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Paper 36
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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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LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

POZEN INC.,
Patent Owner.

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Case IPR2015-01773
Patent 8,858,996 B2

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Before TONI R. SCHEINER, LORA M. GREEN, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

# FINAL WRITTEN DECISION

*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

# I. INTRODUCTION

In this *inter partes* review, Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Petitioner") challenge the patentability of claims 1 and 3–11 of U.S. Patent No. 8,858,996 B2 (Ex. 1001, "the '996 patent"), assigned to Pozen Inc. ("Patent Owner"). We have jurisdiction under 35 U.S.C. § 6. For the reasons discussed below, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1 and 3–11 ("the challenged claims") of the '996 patent are unpatentable. This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

## *A. Procedural History*

Petitioner filed a Corrected Petition requesting an *inter partes* review of claims 1–19 of the '996 patent. Paper 4 ("Pet."). Patent Owner filed a Preliminary Response. Paper 14 ("Prelim. Resp."). On March 1, 2016, we instituted an *inter partes* review of claims 1 and 3–11 of the '996 patent on one asserted ground of unpatentability (i.e., Ground 4).[1] Paper 15 ("Dec."). After institution, Patent Owner filed a Patent Owner Response to the Petition (Paper 22, "PO Resp."), and Petitioner filed a Reply (Paper 24, "Reply").

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[1] Following our decision to institute on some, but not all, grounds presented in the Petition, Petitioner filed a Request for Rehearing. Paper 17. We denied the Request. Paper 32. We do not reconsider the arguments set forth in the Request for Rehearing because they are directed to the non-instituted grounds and/or non-instituted claims. Moreover, Petitioner was required to make its obviousness case in the Petition—not the Request for Rehearing. *See Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015) (stating that the patent "challenger [is] obliged to make an adequate case in its Petition and the Reply [is] limited to a true rebuttal role." (citing 37 C.F.R. §§ 42.104(b)(5), 42.23(b))).

An oral hearing was held on November 29, 2016. A transcript of the hearing has been entered into the record. Paper 35 ("Tr.").

*B. Related Matters*

The parties identify the following district court proceedings in which the '996 patent has been asserted: *Horizon Pharma, Inc. v. Actavis Laboratories FL, Ltd.*, No. 3:15-cv-03322-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.*, No. 3:15-cv-03324-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. v. Lupin Ltd.*, No. 3:15-cv-03326-MLC-DEA (D.N.J.); and *Horizon Pharma, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 3:15-cv-03327-MLC-DEA (D.N.J.). Pet. 3–4; Paper 8, 8. The parties also identify a number of judicial and administrative matters involving patents related to the '996 patent or directed to similar subject matter. Pet. 3–4; Paper 8, 8–9; PO Resp. 2.

*C. The '996 Patent*

Non-steroidal anti-inflammatory drugs ("NSAIDs") are "widely accepted as effective agents for controlling pain." Ex. 1001 (col. 1, ll. 35–36). But their administration "can lead to the development of gastroduodenal lesions, e.g., ulcers and erosions, in susceptible individuals." *Id.* (col. 1, ll. 37–38). A "major factor contributing to the development of these lesions is the presence of acid in the stomach and upper small intestine of" those individuals. *Id.* (col. 1, ll. 39–41).

The '996 patent discloses pharmaceutical compositions "that provide for the coordinated release of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID)," such that there is "a reduced likelihood of causing unwanted side effects, especially gastrointestinal side effects, when administered as a treatment for pain." Ex. 1001 (col. 1, ll. 25–31).

Specifically, the '996 patent discloses "a pharmaceutical composition in unit dosage form . . . contain[ing] an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5," *id.* (col. 3, ll. 31–37), and an NSAID "in an amount effective to reduce or eliminate pain or inflammation," *id.* (col. 4, ll. 3–5). "The term 'unit dosage form' . . . refers to a single entity for drug administration. For example, a single tablet or capsule combining both an acid inhibitor and an NSAID would be a unit dosage form." *Id.* (col. 4, ll. 46–49).

The '996 patent teaches that the unit dosage form "preferably provides for coordinated drug release in a way that elevates gastric pH and reduces the deleterious effects of the NSAID on the gastroduodenal mucosa." *Id.* (col. 4, ll. 49–53). Put differently, "the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the GI tract has risen." *Id.* (col. 4, ll. 53–55). The '996 patent continues:

> In a preferred embodiment, the unit dosage form is a multilayer tablet, having an outer layer comprising the acid inhibitor and an inner core which comprises the NSAID. In the most preferred form, coordinated delivery is accomplished by having the inner core surrounded by a polymeric barrier coating that does not dissolve unless the surrounding medium is at a pH of at least 3.5, preferably at least 4 and more preferably, at least 5.

*Id.* (col. 4, ll. 56–63).

"The term 'acid inhibitor' refers to agents that inhibit gastric acid secretion and increase gastric pH." *Id.* (col. 3, ll. 38–40). According to the '996 patent, preferred acid inhibiters are $H_2$-blockers, such as famotidine, but "[o]ther preferred agents that may be effectively used as acid inhibitors are the proton pump inhibitors such as . . . esomeprazole," for example, in a typical amount of 5–100 mg. *Id.* (col. 3, ll. 40–51, col. 8, ll. 17–18).

The ’996 patent also discloses that the NSAID may be a number of different options, such as aspirin, acetaminophen, etc., where the “most preferred NSAID is naproxen in an amount of between 50 mg and 1500 mg, and more preferably, in an amount of between 200 mg and 600 mg.” *Id.* (col. 4, ll. 5–18).

### *D. Illustrative Claim*

Claim 1, the only independent claim of the challenged claims, is illustrative of the claimed subject matter:

> 1. A pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising:
>
> naproxen in an amount of 200–600 mg per unit dosage form; and
>
> esomeprazole in an amount of from 5 to 100 mg per unit dosage form,
>
> wherein upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium, and *release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher*.

*Id.* (col. 21, ll. 24–35) (emphasis added).

### *E. Asserted Ground of Unpatentability*

We instituted an *inter partes* review of claims 1 and 3–11 of the ’996 patent for unpatentability, under 35 U.S.C. § 103(a), for obviousness based

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