MEMORANDUM

To:

All Patent Applicants and Patent Practitioners

From:

John A. Squires

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Subject:

Best Practices for Submission of Rule 132 Subject Matter Eligibility Declarations

(SMEDs)

Date:

December 4, 2025

I. Introduction

This memorandum addresses the best practice for submitting Subject Matter Eligibility Declarations (SMEDs) under 37 CFR 1.132 to address subject matter eligibility (SME) rejections in U.S. patent prosecution. Specifically, it supports the proposition that SMEDs should be submitted as separate documents and not combined with declarations or testimony addressing other issues, such as obviousness (e.g., secondary considerations or motivation to combine). Further, attached as <u>Appendix A</u> is a memorandum distributed to the USPTO Examining Corps, which is intended to alert (and remind) the Examiners that applicants voluntarily may submit SMEDs pursuant to existing Rule 132 (SMED Examiner Memo).

II. USPTO Guidance and Rationale

A. SMEDs and Subject Matter Eligibility

The SMED Examiner Memo highlights the unique evidentiary role of SMEDs in addressing SME rejections. SMEDs are intended to clarify the record and provide objective evidence specifically relevant to the eligibility of the claimed invention under 35 U.S.C. § 101.

The SMED Examiner Memo states:

"For an evidentiary declaration to be relevant, there must be a nexus between the invention as claimed and the evidence provided in the declaration. ... a SMED may demonstrate how one of ordinary skill in the art would interpret a specification that describes a technological improvement to show that the claimed invention is patent-eligible subject matter."

The SMED Examiner Memo further emphasizes that SMEDs must not improperly supplement the specification and must be timely filed, with a clear nexus to the claimed invention.

B. Risks of Combining SMEDs with Other Testimony

Though it is permissible to file a single declaration under 37 CFR 1.132 addressing rejections under multiple statutory requirements, applicants are encouraged to submit a *separate* SMED to address subject matter eligibility. By providing testimony and objective evidence directed solely to the SME of the claimed invention, the applicant may avoid the risk of intertwining issues of enablement, written description, novelty and nonobviousness with those of subject matter eligibility. The USPTO's Manual of Patent Examining Procedure (MPEP) provides separate guidance for declarations addressing SME (§ 101) and those addressing obviousness (§ 103):

- MPEP 716: Declarations under Rule 132 must be relevant to the specific rejection traversed.
- MPEP 2106: Declarations can be submitted to provide evidence traversing a subject matter eligibility rejection under 35 U.S.C. 101. See MPEP 2106.07(b). For example, in response to a subject matter eligibility rejection, a declaration can be submitted to provide testimony on how one of ordinary skill in the art would interpret the disclosed invention as improving technology and the underlying factual basis for that conclusion. See MPEP 2106.05(a).
- MPEP 2145: Declarations for obviousness may address secondary considerations and motivation to combine, which are distinct from SME issues.

Combining these can lead to confusion regarding the evidentiary weight and relevance of the testimony, and may complicate the examiner's analysis and the applicant's record.

C. Examiner Consideration

The SMED Examiner Memo instructs examiners to:

"carefully consider all of the applicant's arguments and the evidence rebutting the subject matter eligibility rejection when evaluating the applicant's response."

As noted above, if a SMED is combined with other, non-SME testimony, the examiner may have difficulty isolating the evidence relevant to SME, potentially diminishing the probative value of the SMED and complicating the Office action. Moreover, MPEP 716.01(d) provides additional information relating to examiner consideration when an applicant timely submits evidence traversing a rejection.

III. Third-Party and USPTO Guidance

A. USPTO Training Materials

USPTO training materials and job aids treat declarations for SME and obviousness as distinct submissions. For example:

- USPTO Entry Level and Training for Experienced Examiner (TEE) Training:
 Declaration Practice Under 37 CFR 1.132: Recommends declarations be tailored to the specific rejection traversed.
- TC 1600 Job Aid on Evidence of Unexpected Results Under 37 CFR 1.132: Focuses solely on obviousness, not SME.

B. Federal Circuit Case Law

Federal Circuit decisions reinforce the need for clear, focused evidentiary records:

- In re Oetiker, 977 F.2d 1443 (Fed. Cir. 1992): The burden of proof shifts depending on the rejection, and evidence must be relevant to the specific issue.
- In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007): The Board must consider all evidence submitted, including multiple declarations, and may not disregard any simply because they address different aspects of patentability.

C. Practitioner Guidance

Patent practitioners routinely advise submitting separate declarations for SME and obviousness. For example:

 AIPLA Practice Guide: Declarations should be responsive to the specific grounds of rejection they seek to overcome and should avoid combining arguments or evidence directed to different statutory requirements in a single declaration. • Fish & Richardson, "Best Practices for Rule 132 Declarations": When addressing multiple statutory issues (e.g., § 101 eligibility and § 103 obviousness), consider using separate Rule 132 declarations. This approach improves clarity, avoids confusion, and ensures that each declaration is focused on the specific rejection being traversed.

IV. Conclusion

Based on USPTO guidance, Federal Circuit precedent, and practitioner best practices, SMEDs addressing subject matter eligibility under Rule 132 should be submitted as separate documents and not combined with testimony on other issues such as obviousness. This approach:

- Ensures clarity and relevance of the evidentiary record.
- Facilitates examiner review and decision-making.
- Enhances the clarity and may bolster probative value of the SMED.
- Reduces risk of procedural or substantive confusion.

References:

- USPTO SMED Memorandum to the Examining Corps, December 4, 2025 (attached as <u>Appendix A</u>)
- MPEP 716, 2106.05(a), 2145
- In re Oetiker, 977 F.2d 1443 (Fed. Cir. 1992)
- In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007)
- AIPLA Practice Guide
- Fish & Richardson, "Best Practices for Rule 132 Declarations"
- USPTO TEE Training Materials

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Appendix A

(USPTO Memorandum to Examiners on Subject Matter Eligibility Declarations)