February 1, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property
and Director U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

via https://www.regulations.gov (Docket Number PTO-P-2022-0025)

Re: Comments Regarding USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights

Dear Director Vidal:

Intellectual Property Owners Association (IPO) submits the following comments and suggestions in response to the USPTO's Federal Register Notice entitled "Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights," published at 87 Fed. Reg. 60130-60134 (Oct. 4, 2022) (RFC).

IPO is an international trade association representing a "big tent" of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO's vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO's mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO supports the USPTO's efforts to promote robust and reliable patent rights. The United States patent system is designed to encourage and empower innovation that fuels economic prosperity. Individuals and businesses alike rely upon a robust and reliable system to protect their innovations. That protection in turn encourages new innovations, resulting in improved technologies, increased economic growth, and the promotion of new and useful ideas. These benefits extend across all industries and technologies, including the high tech, biotech, and pharmaceutical industries. A robust and reliable patent system benefits not only the patent holder, but others in the industry as well, because the patent system supports the sharing of ideas, encourages competition, and spurs continued innovation.

Our responses to the questions posed in the RFC are below.

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

Identifying all information that qualifies statutorily as prior art that should be searched but is not available through the Patents End-to-End Search system warrants its own undertaking. This project should seek to understand where primary technical sources of prior art are likely to be found for different technology areas, including understanding when non-patent prior art might be most relevant, such as technology areas pertaining to machine learning, e-commerce, and academic journal intensive early-stage technologies.

A large trove of machine-translated foreign patents has been added to Patents End-to-End (PE2E) relative to EAST. Examiners should have access to the same sources of prior art that are available via the Scientific and Technical Information Center (STIC), the USPTO's scientific library, which is presumed to cover major scientific journals relevant to all art units. It is IPO's understanding that examiners currently do not have direct access to this library and cannot query the database using similar techniques for patent searching within the Patents End-to-End Search system, including leveraging keyword, Boolean, proximity, and highlighting functionality. This is a major differentiator between examiners and outside patent searchers; it should not be easier for outside searchers to identify relevant prior art. Examples of other collections and resources that should be made available to examiners include GenomeQuest, ProQuest, PubMed, IEEE Explore, and GitHub. Some art units will naturally require different levels of access and types of information access than others.

Patent searching tools used by outside patent searchers have features and UI layouts that improve the prior art searching process. These include the ability to save individual projects that can be reviewed at the query level and shared with colleagues, keyword highlighting schema, the integration of Artificial Intelligence (AI) and other time-saving techniques, family-type grouping so that time is not wasted looking at one document that has essentially the same disclosure as another, multi-window configurations that can be customized, and the ability to export and manipulate relevant data in Office tools (e.g., Excel, Word, etc.). The USPTO should investigate and ensure that examiners have access to the most advanced and efficient searching tools.

Finally, for available resources to be truly accessible, examiners must receive sufficient training to become proficient in identifying which sources are most relevant to an application. The ability to conduct patentability searches efficiently is essential to the functioning of the examining corps. With prior art growing exponentially, the time required to conduct a thorough search also increases. Having the right tools and training is as essential to robust and reliable patents as the identification of additional sources of potential prior art.

2. How, if at all, should the USPTO change claim support and/or continuation practice to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents? Specifically, should the USPTO:

> **a. require applicants to explain or identify the corresponding support in the written description for each claim, or claim limitation, upon the original presentation of the**

claim(s), and/or upon any subsequent amendment to the claim(s) (including requiring a showing of express or inherent support in the written description for negative claim limitations)?

b. require applicants to explain or identify the corresponding support for each claim, or claim limitation, in the written description of every prior-filed application for which the benefit of an earlier filing date is sought, under, e.g., 35 U.S.C. 119, 120, 121, or 365?

c. require applicants to explain or identify the corresponding support for each claim, or claim limitation, in the written description of every prior-filed application for which the benefit of an earlier filing date is sought, under, e.g., 35 U.S.C. 119, 120, 121, or 365 (including requiring such support whenever a benefit or priority claim is presented, including upon the filing of a petition for a delayed benefit or priority claim and upon the filing of a request for a certificate of correction to add a benefit or priority claim)?

d. make clear that claims must find clear support and antecedent basis in the written description by replacing the ``or'' in 37 CFR 1.75(d)(1) with an ``and'' as follows: ``The claim or claims must conform to the invention as set forth in the remainder of the specification, and the terms and phrases used in the claims must find clear support [[or]] and antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description?''

e. require applicants to provide detailed analysis showing support for genus or Markush claims, and require applicants to identify each claim limitation that is a genus, and explain or identify the corresponding support in the written description for each species encompassed in the claimed genus?

f. require applicants to describe what subject matter is new in continuing applications (e.g., continuation, continuation-in-part, and divisional applications) to explain or identify subject matter that has been added, deleted, or changed in the disclosure of the application, as compared to the parent application(s)?

Complying with the written description requirement certainly is important for robust and reliable patents. Currently examiners should consider written description during examination and can require an applicant to explain support for a claim where support is not evident or pointed out by the applicant. *See, e.g., Hyatt v. Dudas*, 492 F.3d 1365, 1370, n.4 (Fed. Cir. 2007). Additionally, continuation and divisional applications are not permitted to include "new matter" relative to the parent application. Regarding continuation-in-part applications, if an examiner is unsure and needs to identify what subject matter is new in order to conduct examination, the examiner can ask the applicant.

We are concerned about burdening applicants with adding additional requirements and do not think a drawing bright line at the claim amendment stage or creating new requirements for all genus or Markush claims make sense. We would like to work with the USPTO to ensure a fair balance of effort between what the USPTO must examine on its own and what additional detail is required from applicants in addition to whether any new process makes sense at the continuation phase.

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

RCEs often are a legitimate step in examination, and the number of RCEs filed in an application is not an indicator of patent quality. An applicant making a *bona fide* effort to overcome all rejections raised in a non-final office action cannot always do so on the first try. This especially can be true in complicated technologies, where both the cited art and claimed invention are complex, or where the rejections touch on difficult legal issues such as written description, enablement, obviousness, or patent eligibility. Even where each response makes progress, multiple iterations may be required.

An RCE can also be an important option after an *ex parte* appeal of an examiner's rejections or may be required to obtain consideration of an Information Disclosure Statement (IDS). (The USPTO should be very cautious about changes to rules or internal practices that might penalize applicants for complying with the duty of disclosure.) That examination includes one or more RCEs does not mean that the goals of fostering innovation, competition, and access to information through robust and reliable patents are not served. Indeed, in some cases the filing of one or more RCEs may evidence a more thorough examination process, and thus a more robust and reliable patent. Thus, IPO would *not* support a general limit on the number of RCEs that could be filed.

That said, IPO supports exploring the possibility of internal USPTO process changes after a threshold number of RCEs have been filed to ensure that examination/prosecution is conducted appropriately. The filing of a third RCE might be an appropriate time to consider such a change, but we do not recommend setting a bright-line rule triggering changes.

Regarding transfer to a different examiner after a threshold number of RCEs has been filed, an automatic transfer might result in "gaming" by examiner or applicant that would undermine robustness and reliability; supervisory discretion should be invoked in deciding whether a transfer is appropriate. IPO suggests the USPTO consider the following factors (which are not intended to be exclusive) when reviewing examination/prosecution to assess whether a transfer is appropriate:

- Was the RCE filed to obtain consideration of an IDS?
- Did the final Office Action cite new art or raise new issues?
- Is subject matter eligibility the only outstanding issue?
- Did the applicant make claim amendments or present new evidence with the RCE?
- Did the examiner refuse to enter amendments/evidence "after final"?
- Was any new art cited in the final Office Action materially different from art cited in a previously overcome rejection?
- Were any new issues raised in the final Office Action issues that could/should have been raised earlier?
- Was the final Office Action properly made "final"?
- Did the examiner refuse to enter an amendment properly presented under AFCP 2.0?
- Has the examiner properly considered all claims, including dependent claims?

- Has the examiner cited the "best" art of record (including items cited in PCT or foreign search reports)?
- Has an interview been conducted?

IPO also suggests considering giving the applicant some input into whether a transfer is made. For example, if the applicant believes examination has been conducted appropriately but multiple RCEs have been required to address newly discovered prior art or because of the technology's complexity, transfer to a new examiner could undermine rather than enhance efficiency. Similarly, the USPTO could give the examiner some input into whether a transfer is made, at least in cases where review of the prosecution record does not reveal significant examiner error.

In addition to considering internal USPTO process changes after a threshold number of RCEs has been filed, IPO urges the USPTO to consider internal changes that could decrease the need for RCE filings. For example, IPO has recommended replacing the present final office action policy and attendant after final practice with a policy that every amendment is entered as a matter of right with applicants paying an RCE fee with every third response and that each response is taken up for action by the examiner within the same time frame. Additionally, IPO urges the USPTO to consider changes to IDS practice that would eliminate the need to file an RCE to obtain consideration of an IDS under additional circumstances. IPO has provided other specific suggestions for reducing the need for RCEs in the following submissions to the USPTO, which IPO encourages the USPTO to revisit:

- Feb. 13, 2013 -- Comments on Request for Continued Examination (RCE) Practice (responsive to 77 Fed. Reg. 72830 (Dec. 6, 2012)) https://ipo.org/wp-content/uploads/2013/03/comments.pdf
- May 6, 2013 -- Comments on Enhancing Patent Quality, at pages 8-9 (responsive to 80 Fed. Reg. 6475 (Feb. 5, 2015)) https://ipo.org/wp-content/uploads/2015/05/IPO-Letter-in-Response-to-Quality-Initiative-5-6-15-1.pdf

4. How, if at all, should the USPTO limit or change restriction, divisional, rejoinder, and/or non-statutory double patenting practice to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents? Specifically, should the USPTO:

a. allow for the examination of two or more distinct inventions in the same proceeding in a manner similar to the practice authorized by 37 CFR 1.129(b), and, if so, consider an offset to patent term adjustment in such cases?

IPO supports considering allowing examination of two or more distinct inventions in the same application where examination can be conducted efficiently. We cannot support an offset to patent term adjustment without more information about any proposed offset.

b. revise the burden requirement before the examiner to impose a restriction, and if so, how?

c. adjust the method by which an examiner appropriately establishes burden for imposing a restriction requirement?

IPO supports considering revising the burden required for an examiner to impose a restriction—or enforcing the existing "serious burden" requirement and adjusting the method by which an examiner establishes burden. For example, examiners should be required to make a determination of independence/distinction based on the entire claim as written (e.g., not merely on the preamble) and taking into account when claims depend from the same base claim. Examiners should be required to specify reasons that justify a "serious burden" (not merely assert that one or more of the possible reasons are met) and provide additional justification when claims depend from the same base claim.

d. authorize applicants, in the case of a Markush group, to suggest how the scope of the claim searched should be expanded if the elected species is not found in an effort to present closely related inventions for consideration together?

IPO supports permitting applicants to suggest how the scope of a search should be expanded in all applicable situations, e.g., claims with a Markush group and all other election of species scenarios.

e. adopt a unity of invention requirement in place of the restriction requirement?

IPO would like more information on this possibility. For example, would the USPTO adopt the same unity of invention standards that are applied at the PCT stage and by other IP5 offices? Would the USPTO permit applicants to pay additional fees to obtain examination of additional inventions in a single application?

f. revise the current practice of authorizing the filing of divisional applications in a series to require all divisional applications to be filed within a set period of time after the restriction requirement is made final and after any petition for review has been resolved?

IPO does not support requiring all divisional applications to be filed within a set time period. Such a requirement would multiply upfront patent filing and prosecution costs and could lead to forfeiture of valuable patent rights based on budget constraints, which could undermine investment in innovation. An increase in costs would include not only the USPTO filing/search/examination fees for the divisional applications, but also the expense (time or professional service charges) associated with filing and prosecuting applications in parallel. While these costs would be felt by all types of applicants, they likely would have a disproportionate impact on *pro se*, micro, and small entities, thereby undermining the USPTO's efforts to promote a more equitable patent system and stimulate innovation by small businesses. Many applicants, but especially those with significant budget constraints, can afford to participate in the patent system because they control costs by filing and prosecuting patent applications serially.

A requirement to file and prosecute divisional applications in parallel would complicate prosecution due to the potential need to file cross-citing IDSs across all co-pending divisional applications throughout prosecution. Such a requirement also would eliminate the ability to streamline examination of subsequent divisional applications (e.g., by leveraging successful claim amendments, arguments, and evidence). For these reasons, such a requirement could have a significant negative impact on small businesses and individual inventors.

We note that the EPO implemented a similar requirement that any divisional application had to be filed within two years of receiving a first examination report or lack of unity objection. One of the reasons this was implemented was to provide certainty for third parties as to how many applications could be pursued in a family. However, the requirement was discontinued in 2014 because applicants had to make critical decisions too early in the patenting process, time limits were cumbersome to monitor, and the requirement seemed to be slowing the pace of examination. Now divisional applications can be filed at the EPO any time during the pending of a family member patent application, similar to current U.S. law and practice.

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

IPO would like more information on this proposal. IPO supports giving an applicant a certain time period after some claims have been found allowable to amend unelected claims to recite allowable subject matter for rejoinder and allowance.

> **h. limit or change non-statutory double patenting practice, including requiring applicants seeking patents on obvious variations to prior claims to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer to obviate the rejection;** ….

Non-statutory double patenting (also referred to as "obviousness-type double patenting" or "OTDP") prevents the grant of multiple patents that are alleged to be obvious variations of each other but would otherwise be allowable under the patent statutes (e.g., there is no invalidating prior art). Two objectives of the OTDP doctrine are to prevent unjustified extension of patent term by the grant of multiple patents and to prevent harassment by different patent owners that could occur if the patents were transferred to different owners.

Some OTDP rejections rely on additional prior art references to bridge the gap between the examined claims and the cited claims. Thus, an OTDP rejection might be made where grant of one patent would not necessarily result in the timewise extension of the right to exclude associated with the other. Thus, terminal disclaimers can be required to obtain protection of the full scope of invention(s) described in a given patent application and thereby promote the *quid pro quo* of the U.S. patent system.

Terminal disclaimer practice directly addresses and eliminates OTDP concerns by requiring the patents to expire on the same date and to remain commonly owned to be enforceable. *See* 37 C.F.R. § 1.321. The ability to overcome OTDP issues with a terminal disclaimer serves an important public interest "because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public." *In re Berg*, 140 F.3d 1428, 1436 (Fed. Cir. 1998).

We do not believe the USPTO has statutory authority to substantively restrict or modify the judicially created OTDP doctrine or the remedy provided by terminal disclaimer practice, because it does not have the power to create or modify common-law principles or remedies. We also believe the proposed required stipulation, which would require applicants seeking patents on allegedly obvious variations of

prior claims to admit that the claims are not patentably distinct as an additional condition for acceptance of a terminal disclaimer, contradicts existing law. Specifically, it would be directly contrary to 35 U.S.C. § 253, which holds that "[w]henever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid" and would not only violate the requirement to treat claims of the *same* patent independently but would go further by effectively requiring claims of *different patents* to stand or fall together. Moreover, the Federal Circuit has foreclosed any inference that filing a terminal disclaimer should be equated with such an admission. *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-1168 (Fed. Cir. 2018).

For similar reasons, the proposed required stipulation would amount to a substantive rulemaking for which the USPTO lacks authority. The OTDP doctrine and associated terminal disclaimer practice are "substantive" because they effectively impose additional patentability/validity requirements and affect an applicant's ability to obtain patents that 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."); *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."). Terminal disclaimer practice is an integral part of the OTDP doctrine and is substantive in that, without it, patents would not be granted or could be invalidated.

The proposed stipulation also could compromise overall patent quality. Terminal disclaimers are often filed due to time- and cost-saving concerns unrelated to the merits of the OTDP rejection. This is particularly true for continuing applications, which are typically owned by the same entity and expected to expire on the same date even without a terminal disclaimer. In these situations, it would make little sense for an applicant to contest the merits of an OTDP rejection if a terminal disclaimer would readily overcome a rejection.

Compelling applicants to effectively admit the merits of OTDP rejections would lead applicants to contest, and obligate examiners to defend, the merits of the OTDP rejections that otherwise would go unchallenged. This would increase prosecution costs for all types of applicants, cause unnecessary prosecution delays, lead to more *ex parte* appeals of examiner rejections, give rise to litigation, and waste valuable USPTO resources. Ironically, if an OTDP rejection were successfully challenged, the resulting patent could be entitled to a *longer* term due to statutory patent term adjustment, thereby prolonging patent exclusivity. Compelling applicants to effectively admit the merits of OTDP rejections could require legally inconsistent positions to be taken in a "divisional" application that does not qualify for the protections of 35 U.S.C. § 121. The proposed stipulation also would encourage applicants to file many claims in a single patent application to preserve the protections of § 253, which would make patent examination more complex and difficult.

The Federal Circuit has developed an effective approach to address the effect of terminal disclaimers on related patents, finding that a terminal disclaimer, although not conclusive, is a strong clue that the relevant claims in a continuation patent may lack a patentable distinction over the parent. In *SimpleAir*, 884 F.3d at 1168, 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, even without the proposed stipulation, a terminal disclaimer is relevant to a determination of the patentability/validity of the terminally disclaimed patent and has been used to streamline resolution of patent disputes. The Federal Circuit's approach, *i.e.*, considering terminal disclaimers relevant but not conclusive, strikes a good balance between different policy considerations.

Finally, we question whether the proposed stipulation meaningfully addresses valid policy concerns. It appears designed to address allegations that large numbers of "obvious variant" patents form "patent thickets" around pharmaceutical products that unreasonably delay generic and biosimilar competition. The RFC states that "multiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before PTAB and in district court," and asserts that "later issued patents to obvious variants may delay resolution of ongoing district court litigation thereby potentially delaying generic and biosimilar entry into the market." Underlying these statements is an assumption that the patents are not valid, e.g., that the challenges would be successful, but the RFC does not present or discuss data supporting the premise that large numbers of *invalid* patents are preventing competition or provide evidence of a systemic problem that justifies a systemic policy change.

> **h. … rejecting such claims as not differing substantially from each other or as unduly multiplied under 37 CFR 1.75; ….**

IPO does not believe 37 C.F.R. § 1.75(b) is applicable to OTDP. First, it allows more than one claim to be presented in a single application, "provided they differ substantially from each other and are not unduly multiplied," and does not address claims in two different applications. Second, it concerns 35 U.S.C. § 112(b). OTDP arises between two different patents or applications, and its underlying legal analysis is based on 35 U.S.C. § 103; OTDP does not typically implicate § 112(b) concerns. Claims rejected under OTDP may well satisfy the requirements of § 112(b), which is determined based on whether the claims "inform those skilled in the art about the scope of the invention with reasonable certainty" when "viewed in light of the specification and prosecution history." *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014) ("[W]e read § 112, ¶2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.").

If the USPTO intends to invoke 37 C.F.R. § 1.75(b), IPO urges the USPTO to clarify the term "unduly multiplied," which is not employed in any patent statute or other rules of patent practice. It is unclear if "undue multiplicity" refers to substantially identical claims that would trigger statutory double patenting rejections or is so broad as to encompass claims that are obvious over each other but not substantially identical. Additionally, it is unclear whether "unduly multiplied" would apply to claims that are obvious over, but not substantially identical to, each other (including between dependent and independent claims,

a common scenario in which the USPTO currently does not normally rely on 37 C.F.R.§ 1.75(b) to reject dependent claims).

h. … 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).

Under 37 C.F.R. § 1.78(f), the USPTO may require an applicant to restrict "patentably indistinct" claims into a single application "in the absence of good and sufficient reason." However, IPO does not believe examiners invoke this rule frequently. In the context of OTDP, it seems that 37 C.F.R. § 1.78(f) only could be applied to co-pending continuation applications and not to address OTDP over a granted patent or application that does not describe the claims at issue. Whereas existing terminal disclaimer practice serves important policy objectives by addressing OTDP concerns and promoting disclosure of follow-on innovations, invoking 37 C.F.R. § 1.78(f) would not have the same effect.

Use of 37 C.F.R. § 1.78(f) to restrict normal continuation practice could unlawfully restrict rights under 35 U.S.C. § 120, which permits filing a continuation application "for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed." Section 120 does not set forth any limitation on the claims of a continuation application. Relatedly, we suspect that if 37 C.F.R. § 1.78(f) were used to restrict continuation application claims, it would be transformed into a substantive rule for which USPTO lacks authority. The district court for the Eastern District of Virginia previously found that a USPTO rule limiting the number of continuation applications was a substantive rule and therefore impermissible under the law. *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).

In the OTDP context, filing a terminal disclaimer still would be a "good and sufficient reason" for retaining patentably indistinct claims. The USPTO considers the term "patentably indistinct" in 37 C.F.R. § 1.78(f) to mean "same or substantially the same." 37 C.F.R. § 42.401. Courts have developed a "two-way test" to determine "same or substantially the same" in the context of an interference. *See Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc*., 655 F.3d 1291, 1302 (Fed. Cir. 2011). If two patent applications meet this "two-way" test and are considered "patentably indistinct," it would be a typical OTDP scenario for which the courts have already created an effective remedy through terminal disclaimers.

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

IPO supports several of these initiatives that promise to improve patent quality and reliability, foster innovation, and promote competition, including introducing more examination time for each type of applications, providing more training and resources to examiners, enhancing communication between examiners and the PTAB, and encouraging disclosure of relevant material information to the examiners. We have concerns about suggested initiatives that would apply greater scrutiny to specific subsets of applications or modify OTDP and terminal disclaimer practice and about how greater scrutiny would be

applied. Would a different evidentiary standard be applied during examination (e.g., some standard other than preponderance of the evidence)? Would patents granted after greater scrutiny be accorded a stronger presumption of validity? Would subjecting some applications to lesser scrutiny lead to lower-quality patents?

Continuation applications serve important policy objectives and should not be discouraged. They help promote the *quid pro quo* of patent disclosure by providing inventors with meaningful opportunities to protect all aspects of their inventions, thereby encouraging inventors to fully and timely disclose their inventions without fear that certain aspects might not be protected if disclosed but not initially claimed. Continuation applications also help promote innovation and prevent gamesmanship by encouraging others to design around and improve upon what is *disclosed* as opposed to merely what is claimed.

Under Initiative 2f, the USPTO states that "multiple patents directed to obvious variants 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 asserts that "later issued patents to obvious variants may delay resolution of ongoing district court litigation thereby potentially delaying generic and biosimilar entry into the market." But evidence is lacking that competition is deterred by the number of patents protecting a product. The Federal Circuit approach to the impact of a terminal disclaimer on validity (e.g., treating it as relevant information, but not giving rise to a presumption) is an effective tool for discouraging patentees from asserting "obvious variant" patents after the reference patent has been finally held invalid or unpatentable over prior art.

The U.S. patent system operates under a well-defined statutory framework, but it is shaped by common law principles that help ensure equity and fairness. These unique legal underpinnings provide the U.S. patent system with adequate flexibility to accommodate fast-evolving technological advances and ever-changing business landscapes. In comparison, other patent systems appear to be overly bureaucratic, rigid, fragmented, and/or not readily able to adapt to today's technology and innovation environments. We urge the USPTO to be cautious when considering sweeping changes to U.S. patent practice.

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?

We do not support eliminating terminal disclaimers. In addition to reasons stated above, this would frustrate the legislative intent of 35 U.S.C. § 102(c), discourage research collaboration, and curtail American innovation. Congress enacted §102(c) (pre-AIA 35 U.S.C. § 103(c)(2)) to facilitate the patenting of inventions made under joint research collaborations, by deeming certain background technologies contributed by one of the participants of the collaboration not patentability defeating. It was enacted "with the same intent to promote joint research activities that was expressed, including the legislative history, through the enactment of the Cooperative Research and Technology Enhancement Act of 2004 (Public Law 108-453; the 'CREATE Act')." *See* Pub. L. 112–29, §3(b)(2), Sept. 16, 2011, 125 Stat. 287. Thus, § 102(c) reflects Congressional interest in encouraging cooperative research and development among universities, government, and the private sector. Prior to its enactment, inventions under a joint research collaboration frequently were rejected as obvious over background technologies contributed by one of the participants of the collaboration.

The enactment of 35 U.S.C. § 102(c) has not changed OTDP practice. Patents directed to inventions made under a joint research collaboration can still be *rejected* under the doctrine of OTDP over background technology patents owned by one of the collaboration participants. However, because terminal disclaimers can be filed under 37 C.F.R. § 1.321(d) to obviate such OTDP rejections, inventions made under joint research collaboration can be patented over those background technologies if the terminal disclaimer requirements are met (including a shortened patent term for the joint research collaboration patent). We are concerned that eliminating terminal disclaimers under 37 C.F.R. § 1.321(d) would preclude patenting many inventions made under joint research collaborations, thereby frustrating the primary legislative purpose of 35 U.S.C § 102(c) and effectively nullifying the CREATE Act of 2004 by discouraging research collaborations that have been key to the success of American innovation, in addition to recreating the circumstances the CREATE Act was designed to address.

Regarding terminal disclaimers generally, as explained above, eliminating terminal disclaimers under 37 C.F.R. § 1.321(c) would chill innovation by effectively blocking continuation patents, thereby limiting the value an applicant can obtain from a patent disclosure and decreasing the incentive for making a full disclosure. Continuation applications are often subject to OTDP rejections over parent patents; without the ability to file terminal disclaimers, continuation applications could be unpatentable. But continuation patents are crucial to the effectiveness and robustness of the U.S. patent system and American innovation. As discussed above, continuation patents support the *quid pro quo* of patent disclosure by providing inventors flexibility and a meaningful opportunity to protect all aspects of their inventions. The ability to pursue continuation patents allows inventors to allocate limited resources to pursue protection of different embodiments of their inventions at different times. This encourages inventors to fully and promptly disclose inventions in their initial application filings, knowing that they will have sufficient opportunity to protect the various aspects of the invention. If continuation patents were limited through eliminating terminal disclaimers, inventors would be incentivized to make piecemeal disclosures of their inventions or to disclose only some aspects.

Continuation patents can facilitate patent examination and help improve patent quality. Continuation patents allow inventors to pursue different embodiments in different applications and reduce the total number of claims that must be presented in each application, which streamlines examination. If terminal disclaimers were eliminated, thereby eliminating continuation applications, inventors would have to prosecute many claims in a single application to cover different embodiments. This would make patent examination more complex and time-consuming.

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?

IPO does not believe filing a terminal disclaimer should be deemed an admission of obviousness or result in patents standing and falling together, for several reasons already discussed above. Applicants often file terminal disclaimers for reasons unrelated to the merits of OTDP rejections. For example, terminal disclaimers have been filed for convenience when an application (e.g., a continuation application) is expected to remain owned by the same entity and already expires on the same date (or earlier) than the reference patent, and it makes little sense for an applicant to contest the merits of an

OTDP rejection if a terminal disclaimer would overcome the rejection. Terminal disclaimers are also filed to avoid additional prosecution costs or expedite grant of patents to help obtain financing or attract investment. Saddling practical decisions with the consequence of invalidity could disparately impact small businesses and individual inventors who may be more sensitive to financial and time pressures.

Additionally, deeming the filing of a terminal disclaimer an admission of obviousness also would also raise questions of fairness and due process. A patent claim can be found invalid/unpatentable for a variety of reasons, not just prior art. Even if claims are considered to be "obvious variants," if one is found invalid/unpatentable under 35 U.S.C. § 101 or § 112, the same issue may not pertain to the other claim. Moreover, terminal disclaimers can be filed even if only some claims are subject to an OTDP rejection and there would be no justification for tying the validity of the non-rejected claims to the validity of the terminally disclaimed patent. Similarly, an OTDP rejection may rely on only some claims of the cited application/patent and there would be no justification for tying validity to the validity of claims not cited in the OTDP rejection.

Regarding due process, a patentee may have less incentive to defend one patent versus the other, such as where only one patent covers a competitor's product. A "stand-and-fall" requirement would require a patentee to vigorously defend all patents linked by terminal disclaimers just to preserve that one. This would deny the patentee a full and fair opportunity to defend the patent of interest without also having to defend the other patent(s), which could be prohibitively expensive, especially for a small business or sole inventor. *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 which stand squarely against their position.").

As discussed above, the Federal Circuit in *SimpleAir* developed an approach to address the impact of terminal disclaimers on related patents that has proven effective in streamlining the resolution of patent disputes involving terminally disclaimed patents and strikes the appropriate balance of policy considerations.

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?

Every patent must satisfy the statutory requirements for patentability, including those set forth in 35 U.S.C. § 112 in addition to §§ 101, 102, 103, and double patenting. Examiners should be trained to evaluate patent claims in view of the statutory requirements, whether the application is a continuation or otherwise. No different standard including a "second look" should exist simply because an application claims priority to an earlier-filed application.

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

Examiners should be trained to evaluate whether all proposed patent claims satisfy the statutory legal requirements for patentability. No different standard is necessitated by an application that claims priority to an earlier-filed application.

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 time for filing an application claiming priority to an earlier application (such as a continuation application) is governed by 35 U.S.C. § 120, which provides that an application shall have the same effect as to invention as though filed on the date of the prior application "if 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."

The question may be referring to Director discretion in setting a time period for making a priority claim to an earlier-filed patent application. See 35 U.S.C. § 119(b). There is no Director discretion regarding the time period for filing the continuation application itself. This issue was addressed in the *Tafas v. Dudas* litigation. *See* 511 F. Supp. 2d 652 (E.D. Va. 2007).

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?

IPO urges the USPTO to exercise caution before attempting to adjust the fee schedule to influence applicant behavior. IPO doubts that increasing up-front fees would "discourage[e] filing of patents unlikely to succeed." We assume most applicants believe their applications are likely to succeed. We also doubt that increasing fees for continuation applications would lead to more thorough examination, unless examiners are given more count credit for examining a continuation application. Even then, an examiner might be incentivized to examine continuation applications quickly to earn more count credit in less time. Finally, we doubt increasing fees would discourage the filing of continuation applications, because applicants already are planning to spend more than the up-front costs (such as attorney fees, issue fees, and maintenance fees).

Additional comment

As stated above, IPO supports the USPTO's efforts to promote robust and reliable patent rights across all technology areas. However, it appears that RFC was motivated by scrutiny of the pharmaceutical

technology area, rather than a technology-neutral goal of improving the patent system across all industries. For example, the RFC highlights efforts to minimize continuation practice for pharmaceutical patents, discussing a September 10, 2021, letter from the FDA to the USPTO that referred to "brand use of the patent continuation process to create patent thickets, product hopping, and evergreening" and a June 8, 2022, letter from certain Senators to the USPTO that raised the specter of "patent thickets." These communications imply that the pharmaceutical industry disproportionately and nefariously benefits from continuation practice in comparison to other industries. However, continuation applications are widely filed across technology sectors for many reasons consistent with a robust and reliable patent system.

The RFC also seems to be influenced by assertions that pharmaceutical companies file and/or obtain a disproportionate number of patents relative to other technology sectors. However, this contention is neither supported by facts nor data. Based upon data reported by IPO, of the top 300 organizations granted patents in 2021, fewer than 3% were pharmaceutical companies. *See IPO 39th Annual Listing of Top 300 Organizations Granted U.S. Patents in 2021* (January 6, 2022) (available at https://ipo.org/wp-content/uploads/2022/01/2021-Patent-300%C2%AE-IPO-Top-Patent-Owners-List-FINAL.pdf). The average rank of the pharmaceutical companies on the list was 198th. Data indicate that when normalized by R&D spend, pharmaceutical companies file and obtain far fewer patents than companies in other sectors. *See* Shackelford, B., *One in Five U.S. Businesses with R&D Applied for a U.S. Patent in 2008* (2013) (available at https://www.nsf.gov/statistics/infbrief/nsf13307/); Wolfe, R., *Business Research and Development and Innovation: 2016* (2019) (available at https://ncses.nsf.gov/pubs/nsf19318/).

We urge careful consideration of validated facts regarding the promotion and protection of innovation and competition, especially when assessing the appropriateness of systemic changes.

Thank you for considering IPO's comments. As one of the primary organizations representing IP owners, IPO would welcome the opportunity for additional dialogue regarding this important topic.

Best regards,

Karen Cochran
President