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Paper 31
Entered: December 22, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

PGR2018-00092
Patent 9,820,999 B2

Before GRACE KARAFFA OBERMANN, SHERIDAN K. SNEDDEN, and CHRISTOPHER M. KAISER, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

We issue this revised Final Written Decision after our decision to grant Petitioner's Request for Rehearing (Paper 29) and vacate our original Final Written Decision (Paper 25).

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 1–30 of U.S. Patent No. 9,820,999 B2 (Ex. 1001, "the '999 patent") are unpatentable.

A. Procedural Background

Petitioner filed a Petition requesting *inter partes* review of claims 1–30 ("the challenged claims") of the '999 patent. Paper 2 ("Pet."). Patent Owner did not file a Patent Owner Preliminary Response. Upon consideration of the information presented in the Petition, we instituted an *inter partes* review of claims 1–30 of the '999 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 10; "PO Resp."), Petitioner filed a Reply (Paper 11; "Reply"), and Patent Owner filed a Sur-Reply (Paper 18; "Sur-Reply").

The Petition is supported by the Declaration of Lawrence Poree, M.D., Ph.D. Ex. 1003. In its Reply, Petitioner relies on the Declaration of Dr. Philip Robinson, MBChB, PhD, FRACP (Ex. 1044).

Oral argument was conducted on November 21, 2019. A transcript is entered as Paper 23 ("Tr.").

Petitioner timely filed a Request for Rehearing (Paper 26, "Req. Reh'g.") requesting rehearing of our original Final Written Decision (Paper 25). We granted Petitioner's request for rehearing and vacated our original Final Written Decision. Paper 29.

In this revised, corrected Final Written Decision, we address all arguments and evidence set forth in the Papers to the extent necessary to resolve the dispute between the parties.

B. The '999 Patent (Ex. 1001)

The '999 patent is titled "Neridronic Acid for Treating Complex Regional Pain Syndrome." Ex. 1001, [54]. The specification of the '999 patent describes "[o]steoclast inhibitors, such as neridronic acid, in an acid or salt form" for treating or alleviating "pain or related conditions, such as complex regional pain syndrome" ("CRPS"). *Id*., [57]. Two bisphosphonates specifically discussed in the specification are zoledronic acid and neridronic acid. *See* Ex. 1001, Figs. 1–16, 2:64–4:3 (figures and descriptions of figures, all pertaining to a method that employs zoledronic acid); *see also id*. at 2:50–60, 4:8 (identifying both zoledronic acid and neridronic acid as useful for treating CRPS triggered by bone fracture).

The '999 patent specification discusses a method of administering bisphosphonates—and, in particular, zolendronic acid or neridronic acid—for treating "bone fractures or to enhance the healing of bone fractures" in "a

human being that is treated for CRPS, suffered from a precipitating injury such as a bone fracture." *Id*. at 8:27–37. The specification, moreover, states that "[a]n oral dosage form of bisphosphonate such as zoledronic acid may be used to treat, or provide relief of, any type of pain including, but not limited to," for example, CRPS. *Id*. at 7:43–52. The specification identifies "bisphosphonate" compounds generally, and neridronic acid in particular, as useful for mitigating "pain associated" with, for example, "vertebral crush fractures" in a human being. Ex. 1001, 7:66–8:19, 8:64–67, 15:25–37, 91:5–7 (Embodiment 282), 93:50–94:5–32 (Embodiments 314–318).

Example 3 relates to "[t]he effect of orally administered zoledronic acid" in a "rat tibia fracture model of" CRPS. *Id*. at 51:28–30. Example 3 reports that zoledronic acid mitigates pain associated with CRPS, where that condition is induced in "rats by fracturing the right distal tibias of the animals." *Id*. at 51:30–31. 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 51:47–52:11. In addition, Example 3 explains that "[t]his animal model has been shown to replicate the inciting trauma" (for example, a bone "fracture") that is "observed in human CRPS patients." *Id*. at 51:33–38.

The '999 patent includes no working example using neridronic acid as the bisphosphonate. The general disclosure provides dosing information pertaining to neridronic acid when that compound is selected for use in the claimed method. *See, e.g.*, *id*. at 26:30–43.

C. Illustrative Claim

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 selecting *a human being having CRPS triggered by bone fracture* and administering neridronic acid or a pharmaceutically acceptable salt thereof to the human being, wherein the treatment is effective in reducing pain.

Ex. 1001, 106:25–30 (emphasis added).

The other challenged claims (namely, claims 2–30) depend directly or indirectly from claim 1 and specify additional limitations that pertain 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 106:31–107:26.

D. Asserted Prior Art

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

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

(2) M. Varenna et al., *Predictors of responsiveness to bisphosphonate treatment in patients with complex regional pain syndrome type I: A retrospective chart analysis*, PAIN MED. 18:1131–38 (2017) (Ex. 1015, "Varenna 2016");

(3) Manara et al., *SAT0524 Predictors of a Clinical Response to Bisphosphonates Treatment in Patients with Complex Regional Pain Syndrome Type I*, ANNALS OF THE RHEUMATIC DISEASES, 73 (Suppl. 2) (2014) (Ex. 1037, "Manara");

(4) S. Bruehl, "*How common is complex regional pain syndrome-Type I?*," PAIN 129:1–2 (2007) (Ex. 1006, "Bruehl");

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