using a formulation and delivery that hinders misuse of the narcotic." *Id.* at 4:64–67. The '454 patent further explains that "the present invention provides a method of treating narcotic dependence by providing an orally dissolvable film dosage, which provides a bioequivalent effect to Suboxone®. The film dosage preferably provides buccal adhesion while it is in the user's mouth, rendering it difficult to remove after placement." *Id.* at 5:4–10.

The '454 patent further states that "[t]he film dosage composition preferably includes a polymer carrier matrix. Any desired polymeric carrier matrix may be used, provided that it is orally dissolvable." *Id.* at 5:11–13. According to the '454 patent, "[t]he film may contain any desired level of self-supporting film forming polymer, such that a self-supporting film composition is provided." *Id.* at 13:1–3.

The '454 patent describes film compositions that "desirably contain[] a buffer so as to control the local pH of the film composition." *Id.* at 13:26–27. The '454 patent also describes several examples and states that "[t]he

data indicates that not only is the local pH of significant importance, but the amount of buffer present in the formula is also important." *Id.* at 23:54–56.

D. Illustrative Claims

Claim 1 recites:

> 1. An oral, self-supporting, A mucoadhesive film comprising:
> (a) about 40 wt % to about 60 wt % of a water-soluble polymeric matrix;
> (b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof;
> (c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and
> (d) an acidic buffer;
> wherein the film is mucoadhesive to the sublingual mucosa or the buccal mucosa;
> wherein the weight ratio of (b):(c) is about 4:1;
> wherein the weight ratio of (d):(b) is from 2:1 to 1:5; and
> wherein application of the film on the sublingual mucosa or the buccal mucosa results in differing absorption between buprenorphine and naloxone, with a buprenorphine C_{max}[3] from about 0.624 ng/ml to about 5.638 ng/ml and a buprenorphine AUC[4] from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml; and a naloxone C_{max} from about 41.04 pg/ml to about 323.75 pg/ml and a naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml.

Ex. 1001, 24:25–46.

Claim 5 recites:

> 5. The film of claim 1, wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5.

Id. at 24:53–54.

Claim 13 recites:

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[3] "[T]he term C_{max} refers to the mean maximum plasma concentration after administration of the composition to a human subject." Ex. 1001, 3:23–25.
[4] "[T]he term AUC refers to the mean area under the plasma concentration-time curve value after administration of the compositions formed herein." Ex. 1001, 3:25–28.

> 13. A method for treating opioid dependence in a patient in need thereof comprising sublingually or buccally administering the mucoadhesive film of claim 1 to a sublingual or buccal mucosal tissue of the patient to treat the opioid dependence.

Id. at 25:8–12.

E. The Asserted Ground of Unpatentability and Declaration Evidence

Petitioners contend that the challenged claims are anticipated by U.S. Patent Publication No. US 2011/0033541 A1, filed August 7, 2009, and published February 10, 2011 (Ex. 1010, "Myers"), under post-AIA[5] 35 U.S.C. § 102(a)(1) (Pet. 7), as shown in the chart below:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–5, 7–14	102(a)(1)	Myers

Petitioners rely on the Corrected Declaration of Nandita Das, Ph.D. Ex. 1003. Patent Owner relies on the Declaration of Karsten Cremer, Ph.D, submitted with Patent Owner's Response. Ex. 2008.

Patent Owner also filed a Declaration of Dr. Karsten Cremer, Ph.D. dated March 7, 2019 (Ex. 2001, "First Cremer Declaration") with its Preliminary Response (Paper 12). Dr. Cremer testified during trial that he still held all the opinions expressed in the First Cremer Declaration, and was not withdrawing any of those opinions. Ex. 1030, 12:2–7; Reply 5–6 & n.2.

II. DISCUSSION

A. Level of Ordinary Skill in the Art

Petitioners assert that a person of ordinary skill in the art ("POSA") with respect to the technology disclosed in the '454 patent, "would include a person who possessed a Master's or Ph.D. in pharmaceutical sciences,

[5] Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011).

formulation chemistry, or a related field, plus a number of years of relevant experience in developing drug formulations." Pet. 16 (citing Ex. 1003 ¶ 42). Petitioners further state that "[a]s part of a collaborative team working to develop a new drug product, the POSA would have consulted as needed with others possessing the skills that are typically employed in drug development and manufacturing." *Id.* at 16–17 (citing Ex. 1003 ¶ 42).

Patent Owner does not oppose Petitioners' proposed description of a POSA or set forth an alternative description of a POSA. *See generally* PO Resp.; Sur-reply.

We adopt and apply Petitioners' assessment of a POSA because it appears to be consistent with the level of ordinary skill in the art at the time of the invention as reflected in the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))). We also find on this record that Dr. Das and Dr. Cremer are persons of at least ordinary skill in the art under this standard. *See* Ex. 1004; Ex. 1003 ¶¶ 3–12; Ex. 2008, Appendix A, ¶¶ 5–15.

B. Claim Construction

In this *inter partes* review, filed November 13, 2018,[6] we construe the claims of the '454 patent using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C.

[6] The claim construction standard to be employed in *inter partes* reviews has changed for proceedings in which the petition was filed on or after November 13, 2018. 37 C.F.R. § 42.100(b) (2019).

§ 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2019); *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

We determine that we need not expressly construe any claim terms. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. General Principles of Law

To prevail in their challenge to the patentability of the challenged claims, Petitioners must demonstrate by a preponderance of the evidence that the challenged claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

D. Priority Date of the Challenged Claims

The '454 patent issued on June 27, 2017, from Application No. 14/989,669, filed January 6, 2016 ("the '669 application"). Ex. 1001, codes (21), (22), (45). The '669 application is one of a series of continuation applications claiming priority to Application No. 12/537,571, filed on August 7, 2009 ("the '571 application"),[7] that published as Myers. Ex. 1010, codes (21), (22); Ex. 1001, code (63). The first continuation application after the filing of the '571 application was Application No. 13/923,749, filed June 21, 2013 ("the '749 application"). Ex. 1001, code (63).

On September 9, 2016, during prosecution of the '669 application, pending claims 1–10 were cancelled and new claims were added. Ex. 1002, 615–22. Those new claims included the limitations "about 40 wt % to about 60 wt % of a water-soluble polymeric matrix" (issued claim 1), "wherein the film comprises about 48.2 wt % to about 58.6 wt % of the water soluble polymeric matrix" (issued claims 7, 12), "about 48.2 wt % of the water soluble polymeric matrix" (issued claim 8), and "wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5" (issued claims 5, 12). *Id.* at 16–18.

At the time the new claims were added, Patent Owner directed the Examiner to paragraph 33 of the '669 application (paragraph 32 of the '571 application) as providing written description support for the limitation in claim 1 of "about 40 wt % to about 60 wt % of a water-soluble polymeric matrix." Ex. 1002, 619. As Petitioners explain, paragraph 32 of the '571

[7] The '571 application issued on July 2, 2013, as the '832 patent. Ex. 1005. References to "the '571 application" herein are to its Specification as of its filing date of August 7, 2009.

application refers to "about 40% to about 60% by weight" of the polymer component, which refers to "the total amount of polymer components added together, without regard to the other ingredients" (i.e. a different weight percentage than claimed in the '454 patent). Pet. 23 n.6 (citing Ex. 1003 ¶¶ 64, 65; Ex. 1011, 1436 ¶ 32). Patent Owner does not dispute that this paragraph 32/33 does not provide written description support for the claimed polymer weight percentage limitation of "about 40 wt % to about 60 wt %." Reply 2–3 n.1 (citing Ex. 1030, 87:11–89:15; PO Resp. 29–30). Patent Owner now points to other disclosure in the Specification of the '571 application, such as exemplary test formulations, as providing such written description support. PO Resp. 11–61.

According to Petitioners, the effective filing date of the '454 patent is no earlier than June 21, 2013, the filing date of the '749 application, because the '571 application does not provide written description support for the above-referenced limitations that were added during prosecution of the '669 application. Pet. 18–30. Patent Owner disagrees, and argues that the challenged claims have written description support in the '571 application, and that the '454 patent is thus entitled to a filing date of August 7, 2009, the filing date of the '571 application. PO Resp. 11–61. Therefore, according to Patent Owner, Myers is not prior art to the '454 patent and, thus, does not anticipate the challenged claims. *Id.* at 1.

E. Analysis

Our decision in this case turns on whether any of the challenged claims of the '454 patent can effectively claim priority to the '571 application based on satisfaction of the written description requirement of 35 U.S.C § 112. Specifically, the issue before us is whether the claimed

polymer weight percentage and ranges of polymer weight percentages, and claimed range of buprenorphine:polymer/(b):(a) ratios, have written description support in the '571 application.

We first determine whether any of the challenged claims lack written description support in the '571 application. As to any challenged claim for which we find no written description support, we then determine whether that challenged claim is anticipated by Myers, as asserted by Petitioners.

1. Written Description

Claim 1 recites that the film comprises "(a) about 40 wt % to about 60 wt % of a water-soluble polymeric matrix." Ex. 1001, 24:27–28. Dependent claims 7 and 12 narrow that range to "about 48.2% to about 58.6%," and dependent claim 8 recites "about 48.2%" of the water soluble polymeric matrix. *Id.* at 24:57–61; 25:3–7. Claims 5 and 12 depend directly on claim 1, and recite that "the weight ratio of (b):(a) is from about 1:3 to about 1:11.5." Ex. 1001, 24:53–54, 25:4–5.

a) Petitioners' Arguments

Petitioners argue that the '571 application lacks written description support for limitations directed toward the amount of polymer in the claimed films. Pet. 20. As Petitioners explain, those limitations take the form of (1) expressing the amount of polymer as a percentage of the overall weight of the film (claims 1, 7, 8, and 12), and (2) limiting the amount of polymer in the film by requiring the film to have a ratio of buprenorphine-to-polymer ((b):(a)) that falls within a specified range (claims 5 and 12).

(1) Paragraph 65

Petitioners argue that "[t]here is nothing in the text of the '571 application that demonstrates the inventors believed that the polymer weight

percentages and (b):(a) ratios later added to the challenged claims were part of their invention." Pet. 21. Petitioners support this assertion by referring to paragraph 65 of the '571 application that reads as follows:

> The film may contain **any desired level of self-supporting film forming polymer**, such that a self-supporting film composition is provided. In one embodiment, the film composition contains a film forming polymer in **an amount of at least 25% by weight** of the composition. The film forming polymer may alternatively be present in **an amount of least 50% by weight** of the composition.

Id. (quoting Ex. 1011, 1444 ¶ 65 (emphasis added by Petitioners)).[8]

Petitioners argue that paragraph 65 is the only discussion in the '571 application concerning the amount of polymers that should be in the films. Pet. 21. According to Petitioners, paragraph 65 makes clear that "the '571 application does not limit the amount of polymer to a closed range or express it as a (b):(a) ratio, but instead instructs that 'any desired level of . . . polymer' can be used in the films." *Id.* Moreover, according to Petitioners, this short description of open-ended ranges does not provide a POSA any guidance to, and directs a POSA away from, the polymer weight percentage ranges recited in claims 1, 5, 7, 8, and 12. *Id.* (citing Ex. 1003 ¶ 61).

Petitioners further argue that "there is nothing in the '571 application that suggests that the bottom end of the range should be '40 wt %' (claim 1) or '48.2 wt %' (claims 7 and 12)," and there is no disclosure "of the top-end [of the] range, whether it is '60 wt %' (claim 1) or '58.6 wt %' (claims 7 and 12)." Pet. 21–22 (citing Ex. 1003 ¶ 61). Petitioners argue that "[i]t is well established that '[t]he disclosure of a broad range of values does not by itself

[8] Original claim 5 recites "[t]he composition of claim 1, wherein said polymeric carrier matrix comprises at least one polymer in an amount of at least 25% by weight of said composition." Ex. 1011, 1459 (claim 1).

provide written description support for a particular value within that range.'" *Id.* at 22 (quoting *Gen. Hosp. Corp. v. Sienna Biopharm., Inc.*, 888 F.3d 1368, 1372 (Fed. Cir. 2018)). In this case, according to Petitioners, "given the complete lack of guidance in the specification, '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.'" *Id.* (quoting *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967)). Petitioners argue further that the '571 application "describes only open-ended ranges, i.e., 'greater than' and provides no direction that other values or narrower ranges were within the scope of the invention." *Id.* at 22–23 (citing Ex. 1003 ¶ 61).

Petitioners also argue that "[t]he '571 application is entirely silent as to the claimed (b):(a) ratios," and does not refer to a (b):(a) ratio at all or any (b):(a) ratio ranges claimed in the '454 patent. Pet. 24 (citing Ex. 1003 ¶ 69). Petitioners further argue that the '571 application does not provide any guidance to a POSA to craft a ratio of buprenorphine-to-polymer, although it "lists dozens of 'optional components' that may be included in the films, and that can be expressed in thousands of different ratios to one-another." *Id.* (citing Ex. 1003 ¶ 69). According to Petitioners, this lack of disclosure "stands in sharp contrast to the **other ingredients** the inventors specifically expressed in the form of a ratio," such as the (d):(b) ratio and the (b):(c) ratio. *Id.* at 24–25 (citing Ex. 1003 ¶ 70; Ex. 1011, 1445 ¶¶ 66, 67) (emphasis added by Petitioner). Petitioners thus argue that, although "the '571 application makes clear when the applicants regarded certain ratios to be within the scope of the invention," a POSA would not understand that the inventors were in possession of the claimed (b):(a) ratios because no similar

discussion appears anywhere in the '571 application. *Id.* at 25 (citing Ex. 1003 ¶ 67).

Petitioners argue that there is nothing in the '571 application that directs a POSA to the specific (b):(a) range claimed in the '454 patent, asserting that the '571 application discloses only that "any desired level" of polymer may be used for the "(a)" component of the ratio and that "[a]ny desired level of agonist" may be used for the "(b)" component. Pet. 25 (citing Ex. 1011, 1445 ¶ 66; *see also id.* ¶ 65). Petitioners thus argue that "[t]here is simply no reason a POSA would understand the inventors to have been in possession of limitations directed toward specific ratios of two ingredients that the application taught could be present in 'any' amount." *Id.* at 25–26 (citing Ex. 1003 ¶¶ 67–70).

(2) Table 1

Petitioners assert that, during prosecution of the '669 application that lead to the '454 patent, Patent Owner claimed that Table 1 of the '669 application provided written description support for the claimed polymer weight percentage ranges, and that Patent Owner "appears to contend that written description requires only that one can back-calculate seemingly random ranges and ratios from one of the many examples in the specification."[9] Pet. 26 (citing Ex. 1003 ¶ 58; Ex. 1011, 190–97). Table 1 provides components and amounts thereof for various compositions of film dosages, and is set forth below:

[9] Petitioners note that "[a]s a factual matter, Table 1. . . discloses polymer weight percentages of 48.2% and 58.6%." Pet. 26 n.8.

Table 1 – Various Compositions of Film Dosages

Components	Buprenorphine/Naloxone Films Unit Formula (mg per film strip)			
Buprenorphine/Naloxone Ratios	**16/4**	**12/3**	**8/2**	**2/0.5**
Active Components				
Buprenorphine HCl	17.28	12.96	8.64	2.16
Naloxone HCl Dihydrate	4.88	3.66	2.44	0.61
Inactive Components				
Polyethylene Oxide, NF (MW 200,000)	27.09	20.32	13.55	--
Polyethylene Oxide, NF (MW 100,000)	12.04	9.03	6.02	19.06
Polyethylene Oxide, NF (MW 900,000)	4.82	3.62	2.41	2.05
Maltitol, NF	12.04	9.03	6.02	5.87
Flavor	6.0	4.5	3.0	2.4
Citric Acid, USP	5.92	4.44	2.96	2.96
HPMC	4.22	3.16	2.11	2.34
Ace-K	3.0	2.25	1.5	1.2
Sodium Citrate, anhydrous	2.68	2.01	1.34	1.34
Colorant	0.03	0.02	0.01	0.01
Total (mg)	100	75	50	40

Ex. 1011, 1449–50, ¶ 81.[10] Table 1 above is a listing of various compositions of film dosages.

Petitioners argue that the Federal Circuit's decision in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000), controls in this case, and that "the application itself must provide sufficient 'blaze marks' directing POSAs to the specific ranges and ratios claimed," but that "[h]ere, no such blaze marks exist." Pet. 26 (citing Ex. 1003 ¶¶ 73–80). Petitioners argue that the claims at issue in *Purdue* "were directed to the administration of opioid analgesics where the maximum amount of drug in the bloodstream

[10] The four polymer components identified by the parties in Table 1 are the three "Polyethylene Oxide, NF" components (with different molecular weights) and hydroxypropylmethyl cellulose (HPMC). Ex. 1011, 1433 ¶ 25; Ex. 2008 ¶ 31.

(C_{max}) is 'more than twice' the amount of drug in the bloodstream after 24 hours (C_{24})." *Id.* at 26–27 (citing *Purdue Pharma*, 230 F.3d at 1322–23). Petitioners quote *Purdue* as stating that "[a]lthough the examples provide the data from which one can piece together the C_{max}/C_{24} limitation, neither the text accompany[ing] the examples, nor the data, nor anything else in the specification in any way emphasizes the C_{max}/C_{24} ratio." *Id.* at 27 (quoting *Purdue Pharma*, 230 F.3d at 1326). Petitioners further argue that "[t]he Court found that there was nothing in the specification 'that would suggest to one skilled in the art that the C_{max}/C_{24} ratio is an important defining quality of the formulation, nor does the disclosure even motivate one to calculate the ratio,'" and that "[f]inding no blaze marks, the Federal Circuit held the claimed ratios found no written description support." *Id.* (quoting *Purdue Pharma*, 230 F.3d at 1326–28).

Petitioners argue that, like *Purdue*, Patent Owner "crafted claim limitations directed toward disparate characteristics of formulas in a single table [Table 1] of the '571 application," but the '571 application "does not mention those characteristics, even 'in passing.'" Pet. 27 (quoting *Purdue Pharma*, 230 F.3d at 1327). According to Petitioners, there is no indication in the '571 application that the inventors gave any importance to the amount of polymer in the film and, to the contrary, "the '571 application states that 'any' amount of polymer can be used in the purportedly inventive films." *Id.* at 27–28 (citing Ex. 1011, 1444 ¶ 65). Petitioners further argue that "[i]t is no surprise, therefore, that the '571 application does not provide direction that the claimed polymer weight ranges and (b):(a) ratios impart any desirable mucoadhesive, absorption, dissolution, or pharmacokinetic

properties in the inventive films." *Id.* at 28 (citing Ex. 1003 ¶¶ 62, 63, 71, 72, 75, 76).

Petitioners argue that "the '571 application identifies that the principal objectives of the inventive films are to (i) provide an active agent for treating narcotic dependence and (ii) provide sufficient buccal properties." Pet. 28 (citing Ex. 1011, 1463). Petitioners further argue that "[a] POSA reading the specification would have understood the primary focus of the purported invention of the '571 application was the use of buffering agents that would adjust the pH of the films in order to achieve a pharmacokinetic profile that was bioequivalent to the prior art Suboxone® tablets." *Id.* (citing Ex. 1003 ¶ 62). However, as argued by Petitioners, the '571 application "contains no description that the specific amount of polymers used in the films had any impact on these properties of the film," and does not "communicate to a POSA that the amount of polymer in the films impacts the mucoadhesive or disintegration properties of the film." *Id.* (citing Ex. 1003 ¶¶ 63, 71).

(3) Table 5

Petitioners argue that "there is specific data in the specification that directs a POSA **away from** concluding that the polymer weight ranges and (b):(a) ratios had any significance to the inventors." Pet. 29 (citing Ex. 1003 ¶¶ 76–80 (discussing Table 5)) (emphasis added by Petitioner). According to Petitioners, the three formulations used to test the bioequivalence of certain films to Suboxone® tablets (the principal objective in the '571 application) are reported in Table 5 (not Table 1). *Id.* (citing Ex. 1011, 1430, ¶ 13, 1453 ¶ 89; Ex. 1003 ¶ 76). Table 5 provides three formulations of test films at various pH levels, and is set forth below:

Table 5 – Formulations of Test Films at Various pH Levels

Component	**Test formulation 1 8 mg/2 mg pH = 6.5**		**Test formulation 2 8 mg/2 mg pH = 3-3.5**		**Test formulation 3 8 mg/2 mg pH = 5-5.5**	
	%w/w	Mg/film	%w/w	Mg/film	%w/w	Mg/film
Buprenorphine HCl	21.61	8.64	17.28	8.64	17.28	8.64
Naloxone HCl Dihydrate	6.10	2.44	4.88	2.44	4.88	2.44
Polymer	5.05	2.02	4.82	2.41	4.82	2.41
Polymer	28.48	11.39	27.09	13.55	27.09	13.55
Polymer	12.65	5.06	12.04	6.02	12.04	6.02
Polymer	4.43	1.77	4.22	2.11	4.22	2.11
Sweetener	12.65	5.06	12.04	6.02	12.04	6.02
Sweetener	3	1.2	3	1.5	3	1.5
Flavor	6	2.4	6	3	6	3
Citric acid	0	0	5.92	2.96	2.51	1.26
Sodium citrate	0	0	2.68	1.34	6.08	3.04
FD&C yellow #6	0.025	0.01	0.03	0.02	0.03	0.02
Total	**100**	**40**	**100**	**50**	**100**	**50**

Ex. 1011, 1453, ¶ 89.

Table 5 above is a listing of three formulations of test films at various pH levels.

Petitioners argue that "Test formulation 1" and "Test formulation 3" of Table 5 did not produce films that were bioequivalent to Suboxone® tablets, yet they had polymers in amounts "that fell within the polymer weight ranges recited in claims 1, 7, 8, and 12." Pet. 29 (citing Ex. 1011, 1453–56; Ex. 1003 ¶ 77 (reporting polymer weight percentage of 50.6% for Test formulation 1 and 48.2% for Test formulation 3)). Petitioners further argue that Test formulation 2 and Test formulation 3 had the same (b):(a) ratio, but Test formulation 2 succeeded and Test formulation 3 failed. *Id.* (citing Ex. 1003 ¶ 78 (reporting same (b):(a) ratio of 1:2.8 for Test formulations 2 and 3)). Petitioners thus argue that "[i]n view of this conflicting data and the explicit instruction that a POSA could use 'any'

amount of polymer, there is no reason that a POSA would understand the applicants placed any significance on particular weight ranges for polymers or specific (b):(a) values from Table 1." *Id.* (citing Ex. 1003 ¶¶ 70–72, 75, 76, 80). Rather, according to Petitioners, the experiments reflected in Table 5 would have "indicated to a POSA that variations in the amount of buffer, not variations in polymer amounts, were the focus of the purported invention." *Id.* (citing Ex. 1003 ¶¶ 70–72, 75, 76, 80).

b) Patent Owner's Response, Petitioners' Reply, and Patent Owner's Sur-reply Regarding Polymer Weight Percentages

Patent Owner argues that "[a] POSA would have understood that the inventors possessed the polymer weight percentages recited in challenged claims 1, 7, 8, and 12." PO Resp. 11.

(1) Polymer Weight Percentage of "about 48.2 wt %"

Patent Owner argues that the limitation in claim 8 of "about 48.2 wt %" is directly supported by the 48.2 wt % polymer amount in the 16/4, 12/3, and 8/2 formulations in Table 1, as well as Test Formulation 2 in Table 5. PO Resp. 12–14 (citing Ex. 2008 ¶ 34; Ex. 1011, 1457 ¶ 101, 1432 ¶ 22; Ex. 2009, 118:14–119:2 (Petitioners' expert conceding that inventors "[gave] us an example of a film that has 48.2% polymer"), 119:22–121:7. Patent Owner also points to Petitioners' acknowledgment that Table 1 discloses the polymer weight percentage of 48.2%. *Id.* at 14 (citing Pet. 26 n.8).

(2) Polymer Weight Percentage Range of "about 48.2 wt % to about 58.6 wt %"

Patent Owner argues that the '571 application "reasonably conveys to a POSA that the inventors possessed the polymer weight percentage range of 'about 48.2 wt % to about 58.6 wt %' recited in Claims 7 and 12." PO Resp.

14 (Ex. 2008 ¶¶ 36–45). Patent Owner also argues that "this range is not only within the disclosed range of 'at least 25%' . . . but each endpoint is also ***directly*** supported by the 48.2% and 58.6% polymer weight percentages disclosed in the exemplary film formulations provided in Tables 1 and 5." *Id.* at 14–16 (citing Ex. 1011, 1444 ¶ 65, 1459 (claim 5); Ex. 2008 ¶ 36; Ex. 1003 ¶¶ 74, 77) (emphasis added by Patent Owner).

Petitioners reply to the argument that the recited range of "about 48.2 wt % to about 58.6 wt %" is within the disclosed range of "at least 25%" (PO Resp. 14–15) by arguing that paragraph 65 does not provide any upper endpoint for the polymer weight range, citing Dr. Cremer. Reply 3–4 (citing Ex. 1011 ¶ 65; Pet. 21; Ex. 1030, 51:7–53:5, 54:1–15 ("Q. But there's no upper limit identified in paragraph 65 numerically, right? A. That's what I said. Yes."); *see also* 55:3–16). Petitioners advance the same argument with respect to originally filed claim 5. *Id.* at 3–4 (citing Ex. 1030, 55:3–16).

Petitioners reply to the argument that each endpoint is directly supported by the polymer weight percentages of 48.2% and 58.6% disclosed in the exemplary film formulations in Table 1 and Table 5 (PO Resp. 15–16) by arguing that neither Table 1 nor Table 5 disclose the total polymer weight percentage. Reply 4 (citing Ex. 1011, Tables 1 & 5; Ex. 1030, 57:10–58:17, 59:14–60:1, 62:3–19, 63:10–20, 121:11–122:8). Petitioners further argue that "Dr. Cremer back-calculated . . . the total polymer weight percentage values from these example formulations by summing the concentrations of each of the individual polymer weights and calculating the percentage of the total polymer component as compared to the total weight of the formulation." *Id.* (citing Ex. 2008 ¶¶ 31–33). As argued by Petitioners, "[t]he '571 application provides no direction to perform these calculations,

and even then Dr. Cremer obtains only two fixed values (48.2% and 58.6%), not a range." *Id.*; *see also* Reply 1.

Patent Owner replies that "Dr. Das conceded the '571 Application discloses polymer weight percentages and that a POSA would have understood their importance to the inventive films (because of functions expressly disclosed in the '571 application)." Sur-reply 6; *see also id.* at 4–5 citing Ex. 1003 ¶¶ 74, 77; Ex. 2009, 50:7–51:24, 57:17–25, 59:8–12; 93:19–23, 107:7–16, 118:14–120:3.

Patent Owner advances the following additional arguments in support of its contention that a POSA would have understood that the inventors possessed the claimed polymer weight percentage range of "about 48.2% to about 58.6%." PO Resp. 16–22.

(a) Formulations in Table 1 and Test Formulation 2 in Table 5

Patent Owner argues that "[a] POSA would . . . have understood that the inventors possessed formulations with polymer weight percentages of 48.2% and 58.6%" based on the formulations in Table 1 and Test Formulation 2 in Table 5. PO Resp. 17 (citing Ex. 2009, 107:7–16, 118:14–120:3). Patent Owner further argues that "a POSA 'would have understood that the exemplary formulations in Table 1 and Test Formulation 2 in Table 5 all pertained to the same invention with generally the same properties, the same operability, and the same ability to achieve any desired result.'" *Id.* (quoting Ex. 2008 ¶ 38). Patent Owner also quotes Dr. Cremer to argue that "[a] POSA would have understood that 'the inventors possessed not only polymer weight percentages of 48.2% and 58.6%, but also the polymer weight percentages between those two values, that is, the

polymer weight percentage range of 48.2% to 58.6%.'" *Id.* (quoting Ex. 2008 ¶ 38).

Petitioners reply by arguing that the '571 Application does not disclose a bounded range, and also reply to Patent Owner's "same invention" argument, as further discussed below. *See infra* Section II.E.1.b)(2)(c); Reply 5–9.

(b) "about 48.2 wt % to about 58.6 wt %" and Optional Ingredients

Patent Owner argues that the exemplary film formulations disclosed in the '571 application contain optional ingredients, such as flavors and sweeteners. PO Resp. 18. Patent Owner further argues that "a POSA would have recognized that the amounts of these ingredients could vary, changing the polymer weight percentage of the film," and that a POSA "would therefore have immediately discerned . . . that the inventors possessed not merely the polymer weight percentage of 48.2%, but also a range of polymer weight percentages encompassing that value, such as a range extending from 7.2% below to 12.8% above 48.2%." *Id.* (citing *Purdue*, 230 F.3d at 1323) Patent Owner also argues that "[a] POSA would have understood that a polymer weight percentage of 61.0% (48.2% + 12.8%) ***is*** 'about 58.6%.'" *Id.*

According to Patent Owner, the exemplary formulas in Table 1 and Test Formulation 2 in Table 5 of the '571 application give examples of the amounts of flavor and sweetener that could be added or removed, thereby changing the polymer weight percentage of the films, while staying within the invention. PO Resp. 18 (citing Ex. 2008 ¶ 40); *see also id.* at 15 n.9. Patent Owner quotes Dr. Cremer for the assertion that "films prepared according to the '571 Application would remain within the scope of the

disclosed invention even if the flavor and sweetener were removed, added, or varied in amount by a reasonable degree." *Id.* at 19 (quoting Ex. 2008 ¶ 40).

Patent Owner argues that the foregoing assertion by Dr. Cremer is illustrated by five examples derived from disclosed formulations in which, by Dr. Cremer's calculations, (1) flavor and sweetener are removed from the Table 1 formulations and Test Formulation 2 in Table 5, resulting in polymer weight percentages of 52.9% or 61.0% rather than 48.2% (Examples 1 and 3) or 64.4% rather than 58.6% (Example 2), or (2) sweetener is added to formulations in Table 1, resulting in polymer weight percentages of 42.2% rather than 48.2% (Example 4) or 51.4% rather than 58.6% (Example 5). *Id.* at 19–20 (citing Ex. 2008 ¶ 41). According to Patent Owner, these examples "demonstrate that polymer weight percentages could be decreased by at least 7.2% or increased by at least 12.8% of the total weight of the films while staying within the scope of the invention." *Id.* at 20 (citing Ex. 2008 ¶¶ 41, 42). Patent Owner thus argues that "a POSA would have understood that the inventors possessed the claimed polymer weight percentage range of 'about 48.2% to about 58.6%.'" *Id.*; *see also id.* at 15 n.9.

Petitioners reply that "Dr. Cremer's opinions based on altering the presence or quantity of particular 'optional ingredients' in the formulations of Tables 1 and 5—and his examples based thereon (Ex. 2008, ¶¶ 40–41)—are arbitrary, unsupported, and inconsistent with his other opinions," and "should therefore be disregarded." Reply 9. Petitioners argue that Dr. Cremer "undertook multiple steps ungrounded in the explicit disclosure

of the '571 application" in obtaining these exemplary formulations, and "each step is questionable in its reasoning." *Id.* at 9–10.

According to Petitioners, Dr. Cremer first looked at Tables 1 and 5 and determined "which of the ingredients in those formulations could be considered optional." Reply 10. Petitioners argue that Dr. Cremer testified that the optional ingredients in the Table 1 formulations included the sweetener (Ace-K), colorant, and flavor, but that Dr. Cremer would not say whether maltitol (a sugar alcohol) should also be understood as an optional ingredient, even though the '571 application identified maltitol as an optional ingredient. *Id.* (citing Ex. 1030, 66:12–69:4; Ex. 1011, ¶¶ 34, 39). Petitioners further argue that Dr. Cremer testified that he had not "performed that analysis for maltitol" and that his analysis would have changed had he considered maltitol to be an optional ingredient in the Table 1 formulations. *Id.* (citing Ex. 1030, 70:8–71:6, 74:10–77:21, 82:4–84:5). Petitioners thus argue that Dr. Cremer's analysis "fails at step one, and shows the degree of speculation and unbounded variation required by a POSA to proceed with Dr. Cremer's 'optional ingredients' theory." *Id.*

Petitioners further argue that the "optional" ingredients theory is flawed because Dr. Cremer "bases his opinion on which components could be added or removed without 'substantially affect[ing]' the overall formulation." Reply 10–11 (citing Ex. 1030, 72:3–12). According to Petitioners, "Dr. Cremer testified in a conclusory manner that if an optional component is varied in a 'reasonable' amount, it will not 'substantially affect' product characteristics—yet, he refused to explain what he meant by 'reasonable.'" *Id.* at 11 (citing Ex. 1030, 72:3–73:2, 73:18–21). Petitioners further argue that Dr. Cremer "said that the particular examples he proposed

would not require testing to determine whether the presence or absence of a specific component would affect the product characteristics, but admitted that he relied on no scientific literature to support this opinion." *Id.* (citing Ex. 1030, 74:10–76:10). Thus, according to Petitioners, "Dr. Cremer's opinion about which ingredients are properly considered 'optional' in the Table 1 and Table 5 formulations is therefore speculative and not credible." *Id.*

Petitioners then argue that "Dr. Cremer took the ingredients he determined to be optional, varied their amounts within the formulations disclosed, and re-calculated the polymer weight percentage amounts that resulted from his decisions on what to add or remove," but Dr. Cremer "made the decision of how to vary, add, or remove the 'optional' ingredients without relying on any direction from the specification." Reply 11 (citing Ex. 2008 ¶¶ 41, 42; Ex. 1030, 78:14–82:19; Ex. 1011, Tables 1 and 5). Thus, as argued by Petitioners, there is no reason for a POSA to alter the disclosed formulations by adding, removing, or changing the amounts of the ingredients based on the '571 application, and Dr. Cremer's explanation for doing so (a "POSA would not expect instructions like that") is neither supported by objective evidence nor credible. *Id.* at 11–12 (quoting Ex.1030, 80:22–81:1).

Petitioners next argue that Dr. Cremer used his re-calculated values "to support a theory that the application actually discloses polymer weight percentages of 52.9%, 64.4%, 61.0%, 42.2%, and 51.4%." Reply 12 (citing Ex. 2008 ¶¶ 41–42). Petitioners further argue that that "Dr. Cremer opines that a POSA would understand that the polymer weight percentages of the films could be decreased by at least **7.2%** or increased by at least **12.8%**

while staying within the scope of the invention." *Id.* at 12–13 (citing Ex. 2008 ¶ 42; PO Resp. 19–20 (citing Ex. 2008 ¶¶ 41, 42); Ex. 1030, 116:20–117:6). But, according to Petitioners, "Dr. Cremer admitted that he crafted his examples of potential formulations by choosing at random how to vary the amounts or presence of 'optional' ingredients," and "emphasized that one could obtain different values depending on the variation of optional ingredients and amounts chosen." *Id.* at 13 (citing Ex. 1030, 82:4–84:4, 117:3–6, 134:8–135:15).

Petitioners argue that Dr. Cremer's "optional ingredients" analysis is arbitrary, and "not based on any express disclosure or direction in the '571 application." Reply 13. Petitioners cite to Dr. Cremer's testimony that his examples are "formulations that are not specifically disclosed in here." *Id.* (citing Ex. 1030, 134:8–135:5) (Petitioners' emphasis omitted). Petitioners further argue that "even if Dr. Cremer's 'optional ingredients' analysis would have been obvious to a POSA reading the '571 application, that would still be insufficient to render the subject matter disclosed for purposes of priority." *Id.* (citing cases).

Petitioners further argue that Dr. Cremer's "optional ingredients" opinions should be disregarded because he used the same formulation to support two different claimed endpoints. Reply 13–14. Specifically, Petitioners point to Test Formulation 2 in Table 5 (calculated by Dr. Cremer as 61% polymer weight), and Dr. Cremer's opinions that (1) 61% is "about 58.6%" and supports the upper endpoint of 58.6% in claims 7 and 12, and (2) the 61% polymer weight derived from the same formulation provides written description support for the 60% upper bound in claim 1. *Id.* at 14 (citing PO Resp. 19–20, 31; Ex. 2008 ¶ 41, 42, 48; Ex. 1030, 119:14–18).

Petitioners thus argue that Dr. Cremer's "optional ingredients" opinions do not solve the problem of the absence of a disclosure of a range endpoint, but rather "they show the degree of speculation required by a POSA to derive a bounded range from the disclosure in the '571 application, or even to reach the conclusion that a range is disclosed at all." *Id.*

Patent Owner replies that Dr. Cremer explained "why the disclosure of optional ingredients reasonably conveys to a POSA that the invention includes polymer weight percentage ranges." Sur-reply 8 (citing Ex. 2008 ¶ 40; Ex. 1030, 72:3–12). Patent Owner further replies that "the polymer weight percentages . . . could be decreased . . . or increased . . . while staying within the scope of the claimed invention," and that "a POSA would have immediately discerned that the inventors possessed not only the polymer weight percentage of 48.2%, but also a range of polymer weight percentages that encompasses that value." *Id.* at 8–9 (quoting Ex. 2008 ¶¶ 39, 41, 42).

Patent Owner further replies that "[a]lthough Petitioners attempt to criticize Dr. Cremer for not defining the outer bounds of reasonable variation in flavor and sweetener amounts, there was no reason or need to do so because he provided examples of such variation in his Examples 1–5." Sur-reply 9 (citing Ex. 2008 ¶ 41). According to Patent Owner, the removal of flavor and sweetener and the addition of sweetener was "based on a POSA's understanding that [formulations in Table 1 and Test Formulation 2 in Table 5] pertained to the same invention," and were not selected "at random." *Id.* (citing Ex. 2008 ¶¶ 38, 41); *see also id.* at n.2 (citing Reply 13). Patent Owner further argues that "[w]hatever the outer bounds of reasonable variation, it includes at least the variation in Examples 1–5," and that "Dr. Cremer testified that the extent of reasonable variation would have

been 'clear' to a POSA from 'the application as a whole.'" *Id.* at 9–10 (citing Ex. 1030, 72:14–74:6).

Patent Owner also argues that "the outer bounds of reasonable variation are immaterial to Dr. Cremer's testimony that the invention encompasses variation in optional ingredient amounts and polymer weight percentages, and thus includes ranges of polymer weight percentages around the disclosed embodiments of 48.2% and 58.6%." Sur-reply 10. According to Patent Owner, Dr. Cremer testified that "'the gist of [his] examples' is that, in light of permissible variation in optional ingredient amounts, it would be 'apparent to the POSA' that the inventors possessed not only the disclosed embodiments, but also 'a margin or a range that encompasses' them." *Id.* (citing Ex. 1030, 123:14–124:21).

Patent Owner replies to Petitioners' argument regarding Dr. Cremer's lack of "testing or other basis to say" that varying the amounts of flavor or sweetener by a reasonable degree would result in a film pertaining to the same invention (Reply 9–11), by arguing that "given the disclosed formulations in Tables 1 and 5 and the express disclosure that the flavor and sweetener are optional . . . there was no reason or need for Dr. Cremer to cite testing or additional scientific literature." Sur-reply 10 (citing Ex. 2008 ¶¶ 39–40 (citing Ex. 1011, 1436–37 ¶¶ 34, 35)). Patent Owner further argues that "the written description requirement asks what a POSA would have understood from the '571 Application, not from independent testing or research, and Dr. Cremer is qualified to opine on that." *Id.* at 10–11; *see also id.* at 2–4.

Patent Owner further replies that "Petitioners wrongly allege that Dr. Cremer 'could not explain' his decision not to consider whether maltitol

was optional." Sur-reply 11 (citing Reply 9–10). Patent Owner argues that, "[t]o the contrary, Dr. Cremer testified that 'he did not need to analyze' maltitol in his analysis of varying the amount of flavor and sweetener as exemplary optional ingredients," and further that "because maltitol can perform several functions and 'we don't know for sure [its] predominant' function in the inventive films, he decided to 'work[] with other ingredients' whose functions are unambiguous." *Id.* (citing Ex. 1030, 70:4–7, 77:6–21).

Patent Owner replies to "Petitioners' argument that there is 'no direction from the specification' to perform the exact calculations in Dr. Cremer's Examples 1–5 . . . is inapposite," because "Examples 1–5 'are just examples,'. . . which 'illustrate' that films 'would remain within the scope of the disclosed invention even if the flavor and sweetener were . . . varied in amount by a reasonable degree." Sur-reply 11–12 (citing Reply 11–14; Ex.1030, 82:20–84:4; Ex. 2008 ¶¶ 40–41).

Patent Owner also argues that "Petitioners posit a conflict in Dr. Cremer's testimony that the 61.0% polymer weight percentage from his Example 3 is both 'about 58.6%' and 'about 60%'" (Reply 13–14), but that is not correct because "Dr. Cremer's testimony simply reflects his judgment that a POSA would have understood 'about 58.6%' and 'about 60%' to overlap in the context of the invention," and "a disclosure may support several claim limitations." Sur-reply 12 (citing *Ex Parte Bo L. Tran*, 2016 WL 4128591, at *1–2 (PTAB July 14, 2016)).

(c) Polymer Weight Percentage Range of "25% to About 58.6"

Patent Owner argues that the '571 application discloses a polymer weight percentage range of "at least 25%" and a polymer weight percentage of 58.6% (calculated from the 2/0.5 formulation), and that "a POSA would

have understood that this polymer weight percentage [58.6%] is an example of the amount of polymer that could be included in the inventive films in light of the constraints imposed by the presence of other ingredients." PO Resp. 21 (citing Ex. 1011, 1444 ¶ 65, 1459 (claim 5); quoting Ex. 2008 ¶ 43). Patent Owner thus argues that "a POSA would have understood that the inventors possessed a polymer weight percentage range of 25% to 58.6%," and further that, because other optional ingredients could be included in varying amounts, "a POSA also would have understood that the inventors possessed a polymer weight percentage range of 25% to *about* 58.6%." *Id.* at 21–22 (quoting Ex. 2008 ¶ 44).

Patent Owner further argues that "[a] POSA also would have understood that the inventors possessed the narrower range of about 48.2% to about 58.6%." PO Resp. 22. Patent Owner supports this argument with the contentions that the '571 application discloses a polymer weight percentage of 48.2%; "the disclosed range of 25% to about 58.6% encompasses the claimed range from about 48.2% to about 58.6%; and films with polymer weight percentages within the two respective ranges pertain to the same invention with generally the same properties, operability, and ability to achieve any desired result." *Id.* (citing Ex. 2008 ¶ 45; *In re Wertheim,* 541 F.2d 257, 264 (CCPA 1976)); Sur-reply 12–15.

Petitioners reply that Patent Owner repeatedly refers to the "disclosed" range of about 25%–58.6% (and about 25–60%) as if they are explicitly discussed on the face of the '571 Application, but "all the '571 Application discloses are polymer weights of 'at least 25%' and 'at least 50%.'" Reply 5 (citing PO Resp. 16, 21–22, 24–25, 26, 30–33); Ex. 1011 ¶ 65, claim 5). Petitioners also argue that while these ranges of at least 25%

and at least 50% "are necessarily limited to *some* end point, that end point is not disclosed in the '571 application," and that "Dr. Cremer conceded as much at his deposition." *Id.* (quoting Inst. Dec. 19; citing Ex. 1030, 52:1–53:5, 54:1–15, 55:3–16, 57:10–58:17, 59:14–60:1, 62:3–19, 63:10–20). Thus, as argued by Petitioners, "despite Patent Owner's characterizations to the contrary, there is no bounded range 'disclosed' by the '571 application in any respect." *Id.*

Petitioners contend that "Patent Owner now argues that films within the two fictional ranges of 25%–58.6% and 25%–60%, as well as the claimed ranges of 48.2%–58.6% and 40%–60%, 'pertain to the same invention with generally the same properties, operability, and ability to achieve any desired result.'" Reply 7 (citing PO Resp. 22 (citing Ex. 2008 ¶ 45), 32 (citing Ex. 2008 ¶ 50)). According to Petitioners, this argument by Patent Owner "is based on Dr. Cremer's conclusory opinion that changes in polymer weight percentages within these ranges would have no effect on the 'operability' of the films," but that "Dr. Cremer performed no testing and does not rely on any discussion in the '571 application to support this conclusion." *Id.* (citing Ex. 2008 ¶¶ 45, 49–50). Petitioners further argue that Dr. Cremer "cited no scientific literature anywhere in his declarations, despite his assertion that his opinions in this regard are based on the 'variability that would be typical in this field.'" *Id.* (citing Ex. 1030, 105:17–106:5, 152:7–22; Ex. 2008 ¶¶ 45, 49–50). Petitioners also argue that "Dr. Cremer testified that he did not even consider whether there would be any difference in operability between films with 40% (as in claim 1) or 48.2% (as in claim 8) total polymer weight." *Id.* (citing Ex. 1030, 102:22–104:10, 106:20–108:11).

Patent Owner's reply to Petitioners' lack of testing argument is set forth above. *See infra* Section II.E.1.b)(2)(b).

(d) Patent Owner's Case Law Arguments and Petitioners' Reply

Patent Owner argues the Federal Circuit's recent decision in *Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019),[11] *petition for cert. filed* (No. 19-1131), March 13, 2020, supports a finding of adequate written description. PO Resp. 22–23. According to Patent Owner, the court in *Nalpropion* "held that the specification's embodiments of 39% and 67% naltrexone release in one hour and 62% and 85% naltrexone release in two hours adequately supported claimed ranges of 'between 39% and 70% naltrexone released in one hour' and 'between 62% and 90% of naltrexone released in two hours.'" *Id.* (citing *Nalpropion* 934 F.3d at 1349–51). Patent Owner further argues that the court in *Nalpropion* "emphasized that '[i]t is not necessary that the exact terms of a claim be used *in haec verba* in the specification' and that '[r]igidity should yield to flexible, sensible interpretation.'" *Id.* (citing *Nalpropion*, 934 F.3d at 1350–51).

Patent Owner argues that the written description support for the claimed range of about 48.2% to about 58.6% "is far stronger" because the '571 Application "discloses a range of 25% to about 58.6% as well as an embodiment of 48.2%, and discloses that films containing 48.2 wt % and 58.6 wt % polymer also contain optional ingredients," and that those optional ingredients could be removed, added, or varied in amount, "which a POSA would have understood to correspondingly change the polymer

[11] Patent Owner cites to *Nalpropion's* Westlaw citation, 2019 WL 3819335. PO Resp. 22. Citations herein are to the Federal Reporter.

weight percentage with no change in the functionality of the invention." *Id.* at 23 (citing Ex. 2008 ¶¶ 39–42).

Patent Owner also argues that the court in *Wertheim* held that a description of solid contents within the range of 25–60%, along with specific embodiments of 36% and 50%, provided written description support for processes employing a 35–60% solids content range. PO Resp. 23 (citing *Wertheim*, 541 F.2d at 265). Patent Owner cites to language from *Wertheim* to argue that Petitioners "proffered 'no evidence . . . that there is in fact any distinction, in terms of the operability of [the inventive films] or of the achieving of any desired result,' . . . between the disclosed polymer weight percentage range from 25% to about 58.6% and the encompassed claimed range from about 48.2% to about 58.6%." *Id.* at 23–24 (citing Ex. 2008 ¶ 45; *Wertheim*, 541 F.2d at 264). Thus, according to Patent Owner, "the '571 Application's disclosed range of 25% to about 58.5% and a specific embodiment of 48.2% clearly supports the claimed polymer weight percentage range of about 48.2% to about 58.6%," and "the claimed polymer weight percentage range of about 48.2% to about 58.6% is ***fully encompassed*** by the polymer weight percentage range of 25% to 58.6%." *Id.* at 24.

Petitioners reply that *Nalpropion* and *Wertheim* do not support Patent Owner's position because there are no bounded ranges disclosed in the '571 application. Reply 8. Petitioners assert that "*Nalpropion* is distinguishable because, unlike here, both upper and lower boundary limits of the claimed range were actually disclosed in the specification." *Id.* (citing *Nalpropion*, 934 F.3d at 1349). Petitioners further assert that *Wertheim* is likewise distinguishable "because the disclosure in that case included a range of 25%

to 60% with a specifically disclosed endpoint of 60%." *Id.* (citing Inst. Dec. 21 (citing *Wertheim*, 541 F.2d at 264)). Patent Owner states in reply that satisfaction of the written description requirement is stronger here than in *Nalpropion* and *Wertheim* because a POSA would have understood that the '571 application discloses "the precise claimed endpoints of 48.2% and 58.6%, and the range between them," and "a range of 25% to about 58.6% . . . which 'describes the somewhat narrower claimed range' of about 48.2% to about 58.6%, especially given the disclosure of 48.2%." Sur-reply 15–16 (citing *Wertheim*, 541 F.2d at 264).

Patent Owner also cites to *In re Molenda*, 2017 WL 3620343 (PTAB Aug. 18, 2017) (Decision on Appeal), and asserts that the original application in *Molenda* disclosed polymer concentration ranges, as well as an embodiment of 3.5% that fell within those ranges. PO Resp. 24–25 (citing *Molenda*, 2017 WL 3620343, at *7). Patent Owner further asserts that "[t]he Board found that this disclosure adequately supported a claimed polymer concentration of about 5% even though that concentration was not explicitly disclosed." PO Resp. 25 (citing *Molenda*, 2017 WL 3620343, at *7). Petitioners reply that the Board in *Molenda* found that the claimed concentration was within a range disclosed in the specification, whereas the '571 application does not disclose bounded ranges of polymer weights. Reply 8–9 (citing *Molenda*, 2017 WL 3620343, at *6–7). Patent Owner argues in reply that the written description support is stronger here than in *Molenda* for the same reasons argued with respect to *Nalpropion* and *Wertheim*. Sur-reply 16 n.5 (citing *Molenda*, 2017 WL 3620343, at *7).

Patent Owner also advances arguments that "[t]he decisions cited by Petitioners are inapposite." PO Resp. 25. Patent Owner argues that *General*

Hospital is distinguishable because the disclosed range minimally overlapped with the claimed range whereas "here the disclosed range completely encompasses the claimed range." *Id.* at 26 (citing *General Hospital*, 888 F.3d at 1372–73). Patent Owner further argues that the concentration claimed in *General Hospital* was merely one discrete point within much broader disclosed ranges, "here the claimed ranges of about 48.2% to about 58.6% and about 40% to about 60% claim a much larger portion of the disclosed ranges of 25% to about 58.6% or 25% to about 60%." *Id.* (citing *General Hospital*, 888 F.3d at 1372).

Patent Owner further argues that in *Ruschig* "the court found no written description support for a specific claimed compound not mentioned in the specification." PO Resp. 27 (citing *Ruschig*, 379 F.2d at 996). Patent Owner asserts that the court explained that "[s]pecific claims to single compounds require reasonably specific support disclosure" and that "something more than the disclosure of [a large class of] compounds is required." *Id.* (citing *Ruschig*, 379 F.2d at 994). According to Patent Owner, "the written description support is significantly stronger than in *Ruschig*" because the claimed polymer weight percentages are within "the disclosed polymer weight percentage range of 25% to about 58.6%," and there is support in the '571 Application "for each specific polymer weight percentage recited in the challenged claims." *Id.* (citing Ex. 2008 ¶¶ 30–51). According to Patent Owner, "*Wertheim* recognized that the issue in *Ruschig* of whether a disclosed compound genus supports a claimed compound species is different from the issue of whether a disclosed percentage range supports a claimed percentage range within the disclosed range." *Id.* at 27–28 (citing *Wertheim*, 541 F.2d at 264). Patent Owner also points to the

district court's decision, affirmed in relevant part in *Nalpropion*, to argue that the district court rejected "the defendant's argument that the specification 'fails to provide 'blazemarks' that would direct a [POSA] to select th[e] specific bounds' of the claimed range of dissolution profiles." *Id.* at 28 (citing *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 803 (D. Del. 2017), *aff'd in part, rev'd in part sub nom. Nalpropion*, 934 F.3d 1344).

(3) Polymer Weight Percentage Range of "about 40 wt % to about 60 wt %"

Patent Owner argues that the '571 application reasonably conveys to a POSA that the inventors possessed the polymer weight percentage range of "about 40 wt % to about 60 wt %" as recited in claim 1. PO Resp. 29 (citing *Nalpropion*, 934 F.3d at 1349–51). Patent Owner also argues that "this claimed range is within the disclosed range of 'at least 25%' . . . and it encompasses the 48.2% and 58.6% polymer weight percentages disclosed in Tables 1 and 5." *Id.* at 29–30 (citing Ex. 1011, 1444 ¶ 65, 1459 (claim 5); Ex. 2008 ¶ 46; Ex. 1003 ¶¶ 74, 77).

Petitioners' reply arguments regarding the lack of a disclosure of bounded ranges in the '571 Application is set forth above. *See supra* Section II.E.1.b)(2)(c). In addition, Petitioners further reply that, as for the lower claimed value, Patent Owner takes the position that the claimed 40% lower endpoint is supported by the '571 application because it is "closer to" 48.2% than 25%. Reply 5–6 (citing Paper 12, 13; Ex. 2001 ¶ 42). According to Petitioners, "[u]nder this 'closer to' logic, the patentee could have claimed any percentage value between 25% and 48.2% as the lower boundary, so long as the chosen number was 'closer to' 48.2% than 25% (i.e. anything greater than 36.6%)." *Id.* at 6. Petitioners further argue that

"Dr. Cremer refused to offer an opinion as to whether 41%, 42%, etc. could have also been claimed as the lower endpoint, stating that he only considered whether 'about 40%' was supported by the '571 application." *Id.* (citing Ex. 1030, 101:4–102:11, 104:1–10). Patent Owner replies that "Dr. Cremer did not say that being 'closer to' 48.2% than 25% would itself be sufficient for written description support, but rather that this is one consideration that, together with the other facts discussed in his declarations, reasonably conveys to a POSA that the inventors possessed the range of about 40% to about 60%." Sur-reply 17.

(a) "about 40 wt % to about 60 wt %" and Optional Ingredients

Patent Owner argues that "[a] POSA would have understood that optional ingredients may be removed, added, or varied in amount by a reasonable degree while staying within the invention," and that a POSA would have therefore understood "that the inventors possessed polymer weight percentages extending about 7.2% below and about 12.8% above the disclosed embodiment of 48.2%, that is, a range of 41.0% to 61.0%." PO Resp. 31 (citing previous arguments, *see supra* Section II.E.1.b)(2)(b)). According to Patent Owner, "[a] POSA would have understood that a polymer weight percentage of 41.0% ***is*** a polymer weight percentage of 'about 40%' and a polymer weight percentage of 61% ***is*** a polymer weight percentage of 'about 60%.'" *Id.* (citing Ex. 2008 ¶ 48). Patent Owner further argues that "a POSA would have understood that films with a polymer weight percentage in the range of 41.0% to 61.0% and films with a polymer weight percentage in the range of 40% to 60% pertain to the same invention with generally the same properties, operability, and ability to achieve any desired result." *Id.*; Sur-reply 16–17.

Petitioners' reply arguments regarding optional ingredients and Patent Owner's reply thereto are set forth above. *See supra* Section II.E.1.b)(2)(b).

(b) Polymer Weight Percentage Range of "25% to About 60%"

Referring back to its previous arguments (*see supra* Section II.E.1.b)(2)(c)), Patent Owner argues that "a POSA would have understood that the inventors possessed a polymer weight percentage range of 25% to about 58.6%," that a "polymer weight percentage of about 58.6% ***is*** a polymer weight percentage of about 60%," and that a "polymer weight percentage of about 60% is also within the disclosed ranges of 'at least 25%.'" PO Resp. 31–32 (citing Ex. 2008 ¶ 49; Ex. 1011, 1444 ¶ 65, 1459 (claim 5); Ex. 2009, 100:3–17, 101:5–12). Patent Owner further argues that "films with a polymer weight percentage within the range of 25% to 58.6% and films with a polymer weight percentage within the range of 25% to 60% pertain to the same invention with generally the same properties, operability, and ability to achieve any desired result." *Id.* at 32 (citing Ex. 2008 ¶ 49; *Wertheim*, 541 F.2d at 264).

Petitioners' reply to this argument is set forth above. *See supra* Section II.E.1.b)(2)(c).

Patent Owner cites to *Nalpropion* and *Wertheim* as support for the conclusions that "[t]he disclosed polymer weight percentage range of 25% to about 60% would have reasonably conveyed to a POSA that the inventors also possessed the claimed polymer weight percentage range of about 40% to about 60%" (citing *Nalpropion*), and that "[f]ilms with a polymer weight percentage within the range of 25% to 60% and films with a polymer weight percentage within the range of 40% to 60% pertain to the same invention with generally the same properties, operability, and ability to achieve any

desired result" (citing Ex. 2008 ¶ 50; *Wertheim*, 541 F.2d at 264). PO Resp. 32.

Petitioners' reply to Patent Owner's reliance on *Nalpropion* and *Wertheim*, and Patent Owner's Sur-reply thereto, is set forth above. *See supra* Section II.E.1.b)(2)(d).

(4) Particular Polymer Weight Percentages and Bounded Polymer Weight Percentage Ranges

Patent Owner challenges Petitioners' assertion that "the '571 application 'provides no direction' that particular polymer weight percentages or weight percentage ranges 'were within the scope of the invention'" with several arguments. PO Resp. 33 (citing Pet. 22–23).

Patent Owner points to paragraph 65 and original claim 5 as disclosing "embodiments of the inventive films containing a polymer in an amount of at least 25% or at least 50% by weight of the composition." PO Resp. 34 (citing Ex. 1011, 1444 ¶ 65, 1459 (claim 1)). Patent Owner also points to Table 5 as "specifically identif[ying] **percent** by weight of the polymers in each disclosed formulation," and Table 1 as identifying both the polymer weight and the total weight for each formulation. *Id.* (citing Ex. 1011, 1453 (Table 5), 1449–50 (Table 1)) (emphasis added by Patent Owner). According to Patent Owner, "[t]hese express disclosures reasonably convey to a POSA that the inventors possessed particular polymer weight percentages," and "Petitioners' assertion that 'there is no reason that a POSA would understand the applicants placed any significance' on polymer weight percentages . . . strains credulity." *Id.* at 34–35 (citing Ex. 2008 ¶¶ 53–54; Pet. 29; *Nalpropion*, 934 F.3d at 1349–51).

(a) Bounded Polymer Weight Percentage Ranges

Patent Owner also challenges Petitioners' assertion that "the '571 Application discloses only open-ended polymer weight percentage ranges," and directs a POSA away from the claimed polymer weight percentage ranges (Pet. 21–23), by arguing that Petitioners "attempt to isolate individual disclosures from the '571 Application, which is inconsistent with well-established precedent holding that the written description analysis considers what 'the specification as a whole' would have reasonably conveyed to a POSA." PO Resp. 35 (citing Pet. 21–22; Ex. 1003 ¶ 61; Ex. 1011, 1444 ¶ 65); *see also Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1539 (Fed. Cir. 1997).

According to Patent Owner, a POSA would have understood that "the aim of the '571 Application is to create a pharmaceutical film," (quoting Ex. 2008 ¶ 56), that the polymer is an important component of the inventive films, that the '571 Application discloses minimum polymer weight percentages of at least 25% or at least 50%, that the polymer weight percentages can vary because they can include different amounts of optional ingredients, and that "the *necessary* presence of actives and a buffer, together with the optional presence of other ingredients, would constrain the possible polymer weight percentage in the film." PO Resp. 35–36 (citing Ex. 2008 ¶ 56; Ex. 2009, 109:21–110:12; Ex. 1011, 1459 (claim 1), 1443 ¶ 60, 1445 ¶ 67, 1463, Abstract). Patent Owner thus argues that "a POSA reading the '571 Application as a whole would have understood that there is an upper bound to the polymer weight percentages of the inventive films." *Id.* at 36 (citing Ex. 2008 ¶ 56). Patent Owner cites to *Rimfrost AS v. Biomarine Antartic AS.*, PGR2018-00033, Paper 9 at 15–16, 2018 WL

4183083 (PTAB Aug. 29, 2018) (Denying Institution of Post Grant Review) as construing a claim reciting a minimum amount of astaxanthin esters, and stating that "one skilled in the art would understand that the upper boundary is not infinity." *Id.* (citing *Rimfrost*, 2018 WL 4183083, at *7).

Petitioners' reply arguments regarding the lack of disclosure of bounded ranges are set forth above. *See supra* Section II.E.1.b)(2)(c). Petitioners reply to Patent Owner's *Rimfrost* discussion by arguing that the claim limitation at issue in *Rimfrost* only set forth the minimum amount of astaxanthin esters. Reply 8 (citing *Rimfrost*, 2018 WL 4183083, at *7).

Patent Owner argues that the exemplary formulations in Table 1 and Test Formulation 2 in Table 5 illustrate the constraints that other ingredients place on the polymer weight percentage ranges. PO Resp. 36–38 (citing Ex. 2008 ¶¶ 57–59). Patent Owner also argues that the "optional ingredients" that may be included in the films could further restrain the polymer weight percentage of the inventive films. *Id.* at 38–39 (citing Ex. 1011, 1438 ¶ 39, 1436–42 ¶¶ 34–57; Ex. 2008 ¶ 60). Patent Owner thus argues that "a POSA would have understood that the '571 Application discloses an upper bound to the disclosed polymer weight percentage ranges in light of the necessary presence of the actives and buffer and the optional presence of other ingredients." *Id.* at 39 (citing Ex. 2008 ¶ 60).

Petitioners' arguments regarding optional ingredients and the lack of disclosure of a bounded range, and Patent Owner's reply thereto, are set forth above. *See supra* Section II.E.1.b)(2)(b) & (2)(c).

(b) Importance of Polymer and Amount of Polymer

Patent Owner argues that "[t]he '571 Application discloses that polymers are important to the inventive films," because of its disclosure that

"[t]he film dosage composition preferably includes a polymeric carrier matrix," and that the polymers provide a "self-supporting film composition." PO Resp. 39 (citing Ex. 1011, 1432 ¶ 23, 1444 ¶ 65, 1459 (claim 1); Ex. 2009, 39:15–18, 111:9–112:20; Ex. 2008 ¶ 61). Patent Owner further argues that the carrier "performs a crucial role in a pharmaceutical composition," and that the '571 Application "teaches that the polymers 'provide mucoadhesive properties to the film, as well as a desired dissolution and/or disintegration rate,'" and "explains that these properties are important to the inventive films." *Id.* (citing Ex. 2008 ¶ 61; Ex. 1011, 1435–36 ¶¶ 30, 31). Patent Owner also argues that a POSA would also have understood that the polymer is important to the inventive films "from the '571 Application's disclosure that the inventive films can comprise at least 25% by weight polymer or at least 50% by weight polymer," that "each formulation in Tables 1 and 5 . . . includes a polymer," and that a polymer is required by the independent claims of the '571 application. *Id.* at 39–40 (Ex. 1011, 1444 ¶ 65, 1459 (claim 5), 1449–50, 1453, 1459–61). Patent Owner further argues that "Dr. Das conceded at her deposition that 'all mucoadhesive pharmaceutical films . . . use polymers." *Id.* at 40 (citing Ex. 2009, 19:13–16; 112:12–20).

Patent Owner argues that a POSA would have immediately discerned from reading the '571 Application that "not only the polymer, but also the amount of the polymer in the film is important to the invention." PO Resp. 40. Patent Owner quotes Dr. Cremer to assert that a POSA would have understood that "the amount of polymer would generally need to be selected in light of the total weight of the film so that the polymer weight percentage was within a range that enabled the polymer to function effectively as a

carrier, provide a self-supporting film, and achieve the desired mucoadhesion level and dissolution and/or disintegration rates." *Id.* (citing Ex. 2008 ¶ 62).

Patent Owner also cites to the testimony of Dr. Das to argue that "a POSA would have understood that the polymer weight percentage of a film 'could potentially impact the [film's] adhesive properties and drug release profile,' both of which 'have relevance for a pharmaceutical film.'" PO Resp. 40–41 (citing Ex. 2009, 50:7–51:24, 54:4–15, 57:17–25, 76:20–77:14, 113:24–114:9). Patent Owner further cites to the testimony of Dr. Das to argue that "a POSA would have understood that, 'if I take an individual polymer and I vary the concentration of that, will I expect an impact on all of the properties of my formulation? The answer is yes." *Id.* at 41 (citing Ex. 2009, 58:2–59:25). Patent Owner also cites to the testimony of Dr. Das to argue that, prior to 2004, "[t]here [were] plenty of published papers" that would have indicated to a POSA that different polymer concentration levels could lead to different film properties, further citing to a paper co-authored by Dr. Das and published in 2006.[12] *Id.* (citing Ex. 2009, 30:18–33:21, 53:2–54:15; Ex. 2007, 381, 386).

(c) Constant Polymer Weight Percentage

Patent Owner argues three of the four formulations in Table 1 and Test Formulation 2 in Table 5 had a polymer weight percentage of 48.2% with total film weights ranging from 50 mg to 100 mg. PO Resp. 41 (citing Ex. 1011, 1449–50, 1453). Thus, according to Patent Owner, a POSA

[12] M.S. Surapaneni et al., *Effect of Excipient and Processing Variables on Adhesive Properties and Release Profile of Pentoxifylline From Mucoadhesive Tablets*, DRUG DEV. AND INDUS. PHARMACY 32, 377–87 (2006). Ex. 2007.

reading the '571 Application "would have noticed that the polymer weight percentages of these formulations were kept constant because the POSA would have been attuned to polymer weight percentages." *Id.* at 41–42 (quoting Ex. 2008 ¶ 63). Patent Owner cites to the testimony of Dr. Das that "any formulator would be very geared to see the numbers [in formulations 16/4, 12/3, and 8/2] and how they move and recognize that this is not three different formulations but, indeed, one single formulation, just three different portion sizes pulled out from there." *Id.* (citing Ex. 2009, 117:7–118:13).

Patent Owner argues that a "POSA would have read the disclosure [of the '571 Application] with an eye toward how to make a pharmaceutical film," and "would have been particularly attuned to the weight percentages and ratios of the required ingredients in a film," especially the polymer weight percentages. PO Resp. 42–43 (citing Ex. 2008 ¶¶ 64–68). According to Patent Owner, "[a] POSA would have appreciated the similarity between the polymer weight percentages of these four formulations and would have been led to calculate the percentages." *Id.* at 43–44 (citing Ex. 2009, 85:11–86:6). Patent Owner thus argues that "[o]bserving that the inventors kept the polymer weight percentage constant across films with widely varying total weights, a POSA would have understood that the inventors possessed polymer weight percentages and considered them important in constructing the inventive films." *Id.* at 44 (citing Ex. 2008 ¶ 68).

Petitioners reply that the argument that the inventors in most cases kept the polymer weight percentage constant "conflicts with Patent Owner's

argument that a POSA would understand polymer weight percentage *ranges* to be disclosed." Reply 22 n.5.

(d) pH and Polymer Weight Percentages

Patent Owner contests Petitioners' argument that the '571 application shows that the inventors focused their testing on the pH of the films, and that the pH determined whether the films were bioequivalent to the Suboxone® tablets. PO Resp. 44 (citing Pet. 29–30; Ex. 1003 ¶¶ 75–80). Patent Owner refers to Dr. Cremer's explanation that there could have been any number of reasons why the testing disclosed in Examples 5–8 of the '571 Application "focused on the inventive films' pH instead of their polymer weight percentages, such as that the inventors already knew which polymer weight percentages worked well in the inventive films and thus did not need to perform testing directed to this parameter." *Id.* at 44–45 (quoting Ex. 2008 ¶ 69). Patent Owner further cites to Dr. Cremer's testimony for the assertion that the disclosure of testing directed to pH rather than polymer weight percentages "would not have indicated to a POSA that the inventors considered this [polymer] parameter unimportant, but simply that the inventors were interested in the relationship between pH and bioequivalence to the Suboxone tablet." *Id.* at 45 (quoting Ex. 2008 ¶ 69).

Patent Owner cites to *Nalpropion* and *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), to argue that the written description requirement does not require a disclosure "that the claimed element be essential to the invention or even important to achieving the invention's objectives." PO Resp. 45–46 (citing *Nalpropion*, 934 F.3d at 1350, and *Vas-Cath*, 935 F.2d at 1565); *see also* Sur-reply 20 n.9. Thus, Patent Owner argues that "there is ample disclosure that the polymer weight percentages and (b):(a) ratios were important to the invention . . . , but even without these

disclosures, there would still be sufficient written description support because the '571 Application reasonably conveys to a POSA the inventors' possession of them" at the time of filing the '571 Application. *Id.* at 46.

c) Patent Owner's Response, Petitioners' Reply, and Patent Owner's Sur-reply Regarding Buprenorphine:Polymer/(b):(a) Ratios

Petitioners' arguments in its Petition regarding the lack of written description support for the claimed buprenorphine:polymer/(b):(a) ratios and range are set forth above. *See supra* Section II.E.1.a). Patent Owner responds by arguing that dependent claims 5 and 12 recite a (b):(a) ratio range of "about 1:3 to about 1:11.5," that this recited range is directly supported by Tables 1 and 5 of the '571 application, and that the '571 application discloses that (b):(a) ratios were an aspect of the inventive films. PO Resp. 46–61.

(1) Buprenorphine:Polymer Ratio Range

Patent Owner cites to the Cremer Declaration to argue that "a POSA would have understood that the 16/4, 12/3, and 8/2 formulations in Table 1 as well as Test Formulation 2 in Table 5 each contain (b):(a) ratios of 1:2.8, and the 2/0.5 formulation contains a (b):(a) ratio of 1:10.9." PO Resp. 46–47 (citing Ex. 2008 ¶ 71). Patent Owner also cites to the testimony of Dr. Das to argue that he conceded that the inventors created films with (b):(a) ratios of 1:2.8 and 1:2.9.[13] *Id.* at 47 (citing Ex. 1003 ¶¶ 74, 78; Ex. 2009, 122:22–124:2).

Patent Owner further argues that a POSA would have understood the cited test formulations having a (b):(a) ratio of 1:2.8 "pertain to the same

[13] It appears that Patent Owner intended to write 1:10.9 rather than 1:2.9.

invention with generally the same properties as the 2/0.5 formulation in Table 1, which had a (b):(a) ratio of 1:10.9," and that a POSA would have understood that the inventors possessed not just those discreet ratios, "but also the range of (b):(a) ratios of 1:2.8–1:10.9." PO Resp. 48 (citing Ex. 2008 ¶ 72). Patent Owner also argues that the disclosed (b):(a) ratio of 1:2.8 is a ratio of about 1:3, the disclosed (b):(a) ratio of 1:10.9 is a ratio of about 1:11.5, and that "a POSA would have understood that films with a (b):(a) ratio within the range of 1:2.8–1:10.9 and films with a (b):(a) ratio within the range of 1:3–1:11.5 pertain to the same invention with generally the same properties, operability, and ability to achieve any desired result." *Id.* (citing Ex. 2008 ¶ 73; *Wertheim*, 541 F.2d at 264).

Petitioners reply that there is no mention of the buprenorphine:polymer ratio in the '571 application, and no reason for a POSA to calculate the (b):(a) ratio. Reply 15. Petitioners further argue that there is no discussion in the '571 application "of mucoadhesive, absorption, dissolution, or pharmacokinetic properties based on the (b):(a) ratio that would give a POSA a reason to calculate the ratios." *Id.* (citing Ex. 1030, 148:13–22, 150:4–19).

Petitioners argue that "Patent Owner points only to values Dr. Cremer calculated from Tables 1 and 5 as support for the claimed ratio range," and that Dr. Cremer's two calculated (b):(a) ratios from Tables 1 and 5 (1:2.8 and 1:10.9) are not the endpoints of the claimed (b):(a) ratio range. Reply 15–16 (citing PO Resp. 46–48; Ex. 1030, 153:10–154:20, 156:8–157:1; Ex. 2008 ¶ 71 n.8, 9). Petitioners contest Dr. Cremer's "arbitrary and unsupported" opinions "that a POSA would have understood that the formulations with a (b):(a) ratio of 1:2.8 'pertain to the same invention with

generally the same properties' as the formulation with a (b):(a) ratio of 1:10.9." *Id.* at 16 (citing PO Resp. 48). Petitioners specifically argue that "Dr. Cremer cites no literature or other support for his assumptions concerning the properties of films with the various ratios . . . [and] he did not conduct any testing or experiments that could have shown the ratio had no effect on the ultimate film within this range." *Id.* at 16–17 (citing Ex. 2008 ¶¶ 72, 73).

Petitioners next contest "Patent Owner's argument that the calculated (b):(a) ratio of 1:2.8 is 'about' the claimed 1.3 ratio and the calculated 1:10.9 is 'about' the claimed 1:11.5" as lacking any credible support from Dr. Cremer. Reply 17 (citing PO Resp. 48). Petitioners argue that the ratio 1:11.5 has no logical connection to the ratio 1:10.9, and "Dr. Cremer did not identify one," despite Dr. Cremer's assertions "that he 'looked at 1:11.5' and determined it was the 'same' as 1:10.9." *Id.* (citing Ex. 1030, 158:16–160:10; Ex. 2001 ¶ 76; Ex. 2008 ¶ 73). According to Petitioners, "[u]nder this theory, the inventors could have claimed any value between 1:10.9 and 1:11.5, evidencing the arbitrariness of the claimed ratio." *Id.*

Petitioners further argue that Dr. Cremer "would not offer an opinion as to whether a value of 1:10.9 would have also supported a claimed range of up to 1:11, rather than 1:11.5." Reply 17 (citing Ex. 1030, 159:14–160:16). Petitioners assert that Dr. Cremer testified at his deposition that he "ha[dn't] really thought it through," because the challenged claims do not recite a ratio of 1:11, and thus "[i]t's not a question that [he] analyzed." *Id.* (citing Ex. 1030, 155:9–156:5). According to Petitioners, "[t]his again speaks to the fact that Dr. Cremer's analysis here proceeded by first looking at the claim limitation and then attempting to find support for it in the

specification, contrary to the requirement that a POSA 'immediately discern the limitation at issue in the claims' based on the disclosure in the specification." *Id.* at 17–18 (citing *Purdue Pharma*, 230 F.3d at 1323).

Patent Owner contests Petitioners' argument that there is no reason for a POSA to calculate the (b):(a) ratio (Reply 15) by citing to Dr. Cremer's explanation that "a POSA reading the '571 Application 'would have been focused on the ratios between the necessary ingredients—the active ingredients, buffer, and polymer—because such ratios are important to constructing pharmaceutical films.'" Sur-reply 18–19 (citing Ex. 2008 ¶¶ 74, 79; Ex. 2009, 106:20–107:6 (calculating (b):(a) ratio is within the capability of POSA)). Patent Owner also restates its "same invention" arguments and asserts that Petitioners "mistakenly criticize Dr. Cremer for not citing testing or literature outside the '571 Application . . . [because] the written description requirement asks what **the '571 Application** reasonably conveys to a POSA, and it is undisputed that Dr. Cremer's education and experience qualify him to testify about that." *Id.* at 22–23 (citing Reply 15–17 (emphasis added by Patent Owner); Sur-reply 2–4 (discussing Dr. Cremer's education and experience (Ex. 2008 ¶¶ 4–7, 12, 22))). Patent Owner also contests Petitioners' argument that "1:11.5 has no logical connection to 1:10.9" (Reply 17) by arguing that "[t]his argument is inapposite: the issue is how a POSA would have understood 'about 1:11.5,' and Dr. Cremer's unrebutted expert opinion is that a POSA would have understood that '1:10.9 is . . . about 1:11.5.'" *Id.* at 23 (citing Ex. 2008 ¶ 73; *see also id* at 23 n.10 (noting that "the written description requirement does not require a 'logical connection' between the disclosure and claim limitation.").

(2) Buprenorphine:Polymer Ratios

Patent Owner argues that "a POSA reading the '571 Application would have been attuned to the ratios between required ingredients," and advances several arguments in support of the contention that the '571 Application "discloses that the buprenorphine:polymer ratio in particular was an aspect of the inventive films." PO Resp. 48–49.

(a) Buprenorphine and Polymer Components

Patent Owner argues that "[a] POSA would have understood from the '571 Application that buprenorphine is an especially important ingredient in the inventive films." PO Resp. 49. Patent Owner supports that argument by asserting that "a POSA would have understood that the buprenorphine is the active that directly treats narcotic dependence, while the naloxone is used only to prevent abuse of the buprenorphine," and that "buprenorphine is the largest active ingredient by mass" in each exemplary formulation in Table 1, as well as Test Formulation 2 in Table 5. *Id.* at 49–50 (citing Ex. 1011, 1432 ¶ 21, 1448 ¶ 78, 1449–50, 1453; Ex. 2008 ¶ 75).

Patent Owner argues that "[a] POSA would have understood from the '571 Application that the polymer is a critical component in the inventive films." PO Resp. 50. Patent Owner refers back to its discussion of polymer importance in connection with polymer weight percentages (*see supra* Section II.E.1.b)(4)(b)), and further argues that the polymer is the largest inactive ingredient by mass in the subject film formulations, which a POSA would have immediately discerned. *Id.* (citing Ex. 2008 ¶ 76). Patent Owner quotes Dr. Cremer's testimony that "a POSA reading the '571 Application would immediately have discerned that the buprenorphine and polymer are especially important components of the inventive films and are the largest active ingredient by mass . . . [and] the largest inactive ingredient

by mass." *Id.* (quoting Ex. 2008 ¶ 77). Thus, according to Patent Owner "[t]he buprenorphine:polymer ratio would . . . have been 'especially salient to a POSA, who would already have been paying attention to the ratios between the required ingredients in the disclosed films.'" *Id.* at 50–51 (quoting Ex. 2008 ¶ 77).

Petitioners reply that "[t]he relative weights of the components alone, however, cannot inform a POSA of the 'importance' of these components, let alone the 'importance' of the ratio between these two components," citing to Dr. Cremer's testimony that a component of a formulation may be "important" regardless of its concentration. Reply 19 (citing Ex. 1030, 142:5–17 ("[i]t is not necessarily so that every [inactive] ingredient that is present in small amounts is not important to take into consideration.").

Patent Owner replies that Dr. Cremer did not rely on the relative weights of buprenorphine and polymer alone, but "instead explained that the buprenorphine and polymer are important based on *both* their weights and their disclosed functions." Sur-reply 19 (citing Ex. 2008 ¶¶ 74–76, 83–84; Ex. 2009, 19:13–16, 39:15–18, 111:9–112:20; Ex. 1030, 138:7–139:11, 148:13–151:7).

(b) (b):(a) Ratio Consistent and Scaled Up from Unit Formulas

Patent Owner argues that "[i]n light of her focus on the weight percentages and ratio of the actives, polymer, and buffer, . . . 'a POSA would have immediately noticed the similarity between the buprenorphine:polymer ratios of the disclosed formulations with varying dosage strengths." PO Resp. 51 (quoting Ex. 2008 ¶ 78; citing Ex. 1011, 1449–50, 1453). Patent Owner points to the example formulations (with different dosage strengths) having a (b):(a) ratio of 1:2.8. *Id.* (citing Ex.

2008 ¶ 78; Ex. 1011, 1449–50, 1453; Ex. 1003 ¶ 74). According to Patent Owner, "[a] POSA would have been led to calculate the buprenorphine:polymer ratios of the disclosed films because they are important to constructing those films, and the POSA would have seen that the (b):(a) ratios were in most cases kept consistent across the different disclosed formulations," and that "[t]his would have indicated to a POSA that these (b):(a) ratios were chosen deliberately by the inventors, and thus that the inventors possessed buprenorphine:polymer ratios and considered them important in constructing the inventive films." *Id.* (citing Ex. 2008 ¶ 79).

Patent Owner also argues that "[t]he inventors actually prepared films according to the formulations in Tables 1 and 5, which disclose the ingredient weights on a 'mg per film' basis." PO Resp. 52 (citing Ex. 1011, 1449 ¶ 81, 1453 ¶ 89; Ex. 2009, 94:23–95: 9). Patent Owner specifically asserts that Table 10 of the '571 application "discloses that the inventors produced at least 14 films according to Test Formulation 2." *Id.* (citing Ex. 1011, 1456, Table 10 (n=14)). According to Patent Owner, "[a] POSA would have understood that, 'to scale up from the disclosed unit formulas to multi-unit batches, the inventors would have kept the weight percentage of each ingredient and the ratios between ingredients constant,'" and that "Dr. Das admitted that a POSA would have expected the polymer weight percentage of a film to remain constant when the formulation was scaled up to create larger batches." *Id.* at 52–53 (quoting Ex. 2008 ¶ 81; Ex. 2009, 43:25–44:16). Patent Owner thus contends that "the '571 Application reasonably conveys to a POSA that the inventors possessed polymer weight

percentages and buprenorphine:polymer ratios." *Id.* at 53 (citing Ex. 2008 ¶ 81).

Petitioners reply that Patent Owner's arguments that the calculated ratio is largely consistent across the formulations in Tables 1 and 5, and that the inventors scaled up from the unit formulations, "conflict[] with Patent Owner's opinion that *ranges* were disclosed by the values calculated from Tables 1 and 5." Reply 21 (citing PO Resp. 51–52). Petitioners argue that this conflict is exemplified by Patent Owner's argument that, on the one hand, "to move from a dosage form with 8 mg buprenorphine to a dosage form with 12 mg buprenorphine while maintaining the same properties, the polymer amount would generally need to be adjusted proportionately to the amount of buprenorphine, maintaining a *constant* buprenorphine:polymer ratio," while, on the other hand, "Patent Owner argues that a POSA would understand that a film with any ratio within the claimed range would have the same properties and operability." *Id.* (citing PO Resp. 54, 48). Petitioners further argue that "[b]ased on Patent Owner's own logic, then, a POSA who calculated the ratio values (notwithstanding that there is no reason for doing so) would not understand a range to be disclosed but rather a 'consistent' value that is 'constant' across scaled up and scaled down formulations." Reply 21–22.

Patent Owner replies by restating the generally "constant" (b):(a) ratio and further arguing that "Dr. Cremer testified that a POSA would have 'look[ed] at compositions in terms of the relative content of the ingredients quantitatively in order to be able to understand the formulation and to be able to scale it up or . . . down.'" Sur-reply 20–21 (citing Ex. 1030, 160:22–161:17).

(c) Importance of Buprenorphine:Polymer Ratio

Referring back to its prior arguments regarding the functions of the polymer, Patent Owner asserts that the amount of polymer is important to constructing the inventive films (*see supra* Section II.E.1.b)(4)(b)), and that "[a] POSA would further have understood that the buprenorphine:polymer ratio is important to the invention." PO Resp. 53 (citing Ex. 2008 ¶ 82). Patent Owner quotes Dr. Cremer as stating that a POSA would have "understood that the amount of polymer would generally need to be selected in light of the amount of buprenorphine so that the buprenorphine:polymer ratio was within a range that enabled the polymer to achieve the desired mucoadhesion level and dissolution and/or disintegration rates," and have further understood that, "for the polymer to function effectively as a carrier and provide a self-supporting film, the amount of polymer would generally need to be selected in light of the amount of buprenorphine as well as other ingredients." *Id.* at 53–54 (quoting Ex. 2008 ¶ 83). Patent Owner also argues that "the (b):(a) ratio isolates the important relationship between the buprenorphine and polymer, two critical ingredients in the disclosed films," and that a POSA "would therefore have understood that the (b):(a) ratio is important to constructing the inventive films." *Id.* at 54 (citing Ex. 2008 ¶ 84).

Petitioners reply that the '571 application would have directed a POSA "away from concluding the buprenorphine:polymer ratio had any significance to the inventors," because Test Formulation 3 in Table 5 had the same ratio (1:2.8) calculated for the 16/4, 12/3 and 8/2 formulations in Table 1 and Test Formulation 2 in Table 5, relied on by Patent Owner to support the claimed 1:3 endpoint. Reply 19. However, as argued by Petitioners, "Test Formulation 3 had negative results in terms of bioequivalency to the

prior art tablet, the object of the invention claimed in the '454 patent . . . and was not considered an embodiment of the invention by the applicants." *Id.* (citing Ex. 1011, 1453–56; Pet. 29–30). According to Petitioners, "[b]ecause the same buprenorphine:polymer ratio resulted in two formulations, one that was operable and one that was not, a POSA would not have understood the ratio to have any significance in the invention (assuming a POSA would have calculated the ratio in the first place)." *Id.* (citing Pet. 29–30). Patent Owner replies by generally repeating its arguments regarding the importance of the (b):(a) ratio. Sur-reply 19.

(d) Patent Owner's Challenge to Petitioners' Arguments

(i) Purdue Pharma

Patent Owner asserts that the court in *Purdue Pharma* found that "[a]lthough the examples provide the data from which one can piece together the C_{max}/C_{24} limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the C_{max}/C_{24} ratio," and "one of ordinary skill in the art would not be directed to the C_{max}/C_{24} ratio as an aspect of the invention." PO Resp. 55 (quoting *Purdue Pharma*, 230 F.3d at 1326). Patent Owner further cites to *Purdue Pharma* as stating that "there is nothing in the written description of Examples 1 and 3 that would suggest to one skilled in the art that the C_{max}/C_{24} ratio is an important defining quality of the formulation, nor does the disclosure even motivate one to calculate the ratio." *Id.* (quoting *Purdue Pharma*, 230 F.3d at 1327).

According to Patent Owner, "the support in the '571 Application for the claimed polymer weight percentages and (b):(a) ratios is far more extensive than the support for the C_{max}/C_{24} ratio in *Purdue*." PO Resp. 55.

Patent Owner argues that "[w]hereas the specification in *Purdue* did not disclose C_{max} or C_{24} values for any examples disclosed as embodiments of the invention, much less that embodiments of the invention had a C_{max}/C_{24} ratio greater than 2," the specification of the '571 application disclosed that Test Formulation 2 (Table 5) had a polymer weight percentage of 48.2% and a (b):(a) ratio of 1:2.8, which were both within the claims, and for the Table 1 formulations, the buprenorphine and polymer weights were disclosed, and the polymer weight percentages and (b):(a) ratios were within the claims. *Id.* at 55–56 (citing Ex. 1011, 1457 ¶ 101, 1432 ¶ 22). Patent Owner further argues that "[t]he '571 Application provides 'blaze marks directing the skilled artisan' to polymer weight percentages and (b):(a) ratios," which were "important to the invention and [a POSA] would have been motivated to calculate them." *Id.* at 56–57 (quoting *Purdue Pharma*, 230 F.3d at 1326); *see supra* Sections II.E.1.b)(4) & c)(2)(a)–(c))

Petitioners' arguments regarding *Purdue* are set forth above. *See supra* Section II.E.1.a).

(ii) Recitation of a Claimed Ratio

Patent Owner argues that Petitioners incorrectly suggest that a claimed ratio must be referenced explicitly in the disclosure to have adequate written description support. PO Resp. 57 (citing Pet. 24–25). Patent Owner argues that, to the contrary, "a claimed ratio may be supported even if it is not explicitly recited in the specification." *Id.* (citing *Wertheim*, 541 F.2d at 265).

Patent Owner cites to *Ex Parte Lomaga*, 2017 WL 657405 (PTAB Feb. 10, 2017) (Decision on Appeal) to argue that "the Board found support for a claimed 'ratio of acetaminophen to ibuprophen [of] 0.8125:1 to 2.5:1'

even though the specification did not disclose ratios of acetaminophen to ibuprofen." PO Resp. 57 (citing *Lomaga*, 2017 WL 657405, at *1–2). According to Patent Owner, the Board found that a table in the specification of exemplary pharmaceutical formulations listing amounts of ibuprofen, acetaminophen, and pseudoephedrine, similar to Tables 1 and 5 of the '571 application, "would convey to one skilled in the art that Appellant had the claimed invention in his possession." *Id.* at 57–58 (citing *Lomaga*, 2017 WL 657405, at *2). Patent Owner further asserts that "[t]he Board reasoned that the claimed ratios were 'derived from specific formulations recited in the Specification,' and 'calculating the ratios is well within the capability of one skilled in the art and need not be disclosed in the Specification." *Id.* at 58 (citing *Lomaga*, 2017 WL 657405, at *2). Patent Owner also cites to *Ex Parte Siemens Engergy, Inc.*, 2010 WL 5137101, at *3, *5 (BPAI Dec. 15, 2010) (Decision on Appeal) for the proposition that the "claimed 'ratio of heated fuel to non-heated fuel' in the mixed fuel stream was adequately supported by the disclosure of controlling the temperature of the mixed fuel stream by adjusting the amount of unheated fuel, even though [the] claimed ratio was not explicitly disclosed." *Id.* (citing Ex. 2003).

Patent Owner argues that "[j]ust as the acetaminophen and ibuprofen were two of the principal ingredients of the formulations in *Lomaga* and the heated and non-heated fuel were principal components of the mixed fuel in *Siemens*, the buprenorphine and polymer are two of the principal and necessary ingredients in the inventive films. PO Resp. 58. Patent Owner further argues that "calculating the [buprenorphine:polymer] ratios is well within the capability of one skilled in the art," and "a POSA would have understood from the '571 Application that the inventors possessed

buprenorphine:polymer ratios and considered them important in constructing the inventive films." *Id.* at 58–59 (citing Ex. 2008 ¶ 79; Ex. 2009, 106:20–107:6; *Lomaga*, 2017 WL 657405, at *2).

Petitioners reply that *Lomaga* is distinguishable because "unlike here, the claimed ranges were supported by the disclosure in the specification of both the endpoints of the ranges as well as the points between those endpoints." Reply 20 (citing *Lomaga*, 2017 WL 657405, at *2). Petitioners further reply that *Siemens* is also distinguishable because the Board "found that 'the *description* on which the Patent Owner relies' provided adequate support, 'including the concept of adjusting the relative amounts of heated and unheated fuels (i.e., 'a desired ratios of heated fuel to non-heated fuel' as recited in claim 1) to control the temperature of the mixed fuel." *Id.* (citing *Siemens Energy*, 2010 WL 5137101, at *3). According to Petitioners, "[t]here is no similar disclosure concerning the relative amounts of the buprenorphine and polymer here," and in neither *Lomaga* nor *Siemens* "did the Board rely on a finding that two ingredients were 'principal and necessary' for support for a claimed ratio, as Patent Owner suggests." *Id.* (citing PO Resp. 58).

Patent Owner replies that Petitioners cannot distinguish *Lomaga* and *Siemens*. Sur-reply 21–22. According to Patent Owner, Petitioners "ignore *Lomaga's* core holding: that the claimed 'ratio of acetaminophen to ibuprofen' was adequately supported by disclosed formulations including acetaminophen and ibuprofen . . . even though the claimed ratio itself was not expressly disclosed." *Id.* at 21 (citing *Lomaga*, 2017 WL 657405, at *1–2; Ex. 2002, 21). Patent Owner asserts that "[s]imilarly here, although the

(b):(a) ratio was not expressly disclosed, it is supported by, *inter alia*, the exemplary formulations in Tables 1 and 5." *Id.* (citing Ex. 2008 ¶¶ 71–73).

Patent Owner also asserts that Petitioners' discussion of *Siemens* is misleading. Sur-reply 21–22. According to Patent Owner, the specification in *Siemens* did not expressly disclose "the relative amounts of heated and unheated fuels" (Reply 20), "but rather disclosed altering the amount of unheated fuel in the mixed fuel stream, which the Board found 'more than adequately supports . . . the concept of adjusting the relative amounts of heated and unheated fuel (i.e., 'a desired ratio of heated fuel to non-heated fuel' . . .)." *Id.* (citing *Siemens Energy*, 2010 WL 5137101, at *5). Patent Owner asserts that "[s]imilarly here, the '571 Application's disclosure of, for example, the importance of the buprenorphine and polymer, and the functions of the polymer that are affected by its ratio to the buprenorphine, would reasonably convey to a POSA that the inventors possessed the (b):(a) ratio." *Id.* at 22 (citing Ex. 2008 ¶¶ 82–84).

(iii) Express Disclosure of Other Ratios

Patent Owner challenges Petitioners argument that, because certain ratios are expressly disclosed while the buprenorphine:polymer ratio is not, "a POSA would not understand that the inventors were in possession of that ratio." PO Resp. 59 (citing Pet. 24–25; Ex. 1003 ¶ 70). Patent Owner argues, however, that "the invention claimed does not have to be described *in ipsis verbis* in order to satisfy the written description requirement of [section] 112." *Id.* (quoting *Wertheim*, 541 F.2d at 265). According to Patent Owner, "[t]he lack of express disclosure of buprenorphine:polymer ratios in the '571 Application does not convey to a POSA that the inventors did not consider such ratios an aspect of their invention," but rather "a POSA would have understood from the '571 Application that the inventors

possessed buprenorphine:polymer ratios and considered them important to constructing the inventive films." *Id.* (citing Ex. 2008 ¶ 86; *see supra* Section II.E.1.c)(2); *Nalpropion,* 934 F.3d at 1349–51).

Petitioners repeat their argument that "where the inventors did consider a ratio to be significant, they expressly discussed it in the specification," but "there is no indication in the '571 application that the inventors considered the claimed buprenorphine:polymer ratio to be part of the allegedly inventive film, as there is indisputably no mention of it anywhere." Reply 20 (citing Pet. 25; Ex. 1003 ¶¶ 69, 70; Ex. 1030, 146:9–151:7). Patent Owner replies that a POSA would not have concluded that from the lack of an express "mention" of the (b):(a) ratio, that the inventors did not consider such ratios an aspect of their inventive films. Sur-reply 20 (citing Ex. 2008 ¶ 86).

(iv) Petitioners' Argument that the '571 Application Discloses Unlimited Amount of Buprenorphine and Polymer

Patent Owner challenges Petitioners' argument that the '571 Application discloses "[a]ny desired level of agonist," such as buprenorphine, and "any desired level of . . . polymer," and that such disclosures "teach away from the claimed (b):(a) ratios because a POSA allegedly would not 'understand the inventors to have been in possession of limitations directed toward specific ratios of two ingredients that the application taught could be present in 'any' amount.'" PO Resp. 60 (citing Ex. 1011, 1445 ¶ 66, 1444 ¶ 65, 1447 ¶ 75; Pet. 25–26; Ex. 1003 ¶ 67). According to Patent Owner, "Petitioners confuse *amounts* with *ratio*," and that "[e]ven if the *amounts* of the buprenorphine and polymer were truly

unbounded, that would have nothing to do with the *ratio* between the amounts of those ingredients." *Id.* (citing Ex. 2008 ¶¶ 87–89).

Patent Owner argues that the '571 Application discloses a closed range of buprenorphine amounts because of the disclosure that the inventive films would "desirably be bioequivalent to Suboxone tablets" containing dosages of 2 mg to 16 mg buprenorphine, "the requirement that the films be administered orally constrains the total film weight," and the disclosure of limited ranges of buprenorphine amounts (e.g. about 2 mg to about 16 mg). *Id.* at 60–61 (citing Ex. 1011, 1432 ¶ 22, 1431 ¶ 18, 1445–47 ¶¶ 66, 72, 75, 1459 (claim 8), 1462 (claim 30); Ex. 2009, 101:14–102:6, 110:13–25). Patent Owner also reasserts its argument that the '571 Application discloses "that the inventors possessed a closed range of polymer amounts," and "a lower bound based on the need for the film to be self-supporting and an upper bound based on the need for the film to be administered orally and to include ingredients other than the polymer." *Id.* at 61; *see supra* Section II.E.1.b)(2)(c) & b)(4).

d) Analysis of Written Description Requirement

We first determine whether the challenged claims have written description support in the '571 application. We set forth below our findings that address the parties' respective arguments.

"[T]he hallmark of written description is disclosure," and "the test [for satisfaction of the written description requirement] requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description "must 'clearly allow persons of ordinary skill in the art to recognize that [the

inventor] invented what is claimed,'" and "reasonably" convey to those skilled in the art "that the inventor had possession of the claimed subject matter as of the filing date."[14] *Id.* (alteration in original, internal citations omitted). Stated another way, "one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." *Purdue Pharma*, 230 F.3d at 1323. "Whether a claim satisfies the written description requirement is a question of fact." *Nalpropion*, 934 F.3d at 1348 (citing *Ariad*, 598 F.3d at 1351).

(1) The '571 Application

The '571 application was filed on August 7, 2009, and its express disclosure at that time included paragraph 65, Table 1, Table 5, and original claim 5 as set forth above. Ex. 1011, 1415, 1444, 1449–50, 1453; Ex. 1003 ¶ 55. The '571 application published as Myers on February 10, 2011. Ex. 1010, code (43); Ex. 1003 ¶ 55 n.5.

(2) Specific Polymer Weight Percentages

Table 1 of the '571 application discloses the weight (mg per film strip) of the components of various film compositions, including unit formulas 16/4, 12/3, and 8/2 from which a polymer weight percentage of 48.2 wt % could be calculated by a POSA, and unit formula 2/0.5 from which a polymer weight percentage of 58.6 wt % could be calculated by a POSA. Pet. 26 n.8; Ex. 1003 ¶ 74; Ex. 2009, 93:19–23, 118:14–119:11. Petitioners acknowledge that "[a]s a factual matter, Table 1 . . . discloses polymer weight percentages of 48.2% and 58.6%." Pet. 26 n.8. Table 5 also

[14] The court in *Ariad* clarified that "possession as shown in the disclosure" is a more complete formulation than simply "possession," because the term "possession" implied that production of written records outside of the patent specification could show "possession." *Ariad*, 598 F.3d at 1351.

discloses Test Formulations 2 and 3 from which a polymer weight percentage of 48.2 wt % could be calculated by a POSA, and Test Formulation 1 from which a polymer weight percentage of 50.6 wt % could be calculated by a POSA. Ex. 1003 ¶ 77; Ex. 2009, 119:12–120:3.

Accordingly, we find that the '571 application provides written description support for the limitation "wherein the film comprises about 48.2 wt % of the water soluble polymeric matrix," as recited in dependent claim 8.

(3) Ranges of Polymer Weight Percentages

We find that paragraph 65 of the '571 application, and original claim 5, are the only discussion in the '571 application of the amount of polymer that should be in the film compositions, and only describe open-ended ranges (e.g. at least 25% by weight of the composition) that, rather than providing guidance to a POSA to specific bounded ranges, lead a POSA away from concluding that the '571 application discloses the claimed polymer weight percentage ranges of "about 40 wt % to about 60 wt %" and "about 48.2 wt % to about 58.6 wt %." Ex. 1003 ¶¶ 60, 61; Ex. 1011, 1444; *see generally* Ex. 1011, 1427–63. We further find that the '571 application does not suggest, or reasonably convey to a POSA, a "bottom end" of the claimed ranges (40 wt % or 48.2 wt %) or a "top-end" of the claimed ranges (60 wt % or 58.6 wt %). Ex. 1003 ¶ 61; *see generally* Ex. 1011, 1427–63.

We also find that the '571 application does not reasonably convey to a POSA any focus or emphasis on the amount of polymer in the film composition, referring instead to "any desired level" of polymer such that a self-supporting film composition is provided, and does not reasonably convey to a POSA any indication that particular polymer weight

percentages, let alone ranges thereof, impart any desirable properties in the films, focusing instead on pH based on the amount of buffer in the film composition. Ex. 1011, 1444 ¶ 65; Ex. 1003 ¶¶ 62, 63, 71, 72, 75, 76. We find that Table 5 of the '571 application also leads a POSA away from specific polymer weight percentages and ranges thereof because Test formulation 1 and Test formulation 3 had polymer weight percentages of 50.6% and 48.2%, respectively, that fell within the claimed ranges, but did not produce films bioequivalent to Suboxone® tablets. Ex. 1003 ¶¶ 76–80; Ex. 1011, 1453–57; *see also supra* Section II.E.1.a).

We address Patent Owner's arguments below.

(a) Range Endpoints

Patent Owner argues that the '571 application reasonably conveys to a POSA possession of the claimed polymer weight percentage ranges because both ranges are within the disclosed range of "at least 25%," and that (1) exemplary formulations in Tables 1 and 5 directly support each endpoint of 48.2 wt % and 58.6 wt %, and (2) the range of "at least 25%" encompasses the polymer weight percentage endpoints of 40% and 60%. *See supra* Sections II.E.1.b)(2) and II.E.1.b)(3). However, there is no mention of, and a POSA would not have immediately discerned, any polymer weight percentage "endpoint" in the '571 application, other than the "lower" endpoint disclosures of "at least 25% by weight" or "at least 50% by weight." Ex. 1011, 1444 ¶ 65; Ex. 1003 ¶ 61. This is confirmed by the testimony of Patent Owner's expert: "in this paragraph [65] there's no express limitation here . . . [a POSA] would understand that there must be an upper limit to that . . . in paragraph 65, there's expressly no numeric number [identified for that upper end point] . . . [original claim 5] does not expressly

provide an upper limit, a numerical upper limit." Ex. 1030, 52:1–54:15. Moreover, the disclosure of at least 25% (or at least 50%) "does not by itself provide written description support for a particular value within that range." *See Gen. Hosp. Corp.*, 888 F.3d at 1372.

Accordingly, based on the foregoing, we find that the '571 application does not reasonably convey to a POSA or disclose any closed or bounded ranges, and that the calculated polymer weight percentages of 48.2 wt % and 58.6 wt % are simply disclosures of discrete values associated with particular "exemplary" formulations rather than range endpoints.

(b) Variation of Optional Ingredients

The '571 application discloses that "[a] variety of optional components and fillers may also be added to the films." Ex. 1011, 1436–37 ¶ 34; *see also id.* at ¶¶ 35–52; Pet. 24 n.7; Ex. 1003 ¶ 69. Patent Owner argues that, for both claimed polymer weight percentage ranges, the ability of a POSA to add or remove optional ingredients establishes the claimed range, relying on Dr. Cremer's calculations. *See supra* Sections II.E.1b)(2)(b) and II.E.1b)(3)(a). However, the '571 application does not disclose or reasonably convey any direction or reason for a POSA to perform the specific calculations undertaken by Dr. Cremer, and Dr. Cremer conceded that one could obtain different weight percentage values depending on the variation of optional ingredients and amounts chosen. *See* Ex. 1030, 83:20–84:4 ("Q. You might end up with different numbers depending on which variation you took, right? A. If you mean . . . that my choices are just examples and there could be more, that's correct. There could be more examples."); *see generally* Ex. 1011, 1427–63.

Accordingly, we agree that the '571 application discloses that the film compositions may include optional ingredients, and further agree that a POSA could obtain different values of polymer weight percentages depending on the variation of optional ingredients and amounts chosen. Ex. 1030, 82:4–84:4, 117:3–6, 134:8–135:5. We also find that Dr. Cremer's calculated polymer weight percentages (Examples 1–5) only show that "any desired level" of polymer weight percentage, sufficient to provide a self-supporting film composition, may be used in the film compositions, but not that the '571 application discloses a particular polymer weight percentage or a defined or bounded range of polymer weight percentages.

(c) Same Invention

Patent Owner also argues that a POSA would have understood that the exemplary formulations in Table 1 and Test formulation 2 in Table 5, as well as polymer weight percentage ranges of "25% to about 58.6%," "about 48.2% to about 58.6%," "41% to 61%," and "40% to 60%" pertain to "the same invention with generally the same properties, the same operability and the same ability to achieve any desired result." *See supra* Sections II.E.1.b)(2)(a), (2)(c), & (3)(a). However, we find that the disclosure of the '571 application would not lead a POSA to conclude that formulations having polymer weight percentages within the asserted ranges pertain to the same invention. That is because the '571 application also discloses that Test formulations 1 and 3 of Table 5 are not the "same" invention, yet their polymer weight percentages are 50.6% and 48.2%, respectively, and fall within both of the claimed polymer weight percentage ranges. Ex. 1003 ¶¶ 76–80; Ex. 1011, 1453–57 (Test Formulations 1 (pH 6.5) and 3 (pH 5–

5.5) "did not provide a bioequivalent" effect or result as the Suboxone® tablet for both buprenorphine and naloxone).

Accordingly, we find that in the '571 application, films having the same polymer weight percentage, or polymer weight percentages within the claimed ranges, are not necessarily the "same" invention.

(d) Range of 25% to about 58.6%

Patent Owner argues that the disclosure of a polymer weight percentage range of "25% to about 58.6%" shows possession of polymer weight percentage ranges of "about 48.2 wt % to about 58.6 wt %" and "about 40 wt % to about 60 wt %." *See supra* Sections II.E.1b)(2)(c) and II.E.1b)(3)(b). According to Patent Owner, the '571 application "discloses" the range of "25% to about 58.6%" because it discloses the range of "at least 25%" and the specific weight percentage of 58.6%, and "a POSA would have understood that the inventors possessed a polymer weight percentage range of 25% to 58.6%." PO Resp. 21 (citing Ex. 2008 ¶ 44).

Patent Owner's reasoning regarding a polymer weight percentage range of "25% to about 58.6%" seemingly ignores the absence of any disclosure that the polymer weight percentage of 58.6% is an endpoint or that any such bounded range was even contemplated by the inventors, let alone disclosed. *See* Ex. 2008 ¶ 44; Ex. 1003 ¶¶ 59, 60; *see generally* Ex. 1011, 1427–63. To the extent that Patent Owner's argument that the '571 application discloses a polymer weight percentage range of 25% to 58.6% relies on Patent Owner's "range endpoints," "optional ingredients," or "same invention" arguments, we find those arguments are unpersuasive for the reasons discussed above.

Accordingly, for the foregoing reasons, we find that the '571 application does not disclose, or provide written description support for, a polymer weight percentage range of "25% to about 58.6%," or show possession by the inventors of polymer weight percentage ranges of "about 48.2 wt % to about 58.6 wt %" or "about 40 wt % to about 60 wt %."

(e) Weight Percentages as Aspect of Films

Patent Owner argues that claimed polymer weight percentage ranges are an aspect of the inventive films. *See supra* Section II.E.1b)(4). We find, as argued by Patent Owner and in considering the '571 application as a whole, that the '571 application reasonably conveys to a POSA (1) the specific polymer weight percentages of 48.2% and 58.6%; (2) that the polymer weight percentage of 48.2% is constant across three formulations in Table 1 and Test formulation 2 in Table 5; (3) that the presence of other ingredients in the film compositions would result in a polymeric carrier matrix weight percentage of less than 100%; and (4) that variations in the amounts of ingredients (including optional ingredients) would also vary the polymer weight percentage. *See* Pet. 26 n.8; Ex. 2008 ¶ 63; Ex. 1030, 82:4–84:4, 117:3–6, 134:8–135:5. We also find that, because a polymeric carrier matrix is required by the claims and that the level of polymer should be sufficient to provide a self-supporting film composition, a POSA reading the '571 application would have considered the amount of polymer chosen by the POSA to be "important" to the film composition. Ex. 1011, 1444 ¶ 65, 1459 (claim 1).

Although we find that the polymer weight percentage of 48.2% is constant across three formulations in Table 1 and Test formulation 2 in Table 5, that fact is inconsistent with Patent Owner's argument that ranges

of polymer weight percentages are disclosed in the '571 application. *See id.* at 1449 (Table 1), 1453 (Table 5); Ex. 2008 ¶¶ 36, 46, 63; Ex. 1003 ¶¶ 74, 77.

(4) Buprenorphine:Polymer Ratios and Range

We find that the '571 application does not refer to a (b):(a) ratio, or any (b):(a) ratio ranges, or mention any reason for a POSA to calculate the (b):(a) ratio, which stands in contrast to other ingredient ratios that were expressed in the '571 application in the form of a ratio (e.g. (d):(b) and (b):(c)). Ex. 1003 ¶¶ 69, 70; Ex. 1011, 1445; *see generally* Ex. 1011, 1427–63. We thus find that the inventors expressly disclosed those ratios that they actually considered part of the claimed invention. *See, e.g.,* 1011, 1459 (claim 6, ratio of buffer to buprenorphine). We further find that the '571 application discloses that "[a]ny desired level of agonist" may be used for the "(b)" component of the claimed ratios, and "any desired level" of polymer may be used for the "(a)" component of the claimed ratios, thereby evidencing that the disclosure of the '571 application would not have reasonably conveyed to a POSA any particular range of (b):(a) ratios. Ex. 1011, 1444–45 ¶¶ 65, 66. We also find that data in Table 5 of the '571 application is further evidence that a POSA would not attribute any significance to the (b):(a) ratio because Test formulation 2 and Test formulation 3 had the same (b):(a) ratio of 1:2.8, but Test formulation 2 was considered within the scope of the invention whereas Test formulation 3 was not. Ex. 1011, 1453–57.

Patent Owner advances several arguments in support of its position that the '571 application provides written description support for the claimed range of (b):(a) ratios (about 1:3 to about 1:11.5).

(a) Specific (b):(a) Ratios

Tables 1 and 5 of the '571 application disclose film formulations from which a POSA could calculate the (b):(a) ratio. Ex. 1011, 1449–50 (Table 1), 1453 (Table 5); Ex. 1003 ¶¶ 74, 78. Patent Owner argues that the 16/4, 12/3, and 8/2 formulations in Table 1, and Test Formulation 2 in Table 5, have a calculated (b):(a) ratio of 1:2.8, and that the 2/0.5 formulation in Table 1 has a calculated (b):(a) ratio of 1:10.9. PO Resp. 46–47 (citing Ex. 2008 ¶ 71). Petitioners do not dispute the calculation of those specific (b):(a) ratios from those disclosed formulations. Ex. 1003 ¶¶ 74, 78; Ex. 2009, 122:22–124:2. Accordingly, there is no dispute on this point, and we find that there is written description support in the '571 application for the specific (b):(a) ratios of 1:2.8 and 1:10.9.

(b) Range of (b):(a) Ratios

Patent Owner argues that a POSA would have understood that the inventors also possessed the (b):(a) ratio range of 1:2.8–1:10.9; that the (b):(a) ratio of 1:2.8 is about 1:3; that the (b):(a) ratio of 1:10.9 is about 1:11.5; and that films with a (b):(a) ratio of 1:2.8–1:10.9 and a (b):(a) ratio of 1:3–1:11.5 pertain to the "same invention with generally the same properties, operability, and ability to achieve any desired result." *See supra* Section II.E.1.c)(1). Regarding the challenged connection between 1:10.9 and 1:11.5, Patent Owner argues that the proper issue is how a POSA would have understood "about 1:11.5," and that Dr. Cremer's unrebutted expert opinion is that a POSA would have understood that 1:10.9 is about 1:11.5. Sur-reply 23 (citing Ex. 2008 ¶ 73).

We find that the contention that the inventors even contemplated that the polymer portion ((a)) of the claimed (b):(a) ratio would be constrained

by the amount of buprenorphine ((b)) is inconsistent with the express disclosure of the '571 application that "any desired level" of polymer may be used, such that a self-supporting film composition is provided. Ex. 1011, 1444 ¶ 65; Ex. 1003 ¶ 67. We also find that the '571 application would not have led a POSA to conclude that polymers having a (b):(a) ratio within the claimed range pertain to the "same" invention, because such a conclusion is inconsistent with the express disclosure of the '571 application that Test formulation 3 of Table 5 had a (b):(a) ratio of 1:2.8, yet that formulation was not the "same" invention as Test formulation 2 having a (b):(a) ratio of 1:2.8. Ex. 1003 ¶ 78; Ex. 1011, 1453–57.

(c) (b):(a) Ratio as Aspect of Inventive Films

Patent Owner also argues that the (b):(a) ratio is an aspect of the inventive films because a POSA would have understood that buprenorphine and polymer are important ingredients in the inventive films; that because they are important to constructing pharmaceutical films, a POSA would have been focused on ingredient ratios; that because of their importance, a POSA would have been led to calculate their ratio and would have seen that in most cases the ratio was kept consistent; and that to scale up from unit formulas to multi-unit batches, the ratios between ingredients would have been kept constant. *See supra* Section II.E.1.c)(2). Patent Owner also argues that, merely because some ratios of ingredients were expressly disclosed in the '571 application and the (b):(a) ratio was not, does not mean that inventors did not consider the (b):(a) ratio an aspect of the invention because the claimed invention does not have to be described *in ipsis verbis*. *See supra* Section II.E.1.c)(2)(d)(iii). Patent Owner also responds to Petitioners' argument regarding the disclosure of unlimited amounts of buprenorphine

and polymer by arguing that Petitioners confuse amounts with ratio, and that even if the amounts were unlimited, that would have nothing to do with the ratio between those amounts. *See supra* Section II.E.1.c)(2)(d)(iv).

We find that the '571 application does not disclose, or reasonably convey to a POSA, that the buprenorphine to polymer ratio, or any range of (b):(a) ratios, was an aspect of the invention disclosed in the '571 application. Ex. 1011, 1459–62; Ex. 1003 ¶¶ 70, 76; *see generally* Ex. 1011, 1427–63. We further find that the disclosure of the '571 application would not indicate to a POSA that any such (b):(a) ratio or range of ratios was an aspect of the invention because the calculated (b):(a) ratio of 1:2.8 was kept consistent across most formulations, including formulations that were not within the scope of the invention, and because the inventors clearly identified ratios that were an aspect of the invention, including (d):(b) and (b):(c). Ex. 1003 ¶¶ 70, 74, 76; Ex. 1011, 1445; Ex. 2008 ¶ 78. We further find that the express disclosure in the '571 application that "any" desired level of (b) or (a) may be used in the film compositions indicates that no particular (b):(a) ratio was contemplated by the inventors, and certainly no range of ratios. Ex. 1011, 1444–45 ¶¶ 65, 66.

(5) Credibility of Arguments

We find that several of Patent Owner's arguments lack credibility, based on the testimony of Dr. Cremer. For example, although Patent Owner argues that films having polymer weight percentage ranges of "25% to about 58.6%," "about 48.2% to about 58.6%," "41% to 61%," and "40% to 60%" all pertain to "the same invention," Dr. Cremer testified that he did not consider whether there would be any difference in operability or ability to achieve a desired result between films with 40 wt % polymer and 48.2 wt %

polymer. Ex. 1030, 106:20–107:5 ("Q. What about the difference between 40 percent and 48.2 percent? Would you expect any difference in operability or ability to achieve a desired result between those—with that difference?" [Object. Scope.] "A. I haven't looked—I haven't thought about that." . . . "I don't think I've performed the analysis of 40 percent versus 48.2 percent. So I would like to not say anything about that."). In our view, it is not credible to assert that films having polymer weight percentages within a range pertain to the same invention, but then be unwilling to say whether films having particular polymer weight percentages within that range also pertain to the same invention.

Similarly, Dr. Cremer refused to offer an opinion on whether the inventors could have claimed the range of about 45% to about 60% and still have written description support, notwithstanding his opinions that the '571 application "disclosed" a range of "about 40 wt % to about 60 wt %" and that films within that polymer weight percentage range pertain to the same invention. *See* Ex. 1030, 102:2–11 ("Q. So could have [the] inventors have claimed the range of about 45 percent to about 60 and still had support, in your opinion? [Objection form] A. [I]t's a fictitious question . . . there's no [45% to 60%] range claimed in the '454 patent, so I did not perform that analysis. . . . I don't think I want to offer an opinion on that."). In our view, it is not credible to allege that the '571 application supports a particular range of polymer weight percentages and that films having a polymer weight percentage within that range pertain to the same invention, but then be unwilling to say whether the '571 application also supports a *narrower* range within that range.

Dr. Cremer's also testified that a (b):(a) ratio of 1:10.9 is about 1:11.5, but refused to testify whether a (b):(a) ratio of 1:10.9 would also be about 1:11. Ex. 1030, 155:9-156:5, 159:14–160:16. Given his opinion that 1:10.9 is "about" 1.11.5, that opinion would seem to necessarily justify the opinion that a ratio of 1:11 (which is closer to 1:10.9 than 1.11.5) is *also* about 1:10.9. Dr. Cremer also testified, with respect to Patent Owner's "optional ingredients" argument, that "if an optional component is present in reasonable amounts or varied in reasonable amounts . . . it will not substantially affect the product characteristics." Ex. 1030, 72:8–12; Ex. 2008 ¶ 36 n.3 (Dr. Cremer testifying that his calculations varied optional ingredients "by a reasonable degree . . . while staying within the invention"). But when questioned about what he meant by "reasonable amounts," Dr. Cremer testified "I mean not unreasonable amounts . . . I think it's not easy to give a generally applicable definition. I have not worked on a definition of what the scope of reasonable is. But I think that . . . it would be clear to the POSA what the unreasonable or reasonable amount of . . . optional ingredients is." Ex. 1030, 72:14–73:7.

(6) Case Law Analysis of Claimed Ratio and Ranges

Patent Owner attempts to distinguish *Purdue* by arguing that "the specification in *Purdue* did not disclose C_{max} or C_{24} values for any examples disclosed as embodiments of the invention, much less that embodiments of the invention had a C_{max}/C_{24} ratio greater than 2." PO Resp. 55–56 (citing *Purdue Pharma*, 230 F.3d at 1323, 1326–27). In contrast, according to Patent Owner, the specification of the '571 application disclosed that Test Formulation 2 (Table 5) had a polymer weight percentage of 48.2% and a (b):(a) ratio of 1:2.8, which were both within the claims, and, for the Table 1

formulations, the buprenorphine and polymer weights were disclosed, and the polymer weight percentages and (b):(a) ratios were within the claims. *Id.* at 55–56 (citing Ex. 1011, 1457 ¶ 101, 1432 ¶ 22).

We are not persuaded by Patent Owner's distinction of *Purdue*. Patent Owner actually calculated the specific polymer weight percentages and (b):(a) ratios from data in Tables 1 and 5, without any direction or reason provided in the '571 application to do so, thereby providing data that Patent Owner "piec[ed] together" to arrive at the claimed ranges of polymer weight percentages and ratios. Ex. 1003 ¶ 74, 75; *Purdue Pharma*, 230 F.3d at 1326. Moreover, like *Purdue*, there is no mention or discussion in the '571 application that emphasizes any (b):(a) ratio or range, or polymer percentage ranges, or suggests to one skilled in the art that the specific (b):(a) ratios or any of the claimed ranges are an important defining quality of the formulation, nor does the '571 application even motivate one to calculate the specific (b):(a) ratios or claimed ranges. *See Purdue Pharma*, 230 F.3d at 1327.

Patent Owner argues that *Nalpropion* supports a finding of adequate written description in the present case. *See supra* Section II.E.1.b)(2)(d). We disagree. *Nalpropion* involved a claim (claim 11) to a method of treating overweight or obesity that included administration of naltrexone and bupropion in sustained-released formulations. *Nalpropion*, 934 F.3d at 1349. The claim also recited a dissolution profile wherein between 39% and 70% of naltrexone is released in one hour and between 62% and 90% of naltrexone is released in two hours based on a dissolution test referred to as USP Apparatus 2 Paddle Method ("USP 2"). *Id.* The Federal Circuit affirmed the district court's finding of adequate written description support

based on Example 1 which released 39% of its naltrexone at one hour and 62% at two hours, and Example 3 which released 67% of its naltrexone in one hour and 85% in two hours. *Id.* at 1349–50. Thus, both Example 1 and Example 3 produced their own closed range of naltrexone dissolution (between one and two hours), and the district court found that the bounded range of Example 3 "fell squarely within the claimed range in claim 11." *Id.* at 1349 (citation omitted). *Nalpropion* is distinguishable because no such closed or bounded range is disclosed in the '571 application.

Patent Owner refers to the Federal Circuit's statement in *Nalpropion* that "[r]igidity should yield to flexible, sensible interpretation." PO Resp. 22–23 (citing *Nalpropion*, 934 F.3d at 1351); Sur-reply 1. That statement arises out of the "peculiarity of claim 11," in which the dissolution profile "relates only to the measurement of resultant in vitro parameters, not to the operative steps to treat overweight or obesity." *Nalpropion*, 934 F.3d at 1350. Moreover, claim 11 recited that the dissolution profile was measured by "USP 2," whereas the data listed in Examples 1 and 3 was arguably obtained using "USP 1," which the district court concluded was a "substantially equivalent" dissolution profile method. *Id.* at 1350–51. The Federal Circuit thus determined that "[w]hile as a general matter written description may not be satisfied by so-called equivalent disclosure, in this case, buttressed by the district court's fact finding, *and where the so-called equivalence relates only to resultant dissolution parameters rather than operative claim steps*, we affirm the district court's conclusion." *Id.* at 1351 (emphasis added). It is in that context, and following that sentence, that the court states "[r]igidity should yield to flexible, sensible interpretation." *Id.* Here, the limitations at issue are affirmatively recited in the body of the

challenged claims as "operative" aspects of the film. *Nalpropion* is distinguishable for this reason as well.

Wertheim and *Molenda* are similarly distinguishable because bounded ranges were disclosed in both cases. *Wertheim*, 541 F.2d at 265; *Molenda*, 2017 WL 3620343, at *6–7. *Lomaga* and *Siemens* are nonbinding PTAB decisions in an *ex parte* appeal or *ex parte* reexamination proceeding, respectively. *Lomaga*, 2017 WL 657405; *Siemens Engergy*, 2010 WL 5137101. However, *Lomaga* is distinguishable because the claimed ratio and weight percentage ranges were supported by the express disclosure of multiple examples showing both endpoints and multiple values in between those endpoints. *Id.* at 2017 WL 657405, at *2. As discussed above, the '571 application does not disclose bounded ranges. *Siemens* is also distinguishable because its express disclosure discussed mixing unheated fuel with heated fuel in a manner that would decrease or increase the temperature of the heated fuel. *Siemens*, 2010 WL 5137101, at *3. That express disclosure was found to support a claim limitation to a mixed fuel stream having a desired ratio of heated fuel to non-heated fuel. *Id.* at *2. The '571 application does not disclose the desirability of a particular (b):(a) ratio, let alone a range of (b):(a) ratios as claimed. *Rimfrost* is also a nonbinding PTAB decision denying institution of post grant review. *Rimfrost*, 2018 WL 4183083. In *Rimfrost*, the claim limitation recited "astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil." *Rimfrost*, 2018 WL 4183083, at *2. Patent Owner stated in its Preliminary Response that "the limitation at issue only sets forth the minimum amount of astaxanthin esters" and the "upper boundary is not

infinity." *Id.* at *7. Here, we agree that the upper boundary of the "at least 25% by weight" embodiment is not infinity.

(7) Summary of Written Description Analysis

We find that all of the disputed ranges and ratios in claims 1–5, 7, and 9–14 place limits on the amount of polymer in the claimed films, but that no such limits are disclosed in the '571 application sufficient to provide written description support for those limitations. Neither paragraph 65, nor Tables 1 or 5, discuss or refer to bounded or closed ranges of polymer weight percentages. Ex. 1011, 1444 ¶ 65, 1449–50 (Table 1), 1453 (Table 5). As we stated in our Institution Decision, although "we agree with Patent Owner that the disclosures of 'at least 25% by weight' and 'at least 50% by weight' are necessarily limited to *some* end point, that end point is not disclosed in the '571 application." Ins. Dec. 19. We also find that the express statement in the '571 application that "[t]he film may contain any desired level of self-supporting film forming polymer" would lead a POSA away from a particular bounded range of polymer levels. Ex. 1011, 1444 ¶ 65.

We also find that the '571 application does not mention or describe any (b):(a) ratio at all, although it does disclose formulations from which a (b):(a) ratio could be calculated if a POSA had a reason or desire to do so. Moreover, we further find that if a POSA actually calculated (b):(a) ratios from the disclosed formulations, she would find that a successful formula within the scope of the invention had the same (b):(a) ratio (1:2.8) as an unsuccessful formulation outside the scope of the invention, thereby evidencing the lack of any significance of the (b):(a) ratio. We further find that the '571 application provides no written description support for a *range* of (b):(a) ratios.

The testimony of Patent Owner's expert, Dr. Cremer, reflects an improper approach of simply working backward from the disputed claim limitations to "find" some alleged written description support, but the proper analysis is "from the standpoint of one with no foreknowledge of the [claim limitation]." *Ruschig*, 379 F.2d at 995; *see, e.g.*, Ex. 1030, 123:1–3 (unclaimed polymer weight percentages "not a question that had to be evaluated"); 102:2–11 (refusal to offer opinion regarding support for the polymer weight percentage range of about 45% to about 60% because that range was not claimed in the '454 patent); 155:9-156:5, 159:14–160:16 (testifying that 1:10.9 is about 1:11.5 but refusing to say whether 1:11 would also be about 1:10.9); *see also* Sur-reply 23 ("the issue is how a POSA would have understood 'about 1:11.5'"); *see id.* at 18 ("Dr. Cremer appropriately focused his analysis on the challenged claim limitations").

"Working backward from a knowledge of [the claim limitation], that is by hindsight" (*Ruschig*, 379 F.2d at 995), Dr. Cremer uses the challenged claims and the '571 application to opine on what the inventors envisioned, or what would have been obvious from the '571 application. But that approach fails to establish written description support. *See Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) ("It is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose."); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010) ("Entitlement to a filing date extends only to subject matter that is disclosed; not to that which is obvious.").

We acknowledge that "[i]t is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient." *Nalpropion*, 934 F.3d at 1350. Indeed, polymer weight percentages of 48.2 wt % and 58.6 wt %, as well as (b):(a) ratios of 1:2.8 and 1:10.9, have been found to be supported by formulations disclosed in the '571 application, notwithstanding the absence of any express disclosure of those values. Although "equivalent language may be sufficient," the law of written description is based on disclosure as of the filing date, and whether a POSA would have "immediately discerned the limitation at issue" from such disclosure. *Id.*; *Purdue Pharma,* 230 F.3d at 1323.

Accordingly, we find that a POSA, reading the '571 application, would not have immediately discerned the disputed limitations in claims 1, 5, 7, and 12. Thus, we also find that Petitioners have shown by a preponderance of the evidence that the '571 application fails to provide written description support for the claim limitations "about 40 wt % to about 60 wt % of a water-soluble polymeric matrix" (claim 1), "about 48.2 wt % to about 58.6 wt % of the water soluble polymeric matrix" (claims 7 and 12), and "wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5" (claims 5 and 12).[15] We also find that claims 2–5, 9–11, 13, and 14 also lack written description support due to their dependency from claim 1. *See*

[15] Patent Owner cites *Dynamic Drinkware* in its Sur-reply to argue that Petitioners "have failed to meet their burden." Sur-reply 4 (citing *Dynamic Drinkware*, 800 F.3d at 1379–80). Patent Owner argues that, having filed its Response and the Cremer Declaration, Petitioners failed to file a reply declaration by Dr. Das. *Id.* at 3–4. But, as *Dynamic Drinkware* makes clear, the burden of production is not the same as the burden of persuasion, and we find that Petitioners have met their burden of persuasion as to claims 1–5, 7, and 9–14. *See Dynamic Drinkware*, 800 F.3d at 1379–1380.

Lockwood, 107 F.3d at 1572. However, we also find that Petitioners have not shown by a preponderance of the evidence that the '571 application fails to provide written description support for the specific polymer weight percentage (about 48.2 wt %) recited in claim 8.

2. Anticipation

Having found that claims 1–5, 7, and 9–14 do not have written description support in the '571 application, we find that those claims have an effective filing date of no earlier than June 21, 2013, and turn to the issue of whether Myers anticipates challenged claims 1–5, 7, and 9–14 under 35 U.S.C. § 102(a)(1).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (citation omitted). Anticipation is a question of fact. *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999).

Petitioners identify disclosures in Myers that they argue disclose the limitations of the challenged claims. Pet. 33–41. Other than its arguments regarding written description support by the '571 application, and corresponding entitlement to a priority date of August 7, 2009, Patent Owner does not contest Petitioners' anticipation arguments. *See generally* PO Resp.; Sur-reply; *see also* Tr. 44:8–13.

a) Claim 1

Claim 1 is set forth above. *See supra* Section I.D. Petitioners identify the disclosures in Myers corresponding to each limitation of claim 1. Pet. 33–36 (citing Ex. 1010, 9 (Table 1), ¶¶ 6, 12, 30, 31, 58, 64–67, 72, 85; Ex. 1003 ¶¶ 82–88; *see also* Ex. 1001, 24:25–46). Regarding the limitation of "about 40 wt % to about 60 wt % of a water-soluble polymeric matrix," Petitioners cite to film formulations disclosed in Myers that fall within this range, including formulations in Table 1 that contain about 48.2% and about 58.6% polymer by weight. *Id.* at 33 (citing Ex. 1003 ¶ 82). We find that Petitioners have shown by a preponderance of evidence that claim 1 is anticipated by Myers.

b) Claims 2, 3, and 14

Claims 2, 3, and 14 depend from claim 1 and further narrow the weight ratio of (d):(b) recited in claim limitation 1(g).[16] Ex. 1001, 24:47–50, 25:13–14. Petitioners identify the disclosures in Myers corresponding to the limitations of claims 2, 3, and 14, and further assert that claims 2, 3, and 14 are anticipated by Myers for the same reasons that Myers anticipates the ratios of acidic buffer to buprenorphine recited in claim limitation 1(g). Pet. 36–37, 40–41 (citing Ex. 1010 ¶ 67; Ex. 1003 ¶¶ 90, 91, 102). We find that Petitioners have shown by a preponderance of evidence that claims 2, 3, and 14 are anticipated by Myers.

[16] The four wherein clauses in claim 1 are identified (in order) in the Petition and herein as 1(e), 1(f), 1(g), and 1(h) for purposes of clarity. Claim limitation 1(g) recites "wherein the weight ratio of (d):(b) is from 2:1 to 1:5." Ex. 1001, 24:37.

c) Claim 4

Claim 4 depends from claim 3 and recites "wherein the acidic buffer is citric acid." Ex. 1001, 24:51–52. Petitioners identify the disclosure in Myers that "the buffer may include sodium citrate, citric acid, and combinations thereof." Pet. 37 (citing Ex. 1010 ¶ 67). We find that Petitioners have shown by a preponderance of evidence that claim 4 is anticipated by Myers.

d) Claim 5

Claim 5 recites "wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5." Ex. 1001, 24:53–54. Petitioners identify the 2/0.5 dosage strength in Table 1 of Myers as having a (b):(a) ratio of 1:10.9, which is included in the range recited in claim 5. Pet. 37–38 (citing Ex. 1003 ¶ 93). We find that Petitioners have shown by a preponderance of evidence that claim 5 is anticipated by Myers.

e) Claim 7

Claim 7 recites "wherein the film comprises about 48.2 wt % to about 58.6 wt % of the water soluble polymeric matrix." Ex. 1001, 24:57–59. Petitioners assert that "these values are anticipated by the polymer weight percentages in the formulations in Table 1" of Myers. Pet. 38 (citing Ex. 1003 ¶¶ 94, 95). We find that Petitioners have shown by a preponderance of evidence that claim 7 is anticipated by Myers.

f) Claim 8

Claim 8 recites "[t]he film of claim 7, wherein the film comprises about 48.2 wt % of the water soluble polymeric matrix." Ex. 1001, 24:60–61. Petitioners assert that this value is anticipated by the polymer weight percentage in three formulations in Table 1 of Myers. Pet. 38 (citing

Ex. 1003 ¶ 96). However, the 48.2 wt % limitation has written description support in the '571 application, and Petitioners have thus not established that Myers is prior art to claim 8. *See supra* Section II.E.1.b)(1). We find that Petitioners have not shown by a preponderance of evidence that claim 8 is anticipated by Myers.

g) Claims 9, 10, and 11

Claim 9 recites "wherein the water-soluble polymeric matrix comprises a polyethylene oxide polymer alone or in combination with a hydrophilic cellulosic polymer," claim 10 recites "[t]he film of claim 9, wherein the hydrophilic cellulosic polymer is hydroxypropyl cellulose, hydroxypropylmethyl cellulose, or a combination thereof," and claim 11 recites "[t]he film of claim 10, wherein the hydrophilic cellulose polymer is hydroxypropylmethyl cellulose." Ex. 1001, 24:62–25:2. Meyers discloses that "[i]n some embodiments, the water-soluble polymer may include hydrophilic cellulosic polymers, such as hydroxypropyl cellulose and/or hydroxypropylmethyl cellulose." Pet. 38–39 (citing Ex. 1010 ¶ 32; Ex. 1003 ¶¶ 97–99). We find that Petitioners have shown by a preponderance of evidence that claims 9, 10, and 11 are anticipated by Myers.

h) Claim 12

Claim 12 recites "wherein the weight ratio of (d):(b) is from about 1:1 to 1:5; wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5; and wherein the film comprises about 48.2 wt % to about 58.6 wt % of the water soluble polymeric matrix." Ex. 1001, 25:3–7. Petitioners assert that claim 12 contains the same limitations as claims 2, 5, and 7, and that claim 12 is anticipated for the same reasons as claims 2, 5, and 7. Pet. 40 (citing

Ex. 1003 ¶ 100). We find that Petitioners have shown by a preponderance of evidence that claim 12 is anticipated by Myers.

i) Claim 13

Claim 13 is set forth above. *See supra* Section I.D. Petitioners identify disclosures in Myers describing the method of claim 13. Pet. 40 (citing Ex. 1010 ¶¶ 79, 80; Ex. 1003 ¶ 101). We find that Petitioners have shown by a preponderance of evidence that claim 13 is anticipated by Myers.

III. CONCLUSION[17]

For the foregoing reasons, we conclude that Petitioners have established by a preponderance of evidence that claims 1–5, 7, and 9–14 of the '454 patent are unpatentable. We also conclude that Petitioners have failed to establish by a preponderance of the evidence that claim 8 of the '454 patent is unpatentable.

In summary:

IPR2019-00329 U.S. Patent No. 9,687,454 B2				
Claims	**35 U.S.C. §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
1–5, 7–14	102(a)(1)	Myers	1–5, 7, 9–14	8

[17] 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).

Overall Outcome			1–5, 7, 9–14	8

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioners have proven by a preponderance of the evidence that claims 1–5, 7, 9–14 of U.S. Patent No. 9,687,454 B2 are unpatentable;

FURTHER ORDERED that Petitioners have failed prove by a preponderance of the evidence that claim 8 of U.S. Patent No. 9,687,454 B2 is unpatentable; 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.

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