

Filed: November 6, 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

**REPLY IN SUPPORT OF
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. Mylan Fails to Support Admissibility of the Post-Priority Date Publications

Mylan contends that it appropriately relies on Fox 2011, EMA 2013, and Phillips 2013 “to show how skilled artisans would interpret the prior art and to refute Biogen’s claim of unexpected results,” relying on *Yeda Research v. Mylan Pharmaceuticals Inc.*, 906 F.3d 1031 (Fed. Cir. 2018). Opp. 2. However, *Yeda* does not support relevance under FRE 401-403 for documents:

- created years after the priority date;
- written with reliance on non-public data;
- providing no information on the activities of POSAs before the priority date; and
- written with hindsight knowledge of the claimed invention.

Yeda addressed an article documenting what had actually been done before the priority date and published just 3 weeks thereafter. *Yeda*, 906 F.3d at 1037, 1040-42. Here, by contrast, the challenged exhibits were published **4-6 years** after the February 2007 priority date. It is also undisputed that the authors had access to and relied on **unpublished data** from the Phase II trial as well as knowledge that 480 mg/day DMF had an unexpectedly high magnitude of clinical efficacy similar to 720 mg/day in Biogen’s Phase III trials. Mot. 2-3.

Yeda also does not support Mylan’s use of these hindsight references to **contradict** what was known at the time of invention (i.e., ineffectiveness of 360

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