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Paper 25
Date: July 28, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

PGR2019-00028
Patent 10,052,338 B2

Before GRACE KARAFFA OBERMANN, CHRISTOPHER M. KAISER, and WESLEY B. DERRICK, *Administrative Patent Judges*.

KAISER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Claims Unpatentable
35 U.S.C. § 328(a)

INTRODUCTION

A. Background

Grünenthal GmbH ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting a post-grant review of claims 1–30 of U.S. Patent No. 10,052,338 B2 (Ex. 1003, "the '338 patent"). Antecip Bioventures II LLC ("Patent Owner") did not file a Preliminary Response. We instituted review of all challenged claims on each of the grounds asserted in the Petition. Paper 6 ("Dec. Inst.").

Following institution, Patent Owner filed a Response (Paper 11, "PO Resp."), Petitioner filed a Reply (Paper 13, "Reply"), and Patent Owner filed a Sur-Reply (Paper 16, "PO Sur-Reply"). Patent Owner also filed a motion to exclude certain evidence. Paper 21 ("Mot. Exclude"). Petitioner opposed this motion (Paper 22, "Opp. Mot."), and Patent Owner filed a Reply (Paper 23, "Reply Mot."). We held a hearing on April 24, 2020, the transcript of which has been entered into the record. Paper 24.

We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision pursuant to 35 U.S.C. § 328(a). We conclude that Petitioner has established by a preponderance of the evidence that claims 1–30 of the '338 patent are unpatentable.

B. Related Matters

The parties do not direct us to any judicial matter that would be affected by the outcome of this proceeding. Pet. 5–6; Paper 3, 2. Petitioner has, however, challenged patents related to the '338 patent in additional petitions. Pet. 5; Paper 3, 2. In particular, according to the parties, the Board has issued final written decisions in PGR2017-00008 and PGR2017-

00022, and petitions are pending in PGR2018-00001,[1] PGR2018-00062, PGR2019-00003, PGR2019-00026, and PGR2019-00027. *Id.*

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–30 of the '338 patent are unpatentable based on the following grounds (Pet. 24–78):[2]

35 U.S.C. §	References/Basis	Challenged Claims
103	Varenna 2011,[3] Gatti,[4] and/or Muratore;[5] and Harden[6]	1–16

[1] After the parties identified related matters, the Board issued a final written decision in PGR2018-00001. *See* PGR2018-00001, Paper 48 (PTAB Apr. 29, 2019).

[2] Petitioner also relies on a Declaration from Lawrence Poree, M.D., Ph.D. Ex. 1004.

[3] Massimo Varenna, *The Clinical Framework of Algodystrophy (Complex Regional Pain Syndrome Type I), An Update*, 37 IT. J. ORTHOPEDICS & TRAUMATOLOGY 227, 227–34 (Oct. 2011) (Ex. 1006, "Varenna 2011") (English translation).

[4] Davide Gatti, Ombretta Viapiana, Luca Idolazzi, Elena Fracassi & Silvano Adami, *Neridronic Acid for the Treatment of Bone Metabolic Diseases*, 5 EXPERT OPINION ON DRUG METABOLISM & TOXICOLOGY 1305, 1305–11 (2009) (Ex. 1008, "Gatti").

[5] M. Muratore, F. Calcagnile, L. Cosentino, M. Serra, C. Circhetta, & E. Quarta, *Neridronate in the Treatment of Reflex Sympathetic Hip Algodystrophy: Open Comparison with Clodronate*, PROGRESS IN RHEUMATOLOGY (Apr. 2004) (Ex. 1007, "Muratore") (English translation).

[6] R. Norman Harden, Stephen Bruehl, Roberto S.G.M. Perez, Frank Birklein, Johan Marinus, Christian Maihofner, Timothy Lubenow, Asokumar Buvanendran, Sean Mackey, Joseph Graciosa, Mila Mogilevski, Christopher Ramsden, Melissa Chont, & Jean-Jacques Vatine, *Validation of Proposed Diagnostic Criteria (the "Budapest Criteria") for Complex Regional Pain Syndrome*, 150 PAIN 268, 268–74 (Apr. 2010) (Ex. 1009, "Harden").

35 U.S.C. §	References/Basis	Challenged Claims
112	Indefiniteness	17–30
103	Varenna 2011, Gatti, and/or Muratore; Harden; and Drummond[7]	17–30
112	Written Description	1–30

D. The '338 Patent

The '338 patent, titled "Neridronic Acid for Treating Complex Regional Pain Syndrome," issued on August 21, 2018. Ex. 1003, code (45), (54). The '338 patent relates to "[o]ral dosage forms of osteoclast inhibitors, such as neridronic acid, in an acid form or a salt form" that "can be used to treat or alleviate pain or related conditions, such as allodynia associated with complex regional pain syndrome." *Id.* at code (57). According to the patent, "[b]isphosphonate compounds are potent inhibitors of osteoclast activity, and are used clinically to treat bone-related conditions such as osteoporosis and Paget's disease of bone," as well as "cancer-related conditions including multiple myeloma, and bone metastases from solid tumors," but these compounds "generally have low oral bioavailability." *Id.* at 1:58–63. "[O]ral dosage forms of bisphosphonate compounds . . . can be used to treat or alleviate pain or related conditions." *Id.* at 2:3–5. One of these conditions is "allodynia . . . after a precipitating event such as fracture that is

[7] Peter D. Drummond, *Sensory Disturbances in Complex Regional Pain Syndrome: Clinical Observations, Autonomic Interactions, and Possible Mechanisms*, 11 Pain Medicine 1257, 1257–66 (2010) (Ex. 1010, "Drummond").

associated with [complex regional pain syndrome]," which "is a debilitating pain syndrome" that "is characterized by severe pain in a limb that can be accompanied by edema, and autonomic, motor and sensory changes." *Id.* at 3:19–24, 13:23–26.

None of the figures or working examples in the specification of the '338 patent relate to the use of neridronic acid. *Id.* at 3:28–4:18, 49:15–63:18, Figs. 1–16 (all discussing the use of zoledronic acid). Nevertheless, the specification identifies neridronic acid as a bisphosphonate suitable for use in the invention and contains information pertaining to daily oral dosing of neridronic acid. *Id.* at 3:19–24, 31:26–31. The specification also refers to a "molecular complex comprising neridronic acid" that "is administered in an amount that results in" certain disclosed blood plasma concentration curves. *Id.* at 26:16–29. Moreover, the specification contains other general information pertaining to the dosing of neridronic acid. For example, the '338 patent describes the administration of "[a]ny suitable amount of an osteoclast inhibitor, including a bisphosphonate," from a list that includes "neridronic acid" and identifies broad dosing ranges (from about 0.005 mg to about 2000 mg). *Id.* at 33:12–44. The patent also describes the administration of "any amount of osteoclast inhibitor" that is "in a range bounded by, or between, any of these values." *Id.* The specification compares oral forms of bisphosphonates to "parenteral modes of administration, such [as] intravenous or subcutaneous" modes. *Id.* at 26:43–47.

E. Illustrative Claims

Claims 1–30 of the '338 patent are challenged. Claims 1 and 17 are independent and illustrative; they recite:

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