

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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

Petitioners,

v.

BIOGEN MA INC.,

Patent Owner.

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Case IPR2019-00789

Patent 8,399,514

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**PATENT OWNER'S PRELIMINARY RESPONSE**

## Contents

I.	Introduction.....	1
II.	The RPI Requirement and Petitioner’s Inadequate Identification of All RPIs.....	3
	A. The Petition Must Identify as RPIs Beneficiaries Having A Preexisting, Established Relationship with Petitioner .....	3
	B. The Petition’s Incomplete Identification of RPIs .....	5
	C. Petitioner’s Generic Product and District Court Litigation .....	5
	D. The Sawai - Sumitomo Strategic Alliance .....	7
III.	Sawai Has Not Named All Real Parties in Interest .....	12
	A. Petitioner Sawai Japan Is Sumitomo’s “Attorney-In-Fact or Its Express Or Implied Litigating Agent” For IP Strategy.....	12
	B. Sumitomo Is A Clear Beneficiary Through Its Ownership Stake in Sawai America and Upsher-Smith.....	13
	C. The Hiramatsu Declaration Is Not Competent to Exclude Sumitomo as an RPI.....	15
IV.	The Board Should Deny Institution Under Its Discretion.....	17
V.	Conclusion .....	24

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>Cases</b>	
<i>Amazon.com, Inc. v. Appistry, Inc.</i> , IPR2015-00480, Paper 18 (PTAB July 13, 2015) .....	4
<i>Applications in Internet Time, LLC v. RPX Corp.</i> , 897 F.3d 1336 (Fed. Cir. 2018) .....	<i>passim</i>
<i>Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.</i> , IPR2013-00453, Paper 88 (PTAB Jan. 6, 2015) .....	4
<i>Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha</i> , IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017).....	18, 21-23
<i>NHK Spring Co. v. Intri-Plex Techs., Inc.</i> , IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018).....	23
<i>Phigenix, Inc. v. Immunogen, Inc.</i> , 845 F.3d 1168 (Fed. Cir. 2017) .....	16
<i>Power Integrations, Inc. v. Semiconductor Components Indus., LLC</i> , No. 2018-1607, Slip Op. (Fed. Cir. June 13, 2019).....	7
<i>Toshiba Memory Corp. v. Anza Tech., Inc.</i> , IPR2018-01597, Paper 12 (PTAB Mar. 12, 2018) .....	4
<i>Unified Patents, Inc. v. Personalized Media Commc 'ns, LLC</i> , IPR2015-00521, Paper 13 (PTAB June 8, 2015) .....	17, 19, 20, 23
<i>Valve Corp. v. Elec. Scripting Prods., Inc.</i> , IPR2019-00062, Paper 11 (PTAB Apr. 2, 2019) .....	18-21, 23
<i>ZTE (USA) Inc. v. Fundamental Innovation Sys. Int'l LLC</i> , IPR2018-01076, Paper 14 (PTAB Dec. 3, 2018) .....	21
<b>Federal Statutes</b>	
35 U.S.C. § 312(a)(2).....	2, 3
35 U.S.C. § 314(a) .....	<i>passim</i>

35 U.S.C. § 315(b) .....1, 6, 7, 21

35 U.S.C. § 315(c) .....17

35 U.S.C. § 325(d) .....3, 17, 19, 20

**Regulations**

37 C.F.R. § 42.108(a).....17

## **I. Introduction**

Petitioners Sawai USA, Inc. (“Sawai USA”) and Sawai Pharmaceutical Co., Ltd. (“Sawai Japan”) (collectively “Sawai” or “Petitioner”) waited over a year and a half after being sued for infringement before filing its Petition against Biogen’s U.S. Patent No. 8,399,514 (“the ’514 patent”). Because the one-year deadline under 35 U.S.C. § 315(b) had long passed, Sawai resorted to filing its Petition along with a request to join IPR2018-01403 (“the Mylan IPR”). Patent Owner Biogen opposed joinder for multiple reasons, including the complication, delay, and subsequent prejudice to Biogen that Sawai’s late entrance into the Mylan IPR would cause. Papers 9, 14. Separate and apart from joinder issues, Sawai’s Petition does not warrant institution.

First and foremost, the Petition fails to establish a reasonable likelihood that Sawai would prevail with respect to at least one claim, let alone all twenty. 35 U.S.C. § 314(a). The challenged claims are patentable and for this reason alone, Sawai’s Petition should be denied outright.<sup>1</sup>

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<sup>1</sup> While this Preliminary Response does not address the merits of Sawai’s unpatentability arguments, Patent Owner Biogen does not waive or concede any argument and reserves all rights to argue all substantive issues and to take all

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