Trials@uspto.gov
Tel: 571-272-7822

Paper 11
Entered: February 16, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,
Petitioner,

v.

GALDERMA LABORATORIES, INC.,
Patent Owner.

Case IPR2015-01778
Patent 8,603,506 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") filed a Petition (Paper 1; "Pet.") to institute an *inter partes* review of claims 1, 7, 8, 14, 15, and 20 of US 8,603,506 B2 (Ex. 1001; "the '506 patent"). Galderma Laboratories Inc. ("Patent Owner")[1] filed a Patent Owner Preliminary Response. Paper 8 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '506 patent. *See* 35 U.S.C. § 314(a). We, therefore, deny the Petition for an *inter partes* review.

a. *Related Proceedings*

Petitioner indicates that the '506 patent has been asserted in the United States District Court for the District of Delaware (Civil Action No. 15-670). Pet. 2; Paper 6, 2.

In addition to the case before us, Petitioner has requested *inter partes* review of claims 1, 7, 8, 14, 15, and 20 of US 8,603,506 B2 on other grounds in Case Nos. IPR2015-01777 and IPR2015-01782.

---

[1] Petitioner further indicates that the Complaint in Civil Action No. 15-670 states that Nestlé Skin Health S.A. is now the owner of the '506 patent. Pet. 2, n.1. Although Patent Owner does not directly address this assertion in the Preliminary Response, the USPTO Assignment Database indicates that patent is assigned to Galderma Laboratories, Inc. Absent additional information, we refer to Galderma Laboratories, Inc. as the Patent Owner.

b. *The '506 Patent*

The '506 patent is directed to the treatment of "all known types of acne," broadly defined as "a disorder of the skin characterized by papules, pustules, cysts, nodules, comedones, and other blemishes or skin lesions." Ex. 1001, 4:23–32. The genus "acne" is expressly defined as encompassing acne rosacea ("rosacea"),[2] a skin disorder "characterized by inflammatory lesions (erythema) and permanent dilation of blood vessels (telangectasia)." *Id.* at 4:31–43. The specification further states the "[t]he present invention is particularly effective in treating comedones." *Id.* at 4:23–43.[3]

By way of background, the '506 patent discloses that the efficacy of systemically-administered tetracycline compounds in the treatment of acne is commonly believed to be due, "in significant part, to the direct inhibitory effect of the antibiotics on the growth and metabolism of [] microorganisms" that "release microbial mediators of inflammation into the dermis or trigger the release of cytokines from ductal keratinocytes." Ex. 1001, 1:42–50. In addition to these antibiotic effects, the specification also notes that tetracyclines may have therapeutic anti-inflammatory effects due to, for example, the "inhibition of neutrophil chemotaxis induced by bacterial chemotactic factors," the "inhibition of [polymorphonuclear leukocyte] derived collagenase, and by scavenging reactive oxidative species produced by resident inflammatory cells." *Id.* at 2:21–32, 3:14–25.

---

[2] The parties agree that the term "acne rosacea" in the specification refers to rosacea. Pet. 30–31; Prelim. Resp. 15–16.

[3] Petitioner asserts, and Patent Owner does not contest, that comedones are not a feature of rosacea. Pet. 9, 25; *see* Prelim. Resp. 23–24; Ex. 1004 ¶ 13.

The ’506 patent teaches that although tetracyclines are administered in conventional antibiotic therapy, antibiotic doses of these compounds can result in undesirable side effects such as the reduction or elimination of healthy microbial flora and the production of antibiotic resistant microorganisms. *Id.* at 3:7–17, 3:31–36. To address the need for effective treatments that minimize these side effects, the ’506 patent discloses that “all known types of acne” may be treated by administering a tetracycline compound in an amount having “substantially no antibiotic activity (i.e. substantially no antimicrobial activity)” and, thus, “does not significantly prevent the growth of . . . bacteria.” *Id.* at 3:37–50; 4:31–32; 5:31–35. The ’506 patent defines “effective treatment” as “a reduction or inhibition of the blemishes and lesions associated with acne” (*id.* 5:31–33), which may be achieved by administering non-antibiotic tetracycline compounds (i.e., those lacking substantial antibiotic activity) or by using sub-antibiotic doses of tetracycline compounds having known antibiotic effects (*see, e.g., id.* at 3:26–29, 4:58–61, 5:1–9, 5:35–42). With respect to the latter, the specification indicates that a sub-antibiotic dose may comprise “10–80% of the antibiotic dose,” or “an amount that results in a serum tetracycline concentration which is 10–80% of the minimum antibiotic concentration.” *Id.* at 5:36–42; 6:7–12.

The specification teaches that, whereas exemplary *antibiotic* doses of tetracycline compounds include 50, 75, and 100 milligrams per day of doxycycline, in an especially preferred embodiment, doxycycline (as doxycycline hyclate) is administered as a 20 milligram dose, twice daily. *Id.* at 5:43–45; 5:59–63. The specification teaches that this 40 milligram per day dose provides the maximum non-antibiotic (i.e., sub-antibiotic) of

doxycycline based on steady-state pharmacokinetics. *Id.* at 5:49–52. In terms of serum concentration, doxycycline may also be administered in an amount that results in a serum concentration between about 0.1 and 0.8 μg/ml. *Id.* at 6:29–32.

Example 38 of the '506 patent discloses that in a six-month, placebo-controlled trial for the treatment of acne[4] using 20 mg doxycycline hyclate, twice daily, doxycycline-treated patients showed a statistically significant reduction in both comedones and inflammatory lesions (defined as "papules and pustules, less than or equal to 5 nodules") as compared to placebo. *Id.* at 19:54–55; 20:24–32. The six-month doxycycline treatment "resulted in no reduction in skin microflora . . . nor an increase in resistance counts when compared with placebo." *Id.* at 20:33–37; *see id.* at 5:64–6:4.

c. *Representative Claim*

Claim 1 of the '506 patent recites:

> 1. A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising
>
> administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof, in an amount that
>
> (i) is effective to treat the papules and pustules of rosacea;
>
> (ii) is 10-80% of a 50 mg dose of doxycycline per day; and
>
> (iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

---

[4] Petitioner asserts that Example 38 is directed to treating common acne (acne vulgaris), presumably based on inclusion criteria requiring the presence of comedones, non-inflammatory lesions which are not a symptom of rosacea. *See* Pet. 9, 23, 25; Ex. 1001, 1:20, 19:54; Ex. 1004 ¶ 13. Patent Owner does not dispute this characterization. *See* Prelim. Resp. 21.

The remaining asserted claims recite "an amount [of doxycycline] which provides a serum concentration in the range of about 0.1 to about 0.8 μg/ml" (claims 7, 14, and 20), "40–80% of a 50 mg dose of doxycycline per day" (claim 8), and "doxycycline, or a pharmaceutically acceptable salt thereof, in an amount of 40 mg per day" (claim 15).

d. *Asserted Grounds of Unpatentability*

Petitioner asserts the following grounds of unpatentability.

Claims challenged	Basis	Reference
1, 7, 8, 14, 15, and 20	§ 102	Ashley '572[5]
1, 7, 8, 14, 15, and 20	§ 103	Ashley '572
1, 7, 8, 14, 15, and 20	§ 103	Ashley '267[6]
1, 7, 8, 14, 15, and 20	§ 102	OREACEA[7]

ANALYSIS

a. *The '506 Priority Documents*

The '506 patent issued from a chain of continuation and divisional applications (collectively, "non-provisional parent applications") first filed on April 5, 2002. Ex. 1001. More specifically, the '506 patent issued from Application No. 13/277,789, filed October 20, 2011, which, as set forth on column 1 of the patent,

> is a continuation of U.S. application Ser. No. 11/876,478, filed on Oct. 22, 2007[,] now U.S. Pat. No. 8,052,983, allowed, which is a continuation of U.S. application Ser. No. 10/757,656, filed

[5] Ashley, US 7,232,572. Ex. 1020.
[6] Ashley, US 7,211,267. Ex. 1016.
[7] ORACEA™, *Physicians' Desk Reference* (61st ed. 2007), *available at* http://www.pdr.net. Ex. 1043.

> on Jan. 14, 2004, abandoned, which is a divisional application of U.S. application Ser. No. 10/117,709, filed on Apr. 5, 2002, now U.S. Pat. No. 7,211,267, which claims the benefit of U.S. Provisional Application No. 60/281,916, filed Apr. 5, 2001, and U.S. Provisional Application No. 60/325,489, filed Sep. 26, 2001.

As illustrated in the flow chart on page 12 of Patent Owner's Preliminary Response, Ashley '267 issued from the earliest non-provisional application in this chain, whereas Ashley '572 issued from a related, non-priority application. Petitioner contends that Ashley '267, Ashley '572, and ORACEA qualify as prior art because the challenged claims of the '506 patent lack written descriptive support in the non-provisional parent applications and are, therefore, not entitled to claim the benefit of the filing date of those applications under 35 U.S.C. § 120. Pet. 5–6.

The parties do not dispute that the'506 patent and the non-provisional parent applications share substantially the same specification. Indeed, Petitioner cites to the '506 patent in arguing that the non-provisional parent applications fail to provide written descriptive support for the challenged claims. *See, e.g.*, Pet. 22; Prelim. Resp. 12. Accepting that the '506 patent is representative of the disclosure in these earlier-filed applications, we adopt Petitioner's convention of citing to the '506 patent as a surrogate for the specification of any of the non-provisional parent applications.

Patent Owner argues that Petitioner's attack on the written descriptive support in the priority documents should be rejected as a thinly-veiled attempt to circumvent 35 U.S.C. § 311(b), which permits *inter partes* review "only on a ground that could be raised under section 102 or 103." *See* Prelim. Resp. 39–42. Although recognizing that "the Board has the

authority to determine priority entitlement . . . where there is legitimate intervening prior art," Patent Owner contends that this authority is cabined to situations where the priority documents do not share the same specification with the challenged patent. Prelim. Resp. 39 (citations omitted). We do not find Patent Owner's distinction persuasive; nor is this a matter of first impression. *See Bioactie Labs. v. BTG Int'l Inc*., Case IPR2015-01305 (PTAB Dec. 15, 2015) (Paper 19) (finding that Petitioner failed to demonstrate that parent application having same specification as challenged patent lacked written descriptive and enablement support with respect to challenged claims). Accordingly, we address the substance of Petitioner's priority challenge.

b. *Claim Construction*

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–81 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 84 U.S.L.W. 3218 (U.S. Jan. 15, 2016) (No. 15-446). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention,[8] in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). And

[8] Patent Owner provisionally adopts, as do we, Petitioner's definition of a person of ordinary skill in the art as "a licensed and practicing dermatologist with as little as one year of treating patients in a hospital, clinical, and/or private setting." Prelim. Resp. 5; Pet. 36 (both quoting Ex. 1004 ¶ 11).

"[a]lthough an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision. 'Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change.'" *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (citation omitted). "In such cases, the inventor's lexicography governs." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). Only terms which are in controversy need to be construed, however, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). For this reason, we provide express constructions for only the following terms.

i. Rosacea

The parties agree that the '506 patent identifies rosacea ("acne rosacea") as a form of acne. Pet. 30–31; Prelim. Resp. 7. Although Petitioner contends that one of ordinary skill in the art would not classify rosacea as a form of acne (Pet. 22; Ex. 1004 ¶¶ 12, 13), we apply the inventor's clearly expressed definition that "acne include[s] . . . acne rosacea" (Ex. 1001 4:31–41). With respect to the symptoms of rosacea, however, neither party contends that uncommon meanings apply. Pet. 30–31; Prelim. Resp. 6–8. We therefore construe rosacea as a form of acne having symptoms including papules, pustules, erythema, and telangiectasia, where the predominant lesions are papules and pustules. *See* Ex. 1001, 4:23–43; Ex. 1004, ¶¶ 7, 19 ("'The predominant lesions [in rosacea] are papules and pustules.' ([Ex. 1056] at 680; *see also* Exh. 1046, at 852, 958;

Exh. 1047, at 1023, 1175.)."

ii. Papules and Pustules

The '506 patent does not define the terms "papules" and "pustules" as other than as "[i]nflammatory lesions" or blemishes of the skin. *See* Ex. 1001, 3:17–19, 4:24–27, 19:54–55. Patent Owner argues that papules and pustules should be accorded their plain and customary meanings. Prelim. Resp. 8–9. Petitioner does not expressly suggest a meaning for these terms but points to its expert's statement that "'[a] papule is a small, solid, elevated lesion . . . smaller than 1 cm in diameter, and the major portion of a papule projects above the plane of the surrounding skin,'" whereas, "'[a] pustule is a circumscribed, raised lesion that contains a purulent exudate. . . . Pus, composed of leukocytes, with or without cellular debris, may contain bacteria or may be sterile . . . .'" Pet. 31–32; Ex 1004 ¶ 19 (both quoting Ex. 1056, 27, 31). Petitioner contends that "[t]hese definitions align well with those provided by applicant during prosecution." *Id.* at 31 (citing Ex. 1070, 6).

In view of the above, and applying the broadest reasonable definition consistent with the specification, we interpret "papules and pustules" as inflammatory lesions or blemishes of the skin, where "papules" are solid, rounded bumps rising from the skin that are each usually less than 1 centimeter in diameter, and "pustules" are small, inflamed, pus-filled, blister-like lesions of the dermis or epidermis.

c. *Written Descriptive Support in the Continuation Applications*

i. "A method for treating papules and pustules of rosacea"

In contending that the parent applications lack written descriptive support for treating papules and pustules of rosacea, Petitioner notes that

rosacea is only mentioned twice in the specification and using the "antiquated and outdated term," acne rosacea. Pet. 22. And although common acne (acne vulgaris) and rosacea are both skin conditions involving inflammatory papules and pustules, "no dermatologists of ordinary skill in the art would have lumped them together in a single genus as types of 'acne.'" *Id.* Moreover, Petitioner argues, among the symptoms the '506 patent attributes to acne generally, comedones are not symptomatic of rosacea, whereas papules and pustules "are only mentioned in connection with treating acne vulgaris in Example 38 . . . and once again in a list of possible symptoms characterizing the genus in 'acne.'" *Id.* at 23 (citations omitted).

We do not find Petitioner's arguments persuasive. As an initial matter, we note that Petitioner has not established that the term "acne rosacea" was "antiquated and outdated" as of the earliest filing date of the chain of applications leading to issuance of the '506 patent. Nor does Petitioner establish that one of ordinary skill in the art would not have understood that term to indicate rosacea—a condition commonly known to encompass inflammatory papules and pustules, albeit not comedones. *See* Pet. 22; Prelim. Resp. 18–19; Ex. 1004 ¶ 13; Ex. 1034, 144.

To the extent a dermatologist would not, as Petitioner argues, "have lumped [acne vulgaris and rosacea] together in a single genus," does not persuade us that written description is lacking. An inventor may choose to be his own lexicographer and give terms uncommon meanings if "done with reasonable clarity, deliberativeness, and precision." *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). In the present case, we find no ambiguity in the '506 patent's definition of the invention as directed to the treatment of

"all known types of acne," including both acne vulgaris and rosacea. *See* Ex. 1001, 4:31–43.

The '506 patent characterizes the genus acne as "a disorder of the skin characterized by papules, pustules . . . and other blemishes or skin lesions," and notes that rosacea evinces specific characteristics of "inflammatory lesions (erythema) and permanent dilation of blood vessels (telangiectasia)." *Id.* at 4:23–30, 41–43. We are not persuaded that written description is lacking because not all of the symptoms attributed to the genus acne apply to rosacea, or that a symptom specific to rosacea (i.e, telangiectasia) may only be treated surgically. *See* Pet. 23. Rather, we find it sufficient that the specification teaches the treatment of papules and pustules of the genus "acne"—expressly defined by the inventor as including rosacea.

We also agree with Patent Owner's position that Example 38 of the '506 patent further supports the treatment of papules and pustules of rosacea. *See* Prelim. Resp. 20. Example 38 discloses that a six-month treatment with 20 mg doxycycline, twice daily, resulted in a statistically significant reduction in inflammatory lesions (defined as "papules and pustules, less than or equal to 5 nodules") as compared to placebo. Ex. 1001, 19:37–2037.

Petitioner contends that Example 38 fails to support the treatment of papules and pustules *of rosacea* because it is directed to the treatment of acne vulgaris, rather than rosacea. *See* Pet. 23. We do not find this logic compelling, particularly in view of Petitioner's admissions regarding the commonality of papules and pustules in the two conditions. Petitioner admits that acne vulgaris and rosacea are both skin conditions involving inflammatory papules and pustules (Pet. 22); that such "[p]apules and pustules are extremely common to both common acne (acne vulgaris) and

rosacea (as well as other skin disorders)"; and that "the resulting papules and pustules in both diseases share common underlying properties in that they are inflammatory in nature" (*id.* at 32; Ex. 1004, ¶ 19).

We find the above admissions sufficient to support our conclusion. In addition, Petitioner's statements regarding the correlation between the papules and pustules of common acne and rosacea are further underscored in Petitioner's Paragraph IV Notice Letter to Galderma Laboratories L.P. ("Letter") indicating that Petitioner sought FDA approval to market a proposed 40 mg doxycycline product for use in treating inflammatory lesions of rosacea. Ex. 2005.[9] According to the Letter, "the prior art and the disclosure of the '506 Patent itself, makes the correlation between acne and rosacea indisputable." Ex. 2005, 39. With respect to the '506 Patent, the Letter further states that "the specification defines acne as a genus encompassing the species acne vulgaris and acne rosacea . . . [,] discusses the papules and pustules of acne as incorporating both inflammatory and infectious symptoms, and similarly notes that rosacea is also accompanied with inflammatory lesions, among other symptoms." *Id.* Moreover, the Letter contends, "the prior art is replete with statements made concerning the similarities between the inflammation accompanying acne and the inflammation accompanying rosacea," and "makes it quite clear that the papules and pustules of both acne and rosacea are inflammatory in nature

[9] Letter from Petitioner to Chief Executive Officer, Galderma Laboratories L.P. titled, "Notice of Paragraph IV Certification Re Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.'s Doxycycline Capsules 40mg; U.S. Patent Nos. 7,211,267; 7,232,572; and 8,603,506" (June 22, 2015).

and should be treated in the same way." *Id.* at 38–39.

In view of the above, we find that Petitioner does not persuade us that the non-provisional parent applications lack descriptive support for the treatment of papules and pustules of rosacea as set forth in the asserted claims of the '506 patent.

ii. "A method for treating papules and pustules of rosacea . . . comprising administering . . . doxycycline, or a pharmaceutically acceptable salt thereof"

Petitioner argues further the parent applications lack written descriptive support for administering doxycycline as recited in the claimed method. Specifically, Petitioner asserts that "nothing in the specification . . . point[s] a dermatologist of ordinary skill in the art to select doxycycline from at least hundreds of identified compounds and to do so when treating not just rosacea, but its papules and pustules." Pet. 25. We do not find this argument compelling.

As discussed above, Petitioner has not demonstrated a lack of support for the treatment of papules and pustules of rosacea generally. Nor do we find any lack of support for the use of doxycycline for treating "all known types of acne," including rosacea (*see* Ex. 1001, 4:31–43), which, as discussed above, was commonly recognized as involving inflammatory papules and pustules. With respect to the use of doxycycline in particular, we note that while the specification highlights the use of doxycycline to treat comedones (*see id.* at 4:44–45; 5:59–60; 7:1–4), which are not associated with rosacea (Ex. 1004 ¶ 13), it also more generally describes the administration of a 20 mg dose of doxycycline hyclate, twice daily, as "an especially preferred embodiment" (*id.* at 5:59–60; *see also id.* at 4:62–67).

Considering the specification as a whole, we do not read the '506 patent as directed solely to the treatment of comedones, or types of acne characterized by comedones and, accordingly, find that Petitioner has not established a lack of written descriptive support for the use of doxycycline to treat papules and pustules of rosacea.

> *iii. "10-80% of a 50 mg dose of doxycycline per day;" "40–80% of a 50 mg dose of doxycycline per day;" "40 mg per day" "an amount which provides a serum concentration in the range of about 0.1 to about 0.8 μg/ml"*

Petitioner contends also the parent applications lack written descriptive support for dosage regimen of doxycycline recited in the claimed method. Specifically, Petitioner asserts that "[n]othing in the specification teaches the use of any particular amount of an antibiotic or nonantibiotic compound to treat rosacea and certainly nothing teaches that one could administer, for example, 10-80% of a 50mg dose to treat rosacea's papules and pustules." Pet. 25–26. Emphasizing the treatment of rosacea rather than the disclosure of the doses, *per se*, Petitioner further argues that "neither of the ranges in independent claims 1 and 8 is explicitly taught in the specification of the '506 Patent or any of its predecessor patents as a proper dose of doxycycline to treat papules and pustules of rosacea. The 40mg dose of claim 15 is likewise not disclosed for the treatment of papules and pustules of rosacea." Pet. 28. As discussed above, however, Petitioner has not established a lack of written descriptive support for the use of doxycycline to treat papules and pustules of rosacea.

With respect to the specific amounts of doxycycline recited in the challenged claims, Petitioner merely states that, "where the specification

does discuss various dosage levels, there are contradictory statements as to which are antibiotic and which are nonantibiotic (which also creates confusion around the claim element in claims 1, 8, and 15 concerning the effect on skin microflora. (*See* Exhs.1004 ¶¶ 20, 21, 22, 23; 1001 col.5 ll. 38–40, 43–44, 54–58.)" Pet. 28. We note that the specification describes *antibiotic* doses of doxycycline as including 50 milligrams per day (Ex. 1001, 5:43–45); the maximum *non-antibiotic* dose of doxycycline as 40 milligrams per day, i.e., 20 milligrams, twice daily (*id.* at 5:49–51); and that a six-month treatment with this maximum non-antibiotic dose "resulted in no reduction in skin microflora" (*id.* at 20:33–35). Absent any further explanation of the alleged contradictions and confusion, we find that Petitioner has not established a lack of written descriptive support for the use of the claimed doses.

iv. "Administering . . . doxycycline, or a pharmaceutically acceptable salt . . . without administering a bisphonate compound"

Petitioner recognizes that column 3, lines 46–50 of the specification expressly teaches administration of "a tetracycline compound in an amount that is effective to treat acne but has substantially no antibiotic activity (i.e. substantially no antimicrobial activity), without administering a bisphosphonate compound." Pet. 29; *see also* Ex. 1001 at 8:14–15 ("[T]he tetracycline compounds are administered without administering a bisphosphonate compound."). Despite these express teachings, Petitioner contends that the limitation "without administering a bisphonate compound," is without written descriptive support because the specification provides no reason to exclude a bisphonate compound. Pet. 28–29 (citing *Santarus, Inc.*

v. Par Pharm., Inc., 694 F.3d 1344, 1351 (Fed. Cir. 2012) ("Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation.")). Petitioner's argument is premised on a reading of *Santarus* that would require the specification to detail the benefits of a negative limitation. The Federal Circuit, however, has since clarified that *Santarus* did not articulate such a new and heightened standard for negative claim limitations:

> When viewed in its proper context, Santarus simply reflects the fact that the specification need only satisfy the requirements of § 112, paragraph 1 as described in this court's existing jurisprudence, including through compliance with MPEP § 2173.05(i) ("If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.") and *In re Johnson*, 558 F.2d at 1018 ("It is for the inventor to decide what bounds of protection he will seek.").

Inphi Corp. v. Netlist, Inc., 805 F.3d 1350, 1356 (Fed. Cir. 2015).

Accordingly, we find that Petitioner has not demonstrated a lack of written description for this term.

CONCLUSION

Petitioner does not convince us that non-provisional parent applications of the '506 patent (as represented by the specification of the '506 patent) fail to provide adequate written descriptive support for the challenged claims. Accordingly, we do not agree with Petitioner's contention that the '506 patent is not entitled to the benefit of the April 5, 2002, filing date of the earliest of those applications under 35 U.S.C. § 120 such that Ashley '572, Ashley '267, and/or ORACEA would qualify as prior

art.[10] Consequently, Petitioner has failed to establish a reasonable likelihood that it would prevail in showing that claims 1, 7, 8, 14, 15, and 20 are unpatentable in view of the asserted references.

ORDER

Accordingly, it is

ORDERED that the Petition is *denied* as to all challenged claims of the '506 patent.

[10] Accordingly, we need not reach Patent Owner's argument that the Board should deny the Petition because the same or substantially the same arguments were previously considered by the Office. *See* Prelim. Resp. 42–45.

PETITIONER:

William L. Mentlik
Michael H. Teschner
Brian R. Tomkins
Maegan A. Fuller
LITTENBERG, KRUMHOLZ & MENTLIK, LLP
WMentlik.ipr@ldlkm.com
MTeschner.ipr@ldlkm.com
BTomkins.ipr@ldlkm.com
MFuller.ipr@ldlkm.com

PATENT OWNER:

Stephen Maebius
Sujnit Talapatra
Michael Houston
FOLEY & LARDNER LLP
smaebius@foley.com
stalapatra@foley.com
mhouston@foley.com

Gerald Flattmann
PAUL HASTINGS LLP
geraldflattmann@paulhastings.com