BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. and SAWAI PHARMACEUTICAL CO., LTD.

Petitioners,

v.

BIOGEN MA INC.,

Patent Owner.

Case IPR2019-00789

Patent 8,399,514

PATENT OWNER'S SUR-REPLY IN OPPOSITION TO PETITIONER'S MOTION FOR JOINDER

Contents

Biogen's Opposition to Sawai's Motion for Joinder presented three reasons to deny joinder: (1) Sawai's declarants introduce new issues, (2) the Sawai RPI issue will require additional briefing and discovery, and (3) joining Sawai would frustrate the Mylan IPR and not provide an efficient alternative to the litigation. Sawai's response on the RPI issues included a new declaration of Tatsufumi Hiramatsu (Ex. 1060) that raises more RPI questions than it answers. Moreover, it establishes that joinder is unwarranted because availability of this declarant for cross-examination is ***required*** as routine discovery under 37 CFR § 42.51(b)(1) and merely the "***potential*** for additional discovery [to address Petitioner's failure to identify all RPIs] presents a new substantive issue… [that] weighs in favor of denying Petitioner's Motion for Joinder." *Unified Patents Inc. v. Personalized Media Commc'ns, LLC*, IPR2015-00521, Paper 14 at 5 (PTAB Jun. 8, 2015) (emphasis added). Moreover, Sawai reinforces Biogen's first basis for opposition to joinder: Sawai's introduces new declarations to be cross-examined without "offer[ing] a practical way to accommodate the additional discovery without inconveniencing all involved or delaying the due dates in the [earlier] IPR." *Mylan Pharma., v. Janssen Oncology, Inc.*, IPR2016-01332, Paper 21 at 11 (PTAB Jan. 10, 2017); *see*, *e.g.*, Opp. at 1-3. Joinder should be denied.

I. Sawai Established Even More Reason to Deny Joinder

There is even more reason to deny joinder here than in *Unified Patents*,

where the Board found that it was "not unreasonable for Patent Owner to seek authorization for additional discovery" relating to the appropriate RPIs and held that "***[t]his potential*** for additional discovery… weighs in favor of denying Petitioner's Motion for Joinder." IPR2015-00521, Paper 14 at 4-5 (emphasis added). Here, there is not just the "potential" for additional RPI discovery: The Board's self-executing, routine discovery rules specifically authorize the cross-examination of declarants like Sawai's Mr. Hiramatsu. *See* § II, below.

While the ultimate resolution of the RPI issue is outside the scope of this motion, and Patent Owner anticipates addressing it further in the POPR, Sawai's new declaration confirms an RPI issue. It admits a pre-existing relationship between Petitioner Sawai Japan and Sumitomo as co-owners (via wholly owned intermediates) of an intended beneficiary of the IPR and fails to dispute the evidence of Sumitomo's role in running Upsher-Smith. Resp. at 3, 5 n.1; Ex. 1060 at ¶ 10; Opp. at 9-11; Exs. 2001, 2002.

II. Sawai's New Declarant Must Be Produced for Cross-Examination

The Opposition explained that a new Sawai declarant is reason enough to deny joinder, as cross-examination would necessarily complicate and delay the Mylan IPR. Opp. at 4 (citing *Unified Patents*, IPR2015-00521, Paper 14 at 4-5). Sawai responded that it "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." Resp. at 1. While the parties dispute Sawai's contention that it can pull its expert declarants off the field (*see id.*), Sawai does not dispute that Biogen is entitled to the cross-examination of Sawai's Mr. Hiramatsu based on his declaration. 37 CFR § 42.51(b)(1); *see also BlackBerry Corp. v. Wi-Lan USA Inc.*, IPR2013-00126, Paper 15 at 2 (PTAB Aug. 19, 2013) (noting that "routine discovery under 37 C.F.R. § 42.51(b)(1) is self-executing and self-enforcing").

Notwithstanding its introduction of another new declarant, Sawai ignores its obligation to provide practical means to accommodate the discovery, at least cross-examination, without inconveniencing all involved and delaying the Mylan IPR. *Mylan*, IPR2016-01332, Paper 21 at 11; *see, e.g.*, Opp. at 1-3, 8. Indeed, there is no reasonable way to accommodate the cross-examination of Mr. Hiramatsu and briefing on Sawai's RPI issue given that an institution decision in the Sawai IPR is not due until late in the Mylan IPR schedule and only shortly before Sawai's district court trial.

III. Conclusion

For the reasons above and in the Opposition, Joinder should be denied.

Respectfully submitted,

Dated: May 21, 2019

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