Trials@uspto.gov
Tel: 571-272-7822

Paper 18
Entered: March 8, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.,
Patent Owners.

Case IPR2017-01995
Patent 9,220,698 B2

Before TONI R. SCHEINER, MICHELLE N. ANKENBRAND, and DEBRA L. DENNETT, *Administrative Patent Judges.*

DENNETT, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") on August 24, 2017, requesting an *inter partes* review of claims 1–7 of U.S. Patent No. 9,220,698 B2 (Ex. 1001, "the '698 patent"). Pozen Inc. and Horizon Pharma USA, Inc. ("Patent Owners") filed a Preliminary Response. Paper 10 ("Prelim. Resp."). With permission, Petitioner filed a Reply. Paper 16.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Applying that standard, and upon consideration of the information presented in each Petition and Preliminary Response, we institute an *inter partes* review as to claims 1–7 of the '698 patent.

II. BACKGROUND

A. Related Matters

Petitioner identifies the following pending litigation involving the '698 patent: *Horizon Pharma, Inc. v. Mylan Pharms. Inc.*, No. 15-3327 (D.N.J.); *Horizon Pharma, Inc. v. Mylan Pharms. Inc.*, No. 16-4921 (D.N.J.); *Horizon Pharma, Inc. v. Actavis Labs. FL, Inc.*, No. 16-4916 (D.N.J.), *Pozen, Inc. v. Actavis Laboratories FL, Inc.*, Nos. 17-1615, 17-1616 (Fed. Cir.); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Inc.*, No. 16-4918 (D.N.J.); and *Horizon Pharma, Inc. v. Lupin Ltd.*, No. 16-4920 (D.N.J.). Pet. 1–2.

We remind the parties of their continuing obligation to file an updated mandatory notice "within 21 days of a change of the information" required in the notices. 37 C.F.R. § 42.8(a)(3).

B. The '698 Patent (Ex. 1001)

The '698 patent, titled "Method for Delivering a Pharmaceutical Composition to Patient in Need Thereof," issued December 29, 2015. Ex. 1001. The '698 patent relates to methods for treating a patient with a pharmaceutical composition of naproxen and esomeprazole in a unit dose form. *Id.* col. 1, ll. 13–18.

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen are used widely to treat pain and inflammation, but many NSAIDs are associated with gastrointestinal complications. *Id.* col. 1, ll. 19–24. The presence of acid in the stomach and upper small intestine is a major factor in development of gastrointestinal disease in patients taking NSAIDs. *Id.* col. 1, ll. 24–26.

Esomeprazole is a proton pump inhibitor ("PPI"). PPIs inhibit gastric acid secretion, and thus raise the gastrointestinal tract pH. *Id.* col. 1, ll. 30–33. PPIs used in conjunction with NSAIDs reduce the risk of gastrointestinal injury. *Id.* col. 1, ll. 27–30.

The specification explains that formulations providing dosages of PPIs and naproxen may produce desired pharmacodynamic ("PD") response and pharmacokinetic ("PK") values, such as an intragastric pH of about 4 or greater, and a plasma level of naproxen that is efficacious. *Id.* col. 1, ll. 34–37, ll. 46–48. The specification discloses the results of a clinical trial comparing PD responses and PK values resulting from twice daily orally-administered formulations of enteric coated naproxen 500 mg combined with non-enteric coated esomeprazole in dosages of 10, 20, and 30 mg, with twice daily orally-administered 500 mg non-enteric coated naproxen and once daily orally-administered enteric coated esomeprazole. *Id.* col. 24, l. 42–col. 45, l. 67.

The claims recite targeting naproxen and esomeprazole PK profile ranges for C_{max}, T_{max}, and AUC.[1]

The formulation may be used to treat osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, or a combination thereof. *Id.* col. 2, ll. 27–31.

C. Illustrative Claim

Petitioner challenges claims 1–7 of the '698 patent. Claim 1, the sole independent claim, is illustrative of the claimed subject matter and recites:

> 1. A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours (±20%) later, a PM unit dose form, wherein:
>
> the AM and PM unit dose forms each comprises:
>
> naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and
>
> esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole;
>
> said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater,
>
> the AM and PM unit dose forms target:
>
> i) a pharmacokinetic (pk) profile for naproxen where:
>
> a) for the AM dose of naproxen, the mean C_{max} is 86.2 μg/mL (±20%) and the median T_{max} is 3.0 hours (±20%); and

[1] C_{max} refers to the maximum plasma concentration of the drug administered, T_{max} (or t_{max}) refers to the time to the maximum plasma concentration of the drug administered, and AUC refers to the area under the plasma-concentration time curve from time zero to a specified time after drug administration. Ex. 1001, Table 1.

b) for the PM dose of naproxen, the mean C_{max} is 76.8 μg/mL (±20%) and the median T_{max} is 10 hours (±20%); and

ii) a pharmacokinetic (pk) profile for esomeprazole where:

a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10 hours (±20%) after the AM dose is administered ($AUC_{0\text{-}10,am}$) is 1216 hr*ng/mL (±20%),

b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours (±20%) after the PM dose is administered ($AUC_{0\text{-}14,pm}$) is 919 hr*ng/mL (±20%), and

c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours (±20%) after the AM dose is administered ($AUC_{0\text{-}24}$) is 2000 hr*ng/mL (±20%); and

the AM and PM unit dose forms further target a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

Ex. 1001, 52:26–67.[2]

D. The Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims of the ’698 patent are unpatentable based on the following grounds:

[2] Claim 1 includes the corrections set forth in the Certificate of Correction issued on July 12, 2016.

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