Request for comments (RFC) addresses a variety of topics, including prior art searching, support for claimed subject matter, request for continued examination (RCE) practice, and restriction practice, and certain initiatives related to these topics that are outlined in the USPTO’s July 6, 2022, letter to the Food and Drug Administration (FDA). This RFC also seeks comments on the questions set forth in a June 8, 2022, letter to the USPTO from six United States Senators. The USPTO is studying additional topics and initiatives to bolster the robustness and reliability of U.S. patents and will seek public comments on those separately.

**DATES:** Comment Deadline: Written comments must be received on or before January 3, 2023, 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, enter docket number PTO–P–2022–0025 on the homepage and click “search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this RFC and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE portable document format 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 (www.regulations.gov) for additional instructions on providing comments via the portal. If electronic submission of 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 regarding how to submit comments by mail or by hand delivery, based on the public’s ability to obtain access to USPTO facilities at the time.


**SUPPLEMENTARY INFORMATION:** The USPTO is seeking public input and guidance on proposed initiatives directed at bolstering the robustness and reliability of patents. These initiatives are meant to ensure that the patent rights granted by the USPTO fulfill their intended purpose of furthering the common good, incentivizing innovation, and promoting economic prosperity.

**I. Background and the USPTO’s July 6, 2022, Letter to the FDA**

On July 9, 2021, President Biden issued an Executive Order (E.O.) on “Promoting Competition in the American Economy,” 86 FR 36987 (July 14, 2021) (“Competition E.O.”). To advance the Biden Administration’s goals of promoting access to prescription pharmaceuticals for American families and increasing competition in the marketplace, section 5(p)(vi) of the E.O. directs the Secretary of Health and Human Services (HHS) “to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.” In particular, section 5(p)(vi) of the E.O. directs the HHS Secretary, “through the Commissioner of Food and Drugs” and “not later than 45 days after the date of this order,” to “write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA.”

In response to the Competition E.O., on September 10, 2021, the FDA sent a letter to the USPTO outlining ideas for further engagement with the USPTO. On July 6, 2022, the USPTO sent a responsive letter (USPTO Letter) discussing specific initiatives the USPTO was exploring to further promote robust and reliable patent rights across all technology areas and suggesting additional ways in which the USPTO could work with the FDA to ensure that our patent system properly and adequately protects innovation while not unnecessarily delaying generic and biosimilar competition, which provides more affordable versions of pharmaceuticals for Americans who need them. The Competition E.O. and the letters are available at www.uspto.gov/initiatives/drug-pricing-initiatives.

The USPTO Letter explains that the United States is a global leader in the development of drugs and biologics due to its strong patent system. Robust and reliable patents are important to incentivize and protect the immense research and development investment.
essential to bringing such products to market and to spur the collaboration necessary for quick and speedy drug and biologic development. Our laws also strive to ensure that our system, as a whole, does not unnecessarily delay generic and biosimilar competition, which provide cost savings to Americans when they purchase pharmaceutical products.

To further the objectives of the Competition E.O., the USPTO recently outlined initiatives to execute the President’s agenda. The USPTO’s initiatives to ensure robust and reliable patents, as discussed in Paragraph 2 of the USPTO Letter, are reproduced below.

2. Improve procedures for obtaining a patent so that the USPTO issues robust and reliable patents. Specifically, the USPTO will:
   a. Introduce more examining time into the patent examination system. The USPTO recently made changes to examination time and is implementing changes, particularly in cases with several continuations (large family cases) and cases with evidence submitted in support of patentability.
   b. Give patent examiners more training and resources. The USPTO has released a new search system for patent examiners to use in identifying relevant prior art to make patentability determinations. The new Patents End-to-End Search system includes significant enhancements, such as access to more than 76 million foreign documents with high-quality English translations and new, improved search capabilities. The USPTO is exploring additional technology and resources of prior art to improve patent quality. The USPTO also recently announced a collaboration with the American Intellectual Property Law Association and the Intellectual Property Owners Association to develop examiner training on enhancing the clarity of the prosecution record. The USPTO also is exploring additional training for examiners on new matter, assessing claim scope, and the use of functional claiming.
   c. Enhance communication between patent examiners and the Patent Trial and Appeal Board (PTAB), which hears challenges to patents once they have issued as well as appeals from rejections of pending patent applications during examination. The USPTO has put in place processes for the PTAB to share feedback as it relates to ex parte appeals, including sharing final decision tables with detailed information about the PTAB’s ruling on each individual rejection and claim in an ex parte appeal and using surveys to facilitate information sharing between PTAB judges and the patent examination corps. Examiners are also notified when they have an application related to an ex parte appeal, so they can easily access prior art and relevant statements that may impact their examination in the application before them. In addition, examiners are now able to more quickly identify prior art relied upon and PTAB’s rulings on each individual ground and claim in the post-grant proceeding via final written decision tables, which are now incorporated into all final written decisions. The USPTO is also exploring how data collected from the decision tables in both ex parte appeal and AIA proceedings can be relied upon to identify quality trends, such as prior art terrorism and grant proceedings (e.g., commonly relied upon non-patent literature and foreign language patents) as well as opportunities to develop examiner training or guidance based on findings or lessons learned from surveys.
   d. Consider enhancing the process for information disclosure statements. The USPTO will continue our efforts to explore changes to the procedures for identifying prior art on information disclosure forms to provide efficiencies for applicants and to allow examiners to more readily identify key prior art through the development of an automated tool for USPTO examiners that imports relevant prior art and other pertinent information into pending U.S. patent applications.
   e. Consider applying greater scrutiny to continuation applications in large families and/or the use of declaratory evidence to overcome rejections. The USPTO is considering additional guidance for examiners and quality reviews by the Office of Patent Quality Assurance when continuation applications in large families are filed, or when applicants submit declaratory evidence to rebut an examiner’s determination of unpatentability.
   f. Revisit obviousness-type double patenting practice. Obviousness-type double patenting occurs when a patent owner tries to secure a patent for an obvious variant of the innovation covered by another of their own patents. In these instances, under current practices, a patent applicant is required to file a terminal disclaimer so that the later patent application on an obvious variant of an earlier-patented invention may not be used to extend the term of patent protection. Although a terminal disclaimer ensures that the later patent will remain commonly owned with and have the same patent term asset, multiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before PTAB and in district court. And later issued patents to obvious variants may delay resolution of ongoing district court litigation thereby potentially delaying generic and biosimilar entry into the market. The USPTO will explore whether any changes need to be made to the patent system regarding obviousness-type double patenting.
   g. Revisit procedures for third-party input. The USPTO is considering revising its procedures for allowing third-party input during prosecution. The USPTO currently has a procedure to allow third-party submissions of prior art applications under examination. This procedure is not widely used. The USPTO will seek public input on whether aspects of the current procedure could be changed to make it more useful.
   h. Conduct a comparative analysis of the examination and issuance of pharmaceutical and biological patents in the U.S. versus in other countries and any underlying lessons learned from the same. The USPTO plans to conduct a comparative analysis to evaluate whether any additional initiatives or changes will strengthen our intellectual property system. Director Vidal and the USPTO team will also explore this topic in bilateral and multilateral discussions with other countries.
   i. The USPTO will provide technical input on proposed legislative efforts.

A primary intention of this RFC is to seek written public comments on the initiatives described in the USPTO Letter reproduced above (2(a)–(2)(i)), and as reflected in questions 1–5 below. The questions in this RFC focus on some of these initiatives, and the USPTO plans to issue an additional RFC that will address other initiatives and additional topics concerning improvements to the patent application process, including, without limitation, enhancing the information disclosure statement process, increasing clarity and certainty in functional claiming, and transcribing inventor interviews.

II. June 8, 2022, Letter From Senators to the USPTO

On June 8, 2022, the USPTO received a letter from United States Senators Leahy, Blumenthal, Klobuchar, Cornyn, Collins and Braun raising a concern about “large numbers of patents that cover a single product or minor variations on a single product, commonly known as patent thickets.” In the letter, the Senators commented that the practice of obtaining large numbers of patents on a single drug product “impedes generic drugs’ production, hurts competition, and can even extend exclusivity beyond the congressionally mandated patent term.” The Senators requested that the USPTO consider changes to its regulations and practices by issuing a notice of proposed rulemaking or a public RFC on a list of six questions. We are including the Senators’ six questions in this RFC (questions 6–11 below) and welcome feedback on them, in addition to the proposed USPTO initiatives as reflected in questions 1–5 below.

III. Specific Topics and Initiatives

A. Prior Art Searching

The USPTO Letter, section 2(b), indicates the USPTO “is exploring additional technology and resources of prior art.” Patent examiners have access to many resources for searching for prior art during the examination of patent applications. The new Patents End-to-End Search system includes access to U.S. patents and non-patent publications and more than 76 million foreign patent documents with high-quality English
translations and new, improved search capabilities. In addition, examiners search general and technology-specific databases for non-patent prior art and are provided the services of trained professional online search personnel for non-patent prior art searching. See Manual of Patent Examining Procedure (MPEP) 904. In question 1 below, the USPTO seeks public input on specific sources of prior art to ensure that patent examiners have access to the most relevant information. Specifically, the USPTO seeks public input on robust sources of technology-specific, non-patent literature. The USPTO also seeks public input on best practices to ensure that examiners are aware of public use and on-sale activity that is relevant to examination.

B. Support for Patent Claims

The USPTO Letter, section 2(e), indicates the USPTO will “[e]nsure they claim entitlement to the benefit of support in the application from which an earlier filing date (Dec. 21, 2021) (placing the burden of proof on the examiner).” By contrast, the reexamination and reissue rules (rules 1.530(e) and 1.173(c), respectively) require that during reexamination or reissue proceedings, patentees “must” supply an “explanation of the support in disqualification” for new and amended claims.

Similarly, in inter partes review and post-grant review proceedings, motions to amend must set forth “the support in the original disclosure of the patent for the changes to the claims made by the amendment paper.”

C. RCE Practice

With rare exception, after an examiner closes prosecution, including after the mailing of a notice of allowance or when an appeal has been taken to the PTAB, an applicant may file an RCE under 37 CFR 1.129. Upon receipt of an appropriate RCE, the examiner will reopen prosecution and issue another action. Currently, this cycle may proceed indefinitely, subject only to a finding of prosecution laches. See MPEP 706.07(h) and 2190. The USPTO seeks input through question 3 below on this current practice and whether there should be internal process changes once the number of RCEs filed in an application reaches a certain threshold, such as transferring the application to a new examiner or increasing the scrutiny given in the examination of the application.

D. Restriction, Divisional, Rejoinder and Non-Statutory Double Patenting Practice

In situations in which two or more independent and distinct inventions are claimed in a single patent application, the USPTO is authorized by the patent laws and implementing regulations to require the applicant to restrict the application to one invention. The practice for requiring an applicant to restrict an application to one invention in such situations is known as restriction practice. See MPEP 800.

According to the USPTO’s records, the number of divisional applications fell from more than 21,000 in fiscal year (FY) 2010 to fewer than 15,500 in FY 2021, while the total application filings increased significantly. At the same time, the filing of continuation applications increased significantly. The USPTO has received feedback that one reason many continuing applications are filed is related to restriction practice. See MPEP 800.

With respect to question 4 below, the USPTO seeks input on improvements to restriction practice, including by allowing for the examination of two or more distinct inventions in the same proceeding in a manner similar to the practice authorized by 37 CFR 1.129(b), and also seeks input on whether any offset to patent term adjustment should be considered in such cases. The USPTO also seeks input on whether the burden requirement before the examiner to impose a restriction should be revised, and if so, how. See MPEP 808.02. In particular, the USPTO seeks input on whether it should adjust the method by which an examiner appropriately establishes burden. The USPTO also seeks input on its
restriction practice with respect to Markush claims. See MPEP 803.02. For example, the USPTO seeks input on whether the applicant should be authorized to suggest how the scope of the claim searched should be expanded if the elected species is not found in an effort to present closely related inventions for consideration together. The USPTO also seeks input on the advantages, or disadvantages, of unity of invention practice as compared to restriction practice.

Additionally, with respect to question 4 below the USPTO seeks feedback on serial filings of divisional applications, including whether the current practice of authorizing the filing of divisional applications in a series should be revised to require all divisional applications to be filed within a set period of time after the restriction requirement is made final and after any petition for review has been resolved. Specifically, the USPTO also seeks feedback on guidance, petition practice, rejoinder, and continuation with respect to restriction practice. The USPTO seeks input on whether to make changes to the rejoinder practice after a final rejection has been made. See MPEP 821.04(a). For example, the USPTO seeks input on whether applicants should be given a certain time period after final rejection to provide appropriate claims for rejoinder.

As a corollary to restriction practice, non-statutory double patenting occurs when a patent owner tries to secure a patent for a patentably indistinct variation of the same invention, or otherwise tries to obtain an unjustified timewise extension of patent rights. See MPEP 804 and 1504.06. A common form of non-statutory double patenting occurs when a patent owner files a patent application claiming an obvious variation of the innovation covered by another of their own patents. In these instances, under current practices, a patent applicant is required to file a terminal disclaimer so that the later patent application on an obvious variant of an earlier-patented invention may not be used to extend the term of patent protection. Although a terminal disclaimer ensures that the later patent will remain commonly owned with and have the same patent term as the earlier patent, multiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before PTAB and in district court. Also, multiple patents directed to obvious variants of an invention can pose a heavy burden on examiners because examiners are required to compare the claims in these multiple patents and pending applications to determine if the claims are patentably indistinct from one another such that a non-statutory double patenting rejection is proper. The USPTO seeks input, through question 4 below, on whether any changes need to be made to the patent system regarding non-statutory double patenting.

IV. Questions for Public Comment

The USPTO invites written responses to the following questions and requests. Commenters are welcome to respond to any or all of the questions.

1. Identify any specific sources of prior art not currently available through the Patents End-to-End Search system that you believe examiners should be searching. How should the USPTO facilitate an applicant’s submission of prior art that is not accessible in the Patents End-to-End Search system (e.g., “on sale” or prior public use)?

2. How, if at all, should the USPTO change claim support and/or continuation practice to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents? Specifically, should the USPTO:
   a. require applicants to explain or identify the corresponding support in the written description for each claim, or claim limitation, upon the original presentation of the claim(s), and/or upon any subsequent amendment to the claim(s) (including requiring a showing of express or inherent support in the written description for negative claim limitations);
   b. require applicants to explain or identify the corresponding support for each claim, or claim limitation, in the written description of every prior-filed application for which the benefit of an earlier filing date is sought, under, e.g., 35 U.S.C. 119, 120, 121, or 365?
   c. require applicants to explain or identify the corresponding support for each claim, or claim limitation, in the written description of every prior-filed application for which the benefit of an earlier filing date is sought, under, e.g., 35 U.S.C. 119, 120, 121, or 365 (including requiring such support whenever a benefit or priority claim is presented, including upon the filing of a petition for a delayed benefit or priority claim and upon the filing of a request for a certificate of correction to add a benefit or priority claim)?
   d. make clear that claims must find clear support and antecedent basis in the written description by replacing the “or” in 37 CFR 1.75(o)(1) with an “and”, as follows: “The claim or claims must conform to the invention as set forth in the remainder of the specification, and the terms and phrases used in the claims must find clear support or and antecedent basis in the description so that the meaning of the terms in the claims may be ascertained by reference to the description”?
   e. require applicants to provide detailed analysis showing support for genus or Markush claims, and require applicants to identify each claim limitation that is a genus, and explain or identify the corresponding support in the written description for each species encompassed in the claimed genus?
   f. require applicants to describe what subject matter is new in continuing applications (e.g., continuation, continuation-in-part, and divisional applications) to explain or identify subject matter that has been added, deleted, or changed in the disclosure of the application, as compared to the parent application(s)?

3. How, if at all, should the USPTO change RCE practice to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents? Specifically, should the USPTO implement internal process changes once the number of RCEs filed in an application reaches a certain threshold, such as transferring the application to a new examiner or increasing the scrutiny given in the examination of the application?

4. How, if at all, should the USPTO limit or change restriction, divisional, rejoinder, and/or non-statutory double patenting practice to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents? Specifically, should the USPTO:
   a. allow for the examination of two or more distinct inventions in the same proceeding in a manner similar to the practice authorized by 37 CFR 1.129(b), and, if so, consider an offset to patent term adjustment in such cases?
   b. revise the burden requirement before the examiner to impose a restriction, and if so, how?
   c. adjust the method by which an examiner appropriately establishes burden for imposing a restriction requirement?
   d. authorize applicants, in the case of a Markush group, to suggest how the scope of the claim searched should be expanded if the elected species is not found in an effort to present closely related inventions for consideration together?
   e. adopt a unity of invention requirement in place of the restriction requirement?
   f. revise the current practice of authorizing the filing of divisional
applications in a series to require all divisional applications to be filed
within a set period of time after the restriction requirement is made final and after any petition for review has been resolved?

g. make changes to the rejoinder practice after a final rejection has been made, such as giving applicants a certain time period after final rejection to provide appropriate claims for rejoinder?

h. limit or change non-statutory double patenting practice, including requiring applicants seeking patents on obvious variations to prior claims to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer to obviate the rejection; rejecting such claims as not differing substantially from each other or as unduly multiplied under 37 CFR 1.75; and/or requiring a common applicant or assignee to include all patentably indistinct claims in a single application or to explain a good and sufficient reason for retaining patentably indistinct claims in two or more applications? See 37 CFR 1.76(f).

5. Please provide any other input on any of the proposals listed under initiatives 2(a)–2(i) of the USPTO Letter, or any other suggestions to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents.

The USPTO also invites public input on the following questions, which are presented verbatim (except for minor changes to internal citation format) as they appeared in the June 8 letter from Members of Congress. Any comments relating to fee setting will be taken into consideration when the USPTO takes up fee setting more broadly.

6. Terminal disclaimers, allowed under 37 CFR 1.321(d), allow applicants to receive patents that are obvious variations of each other as long as the expiration dates match. How would eliminating terminal disclaimers, thus prohibiting patents that are obvious variations of each other, affect patent prosecution strategies and patent quality overall?

7. Currently, patents tied together with a terminal disclaimer after an obviousness-type double patent rejection must be separately challenged on validity grounds. However, if these patents are obvious variations of each other, should the filing of a terminal disclaimer be an admission of obviousness? And if so, would these patents, when their validity is challenged after issuance, stand and fall together?

8. Should the USPTO require a second look, by a team of patent quality specialists, before issuing a continuation patent on a first office action, with special emphasis on whether the claims satisfy the written description, enablement, and definiteness requirements of 35 U.S.C. 112, and whether the claims do not cover the same invention as a related application?

9. Should there be heightened examination requirements for continuation patents, to ensure that minor modifications do not receive second or subsequent patents?

10. The Patent Act requires the USPTO Director to set a “time during the pendency of the [original] application” in which continuation status may be filed. Currently there is no time limit relative to the original application. Can the USPTO implement a rule change that requires any continuation application to be filed within a set timeframe of the ultimate parent application? What is the appropriate timeframe after the applicant files an application before the applicant should know what types of inventions the patent will actually cover? Would a benchmark (e.g., within six months of the first office action on the earliest application in a family) be preferable to a specific deadline (e.g., one year after the earliest application in a family)?

11. The USPTO has fee-setting authority and has set [fees] for filing, search, and examination of applications below the actual costs of carrying out these activities, while maintenance fees for issued patents are above the actual cost. If the up-front fees reflected the actual cost of obtaining a patent, would this increase patent quality by discouraging filing of patents unlikely to succeed? Similarly, if fees for continuation applications were increased above the initial filing fees, would examination be more thorough and would applicants be less likely to use continuations to cover, for example, inventions that are obvious variations of each other?

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

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2021–0042]

Extension of the Patent Trial and Appeal Board Motion To Amend Pilot Program


ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is extending the Motion to Amend (MTA) Pilot Program, initiated on March 15, 2019, and first extended on September 16, 2021. The MTA Pilot Program provides additional options for a patent owner who files an MTA in an America Invents Act (AIA) trial proceeding before the Patent Trial and Appeal Board (PTAB). In particular, the program provides a patent owner who files an MTA with options to request preliminary guidance from the PTAB on the MTA and to file a revised MTA. The MTA Pilot Program also provides timelines for briefing to accommodate these options.

DATES: Applicability Date: October 4, 2022. Duration: The MTA Pilot Program will run until September 16, 2024 (or it may end sooner if replaced by a permanent program after notice-and-comment rulemaking). The USPTO may further extend the MTA Pilot Program (with or without modification) on either a temporary or a permanent basis, or may discontinue the program after that date.

FOR FURTHER INFORMATION CONTACT: Miriam L. Quinn, Acting Vice Chief Administrative Patent Judge; or Melissa Haapala, Vice Chief Administrative Patent Judge; at 571–272–9797 (Miriam.Quinn@uspto.gov or Melissa.Haapala@uspto.gov, respectively).

SUPPLEMENTARY INFORMATION: A patent owner in an AIA trial proceeding may file an MTA as a matter of right. See 35 U.S.C. 316(d)(1), 326(d)(1). After receiving public feedback about the PTAB’s MTA practice, in October 2018 the USPTO published a Request for Comments in the Federal Register seeking written public comments on a proposed amendment process in AIA trials that would involve preliminary guidance from the PTAB on the merits of an MTA and an opportunity for a patent owner to file a revised MTA. See Request for Comments on MTA Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 83