Patent Eligibility Bulletin: New USPTO Guidance And AI Risks

By **David Glass and Reilley Keane** (July 31, 2026)

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This article is part of a quarterly column that discusses the rapidly evolving field of subject matter eligibility at the U.S. Patent and Trademark Office and courts, and practical guidance for practitioners. In this installment, we discuss a recent decision from the U.S. Court of Appeals for the Federal Circuit reinforcing the boundaries of patent eligibility as it concerns artificial intelligence and machine learning models, as well as the updated USPTO guidance on subject matter eligibility declarations.

As discussed in our prior installment, under Director John Squires, the U.S. Patent and Trademark Office has signaled a more permissive stance toward patent eligibility, particularly for AI-related inventions.

However, the Federal Circuit continues to apply the framework established by the Supreme Court's 2014 decision in Alice Corp. v. CLS Bank International rigorously.

Additionally, a recent decision concerning application of an AI/ML model illustrates the persistent risks facing claims that merely apply a generic AI/ML model within a new environment, without more, will not render the claims patent-eligible subject matter.

Meanwhile, the USPTO has issued updated guidance on subject matter eligibility declarations, or SMEDs, reinforcing their utility as a prosecution tool for overcoming subject matter eligibility rejections under Title 35 of the U.S. Code, Section 101.

Updated USPTO Guidance on Subject Matter Eligibility Declarations

On April 30, Squires issued an updated memorandum, superseding the December 2025 guidance for best practices for submission of Rule 132 subject matter eligibility declarations.

The memorandum is consistent with and reinforces the December guidance, and signals that SMEDs have been helpful to applicants. A SMED is a voluntary declaration that patent applicants may submit to present objective evidence showing how someone skilled in the

art in a relevant field would view the specification and recognize that the invention describes a technological advance that is patent-eligible under Section 101.

The USPTO proposes making the SMED memo a living document that will incorporate periodic updates based on practitioner experience and gathered knowledge. The USPTO has indicated that early feedback shows voluntary submitters of SMEDs are having success.

However, the USPTO emphasized that SMEDs should be separate from other Rule 132 declarations. The USPTO is encouraging practitioners to file stand-alone SMEDs dedicated solely to Section 101 issues. Doing so minimizes the risk of conflating Section 101 eligibility issues with those arising under other statutory provisions, such as Section 102 or Section 103.

Additionally, for an evidentiary SMED to be relevant, there must be a nexus between the invention as claimed and the evidence provided in the SMED. A SMED may demonstrate how someone skilled in the art would interpret a specification describing a technological improvement to show patent eligibility, but the USPTO cautioned that SMEDs must not improperly supplement the specification and must provide a clear nexus to the claimed invention, in addition to being timely filed.

In situations where a SMED contains unrelated testimony, the USPTO cautioned practitioners that examiners may struggle to isolate the evidence relevant to subject matter eligibility, which may ultimately complicate the resulting office action.

Further, the USPTO noted that it received suggestions that the Manual of Patent Examining Procedure's Section 716.01(c)(III) may not describe the full meaning of a declaration as evidence and is taking such suggestions under advisement to determine if a revision to this MPEP section is warranted. Specifically, commentators have suggested that declarations need not affirmatively persuade, and that absent contrary evidence, they should not be treated as subject to open-ended weighing.

Notably, the USPTO confirmed, based on practitioner feedback, that examiners bear the initial burden upon review of all grounds presented under Rule 132 affidavits, including SMED submissions.

Submitting a stand-alone SMED may carry greater weight in traversing a Section 101 rejection and is less likely to generate procedural complications associated with

prosecution of a patent application. The evidence provided in the SMED should have a nexus to the claimed invention and should not supplement the written description. This is particularly relevant for applicants in subject matter areas where eligibility under Section 101 remains a frequently contested issue, such as software, AI, data analytics and computation, and medical diagnostics.

Dental Monitoring

In Dental Monitoring SAS v. Align Technology Inc., **decided** by the Federal Circuit on July 21, Dental Monitoring appealed a final decision granting summary judgment that Claims 1 and 14 of U.S. Patent 11,049,248 and Claims 1, 7 and 12 of U.S. Patent 10,755,409 are directed to ineligible subject matter under Section 101.

The '248 patent is directed to a method for assessing the shape of an orthodontic aligner using a deep learning device. The '409 patent is directed to a method for acquiring an image of a dental arch and analyzing it using a deep learning device.

At Step 1 of the Alice framework, the court found that the showdown claims were directed to an abstract idea because they focus on collecting information, analyzing it, and displaying certain results of the collection and analysis.

Dental Monitoring argued that the deep learning device can perform a more precise and objective evaluation of the fit of an aligner than was previously possibly. The court rejected this argument because it ignored that the language of the showdown claims did not require such an evaluation.

Further, the court noted that use of a deep learning device does not change the eligibility analysis and simply applying machine learning to the abstract idea within a new environment does not transform the claims into patent-eligible subject matter.

Dental Monitoring additionally argued that the deep learning device was trained on specific data that provides a specific technological solution embodied in the showdown claims. The court also rejected this argument, noting that training on specific data does not confer eligibility.

While Claim 14 of the '248 patent and Claim 7 of the '409 patent require that the deep learning device be trained on a learning base that comprises more than a thousand images of dental arches, the court reasoned that it did not mean those claims provided a specific

technological solution, and that training a deep learning device on a specific subset of data is incidental to the very nature of machine learning, and thus is not a technological improvement that would render the claims patent-eligible under Section 101.

Finally, the court noted that the claim language reciting a "determination ... of an amplitude of said separation [between the tooth and the aligner]" is regularly performed by dentists without the use of a deep learning device, such that the claims at best provide greater efficiency or speed, which the court reasoned does not render the claims as patent-eligible under Section 101, and the court found that the claims were directed to an abstract idea under Step 1.

At Step 2, the court found that the showdown claims did not recite an inventive concept that was sufficient to transform the ineligible abstract idea into patent-eligible subject matter.

Dental Monitoring argued that the claims recite an inventive concept because the deep learning device must be trained with a specific process and the court disagreed, once more reasoning that specially training a machine learning model is incidental; to the very nature of machine learning, such that it does not render the machine learning model recited in the claims as nongeneric.

Dental Monitoring additionally argued that using a deep learning device to guide orthodontic treatment was not conventional at the time the patent issued, but the court noted that the relevant inquiry is not whether the claimed invention as a whole is unconventional or nonroutine, but rather whether the claim recites an inventive concept that transforms the claim into significantly more than the abstract idea.

The court noted that given the patents themselves confirm that the deep learning device is generic based on the description provided in the specification, the argument was unavailing.

Alternatively, Dental Monitoring argued that there is a factual dispute regarding the well-understood nature of the claims so as to prevent a grant of summary judgment, which the court also rejected noting that the patents themselves confirm the conventional nature of the deep learning device.

The outcome of this case reinforces the Federal Circuit's approach from Recentive Analytics v. Fox Corp. last year, as it relates to determining subject matter eligibility of

AI/ML-related patent claims under Section 101.

Conclusion

The second quarter of 2026 has continued to illustrate the juxtaposition of the USPTO's increasingly permissive stance toward patent eligibility and the Federal Circuit's rigorous application of the Alice framework.

The decision in Dental Monitoring serves as a reminder that applying generic machine learning or deep learning components to a new field of use — here, dental aligner assessment — does not confer patent eligibility.

Even if the generic machine learning model is trained on domain-specific data, such training is still generic as the training of the model is incidental to the very nature of machine learning, and cannot provide an inventive concept.

Finally, even if the claims recite performing a task using a machine learning model that provides greater speed or efficiency over humans who previously performed the task, it will not provide a specific implementation that renders the claims patent-eligible under Section 101.

The USPTO's updated SMED guidance provides practitioners with a refined tool for overcoming Section 101 rejections during prosecution.

These developments underscore the importance of strategic claim drafting that emphasizes concrete technical mechanisms, supported by specifications that clearly articulate the technical problem, solution and corresponding benefits and considering the use of a SMED to confirm the technical problem, solution and corresponding benefits during prosecution. This approach positions applications to better withstand eligibility scrutiny in both the USPTO and the courts.

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