

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INVAGEN PHARMACEUTICALS, INC.,
Petitioner,

v.

BAYER PHARMA AKTIENGESELLSCHAFT,
Patent Owner.

IPR2022-01515
Patent 10,828,310 B2

Before TINA E. HULSE, ROBERT A. POLLOCK, and RYAN H. FLAX,
Administrative Patent Judges.

HULSE, *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

Invagen Pharmaceuticals, Inc. (“Invagen”) filed a Petition requesting an *inter partes* review of claims 1–8 is U.S. Patent No. 10,828,310 B2 (Ex. 1001, “the ’310 Patent”). Paper 1 (“Pet.”). Concurrently with the Petition, Teva filed a Motion for Joinder to join this proceeding with *Mylan Pharmaceuticals Inc. v. Bayer Pharma Aktiengesellschaft*, IPR2022-00517 (“the -517 IPR”). Paper 3 (“Mot.”). The parties filed a Joint Notice of Stipulation Concerning Joinder, in which the parties agreed to the joinder, subject to the terms set forth in the stipulation. Paper 9 (“Stipulation”).

As explained further below, we institute trial on the same grounds as instituted in IPR2022-00517 and grant Invagen’s Motion for Joinder.

A. *Real Parties-in-Interest*

Invagen identifies itself and Cipla (ET Limited), Cipla Limited, and Cipla USA Inc. as the real parties-in-interest. Pet. 2. Patent Owner identifies Bayer Pharma AG, Bayer Pharma Aktiengesellschaft (a/k/a Bayer AG), and Janssen Pharmaceuticals, Inc. as the real parties-in-interest. Paper 5, 2.

B. *Related Proceedings*

Patent Owner has asserted the ’310 Patent in several district court cases, which have been consolidated in a multidistrict litigation pending before the U.S. District Court for the District of Delaware styled *In re: Xarelto (Rivaroxaban) (’310) Patent Litigation*, No. 1:21-md-03017 (D. Del.). Paper 5, 2–4. The consolidated actions are: *Bayer Pharma AG v. Lupin Limited*, No. 21-314-RGA (D. Del.); *Bayer Pharma AG v. Dr. Reddy’s Laboratories, Inc.*, No. 21-732-RGA (D. Del.); *Bayer Pharma AG v. Taro Pharmaceutical Industries Ltd.*, No. 21-1000-RGA (D. Del.); *Bayer Pharma AG v. Teva Pharmaceuticals USA, Inc.*, No. 21-cv-

02002 (D. Del.); and *Bayer Pharma AG v. Mylan Pharmaceuticals Inc.*, No. 21-1742-RGA (D. Del.).

Patent Owner has also asserted the '310 patent in *Bayer Pharma AG v. USV Private Ltd.*, No. 22-cv-05485 (D.N.J.). Paper 5, 4.

The '310 patent is also the subject of IPR2022-00517, which was instituted on August 9, 2022, and IPR2022-01513, styled *Teva Pharmaceuticals USA, Inc. v. Bayer Pharma Aktiengesellschaft*, which is concurrently instituted and joined to the -517 IPR along with the instant proceeding.

II. DISCUSSION

In the -517 IPR, Mylan Pharmaceuticals Inc. (“Mylan”) challenged claims 1–8 of the '310 patent on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4	102	EMA ¹
1–8	103	EMA
1–2	102	Foley ²
1–2, 5, 8	103	Foley
3–4, 6–7	103	Foley and Plosker ³

We instituted trial in the -517 IPR on all grounds. IPR2022-00517, Paper 15 at 29.

Invagen’s Petition here is substantively identical to Mylan’s Petition in the -517 IPR, challenging the same claims based on the same art and the same grounds. *Compare* IPR2022-00517, Paper 1 *with* IPR2022-01515, Paper 1. For

¹ European Medicines Agency, *Assessment Report, Xarelto*, EMA/CHMP/794349/2012 (2013). Ex. 1005 (“EMA”).

² Foley et al., *Antithrombotic therapy in peripheral artery disease*, 21 VASCULAR MED. 156–69 (2016). Ex. 1006 (“Foley”).

³ Plosker, *Rivaroxaban: A Review of Its Use in Acute Coronary Syndromes*, 74 DRUGS 451–64 (2014). Ex 1007 (“Plosker”).

the same reasons stated in our Decision Granting Institution of *Inter Partes* Review in IPR2022-00517, we institute trial in this proceeding on the same five grounds. *See* IPR2022-00517, Paper 15.

Having determined that institution is appropriate, we now turn to Invagen’s Motion for Joinder. Based on authority delegated to us by the Director, we have discretion to join an *inter partes* review to a previously instituted *inter partes* review. 35 U.S.C. § 315(c). Section 315(c) provides, in relevant part, that “[i]f the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311.” *Id.* When determining whether to grant a motion for joinder, we consider factors such as timing and impact of joinder on the trial schedule, cost, discovery, and potential simplification of briefing. *Kyocera Corp. v. SoftView, LLC*, IPR2013-00004, Paper 15 at 4 (PTAB Apr. 24, 2013).

Under the circumstances of this case, we determine that joinder is appropriate. As Invagen notes, the Motion is timely, as it was filed within one month of our decision instituting trial in the -517 IPR. Mot. 6. The Petition in this proceeding is substantively identical to the Mylan Petition. Mot. 6; *see also* Stipulation ¶ 5. Invagen relies on the same expert declaration submitted in the -517 IPR.⁴ Mot. 5. Moreover, Invagen has agreed to assume a “passive understudy” role in the joined proceedings, as long as Mylan remains a party to the proceeding. *See* Stipulation ¶¶ 3–6. Invagen further contends that there will be no impact on the trial schedule of the -517 IPR, and that joinder will promote the just,

⁴ Although Invagen submitted a declaration from Dr. Mark Eisenberg with its Petition, Invagen has agreed to unconditionally withdraw the Eisenberg Declaration following the deposition of Mylan’s expert, Dr. Randall Zusman, in the joined proceeding. Stipulation ¶ 5.

speedy, and inexpensive resolution of the proceedings without prejudice to the parties. Mot. 7–10.

In view of the foregoing, we find that joinder based upon the conditions stated in the Stipulation will have little or no impact on the timing, cost, or presentation of the trial on the instituted grounds. Moreover, discovery and briefing will be simplified if the proceedings are joined. Thus, Invagen’s Motion for Joinder is granted.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–8 of U.S. Patent No. 10,828,310 B2 is instituted with respect to all challenged claims and all grounds set forth in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial;

FURTHER ORDERED that Invagen’s Motion for Joinder with IPR2022-00517 is *granted*, and Invagen Pharmaceuticals, Inc. is hereby joined as a petitioner in IPR2022-00517;

FURTHER ORDERED that the parties shall abide by the terms set forth in the Joint Notice of Stipulation Concerning Joinder (Paper 9);

FURTHER ORDERED that the Scheduling Order in place for IPR2022-00517 (Paper 16), unless modified by joint stipulation (e.g., Paper 19), shall govern the joined proceeding;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2022-00517;

FURTHER ORDERED that the case caption in IPR2022-00517 for all further submissions shall be changed to add Invagen as a named Petitioner with

IPR2022-01515
Patent 10,828,310 B2

Mylan, and to indicate by footnote the joinder of IPR2022-01515 (and IPR2022-01513) to that proceeding, as indicated in the attached sample case caption; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2022-00517.

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SAMPLE CASE CAPTION

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IPR2022-00517⁵
Patent 10,828,310 B2

⁵ IPR2022-01513 and IPR2022-01515 have been joined with this proceeding.