

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

HOFFMANN-LA ROCHE INC.,
Patent Owner.

IPR2018-01219
Patent 8,314,225 B2

PATENT OWNER PRELIMINARY RESPONSE

I. INTRODUCTION

The Board should deny institution under 35 U.S.C. § 325(d) because (a) all but one challenged claim has been disclaimed; (b) a reexamination of the patent commenced nearly one year ahead of the Petition is addressing new claims presented by amendment; and (c) the Petition duplicates issues currently engaged in the reexamination.

II. THE PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 325(D)

U.S. Patent No. 8,314,225 (the “225 patent”) is the subject of *ex parte* reexamination Control Number 90/014,063, which was filed on January 10, 2018, instituted on March 7, 2018, received a non-final action on the merits on June 29, 2018, and now awaits further action by the Examiner on a response just filed by Patent Owner. No benefit is gained from having a second tribunal within the Office institute a second layer of proceedings nearly one year out of sync, especially because the issues raised in the Petition are already being addressed in the reexamination. As the Board explained in another case under nearly identical circumstances, initiating a second, concurrent proceeding on similar grounds consumes considerable Office resources, and creates uncertainty for the Patent Owner, while contributing little to the common goal of *inter partes* review and reexamination to correct errors by the Office in allowing a patent. *Fox Factory, Inc. v. SRAM, LLC*, IPR2017-01439, Paper 7, 8 (P.T.A.B. Dec. 8, 2017) (citing *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00739, Paper 16, 8 (P.T.A.B. July 27, 2017) (informative)).

Patent Owner has disclaimed all challenged claims except claim 20, so only claim 20 remains under consideration in the Petition. 37 C.F.R. § 42.107(e) (barring review of claims canceled by statutory disclaimer); Ex. 2001, Statutory

Disclaimer in U.S. Patent No. 8,314,225 under 37 C.F.R. § 1.321(a) (filed Sept. 20, 2018). In addition, new claims have been added by amendment and are now under consideration in the reexamination.

Patent Owner has not introduced new testimonial evidence in the reexamination. The reexamination, thus, is being conducted on substantially the same record as that presented in the Petition.

Critically, the same substantive issues raised in the Petition are being addressed in the reexamination. Of the three references Petitioner relies on here, one (Loetscher, Ground 2) is cited in a reexamination anticipation rejection of claim 20 in which the Examiner relies on the same disclosure as Petitioner—specifically, Loetscher’s SEQ ID NO:23. Ex. 2002, *Ex Parte* Reexamination of U.S. Patent No. 8,314,225, Control No. 90/014,063, Office Action 4–5 (mailed June 29, 2018) (Loetscher rejection in reexamination office action); Ex. 1004, 10–12 (Loetscher SEQ ID NO:23). Patent Owner has already filed a response to this rejection, including an amendment adding new claims 21–32. Ex. 2003, *Ex Parte* Reexamination of U.S. Patent No. 8,314,225, Control No. 90/014,063,

Reexamination Amendment A 2–3 (filed Sept. 20, 2018).¹

The other two references, Denney (Ground 1, Ex. 1003) and Rosenthal (Ground 3, Ex. 1005) are not cited in reexamination rejections, but they present issues redundant to those raised by Loetscher and the other reexamination references. As with Loetscher, Petitioner relies on Denney and Rosenthal for descriptions of sequences encoding at least a domain of an immunoglobulin heavy chain constant region and some of the nucleic acid sequences recited in claim 20; the Examiner has applied exactly the same rationale in the reexamination rejections. Ex. 2002, 4–11 (citing, for each rejection, heavy chain sequences recited in claim 20). Petitioner even concedes this redundancy, in portraying Denney, Loetscher, and Rosenthal as “just three of many” examples of prior art references applied in challenges and/or the reexamination office action. Pet. at 2.

Simply put, Denney, Loetscher, and Rosenthal are alternative pieces of

¹ The File History of the *Ex Parte* Reexamination of 8,314,225, Control No. 90/014,063, is attached as Exhibit 2005. As shown in Exhibit 2005, the co-pending reexamination has generated 2874 pages of File History as of the filing of this paper.

evidence being used by Petitioner to press the same argument: alleged anticipation by the prior art. Petitioner relies on them in essentially the same manner as the references used in the reexamination. The general issue before the Office—whether the prior art discloses the claimed method involving a nucleic acid encoding an immunoglobulin heavy chain with a particular sequence—is identical among the nine rejections playing out in the reexamination and the three challenges here.

When, as here, the Office already has before it substantially the same issues on substantially similar art, the Board is disinclined to institute *inter partes* review, because a second review merely depletes additional Office resources toward the same goal already being addressed by reexamination: whether the patent was erroneously granted over prior art. *Fox Factory* at 8. This inefficient use of resources is particularly acute when the earlier proceeding is at an advanced stage, after the Office has already dedicated a large amount of resources conducting the first proceeding and now faces the prospect of committing many more. *Id.* A second proceeding also robs the Patent Owner of the repose and predictability that come from the Office rendering *one* decision on the *one* general issue presented to it. *See Ex. 2004, Remarks by Director Andrei Iancu at the Ceremonial Swearing-In* (USPTO, Feb. 23, 2018) (“we must

endeavor to provide reliable, predictable, and high-quality IP rights that give owners and the public alike confidence in those rights.”).

In *Fox Factory*, the Board exercised its discretion to deny institution of a petition under § 325(d), under circumstances remarkably similar to the present case. A co-pending *ex parte* reexamination had earlier presented the Office with a “nearly identical ground” to that presented in a petition nearly one year later. *Fox Factory* at 8. The sole ground in the Petition was not founded on identical art to that presented in the reexamination, yet the Board was “unpersuaded” that the difference “meaningfully alters the substance of the ground of unpatentability” presented in the Petition. *Id.* at 8, n.2. The Board noted that the reexamination was “not yet complete” and that reconsidering “essentially the same ground” as that presented in reexamination “would be an inefficient use of the Office’s resources,” and thus concluded “the interests of conservation of resources and finality to weigh strongly in favor of exercising [their] discretion of not instituting” *Id.* at 8; accord *Baker Hughes Oilfield Operations, Inc. v. Smith Int’l, Inc.*, IPR2016-01450, Paper 10, 7–11 (P.T.A.B. Dec. 22, 2016) (denying institution when co-pending reexamination was on appeal).

The Board also has held, on multiple occasions, that citing a new reference as evidence of the same old facts already presented to the Office is just the sort

of situation envisioned in 35 U.S.C. § 325(d) as unsuitable for trial. *Unified Patents Inc. v. John L. Berman*, IPR2016-01571, Paper 10, 11–12 (P.T.A.B. Dec. 14, 2016) (informative) (denying petition under § 325(d) that presented art that had been considered by the Examiner, and art that was “relie[d] on . . . in substantially the same manner” as previously considered art); *Kingston Tech. v. Polaris Innovations LTD*, IPR2017-00974, Paper 8, 13 (P.T.A.B. Aug. 14, 2017) (declining to institute where the Board found the asserted prior art was substantially the same as in a prior proceeding because each reference “serve[s] the same purpose” as the previously considered art); *Neil Ziegman, N.P.Z., Inc. v. Stephens*, IPR2015-01860, Paper 11, 10 (P.T.A.B. Feb. 24, 2016) (denying petition under §325(d) where an old reference was “used in the same manner by the Office as Petitioner uses [a new reference] in the instant proceeding.”).

The Board repeatedly has denied institution under § 325(d) when new references are used in the same manner as references previously considered by the Office, as exemplified by the cases cited above. Petitioner here, as in *Fox Factory*, recycles issues under consideration in the nearly year-old reexamination using the same or “essentially the same” art, without adding anything new, and thus only imposes additional burden on both Patent Owner and the Office. *See Fox Factory*, at 8. The letter, spirit, and underlying policy goals of § 325(d), as

reflected in *Fox Factory* and the Board's many precedential and informative decisions of the past year, are promoted by denying institution to allow the ongoing reexamination to proceed. Institution of review at this time will bring no clarity to the patentability of claim 20 for the benefit of the reexamination and cannot resolve the patentability of the new claims now pending in the reexamination.

For these reasons, the Petition should be denied under 35 U.S.C. § 325(d).

III. CONCLUSION

The Board should deny institution of *inter partes* review for the '225 patent.

Respectfully submitted,

Dated: September 20, 2018

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that the present paper contains 1,462 words based on the word count indicated by the word-processing program used to generate the paper and excluding those portions exempted by 37 C.F.R. §§ 42.24(a) and (b).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, I certify that on the date listed below, a copy of this paper and every exhibit filed with this paper was served on the Petitioner by electronic mail to the following counsel of record for Petitioner:

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