



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2024-0003]

RIN 0651-AD76

Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The USPTO proposes to amend the rules of practice to add a new requirement for an acceptable terminal disclaimer that is filed to obviate (that is, overcome) nonstatutory double patenting. The proposed rule change would require terminal disclaimers filed to obviate nonstatutory double patenting to include an agreement by the disclaimant that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made. This action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** 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-2024-0003 on the homepage and click “search.” The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this proposed rule and click on 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: Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7711; or Nicholas Hill, Legal Advisor, Office of Patent Legal Administration, at 571-270-1485.

SUPPLEMENTARY INFORMATION: Under U.S. law, a person is entitled to a patent, absent certain exceptions, for an invention that is new and not obvious as of the effective filing date of the claimed invention. Because a patent owner may file continuing applications and obtain follow-on patents with claims that have the same effective filing date as those of the original patent, patent owners may pursue multiple patents with claims that vary in only minor ways from each other. A patent owner may also, under certain circumstances (for example, when two applications are filed on the same day),

obtain patents that are not part of the same patent family for obvious variants of an invention. As a result, obviousness-type double patenting (also referred to as nonstatutory double patenting) may exist between patents and/or applications in the same patent family or in a different patent family. Under the doctrine of obviousness-type double patenting, the USPTO rejects patentably indistinct claims filed in patent applications when these applications and the applications and/or patents whose claims form the basis of the nonstatutory double patenting: (1) have the same inventive entity, at least one common (joint) inventor, a common applicant, and/or a common owner/assignee; or (2) are not commonly owned but are owned by parties to a joint research agreement.

Under current practice, a patent applicant or patent owner (also referred to as a patentee) may, in most instances, obviate nonstatutory double patenting by filing a terminal disclaimer meeting the requirements of 37 CFR 1.321(c) or (d). A terminal disclaimer will ensure that the term of the patent with the terminal disclaimer will not extend beyond the term of the patent forming the basis of the nonstatutory double patenting. To prevent the harassment of an alleged infringer by multiple parties, under current 37 CFR 1.321(c) or (d) a terminal disclaimer must state that the patent in which the terminal disclaimer is filed shall be enforceable only for and during the period that the patent is commonly owned, or commonly enforced, with the patent which formed the basis for the nonstatutory double patenting.

Even with the protections currently provided by a terminal disclaimer, multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings.

Currently, a terminal disclaimer filed to obviate nonstatutory double patenting over a conflicting patent must include a disclaimer of term, if any, extending beyond the term of the conflicting patent and a common ownership or common enforcement

agreement. Under the proposed rule, the USPTO will not issue a patent to a common owner or inventor with a claim that conflicts with a claim of a second patent unless the terminal disclaimer includes an additional agreement that the patent with the terminal disclaimer will not be enforced if any claim of the second patent is invalidated by prior art. That means to resolve a dispute where there are multiple patents tied by terminal disclaimers, competitors could focus on addressing the validity of the claims of a single patent. As is the case under current practice, a terminal disclaimer under the proposed rule would be unidirectional, encumbering only the patent with the terminal disclaimer and not the conflicting patent. The reason for this is that a terminal disclaimer is signed only by the owner of the patent with the terminal disclaimer, and that patent and the conflicting patent might not be commonly owned when the terminal disclaimer is filed. See 35 U.S.C. 253 (providing for filing of a terminal disclaimer by the owner of the patent in which it is filed). The proposed rule is intended to promote competition by lowering the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers. The proposed rule furthers the objectives of Executive Order 14036 on “Promoting Competition in the American Economy,” 86 FR 36987 (July 14, 2021).

As an example of how the proposed rule would lower costs of challenging multiple related patents, in a litigation in which a patent owner is enforcing a patent along with several other patents that are tied by one or more terminal disclaimers to that patent, a competitor could seek to have the court narrow any validity disputes to address only that patent. Narrowing validity disputes in litigation to only one such patent could result in more focused claim construction hearings, lower litigation costs, and faster resolution. Similarly, a competitor could petition for an inter partes or post-grant review of just a single patent to which multiple patents are tied by one or more terminal disclaimers with the proposed agreement. The outcome of the post-grant challenge to the claims in the

selected patent may also resolve the enforceability of the multiple patents tied to that selected patent. Because only one patent can be challenged per post-grant petition, the proposed terminal disclaimer rule would lower the cost of administrative proceedings by enabling a challenger to seek the freedom to operate through the review of only one patent, as opposed to seeking the review of a number of patents claiming obvious variants of a single invention.

I. Background

A. Request for Comments on Whether Any Changes Need to Be Made to the Patent System Regarding Nonstatutory Double Patenting: In a recent request for comments, the USPTO sought public input on whether changes are needed in terminal disclaimer practice to help ensure that the U.S. patent system properly and adequately protects innovation while not unnecessarily harming competition. *See Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights*, 87 FR 60130 (October 4, 2022) (“Request for Comments”). In the Request for Comments, the USPTO recognized that existing practice may not adequately address concerns that multiple patents directed to obvious variants of an invention could deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before the PTAB or in district court. To address this issue, the Request for Comments asked whether applicants seeking patents on obvious variations to prior claims should be required to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer to obviate an obviousness-type double patenting rejection. The Request for Comments also recognized that, under current practice, patents tied together with a terminal disclaimer after an obviousness-type double patenting rejection must be separately challenged on validity grounds. The Request for Comments asked whether the filing of a terminal disclaimer in

these patents should be an admission of obviousness and, if so, whether the patents, when their validity is challenged after issuance, should stand and fall together.

The USPTO received comments expressing a range of views on the questions posed in the Request for Comments. Some comments supported the stipulation requirement and the proposition that the filing of a terminal disclaimer should be an admission of obviousness such that patents tied by terminal disclaimers should stand and fall together. These include comments suggesting that a stipulation could clarify the intrinsic record or simplify subsequent litigation. Some comments stated that a stipulation or admission could reduce the cost and risk of challenging multiple duplicative patents and lower drug prices for drugs that are no longer considered innovative. Some comments also indicated that a stipulation could create an incentive for applicants to address nonstatutory double patenting questions on the merits and that this would encourage innovators to create more inventions, stimulating investment into innovation.

Other comments opposed the stipulation requirement and the proposition that the filing of a terminal disclaimer should be an admission of obviousness such that patents tied by terminal disclaimers should stand and fall together. These include comments asserting that the decision of whether to file a terminal disclaimer is often driven by a desire to expedite prosecution and reduce costs rather than by the merits of the nonstatutory double patenting rejection, that a stipulation requirement would cause delays and increase burdens on applicants, and/or that a stipulation requirement would encourage applicants to file a large number of claims in a single application. Comments opposed to treating the filing of a terminal disclaimer as an admission of obviousness include comments citing *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018), or earlier Federal Circuit cases, for the proposition that a terminal disclaimer should not be considered an admission or give rise to a presumption/estoppel. Comments opposing the changes in terminal disclaimer practice discussed in the Request for Comments also

include comments asserting the following: validity is determined on a claim-by-claim basis; claims are presumed valid under 35 U.S.C. 282; the fact that prior art invalidates a claim in one of two patents tied together by a terminal disclaimer does not necessarily mean that the same prior art would invalidate a claim in the other patent; and/or these changes raise questions of due process and fairness.

In addition, some comments broadly opposed any changes to terminal disclaimer practice. Commenters were concerned that such changes would increase the burden on applicants. Some commenters asserted that the stipulation requirement described in the Request for Comments would be a substantive rule that the USPTO does not have authority to make.

Upon consideration of the comments, the USPTO has opted not to propose a rule requiring a stipulation that the claims are not patentably distinct or an agreement by the disclaimant that filing a terminal disclaimer is an admission of obviousness. The proposed rule does not concern the validity of claims. Instead, the proposed rule would require an agreement by the disclaimant that the patent with the terminal disclaimer will be enforced only under certain conditions. To the extent an applicant believes claims are patentably distinct, they may either challenge the rejection or move those claims to an application in which a terminal disclaimer has not been, and will not be, filed. A rule requiring that terminal disclaimers filed to obviate nonstatutory double patenting include language placing conditions upon enforcement was previously upheld as within the USPTO's rulemaking authority. See *In re Van Ornum*, 686 F.2d 937 (CCPA 1982).

B. Current Practice: Nonstatutory double patenting may be obviated, in most instances, by filing a terminal disclaimer. The terminal disclaimer will ensure that the term of the patent with the terminal disclaimer will not extend beyond the term of the patent forming the basis of the nonstatutory double patenting. In addition, the enforcement provision of the terminal disclaimer will prevent the harassment of an alleged infringer by multiple

parties. Under current USPTO regulations, two types of terminal disclaimers may be used to obviate nonstatutory double patenting. The first type is filed pursuant to 37 CFR 1.321(c) and must include a provision that the patent in which the terminal disclaimer is filed (that is, the subject patent) or any patent granted on the application in which the terminal disclaimer is filed (that is, any patent granted on the subject application) shall be enforceable only for and during the period that the subject patent or any patent granted on the subject application is commonly owned with the reference patent or any patent granted on the reference application which formed the basis for the nonstatutory double patenting. The second type is filed pursuant to 37 CFR 1.321(d) and must include a provision that the subject patent or any patent granted on the subject application shall be enforceable only for and during such period that the subject patent or any patent granted on the subject application and the reference patent or any patent granted on the reference application which formed the basis for the nonstatutory double patenting are not separately enforced. The second type obviates nonstatutory double patenting based on a non-commonly owned reference patent or application that is excepted or disqualified as prior art as a result of the subject matter of the reference patent or application and the claimed invention in the subject patent or application being treated as commonly owned on the basis of a joint research agreement.

Currently, claims in patents tied by a terminal disclaimer filed under 37 CFR 1.321(c) or (d) to obviate nonstatutory double patenting must be separately challenged on validity grounds. See 35 U.S.C. 282(a); see also *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-68 (Fed. Cir. 2018) (“[O]ur cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims.”); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) (“A terminal disclaimer simply is not an admission that a later-filed invention is obvious.”); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941 (Fed. Cir. 1992) (rejecting the argument

that the patent applicant admitted to obviousness-type double patenting by filing a terminal disclaimer); *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) (“[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection.”). The current state of the law exposes competitors attempting to enter the market to potentially high costs because they may have to defend against patents to obvious variants of a single invention despite the presence of terminal disclaimers.

II. Proposed Changes

A. Changes to Current Practice: The USPTO proposes to revise the enforcement provisions in 37 CFR 1.321(c) and (d) to require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the subject patent or any patent granted on the subject application shall be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: (1) any claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 (statutory provisions for anticipation or obviousness as referred to in the SUMMARY above) by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or (2) a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made. The new requirement for a terminal disclaimer in this proposed rule differs from the stipulation described in the Request for Comments discussed above. See 87 FR at 60134. Specifically, the proposed rule does not require an applicant or a patentee to make a statement in the terminal disclaimer regarding conflicting claims being patentably indistinct. The new requirement has the likely advantages of reducing litigation and administrative proceeding costs and increasing predictability compared with the stipulation requirement in the Request for

Comments because a comparison of claims is not necessary to determine which claims are subject to a stipulation (or an agreement), including claims that are amended during prosecution after the terminal disclaimer is filed. The proposed agreement would not affect the validity of the claims in the subject patent or any patent granted on the subject application because it is a voluntary agreement by the patentee that the patent with the terminal disclaimer will be enforceable only under certain conditions and does not touch on the validity of the claims. The new requirement solves the current problem of requiring a competitor to invalidate multiple patents tied by terminal disclaimers in order to have the freedom to operate. To the extent an applicant believes claims are patentably distinct, they may either challenge the rejection or move those claims to an application in which a terminal disclaimer has not been, and will not be, filed.

(1) Meaning of Direct and Indirect Tying

a. Direct Tying - By One Terminal Disclaimer

The subject patent or any patent granted on the subject application is tied directly by a terminal disclaimer to another patent when: (1) the terminal disclaimer is filed in the subject patent or application; and (2) the other patent, or the application that issued as the other patent, is the reference patent or application identified in the terminal disclaimer. The tying by a terminal disclaimer is unidirectional and is effective only for the patent with the terminal disclaimer. Therefore, a terminal disclaimer that directly ties a subject patent or any patent granted on a subject application to a reference patent or any patent granted on a reference application does not directly tie the reference patent or any patent granted on the reference application to the subject patent or any patent granted on the subject application. Direct tying is illustrated by example 1 in section (II)(A)(3) below.

If timely requested, a recorded terminal disclaimer may be withdrawn before the application in which it is filed issues as a patent, or if a terminal disclaimer is filed in a reexamination proceeding, before the reexamination certificate issues. See section 1490,

subsection VIII of the Manual of Patent Examining Procedure (MPEP) (Ninth Edition, Revision 07.2022, February 2023). After a patent or reexamination certificate issues, a recorded terminal disclaimer will not be nullified. *Id.* For a terminal disclaimer filed in a patent, the recorded terminal disclaimer is considered part of the original patent. See 35 U.S.C. 253(b) and 37 CFR 1.321(a). By contrast, a terminal disclaimer filed in a reexamination proceeding is a proposed amendment to the patent that does not take effect until the reexamination certificate issues. See MPEP 2288.

Where a terminal disclaimer is filed in an application, if the terminal disclaimer is withdrawn before a patent issues from the application, then the patent containing the withdrawn terminal disclaimer is not tied and has never been tied to the patent identified in the withdrawn terminal disclaimer (or to any patent granted on the application identified in the withdrawn terminal disclaimer).

b. Indirect Tying - By Two or More Terminal Disclaimers

The subject patent or any patent granted on the subject application is tied indirectly by two terminal disclaimers to another patent when: (1) a terminal disclaimer filed in the subject patent or application identifies an intermediate patent/application as the reference patent or application; and (2) a terminal disclaimer filed in the intermediate patent/application identifies the other patent, or the application that issued as the other patent, as the reference patent or application. This is illustrated by example 2 in section (II)(A)(3) below.

As discussed above with respect to direct tying, terminal disclaimers may be withdrawn from an application in certain circumstances. The following four illustrations show the effect on tying of withdrawing a terminal disclaimer from an intermediate application where a terminal disclaimer is also filed in a subject application.

(1) Where the terminal disclaimer filed in the intermediate application identifies the other patent and is withdrawn *before* a patent is granted on the subject

application, the patent granted on the subject application was never tied indirectly to the other patent.

(2) Where the terminal disclaimer filed in the intermediate application identifies the other patent and is withdrawn *after* a patent is granted on the subject application, the indirect tying to the other patent is undone but the patent granted on the subject application was at one point tied indirectly to the other patent.

(3) Where the terminal disclaimer filed in the intermediate application identifies the application that later issues as the other patent and is withdrawn *before* a patent is granted on the subject application or *before* the other patent issues, the patent granted on the subject application was never tied indirectly to the other patent.

(4) Where the terminal disclaimer filed in the intermediate application identifies the application that later issues as the other patent and is withdrawn *after* a patent is granted on the subject application and *after* the other patent issues, the indirect tying to the other patent is undone but the patent granted on the subject application was at one point tied indirectly to the other patent.

Tying by more than two terminal disclaimers is illustrated by example 3 in section (II)(A)(3) below.

(2) Meaning of “a claim has been finally held unpatentable or invalid”

The term “finally held unpatentable” refers to a final determination by the USPTO in a trial established by the Leahy-Smith America Invents Act (AIA) (Pub. L. 112-29 (2011)) or a reexamination proceeding that one or more claims in a patent are unpatentable after all appeals have been concluded or appeal rights exhausted. The term “finally held . . . invalid” relates to a final decision entered in a Federal court in a civil action holding one or more claims of a patent invalid after all appeals have been concluded or appeal rights exhausted. The proposed agreement is independent of the

relative timing of the terminal disclaimer and the final holding of unpatentability or invalidity over prior art. Additionally, the proposed agreement cannot be avoided by filing a statutory disclaimer of a claim under 35 U.S.C. 253(a) after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

(3) Examples

The following examples illustrate the meaning of: (1) direct and indirect tying in the proposed rule, and (2) the possible consequences of the agreement in the proposed rule.

In the examples, all terminal disclaimers include the agreement in the proposed rule and are filed to obviate nonstatutory double patenting, unless otherwise noted.

A single capital letter identifies both an application and any patent that issues from that application, with the letter “A” in parentheses used to identify the application and the letter “P” in parentheses used to identify the patent. Thus, X(P) is any patent that has issued from application X(A).

An arrow represents a terminal disclaimer filed to obviate nonstatutory double patenting. The arrow starts at the subject patent or application and points toward the reference patent or application.

The patents and applications in these examples may be in the same patent family or in a different patent family.

The enumeration of the terminal disclaimers using terms such as “first,” “second,” etc. does not refer to when the terminal disclaimers are filed but is instead used for identification purposes.

Example 1

The subject patent or any patent granted on the subject application is tied directly to the reference patent or any patent granted on the reference application by a terminal

disclaimer filed in the subject patent or application to obviate nonstatutory double patenting based on the reference patent or application.

Thus, if a terminal disclaimer is filed in X(P) or X(A) identifying W(P) or W(A) as a reference patent or application, then X(P) is tied directly to W(P). Example 1 may be represented visually as:

$$W \leftarrow X$$

The tying by a terminal disclaimer is unidirectional. Therefore, in this example, W(P) is not tied to X(P) by the terminal disclaimer filed in X.

In this example, X(P) is the subject patent or any patent granted on the subject application, and W(P) is the reference patent or any patent granted on the reference application. As a result, if a claim of W(P) is finally held unpatentable or invalid over prior art, X(P) may not be enforced. However, if a claim of X(P) is finally held unpatentable or invalid over prior art, W(P) may still be enforced because a terminal disclaimer with the agreement in the proposed rule was not filed in W identifying X as a reference patent or application.

If the terminal disclaimer filed in X(A) is withdrawn before X(A) issues as a patent, then X(P) may be enforced even if a claim in W(P) is finally held unpatentable or invalid over prior art because X(P) was never tied to W(P).

We can further explain example 1 in practical terms. For instance, applicant overcomes a nonstatutory double patenting rejection in application X(A) based on reference patent W(P) by filing a terminal disclaimer with the agreement in the proposed rule, thereby obtaining patent X(P). Under the current rule, both patents X(P) and W(P) may block competitors and need to be separately invalidated or licensed to gain freedom to operate. Under the proposed rule, if a claim of patent W(P) is finally held invalid or unpatentable over prior art, competitors would avoid the enforcement of patent X(P) based on the agreement in the proposed rule in the terminal disclaimer in patent

X(P). However, if a claim of patent X(P) is finally held invalid or unpatentable over prior art, competitors would not be able to, solely on this basis, avoid the enforcement of patent W(P) because a terminal disclaimer containing the proposed agreement was not filed in W identifying X as a reference patent or application.

Additionally, multiple subject patents or applications may have terminal disclaimers identifying the same reference patent or application. Under the proposed rule, if a claim of the reference patent or any patent granted on the reference application is finally held invalid or unpatentable over prior art, competitors would avoid the enforcement of these multiple patents based on the proposed agreement in the terminal disclaimers filed in these patents.

Example 2

Extending example 1 (where the terminal disclaimer filed in X includes the proposed agreement), if a second terminal disclaimer is filed in Y(P) or Y(A) identifying X(P) or X(A) as a reference patent or application, then Y(P) is tied indirectly to W(P). This would be the case even if X(A) is abandoned or remains pending. Example 2 may be represented visually as:

$$\mathbf{W \leftarrow X \leftarrow Y}$$

Consistent with example 1, Y(P) is tied directly to X(P), and X(P) is tied directly to W(P). In this example, X(P) or X(A), as the case may be, is an intermediate patent/application because the two terminal disclaimers tie Y(P) to W(P).

In this example, W(P) is not tied to X(P) or Y(P), and X(P) is not tied to Y(P).

In this example, Y(P) is a subject patent or any patent granted on a subject application for the terminal disclaimer filed in Y, and W(P) is a reference patent or any patent granted on a reference application for the terminal disclaimer filed in X. In this example, X is an intermediate patent/application that is the reference patent or application for the terminal disclaimer filed in Y and the subject patent or application for the terminal

disclaimer filed in X. As a result, if a claim of W(P) is finally held unpatentable or invalid over prior art, and the terminal disclaimer in Y(P) contains the proposed agreement, Y(P) may not be enforced.

As in example 1, if a claim of W(P) is finally held unpatentable or invalid over prior art, X(P) may not be enforced. Similarly, if a claim of X(P) is finally held unpatentable or invalid over prior art, Y(P) may not be enforced.

If the terminal disclaimer filed in X(A) identifying W(P) is withdrawn before Y(A) issues as a patent, then Y(P) would still be enforceable in the event that a claim in W(P) is finally held unpatentable or invalid over prior art because Y(P) was never tied to W(P). On the other hand, if the terminal disclaimer filed in X(A) identifying W(P) is withdrawn after Y(A) has issued as a patent, then Y(P) may not be enforced in the event that a claim in W(P) is finally held unpatentable or invalid over prior art because Y(P) was once tied to W(P).

Note that even if the terminal disclaimer filed in X did not contain the proposed agreement (because it was filed prior to the implementation of this proposed rule), Y(P) is still tied to W(P). In this situation, if a claim in W(P) is finally held unpatentable or invalid over prior art, X(P) may still be enforced (because the terminal disclaimer filed in X does not contain the proposed agreement) even though Y(P) may not be enforced.

Example 3

Indirect tying may also occur through multiple intermediate patents/applications. Extending example 2, if a third terminal disclaimer is filed in Z(P) or Z(A) identifying Y(P) or Y(A) as a reference patent or application, then Z(P) is tied indirectly to W(P). This would be the case even if X(A) and/or Y(A) are/is abandoned or remain(s) pending. Example 3 may be represented visually as:

$$W \leftarrow X \leftarrow Y \leftarrow Z$$

In this example, all the tying relationships of example 2 remain.

Also in this example, Z(P) is a subject patent or any patent granted on a subject application for the terminal disclaimer filed in Z, and W(P) is a reference patent or any patent granted on a reference application for the terminal disclaimer filed in X. X(P) or X(A) and Y(P) or Y(A), as the case may be, are intermediate patents/applications because the three terminal disclaimers tie Z(P) to W(P). As a result, if a claim of W(P) is finally held unpatentable or invalid over prior art and if the terminal disclaimer filed in Z(A) contains the proposed agreement, Z(P) may not be enforced.

As in example 2, if a claim of W(P) is finally held unpatentable or invalid over prior art, Y(P) and X(P) may not be enforced; if a claim of X(P) is finally held unpatentable or invalid over prior art, Y(P) and Z(P) may not be enforced; and if a claim of Y(P) is finally held unpatentable or invalid over prior art, Z(P) may not be enforced.

Example 4

This example shows three patents tied directly and indirectly by terminal disclaimers. In this example, a first terminal disclaimer is filed in X(P) or X(A) identifying W(P) or W(A) as a reference patent or application, directly tying X(P) to W(P).

$$\mathbf{W \leftarrow X}$$

A second terminal disclaimer is filed in W(P) or W(A) identifying X(P) or X(A) as a reference patent or application, directly tying W(P) to X(P).

$$\mathbf{W \rightleftharpoons X}$$

A third terminal disclaimer is filed in Y(P) or Y(A) identifying X(P) or X(A) as a reference patent or application, directly tying Y(P) to X(P).

$$\mathbf{W \rightleftharpoons X \leftarrow Y}$$

A fourth terminal disclaimer is filed in X(P) or X(A) identifying Y(P) or Y(A) as a reference patent or application, directly tying X(P) to Y(P).

$$\mathbf{W \rightleftharpoons X \rightleftharpoons Y}$$

A fifth terminal disclaimer is filed in Y(P) or Y(A) identifying W(P) or W(A) as a reference patent or application, directly tying Y(P) to W(P).

$$W \leftarrow Y$$

A sixth terminal disclaimer is filed in W(P) or W(A) identifying Y(P) or Y(A) as a reference patent or application, directly tying W(P) to Y(P).

$$W \rightleftharpoons Y$$

Example 4 may be represented visually as:

$$W \rightleftharpoons X \rightleftharpoons Y \text{ and } W \rightleftharpoons Y$$

In this example, in addition to W(P), X(P), and Y(P) each being directly tied to one another, they each are indirectly tied to one another. As a result, if a claim in any one of W(P), X(P), or Y(P) is finally held unpatentable or invalid over prior art and if the terminal disclaimers filed in W, X, and Y contain the proposed agreement, the other two patents may not be enforced.

Example 5

The following example illustrates two patents that are not indirectly tied by terminal disclaimers even though each has a terminal disclaimer identifying the same reference patent or application, due to the unidirectionality of tying by a terminal disclaimer.

In this example, a first terminal disclaimer is filed in X(P) or X(A) identifying Y(P) or Y(A) as a reference patent or application, and a second terminal disclaimer is filed in Z(P) or Z(A) identifying Y(P) or Y(A) as a reference patent or application.

Example 5 may be represented visually as:

$$X \rightarrow Y \leftarrow Z$$

In this example, X(P) and Z(P) are both tied directly to Y(P). As a result, if a claim in Y(P) is finally held unpatentable or invalid over prior art and if the proposed

agreement is contained in the terminal disclaimers filed in X and Z, X(P) and Z(P) cannot be enforced.

However, Z(P) is not tied to X(P), X(P) is not tied to Z(P), and Y(P) is not tied to either X(P) or Z(P). Thus, if a claim in X(P) or Z(P) is finally held unpatentable or invalid over prior art, there is no effect on whether the other two patents may be enforced.

(4) Ways to Address Nonstatutory Double Patenting

To obviate nonstatutory double patenting, patent owners and applicants can voluntarily file a terminal disclaimer with the proposed agreement. If applicants and patent owners are concerned about the new requirement and seek to avoid the consequences of the proposed agreement, applicants and patent owners have the option of not filing a terminal disclaimer with the proposed agreement. The nonstatutory double patenting may be dealt with in a number of ways.

An applicant facing a nonstatutory double patenting rejection in an application has a number of options to avoid filing a terminal disclaimer with the proposed agreement such as:

- (1) combining the conflicting claims into a single application,
- (2) canceling or amending any conflicting claims in the application or in the other application containing the conflicting claims that formed the basis of the nonstatutory double patenting,
- (3) arguing that rejected claims in the application are patentably distinct from the claims of the reference patent or application, or
- (4) filing a reissue application of the patent whose claims formed the basis of the nonstatutory double patenting in order to add canceled conflicting claims from the application into the reissue application, provided that the added claims do not introduce new matter into the reissue application.

Alternatively, an applicant may separate the patentably distinct claims into another application and file a terminal disclaimer with the proposed agreement in the application with the indistinct claims.

If the applicant amends the claims after the filing of the terminal disclaimer such that the claims no longer conflict with the claims in the reference patent or application, the applicant may file a petition under 37 CFR 1.182 to withdraw the terminal disclaimer prior to the issuance of the application to avoid the effect of the proposed agreement on patentably distinct claims and any potential loss of patent term. As discussed above, after patent grant, a recorded terminal disclaimer will not be withdrawn. See MPEP 1490, subsection VIII.

B. Changes Consistent with Current Practice:

(1) Who May File a Disclaimer

The proposed rule makes no change to who may file a terminal disclaimer. Consistent with 35 U.S.C. 253, the USPTO proposes to refer to the party with the ownership interest making the disclaimer in 37 CFR 1.321 as the “disclaimant” rather than the patentee, applicant, assignee, or grantee as currently prescribed in the regulations.

(2) Clarify That a Terminal Disclaimer Can Be Filed in a Patent to Obviate Nonstatutory Double Patenting

Current 37 CFR 1.321(c) and (d) state that a terminal disclaimer may be filed in an application or in a reexamination proceeding but do not explicitly state that the terminal disclaimer to obviate nonstatutory double patenting can be filed in a patent not subject to a reexamination proceeding. Consistent with the guidance set forth in the MPEP, a terminal disclaimer may be filed in a patent under 37 CFR 1.321(c) or (d) that is not subject to a reexamination proceeding. See MPEP 1490, subsection II. Proposed 37

CFR 1.321(c) and (d) are amended to explicitly state that a terminal disclaimer may be filed in a patent to obviate nonstatutory double patenting.

(3) Changes to Reflect Current Terminology in the MPEP

Consistent with current usage in the MPEP (see, for example, chapters 800 and 1400), the USPTO proposes the following changes in 37 CFR 1.321: (1) replace “judicially created double patenting” with the phrase “nonstatutory double patenting,” (2) refer to the patent in which a terminal disclaimer is filed and the patent subject to a reexamination proceeding in which the terminal disclaimer is filed as the “subject patent,” (3) refer to the application in which a terminal disclaimer is filed as the “subject application,” and (4) refer to the patent or application forming the basis for the nonstatutory double patenting as the “reference patent or application.”

(4) Changes to Conform with Current Language in the MPEP

MPEP 1490, subsection VII, provides examples of acceptable terminal disclaimer language to use for terminal disclaimers filed under 37 CFR 1.321(c) or (d). In a few of the examples, the language states that the patentee/applicant agrees to the enforcement provision of current 37 CFR 1.321(c)(3) or (d)(3). Consistent with this guidance set forth in the MPEP, the USPTO proposes to amend 37 CFR 1.321(c)(3) and (d)(3) by adding “agreeing” in the enforcement provision.

III. Discussion of Proposed Rules: The following is a discussion of proposed amendments to 37 CFR part 1:

The USPTO proposes to amend § 1.321(a) and (b) by replacing “grantee” with “disclaimant.”

The USPTO proposes to amend § 1.321(a)(3) by replacing “patentee’s ownership interest” with “the disclaimant’s ownership interest.”

The USPTO proposes to amend § 1.321(b)(1) by redesignating current § 1.321(b)(1) as § 1.321(b)(1)(i) and adding new subparagraph § 1.321(b)(1)(ii) to

incorporate the requirements of § 1.321(b)(1) in effect on September 15, 2012. This proposal eliminates the need for the public to consult § 1.321 in effect on September 15, 2012, when filing a terminal disclaimer in an application filed before September 16, 2012, and makes the proposed § 1.321 applicable to all applications, regardless of their filing date. “Inventor” and “applicant” are no longer synonymous for applications filed on or after September 16, 2012. See MPEP 605 and *Changes To Implement the Inventor’s Oath or Declaration Provisions of the Leahy-Smith America Invents Act*, 77 FR 48776, 48778-79 (August 14, 2012) (final rule). The term “applicant” in proposed § 1.321(b)(1)(i) can include an inventor(s), an assignee(s), or others with a sufficient proprietary interest, whereas the term “applicant” in proposed § 1.321(b)(1)(ii) refers to the inventor(s).

The USPTO proposes to amend § 1.321(b)(3) by replacing “applicant’s ownership interest” with “the disclaimant’s ownership interest.”

The USPTO proposes to amend § 1.321(c) by replacing “judicially created double patenting” with “nonstatutory double patenting.”

Additionally, proposed § 1.321(c) would explicitly provide for the filing of a terminal disclaimer in a patent not subject to a reexamination proceeding. As is the case today, when a terminal disclaimer under proposed § 1.321(c) is filed to obviate nonstatutory double patenting in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file. See 37 CFR 1.321(c) and MPEP 1490, subsection III.A.

The USPTO proposes to amend § 1.321(c)(3) by adding “agreeing,” which is consistent with current practice (see MPEP 1490, subsection VII).

The USPTO proposes to amend § 1.321(d) to specify that the type of double patenting that may be obviated by filing a terminal disclaimer is “nonstatutory double patenting.”

Additionally, proposed § 1.321(d) would explicitly provide for the filing of a terminal disclaimer in a patent not subject to a reexamination proceeding. As is the case today, when a terminal disclaimer under proposed § 1.321(d) is filed to obviate nonstatutory double patenting in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file. See 37 CFR 1.321(d) and MPEP 1490, subsection III.A.

The USPTO proposes to amend § 1.321(d)(3) by adding “agreeing,” which is consistent with current practice (see MPEP 1490, subsection VII).

The USPTO proposes to amend § 1.321(c), (c)(3), (d), and (d)(3) to identify the patent or application forming the basis for the nonstatutory double patenting as the “reference patent or application.”

The USPTO proposes to amend § 1.321(c)(2), (c)(3), (d)(2), and (d)(3) to identify an application in which a terminal disclaimer is filed to obviate nonstatutory double patenting as a “subject application” and a patent in which a terminal disclaimer is filed to obviate nonstatutory double patenting as a “subject patent.” The term “subject patent” includes both patents that are undergoing a reexamination proceeding and patents that are not undergoing a reexamination proceeding.

The USPTO proposes to amend § 1.321(c)(3) and (d)(3) to require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which the terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: (1) any claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been

exhausted; or (2) a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

IV. Rulemaking Considerations

A. Administrative Procedure Act: The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules, and do not require notice-and-comment rulemaking. 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) (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”); and *JEM Broadcasting Co. v. F.C.C.*, 22 F.3d 320, 328 (D.C. Cir. 1994) (explaining that rules are not legislative because they do not “foreclose effective opportunity to make one’s case on the merits”).

Nevertheless, the USPTO is publishing this proposed rule for comment to seek the benefit of the public’s views on the Office’s proposed regulatory changes.

B. Regulatory Flexibility Act (RFA): For the following reasons, the Senior Counsel for Regulatory and Legislative Affairs of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

The USPTO is proposing to revise the enforcement provisions in § 1.321(c) and (d) to require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the subject patent, or any patent granted on the subject application, shall be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting: (1) in which any claim has been finally held

unpatentable or invalid under 35 U.S.C. 102 or 103 by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or (2) in which a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made. Thus, the rulemaking does not propose to substantively change when an applicant or patent owner may file a terminal disclaimer under § 1.321.

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 identify themselves on a patent application as qualifying for reduced patent fees, the USPTO captures this data in its patent application data repository (formerly the Patent Application Monitoring and Locating (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). For purposes of this certification, the USPTO defines small entities to include entities who are paying small or micro entity fee rates at the USPTO.

The USPTO estimates that approximately 20% of applicants and patent owners (including small entity applicants and patent owners, who account for approximately 27% of patent filings) that are considering the filing of a terminal disclaimer to obviate nonstatutory double patenting will opt not to file a terminal disclaimer containing the proposed agreement, at least during an initial period after the effective date of the final rule. As mentioned earlier herein, applicants and patent owners who choose not to file a terminal disclaimer with the proposed agreement have a number of alternatives to obviate nonstatutory double patenting. The USPTO estimates that the vast majority of applicants and patent owners who choose not to file a terminal disclaimer with the proposed agreement will opt to argue and/or amend claims to obviate nonstatutory double patenting.

The number of instances in which applicants and patent owners have to obviate nonstatutory double patenting is relatively low. The USPTO issues roughly 650,000 nonfinal and final Office actions per fiscal year, of which 175,500 (or 27%) are issued to

small entities. Of the 175,500 Office actions issued to small entities, approximately 14%, or approximately 24,570, contain at least one nonstatutory double patenting rejection, and approximately 4%, or approximately 7,020, contain only a nonstatutory double patenting rejection(s).

To estimate the potential impact on small entities from this proposed rulemaking, the USPTO refers to the 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association, which estimates a median cost of \$3,500 per Office action response.¹

For purposes of this certification, the USPTO estimates that all of the approximately 20% of the small entity applicants and patent owners who the USPTO estimates will choose not to file a terminal disclaimer with the proposed agreement will opt to argue and/or amend claims to obviate the nonstatutory double patenting rejection(s). The USPTO therefore estimates that the proposed rulemaking could have a potential annual cost to small entities of \$17,199,000 ($24,570 \times 20\% \times \$3,500$) for responding to an Office action containing at least one nonstatutory double patenting rejection by arguing and/or amending claims, rather than filing a terminal disclaimer.

Furthermore, the USPTO estimates that, on the upper range, approximately 50%, or approximately 2,457 ($24,570 \times 20\% \times 50\%$), of the responses filed will fail to obviate at least one nonstatutory double patenting rejection. These cases may potentially incur the additional cost to small entities of \$8,599,500 ($2,457 \times \$3,500$) to respond to an additional Office action. Therefore, the USPTO estimates that the upper range of cost that the proposed rulemaking could have on the approximately 20% of potentially impacted small entities is \$25,798,500 ($\$17,199,000 + \$8,599,500$). The estimated cost will therefore not affect a substantial number (approximately 20%) of small entities.

¹ This cost represents the report's median charges for services categorized as "Application amendment/argument, relatively complex—biotech/chemical" and "Application amendment/argument, relatively complex—electrical/computer."

For at least two reasons, the USPTO believes these estimates to represent the upper range of the potential impact on small entities. First, the preceding estimates do not account for the cost savings, including filing fee savings, from not filing a terminal disclaimer. The USPTO charges a fee of \$170 for filing a terminal disclaimer. Based on the estimated 4,914 small entity applicants that opt to not file a terminal disclaimer, the USPTO estimates terminal disclaimer filing fee savings of \$835,380. In addition, the USPTO estimates that it takes an estimated 0.25 hours (15 minutes) for applicants and patent owners to file a terminal disclaimer. The 2023 Report of the Economic Survey estimates an hourly attorney fee of \$447. Based on the estimated 4,914 small entity applicants that opt to not file a terminal disclaimer, the USPTO estimates cost savings of \$549,140. Therefore, the total cost savings for those not filing a terminal disclaimer because of the proposed rulemaking is \$1,384,520.

Second, the preceding cost estimates are based on all Office actions containing at least one nonstatutory double patenting rejection, including Office actions containing at least one other rejection that is not a nonstatutory double patenting rejection. As stated above, the USPTO estimates that 7,020 Office actions contain only a nonstatutory double patenting rejection(s). Thus, in 17,550 (24,570-7,020) Office actions, small entity applicants and patent owners would have to respond to at least one rejection that is not a nonstatutory double patenting rejection. It therefore follows that at least some portions of the annual costs in the preceding estimates for these 17,550 Office actions should be excluded as they would be attributed to responding to those other rejection(s).

Thus, the total upper range of estimated cost to the 24,570 small entity applicants and patent owners impacted by this rule would be \$24,413,980 (\$25,798,500-\$1,384,520). The USPTO does not have the data to determine the distribution of this cost across the 24,570 small entity applicants and patent owners that would be impacted by

this rule. Thus, for purposes of this certification, the USPTO estimates an average of less than \$1,000 in impact to the 24,570 small entities. However, as mentioned above, this estimate is likely to be overstated as some of that impact would be attributed to costs related to responding to a rejection that is not a nonstatutory double patenting rejection.

For the foregoing reasons, the changes proposed in 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 under Executive Order 12866 (September 30, 1993), as amended by Executive Order 14094 (April 6, 2023).

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) 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 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 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 pertains strictly to Federal agency procedures and does not contain policies with federalism implications sufficient

to warrant the preparation of a Federalism Assessment under Executive Order 13132 (August 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 (November 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 (February 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 (April 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 (March 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 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 proposed 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).

L. Unfunded Mandates Reform Act of 1995: The changes proposed 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.

M. 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.

N. 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.

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking involves information collection requirements that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

This proposed rulemaking impacts the rules of practice pertaining to terminal disclaimers. The general provisions pertaining to terminal disclaimers have been reviewed and approved by the OMB under OMB control number 0651-0031 and are accounted for under the line item Statutory Disclaimers (including terminal disclaimers) as contained in 0651-0031. In a 60-day notice published January 29, 2024 (89 FR 5500), for the renewal of 0651-0031, the USPTO provided estimates for this line item and those estimates appear below.

Under this proposed rulemaking, the USPTO proposes to modify terminal disclaimers to include the additional agreement as discussed in the preamble. The USPTO estimates that approximately 20% of applicants and patent owners that are considering the filing of a terminal disclaimer to obviate nonstatutory double patenting will opt not to file a terminal disclaimer containing the proposed agreement, at least during an initial period after the effective date of the final rule. Therefore, the USPTO proposed estimates below take into account the anticipated 20% reduction in terminal disclaimer filings.

The USPTO will be accounting for this impact in a proposed new information collection that has been submitted to the OMB. The proposed new information collection will reflect an estimated total decrease of 9,990 respondents, 2,498 burden hours and \$1,698,300 in filing fees with respect to terminal disclaimers, because some applicants and patent owners will choose not to file a terminal disclaimer with the proposed agreement. A summary of the change in burden to terminal disclaimers follows. The proposed new information collection will be available at the OMB's Information Collection Review website (www.reginfo.gov/public/do/PRAMain).

Estimated Data Published in the 60-day Notice for 0651-0031 (January 29, 2024)

Estimated number of annual respondents for statutory disclaimers (including terminal disclaimers): 49,950.

Estimated number of annual responses for statutory disclaimers (including terminal disclaimers): 49,950.

Estimated total annual respondent burden hours for statutory disclaimers (including terminal disclaimers): 12,488.

Estimated total annual respondent hourly cost burden for statutory disclaimers (including terminal disclaimers): \$5,582,136.

Estimated total annual respondent non-hourly cost burden for statutory disclaimers (including terminal disclaimers): \$8,491,500 in the form of filing fees.

Proposed New Information Collection Associated with RIN 0651-AD76

OMB control number: 0651-NEW.

Title of collection: Terminal disclaimers.

Needs and uses: The changes under proposed § 1.321 on the filing of terminal disclaimers would be used by an owner (in whole or in part) of a patent or a patent to be granted to agree that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.

The changes would be used by the USPTO to ensure it does not issue a patent to a common owner or inventor with a claim that conflicts with a claim of a second patent, unless the terminal disclaimer includes the additional agreement that the patent with the terminal disclaimer will not be enforced if any claim of the second patent is invalidated by prior art.

The changes would be used by the public to focus on addressing the validity of the claims of a single patent to resolve a dispute where there are multiple patents tied by terminal disclaimers.

Impacted forms in this information collection:

- PTO/AIA/25 (Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection Over a Pending “Reference” Application)
- PTO/SB/25 (Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection over a Pending Second Application)
- PTO/SB/25a (Terminal Disclaimer in a Patent or Proceeding in view of an Application)
- PTO/AIA/26 (Terminal Disclaimer to Obviate a Double Patenting Rejection Over a “Prior” Patent)
- PTO/SB/26 (Terminal Disclaimer to Obviate a Double Patenting Rejection over a Prior Patent)
- PTO/SB/26a (Terminal Disclaimer in a Patent or Proceeding in view of Another Patent)
- PTO/AIA/63 (Terminal Disclaimer to Accompany Petition under 37 CFR 1.137 in a Design Application Filed on or after September 16, 2012)
- PTO/SB/63 (Terminal Disclosure to Accompany Petition)

Type of review: New.

Affected public: Private Sector.

Respondent’s Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated number of annual respondents for statutory disclaimers (including terminal disclaimers): 39,960.

Estimated number of annual responses for statutory disclaimers (including terminal disclaimers): 39,960.

Estimated total annual respondent burden hours for statutory disclaimers (including terminal disclaimers): 9,990.

Estimated total annual respondent hourly cost burden for statutory disclaimers (including terminal disclaimers): \$4,465,530.

Estimated total annual respondent non-hourly cost burden for statutory disclaimers (including terminal disclaimers): \$6,793,200 in the form of filing fees.

The USPTO is soliciting public comments to:

(a) evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information;

(c) enhance the quality, utility, and clarity of the information to be collected; and

(d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting the electronic submission of responses.

Please submit comments on this new collection of information at www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review" or by using the search function and entering the title of the collection. Please send a copy of your comments to the USPTO using the method described under ADDRESSES at the beginning of this document.

All comments submitted in response to this proposed rulemaking are a matter of public record. The USPTO will include or summarize the comments received in the request to the OMB to approve the new information collection requirements.

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 PRA unless that collection of information displays a currently valid OMB control number.

P. 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 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Revise § 1.321 to read as follows:

§ 1.321 Statutory disclaimers, including terminal disclaimers.

(a) A patentee owning the whole or any sectional interest in a patent may disclaim any complete claim or claims in a patent. In like manner any patentee may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted. Such disclaimer is binding upon the disclaimant and its successors or assigns. A notice of the disclaimer is published in the Official Gazette and attached to the printed copies of the specification. The disclaimer, to be recorded in the Patent and Trademark Office, must:

(1) Be signed by the patentee, or an attorney or agent of record;

(2) Identify the patent and complete claim or claims, or term being disclaimed. A disclaimer which is not a disclaimer of a complete claim or claims, or term will be refused recordation;

(3) State the present extent of the disclaimant's ownership interest in the patent;
and

(4) Be accompanied by the fee set forth in § 1.20(d).

(b) An applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted. Such terminal disclaimer is binding upon the disclaimant and its successors or assigns. The terminal disclaimer, to be recorded in the Patent and Trademark Office, must:

(1)(i) For patent applications filed under 35 U.S.C. 111(a) or 363 on or after September 16, 2012, be signed by the applicant or an attorney or agent of record; or

(ii) For patent applications filed under 35 U.S.C. 111(a) or 363 before September 16, 2012, be signed:

(A) By the applicant;

(B) If there is an assignee of record of an undivided part interest, by the applicant and such assignee;

(C) If there is an assignee of record of the entire interest, by such assignee; or

(D) By an attorney or agent of record;

(2) Specify the portion of the term of the patent being disclaimed;

(3) State the present extent of the disclaimant's ownership interest in the patent to be granted; and

(4) Be accompanied by the fee set forth in § 1.20(d).

(c) Except as provided for in paragraph (d) of this section, a terminal disclaimer, when filed in a patent, a reexamination proceeding, or a patent application to obviate nonstatutory double patenting of a claimed invention based on a reference patent or application, must:

(1) Comply with the provisions of paragraphs (b)(2) through (4) of this section;

(2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application (the subject application) or in accordance with paragraph (a)(1) of this section if filed in a patent or in a reexamination proceeding (the subject patent); and

(3) Include a provision agreeing that the subject patent or any patent granted on the subject application shall be enforceable:

(i) Only for and during such period that the subject patent or any patent granted on the subject application is commonly owned with the reference patent or any patent granted on the reference application; and

(ii) Only if the subject patent or any patent granted on the subject application is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which:

(A) A claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been exhausted; or

(B) A statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

(d) A terminal disclaimer, when filed in a patent, a reexamination proceeding, or a patent application to obviate nonstatutory double patenting of a claimed invention based on a reference patent or application that is not commonly owned but was disqualified as prior art as set forth in either § 1.104(c)(4)(ii) or (c)(5)(ii) as the result of activities undertaken within the scope of a joint research agreement, must:

(1) Comply with the provisions of paragraphs (b)(2) through (4) of this section;

(2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application (the subject application) or be signed in accordance with paragraph (a)(1) of this section if filed in a patent or in a reexamination proceeding (the subject patent); and

(3) Include a provision waiving the right to separately enforce the subject patent or any patent granted on the subject application and the reference patent or any patent granted on the reference application, and agreeing that the subject patent or any patent granted on the subject application shall be enforceable:

(i) Only for and during such period that the subject patent or any patent granted on the subject application and the reference patent or any patent granted on the reference application are not separately enforced; and

(ii) Only if the subject patent or any patent granted on the subject application is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which:

(A) A claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been exhausted; or

(B) A statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

Katherine K. Vidal,

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

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