

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. AND
SAWAI PHARMACEUTICAL CO., LTD.
Petitioners,

v.

BIOGEN MA, INC.
Patent Owner.

Patent No. 8,399,514

Inter Partes Review IPR2019-00789

**PETITIONERS' RESPONSE TO PATENT OWNER'S OPPOSITION TO
PETITIONERS' MOTION FOR JOINDER**

Sawai USA, Inc. (“Sawai USA”) and Sawai Pharmaceutical Co., Ltd. (“Sawai Japan”) (collectively, “Sawai” or “Petitioners”) timely filed a Motion for Joinder. In response, Biogen MA Inc. (“Patent Owner”) filed an Opposition to Petitioners’ Motion for Joinder (Paper 9) (“Opp.”). Contrary to Patent Owner’s allegations, Petitioners’ joinder to IPR2018-01403 (herein the “Mylan IPR”) will not delay that proceeding because Petitioners’ declarants will not introduce new issues and there is no real party-in-interest (“RPI”) issue that must be resolved. Therefore, Sawai’s Motion for Joinder should be granted.

I. Sawai’s Declarants Will Not Introduce New Issues Into the Mylan IPR

As an initial matter, Patent Owner does not identify a single “new” substantive issue that will be introduced by Petitioners’ declarants. There is none. That is why Sawai repeatedly requested Mylan’s permission to rely on Mylan’s declarants if Sawai’s Motion for Joinder were granted. Ex. 1061. After Mylan refused to provide an answer, Sawai sought guidance from the Board, and the parties received an email stating, in part, “[t]he panel understands that, if joined to the Mylan IPR (IPR2018-01403), Sawai does not intend to produce its own testifying witnesses or file substantive papers in the Mylan IPR so long as Mylan remains a party to the case.” Ex. 1062 at 1. The panel’s understanding is correct, and Sawai has notified Patent Owner and Mylan of the same. Ex. 1063 at 1; Ex. 1064. Moreover, as the panel suggested, Sawai has no objection to the panel revisiting the declarant situation

should it become an issue when deciding Sawai's Motion for Joinder. *Id.* Accordingly, if joined, Sawai's Declarants will not introduce any new issues into the Mylan IPR.

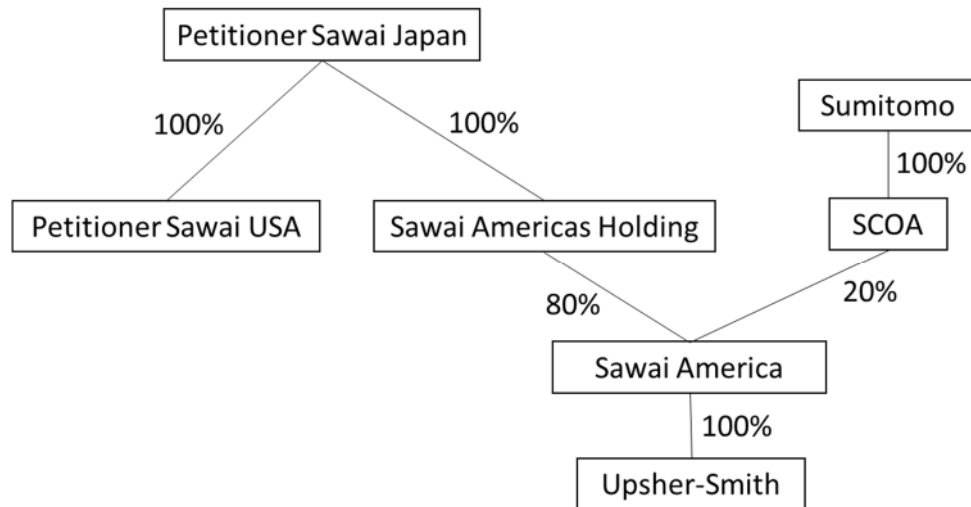
II. Sumitomo Is Not an RPI

Patent Owner attempts to manufacture an "RPI issue" where none exists.

A. Patent Owner Does Not Establish Sumitomo Has Control Over *Petitioners* Sawai Japan or Sawai USA.

Patent Owner cites two press releases for the proposition that Sumitomo "has control over" Upsher-Smith Laboratories, LLC ("Upsher-Smith"). Opp. at 7-9. But, Upsher-Smith is not a petitioner. *See, e.g., Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018) ("Determining whether a non-party is a 'real party in interest' demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward determining whether the non-party is a clear beneficiary that has a preexisting, established relationship *with the petitioner.*") (emphasis added). Even if it is assumed that Sumitomo has control over Upsher-Smith (it does not), there is no evidence that Upsher-Smith controls either *Petitioner*.

While not necessary to determine the instant motion, Petitioners attach herewith the Declaration of Tatsufumi Hiramatsu (Ex. 1060), which demonstrates the following corporate relationship:



As set forth in the Declaration, Upsher-Smith is wholly owned by Sawai America, LLC (“Sawai America”). *Id.* at ¶ 21. Sawai America is owned by a majority owner (80%), Sawai America Holdings, Inc. (“Sawai America Holdings”), and a minority owner (20%), Sumitomo Corporation of Americas (“SCOA”). *Id.* Sumitomo owns 100% of SCOA. *Id.* at ¶ 8. Accordingly, neither Petitioner Sawai Japan nor Petitioner Sawai USA are owned or controlled by Sumitomo, SCOA or Upsher-Smith. Ex. 1060 at ¶¶ 20-21, 23-25.

At most, Patent Owner’s “evidence” shows, consistent with the attached Declaration, part of the corporate tree reproduced above – Sumitomo’s indirect minority ownership in Upsher-Smith. *Accord* Ex. 2001 (stating Sumitomo owns 20% of Upsher-Smith through its subsidiary). Yet, Patent Owner – a named plaintiff in the underlying litigation filed against Sawai – never named Sumitomo or Upsher-Smith as a party in that case, or sought any discovery specifically from those entities. Indeed, Patent Owner offers no precedent where a third party in Sumitomo’s relative

position to Petitioners Sawai Japan and Sawai USA was found to be a RPI. This suggests that Patent Owner is merely speculating about Sumitomo's alleged control in an effort to manufacture an "RPI issue" that does not exist. *See Daifuku Co. Ltd et al. v. Murata Machinery, Ltd.*, IPR2015-01538 Paper 11 at 11 (PTAB Jan. 19, 2016) ("Theoretical, hypothetical, or speculative assertions about effective control, unsupported by evidence, are neither probative nor persuasive.").

B. Sumitomo Does Not Exercise Any Control Over Sawai's Petition.

Patent Owner makes no assertions and cites to no evidence that suggests Sumitomo exercises any control over Sawai's petition. That is because no such control exists. Rather, Petitioners are in control of themselves and all aspects of their petition.

Sawai USA, through its agent Stason Pharmaceuticals, Inc. ("Stason"), submitted Abbreviated New Drug Application No. 210285 ("Sawai's ANDA") seeking to market in the United States dimethyl fumarate delayed release capsules. Ex. 1060 at ¶ 11. Sawai USA was (and continues to be) the sole named applicant for, and owner of all right and title to, Sawai's ANDA. *Id.* Patent Owner received Sawai's Paragraph IV Notice Letter and later sued Petitioners in Delaware alleging infringement, *inter alia*, of U.S. Patent No. 8,399,514 (the "'514 patent") (the "Delaware Litigation"). *Id.* at ¶¶ 12-13. On March 5, 2019, Petitioners sought *inter partes* review the '514 patent and joinder to the Mylan IPR (the "IPR Proceeding").

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