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Paper 22
Entered: May 5, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

PGR2019-00003
Patent 9,867,839 B2

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

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73. Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 326(e) (2012); 37 C.F.R. § 42.1(d) (2018).

For the reasons that follow, we determine that Petitioner has established by a preponderance of the evidence that claims 1–14 of U.S. Patent No. 9,867,839 B2 (Ex. 1001, "the '839 patent") are unpatentable. We also determine that Petitioner has failed to establish by a preponderance of the evidence that claims 15–30 of the '839 patent are unpatentable.

A. Procedural Background

Grünenthal GMBH ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting post grant review of claims 1–30 the '839 patent. Antecip Bioventures II LLC ("Patent Owner") did not file a preliminary response. Upon consideration of the information presented in the Petition, we instituted a post grant review of claims 1–30 of the '839 patent on each ground of unpatentability set forth in the Petition. *See infra* Section I.E.

Subsequently, Patent Owner filed a Patent Owner Response (Paper 9; "PO Resp."), Petitioner filed a Reply (Paper 14; "Reply"), and Patent Owner filed a Sur-Reply (Paper 16; "Sur-Reply").

The Petition is supported by the Declaration of Lawrence Poree, M.D., Ph.D. Ex. 1003.

Oral argument was conducted on February 4, 2020. A transcript is entered as Paper 21 ("Tr.").

We address herein the arguments and evidence set forth in the Papers to the extent necessary to resolve the dispute between the parties with regard to each of the challenged claims.

B. The '839 Patent (Ex. 1001)

The '839 patent is titled "Osteoclast Inhibitors for Joint Conditions" (Ex. 1001, code (54)), and issued on January 16, 2018, from application number 15/438,513 ("the '513 application"), filed February 21, 2017. According to the Specification of the '839 patent, bisphosphonate compounds, such as neridronic acid and zoledronic acid, "are potent inhibitors of osteoclast activity, and are used clinically to treat bone-related conditions such as osteoporosis and Paget's disease of bone; and cancer-related conditions including multiple myeloma, and bone metastases from solid tumors." *Id.* at 1:46–50. In addition, according to the Specification, "neridronic acid and zoledronic acid, in an acid or a salt form, can be used to treat or alleviate pain or related conditions, such as joint conditions" (*id.*, Abstract), including osteoarthritis, rheumatoid arthritis, and complex regional pain syndrome (CRPS) (*id.* at 14:21–24).

"Commonly used measures of pain intensity include the visual analog scale (VAS) and the numerical rating scale (NRS)." *Id.* at 8:61–62. "With the VAS approach, patients rate the severity of their pain by marking a point on a 10-cm (or 100 mm) VAS . . . [w]ith the NRS approach, patients rate the severity of their pain by verbally responding to a 10-pt NRS." *Id.* at 8:62–67. With either approach, 0 equals no pain, and 10 equals the worst possible pain. *Id.* at 8:67–9:1. "Knee pain in a person with a VAS score of 5 cm . . .

or higher, or an NRS score of 5 or higher, may be referred to herein as moderate to severe knee pain." *Id.* at 9:6–9.

Finally, the Specification teaches that "the daily oral dose of neridronate[1] is about 10 mg to about 1,000 mg, about 50 mg to about 500 mg, about 100 mg to about 500 mg, or about 150 mg to about 300 mg," and "the parenteral dose . . . is about 5 mg to about 500 mg, about 5 mg to about 200 mg, or about 10 mg to about 150 mg." *Id.* at 30:17–22.

C. Illustrative Claims

Claims 1 and 15, the only independent claims, are illustrative:

> 1. A method of treating pain associated with a joint comprising: administering neridronic acid in an acid form or a salt form to a patient who has suffered for at least 3 months with 1) pain associated with a joint and 2) a pain intensity of 5 or greater measured using the 0–10 numerical rating scale (NRS) or 5 cm or greater using the 10 cm visual analog scale (VAS).
>
> 15. A method of treating pain associated with a joint comprising: orally administering zoledronic acid in an acid form or a salt form to a patient having 1) pain associated with a joint and 2) a pain intensity of 5 or greater measured using the 0–10 NRS or 5 cm or greater using the 10 cm VAS, wherein a total of about 400 mg to about 600 mg of zoledronic acid is administered in 2 or 3 individual doses within a period of about a month.

Ex. 1001, 105:38–44, 106:14–21.

D. Asserted Prior Art

The Petition identifies the following references as prior art in the grounds of unpatentability:

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[1] Dr. Poree explains that "'neridronate' is synonymous with neridronic acid." Ex. 1003 ¶ 150 (citing Ex. 1001, 32:6).

Ex. 1005: M. Varenna et al., *Treatment of complex regional pain syndrome type I with neridronate: a randomized, double-blind, placebo-controlled study*, 52 RHEUMATOLOGY 534–42 (2012) ("Varenna 2012").

Ex. 1006: M. Muratore et al., *Il neridronato nel trattamento dell'algodistrofia simpatico riflessa del'anca: confront in aperto con il clodronato*, 5 PROGRESSI IN RHEUMATOLOGIA, ABSTRACT BOOK VII CONGRESSO NATIONALE COLLEGIO DEI REUMATOLOGI OSPEDALIERI 89 (2004) (certified English translation: Neridronate in the treatment of reflex sympathetic hip algodystrophy: open comparison with clodronate) ("Muratore").

Ex. 1007: D. Gatti et al., *Neridronic acid for the treatment of bone metabolic diseases*, 5 EXPERT OPIN. DRUG METAB. TOXICOL. 1305–11 (2009) ("Gatti 2009").

Ex. 1009: G.S.E. Dowd et al., *Complex regional pain syndrome with special emphasis on the knee*, 89-B JOURNAL OF BONE AND JOINT SURGERY 285–290 (2007) ("Dowd").

Ex. 1010: M. Walsh, WO 2007/092338 A2, published August 16, 2007 ("Walsh").

Ex. 1011: D. Thompson at al., WO 2005/107751 A1, published November 17, 2005 ("Thompson").

Ex. 1012: Fox et al., US 2004/0063670 A1, published April 1, 2004 ("Fox").

Ex. 1013: M. Rossini et al., *Intra-articular clodronate for the treatment of knee osteoarthritis: dose ranging study vs hyaluronic acid*, 48 RHEUMATOLOGY 773–78 (2009) ("Rossini").

Ex. 1014: M. Varenna, *Efficacy Study of Neridronate to treat Painful Osteoarthritis of the Knee With Bone Marrow Lesions* (2013) available at https://clinicaltrials.gov/ct2/show/record/NCT01803360?view=record ("Varenna Protocol").

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