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Paper 6
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

Case PGR2019-00026
Patent 9,931,352 B2

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

OBERMANN, *Administrative Patent Judge*.

DECISION
Instituting Post Grant Review of Claims 1–30
35 U.S.C. § 324

I. INTRODUCTION

Petitioner filed a Petition for post grant review of claims 1–30 of U.S. Patent No. 9,931,352 B2 (Ex. 1001, "the '352 patent"). Paper 2 ("Pet."). Patent Owner did not file a preliminary response. Applying the standard set forth in 35 U.S.C. § 324(a), which requires demonstration that it is more likely than not that at least one challenged patent claim is unpatentable, we institute a post grant review of the challenged claims based on the grounds of unpatentability identified in the Petition. Pet. 7–8 (statement of grounds).

The following preliminary findings of fact and conclusions of law are made for the sole purpose of determining whether to institute review. Any final decision will be based on the full trial record, including any response to the Petition timely filed by Patent Owner. Taking account of the information presented in the Petition, we find Petitioner meets the threshold showing necessary to support institution of post grant review of claims 1–30.

A. Related Proceedings

The Petition identifies six post grant review proceedings in which Petitioner challenges patents owned by Patent Owner—but none includes a challenge against any claim of the '352 patent. Pet. 4 (citing PGR2017-00008 ("PGR008"); PGR2017-00022 ("PGR022"); PGR2018-00001 ("PGR001"); PGR2018-00062 ("PGR062"); PGR 2018-00092 ("PGR092"); PGR2019-00003 ("PGR003")).

Final written decisions have issued in the first three proceedings. PGR008, Paper 43; PGR022, Paper 50; PGR001, Paper 48. The Board instituted post grant reviews in the other three proceedings (PGR062, PGR092, and PGR003), which are in various stages of our administrative process. *See* Pet. 4.

Petitioner identifies as related two additional petitions for post grant review "filed concurrently with the instant Petition." *Id.*; *see* PGR2018-00027 ("PGR027"); PGR2019-00028 ("PGR028"). Neither challenges a claim of the '352 patent. PGR027, Paper 2; PGR028, Paper 2. We issue concurrently herewith a decision instituting review in PGR027. A timely decision whether to institute review in PGR028 will issue in due course.

The Petition states that each of the above cases involves a patent that "shares the same inventor as the '352 patent and, like the '352 patent, concerns the use of bisphosphonate drugs to treat pain conditions." Pet. 5. The Petition also states that some of those cases involve patents "in the same or related patent families." *Id.*

In PGR092, we made a preliminary finding that that the disclosure of Provisional Application No. 61/646,538 ("the '538 application") does not support the claims of U.S. Patent No. 9,820,999 ("the '999 patent"). PGR092, Paper 7, 14. The Petition in the instant case raises a similar issue in the context of establishing that the '352 patent is eligible for post grant review. Pet. 20. As it did with respect to the '999 patent, challenged in IPR092, Petitioner avers in this case that the '352 patent is not entitled to the benefit of the May 14, 2012, filing date of the '538 application. *Id.*

Specifically, Petitioner avers that the '538 application, as well as nine other applications filed prior to March 16, 2013 (the effective date of the America Invents Act ("the AIA")), from which the '352 patent claims the benefit of priority, "fail to describe and enable the methods of—at a minimum—challenged claims 10–12, 13, 26–28, and 29." *Id.*; *see id.* at 18 (identifying ten priority applications, including the '538 application, that potentially support a filing date for the '352 patent that precedes the

March 16, 2013 effective date of the AIA). We address that averment in our analysis below of post grant review eligibility.

Petitioner states that it is aware of no "other judicial or administrative matters" that involve the '352 patent or "would affect, or be affected by, a decision in this proceeding." *Id*. at 5.

B. The '352 Patent (Ex. 1001)

The '352 patent is titled "Neridronic Acid for Treating Complex Regional Pain Syndrome." Ex. 1001, (54). The challenged claims require parenteral (such as "intravenous or subcutaneous") administration of neridronic acid to a human being suffering from a symptom ("hyperalgesia" or "edema") associated with complex regional pain syndrome ("CRPS"). Ex. 1001, 27:12–13 (identifying modes of parenteral administration), claim 1 (independent claim specifying "hyperalgesia"); claim 17 (independent claim specifying "edema"). To foreshadow several issues raised in the Petition, we observe that the specification describes the oral (as opposed to parenteral) administration of zoledronic acid (as opposed to neridronic acid) in a study of rats (as opposed to human patients). *See, e.g.*, Ex. 1001, Figs. 1–16, Examples 1–3.

According to the specification, "[i]t has been discovered that oral dosage forms of bisphosphonate compounds, such as zoledronic acid, can be used to treat or alleviate pain or related conditions." Ex. 1001, 1:65–67. The specification also identifies neridronic acid as a bisphosphonate suitable for use in the invention. *Id*. at 3:11–16, 16:63–67. The specification mentions neridronic acid alongside zoledronic acid when describing the bisphosphonate compounds useful in the invention, and further, does so

specifically in the context of the administration of a bisphosphonate to a human being suffering from CRPS. *Id*. at 3:11–22, 8:37–47.

All of the figures and working examples set forth in the specification relate to the oral administration of zoledronic acid. *Id*. at Figs. 1–16, 3:27–4:17 (description of figures), 49:52– 65:26 (Examples 1– 10). None of the working examples mentions neridronic acid. *Id*. Examples 7 and 8 discuss zoledronic acid that is administered intravenously (a form of parenteral, as opposed to oral, delivery). *Id*. at 55:40, 57:16. The specification elsewhere describes blood plasma concentrations associated with the parenteral administration of zoledronic acid. *Id*. at 27:27–42.

The specification contains information pertaining to daily oral dosing of neridronic acid. *Compare id*. at 31:58–63 (disclosing "oral" dosages for "neridronate"), *with id*. at claims 1, 17 (the independent claims, requiring parenteral, as opposed to oral, administration of neridronic acid). The specification, however, also refers to a "molecular complex comprising neridronic acid" that "is administered in an amount that results in" certain disclosed blood plasma concentration curves. Ex. 1001, 26:34, 49–62.

The specification contains other general information pertaining to the dosing of neridronic acid—describing, for example, administration of "[a]ny suitable amount of an osteoclast inhibitor, including a bisphosphonate" from a list that includes "neridronic acid," and identifying broad dosing ranges (from about 0.005 mg to about 2000 mg) as well as the administration of "any amount of osteoclast inhibitor in a range bounded by, or between, any of these values." *Id*. at 33:44–34:35. The specification compares oral dosage forms of bisphosphonates to "parenteral modes of administration, such as intravenous or subcutaneous" modes. *Id*. at 27:9–13.

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