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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

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