Unless we certify that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options to minimize any significant economic impact of a regulation on small entities. Most pharmacies meet the Small Business Administration definition of a small entity, which is defined as having annual sales less than $25.5 million for this industry. We are not aware of any routine compounding of these drug products and do not estimate any compliance costs or loss of sales to small businesses as a result of the prohibition against compounding these drug products. Therefore, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

### VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### IX. References

The following references are on display in the Division of Dockets Management (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 *http://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. Mangano, D.T., I.C. Tudor, and C. Dietzel, ''The Risk Associated With Aprotinin in Cardiac Surgery,'' *New England Journal of Medicine,* 354(4):353–365, 2006.
2. FDA News Release, ''FDA Issues Public Health Advisory for Trasylol'' (February 8, 2006), available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108592.htm.*
3. Schneeweiss, S., J.D. Seeger, J. Landon, and A.M. Walker, ''Aprotinin During Coronary-Artery Bypass Grafting and Risk of Death,'' *New England Journal of Medicine,* 358:771–783, 2008.
4. Mangano, D.T., Y. Miao, A. Vuylsteke, et al., ''Mortality Associated With Aprotinin During 5 Years Following Coronary Artery Bypass Graft Surgery,'' *Journal of the American Medical Association,* 297(5):471–479, 2007.
5. Fergusson, D.A., P.C. Hébert, C.D. Mazer, et al., ''A Comparison of Aprotinin and Lysine Analogues in High-Risk Cardiac Surgery,'' *New England Journal of Medicine,* 358(22):2319–2331, 2008.
6. FDA Alert—Aprotinin Injection (Marketed as Trasylol) (October 25, 2007), available at *http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm150815.htm.*
7. FDA News Release, ''FDA Requests Marketing Suspension of Trasylol'' (November 5, 2007), available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm109021.htm.*
8. FDA News Release, ''Manufacturer Removes Remaining Stocks of Trasylol Access Limited to Investigational Use'' (May 14, 2008), available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116895.htm.*
9. FDA–PARLODEL (bromocriptine mesylate) Information, available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM449535.pdf.*
10. FDA Fertility and Maternal Health Drugs Advisory Committee Meeting Minutes (June 1 and 2, 1989), available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM449535.pdf.*
11. FDA Drug Safety Communication—Abnormal Heart Rhythms May Be Associated with Use of Zofran (Ondansetron)(September 15, 2011), available at *http://www.fda.gov/Drugs/DrugSafety/ucm271913.htm.*
12. FDA Drug Safety Communication—New Information Regarding QT Prolongation with Ondansetron (Zofran) (June 29, 2012), available at *http://www.fda.gov/Drugs/DrugSafety/ucm310190.htm.*
13. FDA Drug Safety Communication—Updated Information on 32 mg Intravenous Ondansetron (Zofran) Dose and Pre-Mixed Ondansetron Products (December 4, 2012), available at *http://www.fda.gov/Drugs/DrugSafety/ucm330049.htm.*


### List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 216 be amended as follows:

## PART 216—HUMAN DRUG COMPOUNDING

■ 1. The authority citation for part 216 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

■ 2. Amend § 216.24 by adding, in alphabetical order, to the list of drugs ''Aprotinin'', ''Bromocriptine mesylate'', and ''Ondansetron hydrochloride'' to read as follows:

**§ 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.**

* * * * *

*Aprotinin:* All drug products containing aprotinin.

* * * * *

*Bromocriptine mesylate:* All drug products containing bromocriptine mesylate for prevention of physiological lactation.

* * * * *

*Ondansetron hydrochloride:* All intravenous drug products containing greater than a 16 milligram single dose of ondansetron hydrochloride.

* * * * *

Dated: October 11, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–25005 Filed 10–17–16; 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 Recognizing Privileged Communications Between Clients and Patent Practitioners at the Patent Trial and Appeal Board

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend the rules of practice before the Patent Trial and Appeal Board to recognize that, in connection with discovery conducted in certain proceedings at the United States Patent and Trademark Office (USPTO or Office), communications between U.S.

patent agents or foreign patent practitioners and their clients are privileged to the same extent as communications between clients and U.S. attorneys. The rule would apply to *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings. This rule would clarify the protection afforded to such communications, which is currently not addressed in the rules governing Board proceedings at the USPTO. This new rule will not affect the duty of disclosure and candor before the Office under 37 CFR 1.56.

**DATES:** *Comment date:* The Office solicits comments from the public on this proposed rulemaking. Written comments must be received on or before December 19, 2016 to ensure consideration.

**ADDRESSES:** Comments should be sent by electronic mail message over the Internet addressed to: *acprivilege@uspto.gov.* Comments may also be submitted by postal mail addressed to: Mail Stop OPIA Director of the United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of ''Soma Saha, Patent Attorney, Patent Trial Proposed Rule on Privilege.''

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal at *http://www.regulations.gov. See* the Federal eRulemaking Portal Web site for additional instructions on providing comments via the Federal e-Rulemaking Portal.

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message to be able to more easily share all comments with the public. The Office prefers the comments to be submitted in plain text, but also accepts comments submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that accommodates digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of Policy and International Affairs, currently located in Madison East, Second Floor, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's Internet Web site at *http://www.uspto.gov/patents/law/comments/index.jsp* and at *http://www.regulations.gov.* Because comments will be made available for public inspection, information that the submitter does not desire to be made public, such as address or phone number, should not be included in the comments.

**FOR FURTHER INFORMATION CONTACT:** Soma Saha, Patent Attorney, by email at *soma.saha@uspto.gov* or by telephone at (571) 272–8652; or Edward Elliott, Attorney Advisor, by email at *edward.elliott@uspto.gov* or by telephone at (571) 272–7024.

**SUPPLEMENTARY INFORMATION:**

*Purpose:* This proposed rule would amend the rules of practice before the Patent Trial and Appeal Board (PTAB) to recognize that communications between non-attorney U.S. patent agents or foreign patent practitioners and their clients that pertain to authorized practice before the United States Patent and Trademark Office (Office or USPTO) are privileged to the same extent as communications of that sort conducted between clients and U.S. attorneys. Under the proposed rule, those communications would be protected from discovery in trial practice proceedings at the USPTO. The proposed rule would apply to *inter partes* review (IPR), post-grant review (PGR), the transitional program for covered business method patents (CBM), and derivation proceedings. Currently, the rules governing proceedings at the USPTO do not address the privilege of communications with patent practitioners, and questions regarding that matter are decided on a case-by-case basis under common law principles. This new rule will not affect the duty of disclosure and candor before the Office under 37 CFR 1.56.

*Background:* Within this notice, the term ''patent practitioner'' includes both those authorized to practice patent matters before the USPTO and those authorized to practice patent matters in foreign jurisdictions. When referring to these groups separately, the terms ''U.S. or domestic patent practitioners'' and ''foreign patent practitioners'' will be used, respectively.

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 it should recognize that communications between patent applicants and owners and their U.S. patent agents or foreign patent practitioners are privileged to the same extent as communications between U.S. patent attorneys and patent applicants and owners. Respondents unanimously supported a rule recognizing such privilege. *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'').

The USPTO administers various proceedings that entail discovery procedures, namely the IPR, PGR, and transitional program for CBM patents. In addition, the derivation proceedings provided for by the Leahy-Smith America Invents Act, Public Law 112–29, 125 Stat. 284 (2011) (AIA) permit discovery. Questions regarding privilege issues may arise in the course of discovery, and as some roundtable commenters noted, rules regarding privilege for U.S. patent agents and foreign practitioners during discovery in PTAB proceedings are not well defined.

*Current Practice:* PTAB proceedings are subject to the Federal Rules of Evidence (FRE), which include rules on attorney-client privilege. *See* 37 CFR 42.62(a). Accordingly, privilege may be asserted in PTAB proceedings by licensed attorneys. However, the FRE does not explicitly address privilege for communications with non-attorney U.S. patent agents or with foreign patent practitioners.

The rules governing PTAB practice likewise do not address this matter, and when it arises, PTAB Administrative Law Judges make legal determinations as to which communications may be protected from disclosure on a case-by-case basis, based on common law. *See 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. (It is also noted that Administrative Law Judges in other agencies recognize 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).) The Federal Circuit recently 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, PARTEQ Research and Development Innovations,* No. 2015–145 (Fed. Cir. 2016).

The Office has strong policy reasons to establish a privilege rule governing trial proceedings before PTAB. Such a rule would help ensure consistent outcomes with respect to privilege matters that arise at the Office, would improve public understanding of how privilege questions are decided before PTAB, and would help further judicial economy by providing PTAB judges with a clear, concise statement of when privilege applies.

*Public Comments:* In August 2015, the USPTO published in the **Federal Register** a proposed rule amending the rules for trial practice before the Office. *See* Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 80 FR 50719 (Aug. 20, 2015). Included in that proposed rule was a request for comments on the advisability of a privilege rule for PTAB proceedings. The comments submitted in response to that request are available on the USPTO Web site at *http://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/comments-amendments-rules-practice-trials.*

Those responding to the request universally agreed that a privilege rule for PTAB proceedings should be promulgated. Respondents overwhelmingly favored promulgating such a rule, with some noting that it would lead to clarity and consistency and ''can reduce uncertainty and mitigate discovery costs.'' *See* Letter from Frederick W. Mau II on behalf of Toyota Motor Corp., David B. Kelley on behalf of Ford Motor Co., and Mark Duell on behalf of American Honda Motor Co., Inc., *RE: Comments on Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board,* p. 4–5 (Oct. 16, 2015). Others suggested that ''[i]f patent agents are not entitled to have their communications be considered privileged, however, then their utility—and associated cost savings for stakeholders—is lost.'' *See* Letter from Sharon A. Israel, President of the American Intellectual Property Law Assoc., *RE: Response to Proposed ''Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board,'' 80 FR 50720 (August 20, 2015),* p. 15–16 (Oct. 21, 2015).

Commenters said it ''would be particularly useful for patent agents[']communications to be explicitly protected in the discovery rules for post-grant proceedings (*e.g.,* inter parties [sic] review) before the USPTO.'' *See* Letter from Dorothy R. Auth, President of the New York Intellectual Property Law Assoc., *RE: NYIPLA Comments in Response to ''Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board,''* **Federal Register** *Notice, August 20, 2015, Vol. 80, No. 161 (80 FR 50720),* p. 6–9 (Nov. 18, 2015). Commenters suggested that the rule should extend at least to communications made in connection with acts that patent agents are authorized to perform in their particular jurisdictions, such as prosecuting patent applications. The USPTO agrees that the scope of a privilege rule should be defined by the activities that the agent is authorized to carry out. Others suggested that it should be ''a simple rule . . . that explicitly recognize[s] privilege for communications between patent applicants or owners and their domestic patent agents or foreign professional patent practitioners under the same circumstances as such privilege is recognized for communications between applicants or owners and U.S. attorneys.'' *See* Letter from Andrew D. Meikle, President of the U.S. Section of the International Federation of Intellectual Property Attorneys (FICPI), *RE: Comments on ''Recognizing Privilege for Communications With Domestic Patent Agents and Foreign Patent Practitioners'',* p. 4 (Nov. 24, 2015).

According to these comments, ''[t]his approach would provide the greatest uniformity and certainty, and avoid the need for the PTAB to engage in complex fact based analysis regarding application of the privilege under the common law.'' *Id.* These views were echoed by a law professor who has studied this issue since 2008:

> The privilege should be as broad as the ordinary attorney-client privilege. It should cover not only U.S. patent agents, but also foreign legal representatives. While the best solution would be a privilege that applied in all legal tribunals—not only the PTAB, but also federal and state courts—adoption of a privilege only for the PTAB would be a valuable first step toward this goal.

*See* Letter from John T. Cross, Professor of Law at University of Louisville, *Possible Adoption of a Legal Representation Privilege in Matters Before the Patent Trial and Appeal Board,* p. 2 (Sep. 9, 2015).

The USPTO agrees with these views and believes the proposed rule reflects them. As a policy matter, open and frank discussions between practitioners and clients promotes effective legal representation before the Office.

**Discussion of Specific Rules**

Taking into consideration comments from the public and insight gained from practice, the Office proposes to amend 37 CFR 42 to add new section 42.57 that clarifies which patent practitioners are eligible for assertions of attorney-client privilege.

The term ''patent practitioner'' is used to conform with existing terminology and avoid confusion with other terms used around the world, such as ''IP Advisor'' or ''Patent Advisor.'' It fits with practice elsewhere in Title 37, which refers to domestic ''patent practitioners,'' *i.e.,* U.S. patent agents and patent attorneys registered under 37 CFR 11.6. This narrower meaning is appropriate for most sections of Title 37, which deal with practitioners admitted to practice before the USPTO. For the new rule only, the term also includes comparable foreign counterparts practicing before foreign patent offices.

The rule would provide that the privilege only applies where the practitioner performs legal work authorized by the jurisdiction in which the practitioner practices. For instance, communications between clients and U.S. patent agents relating to patent application matters would be protected as privileged under the rule, but communications between these parties regarding litigation strategies would not be protected. The proposed rule also does not recognize privilege as applying to advice given by lay persons in jurisdictions that do not impose professional qualifications as a requirement to practice. However, the proposed rule can apply to communications from an in-house counsel who performs the functions of a patent attorney under appropriate circumstances, even though some civil law jurisdictions may not grant in-house counsel the privilege-type protections given to attorneys.

The Office invites the public to provide any comments on the proposed rule to inform further action.

*Costs and Benefits:* This rulemaking is not economically significant, and is not significant, under Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

**Rulemaking Considerations**

*A. Administrative Procedure Act (APA)*

This proposed rule revises the rules of practice before PTAB to recognize that

communications between non-attorney or foreign patent practitioners and their clients that pertain to authorized practice before the USPTO are privileged. The changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules. *See Nat'l Org. of Veterans' Advocates* v. *Secretary of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *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).

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*

For the reasons set forth herein, the Deputy General Counsel for General Law of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

The changes proposed in this rule are to revise 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 proposed 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 foregoing reasons, the changes proposed 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 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).

*F. 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).

*G. 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).

*H. 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).

*I. 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).

*J. 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).

*K. 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 USPTO 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).

*L. 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.*

*M. 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.*

*N. 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.

*O. 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 proposed rule not does not involve any new information collection requirements that 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). Any information collections associated with this rule have been previously 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 proposed to be 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; Pub. L. 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 domestic or foreign patent practitioner that is reasonably necessary or incident to the scope of the patent practitioner's authority shall receive the same protections of privilege 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 ''domestic patent practitioner'' means a person who is registered by the United States Patent and Trademark Office to practice before the agency under section 11.6. ''Foreign 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, and regardless of whether that jurisdiction provides privilege or an equivalent under its laws.

Dated: October 12, 2016.

**Michelle K. Lee,**

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

[FR Doc. 2016–25141 Filed 10–17–16; 8:45 am]

**BILLING CODE 3510–16–P**

## LIBRARY OF CONGRESS

### Copyright Royalty Board

### 37 CFR Part 385

**[Docket No. 16–CRB–0003–PR (2018–2022)]**

### Determination of Rates and Terms for Making and Distributing Phonorecords (Phonorecords III); Comment Period Extension

**AGENCY:** Copyright Royalty Board, Library of Congress.

**ACTION:** Proposed rule; extension of comment period for reply comments.

**SUMMARY:** The Copyright Royalty Judges announce that they will accept reply comments in response to comments they received about a proposed rule regarding rates and terms applicable during the upcoming rate period for the section 115 statutory license for making and distributing phonorecords of nondramatic musical works.

**DATES:** Reply comments for the proposed rule published July 25, 2016 (81 FR 48371) are due no later than November 17, 2016.

**ADDRESSES:** The proposed rule and the comments filed in response to it are posted on the agency's Web site (*www.loc.gov/crb*). The proposed rule is also posted at *Regulations.gov* (*www.regulations.gov*). Interested parties may submit reply comments via email to *crb@loc.gov.* Those who choose not to submit reply comments via email should see How to Submit Reply Comments in the **SUPPLEMENTARY INFORMATION** section below for online and physical addresses and further instructions.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Whittle, Attorney Advisor, by telephone at (202) 707–7658, or by email at *crb@loc.gov.*

**SUPPLEMENTARY INFORMATION:** On July 25, 2016, the Judges published a proposed rule and requested comments. 81 FR 48371. The proposed rule was based upon a partial settlement [1] regarding copyright royalty rates and terms applicable during the upcoming rate period for the section 115 statutory license for making and distributing phonorecords of nondramatic musical works. *See Joint Motion to Adopt Partial Settlement,* Docket No. 16–CRB–0003–PR (2018–2022) (June 15, 2016).

On or before August 24, 2016, the Judges received two timely comments, one from the American Association of Independent Music (A2IM) that supported it and one from Sony Music Entertainment (''Sony'') that supported it in part and opposed it in part.

On August 30, 2016, the National Music Publishers' Association and the Nashville Songwriters Association International filed a joint *Motion for Leave to Respond to the Comments and Objections of Sony Music Entertainment Concerning Proposed Settlement (Joint Motion).* In the interest of promoting a more complete record with regard to the proposed rule, the Judges will grant the *Joint Motion.* In addition, the Judges hereby announce that they will accept, without additional motions required, additional reply comments, if any, to the comments filed by A2IM and Sony.

The reply comments, if any, must be submitted no later than November 17, 2016.

**How To Submit Reply Comments**

Interested members of the public must submit reply comments to only *one* of the following addresses. If not submitting by email or online, commenters must submit an original of their reply comments, five paper copies, and an electronic version in searchable PDF format on a CD.

*Email: crb@loc.gov;* or

*Online: http://www.regulations.gov;* or

[1] The participants filing the motion were Church Music Publishers Association, Nashville Songwriters Association International, National Music Publishers Association, Harry Fox Agency, and Songwriters of North America, and licensees Universal Music Group and Warner Music Group.