

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TAKEDA VACCINES, INC.,
Petitioner,

v.

VALNEVA AUSTRIA GMBH,
Patent Owner.

IPR2023-00354
Patent 11,219,681 B2

Before WESLEY B. DERRICK, ROBERT A. POLLOCK, and
JAMIE T. WISZ, *Administrative Patent Judges*.

DERRICK, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. *Background and Summary*

Takeda Vaccine, Inc. (“Petitioner”) filed a petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–15 and 21–25 (“the challenged claims”) of U.S. Patent No. 11,219,681 B2 (“the ’681 patent”). Valneva Austria GmbH (“Patent Owner”) notified the Board, by email dated March 22, 2021, that it had filed a statutory disclaimer, disclaiming claims 1–15 and 21–25 of the ’681 patent. *See* Ex. 3001. Patent Owner further attached a copy of the statutory disclaimer, indicating its payment of necessary fees. *Id.*; Ex. 3002 (“Statutory Disclaimer”). Patent Owner requested that we advise “if any additional filings are necessary to request termination of IPR2023-00354.” Ex. 3001. Patent Owner copied Petitioner on its email to the Board, thereby informing Petitioner of its intentions. *Id.* Petitioner subsequently requested by email, dated March 24, 2023, that Petitioner’s disclaimer of claims “be treated as a request for adverse judgment.” *See* Ex. 3003.

Petitioner requested authorization to file a motion contending that Patent Owner’s statutory disclaimer should be treated as a request for adverse judgment. Ex. 3004. A conference call was held on April 19, 2023. Ex. 1210. On June 6, 2023, we issued an Order denying Petitioner’s request for such a motion. Paper 6.

B. *Real Parties-in-Interest*

Petitioner identifies itself as the real party-in-interest. Pet. 66. Patent Owner identifies itself as the real party-in-interest, noting also that it is a fully-owned subsidiary of Valneva SE. Paper 4, 1.

C. Related Matters

The parties identify no judicial matters, but do identify U.S. Patent Applications 17/548,21 and 18/178,638 as claiming the benefit of priority of the filing date of the '681 patent. Pet. 66; Paper 4, 1.

D. The '681 Patent

The '681 patent is directed to “Zika virus vaccines and compositions and methods of producing and administering said vaccines to subjects in need thereof.” Ex. 1001, code (57). Claims 1–15 and 21–25 are directed to Zika virus vaccine(s). *Id.* at 445:34–67, 446:33–55, 448:11–16.

E. Asserted Grounds of Unpatentability

Petitioner asserts three grounds of unpatentability in the Petition: Ground 1, obviousness under § 103 of claims 1–11, 15, and 21–25 over a combination of five (5) references; Ground 2, obviousness under 35 U.S.C. § 103 of claim 12 over the same references in further combination with an additional reference; and Ground 3 anticipation under § 102 of claims 1–15 and 21–25 over yet another reference. Pet. 15 (identifying the challenges in a table).

II. ANALYSIS

As set forth above, Patent Owner filed a statutory disclaimer, disclaiming all challenged claims of the '681 patent, and paid the requisite fees. *See* Ex. 3002; *see also* 35 U.S.C. § 253(a) (providing that a patentee may disclaim); 37 C.F.R. § 1.321 (setting forth requirements for statutory disclaimer). In particular, based on our review of Ex. 3002 and Patent Office public records, we are satisfied that a disclaimer of the challenged claims of the '681 patent under 35 U.S.C. § 253(a) has been recorded in the Office as of March 21, 2023. *See Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1382 (Fed. Cir. 1998) (holding that a disclaimer filed under

35 U.S.C. § 253 and meeting the requirements of 37 C.F.R. § 1.321(a), is immediately “recorded” on the date the Office receives the disclaimer without any requirements of further action).

Accordingly, we deny institution of the requested *inter partes* review. See 37 C.F.R. § 42.107(e) (“No *inter partes* review will be instituted based on disclaimed claims.”); see also *General Elec. Co. v. United Techs. Corp.*, IPR2017-00491, Paper 9 (PTAB July 6, 2017) (precedential) (“*General Electric*”) (denying institution of *inter partes* review under 37 C.F.R. § 42.107(e) based on disclaimer).

In requesting authorization for a motion addressing the effect of Patent Owner’s statutory disclaimer of the challenged claims, Petitioner correctly notes that the Federal Circuit in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345 (Fed. Cir. 2018), construed Rule 42.73(b) as permitting the Board to enter adverse judgment when a patent owner cancels all challenged claims prior to institution. Paper 6, 2–3; *Arthrex*, 880 F.3d at 1350. Neither *Arthrex* nor Rule 42.73(b), while permitting us to do so, requires us to enter adverse judgment.

In the present instance, and consistent with 35 U.S.C. § 253(a), *Arthrex*, Rule 42.107(e) and the Board’s precedential *General Electric* decision, we determine that a denial of institution is sufficient to dispose of this case. We acknowledge Petitioner’s request to treat the terminal disclaimer as a request for adverse judgment (see Ex. 3003), but determine that denying institution without entering adverse judgment against the Patent Owner is consistent with § 253(a), Rule 42.107(e), and *General Electric*, where there are no pending claims for us to consider following disclaimer of all challenged claims prior to institution of trial.

III. CONCLUSION

Because each of challenged claims 1–15 and 21–25 have been disclaimed under 35 U.S.C. § 253(a), no *inter partes* review is instituted.

IV. ORDER

It is therefore

ORDERED that the Petition is *denied* and no *inter partes* review is instituted.

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