

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GRÜNENTHAL GMBH,  
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,  
Patent Owner.

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PGR2019-00027  
Patent 10,039,774 B2

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

OBERMANN, *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 1–29 of U.S. Patent No. 10,039,774 B2 (Ex. 1002, “the ’774 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 10, “PO Resp.”), Petitioner filed a Reply (Paper 12, “Reply”), and Patent Owner filed a Sur-Reply (Paper 15, “PO Sur-Reply”). Patent Owner also filed a motion to exclude certain evidence. Paper 20 (“Mot. Exclude”). Petitioner opposed this motion (Paper 21, “Opp. Mot.”), and Patent Owner filed a Reply (Paper 22, “Reply Mot.”). We held a hearing on April 24, 2020, the transcript of which has been entered into the record. Paper 23.

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 1–29 of the ’774 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. 4–5; Paper 3, 2. Petitioner, however, challenges patents related to the ’774 patent in additional administrative petitions for review. Pet. 4; 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, PGR2018-00062, PGR2019-00003, PGR2019-00026, and

PGR2019-00028. *Id.* After the parties identified related matters, the Board issued a final written decision in PGR2018-00001. *See* PGR2018-00001, Paper 48 (PTAB April 29, 2019).

*C. The Asserted Grounds of Unpatentability*

Petitioner contends that claims 1–29 of the ’774 patent are unpatentable based on the following grounds (Pet. 22–75):<sup>1</sup>

35 U.S.C. §	References/Basis	Challenged Claims
103	Varena 2011, <sup>2</sup> Gatti, <sup>3</sup> Muratore, <sup>4</sup> Harden, <sup>5</sup> Drummond <sup>6</sup>	1–15

<sup>1</sup> Petitioner also relies on a Declaration from Lawrence Poree, M.D., Ph.D. Ex. 1004.

<sup>2</sup> Massimo Varena, *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, “Varena 2011”) (English translation).

<sup>3</sup> 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”).

<sup>4</sup> 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).

<sup>5</sup> 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”).

<sup>6</sup> Peter D. Drummond, *Sensory Disturbances in Complex Regional Pain Syndrome: Clinical Observations, Autonomic Interactions, and Possible*

35 U.S.C. §	References/Basis	Challenged Claims
103	Varena 2011, Gatti, Muratore, Harden <sup>7</sup>	16–29
112	Written Description	1–29

*D. The '774 Patent*

The '774 patent, titled “Neridronic Acid for Treating Complex Regional Pain Syndrome,” issued on August 7, 2018. Ex. 1002, at (45), (54). The '774 patent relates to “[o]steoclast inhibitors, such as neridronic acid, in an acid or a salt form” that “can be used to treat or alleviate pain or related conditions, such as complex regional pain syndrome” (“CRPS”). *Id.* at (57).

According to the '774 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 1:38–43. “[O]ral dosage forms of bisphosphonate compounds . . . can be used to treat or alleviate pain or related conditions.” *Id.* at 1:51–54. Two of these conditions are “changes in skin blood flow” and “abnormal sudomotor activity” associated with CRPS,

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*Mechanisms*, 11 Pain Medicine 1257, 1257–66 (2010) (Ex. 1010, “Drummond”).

<sup>7</sup> This ground advances the same prior art references as the obviousness ground asserted against claims 1–16. We address this as a distinct ground to mirror the structure of the Petition.

which is a “debilitating pain syndrome[] . . . characterized by severe pain in a limb.” *Id.* at 13:23–32.

None of the figures or working examples in the specification of the '774 patent relate to the use of neridronic acid. *Id.* at 3:21–4:13 (describing Figs. 1–16), 49:33–65:24 (Examples 1–10); *see id.* at 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 3:4–10, 31:40–45. 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 26:30–43. Moreover, the specification contains other general information pertaining to the dosing of neridronic acid. For example, the '774 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 33:25–57. The '774 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.* at 34:12–13. The specification compares oral forms of bisphosphonates to “parenteral modes of administration, such [as] intravenous or subcutaneous” modes. *Id.* at 26:57–61. The specification explains that “[c]ommonly used measures of pain intensity include the visual analog scale (VAS) and the numerical rating scale (NRS).” *Id.* at 10:9–11.

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