Trials@uspto.gov
571-272-7822

Paper 17
Date: September 16, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LTD.
Petitioner,

v.

JANSSEN PHARMACEUTICA NV,
Patent Owner.

IPR2020-00440
Patent 9,439,906 B2

Before JOHN G. NEW, KRISTINA M. KALAN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Petitioner Mylan Laboratories Ltd. ("Petitioner") has filed a Petition (Paper 3, "Petition" or "Pet.") requesting *inter partes* review of claims 1–21 of US Patent 9,439,906 B2 (Ex. 1001, "the '906 patent"). Patent Owner Janssen Pharmaceutica NV ("Patent Owner") has filed a Preliminary Response (Paper 8, "Preliminary Response" or "Prelim. Resp."). On July 2, 2020, the panel issued an order authorizing Petitioner to file a Reply to the Preliminary Response and further authorizing Patent Owner to file a Sure-Reply (Papers 12 and 14, "Reply" and "Sur-Reply," respectively.

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition." Upon consideration of the Petition, and of the supporting evidence, we exercise our discretion under § 314(a) to deny institution.

II. BACKGROUND

A. Real Parties-in-Interest

The real parties-in-interest for Petitioner are Mylan Laboratories Ltd., Mylan Institutional LLC, Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. Pet. 4. Patent Owner's Mandatory Notices identify Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc., which are wholly-owned subsidiaries of Johnson & Johnson ("J&J"), as the real parties-in-interest for Patent Owner. Paper 6, 1.

B. Related Matters

Petitioner identifies the following district court actions involving the '906 patent: (1) *Janssen Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, 2-18-cv-00734 (D.N.J.); (2) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 2-19-cv-16484 (D.N.J.); (3) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 1-19-cv-00153 (N.D. W. Va.); (4) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 1-19-cv-01488 (D. Del.); (5) *Janssen Pharmaceuticals, Inc. et al. v. Pharmascience Inc. et al.*, Case No. 2-19-cv-21590 (D.N.J.); (6) *Janssen Pharmaceuticals, Inc. et al. v. Pharmascience Inc*. et al., 1-19- cv-02313 (D. Del.). Pet. 5. The Patent Owner similarly identifies these actions as involving the '906 patent. Paper 6, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that the '906 patent is unpatentable based on the following grounds:

Claim Challenged	35 U.S.C. §	Reference(s)/Basis
1–7, 15, 17–21	103[1]	Citrome[2], Cleton[3], '544 patent[4]
8–14, 16	103	Citrone, Cleton, Palperidone Formulary[5], '544 patent
1–7, 15, 17–21	103	Citrome, '544 patent
8–14, 16	103	Citrone, Palperidone Formulary, '544 patent

[1] Because the patent at issue has an effective filing date before March 16, 2013, the effective date of the applicable provisions of the Leahy Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA"), we apply the pre-AIA version of 35 U.S.C. §103(a) in this decision.

[2] L. Citrome, *Paliperidone: Quo Vadis*? 61(4) INT. J. CLIN. PRACT. 653–62 (2007) ("Citrome") (Ex. 1004).

[3] The Cleton reference is collectively constituted of: (1) A. Cleton et al., *Assessment of the Dose Proportionality of Palperidone Palmitate 25, 50, 100 And 150 mg eq., A New Long-Acting Injectable Antipsychotic Following Administration in the Deltoid or Gluteal Muscles* (Abstract PI-74); and (2) A. Cleton et al., *Evaluation of the Pharmacokinetic Profile of Gluteal Versus Deltoid Intramuscular Injections of Palperidone Palmitate 100 Mg Equivalent in Patients with Schizophrenia* (Abstract PI-75), in 83(Supp. 1) CLIN. PHARMACOL. & THERAPS. S31 (2008) ("Cleton") (Ex. 1003). The Patent Owner routinely refers to these references as "PI-74" and "PI-75."

[4] US 6,555,544 B2, April 29, 2003 (the "'544 patent") (Ex. 1005).

[5] D.J. Cada et al., *Formulary Drug Review: Palperidone*, 42(7) HOSP. PHARM. 637–47 (2007).

Petitioner also relies upon the Declaration of its expert, Dr. Mansoor M. Amiji (the "Amiji Declaration") (Ex. 1002).

D. The '906 Patent

The '906 patent is directed to a method of treating patients in need of treatment with long acting injectable paliperidone palmitate formulations.

E. Illustrative Claims

Independent claim 1 is representative of the claims of the '906 patent and recites:

> 1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
>
> (1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
>
> (2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and
>
> (3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (± 7 days) after the second loading dose.

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