Filed: March 9, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner.

Case IPR2015-00644

Patent No. 8,399,413

MYLAN'S REPLY TO YEDA'S PATENT OWNER RESPONSE

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ABBREVIATION	DESCRIPTION
CNS	Central nervous system
FDA	U.S. Food and Drug Administration
Fletcher 2002A	Shlomo Flechter et al., *Copolymer 1 (Glatiramer Acetate) in Relapsing Forms of Multiple Sclerosis: Open Multicenter Study of Alternate-Day Administration*. 25:1 CLINICAL NEUROPHARAMCOLOGY, 11-15 (2002) (Ex. 1008)
GA	Glatiramer acetate
IPIRs	Immediate post injection reactions
ISRs	Injection site reactions
MS	Multiple Sclerosis
Pinchasi	Irit Pinchasi: International Publication No. WO 2007/081975 (published July 19, 2007) (Ex. 1005)
POSA	Person of ordinary skill in the art
RRMS	Relapsing remitting multiple sclerosis
SBOA	Ex. 1007, Summary Basis of Approval for the New Drug Application for 20 mg daily Copaxone® (NDA #20-622).
Teva	Teva Pharmaceuticals Industries Ltd. is the exclusive licensee of the '250, '302, and '413 patents. Teva Pharmaceuticals USA, Inc. is the holder of the New Drug Application for Copaxone®, a drug for which the '250, '302, and '413 patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book." Teva Neuroscience, Inc. markets and sells Copaxone® in the United States.
TIW	Three injections per week
Yeda	Yeda Research & Development Co. Ltd.

All claims of the ’413 patent are obvious based on Pinchasi in view of either (1) Flechter 2002A, or (2) the SBOA. Pinchasi disclosed administration of 40 mg of GA every other day, a regimen nearly identical to the claimed 40 mg TIW regimen. As Pinchasi is practically anticipatory, its combination with either Flechter 2002A or the SBOA easily shows obviousness. Patent Owner stakes its case on the untenable position that, despite its own disclosure of 40 mg every other day dosing in Pinchasi, the prior art teaches away from less frequent than daily dosing.

Patent Owner’s position contradicts basic knowledge in the art and overwhelming clinical data. POSAs have long known that patients dislike Copaxone’s daily injections, which cause ISRs, needle fatigue, and noncompliance. At least since an FDA reviewer in 1996 suggested less frequent GA administration as a possible solution (Ex. 1007), artisans have investigated lower frequency dosing, achieving promising results. Only Patent Owner’s blocking patents on GA (and its manufacturing process) impeded earlier commercialization of the claimed regimen. As shown in the table below, by 2009, clinicians had amassed data that showed (1) every other day GA administration is as effective as daily administration (Ex. 1008, 1010, 1011), (2) 40 mg is a safe, efficacious, and well-tolerated dose (Ex. 1005, Ex. 1006), and (3) GA is efficacious in total weekly doses between 70 mg and 280 mg.

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