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Paper 32
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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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PGR2018-00062
Patent 9,707,245 B2

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Before TONI S. SCHEINER, GRACE KARAFFA OBERMANN, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge*.

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

# I. INTRODUCTION

This is a Final Written Decision in a post-grant review of claims 1–30 of U.S. Patent No. 9,707,245 B2 (Ex. 1001, "the '245 patent"). The Board has jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 328(a).

We instituted review based on all grounds asserted in the Petition (Paper 2, "Pet."). *See* Paper 11 ("Dec."), 21. Thereafter, in timely sequence, Patent Owner filed a Response (Paper 15, "Resp."), Petitioner filed a Reply (Paper 18), and Patent Owner filed a Sur-Reply (Paper 21). The Board held a final oral hearing on July 31, 2019. Paper 31 ("Tr."). For reasons that follow, we find unpatentable claims 1–30 of the '245 patent.

## *A. Related Proceedings*

The Petition identifies three related post grant reviews that do not involve the '245 patent. Pet. 5 (citing PGR2017-00008 ("PGR008"); PGR2017-00022 ("PGR022"); PGR2018-00001 ("PGR001")). During the pendency of this proceeding, the Board entered a final written decision in each case. PGR008, Paper 43 (entered June 22, 2018); PGR022, Paper 50 (entered November 14, 2018); PGR001, Paper 48 (entered April 29, 2019).

After we instituted review, Petitioner identified as related five additional post grant reviews that do not involve the '245 patent. Paper 30, 2 (Petitioner's Second Updated Mandatory Notices) (citing PGR2018-00092 ("PGR092"); PGR2019-00003 ("PGR003"); PGR2019-00026 ("PGR026"); PGR2019-00027 ("PGR027"); PGR2019-00028 ("PGR028")). The Board instituted review in each case. PGR092, Paper 7 (entered February 25, 2019); PGR003, Paper 7 (entered May 7, 2019); PGR026, Paper 6 (entered

July 30, 2019); PGR027, Paper 6 (entered July 30, 2019); PGR028, Paper 6 (entered August 20, 2019).

*B. The '245 Patent (Ex. 1001)*

The '245 patent is titled "Neridronic Acid for Treating Complex Regional Pain Syndrome." Ex. 1001, code (54). The Specification describes "[o]ral dosage forms of osteoclast inhibitors, such as nitrogen-containing bisphosphonates" for treating or mitigating "pain or related conditions such as complex regional pain syndrome" ("CRPS"). *Id*. at Abstract. The Specification identifies both zoledronic acid and neridronic acid as among the bisphosphonate compounds useful for treating CRPS by the method of the claimed invention. *See* Ex. 1001, Figs. 1–13, 2:44–3:24 (figures and descriptions of figures, all pertaining to a method that employs zoledronic acid); *see also id*. at 3:29, 3:33, 6:62–67, 12:4–15, 63:3–5, 64:40–42, 65:14–15 (identifying zoledronic acid and neridronic acid as suitable bisphosphate compounds for use in the claimed method).

The Specification also discloses the administration of bisphosphonates for treating "bone fractures or to enhance the healing of bone fractures" as a function separate from mitigating "pain associated with vertebral crush fractures." Ex. 1001, 7:35–37, 7:65. On that point, Example 3 relates to "[t]he effect of orally administered zoledronic acid" in a "rat tibia fracture model of" CRPS. *Id*. at 43:6–8. Example 3 expressly reports, however, that zoledronic acid mitigates pain associated with CRPS, where the condition is induced in "rats by fracturing the right distal tibias of the animals." *Id*. at 43:8–9. Example 3 discusses pain assessment methods and pain reduction achieved in the rat tibia fracture model when zoledronic acid is selected as the bisphosphonate. *Id*. at 43:25–44:31. In addition, Example 3 explains,

"[t]his animal model has been shown to replicate the inciting trauma" (for example, a bone "fracture") that is "observed in human[s]." *Id*. at 43:11–16.

The '245 patent includes no working example that employs neridronic acid as the bisphosphonate. The general disclosure, however, provides dosing information pertaining to neridronic acid for use in the claimed method. *Id*. at 28:5–11, 28:42–45, 29:59–30:50.

### *C. The Challenged Claims*

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

> 1. A method of treating pain associated with complex regional pain syndrome (CRPS) comprising administering neridronic acid to a human being *with CRPS, wherein bone fracture was a predisposing event for CRPS,* and wherein the neridronic acid is in a salt or an acid form.

Ex. 1001, 84:59–63 (emphasis added).

The other challenged claims (namely, claims 2–30) depend directly or indirectly from claim 1 and specify additional limitations pertaining to the type of CRPS, the form of neridronic acid, the method of administration, the age of the treated human being, baseline pain intensity, and dosing regimens. *See id*. at 84:64–86:29.

### *D. The Prosecution History*

We provide a brief overview of the prosecution history to supply context for Petitioner's challenge. In our reproduction of claim 1 above, we emphasize a claim limitation that requires a human being "with CRPS, wherein bone fracture was a predisposing event for CRPS." *Id*. at 84:61–62. Patent Owner added that limitation by

amendment after the Examiner rejected the claim as obvious over prior art that demonstrated bisphosphonates, prior to the date of the claimed invention, were generally recognized as useful for treating and effectively "relieving symptoms of CRPS." Ex. 1022, 453, 510.

The Examiner found, "employing any known bisphosphonates, including neridronic acid, in the method of treating CRPS would be reasonably expected to be effective." Pet. 10 (citing Ex. 1022, 454). In other words, the absence of a working example, specifically directed to the use of neridronic acid, was of little import during patent prosecution, given that "the dosage forms and the herein claimed routes of administration and the dosing regimen are all well-known according to the teachings of the cited prior art." *Id*.

The Examiner allowed claim 1 to issue, however, only after Patent Owner included claim language that requires "bone fracture" as "a predisposing event for CRPS" (Ex. 1022, 506) and submitted evidence that patients "with fracture as the predisposing factor" exhibited a response to bisphosphonates that "was superior" to the response in patients "with other pre-disposing factors." *Id*. at 548; *see id*. at 516–518 (data submitted during patent prosecution to show that humans suffering from CRPS were nearly three times as likely to respond favorably to bisphosphonate treatment when bone fracture was a predisposing event), 547 (notice of allowance). That evidence

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