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Paper 48
Entered: April 29, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

Case PGR2018-00001
Patent 9,539,268 B2

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

OBERMANN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Determining that Claims 3–30 are Unpatentable
35 U.S.C. § 328(a)

I. INTRODUCTION

This is a post-grant review of claims 3–30 of U.S. Patent No. 9,539,268 B2 (Ex. 1001, "the '268 patent"). Prior to institution of review, Patent Owner filed a statutory disclaimer of claims 1 and 2. Paper 13; Ex. 2008. We instituted review of claims 3–30 based on the grounds stated in the Petition (Paper 2, "Pet."). *See* Paper 17 ("Dec."), 2, 8–9, 38. Thereafter, in timely sequence, Patent Owner filed a Response (Paper 22, "Resp."), Petitioner filed a Reply (Paper 36), and Patent Owner filed a Surreply (Paper 39). This decision resolves also Petitioner's Motion to Exclude Evidence (Paper 40) and Patent Owner's Motion to Exclude Evidence (Paper 42). We held a final oral hearing on February 7, 2019. Paper 47 ("Tr."). The Board has jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 328(a).

A. Related Proceedings

The parties identify no related administrative or judicial proceedings. Pet. 4; Paper 3, 1. According to Petitioner, "[t]he '268 patent is a continuation of the application that issued as Patent Owner's U.S. Patent No. 9,408,862" ("the '862 patent"), noting that the two patents "have nearly identical specifications." Pet. 4. Petitioner states that it filed a post grant review of the '862 patent on May 8, 2017, PGR2017-00022 ("PGR022"). Pet. 4. The Board entered a final written decision in PGR022 on November 14, 2018, and Patent Owner filed a notice of appeal of that decision. PGR022, Papers 50, 52. Petitioner states also that a patent in a different family involving similar technology is under challenge in PGR2017-00008 ("PGR008"), which involves the same parties as this

proceeding. Pet. 4; *see also* Paper 3, 2. The Board entered a final written decision in PGR008 on June 22, 2018. PGR008, Paper 43.

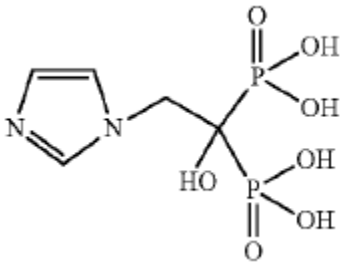
B. The '268 Patent (Ex. 1001)

The '268 patent discloses that pharmaceutical compositions containing "zoledronic acid, Compound 1, and/or Compound 2 (subject compositions), may be used for a number of medical purposes, such as treatment of undesirable conditions or diseases, including disease or conditions related to bone, cancer, and/or pain." Ex. 1001, 1:63–2:1. According to the '268 patent:

> An oral dosage form comprising a subject composition may be used to treat, or provide relief of, any type of pain including, but not limited to, inflammatory pain, arthritis pain, complex regional pain syndrome, lumbosacral pain, musculoskeletal pain, neuropathic pain, chronic pain, cancer-related pain, acute pain, postoperative pain, etc. In some instances, pain relief may be palliative, or pain relief may be provided independent of improvement of the disease or condition or the underlying cause of the disease or condition. For example, although the underlying disease may not improve, or may continue to progress, an individual suffering from the disease may experience pain relief. In some embodiments, enhanced bioavailability of the zoledronic acid may be achieved in treating one of these conditions by administering a dosage form comprising a subject composition wherein zoledronic acid is in the form of a disodium salt. This may allow a reduced molar amount of the disodium salt to be used as compared to what would be used with the diacid form.

Id. at 2:28–46.

The '268 patent discloses that zoledronic acid "is also referred to as zoledronate" and has the structure shown in the following figure:



Id. at 5:66–6:10. The figure above shows the molecular structure of zoledronic acid. *Id.*

The '268 patent discloses:

> The oral bioavailability of zoledronic acid in a subject composition may be enhanced by orally administering the zoledronic acid in the disodium salt form. For example, the bioavailability of zoledronic acid may be improved by at least about 10%, at least about 20%, at least about 30%, at least about 50%, and/or up to about 100%, or up to about 200%, as compared to administration of zoledronic acid in the diacid form.

Id. at 7:65–8:5.

According to the '268 patent:

> Because of the improved bioavailability of the disodium salt a dosage form may contain, or a mammal, such as a human being, may receive, on a molar basis, less of the disodium salt form of zoledronic acid than would otherwise be administered of the diacid form of zoledronic acid. For example, a dosage form may contain, or a mammal may receive, at least about 10 mole % less, at least about 20 mole % less, at least about 40 mole % less, at least about 50 mole % less, and/or up to about 90 mole % less or 95 mole % less, of the disodium salt form as compared to the amount of the diacid form of zoledronic acid that would otherwise be administered, such as a molar amount that would be administered of zoledronic acid in the diacid form in order to achieve the same plasma levels of zoledronic acid.

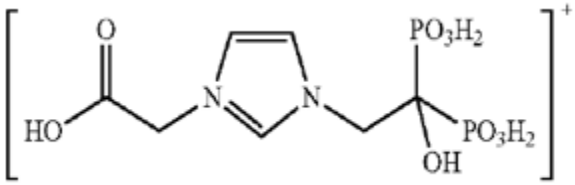
Id. at 8:6–19.

The ’268 patent includes only one working example, which describes syntheses for compounds 1 and 2. *Id.* at 18:12–19:18 (Example 1). The ’268 patent contemplates multiple embodiments. *Id.* at 19:19–27:58.

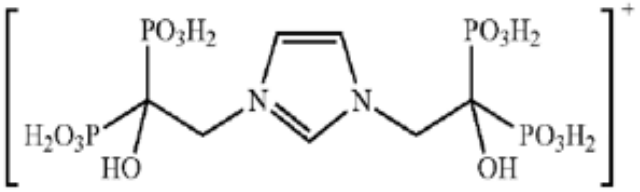
C. The Challenged Claims

Claims 1 and 2 of the ’268 patent are disclaimed and no longer in dispute. Prelim. Resp. 3, Paper 13. Claims 3 and 23 are the remaining challenged independent claims of the ’268 patent and read as follows:

> 3. A method of treating arthritis comprising orally administering a dosage form to a human being suffering from arthritis, wherein the dosage form comprises:
>
> a) zoledronic acid in a salt or an acid form; or
>
> b) one of the following:
>
> 1) zoledronic acid in a salt or an acid form and



> (Ion 1) in a salt form, in an amount that is less than 0.1% w/w and greater than 0% w/w; or
>
> 2) zoledronic acid in a salt or acid form and



> (Ion 2) in a salt form, in an amount that is less than 0.1% w/w and greater than 0% w/w;
>
> or
>
> 3) zoledronic acid in a salt form or an acid form and a combination of Ion 1 in a salt form, in an amount that is less than 0.1 % w/w and greater

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