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# USPTO Ideas For Bolstering Robustness And Reliability Of Patents Demand Attention And Stakeholder Input

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The USPTO has issued a Federal Register Notice soliciting comments on "proposed initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition." The initiatives appear to be responsive to concerns about ***pharmaceutical patents*** in particular, but if implemented they will have a far-reaching impact on the costs and scope of patents in all technology areas. Stakeholders should review the USPTO's proposals and consider providing input to the USPTO and congressional representatives.

## The Backstory

Impetus behind the initiatives include President Biden's July 2021 "Executive Order on Promoting Competition in the American Economy," which was primarily focused on lowering drug costs to American consumers, and a June 8, 2022 letter from Senators Leahy, Blumenthal, Klobuchar, Cornyn, Collins and Braun to the USPTO raising concerns about "large numbers of patents that cover a single product or minor variations on a single product, commonly known as patent thickets."

The Executive Order generally directed the Department of Health and Human Services to coordinate with other federal officials to ensure the patent system does not unjustifiably delay generic and biosimilar competition. The USPTO has set up a webpage highlighting USPTO-FDA collaboration initiatives.

The Senators' letter asks the USPTO to consider the following changes to current U.S. patent practice to address the "problem" of "patent thickets":

1. How would eliminating terminal disclaimers [and] prohibiting patents that are obvious variations of each other, affect patent prosecution strategies and patent quality overall? *[Canada has double patenting rejections with no terminal disclaimer practice, so we can look to our northern neighbors for insight on this topic.]*

2. [S]hould the filing of a terminal disclaimer be an admission of obviousness [as between the two patents]? And if so, would these patents, when their validity is challenged after issuance, stand and fall together?

3. 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?

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

5. Can the USPTO implement a rule change that requires any continuation application to be filed within a set time frame of the ultimate parent application? …. 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)?

   *[Who remembers the October 31, 2007 decision in Tafas v. Dudas? I will never forget being in the courtroom when Judge Cacheris ruled from the bench that the proposed rules limiting the number of continuation applications were invalid.]*

6. If the up-front [patent application] 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?

These topics are presented as questions 6-11 of the USPTO's Federal Register Notice.

## The USPTO's Proposed Initiatives

The Federal Register Notice proclaims a noble goal for the proposed initiatives:

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.

As usual, the devil is in the details.

The Federal Register Notice outlines several initiatives the USPTO already is pursuing or considering:

1. Giving examiners more examining time, particularly in cases with several continuations (large family cases) and cases with evidence submitted in support of patentability.

2. Giving examiners more training and resources.

3. Enhancing communication between patent examiners and the Patent Trial and Appeal Board (PTAB), including making it easier for examiners to identify prior art relied upon in PTAB rulings.

4. Exploring changes to information disclosure practice to provide efficiencies for applicants and

allow examiners to more readily identify key prior art through the development of an automated tools that imports relevant prior art and other pertinent information into pending U.S. patent applications.

5. Considering applying greater scrutiny to continuation applications in large families and/or the use of declaratory evidence to overcome rejections, such as providing additional guidance for examiners and quality review.

6. Revisiting obviousness-type double patenting practice, recognizing that "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."

7. Revisiting procedures for third-party input, including seeking "public input on whether aspects of the current procedure could be changed to make it more useful."

8. Conducting 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.

9. Providing technical input on proposed legislative efforts.

In addition to questions based on the Senators' letter outlined above, the USPTO seeks public input on four other questions, outlined below:

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?

   *Under this question, the USPTO outlines five possible types of "explanations" applicants would have to provide to support new claims, Markush claims, and/or continuation applications generally.*

3. How, if at all, should the USPTO change RCE practice …? 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 …?

   *Under this question, the USPTO outlines eight possible changes, from permitting examination of more than one invention in an application to adopting a unity of invention standard.*

The Federal Register notice also includes a fifth, catch-all question:

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.

## Help the USPTO Bolster Patents Without Breaking The U.S. Patent System

Between President Biden's Executive Order and letters from Congress, the USPTO is under pressure to address perceived problems with the U.S. patent system, so stakeholders should not assume that none of these proposals will come to pass. Now is our chance to help the USPTO identify changes that could "bolster[] the robustness and reliability of patents" without undermining its strong history of promoting innovation and competition.

The current deadline for providing comments on these questions is **January 3, 2023**, although that deadline may be extended. Comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov* under docket number PTO-P-2022-0025.

Stakeholders who disagree with the premises underlying some of the proposed initiatives also may want to consider reaching out to their congressional representatives.



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