Comments of Innovation Alliance in Response to the USPTO's Request for Comments Regarding USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025)

February 1, 2023

The Innovation Alliance appreciates the opportunity to submit these comments in response to the Request for Comments (RFC) issued by the U.S. Patent and Trademark Office ("USPTO" or "Office") regarding the USPTO's proposed initiatives directed at bolstering the robustness and reliability of patents.

The Innovation Alliance is a coalition of research and development-based technology companies representing innovators, patent owners, and stakeholders from a diverse range of industries that believes in the critical importance of maintaining a strong patent system that supports innovative enterprises of all sizes. The Innovation Alliance is committed to strengthening the U.S. patent system to promote innovation, economic growth, and job creation, and we support legislation and policies that help to achieve those goals.

The Innovation Alliance appreciates the USPTO's desire to consider different approaches to improve the examination process with the goal of enhancing the robustness and reliability of issued U.S. patents. Below we provide our comments on the initiatives outlined in the October 4, 2022 Request for Comments of USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights ("the RFC"), including the initiatives included in the USPTO's July 6, 2022 Letter to the FDA ("the USPTO Letter") and the questions raised in the June 8, 2022 Letter from Senators to the USPTO ("the Senators' Letter").

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I. RFC Question 1: Prior Art Searching

The U.S. patent system is often hailed as a global gold standard in assessing patentable inventions. This would undoubtedly not be possible without the skilled professionals making up the USPTO's examination corps. Patent examination is a demanding and challenging role. The Innovation Alliance supports the USPTO providing patent examiners additional resources and applauds the USPTO's efforts on this front.

The RFC asks "[h]ow 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)" and requests that commenters "[i]dentify any specific sources of prior art not currently

available through the Patents End-to-End Search system that you believe examiners should be searching."

The Innovation Alliance appreciates the USPTO's adoption of the Patents End-to-End Search (PE2E) system and believes its adoption is a positive development promoting robust and reliable patent rights. At this time, however, we are not able to fully ascertain the scope and functionality of the PE2E system. The USPTO has not shared or published many details regarding PE2E, other than a few notices regarding the use of AI in PE2E.[1] We believe that the Office should offer additional information regarding PE2E's abilities and scope, including capabilities functionality, limitations, database scope, how AI features are utilized, continued developments, and other details explaining in full how the tool works. Further, and in the spirit of partnership and transparency, the Innovation Alliance requests that the USPTO share PE2E access with patent applicants and require patent examiners to clearly indicate how PE2E is utilized during examination. Such transparency promotes efficient examination and enables closer working between applicants and examiners by allowing applicants to better understand the examiner search process. That said, the Innovation Alliance appreciates the USPTO's efforts to enhance and promote the use of advanced automated searching tools. Continued use of automated searching tools should be studied to promote best-in-class search efforts for examination and to supplement examiner review efforts.

The USPTO's art libraries should be expanded to include additional technical and non-patent literature documents arising out of technical standardization activities to benefit searching and examination practices. For example, examiners should be able to search written materials associated with standards development organizations, such as 3GPP Technical-Documents (i.e., T-docs or written contributions) and 3GPP email exchanges amongst 3GPP delegates (which are publicly stored on the 3GPP email reflector). The art libraries should also include similar documents from other standards organizations, such as ISO, ITU, JEDEC, IEEE, and ANSI, among others. Written contributions submitted to standards development organizations can present relevant, leading technical research relevant to examination, and searching standards-related documents would enhance patent quality in arts where industry standardization occurs.

Relatedly, the Innovation Alliance encourages the USPTO to partner with standards development organizations and other patent offices, such as the European Patent Office ("EPO") to create a searchable database of standards-related documents. Similar to the approach taken by the EPO, the USPTO should provide examiners with a database of non-confidential technical documents, including documents identified as being potentially standards-essential. The USPTO should also provide necessary training to access and fully utilize such information. Having a constantly updated source of technical information from key standards development organizations that is consistent across patent offices and covers cutting edge research and development would contribute significantly to more robust patent examination.

Additionally, the USPTO should consider developing a form that would permit applicants to provide a description of inaccessible prior art such as disclosures qualifying as on sale or

[1] *See* https://www.uspto.gov/web/offices/com/sol/og/2022/week02/TOC.htm#ref10; *see also* https://www.uspto.gov/sites/default/files/documents/ai-sim-search.pdf.

public use prior art. A form would provide a consistent mechanism for applicants to describe, through written summary or images, material relevant to the examination of a patent application. Submissions may particularly point out aspects of the invention absent from prior art embodiments on sale or in public use. Availability of such disclosures may enhance efficiency and quality of examination and offer notice to the public when incorporated into the file history.

II. RFC Question 2: Support for Patent Claims

The RFC requests input on whether the USPTO should "change claim support and/or continuation practice" with the goal of "fostering innovation, competition, and access to information through robust and reliable patents." The RFC lays out six suggestions for changes to claim support practice:

> (a) require an explanation of the support for each claim or claim limitation in the initial application and/or in any subsequent amendment to the claims;
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> (b) require an explanation of the support for each claim or claim limitation in the written description of prior-filed applications for which the benefit of an earlier filing date is sought;
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> (c) require an explanation of the support for each claim or claim limitation in the written description of prior-filed applications for which the benefit of an earlier filing date is sought, "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";
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> (d) replace the "or" in 37 CFR 1.75(d)(1) with an "and" to "make clear that claims must find clear support and antecedent basis in the written description";
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> (e) require a detailed analysis showing support for genus or Markush claims, an identification of each claim limitation that is a genus, and an explanation of the corresponding support in the written description for each species encompassed in the claimed genus; and
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> (f) require a description of what subject matter is new in continuing applications and an explanation of subject matter that has been added, deleted, or changed in the disclosure of the application, as compared to the parent application.

The Innovation Alliance opposes these suggested changes because they misplace the focus of the inquiry of 35 U.S.C. § 112 and add onerous, unnecessary burdens on patent applicants.

Section 112 makes clear that a patent specification's intended audience is the person skilled in the art, not the patent examiner. *See* 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable *any person skilled in the art* to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.") (emphasis added). Thus, 37 CFR 1.75(d)(1)'s requirement that "[t]he 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 antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description" is satisfied as long as a person skilled in the art would understand that "the terms and phrases used in the claims . . . find clear support . . . in the description."

The proposed changes would add additional requirements that the applicant explain or identify for the patent examiner's benefit the support in the specification for each claim limitation. This refocusing of Section 112 toward the patent examiner is unnecessary and overly burdensome to patentees. Claims almost always include several, and often many, claim limitations, and these limitations often find support throughout the remainder of the specification. In many instances, the support for the claim limitations is obvious. Indeed, the USPTO's own quality metrics show that less than 10% of office actions include any rejection under Section 112(a)'s written description requirement.[2] Additionally, the proposed suggestions ignore that "[o]riginal claims are part of the specification and in many cases will satisfy the written description requirement." *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011). And as the RFC notes, applicants are already directed to show support in the original disclosure when adding new claims or amending claims. *See* MPEP 2163.

Requiring a specific listing of the support for every claim limitation upon the original presentation of the claims, as proposed in RFC Question 2(a), would be immensely burdensome on applicants, significantly increasing the cost of filing a patent, while providing limited benefit to examiners. Similarly, the proposals in 2(b) and 2(c), which would require an explanation of support in the written description of every prior-filed application for which the benefit of an earlier date is sought, including when a benefit or priority claim is presented, would also be burdensome. Other major patent offices do not have a similar requirement, and introducing such a requirement significantly complicates the preparation of a patent application, with little gained in return. Similarly, the proposals in 2(e), which would require applicants to provide a detailed analysis of support for genus or Markush claims, and 2(f), which would require applicants to describe what subject matter is new in continuing applications[3] and would impose an additional burden with little benefit. Examiners may already seek this information under Rule 105 (37 CFR 1.105) from applicants when they believe it is necessary. Requiring these additional explanations, identifications, and analyses for every application unduly increases the burden, and the expense, of patenting.

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[2] *See* https://www.uspto.gov/patents/quality-metrics. The USPTO's quality metrics also show no sign that examiners are having difficulty assessing claim support, as fewer than 1% of the audited applications contained written description flaws missed by the examiner.

[3] Question 2(f) proposes requiring "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). But continuations and divisional applications, by definition, do not contain new matter. And in continuation-in-part applications, the new matter is obvious to a person skilled in the art because the new matter is that which differs from the parent application.

Further, 37 CFR 1.75(d)(1) should not be modified, as suggested in Question 2(d), to replace the "or" with "and," requiring the terms and phrases used in the claims to find clear support *and* antecedent basis in the description. The current version of the regulation is aligned with Section 112 and established legal precedent that claims should be given their ordinary meaning as understood by a person of ordinary skill in the art when considering, among other things, the intrinsic record. Requiring antecedent basis support in the description is divorced from the reality that a person of ordinary skill in the art would not be so restrictive when ascertaining the meaning of claim terms. And as observed by courts, 37 CFR 1.75(d) merely implements the written description requirement of the first paragraph of 35 U.S.C § 112. *See Plastic Container Corp. v. Cont'l Plastics of Okla.*, 607 F.2d 885, 892 n.9 (10th Cir. 1979) ("Because Rule 75(d)(1) merely implements the description requirement of the first paragraph of 35 U.S.C. § 112 (Supra note 8), we consider § 112 to be the statutory basis for this conclusion of law."). Therefore, 37 CFR 1.75(d)(1) must be consistent with the written description requirement, which is determined based on whether the patent disclosure reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Indeed, it has been well established that the written description requirement does not require any particular form of disclosure or antecedent basis *in haec verba*. *See id* at 1352 (explaining that "the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*") (internal citation omitted).[4]

With respect to Question 2(e), we are concerned about the proposed requirement for patent applicants to explain or identify the corresponding support in the written description for each species encompassed in a claimed genus. A genus claim meets the written description requirement if the patent disclosure provides a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus. *See id.* at 1350 ("We held that a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus"). In other words, an adequately supported genus claim does not require that each species encompassed in the claimed genus find a corresponding support in the written description. Accordingly, we believe that the proposed requirement for a patent applicant to explain or identify the corresponding support in the written description for each species encompassed in the claimed genus is inconsistent with the written description requirement for genus or Markush claims.

[4] The USPTO provides similar well-established guidance in MPEP 2163: "While there is no *in haec verba* requirement, newly added claims or claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Changing MPEP guidance that applicants have long relied upon runs counter to controlling precedent. *See*, *e.g.*, *In re Kaghan*, 387 F.2d 398, 400-01 (CCPA 1967) ("an applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provisions of the MPEP in the prosecution of his patent application").

III. RFC Question 3: RCE Practice

The RFC's question on requests for continued examination ("RCEs") states that it aims to "foster[] innovation, competition, and access to information through robust and reliable patents, and asks whether the USPTO should "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." The suggested changes, however, are a solution in search of a problem. Rather than advancing the goals stated in the RFC, these proposed changes would decrease efficiency at the patent office and unnecessarily complicate the process of obtaining a patent.

Transferring an application to a new examiner once an arbitrary number of RCEs is reached has the potential to create negative incentives for both the applicant and the examiner. For instance, since statistics on particular examiners are available to applicants (e.g., allowance rate, average number of office actions till allowance, etc.), some applicants may try to file the threshold number of RCEs as quickly as possible to move the application away from an examiner with a lower allowance rate in hopes of the case being moved to an examiner with a higher allowance rate. On the examiner side, merely transferring an application to a new examiner after a certain number of RCEs may create negative incentives for examiners to discount the applicant's arguments, knowing that, if the applicant does not concede to the examiner's rejection, the application will eventually be abandoned or transferred to another examiner.

Even apart from the potential for problematic incentives, the process of automatically moving an application to a new examiner after a certain number of RCEs would be terribly inefficient. A transfer to a new examiner can act as a "reset button," possibly leading to unwanted delays in time and additional expenses to an applicant, and would waste the rapport built between the examiner and the applicant, as well as the examiner's knowledge and understanding of the technology in the application.

As for implementing increased scrutiny on an application after the threshold number of RCEs has been reached, this proposal would unnecessarily harm applicants who have legitimate disagreements with an examiner that are being addressed through the prosecution process. Further, there is a lack of evidence that bad-faith or wasteful RCEs are being filed that would justify such a change, and the expense and time associated with RCEs already serves as a deterrent to abuse of the RCE system.

We are also concerned about the potential of subjecting a particular group of patent applications to "increas[ed] scrutiny." Proposing to increase the scrutiny given to certain applications raises the question of whether the USPTO would apply a different evidentiary standard to that group of applications but not to other applications. It has been well settled that the evidentiary standard used by the USPTO during ex parte patent examination is a preponderance of evidence. *See In re Oetiker,* 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."). Increasing scrutiny on a particular subset of patent applications

would raise the question of whether other types of patent applications would be subject to less scrutiny and therefore result in patents with less quality. Relatedly, applying various levels of scrutiny during examination will have unintended ripple effects impacting validity presumptions of 35 U.S.C. § 282(a). All USPTO-granted patents are presumptively valid yet applying 'less' or 'different' scrutiny to some class(es) of patents may impact the statutory validity presumption that Congress affords to all granted patents—not just those examined with the proposed "increased scrutiny." We believe that the USPTO should apply the same evidentiary standard and the same level of scrutiny to all patent applications, regardless of the type or history of each patent application.

IV. RFC Question 4: Restriction, Divisional, Rejoinder and Non-Statutory Double Patenting Practice

The RFC includes a series of proposals, discussed in turn below, relating to restriction, divisional, rejoinder, and non-statutory double patenting practice. The USPTO's current restriction practice already places more burden on applicants than Congress intended, and the proposed changes in the RFC would make the process even more burdensome. We therefore urge the USPTO not to adopt these proposals, but to consider other changes that would simplify the process and bring restriction practice in line with existing statutory mandates.

A. Question 4(a):

> "Should the USPTO 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?"

35 U.S.C. § 121 codifies a discretionary authority for restriction ("If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions"), and serves as the statutory basis for the USPTO's Restriction and Divisional practice as outlined, *e.g.*, in 37 CFR 1.142 and MPEP Chapter 800. The discretion to restrict under Section 121, however, is not unfettered, but is limited to specific qualifications, as set forth in the statute.

Under current practice, per MPEP 802.02, the USPTO defines "Restriction" as "the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application," where the USPTO interprets "independent" as "unrelated" and "distinct" as "different." Notably, Section 121 requires the multiple inventions subject to restriction as being both "independent" ***and*** "distinct." However, despite the conjunctive "and" in the statute, the USPTO's current practice is to require restriction, not just among independent inventions, but also among distinct but not independent (e.g., related) claims—effectively reading Section 121's "independent and distinct" as "independent or distinct." *See* MPEP 802.01.

If the discretionary restriction is exercised, Section 121 further limits the restriction only to "one"—not two or more—of multiple claimed independent and distinct inventions. The use of

"one" in Section 121 precludes any partial restriction—that is, to elect two or more "independent and distinctive" inventions. Thus, the singular restriction requires: 1) either all claimed inventions must be examined (that is, no restriction); or 2) if restricted, only one of them is to be examined. If Congress intended to grant the Director the discretion to examine two or more inventions but not the others, it would have explicitly stated so in Section 121. The proposed change in Question 4(a) thus appears counter to the statute, and it should not be adopted for this reason.

Even if the statutory authority existed for this proposal, looking to 37 CFR 1.129(b), as the proposal does, is not warranted. This regulation was enacted under specific transitional legislation passed by Congress to approve and implement the trade agreements in the Uruguay Round in 1994, and was limited in time to applications filed before June 8, 1995. *See* 37 CFR 1.129(c). No justification—or, more importantly, legislation—allows for the imposition of this scheme here.

Further, we see no legitimate reason or statutory basis to "offset" patent term adjustment. Patent term adjustment is a statutory mandate. *See* 35 U.S.C. § 154(b) ("if the issue of an original patent is delayed due to failure of the United States Patent and Trademark Office . . . the term of the patent shall be extended . . . ."). The USPTO's discretionary decisions on restriction requirements should have no bearing on the determination of patent term adjustment.

B. Questions 4(b) and 4(c)

"Should the USPTO revise the burden requirement before the examiner to impose a restriction, and if so, how?"

"Should the USPTO adjust the method by which an examiner appropriately establishes burden for imposing a restriction requirement?"

Questions 4(b) and 4(c) both relate to potential changes to the burden requirement for imposing a restriction. The Director has recognized the importance of "careful" administration of the agency discretion to restrict. *See* MPEP 803.01 ("Since requirements for restriction under 35 U.S.C. § 121 are discretionary with the Director, it becomes very important that the practice under this section be carefully administered"). According to MPEP 803, the examiner must establish that "[t]here would be a serious burden on the examiner if restriction is not required . . . If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions."

However, despite the emphasis on the "serious" burden requirement, the USPTO's existing implementation has not adequately safeguarded applicants from restrictions. Under MPEPE 808.02, an examiner is allowed to issue restriction simply because the inventions have a "separate classification," "a separate status in the art when they are classifiable together," or "a different field of search." *See* MPEP 808.02. But examining two inventions having different "classifications" or "fields of search," does not necessarily entail a "serious" burden for the

examiner to search and examine. Related subject matters can often be found in single references, especially when they contain identical or similar terms or technical features. For example, a technical solution in a communication system may involve two related but distinct entities, such as a user device and a network device. Even though the two may be classified differently by the USPTO, the technical features in one can closely correspond to analogous features in the other, and the two entities are commonly described in relation to each other in the art. In such a case, separate searches can often be avoided; restriction would be improper for lack of "serious burden." Nevertheless, the current MPEP rules in 808.02 do not preclude the restriction, and in practice, restrictions of this kind are being issued.

The "burden requirement" in MPEP 808.02 should be strengthened to properly focus on a "serious burden" requirement. For example, the USPTO should require the examiner rely on technical features, rather than formalistic classification metrics, to explain why a search or examination would impose a serious burden. Similarly, examiners should be required to identify key common technical features in the claims, while balancing substantial differences, before considering a restriction requirement. Restriction practice has often ignored the serious burden requirement, increasing the cost to applicants and increasing inefficiency at the Office. Changes should be made to strengthen the burden requirement to bring restriction practice in line with its statutory support.

C. Question 4(d)

"Should the USPTO 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?"

According to MPEP 803.02, when the elected species is not anticipated by or obvious over the prior art, the examiner will extend the search and examination further to non-elected species, but up to and only within the scope of a proper Markush grouping that includes the elected species. Under current practice, the examiner attempts the expanded search and examination without inputs from the applicant. To enhance compact prosecution, the USPTO may allow an opportunity for the applicant to suggest the scope or outline of Markush grouping for the expanded search and examination, as long as it is not made a mandatory requirement on the applicant and does not carry any negative implications.

We also note that applicants often do not have the necessary knowledge or training about conducting searches for the purpose of patent examination. *See, e.g., Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005) (stating that there is no general duty for an applicant to conduct a prior art search). Therefore, if the USPTO decides to invite or authorize an applicant to suggest search or other examination strategies, the USPTO may consider providing the applicant with necessary training before making such invitation or authorization. In addition, we believe that upon such invitation or authorization, the applicant's decision of whether to participate should not change the initial burden of production or the ultimate burden of persuasion on the examiner, or otherwise give rise to any negative or adverse inference. It is well established that "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability," and "[i]f

examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *See In re Oetiker,* 977 F.2d 1443, 1445 (Fed. Cir. 1992) (emphasis original). Therefore, an applicant's decision not to provide any suggestion upon invitation or authorization should not carry any negative inference, or switch the initial burden of production or the ultimate burden of persuasion from the examiner to the applicant.

D. Question 4(e)

"Should the USPTO adopt a unity of invention requirement in place of the restriction requirement?"

The Innovation Alliance opposes the replacement of restriction with a unity of invention requirement. The "unity of invention" is only applicable to "international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. § 371." MPEP 1893.03(d). There is no statutory basis for switching to a unity of invention requirement in U.S. national applications filed under 35 U.S.C. § 111(a), which are governed instead by 35 U.S.C. § 121, which authorizes discretionary restriction. Adopting substantive rules similar to PCT's unity of invention effectively forces all U.S. applicants to adopt PCT standards for which they could have filed a PCT application. Moreover, "independent and distinct inventions" under 35 U.S.C. § 121 is not commensurate with inventions not "so linked as to form a single general inventive concept" under the PCT. We therefore see no statutory basis for the suggested adoption of the unity of invention requirement for non-PCT applications, in place of the traditional restriction requirement. Restriction requirement practice, with the strengthened burdened mentioned above, is the way to best implement the statutory requirements of 35 U.S.C. § 121.

E. Question 4(f)

"Should the USPTO 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?"

The USPTO should not force applicants to file any or all divisional applications within a set period of time after the restriction requirement is made final and after any petition for review has been resolved. Section 121 states: "If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application." Section 120 permits such a divisional application be filed "before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application."

There is no statutory basis for the Director to require all potential divisional applications be filed within a "set period of time" after restriction. Indeed, such a requirement contravenes Sections 120 and 121, by which Congress gives patent applicants primary control on when to file applications, including divisional applications. Proposing to "require" filing behavior within a time limit frustrates robust patenting opportunities for applicants.

We also believe that imposing a USPTO-set time limit on divisional filings would require promulgation of substantive rules that the USPTO has no power to make. *See Merck & Co. v. Kessler,* 80 F.3d 1543, 1550 (Fed. Cir. 1996) ("Congress has not vested the Commissioner with any general substantive rulemaking power"). Elimination of the applicant's ability to file divisional applications beyond the USPTO-set time limit undoubtedly affects the applicant's right to file subsequent applications as authorized by 35 U.S.C. §§ 120 and 121 and therefore would be a substantive rule. *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) ("A rule is substantive when it effects a change in existing law or policy which affects individual rights and obligations.") (cleaned up). However, the USPTO is not authorized to promulgate substantive rules. *See id* ("35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue substantive rules"). *See also Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-1550 (Fed. Cir. 1996) ("[T]he broadest of the PTO's rulemaking powers - 35 U.S.C. § 6(a) - authorizes the Commissioner to promulgate regulations directed only to the conduct of proceedings in the PTO; it does not grant the Commissioner the authority to issue substantive rules.") (emphasis original).

A similar limitation on continuing applications has been found unlawful. *See Tafas v. Dudas*, 541 F.Supp.2d 805 (E.D. Va. 2008) (*vacated in part by Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *rehearing en banc granted and opinion vacated by Tafas v. Doll*, 328 F. App'x 658 (Fed. Cir. 2009). The rule at issue in *Tafas* would permit an applicant to file as a matter of right two continuing applications after the initial application, but any subsequent continuing applications could only be filed with a petition to show cause. The court in *Tafas* found that this limitation on continuing filing was an impermissible substantive rule. *See id* at 814–15. We believe that the suggested time limit for divisional filings is akin to the limitation on continuing filings discussed in *Tafas* and will likely be found as a substantive rule that the USPTO has no power to make.

F. Question 4(g)

"Should the USPTO 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?"

Under MPEP 821.04(a), applicants may seek rejoinder by submitting an amendment presenting additional claims that depend from, or otherwise require all the limitations of, an allowable claim. Amendments submitted after final rejection are governed by 37 CFR 1.116, as is the general case for "Amendments and affidavits or other evidence after final action and prior to appeal," which requires the amendment to be made after the final rejection but before or on the same days as the filing of an appeal. *See* 37 CFR 1.116. The Innovation Alliance believes that the current rules are sufficient to provide applicants opportunities to present claims for rejoinder and that additional rulemaking on a specific time period for rejoinder is not warranted.

G. Question 4(h)

"Should the USPTO 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 1.78(f)."

The Innovation Alliance opposes preconditioning the filing of terminal disclaimer upon applicants' stipulation or concession on the merits of double patenting because the USPTO lacks statutory authority to implement such a practice and because it would be inadvisable as a practical matter. Moreover, Congress has long afforded applicants and patentees authority to disclaim patent rights. *See* 35 U.S.C. § 253 (both pre-AIA and AIA versions grant applicants and patentees various disclaiming options related to patent rights). As a result, the USPTO should not undertake efforts to modify terminal disclaimer practice as proposed.

The USPTO does not have statutory authority to restrict or modify the use of terminal disclaimer to overcome non-statutory double patenting. The obviousness-type double patenting doctrine and its remedy—the terminal disclaimer—were created by courts as part of federal common law to address federal questions that cannot be answered from federal statute alone. *See Milwaukee v. Illinois*, 451 U. S. 304, 313 (1981) ("We have always recognized that federal common law is subject to the paramount authority of Congress. It is resorted to in absence of an applicable Act of Congress, and because the Court is compelled to consider federal questions which cannot be answered from federal statutes alone") (cleaned up). In contrast, the USPTO does not have the same power to create or modify common-law principles or remedies. Instead, "the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979). Accordingly, we believe that the USPTO does not have statutory authority to restrict or modify either the "nonstatutory" obviousness-type double patenting doctrine or its judicially created remedy.

We also believe that the proposed stipulation contradicts the law. The stipulation requires applicants seeking patents on obvious variations to prior claims to admit 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. However, the Federal Circuit has foreclosed any inference that filing a terminal disclaimer functions as an admission regarding the merits of obviousness-type double patenting. Specifically, in *SimpleAir, Inc. v. Google LLC*, the Federal Circuit stated:

> … filing a terminal disclaimer may obviate an obviousness-type double patenting rejection, 37 C.F.R. § 1.321(c), as it did for the patents at issue, in exchange for limiting the patent term and alienability of the resulting continuation patent, see 37 C.F.R. §§ 1.321(d)(3), 1.321(c)(3). But our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims. *See Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer is simply not an admission that a later-filed invention is obvious."); *Ortho Pharm. Corp. v. Smith*,

> 959 F.2d 936, 941 (Fed. Cir. 1992) (rejecting argument that patent applicant admitted to obviousness-type double patenting by filing 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.").

See SimpleAir, Inc. v. Google LLC, 884 F.3d 1160, 1167-1168 (Fed. Cir. 2018); *see also Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870 (Fed. Cir. 1991) (denying the summary judgement for invalidity of one of the two patents, notwithstanding that the patent had been terminally disclaimed over the other patent and the patentee appeared to have conceded the invalidity of the other patent based on prior commercial use). Because the Federal Circuit has plainly rejected the inference that the USPTO attempts to achieve through the proposed stipulation, we believe the proposed stipulation would contradict the settled law.

We further believe that the proposed stipulation would significantly alter the judicially created obviousness-type double patenting doctrine and, therefore, would be a substantive rule that the USPTO has no power to make. The obviousness-type double patenting doctrine is "substantive" in that it effectively imposes an additional patentability/validity requirement, and significantly affects an applicant's ability to obtain certain patents that would otherwise meet all statutory requirements. *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) ("A rule is substantive when it effects a change in existing law or policy which affects individual rights and obligations.") (cleaned up); *see also Am. Hosp. Assoc. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) ("Substantive rules are ones which grant rights, impose obligations, or produce other significant effects on private interests, or which effect a change in existing law or policy.") (cleaned up). The judicially created remedy based on the use of statutory terminal disclaimer to overcome obviousness-type double patenting is an integral part of the obviousness-type double patenting doctrine and is itself substantive in that, without such remedy, the objected patents would be invalid and the objected patent applications would not be allowable. The proposed stipulation would modify the judicially created remedy by adding a new requirement that compels the patent applicant to admit the merits of the underlying obviousness-type double patenting rejection. Accordingly, we believe that the proposed stipulation imposes a substantive obligation and produces a major effect on the patent applicant's ability to obtain certain patents and, therefore, would be a substantive rule that the USPTO has no power to make. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) ("Congress has not vested the Commissioner with any general substantive rulemaking power").

The proposal would also be practically inadvisable. Filing a terminal disclaimer does not automatically establish or imply that the applicants agree with the double patenting rejection; instead applicants may wish to advance or prioritize the prosecution of the continuation applications in other respects (e.g., prior art search).[5] The right to continuation applications

[5] *See Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) (concluding that a terminal disclaimer "is not an admission of obviousness of the later-filed claimed invention in light of the earlier-filed disclosure, for that is not the basis of the disclaimer.").

entitles applicants a right to modify and refine the scope of the patent protection sought in prior applications. Forcing all variants of claim scopes to be presented in a single application effectively deprives applicants their right to continuation applications altogether. Furthermore, as a practical manner, the USPTO already imposes various financial costs and procedural constraints, limiting the applicants' ability to amend or present claims during the prosecution of a prior application. In some cases, continuation applications remain the only viable venue for claim refinement or modification. We further believe that the proposed stipulation will likely compromise overall patent quality. Compelling a patent applicant to make an admission to the merits of an obviousness-type double patenting rejection, as required by the proposed stipulation, would likely force the applicant to contest, and obligate the examiners to defend, the merits of the obviousness-type double patenting rejections. This would increase prosecution costs for all sizes of applicants, cause unnecessary prosecution delays, create potential litigation, and waste valuable resources at the USPTO. If the applicants eventually prevail on the merits, it will result in patents with later expiration dates, thereby prolonging patent exclusivity. Moreover, the proposed stipulation would encourage patent applicants to file a large number of claims in a single patent application, which would make patent examination more complex and difficult, potentially leading to low-quality patents and longer patent terms. Based on all of these reasons, we believe that the proposed stipulation will likely compromise overall patent quality.

The Federal Circuit has developed an effective approach to address the effect of terminal disclaimers on related patents. Specifically, the Federal Circuit found that a terminal disclaimer, although not conclusive, was a strong clue that the relevant claims in a continuation patent may lack a patentable distinction over the parent. In *SimpleAir, Inc. v. Google LLC*, the Federal Circuit observed:

> By filing a terminal disclaimer, a patent applicant waives potentially valuable rights. We do not lightly presume that patent applicants forfeit the right to alienate their patents, and in certain cases years of exclusivity, as a mere procedural expedient. Rather, as occurred here, applicants typically file terminal disclaimers to overcome obviousness-type double patenting rejections. In construing the scope of claims, we give considerable weight to statements made by patent applicants during prosecution in order to overcome examiner rejections. *See, e.g., Alpex Comput. Corp. v. Nintendo Co. Ltd.*, 102 F.3d 1214, 1220 (Fed. Cir. 1996). We see no reason to treat terminal disclaimers any differently.
>
> Thus, a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent. But as our precedent indicates, that strong clue does not give rise to a presumption that a patent subject to a terminal disclaimer is patentably indistinct from its parent patents. It follows that a court may not presume that assertions of a parent patent and a terminally-disclaimed continuation patent against the same product constitute the same cause of action. Rather, the claim preclusion analysis requires comparing the patents' claims along with other relevant transactional facts.

See SimpleAir, Inc. v. Google LLC, 884 F.3d 1160, 1168 (Fed. Cir. 2018). Therefore, a terminal disclaimer is very relevant to the determination of the patentability or validity of the terminally disclaimed patent. This approach effectively discourages the patentees from asserting a terminally disclaimed patent that is truly obvious over the reference patent that has already been finally decided unpatentable or invalid due to prior art. This well-established approach has proven to be effective in helping streamline the resolution of patent disputes involving obvious-variant patents. *See, e.g.*, *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 Fed. Appx. 1024 (Fed. Cir. 2018) (holding that claim preclusion likely barred the assertion of a continuation patent that was patentably indistinct from and terminally disclaimed over a parent patent which had been asserted in a previous ANDA proceeding involving the same parties and the same accused products). We believe that the Federal Circuit's approach—considering terminal disclaimers relevant but not conclusive—strikes the right balance between different policy considerations and should be adequate to address the policy objective that the USPTO attempts to achieve through the proposed restrictions.

Based on all of the above reasons, we urge the USPTO not to adopt the proposed stipulation as a requirement for overcoming obviousness-type double patenting rejections.

V. RFC Question 5: Initiatives from the USPTO Letter

The RFC requests input on the proposals listed under initiatives 2(a)-2(i) in the USPTO Letter, a selection of which are reproduced and discussed here.

A. Initiative 2(a)

> "Introduce more examining time into the patent examination system. The USPTO recently made changes to examination time and is exploring further changes, particularly in cases with several continuations (large family cases) and cases with evidence submitted in support of patentability."

The USPTO is constitutionally tasked with promoting technical advancement by securing inventors with their exclusive rights to innovations. To appropriately align its examination approach with its constitutional goals, the Office should strive for perfect search and examination processes, while recognizing that tradeoffs will always exist in the prosecution process.

The Innovation Alliance generally supports providing examiners with flexibility in regards to examination time. More challenging technologies may merit additional examination time relative to less complex technologies. Examiner experience, technical training, and application-specific factors should also be considered when considering examination time. Aside from examination time, examiners should be allotted adequate time for thorough art searches given that examination results and quality are fundamentally based on search quality. In some scenarios, it may be prudent to increase time allotted for searches, provide examiners help or other assistance with searching, and ensure access to a full range of literature databases, including those likely to possess art specific to an application's technical field.

While the USPTO should continue to study the ways examination time may be optimized, the Office should continue implementing its 2019/2020 examination changes,[6] as the USPTO's quality metrics show that current examination practices yield high-quality examination.[7] As the initiative suggests, increased examination time may be needed in some scenarios where applicants file a number of related applications, including continuation or divisional applications. At the same time, however, examiners examining related or similar applications should gain examination efficiency over time, meaning that in some scenarios, examiners may require less time for examination.

For situations where applicants or patent owners submit evidence supporting patentability, the USPTO should consider the amount and type of evidence in assessing whether to provide additional time. Not all types of evidence supporting patentability equally warrant additional examination time. The USPTO should therefore consider a range of additional time periods that depends on the evidence presented and the stage of prosecution—smaller amounts of evidence submitted early in examination may not require additional time, but larger amounts of evidence submitted later in examination could likely benefit from additional time. For example, one approach of providing additional examination time for evidence consideration is to offer enhancements in time ranges (*e.g.*, 1–2 additional hours for smaller amounts of evidence, 4–6 hours for greater amounts of evidence, 1–2 additional hours for pre-final evidence, 2–3 hours for post-final evidence).

B. Initiative 2(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."

As stated above, the Innovation Alliance approves of the implementation of the Patents End-to-End Search system, lauds the USPTO's efforts to increase the resources available to examiners for prior art searching, and approves of the USPTO's collaboration with AIPLA and IPO on examiner training. The USPTO's training efforts should also include external engagements. While internal training enables patent examiner teams to engage in their own

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[6] *See* https://www.uspto.gov/patents/laws/examination-policy/updates-patent-examination-time-application-routing.

[7] *See* https://www.uspto.gov/patents/quality-metrics (showing that approximately 92% of allowances are compliant under all statutes).

communities and teams, external training provides exposure to stakeholders interested in sharing legal and technical updates to examiners. We applaud the USPTO's efforts to engage with AIPLA and IPO regarding examiner training, and we encourage the USPTO to engage other patent offices and private search firms to ensure that examiners are leveraging today's most advanced search techniques and literature databases. At the same time, examiners should receive continuous training on new search approaches and techniques for their own search efforts. The Innovation Alliance encourages training across all aspects of substantive examination including new matter, assessing claim scope, and use of functional claiming. A well-informed examiner corps applying consistent examination practices grounded in established precedent will continue to result in efficient examination with predictable outcomes for applicants and will positively influence patent quality.

We also support the continued application of consistent practices in ensuring clarity of the prosecution record, as the prosecution record can be a significant source for the public, courts, and the Office in furthering the understanding of the scope of issued patent claims. The existing framework provides appropriate mechanisms and balance for both the Office and applicant to address a range of material issues arising during examination and prosecution. Courts and the public have successfully relied upon and applied these mechanisms in, for example, interpreting appropriate claim scope.

C. Initiative 2(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 AIA proceeding, 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 trends in post-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."

The Innovation Alliance supports efforts to enhance communication between the PTAB and patent examiners across proceedings, including ex parte appeals and AIA proceedings. Examiners should have ready access to detailed information concerning prior art, claim interpretation, and reasoning underlying the PTAB's ruling to all issues relevant to patentability of claims in related patent applications and applications that undergo further examination.

Examiner access to information will continue to drive efficient and effective examination. We also encourage the Office to provide applicants access to these enhanced communication and information sources to promote transparency, clarity of record, and examination efficiency.

We also believe that the Office should ensure that when examiners review applications related to an AIA trial (or any other post-grant review procedure), the Office should mandate that examiners clearly indicate this for the benefit of administrative record development. Not only does this indication promote compact prosecution, it enables applicants to fully understand how an examiner may leverage work from any prior or pending post-grant procedure and to remain on equal footing during an ex parte proceeding.

D. Initiative 2(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."

The Innovation Alliance encourages the USPTO to improve its procedures relating to information disclosure requirements and provides the following recommendations:

First, we recommend that the USPTO implement an enhanced IDS capability in which applicants can enter IDS information into the Patent Center directly, rather than filing IDS forms. The capability should include the ability to automatically import all references from parent or ancestor applications, along with the ability for applicants to cross-cite art from other patents and applications. The capability should further include the ability, within Patent Center, to see a live listing of art considered by the patent examiner. Further, to improve the quality of patent examination and to ensure the availability of a comprehensive collection of prior art, the USPTO should also strive to automatically import and consider references identified by cooperating patent offices.

Second, the USPTO should implement and manage a publicly-accessible document library that can be searched by applicants and that provides for tagging documents by applicants for consideration by the patent examiner further to the information disclosure requirements (rather than uploading copies). This would be particularly useful for Non-Patent Literature (NPL), which can be difficult for applicants to obtain, and could help to simplify and ensure the uniformity of reference citations. Also, a tool that collects publicly available art cited in any application submitted by any applicant would permit more efficient citation of that art in the future, without requiring storage of duplicate copies, which would reduce costs for the USPTO and allow for analytics to be run on cited documents across different applicants and technology areas. Relatedly, the USPTO should implement a capability to machine translate foreign language references, so that these references can be more readily accessible to applicants.

Third, the USPTO should extend the Quick Path Information Disclosure Statement (QPIDS) program to any submissions after receipt of a notice of allowance, not just after

payment of issue fee. Applicants should not be required to pay an issue fee in order to have an IDS considered, given that in some instances prosecution will reopen.

Fourth, the USPTO should mandate that examiners utilize and indicate utilization of the USPTO's Global Dossier tool in the record when examining files having counterpart applications filed with other patent offices. *See* https://globaldossier.uspto.gov/#/. Usage of the Global Dossier tool promotes work sharing among various patent offices that may be examining the same or similar claims, resulting in more robust patents both in the U.S. and abroad.

Finally, the USPTO should also modify time periods for submitting art during examination and consider relaxing or removing art-related certifications. Current Rule 97 (37 CFR 1.97) was drafted years ago when patent offices were not as connected as they are today, before the advent of today's current patent prosecution practices, and prior to patent office work sharing agreements. As a result, the Innovation Alliance believes that aspects of Rule 97 can benefit from updates promoting robust and reliable patent rights.

The Innovation Alliance recommends that the Office update Rule 97's requirements in view of current global patent filing and prosecution practices. Applicants simultaneously pursuing patent rights in multiple jurisdictions often face challenges in timely sharing non-USPTO examination details with USPTO examiners. These challenges are due in part to some of the strict requirements in Rule 97. For example, in some late-stage U.S. prosecution scenarios, practitioners might prefer to use Rule 1.97(e)'s approach for IDS submissions, but this practice creates an unreasonable burden due to certification requirements. Removing these certification requirements or aligning Rule 97(e) practice with QPIDs practice would benefit applicants and result in more robust patents by making it easier for applicants to submit art for consideration. Moreover, in some instances, applicants may have applications pending in multiple foreign jurisdictions undergoing substantive examination at the same time that U.S. examiners decide to allow a counterpart U.S. application. Given Rule 56's requirements, some applicants may find themselves filing multiple RCE/IDS submissions, which increases costs to applicants and usually causes examiners to divert time better suited for other examination tasks. To avoid these issues, we recommend that the USPTO ensure that examiners are always tasked with reviewing status of pending applications with a Global Dossier tool, or are automatically alerted of new prior art by the tool, allowing them to review the status of foreign counterpart prosecution as part of standard examination procedures. The issues arising from current Rule 97 may also be lessened by updating foreign counterpart guidance in the MPEP by adopting the more liberal definition of foreign counterpart found at the USPTO's online glossary. *Compare* "counterpart" defined at https://www.uspto.gov/learning-and-resources/glossary#sec-C *with* "counterpart foreign patent application" defined at MPEP 609.04(b).[8]

[8] Given inconsistencies in the USPTO's definitions, that the MPEP does not "have the force or law or the force of the rules," and Rule 97 does not expressly define "counterpart foreign application," some applicants may face challenges or uncertainties in complying with Rule 97's current certification requirements. *See* MPEP (Foreword) and 37 CFR 1.97(e).

E. Initiative 2(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."

Continuation applications are filed to pursue patent protection that is not yet obtained in the parent applications, but for which the invention has been captured in the disclosure of the parent applications, and thus has been disclosed to the public. Patent owners are, therefore, entitled to protect their invention as pursued in continuation applications, in exchange for their disclosure. Continuation applications filed in a large family do not change these facts and rationales. Limiting continuation practice fails to further "robustness and reliability of patents to incentivize and protect new and nonobvious inventions," as it will likely limit the value and viability of highly important patents on continually evolving technology. Continuations exist to allow for coverage of these kinds of inventions, and they incentivize early and complete disclosures for these technologies.

Continuation applications advance the quid pro quo of patent disclosure by providing inventors with important flexibility and meaningful opportunities to protect all aspects of their inventions. They allow inventors to effectively allocate often-limited resources to pursue different embodiments of their inventions at different times. This encourages inventors to disclose their inventions fully and promptly without the fear that certain aspects of their inventions would not be capable of being protected if disclosed but not initially claimed.

The existing patent infringement law does not help protect subject matters that are disclosed but not claimed. Specifically, the disclosure-dedication doctrine bars a finding of infringement if an infringer copies an embodiment/element that is disclosed but not claimed. *See See Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019) ("Under the disclosure-dedication rule, subject matter disclosed by a patentee, but not claimed, is considered dedicated to the public . . . unless, for example, claimed in a continuation or other application based on the disclosure"); *see also Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1175 (Fed. Cir. 2020) ("The disclosure-dedication doctrine bars application of the doctrine of equivalents."). This is true even if the copied embodiment/element is an obvious variant of what is claimed. This limitation makes the continuation applications crucial to the protection of American innovations and the advancement of the quid pro quo principle of patent disclosure.

Continuation applications also promote innovation by encouraging the public to design around or improve beyond what is disclosed. *See, e.g.*, *WMS Gaming Inc. v. International Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999) ("the patent law encourages competitors to design or invent around existing patents"). Patent claims often do not fully capture what is disclosed in the patent. However, third parties recognize not only what is claimed, but also what is not claimed but can be protected through continuation applications. As a result, continuation applications help prevent gamesmanship by discouraging unscrupulous copying of what is disclosed but not claimed. They help encourage third parties to improve beyond what is

disclosed. Simply copying what has been disclosed but not yet claimed does not advance science or innovation.

Moreover, continuation applications facilitate patent examination and help improve patent quality. Continuation applications allow inventors to pursue different inventions or embodiments in different applications, helping reduce the total number of claims in each application and thereby streamline the examination process. In contrast, if continuation applications are limited, inventors would have to prosecute a large number of claims in a single application in order to cover different inventions/embodiments; this would make patent examination more complex and difficult, causing unnecessary delays and potentially leading to lower-quality patents and prolonging patent exclusivity.

Currently, examiners consistently assess whether patent claims satisfy statutory requirements of patentability for subject matter eligibility, novelty, non-obviousness, and in view of the patent specification—regardless of application type—and they do so with a high degree of accuracy. Applying additional examiner or OPQA resources to continuation applications in large families is unlikely to benefit patent quality. Examination of continuation applications is most often carried out by the same examiner that assessed earlier, parent applications. Indeed, as an examiner grows increasingly familiar with the invention, disclosure, and scope of prior art in examining large families, time required to effectuate examination may decrease. Inserting new, different examination practices or quality review hurdles specific to continuation applications may reduce resources available for examination of original applications and undermines perception of examination quality for those applications. New additional scrutiny and quality reviews for continuations are unnecessary, likely to disincentivize disclosure of innovative technologies, and likely to divert resources from places where they are more needed. We therefore oppose these considered changes to continuation practice.

F. Initiative 2(f)

> "Revisit obviousness-type double patenting practice. Obviousness type double patenting occurs when a patent owner tries to secure a patent for 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. 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."

As discussed above in response to RFC Question 4(h), terminal disclaimers have been a useful tool to guarantee there is no abuse of applications when double patenting is found. A

terminal disclaimer ensures that the continuation patent has the same patent term as the earlier patent, while coupling patent ownership to a single entity. The patent system's current treatment of obviousness-type double patenting (including terminal disclaimer practice) provides a balanced solution that protects the public and promotes free competition by aligning the patent term to that of the earlier patents, as well as granting patent owners the appropriate patent protection that is consistent with the scope of their invention as disclosed in the application. Upsetting this balance violates the quid pro quo exchange between inventors and the patent system that exchanges disclosure of new technologies for patent protection.

Further, as discussed above in Section 4(h), the disclosure-dedication doctrine highlights the necessity of continuation filings and terminal disclaimers. Applicants who disclose subject matter in their applications but do not claim this subject matter dedicate it to the public. *See Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019). While applicants may opt to strategically dedicate some subject matter to the public, applicants should not be foreclosed from covering invention variants in follow-on continuation filings, and removing their ability to do so surrenders a part of their invention to the public.

Through the disclosure-dedication doctrine and other well-established lines of case law (such as the application of preclusion doctrines in cases of terminal disclaimers, *see*, *e.g.*, *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1175 (Fed. Cir. 2020)), courts have balanced the interests of patent owners and the public with regards to continuation practice on variants similar to those disclosed in an original application. Litigation concerns such as those raised in the RFC are thus best dealt with by the courts. Instead, the USPTO should continue to focus its resources on ensuring that patents that meet the statutory requirements, and only patents that meet those requirements, are issued.

G. Initiative 2(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 in 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."

The Patent Act and current regulations afford third parties rights to submit written art into the record of a pending application. Under 35 U.S.C. § 122(e), third parties are allowed to submit relevant prior art in the 6 months (or sometimes longer) following publication of an application (so long as a notice of allowance has not yet been issued). Such submissions are required to include concise descriptions of each submitted document, a submission fee, and a compliance statement. USPTO regulations governing third-party submissions track the statute and add additional formality requirements for third-party art submissions.

Given the ex parte nature of patent examination, the Innovation Alliance believes that the current USPTO regulations and policies limiting third-party involvement in applications are appropriate. Patent prosecution is already challenging and complex. Adopting new procedures to allow third-parties to increase their participation during patent prosecution will further elevate

the costs and complexities of patent prosecution, and could potentially lead to abuse of the system by injecting gamesmanship and delays into the prosecution process. We therefore believe that the patent statute's requirements should continue to be followed and that the USPTO should not enable increased third-party participation into prosecution given the limited and strict requirements that Congress has provided.

VI. Questions from June 8, 2022 Letter from Members of Congress

A. RFC Question 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?"

The Innovation Alliance strongly opposes the elimination of terminal disclaimers.[9] As the name implies, there is no statutory basis for non-statutory obviousness-type double patenting. In fact, Section 102(b)(2)(C) expressly excludes disclosures in applications and patents owned by the same person or subject to an obligation of assignment to the same person. An obvious variation is not equivalent to an obviousness rejection, as the question seems to assume. The current double-patenting practice adequately addresses concerns with these so-called "obvious variations" by limiting the patent term to the term of the patent to which the application claims priority.

Unnecessarily removing terminal disclaimers would have easily-foreseeable negative consequences. Without terminal disclaimers, applicants would be forced to attempt to claim all possible subject matter within the parent application at the initial filing and during that application's prosecution, adding significant cost to patenting, increasing the complexity of patent examination and slowing down the examination and prosecution process. There would also likely be an increase in post-allowance RCEs to add desired claims. Additionally, applicants would be incentivized to attempt to add claims to provoke a divisional application. The added cost and time that would result from eliminating terminal disclaimers, along with likely other unforeseen issues that would arise, outweighs any perceived benefit.

In addition, removing or prohibiting terminal disclaimers would discourage filings of continuation applications. As explained above, continuation applications are critical to the effectiveness and robustness of the U.S. patent system, and restriction on continuation practice would frustrate the quid pro quo principle of patent disclosure, encourage gamesmanship and unscrupulous copying, and compromise overall patent quality. Removing or prohibiting terminal disclaimers also does not meaningfully address any valid policy concerns. The USPTO should leave terminal disclaimer practice as it is.

[9] The question contemplates "eliminating terminal disclaimers," yet 35 U.S.C. § 253 grants applicants and patentees authority to disclaim various aspects of patent rights, so it is unclear how the USPTO can eliminate terminal disclaimers without legislative action.

B. RFC Question 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?"

As discussed above in connection with RFC Question 4(h), we oppose any requirement to concede that the patents are not patentably distinct, or, as Question 7 poses, the later-filed application is obvious in light of the earlier filed application. Terminal disclaimers, as discussed above, involve a tradeoff of reduced term in exchange for speedier prosecution. Deeming terminal disclaimers as an admission of obviousness, or requiring patents subject to terminal disclaimers to stand and fall together, would likely force patent applicants to contest, and obligate the USPTO to defend, the merits of these obviousness-type double patenting rejections. As discussed above, this would increase prosecution costs for all sizes of applicants, making patent examination more complex and difficult, cause unnecessary prosecution delays, create potential litigation, waste valuable resources at the USPTO, and potentially lead to lower-quality patents and prolong patent exclusivity.

In addition, deeming the filing of a terminal disclaimer as an admission of obviousness, or requiring patents that are subject to terminal disclaimers to stand and fall together, would not only contradict longstanding Federal Circuit precedent,[10] it would also raise serious questions of fairness and due process. A patent may be found invalid or unpatentable for a variety of reasons. If a patent is terminally disclaimed over another due to double patenting and later found invalid or unpatentable under Section 112, there should be no reason to infer that the other patent must also be invalid or unpatentable under Section 112. Double patenting typically does not implicate Section 112 concerns. Likewise, if one claim in the first patent is invalidated, there should be no reason to infer that the claims in the second patent that have never been subject to the double patenting rejection over the invalidated claim must also be invalid. There are also situations where the patentee may have little incentive to defend a patent (*e.g.*, if the patent does not cover any competitor's product but covers the challenger's). However, if such patent is found invalid, the "stand-and-fall" requirement would preclude the patentee from defending another patent that is terminally disclaimed over the invalidated patent but covers the competitor's product such that the patentee has all the incentives to defend its validity but has not yet had a full and fair opportunity to do so. We believe that these situations would raise serious questions of fairness and due process.[11]

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[10] *See 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.").

[11] *See Blonder-Tongue Labs. v. University of Illinois Found.*, 1402 U.S. 313, 328 (1971) ("[Some litigants] have never had a chance to present their evidence and arguments on the claim. Due process prohibits estopping them despite one or more existing adjudications of the identical issue

Litigation doctrines relating to claim preclusion already mitigate concerns about "obvious variants." *See*, *e.g.*, *Indivior Inc. v. Dr. Reddy's Lab'ys, S.A.*, 752 F. App'x 1024, 1034 (Fed. Cir. 2018) (applying claim preclusion and noting that while a terminal disclaimer does not conclusively show that the claim scope of a parent patent and a child patent is the same, it was a "strong clue" that a patent examiner and the applicant thought the claims in the continuation lacked a patentable distinction over the parent). The additional requirements suggested in this question would thus provide minimal benefit while wasting resources and should not be implemented.

C. RFC Question 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?"

The Innovation Alliance opposes the adoption by the USPTO of a policy requiring a second look at continuation applications with regard to Section 112 (or any other grounds). The MPEP sets forth detailed examination requirements for assessing the written description (§ 2163), enablement (§ 2164), and definiteness requirements (§ 2173) of 35 U.S.C. § 112. These longstanding requirements are based on, and appropriately summarize, numerous precedential decisions issued over decades of jurisprudence interpreting patentability pursuant to § 112. An examiner must examine patent claims pursuant to these requirements regardless of the type of application (*e.g.*, original or continuation application) or stage of examination (e.g., first office action or subsequent office action). Further, the USPTO already administers a program for reviewing and assessing examination quality of patent applications allowed by examiners—the Office of Patent Quality Assurance reviews a randomly selected sample of applications allowed by each examiner prior to issuance, assesses patentability of the claims, and may return the application to the examiner and have prosecution reopened if the review finds any claim to be unpatentable. The Office's approach to quality review through sampling of allowed applications and office actions, among other initiatives, have been effective in fostering thorough, robust examination. The quality review statistics for FY21 show that allowed claims are compliant with requirements of 35 U.S.C. § 112 at greater than a 96% rate.[12]

Robust examination requirements and examination quality statistics do not suggest that a specialized examination framework to address 35 U.S.C. § 112 is necessary for continuation applications receiving a notice of allowance on a first action. Installing a mandatory second look for first action allowance of continuation applications is unlikely to alter patent quality, and may

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which stand squarely against their position."); *see also Allen v. McCurry*, 449 U.S. 90, 95 (1980) ("But one general limitation the Court has repeatedly recognized is that the concept of collateral estoppel cannot apply when the party against whom the earlier decision is asserted did not have a 'full and fair opportunity' to litigate that issue in the earlier case.").

[12] *See* https://www.uspto.gov/patents/quality-metrics.

draw valuable examiner and quality assurance resources away from other significant responsibilities that could negatively influence examination and patent quality.

D. RFC Question 9

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

The Innovation Alliance opposes applying a heightened examination standard for continuation patents, as explained above. There is no statutory basis, or practical reason, to apply a different standard of examination to continuation applications. This RFC question appears to be concerned with patents for "minor modifications" of an applicant's own invention across different applications, but minor modifications that are not patentably distinct are already dealt with expertly by examiners applying the current examination framework. Different standards for original and continuation applications will create uncertainty and are likely to be inconsistently applied during examination of different applications by different examiners. And applying a purely subjective standard such as the "minor modification" standard suggested by RFC Question 9 would reduce public confidence in the patent system.

Moreover, continuation applications often give applicants a chance to present additional prior art to the examiner that was not considered in the original application. In global patent practice, for example, U.S. prosecution of a patent application may close before prosecution of related foreign applications, and prosecution in those related foreign applications may uncover relevant prior art references not considered during U.S. prosecution. Continuation applications permit such art to be considered, which may lead to claims that appear to have "minor modifications," but which are, in fact, responsive to the newly identified references. In effect, continuation applications result in better patents because the scope of the resulting claims has been examined against a more comprehensive set of prior art.

In practice, examiners typically have greater familiarity with the subject matter of continuation applications and relevant prior art as a result of having already examined related applications, and thus examiners will often have more time to perform examination due to this familiarity. This additional time can be and is already used to address any concerns that are specific to continuation applications.

E. RFC Question 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)?"

The Director should not implement any rule change with regard to the timing for filing continuations. Section 120 does not set forth any time limit or require the Director to set a time limit for continuations, as the question suggests. Rather, Section 120 gives the Director ability to regulate when reference to an earlier application is required. *See* 37 CFR 1.78 (requiring the reference to an earlier application to be filed within four months of the filing date of the later-filed application). In fact, not only does Section 120 not require the Director to set a time limit for filing continuations, it does not permit such action.

In *Immersion v. HTC*, the Federal Circuit stated that the filing of continuations up until the date of patenting has been a norm throughout the entire history of U.S. patent law. 826 F. 3d 1357, 1359 (Fed. Cir. 2016). Overturning such heavily relied upon precedent through such a proposed time-limiting rule change on continuation filing practice would upset the centuries-old practice applicants have relied upon in developing their patent portfolios and filing patent applications with multiple embodiments that they can later file claims on during the entire pendency of the application should those embodiments prove to have commercial value.

Even if the Director had the authority to restrict the ability to file follow-on applications, this proposal would result in harm to inventors. As discussed above, continuations serve important policy objectives by advancing the quid pro quo of patent disclosure, promoting innovation and preventing gamesmanship, and helping improve overall patent quality. Continuations are a critical and valuable tool available to applicants with respect to protecting variations of an invention. Arbitrarily restricting their filing to "a specific deadline" or "a benchmark" after the filing of the ultimate parent may severely diminish their value and directly contradict the USPTO's aims. Until an applicant receives a notice of allowance, an examiner may make rejections that may require the Applicant to amend the claims, including making rejections using new combinations of cited references. Thus, an applicant may not know what types of inventions the patent will actually cover until they receive a Notice of Allowance. Continuation practice allows inventors to claim the full scope of their invention, and the USPTO should not arbitrarily restrict this longstanding and well-developed practice as proposed in this question.

F. RFC Question 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?"

35 U.S.C. § 41 provides USPTO with wide discretion for fee setting. The USPTO should continue to use its fee setting authority to encourage patent filing activity. By providing access to the U.S. patent system from a full range of applicants (with various funding source ranges) the

USPTO levels the playing field and enables patent filing from a range of diverse applicants. Providing heightened entry barriers with increased 'entry' fees likely leads to a downturn of filing generally yet also likely impacts applicants unable to afford increased filing fees. New fee increases must be done with caution to ensure that inventors with lesser means are able to participate in the U.S. patent system.

The current fee breakdown across filing, search, and examination is working well and provides transparency for applicants. Varied filing fees based on applicant business size enable the USPTO to appropriately manage fee settings for a diverse range of applicants. Search and examination fees are standard no matter applicant size.

As to the current maintenance fee approach, the current approach with escalating fees is also properly working. At each maintenance fee opportunity, patent owners can determine whether to maintain patents. That the USPTO's escalated maintenance fee approach increases costs across full patent term also helps appropriately balance exclusion properties of patents. And for patents not maintained, those patented innovations transition into the public domain. Periodic raises of maintenance fees also helps ensure that patent owners maintain patents as they deem appropriate.

On continuations, as noted previously, the U.S. patent statutes and the U.S. patent system have long afforded applicants the ability to file continuation applications, and the USPTO should not disturb its approach for filing continuations by erecting new barriers to these filings. Continuation or divisional applications are, like original applications, applications for patents and do not merit any special procedures. Examination of continuation and divisional applications should be carried out like all other applications.

The USPTO's continuation and divisional filing practice is among the best, if not the best, in the entire world. It enables inventors and applicants to fully protect their innovations and appropriately balance application preparation and prosecution costs. Rather than undermining that reputation with increased barriers to entry, the USPTO should encourage other patent offices to adopt follow-on filing practices like those the USPTO currently employs.

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We appreciate the opportunity to comment on these issues and would welcome the opportunity to discuss them further.

Respectfully submitted,

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Innovation Alliance