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Kelley Dye & Warren LLP
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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

February 21, 2025

FUSION ORTHOPEDICS USA, LLC
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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90019778
PATENT NO. : 11298166
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).



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(Patent Owner)

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(For Third Party Requester)

In re Tyber *et al.*
Ex Parte Reexamination Proceeding
Control No. 90/019,778
Request Deposited: December 13, 2024
For: U.S. Patent No. 11,298,166 B2

:
: **DECISION SUA SPONTE**
: **VACATING EX PARTE**
: **REEXAMINATION**
: **FILING DATE**
:

The *ex parte* reexamination request deposited on December 13, 2024 and assigned Control No. 90/019,778, and the record as a whole, are before the Office of the Central Reexamination Unit for consideration.

This decision constitutes notice that, pursuant to 37 CFR 1.510(c), the filing date of December 13, 2024 that was assigned to the request for the above-captioned *ex parte* reexamination proceeding, is hereby **vacated**, because the request fails to comply with the requirements for a proper certification pursuant to 37 CFR 1.510(b)(6).

PERTINENT BACKGROUND

- On April 12, 2022, U.S. Patent No. 11,298,166 B2 (the '166 patent) issued from Application 17/323,923 to Tyber *et al.* with claims 1-15.

Prior PTAB Proceedings

IPR2023-00894 (Fusion Orthopedics, LLC)

- On April 28, 2023, Fusion Orthopedics, LLC filed a petition for an *inter partes* review challenging claims 1-15 of the '166 patent. The IPR proceeding was assigned case number IPR2023-00894 (the

'894 IPR).¹ The petition proposed the following grounds as raising a reasonable likelihood of prevailing (RLP):²

Claims of the '166 patent	Grounds
1-7, 9, 12, 13	Anticipated by Cognet ³
4, 8, 10, 14, 15	Obvious over Cognet and Brumfield ⁴
11	Obvious over Cognet and Ferrante ⁵
1, 4, 5, 8, 10-12, 14, 15	Anticipated by Simon ⁶
4, 8, 10, 11, 14, 15	Obvious over Simon and Ferrante
9	Obvious over Simon and Cognet
2, 3, 6, 7, 13	Obvious over Simon and Leu ⁷

- On November 17, 2023, the Patent Trial and Appeal Board (PTAB) granted institution and review of all grounds set forth in the petition filed in the '894 IPR.⁸
- On February 8, 2024 and March 6, 2024, Patent Owner filed a motion to amend⁹ and a corrected motion to amend,¹⁰ respectively, ultimately adding substitute claims 16-30.
- On August 7, 2024, Fusion Orthopedics, LLC filed an opposition to Patent Owner's revised motion to add substitute claims 16-30, which asserted **Mazur**¹¹ anticipated, or rendered obvious, each of claims 16-30.¹²
- On November 4, 2024, the PTAB issued a Final Written Decision (FWD) concluding that Fusion Orthopedics, LLC had showed by a preponderance of the evidence that claims 1-10 and 12-15 are unpatentable.¹³ The PTAB also found that Fusion Orthopedics, LLC did not show by a preponderance of the evidence that claim 11 is unpatentable.¹⁴
- On January 31, 2025, an Inter Partes Review Certificate issued for U.S. Patent Number 11,298,166 K1, cancelling claims 1-10 and 12-15 and finding claim 11 patentable.

¹ *Fusion Orthopedics, LLC v. Extremity Medical, LLC*, IPR2023-00894, Paper 1 (PTAB Apr. 28, 2023).

² *Id.* at p. 6.

³ French Patent Appl. Publication No. FR2,861,576A1 to Cognet Jean Michel, published May 6, 2005 (**Cognet**).

⁴ U.S. Patent No. 4,827,917 to David L. Brumfield, issued May 9, 1989 (**Brumfield**).

⁵ U.S. Patent Publication No. 2003/0187447 to Joseph Ferrante *et al.*, published October 2, 2003 (**Ferrante**).

⁶ U.S. Patent Publication No. 2006/0206044 to William Simon, published September 14, 2006 (**Simon**).

⁷ U.S. Patent No. 6,270,499 B1 to Dieter Leu *et al.*, issued on August 7, 2001 (**Leu**).

⁸ *Fusion Orthopedics, LLC*, IPR2023-00894, Paper 15 (PTAB Nov. 17, 2023).

⁹ *Fusion Orthopedics, LLC*, IPR2023-00894, Paper 23 (PTAB Feb. 8, 2024).

¹⁰ *Fusion Orthopedics, LLC*, IPR2023-00894, Paper 26 (PTAB Mar. 6, 2024).

¹¹ U.S. Patent Publication No. 2011/0087227 A1 to Kal U. Mazur *et al.*, published on April 14, 2011 (**Mazur**).

¹² *See Fusion Orthopedics, LLC*, IPR2023-00894, Paper 49, p. 1 (PTAB Aug. 7, 2024).

¹³ *Fusion Orthopedics, LLC*, IPR2023-00894, Paper 64, pp. 65-66 (PTAB Nov. 4, 2024).

¹⁴ *Id.* The PTAB also found substitute claims 16-25 and 27-30 would have been unpatentable over Mazur, but no determination was reached as to claim 26 because it corresponds to claim 11, which was found not unpatentable. *See Fusion Orthopedics, LLC*, IPR2023-00894, Paper 64, pp. 48, 63.

Present Ex Parte Reexamination Proceeding

90/019,778 (Fusion Orthopedics, LLC)

- On December 13, 2024, Fusion Orthopedics, LLC (requester) deposited a request for *ex parte* reexamination of claims 1-15 of the '166 patent (the request).¹⁵ The reexamination proceeding was assigned Control No. 90/019,778 (the '778 reexamination or the present reexamination proceeding). The request proposed the following substantial new questions of patentability:¹⁶

Ground	Claims of the '166 patent	Proposed Substantial New Questions of Patentability ¹⁷
1	1-15	Anticipated by Mazur
2	1-15	Obvious over Mazur

- On December 20, 2024 a Notice of Reexamination Request Filing Date was mailed, which accorded the '778 reexamination request a filing date of December 13, 2024.

DECISION

I. Requirements for certification pursuant to 37 CFR 1.150(b)(6)

Requester deposited a certification with the request in the present reexamination proceeding, pursuant to 37 CFR 1.510(b)(6). Where, as here, the requester provides specific arguments in the request regarding why it is not estopped under 35 U.S.C. 315(e)(1), the Office may, *sua sponte*, analyze the facts of the case prior to the order to determine whether the estoppel provisions of 35 U.S.C. 315(e)(1) apply. If the provisions of 35 U.S.C. 315(e)(1) are determined to apply, the Office may vacate the filing date of the reexamination proceeding and the reexamination proceeding as a whole, as set forth in section IV of this decision.¹⁸

A certification under 37 CFR 1.510(b)(6) is either proper or improper. If any part of the certification is improper, then the entire certification is improper. If the Office determines that any part of requester's certification pursuant to 37 CFR 1.510(b)(6) is improper, the Office will vacate the entire proceeding, including the filing date of the reexamination proceeding.

37 CFR 1.510(b) provides, in pertinent part:

Any request for reexamination must include the following parts:

- *
- *

¹⁵ See "Request For Ex Parte Reexamination," filed December 13, 2024. On page 1 of the request, requester certified that the statutory estoppel provisions of 35 U.S.C. §§ 315(e)(1) and 325(e)(1) do not prevent requester from filing the request.

¹⁶ See Request, p. 3, 14.

¹⁷ A bolded reference indicates Fusion Orthopedics knew about the reference during the '894 IPR.

¹⁸ See also "Decision *Sua Sponte* Vacating *Ex Parte* Reexamination Request Filing Date and Dismissing Petition as Moot," issued September 10, 2020 in 90/014,535, pages 12-13, for a discussion of Office policy.

(6) A certification by the third party requester that the statutory estoppel provisions of 35 U.S.C. 315(e)(1) or 35 U.S.C. 325(e)(1) do not prohibit the requester from filing the *ex parte* reexamination request.

35 U.S.C. 315(e)(1) provides:

PROCEEDINGS BEFORE THE OFFICE.—The petitioner in an *inter partes* review of a claim in a patent under this chapter that results in a final written decision under [35 U.S.C.] 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that *inter partes* review.

II. The estoppel provisions of 35 U.S.C. 315(e)(1) apply to requester

Whether estoppel under 35 U.S.C. 315(e)(1) applies to a claim requested to be reexamined on any of the grounds raised in an *ex parte* reexamination proceeding may be analyzed by determining:¹⁹

1. Whether the third party requester of the *ex parte* reexamination proceeding was a petitioner in the *inter partes* review, or was a real party in interest or a privy of the petitioner;
2. Whether the claim(s) of the patent under *inter partes* review are also requested to be reexamined in the *ex parte* reexamination proceeding;
3. Whether the *inter partes* review has resulted in a final written decision pursuant to 35 U.S.C. 318(a); and
4. Whether the ground(s) raised in the *ex parte* reexamination proceeding are the ground(s) that were raised or reasonably could have been raised by the requester during the *inter partes* review.

A. The record sufficiently shows that element 1 is satisfied

To satisfy element 1, the record must sufficiently show that the third party requester of the present reexamination proceeding was a petitioner in the *inter partes* review, or was a real party in interest or a privy of the petitioner.

The requester of the present reexamination proceeding is Fusion Orthopedics, LLC. In the '894 IPR, Fusion Orthopedics, LLC was the petitioner. Accordingly, the record shows that element 1 has been satisfied.

¹⁹ The four elements set forth in this decision are found in the language of the statute, 35 U.S.C. 315(e).

B. The record sufficiently shows that element 2 is satisfied

To satisfy element 2, the record must sufficiently show that the claims of a patent under *inter partes* review are also requested to be reexamined in the present reexamination proceeding.²⁰

Claims 1-15 of the '166 patent are requested to be reexamined in the present reexamination proceeding. The record shows that claims 1-15 of the '166 patent were also under review in the '894 IPR.²¹ Accordingly, the record shows that element 2 has been satisfied.

C. The record sufficiently shows that element 3 is satisfied

To satisfy element 3, the record must sufficiently show that the *inter partes* review has resulted in a final written decision pursuant to 35 U.S.C. 318(a).

The record shows that a final written decision pursuant to 35 U.S.C. 318(a) regarding claims 1-15 of the '166 patent was rendered by the PTAB in the '894 IPR on November 4, 2024.²² Accordingly, the record shows that element 3 has been satisfied.

D. The record sufficiently shows that element 4 is satisfied

To satisfy element 4, the record must sufficiently show that the ground(s) raised in the reexamination proceeding are the same ground(s) that were raised or reasonably could have been raised by the requester during the prior *inter partes* review. The record shows that the grounds raised by the requester to challenge claims 1-15 in the present reexamination proceeding were not previously raised in the prior *inter partes* review proceedings with regard to claims 1-15. Therefore, this element turns on whether the grounds reasonably could have been raised by the requester during the prior *inter partes* review proceedings.

1. “Reasonably could have been raised”

As an initial matter, the issue of what prior art reasonably could have been raised need not be further addressed if the record provides evidence, for example, that a reference was known to the requester at a time when it could have been raised in the *inter partes* review. The issue of what prior art reasonably could have been raised in an earlier *inter partes* review, however, is not limited to the actual knowledge of the requester. The legislative history of the AIA defines “reasonably could have raised” as “prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover.”²³ In view of the number of commercial databases available to the public, most patents and

²⁰ The Federal Circuit has specifically held that 35 U.S.C. 315(e)(1) applies on a claim-by-claim basis. In *Credit Acceptance v. Westlake Servs.*, 859 F.3d 1044, 1052-53 (Fed. Cir. 2017), the Federal Circuit explained (emphasis original):

On its face, the relevant IPR estoppel statute, § 315(e)(1) . . . applies on a claim-by-claim basis. It provides, “[t]he petitioner in an *inter partes* review of a claim in a patent . . . that results in a final written decision under section 318(a) . . . may not request or maintain a proceeding before the Office with respect to that claim . . .” 35 U.S.C. § 315(e)(1) (emphasis added). There is no IPR estoppel with respect to a claim as to which no final written decision results.

²¹ See *Fusion Orthopedics, LLC*, IPR2023-00894, Paper 64, pp. 65-66.

²² *Id.*

²³ See 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

printed publications, particularly U.S. patents and U.S. patent application publications, may, in general, be expected to be discovered by a skilled searcher conducting a diligent search.

A requester may, however, provide evidence that a skilled searcher conducting a diligent search reasonably could not have been expected to discover the reference. The legislative history of the AIA distinguishes the meaning of the language “reasonably could have raised” from an interpretation which would have required a “scorched-earth search”:²⁴

The present bill also softens the could-have-raised estoppel that is applied by *inter partes* review against subsequent civil litigation by adding the modifier “reasonably.” It is possible that courts would have read this limitation into current law’s estoppel. Current law, however, is also amenable to the interpretation that litigants are estopped from raising any issue that it would have been physically possible to raise in the *inter partes* reexamination, even if only a scorched-earth search around the world would have uncovered the prior art in question. Adding the modifier “reasonably” ensures that the could-have-raised estoppel extends only to that prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover.

The requester may show, for example, that a reference is an “obscure text[] unlikely to be discovered upon a reasonably diligent search of the relevant prior art.”²⁵

2. All grounds in the present request reasonably could have been raised in the prior IPR

At page 1 of the request, requester certified that the statutory estoppel provisions of 35 U.S.C. § 315(e)(1) and 325(e)(1) do not prevent requester from filing the request stating as follows:

Requester certifies that the statutory estoppel provisions of 35 U.S.C. §§ 315(e)(1) and 325(e)(1) do not prevent Requester from filing this Request. In particular, the new reference cited (US2011/0087227 A1 to Mazur) did not come to Requester’s attention until Patent Owner attempted to amend the claims of the ’166 patent during the IPR. The reference was discovered in an updated search commissioned during the IPR that was specifically focused on the new limitation Patent Owner added to the claims in its Revised Motion to Amend.

However, requester’s assertion that Mazur “did not come to Requester’s attention until Patent Owner attempted to amend the claims of the ’166 patent during the IPR” is not sufficient to demonstrate that a ground based on Mazur challenging claims 1-15 of the ’166 patent could not reasonably have been raised when filing the original ’894 IPR petition. For example, this statement by requester does not show that Mazur is an “obscure text[] unlikely to be discovered upon a reasonably diligent search of the relevant

²⁴ 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

²⁵ See *Praxair Distribution, Inc. et al. v. INO Therapeutics, LLC*, IPR2016-00781, Paper 10, p. 9 (PTAB August 25, 2016).

prior art.”²⁶ Rather, the record shows that the Mazur reference is a U.S. Patent with a publication date of April 14, 2011. As discussed above, the legislative history of the AIA distinguishes the meaning of the language “reasonably could have raised” as “prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover.” Here, because the proposed grounds of the present reexamination request are based on a U.S. Patent, a skilled searcher conducting a diligent search reasonably could have been expected to discover the Mazur reference and assert it when initially filing the ’894 IPR petition. Therefore, the proposed grounds asserting a substantial new question of patentability in the present request based on the Mazur reference reasonably could have been raised in the prior ’894 IPR, and the record shows that element 4 has been satisfied.

The record sufficiently shows that the estoppel provisions of 35 U.S.C. 315(e)(1) apply with respect to claims 1-15 of the ’166 patent. As stated above, the record shows that the third party requester of the present reexamination proceeding (Fusion Orthopedics, LLC) is the petitioner of the ’894 IPR, and that IPR resulted in the USPTO issuing a final written decision pursuant to 35 U.S.C. 318(a) regarding claims 1-15. Further, the proposed grounds in the present request reasonably could have been raised by Fusion Orthopedics, LLC in the prior ’894 IPR. The Mazur reference was known to Fusion Orthopedics, LLC during the ’894 IPR and reasonably could have been expected to be discovered when initially filing the ’894 IPR petition. Accordingly, under the particular facts and circumstances in this instance, the requester is estopped under 35 U.S.C. 315(e)(1) from requesting reexamination of claims 1-15 of the ’166 patent on the grounds raised in the request.

III. Requester’s certification pursuant to 37 CFR 1.510(b)(6) is improper

37 CFR 1.510(b)(6) requires the requester to submit, with its request, a certification that the statutory estoppel provisions of 35 U.S.C. 315(e)(1) or 35 U.S.C. 325(e)(1) do not prohibit the requester from filing the *ex parte* reexamination request. As set forth in section II of this decision, requester is estopped under 35 U.S.C. 315(e)(1) from requesting reexamination of claims 1-15 of the ’166 patent on the grounds raised in the request. Thus, requester’s certification pursuant to 37 CFR 1.510(b)(6), which was submitted with its request for *ex parte* reexamination in the present reexamination proceeding, is **improper**.

IV. The request fails to comply with *ex parte* reexamination filing date requirements

To be entitled to a filing date, a request must comply with all of the requirements of 37 CFR 1.510. *See* 37 CFR 1.510(d). If the request is erroneously granted a filing date, it will generally be vacated upon discovery of the error. *See* MPEP 2227, subsection B.

The Office may, at its option, grant a filing date to a request which is sufficiently compliant with the provisions of 37 CFR 1.510, despite the presence of minor formal defects. However, an improper certification pursuant to 37 CFR 1.510(b)(6), i.e., that the estoppel provisions of 35 U.S.C. 315(e)(1) or 35 U.S.C. 325(e)(1) do not prohibit the requester from filing the present reexamination request, is **NOT** a “minor formal defect.”

²⁶ *See* Praxair Distribution, Inc. et al. v. INO Therapeutics, LLC, IPR2016-00781, Paper 10, p. 9 (PTAB August 25, 2016).

In the present case, the request does not meet the requirement set forth in 37 CFR 1.510(b)(6) for a **proper** certification that the estoppel provisions of 35 U.S.C. 315(e)(1) or 35 U.S.C. 325(e)(1) do not prohibit the requester from filing the present reexamination request. For this reason, the request deposited on December 13, 2024 in the present *ex parte* reexamination proceeding **is not entitled to a filing date**.

Accordingly, the filing date of December 13, 2024, which was assigned to the request for the present *ex parte* reexamination proceeding, is hereby **vacated**.

Any other communications issued by the Office in this proceeding, **and the proceeding as a whole**, are hereby **vacated**.

The deposited request papers, previously issued Office communications, and any other papers deposited by the parties in the present reexamination proceeding, were scanned into the electronic Image File Wrapper (IFW) to create a record. Since it has been determined that the request for *ex parte* reexamination deposited on December 13, 2024 was not entitled to a filing date, **all papers**, including the request papers, previously issued Office communications, and any other papers deposited by the parties in the present reexamination proceeding, **will be expunged** by marking the papers “closed” and “non-public,” and will not constitute part of the public record.

A refund of the reexamination filing fee will be made to the requester in due course.

The present decision will, however, **remain open to the public**, to provide a record of the action being taken.

CONCLUSION

1. Requester’s certification, deposited with the request in the present reexamination proceeding, pursuant to 37 CFR 1.510(b)(6) is **improper**. Requester is estopped under 35 U.S.C. 315(e)(1) from requesting reexamination of claims 1-15 of the ’166 patent on the grounds raised in the request.
2. Because the request fails to comply with the requirement for a proper certification pursuant to 37 CFR 1.510(b)(6), the request deposited on December 13, 2024 in the present *ex parte* reexamination proceeding **is not entitled to a filing date**.
3. The filing date of December 13, 2024, which was assigned to the request papers for the present *ex parte* reexamination proceeding, is **vacated**.
4. All other papers issued by the Office in the present reexamination proceeding, and the proceeding as a whole, are **vacated**.
5. **All papers**, including the request papers, previously issued Office communications, and all other papers deposited by the parties in the present reexamination proceeding **will be expunged** by marking the papers “closed” and “non-public,” and will not constitute part of the public record.

6. A refund of the reexamination filing fee will be made to the requester in due course.
7. The present decision **will remain open to the public** to provide a record of the action being taken.
8. Telephone inquiries related to this decision should be directed to Stephen Stein, Managing Quality Assurance Specialist, at (571) 272-1544.

Pinchus M. Laufer

Pinchus M. Laufer
Senior Patent Attorney
Office of Patent Legal Administration

February 21, 2025