Trials@uspto.gov
571-272-7822

Paper 10
Date: March 1, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00099
Patent 10,857,205 B2

Before ERICA A. FRANKLIN, RYAN H. FLAX, and JAMIE T. WISZ, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–3 of U.S. Patent No. 10,857,205 B2 (Ex. 1001, "the '205 patent"). Paper 2 ("Pet."). Regeneron Pharmaceuticals, Inc. ("Patent Owner") elected not to file a Preliminary Response to the Petition. Patent Owner, however, notified the Board by email that it had filed a statutory disclaimer, disclaiming all claims of the '205 patent. *See* Ex. 3001. Thereafter, in accordance with our instruction, *see id.*, Patent Owner filed a copy of the disclaimer in this case as Exhibit 2001. In view of Patent Owner's statutory disclaimer, we decline to institute an *inter partes* review.

B. Real Parties-in-Interest

Petitioner identifies itself, its parent companies, Viatris Inc. and Mylan Inc., as well as Johnson & Johnson, and the wholly-owned subsidiaries of Johnson & Johnson, Momenta Pharmaceuticals, Inc. and Janssen Research & Development LLC, as the real parties-in-interest. Pet. 4–5.

Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

C. Related Matters

The parties explain that the '205 patent has been asserted in a pending district court case: *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 1:22-cv-00061-TSK (N.D. W.Va.). Pet. 5; Paper 4, 3. Petitioner additionally includes *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.) and *Horizon Healthcare Servs., Inc. v. Regeneron Pharms., Inc.*, No. 1:22-cv-10493-FDS (D. Mass.) as matters that would affect or be affected by a decision in this proceeding. Pet. 5.

The parties also identify a number of pending *inter partes review* proceedings involving patents related to the '205 patent, along with a number of U.S. Patent Applications related to the '205 patent. *See* Pet. 5–6; Paper 5, 1–3.

D. The '205 Patent

The '205 patent is directed to "the administration of VEGF antagonists to treat eye disorders caused by or associated with angiogenesis." Ex. 1001, 1:25–27.

E. Asserted Grounds of Unpatentability

Petitioner asserts seven grounds of unpatentability in the Petition, *see* Pet. 24, which are provided in the table below:

Claims Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1–3	102	NCT-072[2]
1–3	102	Regeneron 2009[3]
1–3	102	2009 10-Q[4]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102–103, effective March 16, 2013. Because the '205 patent has an effective filing date after March 16, 2013, the AIA versions of §§ 102 and 103 apply.
[2] Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO), NCT00943072, ClinicalTrials.gov (Jul. 20, 2009), https://clinicaltrials.gov/ct2/history/NCT00943072 (Ex. 1009, "NCT-072").
[3] Press Release, Regeneron, "Regeneron Reports Full Year and Fourth Quarter 2008 Financial and Operating Results" (February 26, 2009) (Ex. 1041, "Regeneron 2009").
[4] Regeneron Pharm., Inc., Quarterly Report (Form 10-Q) (Sept. 30, 2010) (Ex. 1021, "2009 10-Q").

Claims Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1–3	103	NCT-072 alone or in view of Sophie[5] and/or NCT-795[6]
1–3	103	Regeneron 2009 alone or in view of Sophie and/or NCT-795
1–3	103	2009 10-Q alone or in view of Sophie and/or NCT-795
1–3	103	Dixon[7] in combination with Kreatsoulas,[8] either alone or in view of Sophie and/or NCT-795

II. ANALYSIS

As set forth in *General Electric,* "[u]nder 37 C.F.R. § 42.107(e), 'patent owner may file a statutory disclaimer under 35 U.S.C. 253(a) in compliance with § 1.321(a) of this chapter, disclaiming one or more claims in the patent' and '[n]o *inter partes* review will be instituted based on disclaimed claims.'" *Gen. Elec. Co. v. United Tech. Corp.*, IPR2017-00491, Paper 9 at 2 (PTAB July 6, 2017) (precedential). "A disclaimer under 35 U.S.C. § 253(a) is 'considered as part of the original patent' as of the date on which it is 'recorded' in the Office (35 U.S.C. § 253(a))." *Id.* at 2–3.

[5] Raafay Sophie et al., "Aflibercept: a Potent Vascular Endothelial Growth Factor Antagonist for Neovascular Age-Related Macular Degeneration and Other Retinal Vascular Diseases," 2(3) BIOLOGICS THERAPY 1–22 (2012) (Ex. 1010, "Sophie").
[6] Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects with Wet AMD (VIEW 1) (VIEW 1), NCT00509795, ClinicalTrials.gov (Jan. 22, 2009), https://clinicaltrials.gov/ct2/history/NCT00509795 (Ex. 1014, "NCT-795").
[7] James A. Dixon et al., "VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration," 18(10) EXPERT OPIN. INVESTIG. DRUGS 1573–1580 (2009) (Ex. 1006, "Dixon").
[8] Jennifer Kreatsoulas, Ph.D., "News Feature: Expanding Therapeutic Options for Retinal Vein Occlusion," RETINA TODAY 20–21 (2009) (Ex. 1049, "Kreatsoulas").

As noted above, Patent Owner filed a statutory disclaimer, disclaiming all claims challenged in this proceeding. Ex. 2001. Based on our review of Exhibit 2001 and Office public records, we are satisfied that a disclaimer of claims 1–3 of the '205 Patent, under 35 U.S.C. § 253(a) has been recorded in the Office as of February 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).

Thus, in view of the statutory disclaimer filed before institution, and consistent with 37 C.F.R. § 42.107(e) and the Board's precedential *General Electric* decision, we determine a denial of institution is sufficient to dispose of this case. *See Gen. Elec. Co.*, IPR2017-00491, Paper 9. Accordingly, we decline to institute an *inter partes* review.

III. CONCLUSION

Because all the claims challenged by Petitioner have been disclaimed under 35 U.S.C. § 253(a), no *inter partes review* is instituted.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that no *inter partes* review is instituted on claims 1–3 of the '205 patent.

FOR PETITIONER:

Paul J. Molino
Deanne M. Mazzochi
Neil B. McLaughlin
Jeff A. Marx
L. Scott Beall
Thomas H. Ehrich
Steven J. Birkos
Rakoczy Molino Mazzochi Siwik LLP
paul@rmmslegal.com
dmazzochi@rmmslegal.com
nmclaughlin@rmmslegal.com
jmarx@rmmslegal.com
sbeall@rmmslegal.com
tehrich@rmmslegal.com
sbirkos@rmmslegal.com

PATENT OWNER:

Adam R. Brausa
Rebecca Weires
abrausa@mofo.com
rweires@mofo.com