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Paper 15
Entered: December 14, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MSN LABORATORIES PRIVATE LTD. and
MSN PHARMACEUTICALS INC.,
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2023-00016
Patent 7,041,786 B2

Before TINA E. HULSE, CYNTHIA M. HARDMAN, and MICHAEL A. VALEK, *Administrative Patent Judges.*

VALEK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314
Granting Motion for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

On September 14, 2022 in IPR2022-00722, we instituted *inter partes* review of claims 1–6 of U.S. Patent No. 7,041,786 B2 ("the '786 patent") on a petition filed by Mylan Pharmaceuticals Inc. ("Mylan"). IPR2022-00722, Paper 16 ("'722 Institution Decision"). Within one month of the '722 Institution Decision, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively "MSN") filed the present Petition (Paper 1, "Petition"), seeking *inter partes* review of the same patent claims on the same grounds as those in IPR2022-00722.

Along with its Petition, MSN filed a Motion for Joinder with the proceeding in IPR2022-00722. Paper 4 ("Joinder Motion"). Bausch Health Ireland Limited ("Patent Owner") filed an Opposition to the Joinder Motion, objecting to the proposed "understudy role" MSN outlined in the Joinder Motion. Paper 10, 1. We issued an order asking MSN to clarify the scope of the "understudy role" it would accept in the event joinder were granted. Paper 12, 3. In response, MSN filed an authorized Reply providing the requested clarification and indicating that it had "reached an agreement" with Patent Owner regarding its role as an understudy. Paper 14, 3. Patent Owner has since confirmed this agreement and waived the filing of a Preliminary Response to the Petition in this proceeding. Ex. 3001 (Email to the Board dated Dec. 7, 2022).

As explained below, we institute trial on the same grounds and claims previously instituted in IPR2022-00722 and grant the Joinder Motion.

II. DISCUSSION

In IPR2022-00722, after considering the arguments and evidence in Mylan's petition and the preliminary response filed by Patent Owner in that proceeding, we instituted review on the following grounds:

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1	103	Currie[2], Li[3]
2, 4, 5	103	Currie, Li, Narayani[4]
3–5	103	Currie, Li, Narayani, Campieri[5]
6	103	Currie, Li, Ekwuribe[6]

MSN's Petition is identical in substance to the petition in IPR2022-00722, challenging the same claims based on the same grounds and relying on the same declarant testimony and other evidence for support. *See* Pet. 4–5 (stating its grounds are "substantially identical," "challenge the same claims over the same prior art," and "rely on the same exhibits, arguments and expert testimony presented with the Mylan Petition"). Patent Owner does not dispute that MSN's Petition is substantially identical to Mylan's, nor identify any material distinction between the arguments

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. § 103 that became effective after the filing of the application that led to the '786 patent. Therefore, we apply the pre-AIA version of 35 U.S.C. § 103.
[2] U.S. Pat. 5,489,670, issued Feb. 6, 1996 (Ex. 1005) ("Currie").
[3] Zhiping Li et al., *Purification, cDNA Sequence, and Tissue Distribution of Rat Uroguanylin*, 68 Regulatory Peptides 45–56 (1997) (Ex. 1006) ("Li").
[4] R. Narayani et al., *Polymer-coated Gelatin Capsules as Oral Delivery Devices and their Gastrointestinal Tract Behavior in Humans*, 7 J. Biomater. Sci. Polymer Edn. 39–48 (1995) (Ex. 1007) ("Narayani").
[5] M. Campieri et al., *Oral Budesonide is as Effective as Oral Prednisolone in Active Crohn's Disease*, 41 Gut 209–214 (1997) (Ex. 1008) ("Campieri").
[6] U.S. Pat. 5,359,030, issued Oct. 25, 1994 (Ex. 1009) ("Ekwruibe").

presented in the two proceedings. *See generally* Paper 10. Accordingly, for the same reasons stated in the '722 Institution Decision, we institute *inter partes* review on the same grounds here.

Having determined that institution is warranted, we now turn to the Joinder Motion. MSN timely filed the Joinder Motion within one month of the '722 Institution Decision. *See* 37 C.F.R. § 42.122(b) (requiring any joinder motion be filed "no later than one month after the institution date of any *inter partes* review for which joinder is requested"). Our decision whether to grant joinder is subject to discretion. *See* 35 U.S.C. § 315(c). When exercising the discretion delegated to us we are mindful that patent trial regulations, including the rules for joinder, should be construed to secure the just, speedy, and inexpensive resolution of every proceeding. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b). Furthermore, a motion for joinder should (1) set forth reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified. *See Kyocera Corp. v. SoftView, LLC*, IPR2013-00004, Paper 15, 4 (PTAB Apr. 24, 2013).

MSN's Joinder Motion addresses these concerns and we generally agree with the arguments MSN makes for joinder. *See* Paper 4, 8–12. As discussed above, the Petition raises the same unpatentability grounds as IPR2022-00722, and no others. Thus, this review does not present any ground not already at issue in IPR2022-00722. Efficiency favors addressing these challenges in a joined proceeding.

This is particularly so given the silent understudy role MSN has agreed to accept in the joined proceeding. MSN agrees that it will be a silent understudy to Mylan—accepting limitations on its participation similar to those in other Board cases involving an understudy petitioner. *See* Paper 12, 3 (articulating our understanding of a silent understudy role); Paper 14, 2 ("Petitioner hereby adopts the Board's understanding of an understudy"). In particular, MSN has agreed that "so long as Mylan remains a party to the proceeding" it will be bound by Mylan's filings and presentation at oral hearing and not make any substantive filings or presentation of its own; will not take cross-examination testimony of any witness or have a role in defending the cross-examination of a witness; and will not seek any other discovery during the joined proceeding. *Id.* These limits on the scope of MSN's participation greatly streamline matters and mitigate inefficiencies allowing our focus to remain on reaching a timely final written decision addressing the merits of the patentability challenges first raised in IPR2022-00722, and now again in the present Petition.

Patent Owner initially opposed joinder, urging that Petitioner had not agreed to "a complete understudy role." Paper 10, 1. However, the parties have since reached agreement on the conditions of MSN's limited role in the joined proceeding. Paper 14, 3; Ex. 3001, 1. We appreciate the parties' efforts to reach this agreement and understand that, given this agreement, Patent Owner no longer opposes joinder. *See* Paper 10, 1 (stating that Patent Owner "opposes joinder unless and until MSN accepts a complete understudy role").[7]

[7] MSN also represents that Mylan does not oppose joinder. *See* Paper 4, 13.

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