risk of cardiovascular diseases; for use in diabetes management; for identifying or inferring the identity of a microorganism directly from clinical material; for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; for noninvasive testing; or for near-patient testing (point of care).

Exemption from the requirement of premarket notification does not exempt a device from other applicable regulatory controls under the FD&C Act, including the applicable general and special controls. Indeed, FDA's decision to grant 510(k) exemption for these devices is based, in part, on the special controls, in combination with general controls, providing sufficiently rigorous mitigations for the risks identified for this generic type.

This exemption from 510(k), subject to the limitations described above, is immediately in effect for autosomal recessive carrier screening gene mutation detection systems. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulation. Specifically, regulated industry will no longer have to invest time and resources in premarket notifications, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review for devices in this exempted type.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart, E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

IX. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*
2. FDA Guidance for Industry and FDA Staff ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems,'' October 26, 2005, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071104.pdf.*

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 2. In § 866.5940, revise paragraph (b) introductory text to read as follows:

§ 866.5940 Autosomal recessive carrier screening gene mutation detection system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9, except § 866.9(c)(2). Autosomal recessive carrier screening gene mutation detection system must comply with the following special controls:

* * * * *

Dated: November 1, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24162 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2016–0029]

RIN 0651–AD10

Rule on Attorney-Client Privilege for Trials Before the Patent Trial and Appeal Board

AGENCY: Patent Trial and Appeal Board, United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule on attorney-client privilege amends the existing rules relating to the United States Patent and Trademark Office (Office or USPTO) trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings that implemented provisions of the Leahy-Smith America Invents Act (''AIA'') providing for trials before the Office.

DATES: This rule is effective on December 7, 2017.

FOR FURTHER INFORMATION CONTACT: Edward Elliott, Attorney Advisor, by telephone at (571) 272–7024 or by email at *edward.elliott@uspto.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: This final rule clarifies situations where privilege is recognized for communications between clients and their domestic or foreign patent attorneys and patent agents.

Background

In February 2015, the USPTO held a roundtable and solicited comments on attorney-client privilege issues. *See* Notice of Roundtable and Request for Comments on Domestic and International Issues Related to Privileged Communications Between Patent Practitioners and Their Clients, 80 FR 3953 (Jan. 26, 2015). As part of that process, the USPTO requested comments on whether communications between patent applicants or owners with their U.S. patent agents or foreign patent practitioners should be recognized as privileged to the same

extent as communications with U.S. patent attorneys. Respondents unanimously supported a rule recognizing such privilege in courts. *See* USPTO, Summary of Roundtable and Written Comments, available at *http://www.uspto.gov/sites/default/files/documents/Summary%20of%20Privileged%20Communication%20Roundtable.pdf* (''Privilege Report'').

Some roundtable participants noted that rules regarding privilege for U.S. patent agents and foreign practitioners in PTAB discovery proceedings were difficult to discern, as there has been no explicit rule on privilege. When the issue arises before PTAB, Administrative Law Judges make legal determinations as to which communications may be protected from disclosure on a case-by-case basis, based on the Federal Rules of Evidence and common law. *See* 37 CFR 42.62(a); *see also GEA Process Engineering, Inc.* v. *Steuben Foods, Inc.,* IPR2014–00041, Paper 117 (PTAB 2014). U.S. courts have devised several different approaches to determine under what circumstances communications with these practitioners are privileged. As the Privilege Report notes, the common law on privilege for domestic and foreign patent practitioners varies across jurisdictions. Different approaches are taken, and results sometimes conflict. This may lead to administrative inefficiencies and inconsistencies in outcomes, as PTAB must select which set of common law rules to follow.

Administrative Law Judges in other agencies have treated certain confidential communications with a patent agent as privileged. *See, e.g.,* USITC Inv. No. 337–TA–339, slip op. at 2, 1992 WL 811804 (ITC 1992) (finding that confidential communications between a U.S. patent agent and his client in connection with a patent prosecution are privileged). In 2016, the Federal Circuit recognized that attorney-client privilege applies to U.S. patent agents acting within the scope of their authorized practice. *See In re Queen's University at Kingston,* 820 F.3d 1287 (Fed. Cir. 2016).

To address the aforementioned issues with privilege rules, the USPTO put forth a proposed PTAB rule for public comment in October 2016. *See* Rule Recognizing Privileged Communications Between Clients and Patent Practitioners at the Patent Trial and Appeal Board, 81 FR 71653 (Oct. 18, 2016). The Office received eighteen comments from bar associations, trade groups, law firms, and individuals. The Office expresses its gratitude for the thoughtful and comprehensive comments provided by the public, which are available online at *https://www.regulations.gov/docket?D=PTO-P-2016-0029.*

The vast majority of commenters expressed support for this rule, echoing the need for clarity and certainty in this area. The policy arguments they raised in favor are already covered extensively in the Privilege Report. Several commenters raised additional issues about specific language in the proposed rule, which are addressed herein. A few commenters opposed the rule based on misunderstandings of the scope and purpose of the rule, which are clarified herein as well. Based on the feedback, the Office presents the following final rule on recognizing privilege for patent attorneys and agents.

Responses to Comments

Nature of Privilege

Comments: Some comments expressed concern over the scope and interpretation of the proposed rule. One commenter objected to expanding those eligible to practice before PTAB to include agents. Others characterized the rule as primarily to protect communications between clients and counsel involved in PTAB proceedings.

Response: Attorney-client privilege exists to protect clients. It allows them to have full and frank discussions with attorneys when seeking legal advice, without fear that those discussions will be used against them in legal proceedings. The privilege vests with the client, not the attorney, and does not confer authorization to practice law, but rather flows from those already having such authorization. Because of this, recognizing privilege for patent agents does not determine what types of work they are authorized to perform. The authorized functions of patents agents, including representing clients before PTAB, are established in 37 CFR 11.5(b). Likewise, privilege does not confer additional power to patent agents because it vests in the client, not the agent or attorney. Applying the privilege to agents simply recognizes that they perform legal services and that clients deserve the same protections regardless of which type of authorized legal provider they choose. Further, some foreign jurisdictions rely entirely or almost entirely on non-attorney patent agents. In such jurisdictions, hiring an attorney to handle patent matters can be difficult or impossible. *See* the Privilege Report for further discussion of the policy considerations supporting privilege for patent agents.

More fundamentally, this rule is not intended primarily to protect communications between clients and their counsel for purposes of PTAB proceedings. Rather, it is primarily intended to protect communications made when seeking patents at the USPTO or foreign IP offices, such as when prosecuting applications or contemplating whether to file. The counsel on those communications may not be involved in any PTAB proceedings. Communications about prosecution are much more commonly implicated in PTAB discovery proceedings than communications about the PTAB proceeding itself. Perhaps this reflects the inherent asymmetry of privilege protections: Both parties are affected if their communications seeking legal advice about the PTAB proceeding are discoverable, whereas only the patent holder is affected by discovery of communications from prosecution. Regardless, the purpose of the rule is to protect any communications with authorized counsel from discovery in PTAB, not just communications about the instant proceeding.

Similarly, this privilege rule does not affect an attorney, agent, or applicant's duty to disclose material information to the USPTO at any time, as the duty of disclosure under 37 CFR 1.56 continues to be controlling. This duty is not at odds with privilege protections; the duty of disclosure governs all information known by a party and establishes whether information must be provided to the USPTO, while privilege governs material available to third party adversaries in adjudicated proceedings under part 42. For instance, the privilege rule does not apply in the filing and prosecution of a patent application. Further, the privilege only protects information exchanged for purposes of obtaining legal opinions or services, not underlying facts or business documents. The precise metes and bounds of what types of communications are protected by privilege are determined according to Federal law. Finally, this rule does not nullify privilege for others who are not covered by the rule, such as attorneys not admitted to practice before the USPTO or a foreign patent office. Other sources of privilege under Federal law remain unaffected.

Scope of Activities

Comments: Some commenters requested clarity on the scope of covered activities. One commenter asked the USPTO to clarify whether a communication with a registered patent agent about claim interpretation of an issued patent would qualify as privileged. Others asked for general clarification of what activities by patent agents would be covered, with one

requesting examples of activities that would qualify for the privilege. One commenter noted that 37 CFR 11.5(b)(1) may not provide an exhaustive list of authorized activities.

Response: We understand the commenters' desire for clarity on these issues. The USPTO has described the functions agents are authorized to perform before the Office in 37 CFR 11.5(b)(1). Whether a particular scenario falls within the bounds of an agent's authorization is subject to determination by an appropriate authority.

More precisely defining what types of work patent agents are and are not authorized to perform is a much larger issue that goes far beyond privilege considerations. This rulemaking is not the proper forum to address that issue. If the public feels that the general definition of authorized functions put forth by the USPTO in § 11.5(b)(1) should be updated, they should contact the USPTO to express interest in a more comprehensive process to consider that issue, which accounts for the numerous equities involved. We also note that regardless of any clarifications made to the scope of authorized duties for U.S. patent agents, the USPTO cannot alter or clarify the authorized functions of foreign patent agents in their home jurisdiction, which are established by foreign laws and regulations.

Federal Privilege

Comments: One comment suggested clarifying that the ''same protections of privilege'' refers to Federal privilege, since state courts have their own separate sources of privilege.

Response: We concur and have adjusted the rule to specify ''privilege under Federal law'' in paragraph (a).

Direct Communications

Comments: One comment suggested that the rule as written may only cover communications directly between a client and a foreign practitioner, and not communications made by the client's U.S. attorney with the foreign practitioner. According to the comment, communications made between a client's representatives in the absence of the client could be inadvertently excluded by the current phrasing of the rule.

Response: Under U.S. Federal law, attorney-client privilege generally encompasses communications with an attorney made by the client's representatives as well as the client. Similarly, privilege generally encompasses communications made with an attorney's employee or assistant, as well as communications between multiple attorneys working for a client. That is not to say such communications are necessarily privileged; they must still meet the other requirements for privilege, such as appropriate subject matter. However, these parties are generally regarded as parties that fall within the scope of privilege, rather than as third parties who break privilege.

Under the new rule, communications with such parties should similarly be entitled to privilege under the same circumstances as when the practitioner is an attorney. However, we recognize that there is potential for a narrower reading of the proposed rule that does not cover communications with such parties and therefore affords lesser protection to non-attorney practitioners. We have added paragraph (c) to the rule to clarify that the scope of coverage will be the same for practitioners as for attorneys under these types of scenarios and any other situations. For instance, privilege will extend to communications with the aforementioned parties under appropriate circumstances, not just to communications directly between the practitioner and the client.

Limitations and Exceptions

Comments: One comment suggested explicitly defining which ''limitations and exceptions'' should apply to the privilege.

Response: Exceptions to attorney-client privilege such as crime/fraud are based on longstanding common law, which continues to evolve. Our purpose here is not to redefine those exceptions. This may lead to growing discrepancies as the common law changes, which could lead to disparate treatment of privilege for patent attorneys and agents compared with other attorneys. Rather, this rule codifies who is eligible for the privilege, while leaving questions about exceptions and limitations for general jurisprudence to address in a broader manner.

Practitioners With Limited Recognition

Comments: A couple of commenters noted that the rule does not extend to all categories of practitioners, namely, those granted limited recognition under 37 CFR 11.9.

Response: The rule has been amended to cover USPTO practitioners meeting the registration requirements of 37 CFR 11.7. This includes practitioners under both §§ 11.6 and 11.9(b), who have demonstrated the requisite legal, scientific, and technical qualifications and moral character. Foreign practitioners practicing at the USPTO under § 11.9(c) can qualify for privilege under paragraph (b) of the new rule through their admittance to practice in a foreign jurisdiction. Students in the USPTO law school clinic program practicing under § 11.16 can qualify for privilege under paragraph (c) of the new rule since they work under the supervision of a registered practitioner. At this time, we are not convinced an extension to other categories of practitioners is necessary or appropriate. It is not clear that recognizing privilege for these individuals furthers any of the policy reasons for applying privilege to patent agents, or that these individuals play a significant role in providing legal services for applicants.

Relation to In re Queen's

Comments: A few commenters noted the parallels between this rule and the Federal Circuit's decision in *In re Queen's University,* wondering if a USPTO rule is still necessary and whether there would be any distinction between our rule and the Federal Circuit's. One commenter mentioned a supposed difference in coverage for third-party patent validity opinions by agents.

Response: The USPTO supports the Federal Circuit's finding of privilege for patent agents as a matter of public policy. The Privilege Report catalogs the many reasons that privilege for patent agents is warranted. A USPTO rule on privilege is still needed, for at least several reasons. The *Queen's* decision was a 2–1 panel result, which may be revisited in future cases either en banc at the Federal Circuit or at the Supreme Court. There are clarity benefits to having a rule explicitly codified rather than only in common law.

Also, the Federal Circuit decision only addresses domestic patent agents, not foreign attorneys and agents. Without comparable protections in U.S. tribunals for foreign practitioners, privileged communications with U.S. patent attorneys may effectively lose that protection through parallel communications with foreign practitioners prosecuting corresponding foreign applications, which often raise very similar legal issues. Having a U.S. attorney supervise communications with foreign practitioners is not only an undesirable policy, but may not be enough to preserve privilege in all circumstances. Because the U.S. attorney is generally not authorized to practice law in foreign jurisdictions, the foreign attorney might not be considered as working ''under the supervision'' of the U.S. attorney in all instances. Further, some jurisdictions use non-attorney patent agents exclusively or predominantly, so it may not be possible for applicants to rely on

privilege afforded by U.S. courts to foreign attorneys. The new privilege rule protects eligible communications with qualified foreign attorneys and agents from discovery at PTAB, preventing such back door exposure. The rule does not have extraterritorial effects; how communications with U.S. and foreign practitioners are treated by foreign courts is entirely up to the foreign jurisdiction.

Another reason for the USPTO's rule is administrative economy and judicial efficiency, as explained by commenter John Cross of the University of Louisville. The typical approach to privilege for foreign practitioners examines whether the foreign jurisdiction affords something like privilege for attorneys and agents. However, this inquiry can be intensive, difficult, and lead to inconsistent results, because many jurisdictions do not need a comparable protection when their constrained discovery system prevents communications with patent practitioners from even being discoverable. Similarly, U.S. courts that use a ''touch base'' standard often make complex inquiries into a foreign communication's nexus with the United States, which can lead to uncertain and inconsistent results. The USPTO rule simplifies such inquiries by instead considering whether the foreign practitioner was authorized to practice within their home jurisdiction by satisfying their jurisdiction's professional requirements, and whether the communications fall within their authorized scope of practice in that jurisdiction. These criteria are simpler to adjudicate and lead to more predictable and consistent results, helping applicants understand where privilege applies long before they appear at a tribunal.

Also, the USPTO rule applies regardless of the source of privilege for agents. Whether there is a separate agent-client privilege or agents are afforded attorney-client privilege on the basis of practicing patent law does not matter for purposes of this rule. The rule simply recognizes that privilege issues will be treated the same for agents as for attorneys within their scope of authorized practice.

Practice of Law

Comments: Two commenters suggested that the rule would promote the ''unauthorized practice of law'' by U.S. patent agents. It was suggested that participation by patent agents in PTAB proceedings would constitute unauthorized practice, and that agents participating in PTAB proceedings held concurrently with patent litigation on the same patents would constitute unauthorized litigation practice by those agents. One of these commenters also said that state bar rules may conflict with this PTAB rule.

Response: As previously mentioned, the rule does not grant additional powers to patent agents. Privilege is a protection that vests with the client, not the practitioner. Agents are already authorized to practice before PTAB in any USPTO proceedings. Practice before PTAB cannot be unauthorized practice of law because U.S. patent agents are authorized to do so.

The second objection suggests that practicing before PTAB is tantamount to practicing before Federal courts when there is concurrent litigation on the same patents. Because they are separate venues with separate practices and practitioners, this argument is not persuasive. Agents are authorized to advise and represent clients in PTAB proceedings because the issues are restricted to patent law matters they are authorized to perform. Federal courts have different jurisdiction than PTAB and consider a range of non-patent issues. The fact that certain patent issues, such as validity, may arise before both tribunals does not equate practice before both venues. Just because a practitioner is authorized to address the issue in one forum does not mean they are authorized to address it in other forums. This is true regardless of whether the practitioner is an agent or an attorney and whether the two forums are, for instance, PTAB and a Federal court, or a Federal court and a foreign court.

Finally, state bar rules generally are not germane to USPTO rules. The USPTO may properly regulate the conduct of practitioners before the Office, including PTAB proceedings, as authorized by Congress. Similarly, states can properly regulate the practice of law within their borders, subject to federalism principles and rules established by the Supreme Court. The USPTO and states have separate jurisdiction. States may of course consider the policy issues the USPTO has documented when deciding privilege matters within their own courts for domestic and foreign patent agents and attorneys.

Changes From the Proposed Rule

In response to comments received from the public, the USPTO makes the following changes from the proposed rule. The terms for types of practitioners (domestic and foreign) were adjusted slightly for uniformity with other rules. The application of Federal law was clarified. The USPTO registration requirement now points to 37 CFR 11.7 for more precision. Paragraph (c) was added to clarify that non-attorney practitioners are afforded privilege in all the same situations as attorneys, not just for direct communications between practitioner and client.

Rulemaking Considerations

A. Administrative Procedure Act (APA): This final rule revises the rules relating to Office trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings. The changes being adopted in this notice do not change the substantive criteria of patentability. These changes involve rules of agency practice. *See, e.g.,* 35 U.S.C. 316(a)(5), as amended. These rules are procedural and/or interpretive rules. *See Bachow Commc'ns Inc.* v. *F.C.C.,* 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive requirements for reviewing claims.); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.); *JEM Broad. Co.* v. *F.C.C.,* 22 F.3d 320, 328 (D.C. Cir. 1994) (Rules are not legislative because they do not ''foreclose effective opportunity to make one's case on the merits.'').

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law). *See Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))). However, the Office chose to seek public comment before implementing the rule to benefit from the public's input.

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601–612) is required. *See* 5 U.S.C. 603. Nonetheless, for the reasons set forth herein, the Senior Counsel for Regulatory and Legislative Affairs in the Office of General Law of the USPTO has certified

to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b). This rule revises the rules of practice before PTAB to explicitly recognize that communications between non-attorney or foreign patent practitioners and their clients that pertain to authorized practice before the USPTO or foreign patent offices are privileged, and to define those persons who may avail themselves of this privilege. These changes are expected to create no additional burden to those practicing before the Board as this rule merely clarifies rights and protections for the practitioner and client and does not impose a change in practice or requirements. In fact, this rule may produce a small benefit from a reduction in uncertainty and mitigation of discovery costs. For the above reasons, the changes in this rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs): This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

F. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

G. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

H. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

J. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

K. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

L. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this final rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

M. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

N. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

O. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

P. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). This rulemaking does not add any additional information requirements or fees for parties before the Board. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the revisions in this rulemaking do not materially change the information collections approved under OMB control number 0651–0069.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to, a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 42

Administrative practice and procedure, Inventions and patents.

For the reasons set forth in the preamble, 37 CFR part 42 is amended as follows.

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 1. The authority citation for 37 CFR part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 6, 21, 23, 41, 135, 311, 312, 316, 321–326; Public Law 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

■ 2. Add § 42.57 to read as follows:

§ 42.57 Privilege for patent practitioners.

(a) *Privileged communications.* A communication between a client and a USPTO patent practitioner or a foreign jurisdiction patent practitioner that is reasonably necessary and incident to the scope of the practitioner's authority shall receive the same protections of privilege under Federal law as if that communication were between a client and an attorney authorized to practice in the United States, including all limitations and exceptions.

(b) *Definitions.* The term ''USPTO patent practitioner'' means a person who has fulfilled the requirements to practice patent matters before the United States Patent and Trademark Office under § 11.7 of this chapter. ''Foreign jurisdiction patent practitioner'' means a person who is authorized to provide legal advice on patent matters in a foreign jurisdiction, provided that the jurisdiction establishes professional qualifications and the practitioner satisfies them. For foreign jurisdiction practitioners, this rule applies regardless of whether that jurisdiction provides privilege or an equivalent under its laws.

(c) *Scope of coverage.* USPTO patent practitioners and foreign jurisdiction patent practitioners shall receive the same treatment as attorneys on all issues affecting privilege or waiver, such as communications with employees or assistants of the practitioner and communications between multiple practitioners.

Joseph Matal,

Associate Solicitor, performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2017–24190 Filed 11–6–17; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2017–0280; FRL–9969–89–Region 5]

Air Plan Approval; Wisconsin; 2017 Revisions to NR 400 and 406

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the Wisconsin State Implementation Plan (SIP) submitted by the Wisconsin Department of Natural Resources (WDNR) to EPA on May 16, 2017. The revision replaces the definition of ''emergency electric generator'' with a broader definition of ''restricted internal combustion engine''. In addition, the revision makes amendments to procedures for revoking construction permits as well as language changes and other administrative updates. Lastly, WDNR is removing from the SIP two Wisconsin Administrative Code provisions that affect eligibility of coverage under general and construction permits.

DATES: This direct final rule will be effective January 8, 2018, unless EPA receives adverse comments by December 7, 2017. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2017–0280 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, *etc.*) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the official comment (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

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SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. Review of State Submittals

This final rulemaking addresses the May 16, 2017, WDNR submittal for SIP revision, revising the rules in the Wisconsin SIP to align them with Federal requirements. WDNR's submittal includes changes to the term ''electric generator'', replacing it with ''restricted internal combustion engine'' as well as other minor language and administrative changes. Specifically, NR 400.02(136m) replaces the existing definition of emergency ''electric generator'' with a broader definition of ''restricted internal combustion engine'' and NR 406.04(1)(w) amends the exemption language for ''emergency electric generators'', replacing it with exemption for ''restricted use reciprocating internal combustion engines''. NR 406.08(1) and NR 406.10 involve minor changes to language, and NR 406.11(1) amends procedures for revoking construction permits. These changes serve the purpose of aligning the state and Federal regulations and are consistent with the Federal program. WDNR is also requesting the removal of two provisions from the SIP. NR 406.16(2)(d) and NR 406.17(3)(e) affect the eligibility of coverage under general and registration construction permits based on whether the project constituted a Type 2 action under the previous ch. NR 150. However, the current ch. NR 150 was amended and no longer defines or sets requirements for Type 2 actions. Removing these provisions from Wisconsin's SIP ensures consistency with Wisconsin Environmental Protection Act (WEPA)