

Filed: October 24, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
SAWAI USA, INC., AND
SAWAI PHARMACEUTICAL CO., LTD.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

IPR2018-01403*
Patent No. 8,399,514

PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

* Case IPR2019-00789 has been joined with this proceeding.

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TABLE OF ABBREVIATIONS

ABBREVIATION	DESCRIPTION
'514 patent	U.S. Patent No. 8,399,514
Biogen or Patent Owner	Biogen MA Inc.
<i>Bolded Italics</i>	Emphasis added unless otherwise noted
Clinical Trials	Ex. 1010
DMF	Dimethyl fumarate
EMA 2013	Ex. 1037
Fox 2011	Ex. 1036
MS	Multiple sclerosis
Mylan or Petitioner	Mylan Pharmaceuticals Inc.
Phillips 2013	Ex. 1066
POSA	Person of Ordinary Skill in the Art

I. STATEMENT OF RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.64(c), the amended Scheduling Order (Paper 31), and Patent Owner’s timely filed objections (Papers 14, 72), Patent Owner Biogen hereby moves to exclude Exhibits 1010, 1012, 1036, 1037, 1054, 1055, 1066, and 1122 filed by Petitioner Mylan as inadmissible under the Federal Rules of Evidence (“FRE”).

II. ARGUMENT

A. Post-Priority Date Publications (Exs. 1036, 1037, and 1066)

Mylan relies on Fox 2011 (Ex. 1036), EMA 2013 (Ex. 1037), and Phillips 2013 (Ex. 1066) in support of its obviousness allegations. These exhibits were published *after* Biogen’s Phase III results with the claimed 480 mg/day dose were known and long *after* the February 2007 priority date of the ’514 patent. Paper 38, 28-31; Ex. 1036, 2; Ex. 1037, 1; Ex. 1066, 1. They are necessarily tainted by the knowledge that the 480 mg/day dose was effective in Phase III trials—information not known to a POSA as of Biogen’s February 2007 priority date. The law, however, requires assessment of information available in the prior art “at the time the invention was made.” 35 U.S.C. § 103. Exhibits 1036, 1037 and 1066 should therefore be excluded as irrelevant and unfairly prejudicial under FRE 401-403. *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00805, Paper 83 at 34-35 (PTAB Oct. 3, 2018) (rejecting petitioner’s reliance on post-priority date references).

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