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Paper 86
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and AMNEAL PHARMACEUTICALS LLC,
Petitioners,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.,
Patent Owner.

Case IPR2015-00644
Patent 8,399,413 B2[1]

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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[1] Case IPR2015-01980 has been joined with Case IPR2015-00644.

INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a corrected Petition requesting an *inter partes* review of claims 1–20 of U.S. Patent No. 8,399,413 B2 (Ex. 1001, "the '413 patent"). Paper 8 ("Pet."). Yeda Research & Development Co. Ltd. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 12 ("Prelim. Resp."). On August 25, 2015, we instituted an *inter partes* review of claims 1–20 on two grounds of obviousness. Paper 14 ("Dec. Inst."), 16. Patent Owner filed a Response to the Petition. Paper 27 ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response. Paper 59 ("Pet. Reply").

On September 25, 2015, Amneal Pharmaceuticals LLC ("Amneal") also filed a Petition requesting an *inter partes* review of claims 1–20 of the '413 patent in case IPR2015-01980 ("the -1980 case"). IPR2015-01980, Paper 1. Amneal filed a motion to join the -1980 case with this case. *Id.*, Paper 3. On December 28, 2015, we granted Amneal's Petition and its motion for joinder. *Id.*, Paper 9. Accordingly, we terminated the -1980 case and joined the -1980 case with this case.

Both parties filed motions to exclude certain exhibits and testimony. Paper 68 (Patent Owner); Paper 70 (Petitioner). Both parties filed oppositions. Paper 76 (Petitioner Opposition); Paper 73 (Patent Owner Opposition). And both parties filed replies in support of their motions to exclude. Paper 80 (Patent Owner Reply); Paper 81 (Petitioner Reply).

Patent Owner filed observations on the cross-examination of Petitioners' declarants, Ari Green, M.D. and Joel W. Hay, Ph.D. Paper 72. Petitioner filed a response to Patent Owner's observations. Paper 78.

An oral hearing for this proceeding was held on May 11, 2016, a transcript of which has been entered in the record. Paper 85 ("Tr.")

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–20 of the '413 patent are unpatentable.

A. Related Proceedings

Petitioner states that it is a defendant in several litigations involving the '413 patent. Pet. 2. Petitioner also identifies numerous other cases against other defendants involving the '413 patent. *Id.*

We also instituted *inter partes* review of related patents in IPR2015-00643 (US 8,232,250 B2) and IPR2015-00830 (US 8,969,302 B2).

B. The '413 Patent (Ex. 1001)

Multiple sclerosis ("MS") is a chronic, autoimmune disease of the central nervous system. Ex. 1001, 1:16–18. There are five main forms of MS, including Relapsing-Remitting Multiple Sclerosis ("RRMS"). *Id.* at 1:29. Patients suffering from RRMS experience sporadic exacerbations or relapses, as well as periods of remission. *Id.* at 1:30–31.

Glatiramer acetate ("GA" or "copolymer-1") is a mixture of polypeptides that do not all have the same amino acid sequence, and is marketed as Copaxone®. *Id.* at 1:63–65. Administering 20 mg per day of Copaxone is an FDA-approved therapy for patients with RRMS. *Id.* at 2:13–16. The '413 patent discloses "an effective low frequency dosage regimen of GA administration to patients suffering from a relapsing form of [MS], including patients who have experienced a first clinical episode and have MRI features consistent with [MS]." *Id.* at 2:43–47. The disclosed method comprises administering to a patient suffering from RRMS three subcutaneous injections of a therapeutically effective dose of GA over a period of seven days with at least one day between every subcutaneous injection to alleviate a symptom of the patient. *Id.* at 2:51–60.

C. Illustrative Claim

Petitioner challenges claims 1–20 of the '413 patent. Claim 1 is illustrative and is reproduced below:

> 1. A method of reducing the frequency of relapses in a human patient suffering from relapsing-remitting multiple sclerosis or a patient who has experienced a first clinical episode and has MRI features consistent with multiple sclerosis comprising administering to the human patient a therapeutically effective dosage regimen of *three subcutaneous injections of 1 ml of a pharmaceutical composition comprising 40 mg of glatiramer acetate over a period of seven days with at least one day between every subcutaneous injection*, the regimen being sufficient to reduce the frequency of relapses in the patient.

Ex. 1001, 16:26–36 (emphasis on limitation at issue added).

Claims 19 and 20 are the remaining independent claims, and both claims recite the same dosing limitation of "three subcutaneous injections of 1 ml of a pharmaceutical composition comprising 40 mg of glatiramer acetate over a period of seven days with at least one day between every subcutaneous injection." *Id.* at 18:4–7 (claim 19), 18:19–22 (claim 20).

D. Grounds of Unpatentability Instituted for Trial

We instituted trial based on the following grounds of unpatentability:

Claim(s)	Basis	References
1–20	§ 103	Pinchasi[2] and the 1996 SBOA[3]
1–20	§ 103	Pinchasi and Flechter[4]

II. ANALYSIS

A. The Level of Ordinary Skill in the Art

The parties dispute the proper definition of a person of ordinary skill in the art. Petitioner contends that a person of ordinary skill in the art would have had (1) several years of experience in the pharmaceutical industry or in practicing medicine; (2) experience with

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[2] Irit Pinchasi, WO 2007/081975 A2, published July 19, 2007 (Ex. 1005).
[3] Summary Basis of Approval ("SBOA") for the New Drug Application for 20 mg daily Copaxone ® (NDA #20-622) (Ex. 1007).
[4] S. Flechter et al., *Copolymer 1 (Glatiramer Acetate) in Relapsing Forms of Multiple Sclerosis: Open Multicenter Study of Alternate-Day Administration*, 25 CLINICAL NEUROPHARM. 11–15 (2002) (Ex. 1008).

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