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Paper 43
Entered: June 22, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

Case PGR2017-00008
Patent 9,283,239 B2

Before TONI R. SCHEINER, LORA M. GREEN, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Post-grant Review
35 U.S.C. § 328(a) and C.F.R. § 42.73

I. INTRODUCTION

This is a Final Written Decision in a post-grant review challenging the patentability of claims 1–17 of U.S. Patent No. 9, 283,239 B2 (Ex. 1003; "the '239 patent").

We have jurisdiction under 35 U.S.C. § 6. This Decision is issued pursuant to 35 U.S.C. § 328(a). We conclude for the reasons that follow that Petitioner has shown by a preponderance of the evidence that claims 1–17 are unpatentable for a lack of written description.

A. Procedural History

Grünenthal GmbH ("Petitioner") filed a Petition (Paper 2; "Pet.") requesting post-grant review of claims 1–17 of the '239 patent. Antecip Bioventures II LLC ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 6 ("Prelim. Resp."). Based on these submissions, we instituted trial on the following grounds of unpatentability asserted by Petitioner:

Ground	Statutory Basis	Challenged Claims
Written Description	§ 112(a)	1–17

Decision to Institute (Paper 7, "Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 19, "PO Resp."), to which Petitioner filed a corrected Reply to Patent Owner Response (Paper 28, "Reply").

Oral argument was conducted on April 5, 2018. A transcript is entered as Paper 39 ("Tr.").

After the oral argument in this IPR occurred, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less

than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018). In view of *SAS*, we modified our institution decision to institute on all of the challenged claims and all of the grounds presented in the petition. Paper 40. Subsequently, the parties filed a Joint Motion to Limit the Petition, requesting that we limit the issues to be considered in this proceeding to Petitioner's challenge of claims 1–17 based on written description under 35 U.S.C. § 112. Paper 41. We granted the parties' Joint Motion to Limit the Petition. Paper 42. As such, the sole ground of unpatentability remaining in dispute and considered in the Final Written Decision is the challenge to claims 1–17 the '239 patent based on written description under 35 U.S.C. § 112.

Petitioner relies on the Declaration of Dr. Stephen Bruehl, Ph.D. (Ex. 1001) in support of the Petition. Petitioner relies on the Declaration of Dr. David Brayden, Ph.D. (Ex. 1053) to support its Reply.

Patent Owner relies on the Declarations of Dr. Socrates Papapoulos, M.D., Ph.D. (Ex. 2001 and Ex. 2015) and the Declaration of Dr. Christopher Gharibo, M.D. (Ex. 2002) in support of the Patent Owner Response.

B. The '239 Patent

The '239 patent is directed to "oral dosage forms of bisphosphonate compounds, such as zoledronic acid, that can be used to treat or alleviate pain or related conditions." Ex. 1003, 1:35–37. One such condition, Complex Regional Pain Syndrome ("CRPS"), is "a debilitating pain syndrome . . . characterized by severe pain in a limb accompanied by edema, and autonomic, motor and sensory changes." *Id.* at 4:57–59. Bisphosphonates generally have low oral bioavailability, and the '239 patent describes enhancing oral bioavailability of zoledronic acid by administering

it in the disodium salt form. *Id.* at 1:30–31, 38–41. An oral dosage form of zoledronic acid may be used to treat CRPS. *Id.* at 2:12–15.

According to the specification,

> In some embodiments, the monthly dose of zoledronic acid . . . is about 5000 mg or less, about 4000 mg or less, about 3000 mg or less, about 2000 mg or less, about 1000 mg or less, about 700 mg or less, about 600 mg or less, about 1 mg to about 4,000 mg, about 1 mg to about 1,000 mg, about 10 mg to about 1000 mg, about 50 mg to about 1000 mg, about 10 mg to about 600 mg, about 40 mg to about 600 mg, about 50 mg to about 600 mg, or about 100 mg to about 600 mg, about 40 mg to about 2000 mg, about 40 mg to about 800 mg, about 50 mg to about 800 mg, or about 100 mg to about 800 mg, about 40 mg to about 1000 mg, about 50 mg to about 1000 mg, or about 100 mg to about 1000 mg, or any monthly dose in a range bounded by, or between, any of these values.

Id. at 11:34–48.

> The monthly dose may be administered for only 1 month, or may be repeatedly administered for 2 or more months.

Id. at 12:2–3.

Column 10 of the specification provides the following guidance with regard to dosing regimens:

> Any suitable amount of zoledronic acid may be used. Some solid or liquid oral dosage forms, or units of oral dosage forms (referred to collectively herein as "oral dosage form(s)") may contain about 0.005 mg to about 20 mg, about 0.1 mg to about 10 mg, about 0.5 mg to about 10 mg, about 0.2 mg to about 5 mg, about 1 mg to about 500 mg, about 1 mg to about 50 mg, *about 10 mg to about 250 mg*, about 100 mg to about 300 mg, about 20 mg to about 200 mg, about 20 mg to about 150 mg, about 30 mg to about 100 mg, about 1 mg to about 1,000 mg, about 10 mg to about 50 mg, about 10 mg to about 300 mg, about 10 mg to about 150 mg, about 10 mg to about 100 mg, *about 40 mg to about 150 mg*, about 10 mg to about 600 mg, about 40 mg

> to about 600 mg, about 40 mg to about 2000 mg, about 40 mg to about 800 mg, about 25 mg to about 800 mg, about 30 mg to about 800 mg, about 10 mg to about 500 mg, about 50 mg to about 150 mg, about 50 mg, about 100 mg, *about 50 mg to about 500 mg*, about 100 mg to about 2000 mg, about 300 mg to about 1500 mg, about 200 mg to about 1000 mg, *about 100 mg to about 500 mg*, or about 150 mg of zoledronic acid, or any amount of zoledronic in a range bounded by, or between, any of these values. In some embodiments, the oral zoledronic acid is administered daily, weekly, monthly, *every two or three months*, once a year, or *twice a year*.

Id. at 10:40–63 (emphasis added).

Column 13 of the specification provides the following guidance with regard to dosing regimens:

> In some embodiments, an oral dosage form comprises about 10 mg to about 150 mg or *about 10 mg to about 100 mg* of zoledronic acid, and is administered *daily for about 5 to about 10 consecutive days*. This regimen may be *repeated* once monthly, once every two months, once every three months, once every four months, once every five months, *once every six months*, once yearly, or once every two years.

Ex. 1003, 13:34–40 (emphasis added).

Example 3 of the ’239 patent reports on treatment of CRPS with orally administered zoledronic acid in a rat tibia fracture model. *Id.* at 17:18–25. CRPS was induced by fracturing the right distal tibias of the animals, then casting the fractured hindpaws for four weeks. *Id.* at 17:25–28. The animals were orally administered either a vehicle (control) or 18 mg/m^2/day of zoledronic acid for 28 days. *Id.* at 17:32–34. After 28 days, the casts were removed and the animals tested for hindpaw pain, edema, and warmth. *Id.* at 17:37–39. Figures 3–6 of the ’239 patent depict the results of the treatment. The ’239 patent states that “a daily dose of 18

mg/m^2 corresponds to a monthly dose of about 500–560 mg/m^2 or a human dose of about 800–900 mg." *Id.* at 18:50–54.

C. Illustrative Claim

Claim 1, the only independent claim, is illustrative and reproduced below.

> 1. A method of treating complex regional pain syndrome comprising orally administering zoledronic acid to a human being in need thereof, wherein the human being receives about 80 to about 500 mg of zoledronic acid within a period of six months.

II. DISCUSSION

A. Claim Construction

In a post-grant review, the claims of an unexpired patent are interpreted using the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.200(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that the claims do not require explicit construction of any claim term for the purposes of this Final Written Decision. *See, e.g.*, *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed '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)).

B. Asserted Unpatentability under the Written Description Provision of 35 U.S.C. § 112(a)

Petitioner contends that claims 1–17 are unpatentable for insufficient written description of the dosing regimen limitation "about 80 to about 500 mg of zoledronic acid within a period of six months," as recited in independent claim 1. Pet. 19–24. Petitioner separately challenges claim 17 for lacking written description of an oral dosage form containing "at least 10% zoledronic acid." *Id.* at 25. Patent Owner opposes Petitioner's arguments regarding written description of the dosing regimen limitation "about 80 to about 500 mg of zoledronic acid within a period of six months." PO Resp. 13–37. Patent Owner, however, does not specifically address Petitioner's arguments with regard to the limitation "at least 10% zoledronic acid."

We address the parties' arguments below.

1. Law of Written Description

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

> Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed . . . . The test for sufficiency of support . . . is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Vas–Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citations omitted). Moreover, the Federal Circuit has "made clear that the written description requirement does not demand either examples or an actual reduction to practice." *Capon v. Eshhar*, 418 F.3d 1349, 1352 (Fed. Cir. 2005). "An applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc*., 339 F.3d 1352, 1365 (Fed. Cir. 2003). Furthermore, "[a] specification may . . . contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses." *Id.*

Finally, the written description inquiry is a question of fact, is context-specific, and must be determined on a case-by-case basis. *Ariad Pharms., Inc. v. Eli Lilly and Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citing *Ralston Purina Co. v. Far–Mar–Co, Inc*., 772 F.2d 1570, 1575; *Capon v. Eshhar*, 418 F.3d at 1357–58); *See Vas–Cath*, 935 F.2d at 1561–62 (Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.).

2. Claim 1: "about 80 to about 500 mg of zoledronic acid within a period of six months"

a. Petitioner's Contentions

Petitioner contends that "all of the claims contain a dosing regimen limitation requiring that 'the human being receives about 80 to about 500 mg of zoledronic acid within six months.'" Pet. 19–20. Petitioner contends, however, that "[t]he dosing regimen limitation recited in claim 1 does not appear anywhere in the '239 patent specification." *Id*. at 21. Rather, the recited dosing regimen limitation was first added by amendment to application claim 1 on October 28, 2015, and later amended by Examiner's Amendment to its final form. *Id.* (citing Ex. 1009, 363, 426). Petitioner contends that "[a]ll of the '239 patent claims are invalid for lack of written description because the '239 patent specification fails to demonstrate that the inventors were in possession of the dosing regimen limitation." *Id.* at 20.

In support of its position, Petitioner contends that the '239 patent specification "lists dozens of dosage amounts, frequencies and durations of treatment, and conditions to be treated" (Reply 1), which allows Patent Owner "to piece together the claimed dosing regimen by cherry-picking particular amounts, frequencies, and durations of administration from the many options listed" (Reply 4). *See also* Pet. 21 ("The specification does not mention the claimed range, but instead lists dozens of broad dosage ranges."). According to Petitioner, the disclosed broad ranges "allow[] for administration of from 0.005 mg to 730,000 mg of zoledronic acid within one year (i.e., 0.005 mg once a year to 2,000 mg daily) to treat virtually any pain indication." Reply 1 (citing Ex. 1003, 10:40–63); Pet. 21–22. That is, "the specification describes the administration of virtually any amount of

zoledronic acid over virtually any period of time." Pet. 23 (citing Ex. 1001 ¶¶ 74–81).

Petitioner acknowledges that the disclosed ranges are broader than the claimed range, but argues that "this is not enough to satisfy the written description requirement." Pet. 22. Rather, Petitioner contends that

> Even if a claimed range is narrower than the ranges that can be gleaned from the specification, the written description requirement is not satisfied where, as here, the specification does not clearly disclose to a [person of ordinary skill in the art] that the inventors considered the claimed range to be part of their invention.

Id. at 22 (citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1327 (Fed. Cir. 2000)); *see also* Reply 7 ("Given the complete lack of guidance in the specification, 'one is left to selection 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,'" quoting *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967)).

With reference to the disclosure on column 10 of the '239 patent, Petitioner further contends that

> In addition to the many broad ranges listed, the specification states that "any monthly dose in a range bounded by, or between, any of these values" may be employed. Exh. 1003, col. 11, ll. 46–47, 59–61. It further instructs that the "effective amount of zoledronic acid or another bisphosphonate will vary depending on various factors known to the treating physicians." *Id*. at col. 10, ll. 10-16; Exh. 1001, ¶ 75. Essentially, the specification describes the administration of virtually any amount of zoledronic acid over virtually any period of time. Exh. 1001, ¶¶ 74–81.

Id. at 23.

With reference to the disclosure on column 13 of the '239 patent, Petitioner contends that

> column 13 states that from about 10 mg to about 300 mg of zoledronic acid may be administered for about 2 to about 15 consecutive days, repeated anywhere from monthly to every two years. [Ex. 1003,] col. 13, ll. 20–47. Essentially, the specification posits that any amount of zoledronic acid may be administered at any frequency over any time period. *See* Petition at 21–23; Exh. 1001 ¶¶ 74–81.

Reply 4.

Regarding Examples 3 and 7 of the '239 patent, Petitioner contends that the dog bioavailability study of Example 7 and the rat efficacy study of Example 3 do not support the human dosing regimen recited in the claims. Pet. 23 (noting that the '239 patent discloses that the dose used in Example 3 "is equivalent to a monthly human dose of about 800–900 mg" (citing Ex. 1003, 17:32–39, 18:50–55)); Reply 11–22.

Focusing on the claim language "within a period of six months," Petitioner contends as follows:

> the specification does not indicate to a [person of ordinary skill in the art] that the amount of zoledronic acid administered over the course of a period of ***six months***, in particular, is important. For example, the specification discloses dosage ranges and embodiments that specify the amount of zoledronic acid administered in about 1 month, about 3 months, about 6 months, about 1 year, or one month or less. *See, e.g.*, Exh. 1003, col. 25-26, embodiments 46, 47, 48, 49, 51, 62. To the extent the specification does describe periods of six months, it does not specify the administration of the amounts recited in claim 1 over six months.

Id. at 24.

b. Patent Owner's Contentions

Patent Owner contends that the '239 patent specification provides explicit support for the dosage range of about 80 to about 500 mg of zoledronic acid within a period of six months, and does so "in multiple ways." PO Resp. 13–37. First, Patent Owner directs our attention to the following disclosure found on column 10 of the '239 patent specification where the following ranges are expressly disclosed: (i) about 10 mg to about 250 mg, (ii) about 40 mg to about 150 mg, (iii) about 50 mg to about 500 mg, and (iv) about 100 mg to about 500 mg. PO Resp. 13–14 (citing Ex. 1001 10:40–63). In the same paragraph, the '239 patent specification discloses that "[i]n some embodiments, the oral zoledronic acid is administered daily, weekly, monthly, *every two or three months*, once a year, or *twice a year*." *Id.* (emphasis added). Patent Owner characterizes column 10 of the '239 patent as providing "a dosing regimen of 'about 100 mg to about 500 mg[']. . . . administered . . . twice a year, thus disclosing, the upper limit 'about 500 mg' dosage over 6 months verbatim, and also the lower limit 'about 80 mg' over 6 months dosage, rounded up to 100 mg." *Id.*

Moreover, Patent Owner's expert, Dr. Papapoulos, testifies that disclosure of the range "about 20 mg to about 150 mg" found on column 10 the '239 patent further provides express support for the claimed dosing range. Specifically, Dr. Papapoulos testifies as follows:

> With respect to the ranges in the claims and the specification of the '239 patent, a person of ordinary skill in the art would have recognized that the ends of these ranges are estimates, which would preferably be described by a single significant figure. In fact, a single significant figure may be too precise for many estimates and use of the term "about" help to

> further convey that the value is an estimate. For example, the nominal values of about 80 mg to about 500 mg administered every 2 months for six months are 26.7 mg and 166 mg, respectively but to avoid conveying an exaggerated level of precision would be expressed in round number as, for example, at col. 10, lines 47 and 60-62 as "about 20 mg to about 150 mg . . . . administered . . . . every two . . . months. (Ex. 1003, '239 Patent.) Similarly, a six month dose of about 80 to about 500 mg is expressed in round numbers at col. 10, lines 47 and 58-62 as "about 100 mg to about 500 mg . . . administered . . . twice a year." (Ex. 1003, '239 Patent.)

Ex. 2015 ¶ 26; *see also* PO Resp 14.

Next, Patent Owner directs our attention to the following disclosure found on column 13 of the '239 patent specification for support of the claimed dosage range:

> In some embodiments, an oral dosage form comprises about 10 mg to about 150 mg or *about 10 mg to about 100 mg* of zoledronic acid, and is administered *daily for about 5 to about 10 consecutive days*. This regimen may be *repeated* once monthly, once every two months, once every three months, once every four months, once every five months, *once every six months*, once yearly, or once every two years.

Ex. 1003, 13:34–40 (emphasis added; *see* Ex. 2015 ¶ 28); *see also*, Ex. 2015 ¶ 29 ("the paragraphs of the specification immediately before and after the paragraph referred to above likewise encompass an eight-consecutive-day, 10 mg per day dosing regimen, administered once every six months, and thus likewise support my conclusion that the inventor was in possession of a six-month dosing regimen having an 80 mg low end"). Patent Owner contends that this paragraph on column 13 "disclose[s] a dosing regimen of about 10 mg per day and a dosing period of eight consecutive days (totaling 80 mg) with a repetition of the cycle for the dosing period of 'once every six months,' thus disclosing a dosage of 80 mg within a six-month period, the

lower limit of the range." PO Resp. 14; Tr. 24:8–25:7, 30:16–33:11, 45:3–46:22.

Regarding the upper limit of about 500 mg, Patent Owner contends as follows:

> this same dosing regimen of 10 mg per day for eight consecutive days can be "repeated once monthly." (Ex. 1003, '239 patent, at col. 13, lines 37–38.) If this is done for six months, a dose of about 480 mg is administered within a period of six months, which is the same as about 500 mg.

PO Resp. 14 (citing Ex. 2015 ¶¶ 18, 26–29); Tr. 24:8–25:7, 30:16–33:11, 45:3–46:22.

Next, Patent Owner contends a person of ordinary skill in the art would understand

> that the inventor was in possession of a range of about 40 mg to about 250 mg of zoledronic acid administered every three months, . . . which equates to about 80 to about 500 mg over six months, from the single paragraph in the specification stating "*about 40 mg* to about 150 mg" and ". . . about 10 mg to *about 250 mg . . .*" *and "or any amount of zoledronic in a range bounded by, or between, any of these values* . . . administered . . . *every . . . three months* . . . .

PO Resp. 16 (citing Ex. 1003, '239 patent col. 10, lines 46–62 (emphasis added); Ex. 2015 ¶ 20 ("A person with ordinary skill in the art would have known that, due to their specific pharmacological properties, bisphosphonates can be given at different time intervals without losing their efficacy and that the total dose rather than the dosing interval will determine the final response."); *see also id.* at ¶ 24 ("in phase 2 clinical study

intravenous infusions of zoledronic acid 1 mg every 3 months, 2 mg every 6 months, or 4 mg once yearly induced the same pharmacodynamic response").

Next, Patent Owner contends that "a person of ordinary skill in the art would have recognized that the ends of these ranges are estimates, which would preferably be described by a single significant figure," and provides numerous examples in which the end points of the ranges are approximated by the ranges expressly disclosed by the '239 patent, emphasizing the "about" language of the claims. PO Resp. 17–22.

Patent Owner further contends that Examples 3 and 7 of the '239 patent also provides explicit support in the specification for the use of the overall dosage range about 80 mg to about 500 mg to treat CRPS. PO Resp. 23–26.

c. Analysis

We first consider whether the specification provides written description support for the range of "about 80 to about 500 mg of zoledronic acid" recited by the claims. As noted by the Patent Owner, column 10 of the '239 patent specification discloses ranges that would encompass the claimed range. PO Resp. 13–14. In particular, the specification discloses the range of "about 50 mg to about 500 mg," thereby giving literal support to this range and to the endpoint of "about 500 mg." Ex. 1003, 10:56. While the endpoint of "about 80 mg" is not expressly disclosed in combination with the 500 mg endpoint, we note that the Federal Circuit explained that

> If lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach* . . . that "the invention claimed does not have to be described *in ipsis verbis* in

> order to satisfy the description requirement of § 112," is empty verbiage.

Union Oil Co. of California v. Atl. Richfield Co., 208 F.3d 989, 1000 (Fed. Cir. 2000) ("*Unocal*"), quoting *In re Wertheim*, 541 F.2d 257, 265 (C.C.P.A. 1976). We thus consider whether the description "clearly allow persons of ordinary skill in the art to recognize" the claimed invention. *Vas–Cath*, 935 F.2d at 1563.

We find that the facts of this case differ significantly from the facts in *Unocal* or *Wertheim* where the specification clearly allowed persons of ordinary skill in the art to recognize the claimed invention despite the absence of literal support. In *Unocal*, the original disclosure explicitly described the effects of altering the variables, explicitly described the claimed endpoints as preferred, or explicitly recited them in an original claim. Moreover, persuasive expert testimony was offered to support the finding that the specification reasonably conveyed to one skilled in the relevant art that the inventor possessed the later claimed invention. *Unocal*, 208 F.3d at 993, 998–99. In *Wertheim*, the CCPA held that the specification supported the claimed range of 35–60% where the specification described the range of 25–60% along with specific embodiments of 36% and 50%. 541 F.2d at 264–65.

In this case, the '239 patent specification does not clearly allow persons of ordinary skill in the art to recognize the "about 80 mg" endpoint as part of invention described in the '239 patent. There is no disclosure of "about 80 mg" as a preferred endpoint, no disclosure of a specific embodiment including a dose of 80 mg, nor any other description suggesting the importance or criticality of the "about 80 mg" endpoint.

In view of the lack of any explicit disclosure for "about 80 mg" endpoint, Patent Owner suggests that the "about 80 mg" endpoint may be derived from the specification in numerous ways. PO Resp. 13–33; Ex. 2015 ¶¶ 26, 28. For example, Patent Owner argues that the endpoint of 80 mg finds support in column 13 of the specification, which discloses a range of "about 10 mg to about 100 mg" administered over the course of 5 to 10 consecutive days, thereby essentially disclosing a list six different ranges that includes the ranges of about 50 mg to about 500 mg and about 80 mg to about 800 mg. PO Resp. 14 (citing Ex. 2015 ¶¶ 18, 26–29); Tr. 24:8–25:7, 30:16–33:11, 45:3–46:22.

We are aware of cases indicating that the written description analysis requires consideration as to whether one of skill in the art could derive the claimed ranges from the specification. *See e.g., Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d at 1327; *Vas–Cath Inc. v. Mahurkar*, 935 F.2d at 1563–64; *Ralston Purina Co. v. Far–Mar–Co, Inc.*, 772 F.2d at 1575 ; *In re Wertheim*, 541 F.2d at 264–65. For example, we note that "ranges found in applicant's claims need not correspond exactly to those disclosed in [the specification, so long as] one skilled in the art could derive the claimed ranges from the [ ] disclosure." *Vas–Cath*, 935 F.2d at 1566. However, none of the cases concluding that sufficient written description existed such that a person of ordinary skill in the art could derive a claimed range from a specification are factually equivalent to the present case, where, as here, a non-original claim recites a dosage regimen range with endpoints derived from an inordinate amount of picking and choosing from disparate disclosures of various embodiments reciting broader ranges. For example, in *Ralston*, the Federal Circuit held that the disclosure of 25%–27% water in

a soybean mixture did not support broader claims to "at least 20%," "between 20% and 40%," or "in the range of 20%–30%" moisture levels, but did support moisture levels of "at least about 25% by weight" and "at least 25% by weight," reasoning that the open-ended claims would be limited by what a person skilled in the art would understand to be workable. 772 F.2d at 1576; *see also*, *In re Wertheim*, 541 F.2d at 264–65 (discussed hereinabove).

By comparison, we find the factual situation in this case to be closest to the situation in *Purdue Pharm*, where the Federal Circuit held that claims reciting an extended-release drug formulation requiring a certain ratio between the drug's maximum blood concentration (C_{max}) and its concentration at twenty-four hours after administration (C_{24}) could not be derived from the specification. 230 F.3d at 1323. The patentee argued the written description provided adequate support under § 112 because of two examples in the specification in which the C_{max}/C_{24} ratio was greater than two. *Id*. at 1326. The court, however, upheld the district court's finding that the written description was insufficient:

> Although 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. The district court therefore reasonably concluded that one of ordinary skill in the art would not be directed to the C_{max}/C_{24} ratio as an aspect of the invention. . . . [T]he disclosure of the '360 patent discloses a multitude of pharmacokinetic parameters, with no blaze marks directing the skilled artisan to the C_{max}/C_{24} ratio or what value that ratio should exceed.

Id. The court held that the written description requirement was not met, stating that "[b]ecause the specification does not clearly disclose to the

skilled artisan that the inventors . . . considered the C_{max}/C_{24} ratio to be part of their invention, it is immaterial what range for the C_{max}/C_{24} ratio can be gleaned from the examples when read in light of the claims." *Id*. at 1328. Likewise, here, there is no description in the '239 patent specification that attaches any significance to orally dosing a patient using about 80 mg of zoledronic acid, and as such the "about 80 mg" endpoint is not derivable from the '239 patent specification.

Furthermore, we note that the disparate disclosures of the '239 patent specification upon which Patent Owner relies may very well render the "about 80 mg" endpoint of the claimed ranges obvious to a person having ordinary skill in the art. Obviousness, however, is an inappropriate standard to measure a claim's compliance with the description requirement. *Lockwood v. American Airlines, Inc*., 107 F.3d 1565, 1572 (Fed. Cir. 1997) ("One shows that one is "in possession" of *the invention* by describing *the invention*, with all its claimed limitations, not that which makes it obvious.")

Moreover, we note that the claims do not merely require administration of a dose of about 80 mg to about 500 mg of zoledronic acid, they also require that dose to be administered "within a six month period." The '239 patent specification does not use the phrase "within a six month period," but rather discloses that the various described dosage amounts may be administered, for example, "monthly, every two or three months, once a year, or twice a year" or may be "repeated . . . once every six months." Ex. 1003, 10:40–63, 13:27–33. To the extent the specification does describe periods of six months, it also does not specify the administration of the recited doses over six month. Thus, a person of ordinary skill in the art must further derive from the language of the '239 patent specification the time

frame of "within a period of six months" to administer the recited dose of "about 80 to about 500 mg of zoledronic acid," thereby further complicating the process necessary to derive the recited dosing regimen from the '239 patent specification. We thus, conclude that the '239 patent specification does not clearly allow persons of ordinary skill in the art to recognize nor derive the recited dosing regimen of "about 80 to about 500 mg of zoledronic acid within a period of six months."

Accordingly, in view of the above, we conclude that the '239 patent specification would not have directed a person of ordinary skill in the art to construct a range of "about 80 to about 500 mg of zoledronic acid within a six month period" from the various broad ranges disclosed in the specification. *See* Pet. 24 (citing Ex. 1001 ¶¶ 81–83).

3. Claim 17: "orally administered in a dosage form containing at least 10% zoledronic acid"

Claim 17 depends from claim 1 and, further to claim 1's recitation of the range of zoledronic acid that the human being receives within six months, recites "wherein the Zoledronic acid is orally administered in a dosage form containing at least 10% zoledronic acid." Petitioner acknowledges that the '239 patent describes liquid compositions containing from 0.0001 % to about 50% (w/v) zoledronic acid, and solid compositions containing from 5% up to about 90% (w/w) zoledronic acid. Pet. 25 (citing Ex. 1003, 10:17–39). Petitioner argues, however, that because formulations containing more than 90% zoledronic acid are not described in the specification but would be within the scope of claim 17, the written description requirement is not satisfied. *Id.* Petitioner relies on *In re Wertheim*, 541 F.2d at 263–64 (claimed range of "at least 35%" not

supported by disclosure of 25% to 60% range disclosed in priority application).

Patent Owner does not specifically address Petitioner's arguments with regard to claim 17. Nonetheless, we are not persuaded by Petitioner's contentions. Rather, we find that the '239 patent contains a sufficient written description of an oral dosage form containing "at least 10% zoledronic acid." The specification describes a full panoply of zoledronic acid concentrations. Liquid compositions may contain "about 10% (w/v) to about 15% (w/v), about 15% (w/v) to about 20% (w/v), about 20% (w/v) to about 30% (w/v), about 30% (w/v) to about 40% (w/v), or about 40% (w/v) to about 50% (w/v) of zoledronic acid." Ex. 1003, 10:25–28. Solid dosage forms may contain "at least about 10% (w/w), at least about 20% (w/w) . . ." up to "at least about 80% [w/w]" zoledronic acid. *Id.* at 10:30–32. Solid dosage forms also are described as containing zoledronic acid in ranges beginning from "about 10% (w/w) to about 30% (w/w), about 10% (w/w) to about 20% (w/w) . . ." all the way up to a range of "about 80% (w/w) to about 90% (w/w)." *Id.* at 10:32–39. The breadth of zoledronic acid concentration ranges disclosed is more comprehensive than, and therefore distinguishable from, the more limited concentration ranges disclosed in *Wertheim* (claimed range of "at least 35%" not supported by disclosure of 25% to 60% range disclosed in priority application). In short, we determine that a person of ordinary skill in the art – a medical doctor with experience treating CRPS – would have recognized that the "inventor invented what is claimed" and did not overreach in claiming "at least 10% zoledronic acid" in an orally administered dosage form for treating CRPS. *See University of Rochester*, 358 F.3d at 928 (Fed. Cir. 2004).

III. CONCLUSION

We determine that Petitioner demonstrates by a preponderances of the evidence that that claims 1–17 are unpatentable under 35 U.S.C. § 112(a) for failure to satisfy the written description requirement.

IV. ORDER

Accordingly, it is

ORDERED that claims 1–17 of U.S. Patent No. 9,283,239 B2 are *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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