is prepared that contains the basic facts of the event.

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2025–0008]

RIN 0651–AD85

Required Use by Foreign Applicants and Patent Owners of a Patent Practitioner

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is proposing to amend the Rules of Practice in Patent Cases to require patent applicants and patent owners whose domicile is not located within the United States (U.S.) or its territories (hereinafter foreign applicants/inventors and patent owners) to be represented by a registered patent practitioner. A requirement that foreign applicants/inventors and patent owners be represented by a registered patent practitioner would bring the United States in line with most other countries that require that such parties be represented by a licensed or registered person of that country. Additionally, this requirement would increase efficiency and enable the USPTO to more effectively use available mechanisms to enforce compliance by all foreign applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters, and enhance the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

DATES: Comments must be received by January 28, 2026 to ensure consideration.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via the portal, one should enter docket number PTO–P–2025–0008 on the homepage and select ''Search.'' The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this proposed rule and select the ''Comment'' icon, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) or Microsoft Word® format. 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.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of or access to comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Mark Polutta, Senior Legal Advisor, at (571) 272–7709, or Andrew St. Clair, Legal Advisor, at (571) 270–0238, of the Office of Patent Legal Administration or via email addressed to *patentpractice@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to its authority under 35 U.S.C. 2(b)(2), the USPTO is proposing to revise the rules in part 1 of title 37 of the Code of Federal Regulations to require foreign applicants/inventors and patent owners to be represented by a registered patent practitioner, as defined in 37 CFR 1.32(a)(1) (*i.e.,* a registered patent attorney or registered patent agent under 37 CFR 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16) (hereinafter, registered patent practitioner). Requiring all foreign applicants/inventors and patent owners to be represented by a registered patent practitioner (1) treats foreign applicants/inventors and patent owners similarly to how U.S. applicants/inventors and patent owners are treated in other countries and harmonizes U.S. practice with the rest of the world; (2) increases efficiency as the USPTO spends extra resources to handle *pro se* applicants (*i.e.,* an applicant who is prosecuting the application without a registered patent practitioner); (3) enables the USPTO to more effectively use available mechanisms to enforce compliance with statutory and regulatory requirements in patent matters; and (4) enhances the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

A. Harmonization of U.S. Practice With Other Intellectual Property (IP) Offices With Respect to Representation

Almost all IP Offices require foreign applicants/inventors and patent owners to be represented by a person licensed or registered in that country. The USPTO is proposing to implement a similar requirement. Requiring foreign applicants/inventors and patent owners to be represented by a registered patent practitioner would help to harmonize patent filing practice across IP Offices.

B. Increase Efficiency

The USPTO utilizes extra resources to assist *pro se* inventors. Requiring foreign applicants/inventors and patent owners to use registered patent practitioners will increase efficiency, as the applications will be in better form for examination. Applications from *pro se* inventors generally require additional processing by the Office of Patent Application Processing because the application papers are often not in condition for publication, examination, or both. Additionally, *pro se* applications usually require patent examiners to spend examination time on procedural matters, thereby increasing overall patent application pendency. Implementing this proposed rule would help allocate USPTO resources to the merits of examination and, accordingly, decrease patent application processing times.

C. Enforce Compliance With U.S. Statutory and Regulatory Requirements

The requirement for representation by a registered patent practitioner is also necessary to enforce compliance by all foreign patent applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters. Registered patent practitioners are subject to the USPTO Rules of Professional Conduct and disciplinary sanctions for violations of those rules. *See* 37 CFR 11.15, 11.20, and 11.100–11.901. Accordingly, registered patent practitioners have various obligations to the USPTO, including a duty to cooperate with inquiries and investigations. *See, e.g.,* 37 CFR 11.303 and 11.801.

The USPTO has noticed an increase in the number of false micro entity certifications to claim a reduction in fees and other false certification documents being filed. False certifications unjustly diminish the monetary resources of the USPTO, and false certifications on petitions or requests to expedite examination result in applications being unjustly advanced out of turn. Requiring submissions to be

made by registered patent practitioners subject to the USPTO Rules of Professional Conduct and concomitant disciplinary sanctions imposed by the USPTO Director will make it less likely that the submissions will be signed by an unauthorized party or contain inaccurate or fraudulent statements, particularly with regard to any certification of micro entity status to claim a reduction in fees and any certification relevant to expediting the application.

D. Fraud Mitigation and the Integrity of the U.S. Patent System

Requiring foreign patent applicants/inventors and patent owners to use registered patent practitioners will also facilitate fraud mitigation and protect the integrity of the U.S. patent system. As discussed, registered patent practitioners have a duty to cooperate with investigations and respond to lawful requests for information. *See* 37 CFR 11.801(b). Further, it is professional misconduct for a registered patent practitioner to engage in conduct involving dishonesty, fraud, deceit, or misrepresentation. *See* 37 CFR 11.804(c). It is also professional misconduct for a registered patent practitioner to engage in conduct that is prejudicial to the administration of justice. *See* 37 CFR 11.804(d). Because registered patent practitioners are subject to disciplinary sanctions pursuant to 37 CFR 11.15 and 11.20, they have an interest in responding to inquiries and investigations that extends beyond the outcome of a particular application.

For example, the USPTO currently sends fee deficiency notices in applications which appear to have false micro entity certifications, and can also send requests for information or show cause orders in applications in which an apparent misrepresentation has been made. In patent applications with *pro se* inventor-applicants, abandonment of the application effectively terminates the USPTO's ability to gather information. If a subsequent application is filed on the same subject matter, it may be difficult or impossible for the USPTO to establish that the applications are commonly owned or otherwise attributable to the same parties. However, when a registered patent practitioner is of record in the application or files papers in the application, the ability of the USPTO to gather information about the certifications or representations that were made extends beyond abandonment of the application. Therefore, requiring foreign patent applicants/inventors and patent owners to use registered patent practitioners would facilitate fraud mitigation and protect the integrity of the U.S. patent system.

II. Enforcement

Unsigned or improperly signed papers are not entered into the record of the application or patent. *See, e.g.,* MPEP 714.01. As such, when representation by a registered patent practitioner is required, papers such as amendments and other replies, application data sheets, information disclosure statements, or petitions, would not be entered unless they are signed by a registered patent practitioner. This would not apply to papers which are required to be signed by a specific party, such as the inventor's oath or declaration under 37 CFR 1.63.

The definition of the term ''domicile'' is provided in proposed 37 CFR 1.9(p). The domicile of an inventor-applicant will normally be determined by the residence information provided in the application data sheet (ADS) under 37 CFR 1.76, or the inventor's oath or declaration under 37 CFR 1.63 (including a substitute statement under 37 CFR 1.64). The domicile of an applicant who is not an inventor will normally be determined based on the mailing address provided in the Applicant Information section of the ADS. If an ADS is inconsistent with the information provided in another document that was submitted at the same time or prior to the ADS submission, the ADS will control. *See* 37 CFR 1.76(d). This is because the ADS is intended to be the means by which an applicant provides complete bibliographic information. In some instances, the USPTO may refer to sources other than those listed above for purposes of assessing compliance with the domicile requirement. For example, in order to determine whether the domicile is accurate, the USPTO may refer to the notarized Patent Electronic System Verification form or other identity verification information.

A paper filed on behalf of the patent owner may indicate the domicile of the patent owner if such information is not present in the application file. When it is necessary for the USPTO to act on a paper submitted in the file of an issued patent and the paper is not signed by a registered patent practitioner, the paper may not be treated on its merits. For example, if a petition to accept unintentionally delayed payment of a maintenance fee in an expired patent under 37 CFR 1.378(b) is filed that is not signed by a registered patent practitioner, the petition may be dismissed before consideration on the merits if it cannot be determined whether the paper complies with 37 CFR 1.31 and 1.33(b).

Regarding the assessment of compliance referred to above, applicants, patent owners, and practitioners are reminded that the presentation to the Office of any paper by a party, whether a practitioner or non-practitioner, constitutes a certification under 37 CFR 11.18(b). A misrepresentation of the domicile of an applicant or patent owner would not be ''to the best of the party's knowledge, information and belief, formed after an inquiry reasonable under the circumstances'' as required under 37 CFR 11.18(b)(2). Violations of 37 CFR 11.18(b)(2) by a party, whether a practitioner or non-practitioner, may result in the imposition of sanctions under 37 CFR 11.18(c), which may include termination of the proceedings. *See* 37 CFR 1.4(d)(5)(i).

III. Discussion of Specific Rules

The following is a discussion of proposed amendments to 37 CFR part 1:

A. Section 1.9

Section 1.9 is proposed to be amended to add new paragraph (p) defining domicile as the permanent legal place of residence of a natural person or the principal place of business of a juristic entity. The domicile of an inventor-applicant will normally be determined by the residence information provided in the ADS under 37 CFR 1.76, or the inventor's oath or declaration under 37 CFR 1.63 (including a substitute statement under 37 CFR 1.64). The domicile of an applicant who is not an inventor will normally be determined based on the mailing address provided in the Applicant Information section of the ADS. *See* section II. above for further discussion.

B. Section 1.31

Section 1.31 is proposed to be amended to add the title and rule to include ''patent owner,'' and reformatting the rule language into paragraphs (a) and (b). The section is further proposed to be amended to indicate that an applicant as defined in § 1.42 or patent owner whose domicile is not located within the U.S. or its territories must be represented by a registered patent practitioner. The section is also proposed to be amended to require that a patent owner who is a juristic entity must be represented by a registered patent practitioner. The section previously required a juristic entity who was the applicant to be represented by a registered patent

practitioner, but has now been expanded to make a similar requirement for patent owners in post-grant proceedings.

The phrase ''an applicant as defined in § 1.42'' in paragraph (a) encompasses any inventor, joint inventor, legal representative, person to whom the inventor has assigned, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter who is named as an applicant. Thus, an applicant as defined in § 1.42 must be represented by a registered patent practitioner if at least one of the parties identified as the applicant has a domicile that is not located within the U.S. or its territories. *See* § 1.31(a)(2). As a reminder, powers of attorney must be signed by all parties identified as the applicant in order to be effective.

C. Section 1.32

Section 1.32 is proposed to be amended to add the definition of patent practitioner to partially parallel § 11.10(a).

D. Section 1.33

Section 1.33 is proposed to be amended to add paragraph (b)(3) to indicate that for amendments and other papers filed in an application or patent unless otherwise specified submitted on behalf of a juristic entity, an applicant as defined in § 1.42 whose domicile is not located within the United States or its territories, or a patent owner whose domicile is not located within the United States or its territories must be signed by a patent practitioner. These revisions to paragraph (b)(3) are consistent with the changes to § 1.31, discussed above.

A foreign domiciled inventor who is the applicant may initially file a U.S. patent application with the USPTO and pay the filing fee at the time of filing. However, any application data sheet that accompanies the application papers or is submitted later, as well as all follow-on correspondence, must be signed by a patent practitioner. A patent practitioner must also sign any petition that is filed in such an application, including but not limited to a request for prioritized examination and a petition to make special. To pay the issue fee, PTOL–85 Part B would also have to be signed by a patent practitioner.

IV. Rulemaking Considerations

A. Administrative Procedure Act

This rulemaking would revise the procedures governing the representation of patent applicants and patent owners at the USPTO. The proposed changes do not change the substantive criteria of patentability. Therefore, the changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules and do not require notice-and-comment rulemaking, pursuant to 5 U.S.C. 553(b)(A)). *See Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 97, 101 (2015) (explaining that interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers'' and do not require notice-and-comment when issued or amended); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (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''); *In re Chestek PLLC,* 92 F.4th 1105, 1110 (Fed. Cir. 2024) (noting that rule changes that ''do[ ] not alter the substantive standards by which the USPTO evaluates trademark applications'' are procedural in nature and thus ''exempted from notice-and-comment rulemaking.''); and *JEM Broadcasting Co.* v. *F.C.C.,* 22 F.3d 320, 328 (D.C. Cir. 1994) (''[T]he 'critical feature' of the procedural exception [in 5 U.S.C. 553(b)(A)] 'is that it covers agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency.' '' (quoting *Batterton* v. *Marshall,* 648 F.2d 694, 707 (D.C. Cir. 1980))). However, the USPTO has chosen 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 Act analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) is required. *See* 5 U.S.C. 603. Nevertheless, the USPTO publishes this IRFA to examine the impact on small entities of the Office's proposed requirement that patent applicants and patent owners whose domicile is not located within the United States (U.S.) or its territories (hereinafter ''foreign applicants/inventors and patent owners'') be represented by a registered patent practitioner, as defined in 37 CFR 1.32(a)(1), and to seek the public's views. The USPTO developed this IRFA to promote transparency and to inform the public of the impacts of this rule. The term domicile is defined as the permanent legal place of residence of a natural person or the principal place of business of a juristic entity, as provided in new paragraph (p) under 37 CFR 1.9 of this proposed rule. Items 1–5 below discuss the five items specified in 5 U.S.C. 603(b)(1)–(5) to be addressed in an IRFA. Item 6 below discusses any alternatives to this proposal that the Office considered under 5 U.S.C. 603(c).

1. Description of the Reasons That Action by the USPTO Is Being Considered

The USPTO proposes to require that foreign applicants/inventors and patent owners be represented by a registered patent practitioner, as defined in proposed 37 CFR 1.32(a)(1). An ''applicant'' is the person applying for a patent, and can be any inventor, joint inventor, legal representative, person to whom the inventor has assigned, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter who is named as an applicant. Under this proposed rule, foreign applicants/inventors and patent owners must be represented by a registered patent practitioner if at least one of the parties identified as an applicant or a patent owner has a domicile that is not located within the U.S. or its territories. A patent practitioner as defined in proposed 37 CFR 1.32(a)(1) means a registered patent attorney or registered patent agent under 37 CFR 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16. When representation by a registered patent practitioner is required, papers such as amendments and other replies, application data sheets, information disclosure statements, or petitions, will not be entered unless they are signed by a registered patent practitioner; papers which are required to be signed by a specific party, such as the inventor's oath or declaration under 37 CFR 1.63, are excluded. The requirement for a registered patent practitioner is applicable to all applications types (*i.e.,* utility, plant, design, *etc.*). This proposed rule would bring the United States in line with most other countries that require that such parties be represented by a licensed or registered person of that country. Additionally, this proposed rule would increase efficiency and enable the USPTO to more effectively use available mechanisms to enforce compliance by all foreign applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters, and enhance the USPTO's ability to respond to false certifications, misrepresentations, and fraud. The rule

is also amended to require that a patent owner who is a juristic entity must be represented by a registered patent practitioner. The rule previously required a juristic entity who was the applicant to be represented by a registered patent practitioner, and has now been expanded to make explicit a similar requirement for patent owners in post-grant proceedings.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The USPTO undertakes this proposed rule pursuant to its authority under 35 U.S.C. 2(b)(2), which authorizes the USPTO Director to establish regulations, not inconsistent with law, governing the conduct of proceedings in the Office. The policy objectives of the proposed rule are to: (1) treat foreign applicants/inventors and patent owners similarly to how U.S. applicants/inventors and patent owners are treated in other countries and harmonize U.S. practice with the rest of the world; (2) increase efficiency by reducing the extra resources the USPTO spends to handle *pro se* applicants (*i.e.,* an applicant who is prosecuting the application without a registered patent practitioner); (3) enable the USPTO to more effectively use available mechanisms to enforce compliance with statutory and regulatory requirements in patent matters; and (4) enhance the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

3. Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

The Small Business Administration (SBA) small business size standards that are applicable to most analyses conducted to comply with the RFA are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a specified maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. As provided by the RFA, and after consulting with the SBA, the USPTO formally adopted an alternate size standard for the purpose of conducting an analysis or making a certification under the RFA for patent-related regulations. *See* Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR 67109 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office 60 (Dec. 12, 2006). The USPTO's alternate small business size standard is SBA's previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. *See* 13 CFR 121.802.

If patent applicants assert or certify entitlement for reduced patent fees, the USPTO captures this data in its patent application data repository (formerly the Patent Application Locating and Monitoring (PALM) system and now called the One Patent Service Gateway (OPSG) system), which tracks information on each patent application submitted to the Office.

Unlike the SBA small business size standards set forth in 13 CFR 121.201, the size standard for the USPTO is not industry specific. The Office's definition of a small business concern for RFA purposes is a business or other concern that: (1) meets the SBA's definition of a ''business concern or concern'' set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern that would not qualify as a nonprofit organization or a small business concern under this definition. *See* Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR at 67112 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office at 63 (Dec. 12, 2006). Thus, for the purpose of this analysis, the USPTO defines small entities to include applicants/inventors and patent owners who pay ''small'' or ''micro'' entity fees at the USPTO.

In fiscal year (FY) 2022, the USPTO received 512,038 patent applications.[1] As discussed above, this proposed rule would impact those applications from foreign applicants/inventors or patent owners who are not represented by counsel. An applicant is considered to be a foreign applicant/inventor or patent owner if at least one party who was identified as an applicant or a patent owner had a domicile that was not located within the U.S. or its territories.

As seen in Table 1 below, of the total 512,038 patent applications filed in FY 2022, 215,459 (42.1%) were filed by U.S. applicants/inventors and patent owners, and 296,579 (57.9%) were filed by foreign applicants/inventors and patent owners.

TABLE 1—FILINGS FROM FOREIGN OR U.S. APPLICANTS AS A PERCENTAGE OF TOTAL FILINGS

Applicant	FY 2022	Percentage (%)
US	215,459	42.1
Foreign	296,579	57.9
Total	512,038	100.0

Table 2 below shows the number of applications that were filed without a registered patent practitioner (*i.e., pro se*) and those that were filed with a registered patent practitioner, in addition to the entity status of the applicant(s). Of the total 296,579 filings made by a foreign applicant/inventor or patent owner, 295,362 were represented by a registered patent practitioner (foreign represented) and 1,217 were not represented by a registered patent practitioner (foreign *pro se*).[2] The 1,217 foreign *pro se* applications would be impacted by the requirement to retain representation by a registered patent practitioner under this proposed rule.

The USPTO anticipates that this proposed rule would not have a substantial impact on foreign small entities. Of the total 295,362 foreign represented applications, 75,111 are considered to be small entities for the purposes of this analysis because they paid the ''small'' or ''micro'' entity fee (foreign represented small entities), and of the 1,217 foreign *pro se* applications, 1,102 are considered to be small entities because they paid the ''small'' or ''micro'' entity fee (foreign *pro se* small entities). The USPTO acknowledges that representation status in an application is dynamic, and some number of applicants change their status of representation after filing by either retaining a registered patent practitioner or separating from a registered patent practitioner and proceeding *pro se.* For the purposes of this analysis, the USPTO will assume that the 1,102 applications filed by foreign *pro se* small entities did not change their

[1] Fiscal year (FY) 2022 data is being used for this analysis to correspond with the most current available estimates of legal costs as published by American Intellectual Property Law Association in its 2023 Report on the Economic Survey. Patent application data show that filing trends in FY 2023 and FY 2024 have been consistent with FY 2022, with filings in FY 2023 totaling 516,915 and filings in FY 2024 totaling 527,538.

[2] An application is determined to be *pro se* if there are no current attorney(s) associated with the application or if no attorney(s) has been directly associated with the application over the application's prosecution history.

representation status and thus would be subject to the requirement to be represented by a registered patent practitioner. This proposed rule is not expected to significantly impact foreign small entities, as the vast majority are represented by a registered patent practitioner. Only 1,102 foreign *pro se* small entities, or 1.4% of the 76,213 total foreign small entities filing patent applications, would be affected.

TABLE 2

Application type	Total number of applications filed in FY 2022 (per OPPDA data obtained in June 2025)					
	Undisc.	Small	Micro	Total	Percentage (%)	
US *Pro Se*	1,664	1,747	2,180	5,591	1.09	215,459
US Represented	129,805	67,318	12,745	209,868	40.99	
Foreign *Pro Se*						
Foreign Represented	115	490	612	1,217	.24	296,579
	220,251	60,720	14,391	295,362	57.86	
Totals	351,835	130,275	29,928	512,038	100.0	

4. Description of the reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record:

The proposed rule imposes no new reporting or recordkeeping requirements. Compliance with the rule will be enforced by requiring an appropriate signature on papers submitted in patent matters. Any registered patent practitioner retained by the foreign applicants/inventors and patent owners as a result of this proposed rule would be required to be a registered patent attorney or registered patent agent under 37 CFR 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16.

5. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule:

This proposed rule does not duplicate, overlap, or conflict with other Federal rules.

6. Description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities:

The USPTO considered one alternative before proposing the requirement that foreign applicants/inventors and patent owners be represented by a registered patent practitioner, as defined in proposed 37 CFR 1.32(a)(1). A description of the proposed rule and the one alternative follows.

Proposed Rule: Under the proposed rule, the USPTO proposes to require that foreign applicants/inventors and patent owners be represented by a registered patent practitioner, as defined in proposed 37 CFR 1.32(a)(1). An applicant must be represented by a registered patent practitioner if at least one of the parties identified as the applicant or patent owner has a domicile that is not located within the U.S. or its territories. When representation by a registered patent practitioner is required, papers such as amendments and other replies, application data sheets, information disclosure statements, or petitions, will not be entered unless they are signed by a registered patent practitioner; papers which are required to be signed by a specific party, such as the inventor's oath or declaration under 37 CFR 1.63, are excluded. The requirement for a registered patent practitioner is applicable to all applications types (*i.e.,* utility, plant, design, *etc.*).

Due to the difficulty in quantifying the intangible benefits associated with the proposed rule, the Office provides a discussion of the qualitative benefits to patent applicants/inventors and patent owners. The primary benefits of the proposed rule are ensuring compliance by all foreign patent applicants/inventors and patent owners with U.S. statutory and regulatory requirements in patent matters, and facilitating fraud mitigation and protecting the integrity of the U.S. patent system. The USPTO has noticed an increase in the number of false micro entity certifications to claim a reduction in fees and other false certification documents being filed. False certifications unjustly diminish the monetary resources of the USPTO, and false certifications on petitions or requests to expedite examination result in applications being unjustly advanced out of turn. Requiring submissions to be made by registered patent practitioners subject to the USPTO Rules of Professional Conduct and concomitant disciplinary sanctions imposed by the USPTO Director will make it less likely that the submissions will be signed by an unauthorized party or contain inaccurate or fraudulent statements, particularly with regard to any certification of micro entity status to claim a reduction in fees and any certification relevant to expediting the application.

The proposed rule also addresses the increasing problem of patent application pendency. *Pro se* applications generally require additional processing by the Office of Patent Application Processing because the application papers are often not in condition for publication, examination, or both. Additionally, *pro se* applications usually require patent examiners to spend examination time on procedural matters, thereby increasing overall patent application pendency. This proposed rule would help allocate USPTO resources to the merits of examination and, accordingly, decrease patent application processing times. Requiring foreign applicants/inventors and patent owners to use registered patent practitioners will increase efficiency, as the applications will be in better form for examination. Thus, the proposed rule would provide qualitative value to all applicants/inventors and patent owners because this rule would help allocate USPTO resources to the merits of examination and, accordingly, generally decrease processing times for all patent applications.

The RFA requires agencies to consider the economic impact of their regulatory proposals on small entities, specifically

U.S. small businesses, small governmental jurisdictions and small organizations. This proposed rule would require all applicants/inventors and patent owners, in which at least one party identified as the applicant or patent owner has a foreign domicile, to be represented by a registered patent practitioner. Although there will be some number of U.S.-domiciled applicants/inventors and patent owners that will be affected because at least one party identified as the applicant or patent owner has a foreign domicile, the USPTO estimates that the number of foreign *pro se* small entities impacted by this rule (1,102) is small when compared to the 76,213 total foreign small entities that file patent applications. The costs incurred by the 1,102 foreign *pro se* small entities would vary depending on the nature of legal services provided and complexity of the application.

Tables 3, 4, and 5 below provide the estimated costs for a U.S. patent practitioner to prosecute an application based on professional rates as reported by the American Intellectual Property Law Association in the 2023 Report on the Economic Survey.[3] The professional rates [4] shown below are the median charges in FY 2022 for legal services rendered for a utility application.[5] The tables do not include services for which legal counsel is not required (*e.g.,* payment of maintenance fees) or services that are not part of prosecution (such as *ex parte* reexamination, novelty search, validity and infringement opinions, and reference management). The figures in Tables 3 and 4 show the estimated legal cost for prosecuting applications that are of minimal complexity as well as applications that are relatively complex.

Table 3 below provides the estimated cost to impacted entities if a U.S. patent practitioner is retained prior to filing of a non-provisional application. These cases include applications of foreign origin where no substantive direction is provided by the foreign attorney, and thus the patent practitioner would be required to provide substantive legal advice to prosecute the application, including legal services connected with preparing, filing, and prosecuting an application. Based on the total estimated number of applications filed by foreign applicants/inventors and patent owners that are also considered to be small entities, the total legal cost for non-provisional applications to comply with this proposed rule would range from $13,124,820 to $13,334,200 for minimal complexity applications, to $16,430,820 to $19,395,200 for relatively complex applications.

TABLE 3—COST FOR LEGAL SERVICES BY PERFORMED U.S. PATENT PRACTITIONERS (FY 22) PATENTS OF U.S. ORIGIN

Service	Cost for minimal complexity applications	Cost for relatively complex applications (biotech/chemical; electrical/computer; mechanical)
Original (not divisional, continuation, or CIP) non-provisional application on invention	$8,000	$10,000 to $12,000
Application amendment/argument	$2,000	$3,000 to $3,500
Issuing an allowed application	$750	$750
Preparing and filing Information Disclosure Statement (IDS), less than 50 references and more than 50 references	$360 to $550	$360 to $550
Patent Term Adjustment calculation	$400	$400
Formalities, including preparing and filing formal declarations, assignment, and powers of attorney, responding to pre-examination notices and preparing papers to make corrections	$400	$400
Cost	$11,910 to $12,100	$14,910 to $17,600
Pro Se Foreign Applicants/Inventors and Patent Owners (Small Entities) Non-Provisional	1,102	1,102
Total Cost	$13,124,820 to $13,334,200	$16,430,820 to $19,395,200

Table 4 below provides the estimated cost to impacted entities if a U.S. patent practitioner is retained to file a non-provisional application of foreign origin that is in condition for filing and in which the foreign attorney provides substantive direction. In these cases, the U.S. patent practitioner would provide only minimal legal services connected with the initial filing an application and the subsequent filing of other documents. Based on the total estimated number of applications filed by foreign applicants/inventors and patent owners that are also considered to be small entities, the total legal cost for a non-provisional application to comply with this proposed rule would range from $4,336,370 to $4,545,750 for minimal complexity applications, to $5,190,420 to $5,399,800 for relatively complex applications.

TABLE 4—COST FOR LEGAL SERVICES PERFORMED BY U.S. PATENT PRACTITIONERS (FY 22) PATENTS OF FOREIGN ORIGIN

Service	Cost for minimal complexity applications	Cost for relatively complex applications (biotech/chemical; electrical/computer; mechanical)
Filing in USPTO, received ready for filing	$1,200	$1,200

[3] See Am. Intellectual Prop. Law Ass'n, Report of the Economic Survey 43 (2023).

[4] Copy, drawing, and government fees are not included in the rates.

[5] The Report on the Economic Survey provides professional rates for legal services rendered only in utility applications. Because the professional rates in utility applications typically represent the upper range of legal costs, these rates will be used as a proxy to calculate the costs for legal services rendered for all applications, including plant and design applications.

TABLE 4—COST FOR LEGAL SERVICES PERFORMED BY U.S. PATENT PRACTITIONERS (FY 22) PATENTS OF FOREIGN ORIGIN—Continued

Service	Cost for minimal complexity applications	Cost for relatively complex applications (biotech/chemical; electrical/computer; mechanical)
Application amendment/argument, where foreign counsel or client provides detailed response instructions	$1,225	$2,000
Issuing an allowed application	$750	$750
Preparing and filing Information Disclosure Statement (IDS), less than 50 references and more than 50 references	$360 to $550	$360 to $550
Formalities, including preparing and filing formal declarations, assignment, and powers of attorney, responding to pre-examination notices and preparing papers to make corrections	$400	$400
Total Cost	$3,935 to $4,125	$4,710 to $4,900
Pro Se Foreign Applicants/Inventors and Patent Owners (Small Entities) Non-Provisional	1,102	1,102
Total Cost	$4,336,370 to $4,545,750	$5,190,420 to $5,399,800

Table 5 below provides a list of services that may be provided to impacted entities before or during prosecution, but are dependent on the nature of the application. The prosecution of a patent application is highly variable and a particular application may or may not require any of these services. If these services are provided, then the costs below would be added to the total legal costs in Tables 3 or 4, as applicable. The table below provides the percentage of all applications that have utilized these services.

TABLE 5

Service	Cost	Applications utilizing service	Percentage (%)
Appeal to Board with/without oral argument	$5,000 to $8,000	8,205	2
Preparing and filing formal drawings	600	30,822	6
Preparing for and conducting examination interview	1,000	176,908	35
Providing a continuation recommendation (including proposed claim strategy)	1,000	151,130	30
Filing previously prepared US applications as PCT application in US	1,090	57,112	11
Entering National Stage in US Receiving Office from foreign Origin PCT application	1,200	108,855	21
Provisional application	3,900 to 5,000	147,275	29

As seen above, the USPTO estimates that only 1,102 (or 1.4%) foreign *pro se* small entities would be impacted by this proposed rule. This is a very small number when compared to the 76,213 total foreign small entities that file patent applications. Although the number of impacted small entities is not expected to be substantial, the economic impact varies depending on the nature of legal services provided and complexity of the application. Because prosecution of patent applications is highly variable, the legal costs incurred by the 1,102 foreign *pro se* small entities would depend on whether the application is of U.S. origin or foreign origin, with applications of U.S. origin incurring more cost than those of foreign origin, and the level of complexity of the application, with relatively complex applications incurring more cost than minimally complex applications. Legal costs would increase if any of the additional available services are utilized before or during prosecution.

Alternative 1: The USPTO also considered the alternative to take no action and maintain the status quo (''Alternative 1''). Alternative 1 was rejected because the USPTO has determined that the requirement that foreign applicant/inventors and patent owners to be represented by a registered patent practitioner is needed to accomplish the stated objectives to increase efficiency and enable the USPTO to more effectively use available mechanisms to enforce compliance with U.S. statutory and regulatory requirements in patent matters, and to enhance the USPTO's ability to respond to false certifications, misrepresentations, and fraud.

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (September 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The USPTO has complied with Executive Order 13563 (January 18, 2011). Specifically, and as discussed above, the USPTO has, to the extent feasible and applicable: (1) reasonably determined that the benefits of the rule justify its costs; (2) tailored the rule to impose the least burden on society consistent with obtaining the agency's 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 online 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 while maintaining flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 14192 (Deregulation)

This regulation is not an Executive Order 14192 regulatory action because it is not significant under Executive Order 12866.

F. Executive Order 13132 (Federalism)

This rulemaking pertains strictly to federal agency procedures and does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 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 (November 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 (February 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 (April 21, 1997).

K. Executive Order 12630 (Taking of Private Property)

This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (March 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.*), 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 rulemaking are not expected to result in an annual effect on the economy of $100 million 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 rulemaking 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 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 (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 (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 of 1969

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 of 1995

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 of 1995

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. The collection of information involved in this proposed rule has been reviewed and previously approved by OMB under control number 0651–0035. The USPTO will submit an update to the 0651–0035 information collection in the form of a nonsubstantive change request.

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.

Q. E-Government Act Compliance

The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

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

For the reasons stated in the preamble, the USPTO proposes to amend 37 CFR part 1 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), unless otherwise noted.

■ 2. Amend § 1.9 by adding paragraph (p) to read as follows:

§ 1.9 Definitions.

* * * * *

(p) The term domicile as used in this chapter means the permanent legal place of residence of a natural person or the principal place of business of a juristic entity.

■ 3. Revise § 1.31 to read as follows:

§ 1.31 Applicant and patent owner may be represented by one or more patent practitioners or joint inventors.

(a) An applicant for patent or patent owner may file and prosecute the applicant's or patent owner's own case, or the applicant or patent owner may give power of attorney so as to be represented by one or more patent practitioners or joint inventors, except that the following persons or entities must be represented by a patent practitioner:

(1) a juristic entity (*e.g.,* organizational assignee);

(2) an applicant as defined in § 1.42, in which the domicile of at least one of the parties identified as the applicant in the application is not located within the United States or its territories; and

(3) a patent owner, in which the domicile of at least one of the parties identified as the patent owner is not located within the United States or its territories.

(b) The Office cannot aid in the selection of a patent practitioner.

■ 4. Amend § 1.32 by revising paragraph (a)(1) to read as follows:

§ 1.32 Power of attorney.

(a) * * *

(1) *Patent practitioner* means a practitioner registered under § 11.6 or an individual given limited recognition under § 11.9(a) or (b) or § 11.16. Only these persons are permitted to represent others before the Office in patent matters. An attorney or agent registered under § 11.6(d) may only act as a practitioner in design patent applications or other design patent matters or design patent proceedings.

* * * * *

■ 5. Amend § 1.33 by revising paragraph (b)(3) to read as follows:

§ 1.33 Correspondence respecting patent applications, reexamination proceedings, and other proceedings.

* * * * *

(b) * * *

(3) The applicant (§ 1.42) or patent owner. Unless otherwise specified, all papers submitted on behalf of a juristic entity, an applicant as defined in § 1.42 in which the domicile of at least one of the parties identified as the applicant is not located within the United States or its territories, or a patent owner in which the domicile of at least one of the parties identified as the patent owner is not located within the United States or its territories must be signed by a patent practitioner.

* * * * *

John A. Squires,

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

[FR Doc. 2025–23917 Filed 12–23–25; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170, 171, and 172

RIN 0955–AA08

Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal

AGENCY: Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule; withdrawal of non-finalized provisions.

SUMMARY: ASTP/ONC published in the **Federal Register** on August 5, 2024, a proposed rule, titled ''Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability'' (HTI–2), in which it proposed updating and adding regulations regarding health information technology, information blocking, and the Trusted Exchange Framework and the Common Agreement. The comment period closed on October 4, 2024. ASTP/ONC is withdrawing the remaining proposals that have not been finalized from the HTI–2 Proposed Rule.

DATES: The non-finalized provisions of the proposed rule published at 89 FR 63498 on August 5, 2024, are withdrawn effective December 29, 2025.

ADDRESSES: Comments on the proposed rule published at 89 FR 63498 on August 5, 2024, can be found at *https://www.regulations.gov/document/HHS-ONC-2024-0010-0001.*

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION: On August 5, 2024, ASTP/ONC issued the HTI–2 Proposed Rule proposing to update 45 CFR parts 170 and 171 and add part 172. The comment period closed on October 4, 2024.

ASTP/ONC finalized certain proposals from the HTI–2 Proposed Rule in December 2024 through the Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA) (HTI–2) Final Rule (89 FR 101772) and the Health Data, Technology, and Interoperability: Protecting Care Access (HTI–3) Final Rule (89 FR 102512).

On January 31, 2025, President Donald J. Trump signed Executive Order (E.O.) 14192, ''Unleashing Prosperity Through Deregulation.'' [1] Section 1 of E.O. 14192 states that it is the policy of the Administration to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. Consistent with E.O. 14192 and our planned deregulatory proposed rule (Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI–5) Proposed Rule),[2] ASTP/ONC reexamined the HTI–2 Proposed Rule. ASTP/ONC reviewed comments received in response to the HTI–2 Proposed Rule and reevaluated proposals not yet finalized. We determined that certain proposals should be finalized, while other proposals should not be finalized or needed further consideration, revision, or both. Recently, the Office of Management and Budget, the Department of Health and Human Services, and Centers for Medicare & Medicaid Services (CMS), in collaboration with ASTP/ONC, issued separate requests for information (RFIs) related to deregulation. We reviewed comments received on these RFIs related to ASTP/ONC activities. In response to the Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS–ASTP/ONC RFI), commenters expressed a strong desire to modernize the ONC Health IT Certification Program (Certification Program) by making it more modular, application programming interface (API)-focused, and less centered on specific electronic health record (EHR) functionalities. After reviewing these additional comments and the comments submitted in response to the HTI–2 Proposed Rule, we are withdrawing the remaining non-finalized proposals from the HTI–2 Proposed Rule.

We determined that certain proposals would improve interoperability and reduce costs and burden within the U.S. health care system. Therefore, we finalized proposals for six new and one revised certification criteria in the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and

[1] *https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation.*

[2] *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0955-AA09.*