FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

### II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Any collection of information, including a firm's public warning (§ 7.42(b)(2)), has been approved under OMB control number 0910–0249.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Safety/Recalls/default.htm* or *https://www.regulations.gov.*

Dated: January 16, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–00918 Filed 1–18–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF COMMERCE

## United States Patent and Trademark Office

## 37 CFR Parts 1 and 42

**[Docket No.: PTO–P–2017–0034]**

**RIN 0651–AD25**

## Changes To Eliminate Unnecessary Regulations

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) proposes to remove its regulations governing reservation clauses, petitions from the refusal of a primary examiner to admit an amendment, the publication of amendments to the regulations, and limits that the Director can impose on the number of inter partes reviews and post-grant reviews heard by the Patent Trial and Appeal Board. These regulations are unnecessary or superfluous and in some cases have expired, and their removal will help streamline USPTO's body of regulations without reducing the availability of services for the public. This proposed rule arises out of the USPTO's work during FY 2017 to identify and propose regulations for removal, modification, and streamlining because they are outdated, unnecessary, ineffective, costly, or unduly burdensome on the agency or the private sector. The revisions proposed herein would put into effect the work the USPTO has done, in part through its participation in the Regulatory Reform Task Force established by the Department of Commerce pursuant to Executive Order 13777, to review and identify regulations that are candidates for removal.

**DATES:** Written comments must be received on or before February 20, 2018.

**ADDRESSES:** Comments on the changes set forth in this proposed rulemaking should be sent by electronic mail message to: *AD25.comments@uspto.gov.* Comments may also be submitted by postal mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313–1450, marked to the attention of Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration. Comments concerning ideas to improve, revise, and streamline other USPTO regulations, not discussed in this proposed rulemaking, should be submitted to: *RegulatoryReformGroup@uspto.gov.*

Comments may also be submitted via the Federal eRulemaking Portal at *http://www.regulations.gov.* See the Federal eRulemaking Portal website for additional instructions on providing comments via the Federal eRulemaking Portal. Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the internet because the Office may easily share such comments with the public. Electronic comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's internet website (*http://www.uspto.gov*) and at *http://www.regulations.gov.* Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

**FOR FURTHER INFORMATION CONTACT:** Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at (571) 272–7728, for questions regarding the changes to 37 CFR 1.79 and/or 1.127; Susan L. C. Mitchell, Lead Administrative Patent Judge, Patent Trial and Appeal Board, at (571) 272–8715, for questions regarding the changes to 37 CFR part 42; and Nicolas Oettinger, Senior Counsel for Regulatory and Legislative Affairs, Office of the General Counsel, at (571) 272–7832, for questions regarding the change to 37 CFR 1.351 and general questions regarding regulatory reform.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In accordance with Executive Order 13777, ''Enforcing the Regulatory Reform Agenda,'' the Department of Commerce established a Regulatory Reform Task Force (Task Force), comprising, among others, agency officials from the National Oceanic and Atmospheric Administration, the Bureau of Industry and Security, and the USPTO, and charged the Task Force with evaluating existing regulations and identifying those that should be repealed, replaced, or modified because they are potentially outdated, unnecessary, ineffective, costly, or unduly burdensome to both government and private sector operations.

To support its regulatory reform efforts on the Task Force, the USPTO assembled a Working Group on Regulatory Reform (Working Group), consisting of subject matter experts from each of the business units that implement the USPTO's regulations, to consider, review, and recommend ways that the regulations could be improved, revised, and streamlined. In considering the revisions, the USPTO, through its Working Group, incorporated into its analyses all presidential directives relating to regulatory reform. The Working Group reviewed existing regulations, both discretionary and required by statute or judicial order. The USPTO also solicited comments from stakeholders through a web page established to provide information on the USPTO's regulatory reform efforts, and through the Department's **Federal Register** Notice titled ''Impact of Federal Regulations on Domestic Manufacturing'' (82 FR 12786, Mar. 7, 2017), which addressed the impact of regulatory burdens on domestic manufacturing. These efforts led to the development of candidate regulations for removal based on the USPTO's assessment that these regulations were not needed and/or that elimination

could improve the USPTO's body of regulations. To facilitate review and public comment, the USPTO consolidates and proposes in this rule revisions to patent regulations in Part 1 and Patent Trial and Appeal Board regulations in Part 42. Other proposals to remove regulations on other subject areas may be published separately.

**II. Regulations Proposed for Removal**

This proposed rulemaking would remove regulations concerning reservation clauses, petitions from the refusal of a primary examiner to admit an amendment, and publication of amendments to the regulations in 37 CFR part 1. This proposed rulemaking would also remove regulations concerning limits that the Director can impose on the number of inter partes reviews and post-grant reviews in 37 CFR part 42.

In particular, this proposed rulemaking would remove 37 CFR 1.79. Section 1.79 prohibits reservation clauses, *i.e.,* it prohibits a pending patent application from containing a reservation for a future patent application of subject matter disclosed but not claimed in the pending application. An applicant's ability to claim benefit of a prior application is affirmatively provided elsewhere in statute and regulation (as described below), and the explicit prohibition of § 1.79 on reservation clauses (which do not confer this benefit) dates from a time when the mechanism for properly claiming benefit of a prior application was less clear and less fully developed in USPTO's regulations and guidance. The proposed removal of § 1.79 is not an endorsement of reservation clauses nor an invitation for applicants to include reservation clauses in applications. The Office does not expect the use of reservation clauses to significantly increase once the proposed rulemaking is made final, because such reservation clauses provide no legal benefit, regardless of § 1.79. For example, the inclusion of a reservation clause in a pending application would not change any of the requirements for a future application to benefit from the earlier filing date of the pending application. The authority for the future application to benefit from the earlier filing date of the pending application would stem, as it does now, from the fulfillment of requirements set forth in statutory and regulatory provisions in which a reservation clause plays no role, *e.g.,* 35 U.S.C. 120 and 37 CFR 1.78. Nor would the inclusion of a reservation clause protect against rejections for statutory or nonstatutory double patenting. In view of the fact that the inclusion of a reservation clause provides no legal benefit, and given that the affirmative ability to claim benefit of a prior application is more fully and completely described elsewhere in USPTO's regulations and guidance (unlike when § 1.79 was first adopted), the prohibition of reservation clauses in § 1.79 is unnecessary.

Section 1.79 also permits a patent application disclosing unclaimed subject matter to contain a reference to a later filed application of the same applicant or owned by a common assignee disclosing and claiming that subject matter. This provision of § 1.79 is duplicative and therefore unnecessary. 37 CFR 1.78 provides for cross-references to other applications, including cross-references to applications for which a benefit is not claimed, which encompasses the later filed applications identified in § 1.79. Thus, once the proposed rulemaking is made final, applicants will continue to be able to include in a pending application a reference to a later filed application as currently provided for in § 1.79.

This proposed rulemaking would remove § 1.127, which also is duplicative. Section 1.127 indicates that a petition to the Director under 37 CFR 1.181 may be filed upon a refusal by a primary examiner to admit an amendment, in whole or in part. Section 1.127 is unnecessary. The language of § 1.181 makes clear that a refusal by a primary examiner to admit an amendment is petitionable under § 1.181. The *Manual of Patent Examining Procedure* (9th ed. 2014) (Rev. Nov. 2015) also makes this fact clear in its discussion at section 1002.02(c). Thus, once the proposed rulemaking is made final, applicants will continue to be able to petition under § 1.181 the refusal by a primary examiner to admit an amendment, in whole or in part.

This proposed rulemaking additionally would remove 37 CFR 1.351. Section 1.351 states that all amendments to the regulations in 37 CFR part 1 will be published in the *Official Gazette* and in the **Federal Register**. Section 1.351 is unnecessary. In accordance with the requirements of the Administrative Procedure Act (APA) and guidance from the Office of Management and Budget (OMB), the Office publishes any amendments to 37 CFR part 1 in the **Federal Register**. The APA generally requires the Office to give public notice of any regulatory change, and OMB's guidance with respect to rulemaking makes clear that publication in the **Federal Register** is the required means for giving public notice. Furthermore, the Office intends to continue publishing all amendments to the regulations in 37 CFR part 1 in the *Official Gazette.* Thus, once the proposed rulemaking is made final, the Office will continue the practice of publishing all amendments to the regulations in 37 CFR part 1 in the **Federal Register**, as required by OMB, and in the *Official Gazette.*

Finally, this proposed rulemaking would remove 37 CFR 42.102(b) and 42.202(b), both of which are now out of date. Section 42.102(b) provides that the Director may impose a limit on the number of inter partes reviews that may be instituted during each of the first four one-year periods that the Leahy-Smith America Invents Act (AIA) is in effect. Section 42.202(b) has a similar provision for post-grant reviews. Neither rule remains necessary because the fourth anniversary of the effective date of the AIA has passed.

The regulations proposed in this rule for removal achieve the objective of making the USPTO's regulations more streamlined and less burdensome, while enabling the USPTO to fulfill its mission goals. The USPTO's analysis shows that removal of these regulations is not expected to substantially reduce the burden on the impacted community; however, the regulations are nonetheless being eliminated because they are ''outdated, unnecessary, or ineffective'' regulations encompassed by the directives in Executive Order 13777.

**III. Discussion of Proposed Rules Changes**

*Part 1*

Section 1.79: Section 1.79 is removed and reserved.

Section 1.127: Section 1.127 is removed and reserved.

Section 1.351: Section 1.351 is removed and reserved.

*Part 42*

Section 42.102(b): Section 42.102(b) is removed and reserved.

Section 42.202(b): Section 42.202(b) is removed and reserved.

Rulemaking Considerations

*A. Administrative Procedure Act:* The changes in this proposed rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199, 1204 (2015) (Interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers.'' (citation and internal quotation marks omitted)); *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.); *Bachow Commc'ns Inc.* v. *FCC,* 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 standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes in this proposed rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez,* 135 S. Ct. at 1206 (Notice-and-comment procedures are required neither when an agency ''issue[s] an initial interpretive rule'' nor ''when it amends or repeals that interpretive rule.''); *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), does 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))). The Office, however, is publishing these proposed changes for comment as it seeks the benefit of the public's views on the Office's proposed implementation of the proposed rule changes.

*B. Regulatory Flexibility Act:* For the reasons set forth herein, Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO, has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes proposed in this notice will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

This proposed rule would remove the provisions at 37 CFR 1.79, concerning the prohibition of reservation clauses, § 1.127, concerning petitions from refusal to admit amendment, and § 1.351, concerning the publication of amendments to rules. These regulations are removed because they are not necessary. This rule would also remove 37 CFR 42.102(b) and 42.202(b), which provide that the Director may impose a limit on the number of inter partes reviews and post-grant reviews that may be instituted during each of the first four one-year periods that the AIA is in effect. These regulations are no longer necessary because the fourth anniversary of the effective date of the AIA has passed.

Removing these regulations achieves the objective of making the USPTO's regulations more effective and more streamlined, while enabling the USPTO to fulfill its mission goals. The removal of these regulations is not expected to substantively impact parties as parties would either continue to be able to take the same action under a different regulatory provision, or the rights or obligations of the parties would not be changed in any way. For these reasons, this rulemaking 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.

*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 proposed rule is expected to be an Executive Order 13771 deregulatory action.

*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 USPTO will submit a report containing the final 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 notice 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 notice is not expected to result in 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 notice 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 that involve the use of technical standards.

*P. Paperwork Reduction Act:* The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking does not involve an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549).

Notwithstanding any other provision of law, no person is required to respond to nor shall a 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**

*37 CFR Part 1*

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

*37 CFR Part 42*

Administrative practice and procedure, Inventions and patents.

For the reasons stated in the preamble, the Office proposes to amend parts 1 and 42 of title 37 as follows:

## PART 1—RULES OF PRACTICE IN PATENT CASES

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

**Authority:** 35 U.S.C. 2(b)(2).

**§ 1.79 [Removed and reserved]**

■ 2. Section 1.79 is removed and reserved.

**§ 1.127 [Removed and reserved]**

■ 3. Section 1.127 is removed and reserved.

**§ 1.351 [Removed and reserved]**

■ 4. Section 1.351 is removed and reserved.

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

■ 5. The authority citation for 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 and Public Law 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

**§ 42.102 [Amended]**

■ 6. Amend § 42.102 by removing and reserving paragraph (b).

**§ 42.202 [Amended]**

■ 7. Amend § 42.202 by removing and reserving paragraph (b).

Dated: January 11, 2018.

**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. 2018–00769 Filed 1–18–18; 8:45 am]

**BILLING CODE 3510–16–P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 1

**RIN 2900–AP90**

### Consent for Release of VA Medical Records

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulations to clarify that a valid consent authorizing the Department to release the patient's confidential VA medical records to a health information exchange (HIE) community partner may be established not only by VA's physical possession of the written consent form, but also by the HIE community partner's written (electronic) attestation that the patient has, in fact, provided such consent. This proposed rule would be a reinterpretation of an existing, long-standing regulation and is necessary to facilitate modern requirements for the sharing of patient records with community health care providers, health plans, governmental agencies, and other entities participating in electronic HIEs. This revision would ensure that more community health care providers and other HIE community partners can deliver informed medical care to patients by having access to the patient's VA medical records at the point of care.

**DATES:** *Comment Date:* Comments must be received on or before March 20, 2018.

**ADDRESSES:** Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP90 Consent for Release of VA Medical Records.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Stephania Griffin, Director, Veterans Health Administration Information Access and Privacy Office, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; *Stephania.griffin@va.gov,* (704) 245–2492 (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** Under 38 U.S.C. 7332, VA must keep confidential all records of identity, diagnosis, prognosis, or treatment of a patient in connection with any program or activity carried out by VA related to drug abuse, alcoholism or alcohol abuse, infection with human immunodeficiency virus, or sickle cell anemia, and must obtain patients' written consent before VA may disclose the protected information unless authorized by the statute. This requirement applies to communications between VA and community health care providers for the purposes of treatment, except in certain situations, for instance in medical emergencies and when the records are sent to a non-Department entity that provides hospital care to patients as authorized by the Secretary. 38 U.S.C. 7332(b)(2)(A) and (H); Public Law 115–26 (April 19, 2017). Although section 7332 does not explicitly require that the written consent physically be in VA's possession at the time of the disclosure, VA had interpreted the statute to require such possession, and therefore applied 38 CFR 1.475 consistent with that interpretation. VA has reexamined that statutory interpretation in light of contemporary