

in *Amgen*, the method “simply directs skilled artisans to engage in the same iterative, trial-and-error process the inventors followed to discover the eleven antibodies they elected to disclose” and that “[u]nder *Amgen*, such random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a).” *Id.* at \*8, \*10. In response to an argument that the district court’s enablement determination was inconsistent with *Wands*, the Federal Circuit stated, “[w]e do not interpret *Amgen* to have disturbed our prior enablement case law, including *Wands* and its factors,” and “[w]e see no meaningful difference between *Wands*’ ‘undue experimentation’ and *Amgen*’s ‘[un]reasonable experimentation’ standards.” *Id.* at \*10.

In *Medytox*, another post-*Amgen* enablement decision, the Federal Circuit affirmed a PTAB decision in a post-grant review proceeding using the *Wands* factors and found that the full scope of a substitute claim was not enabled. *Medytox*, 71 F.4th at 998–999. The substitute claim was directed to a method of using an animal protein-free botulinum toxin composition that exhibited a longer-lasting effect in the patient than an animal protein-containing botulinum toxin composition, and included a responder rate limitation of 50% or greater. *Id.* at 993. The Federal Circuit interpreted the responder rate limitation as having an upper limit of 100%. *Id.* at 997. The specification contained, at most, three examples of responder rates above 50%. *Id.* at 998. Employing the *Wands* factors, the PTAB found that a skilled artisan, reading the specification, would not have been able to achieve higher than 62% for the responder rate limitation without undue experimentation. *Id.* at 998–99. Citing *Amgen*, the Federal Circuit stated that “[t]he more one claims, the more one must enable” and that although the specification does not need to always “describe with particularity how to make and use every single embodiment within a claimed class, it must nevertheless enable the full scope of the invention as defined by its claims, for example by disclosing [a] general quality of the class that may reliably enable a person skilled in the art to make and use all of what is claimed.” *Id.* at 998 (internal quotations omitted). The Federal Circuit found that the PTAB provided an adequate explanation and reasoning for its enablement finding, which utilized the *Wands* factors, and found no error in the

PTAB’s determination of a lack of enablement. *Id.* at 999.

Finally, in *Starrett*, another post-*Amgen* enablement decision, the Federal Circuit affirmed a PTAB decision in an ex parte appeal upholding an examiner’s rejection for a lack of enablement of a claim to a non-transitory computer readable medium for maintaining augmented telepathic data for telepathic communication. *Starrett*, 2023 WL 3881360 at 1. While reviewing the examiner’s enablement rejection, the PTAB treated the claim as a genus claim because it contained 47 “or” clauses and potentially covered over 140 trillion embodiments. *Id.* at 2. The PTAB affirmed the examiner’s determination of a lack of enablement and found that the examiner properly analyzed all the relevant *Wands* factors when making the determination that the claim lacked enablement. *Id.* The Federal Circuit once again cited *Amgen* for the proposition that “the specification must enable the full scope of the invention as defined by its claims,” and the “more one claims, the more one must enable.” *Id.* at 4. The Federal Circuit found that, as in *Amgen*, “[h]ere, much is claimed, and little is enabled.” *Id.* In reliance on *Amgen*, the Federal Circuit stated that “[a]lthough a finding of enablement is not precluded by a skilled artisan’s need[] to engage in some measure of experimentation, the extent of that experimentation must be reasonable.” *Id.* The Federal Circuit endorsed using the *Wands* factors to determine whether the amount of experimentation required in *Starrett* was reasonable when it stated that “[t]he determination as to whether the extent of experimentation is undue or reasonable is informed by the eight *Wands* factors.” *Id.* In concluding that the claim lacked enablement, the Federal Circuit found that nothing in the specification or claims undermined the PTAB’s reliance on the examiner’s *Wands* factor analysis and that the examiner’s discussion of the *Wands* factors “properly faulted the specification for failing to describe *how* the claim elements function,” thereby indicating that the *Wands* factors should be used to determine whether the experimentation was reasonable. *Id.* at 4–5 (emphasis in original).

#### Conclusion

Therefore, consistent with *Amgen* and the Federal Circuit’s post-*Amgen* decisions of *Baxalta*, *Medytox*, and *Starrett*, when assessing whether the claims in a utility patent application or patent are enabled, regardless of the technology, USPTO personnel will continue to use the *Wands* factors to

ascertain whether the experimentation required to enable the full scope of the claimed invention is reasonable. The explanation in an enablement rejection or in a PTAB determination that a claim is not enabled should focus on those factors and the reasons and evidence that led the examiner or decision-maker to arrive at their conclusion. See MPEP 2164.04. The *Wands* analysis should provide adequate explanation and reasoning for a lack of enablement finding in order to facilitate the USPTO’s clarity of the record goals, as well as the USPTO’s goals of providing consistency between examination and post-grant challenges.

#### Katherine Kelly Vidal,

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

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## DEPARTMENT OF DEFENSE

### Department of the Army

#### Army Education Advisory Committee Meeting Notice

**AGENCY:** Department of the Army, DoD.

**ACTION:** Notice of open committee meeting.

**SUMMARY:** The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Army Education Advisory Committee (AEAC). This meeting is open to the public.

**DATES:** The Army Education Advisory Committee will meet from 8 a.m. to 5 p.m. on both January 24–25, 2024.

**ADDRESSES:** Army Education Advisory Committee, 950 Jefferson Avenue, Building 950, U.S. Training and Doctrine Command (TRADOC) Headquarters, Conference Room 2047, Ft. Eustis, VA 23604.

**FOR FURTHER INFORMATION CONTACT:** Dr. Justin M. Green, the Designated Federal Officer for the committee, in writing at ATTN: ATTG-TRI-G, TRADOC, 950 Jefferson Ave, Fort Eustis, VA 23604, by email at [justin.m.green12.civ@army.mil](mailto:justin.m.green12.civ@army.mil), or by telephone at (757) 501-9935.

**SUPPLEMENTARY INFORMATION:** Due to circumstances beyond the control of the Designated Federal Officer, the Army Education Advisory Committee was unable to provide public notification required by 41 CFR 102-3.150(a) concerning its January 24–25, 2024 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41

CFR 102–3.150(b), waives the 15-calendar day notification requirement.

The committee meeting is being held under the provisions of the Federal Advisory Committee Act (FACA; 5 U.S.C. 10), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

*Purpose of the Meeting:* The purpose of the meeting is to review TRADOC Priorities, the AEAC Charter, and to conduct mandatory annual ethics training. The Committee will also receive an overview of the Fiscal Year 2024 AEAC Study which will focus on the modernization of the Special Operations School of Excellence (SOCoE).

*Agenda:* January 24 and 25: The committee is chartered to provide independent advice and recommendations to the Secretary of the Army on the educational, doctrinal, and research policies and activities of U.S. Army educational programs. The committee will complete all FACA annual requirements, will begin discussions related to the modernization of the Special Operations School of Excellence (SOCoE), and discuss and deliberate provisional findings and recommendations submitted by its subcommittees.

*Public Accessibility to the Meeting:* Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Attendees are requested to submit their name, affiliation, and daytime phone number seven business days prior to the meeting to Dr. Green, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section.

Because the meeting of the committee will be held in a Federal Government facility on a military base, security screening is required. A photo ID is required to enter base. Please note that security and gate guards have the right to inspect vehicles and persons seeking to enter and exit the installation. TRADOC Headquarters is fully handicap accessible. Wheelchair access is available in front at the main entrance of the building. For additional information about public access procedures, contact Dr. Green, the committee's Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

*Written Comments or Statements:* Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the

public or interested organizations may submit written comments or statements to the committee in response to the stated agenda of the open meeting or in regard to the committee's mission in general. Written comments or statements should be submitted to Dr. Green, the committee Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The Designated Federal Official will review all submitted written comments or statements and provide them to members of the committee for their consideration. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Designated Federal Official at least seven business days prior to the meeting to be considered by the committee. Written comments or statements received after this date may not be provided to the committee until its next meeting.

Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public will be permitted to make verbal comments during the Committee meeting only at the time and in the manner described below. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least seven business days in advance to the committee's Designated Federal Official, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. The Designated Federal Official will log each request, in the order received, and in consultation with the committee Chair, determine whether the subject matter of each comment is relevant to the committee's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three minutes during the period, and will be invited to speak in

the order in which their requests were received by Designated Federal Official.

**James W. Satterwhite Jr.,**

*Army Federal Register Liaison Officer.*

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2544–000]

#### Hydro Technology Systems; Notice of Authorization for Continued Project Operation

The license for the Meyers Falls Hydroelectric Project No. 2544 was issued for a period ending December 31, 2023.

Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee(s) under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2544 is issued to Hydro Technology Systems for a period effective January 1, 2024, through December 31, 2024, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before December 31, 2024, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the