AIPLA
American Intellectual Property Law Association

February 1, 2023

Via Federal Rulemaking Portal at https://www.regulations.gov

The Honorable Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

RE: Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights

Dear Director Vidal:

The American Intellectual Property Law Association ("AIPLA") is pleased to have the opportunity to reply to the notice of October 4, 2022, from the United States Patent and Trademark Office's ("Office") Request For Comments on possible initiatives of the Office to ensure the robustness and reliability of patent rights (the "RFC").

AIPLA is a national bar association of approximately 7,000 members that include professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property.

Our members represent both owners and users of intellectual property ("IP").

Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

General Comments

AIPLA applauds the Office's willingness to consider new initiatives in a continuing effort to improve the patent system and to obtain and listen to feedback from stakeholders as a key part of that process. We welcome the opportunity to provide practical insights on day-to-day prosecution practices to help improve the processes of the Office.

While the RFC is not limited to probing the role of patents on access to medicines,[1] AIPLA agrees that patents incentivize development of new drugs and drug therapies. We also agree that patents should not delay generic drug and biosimilar competition by extending protection for drugs "beyond that reasonably contemplated by applicable law."

More generally, we believe some of the proposed initiatives could improve Office examination processes and, thus, promote innovation. We are mindful, however, of unintended consequences.

Disparate impact and effects

The proposed changes to patent prosecution will impact all applicants. Changes motivated to address a perceived or actual problem involving a small subset of applicants may risk creating unintended consequences that adversely or unfairly impact all applicants. In addition, AIPLA is concerned that some of the proposed initiatives may disproportionally burden those users of the patent system who are traditionally under-resourced.

Independent inventors, start-ups, and small to medium enterprises (SMEs) are critical participants in the IP system and the economy. They create jobs and new economic activity at a grass roots level. They create opportunities for innovative and even disruptive technologies to be tested and developed until they take hold and flourish. They challenge larger, more established market participants to keep refreshing their own products and services. The patent system is important, if not critical, to these innovators.

At the same time, independent inventors, start-ups, and SMEs relative to large companies, have limited resources to spend on IP. Increasing burdens on these applicants, especially early in the application process, will likely have a more immediate and substantial adverse impact on them.

Different applicants, different priorities

Independent inventors, start-ups, non-profit institutions, and SMEs benefit by being able to spread prosecution out over time through a family of applications prosecuted consecutively. These innovators have significant resource constraints early in product development. They must carefully marshal resources invested in IP. They need to balance IP expenditures with the need for resources in the development of the core products and services. These entities benefit from filing a single omnibus application around a key inventive concept while they are still under development. This application may include multiple inventions.

Consecutive prosecution of multiple inventions disclosed in an omnibus application supports the patent system's core goal of public disclosure. Patent terms remain limited because terms of later patents claiming priority to an earlier application are limited by the earliest effective filing date. Business decisions on patent protection are typically deferred until greater resources are

[1] The first sentence of the background to the RFC references the July 9, 2021 Executive Order entitled "'Promoting Competition in the American Economy,' 86 FR 36987 (July 14, 2021). . . To advance the Biden Administration's goals of promoting access to prescription pharmaceuticals for American families and increasing competition in the marketplace, section 5(p)(vi) of the E.O. directs the Secretary of Health and Human Services (HHS) 'to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.'"

available and the market provides insight into which inventions will be commercially successful. This pattern, while providing public disclosure and avoiding unwarranted term extension, is economically efficient for both applicants and the Office. Inventors invest fees and resources and pursue patents for disclosed inventions that ultimately make commercial sense to pursue.

Changing the Office's fee structure to increase fees at the front end of the examination process and limiting continuation and divisional practice to require concurrent prosecution, will negatively impact the ability of many applicants to obtain the patent protection they need. This will not only make it more difficult for sole inventors, start-ups, and SMEs to obtain patent protection, it will likely deter open and robust disclosure supporting further innovation. The incentive to invent around prior disclosures forms the basis for the constitutional bargain of the patent system in the first instance.

Responses to Specific Questions

In answering the Office's questions below, AIPLA has tried to balance the needs of the underlying IP reward system and the impact of potential changes among all IP user communities.

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 Office 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)?

AIPLA Response

As a general matter, AIPLA supports the Office identifying and leveraging the results of searches from other offices through the Global Dossier and similar programs. Improving automation and access to references could provide substantial efficiency gains to applicants and the patent system. This could eliminate the need for applicants to repeatedly download, translate, and resubmit references from other jurisdictions to the Office, multiple times across every application in a patent family.

AIPLA also supports the Office's initiatives to expand the amount and types of prior art that are accessible by providing examiners better AI tools to process and prioritize non-patent literature (NPL).

It is our understanding that patent examiners have access to and use some of the most sophisticated databases and libraries of prior art in the world. AIPLA does not, currently, have specific recommendations on new libraries or repositories for search.

In general, AIPLA encourages facilitating access to prior art both during and after examination. AIPLA suggests that applicants be permitted to submit prior art in any format that is easy and simple. This would incentivize and maximize submissions.

As an option, AIPLA believes that there would be significant benefit to having structured input forms that promote consistent citation, storage, tracking, and presentation of prior art. This is particularly true for information that does not fit into standard categories of patents or NPL (e.g., information relating to on-sale or public use of an invention, related products, or nonstandard media such as video or audio recordings).

Generally, AIPLA encourages systems that make it easier for innovators to submit prior art in a consistent and predictable manner, so long as they are structured to provide consistent and reliable access to examiners and the public. AIPLA recommends that, as structured forms are created, care be taken to not require mandatory entry in most fields. Mandatory field entries might unintentionally discourage submission by unduly burdening the applicant to make an entry (e.g., a date) about which the applicant may not have knowledge. Such systems should enable applicants, who are diligently trying, to meet their duty of candor to the Office.

Similarly, mechanisms that prepopulate continuing applications with prior art submitted and/or considered in parent applications promote efficiency. Applicants submitting continuing applications could simply reference parents and focus on citing new information of which they become aware.

Internally, the Office could assign a unique id code to each NPL. This might make it easier to cross-reference those coded references in subsequent applications instead of having to re-submit and re-store the same information.

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?

AIPLA Response

The written description requirement is an important tool to ensure that an applicant is not claiming more than the applicant is otherwise permitted to claim based on the supporting written description. AIPLA fully supports examination of every application for compliance with the written description requirement of 35 U.S.C. § 112(a) (or pre-AIA 35 U.S.C. § 112, first paragraph, if applicable), at all stages of the application process. We recommend giving examiners more time, training, and tools to assess an application for compliance with Section 112(a) and to determine effective filing dates. We include additional suggestions in our response to Question 5.

We are concerned, however, about mandating express identification of Section 112(a) support for claims, as proposed in the subpart questions. Because these concerns are common to all the subparts to this question, we address them first. Additional comments are included in our answers to each of the subparts.

One concern is undue burden. Mandating support for each and every claim limitation would impose a substantial burden on applicants. Much, if not all of this effort, will likely have been wasted in many cases.

Another concern is that MPEP § 2163 evidences that determining whether there is Section 112(a) support for a claim is not a trivial exercise. The entire specification must be considered as-a-whole and support can be inherent. *Ipsis verbis* support is not required.

A further concern is that in many instances, this identification would be made in a vacuum. Until an examiner interprets the claims, identifying written description support in the original disclosure may be unhelpful or irrelevant. Until or unless a patentability issue is raised, the as-filed application is presumed to be patentable. Once an issue is raised, applicant's response can be crafted to address the question.

Yet another concern is that any requirement that an applicant affirmatively identify support is inconsistent with the Office's burden of proof. The Office must first establish that the written description is insufficient. See MPEP § 2163.04. Affirmatively requiring identification by the applicant effectively shifts this burden to applicant. It could also allow an examiner to reject the application based solely on an applicant's identification, rather than an examiner's independent judgment, as required by statute. *Id.* at § 2163.

Even the most carefully considered statements by applicant can have unintended consequences. Making statements without the context of a claim construction or a rejection makes these consequences even more unpredictable.

AIPLA also fears that a requirement that an applicant affirmatively identify support could incentivize examiners not to explore these issues carefully.

We therefore urge the Office to consider other approaches to improve examination for written description support than requiring applicant to identify support for each limitation.

2. Specifically, should the USPTO:

2.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)?

AIPLA Response

As noted above, AIPLA opposes an affirmative requirement to identify written description support in the absence of a showing that the as-filed claim is insufficient. This includes both positive and negative claim limitations.

Section 132 of Title 35 expressly forbids the introduction of new matter into an application by amendment. AIPLA agrees that Section 112(a) is a proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure) (pre-AIA § 112, first paragraph). See *In re Rasmussen*, 650 F.2d 1212, 1214-15 (CCPA 1981).

Many AIPLA members report that they proactively identify support for amended claims in a response. This may reduce the chance of receiving a rejection based on the lack of written support. The decision of whether to cite to passages of a specification or figures in the first instance should, however, be left to the applicant(s).

2.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?

AIPLA Response

AIPLA urges the Office not to impose any requirement that support be identified upon presentation of a claim for the reasons mentioned above and because of the substantial and undue burden on applicants that the requirement would impose.

2.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)?

AIPLA Response

AIPLA urges the Office not to adopt such a requirement for the reasons noted above.

2.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 and antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description?"

AIPLA Response

AIPLA is concerned that amending the rule as proposed and requiring that applicants amend the specification or the claims raises the issues of whether the Office is imposing additional, substantive requirements not required by Section 112(a) and 112(b) or authorized by the statute. We are also concerned that the amended rule could lead to unnecessary and unproductive issues during examination.

As we mention above, and as explained in MPEP § 2163, Section 112(a) does not require that there be a written description containing "clear support and antecedent basis" for "terms and phrases used in the claims" or that "the meaning of the terms in the claims be ascertainable by reference to the description." Similarly, we are not aware of any case law that suggests that a claim must have "clear support and antecedent basis" in the written description to be definite under Section 112(b), even when applying the broad reasonable interpretation standard.

Therefore, we urge the Office to refrain from making this amendment to 37 C.F.R. § 1.75(d)(1). We suggest that the Office focus on other improvements to examination practices that balance

the interests of the public and applicant to ensure that claims inform the public of what constitutes infringement.[2]

2.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?

AIPLA Response

As noted above, AIPLA opposes an affirmative requirement to identify written description support for all claims absent a rejection.

The proposed further requirement might discourage applicants from presenting Markush claims. Markush claims provide important benefits. They allow for patenting of similar structures in a single claim. They also allow patenting of species that are not patentably distinct in a single claim in a single application. Thus, Markush claims directly address the issues raised by the Senators and the Office of too many claims and patents.

A Markush claim is not allowable if the list of alternatives is not a closed grouping or if the Markush group is so expansive that persons skilled in the art cannot determine the meets and bounds of the claimed invention. These determinations are made by the patent examiner. Having an applicant provide a detailed analysis in advance could encourage an examiner to forego an independent detailed analysis. Reliance on an applicant's analysis might, therefore, lead to a less robust examination.

2.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)?

AIPLA Response

AIPLA recommends that such a requirement not be instituted for the reasons noted above. Furthermore, as noted below in our answer to Question 5, automated tools exist or could be developed and deployed by the Office to automatically run comparisons between applications revealing differences between them. Such tools are used in practice to evaluate patent portfolios.

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[2] *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120 (2014) v. ("Section 112, we have said, entails a 'delicate balance.' … On the one hand, the definiteness requirement must take into account the inherent limitations of language. Some modicums of uncertainty, the Court has recognized, is the 'price of ensuring the appropriate incentives for innovation.'") (internal citations removed), q*uoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 731-732, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002)).

Comparisons are much more likely to aid in understanding what was added or removed than any explanation an applicant could provide.

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?

AIPLA Comments

AIPLA recognizes that RCEs are a common and frequently necessary practice. Many of the issues that exist today existed before RCE practice was introduced and appear to stem from the introduction of "compact prosecution" practice.

In current "compact" prosecution practice, RCE's may provide necessary time to work through and mutually understand complex facts and points of law. They often enable examiners and applicants to reach agreements on allowable subject matter.

Yet, at some point RCE's may evidence a failure of communication between an examiner and an applicant, or a breakdown of their relationship. Thus, compact prosecution, after-final practice, and RCE's collectively remain a challenge and frustration for applicants and examiners.

AIPLA is interested in ideas around RCE practice that could refresh or resolve breakdowns between the examiner and the applicant. AIPLA opposes limiting RCE's or restricting applicants' ability to work with examiners to identify and allow allowable subject matters. AIPLA also recognizes that, at some threshold, multiple consecutive RCE's may reflect a breakdown in this process.

AIPLA believes "transferring the application to a new examiner" and "increasing the scrutiny given the application" (second pair of eyes) are two distinct proposals each of which could provide certain possible benefits and different considerations on implementation. This response is interpreting "a new examiner" as providing for a *de novo* review where the new examiner may review the prior work but is not bound by the analysis of the prior examiner on any issue, while the increased scrutiny provides oversight on specific issues in an ongoing prosecution without a full reset.

Transferring the application to a new examiner (de novo review)

AIPLA proposes giving an applicant the option to request that the application be transferred to a new examiner; perhaps after a threshold number of RCEs is reached. This proposal is particularly interesting and worthy of further analysis. AIPLA is not proposing assigning a new

examiner against the wishes of an applicant. In fact, AIPLA would strongly advocate against such an assignment occurring on an automatic basis.

Where progress towards agreement between the examiner and applicant has stagnated, a fresh start on examination by a completely different pair of eyes can be worthwhile. In some circumstances, however, the second or third RCE does not reflect stagnation but, rather, a slow start in a mutual understanding of the invention or difficulty in communication. This is particularly true with complex subject matter. In circumstances where, after multiple RCEs have been filed, progress can be made; transfer to a new examiner would not be efficient.

In other cases, however, even following a first RCE, there may be a disconnect between the examiner and applicant. Prosecution may reach an impasse where the lack of productive communication results in a poorly developed file record that is not ready for appeal. In these circumstances, a *de novo* fresh start could be highly desirable.

Given the variation in technology, issues, and examiner/applicant relationships, AIPLA is concerned that a bright-line, automatic rule, transferring an application after a specific number of RCEs are filed, would be less helpful and potentially detrimental. AIPLA suggests that an applicant be given the option to request a new examiner, with payment of an RCE fee after a defined threshold rather than a mandatory change. The fee could be set at a level to recover some portion of the stranded cost of the first examiner's efforts and duplication of effort by the second examiner.

If the application is transferred to a new examiner, the new examiner should have substantial experience and a different supervising primary examiner. The new examiner should be able to quickly come up to speed and not be prejudiced by the prior examination.

The Office should ensure that the new examiner receives sufficient credit, either in examination time or in production counts, so that they are motivated to put in appropriate effort to ensure quality examination.

If the Office believes that it should also have an option to initiate an examiner refresh, AIPLA would urge, at a minimum, that there should be a role for a second pair of eyes, as discussed below, in helping assess whether progress is being made or a refresh/*de novo* review is needed.

If issues can be resolved at the corps level, even if it takes multiple examiners, the Office would still benefit because PTAB and appeal resources could be more efficiently used.

Increasing the scrutiny given an application (a second pair of eyes)

If additional Office oversight is needed, an alternative would be to bring in a second pair of eyes after a defined threshold of RCE/continuation filings. Once this *cursory* review is done, the examiner and the applicant should be consulted via interview. If the applicant and examiner both

agree that progress is being made, then the second pair of eyes should allow prosecution to continue between the original examiner and applicant. This second pair of eyes would focus on reviewing the state of the prosecution and help work through outstanding legal communication issues.

There are current options available to efficiently provide this type of feedback. The supervising primary examiner or quality assurance specialist may help facilitate prosecution.

Unlike the first option, this second-pair-of-eyes option should be limited to the specific areas of disagreement, rather than a *de novo* review of the prosecution.

AIPLA recommends that an interview be conducted between the second-pair-of-eyes examiner, the original examiner, and the applicant. This would improve the process relative to the current pre-appeal process.

A potential modification to RCE practice as a whole

With respect to RCE practice as a whole, AIPLA would like to raise for consideration a new form of RCE as a part of after final practice. This would effectively be a limited RCE (with a reduced fee) that would only permit a single action. This "single-action RCE" would enhance or replace the current After Final Consideration Pilot ("AFCP") program. This could take the form of an optional third action for a fee or, more accurately, a full reconsideration of a final rejection.

This proposed single-action RCE after a final office action should provide for amendment as a matter of right and give the examiner sufficient time to search and enter a final advisory action (or allowance). No further argument as of right following the final advisory action should be allowed. Prosecution would then be closed. This could alleviate the pressures caused by compact prosecution. AIPLA believes this could reduce costs for the Office and applicants and allow for a more efficient path to allowance or appeal.

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:

4.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?

AIPLA Response

Provided examiners are given additional examination time, AIPLA supports the examination of multiple inventions in a single patent application. Under the transitional practice established in the mid-1990s, applicants were entitled to request examination of additional inventions. The purpose of this Rule 129 practice was to avoid having to file a new divisional application and, therefore, lose the 17-year-from-issue patent term prior to the Uruguay round of TRIPS.

While this process may require additional examination time, AIPLA believes this practice could be adapted into current practice. Distinct and related inventions could be pursued in a single application, once identified by the Examiner.

AIPLA believes adding patentably distinct, but related, inventions would not require the same amount of time for an examiner as the first invention. At this stage, the examiner would be familiar with the general field of prior art and be able to work efficiently and quickly. Adding patentably distinct but related inventions back into an examination could likely be done for less than a full filing fee and take less examination time than if presented in a new application.

Under this proposal, the Office may lose maintenance fee revenue, which currently supports the front-end examination process. If, under current practice three related inventions are issued in separate patents, the Office receives three sets of maintenance fees. If this were reduced to only one maintenance fee because all three inventions were in a single patent, Office revenue would be reduced.

AIPLA recommends that during consideration of the possible change, the Office analyzes its revenue impact to ensure that there are no negative impacts on filing/examination fees, which disproportionately impact small and medium entities (SMEs).

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

AIPLA Response

Title 35, section 121, as implemented by 37 C.F.R. § 1.141, provides authority to restrict patent applications to a single invention. If two or more independent and distinct inventions are claimed in a single application, the Director may limit examination to one such invention. Restriction is optional, not mandatory.

Under current rules, examiners must establish an undue examination burden to restrict examination. The frequency of first action allowances in divisional patent applications suggests that the burden for searching and examining the restricted subject matter is not substantial. For this reason, AIPLA proposes that the standards for when restriction could or should occur be tightened.

A stricter burden requirement would reduce the number of divisional applications. Greater clarity as to what is, or is not, a sufficient burden would assist applicants in responding to a restriction requirement and reduce the number of continuation applications.

If it requires an examiner to review substantially more literature, a stricter burden requirement might negatively impact examination quality. AIPLA has not resolved how the burden requirement could be or should be changed. The Office should consider changing the standard for determining whether claims are patentably distinct. This would likely result in fewer restrictions without imposing substantially higher burdens on examiners.

Currently, restriction requirements are difficult to overcome. Restriction delays the patent process and potentially forces applicant into a larger number of patents.

In making it easier to establish restrictions, the Office has interpreted the "and" from the statute as "or." See, MPEP § 803 (multiple independent or distinct inventions are presented restriction may be made). (Emphasis supplied). AIPLA requests the Office reconsider the plain language of the statute and limit any restriction to independent *and* distinct inventions presented in a single application. Maintaining the current "and"-means-"or" standard unduly separates inventions that can often be examined together with little to no additional effort. This is established by the number of first action allowances in divisional patent applications.

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

AIPLA Response

AIPLA supports adjusting and revising the method by which an examiner establishes his or her burden for imposing a restriction requirement.

Under current practice, there is little an applicant can do to avoid or change a restriction requirement. An applicant's only recourse after a restriction is made final is to file an administrative petition within the Office. During this parallel review, prosecution continues; by the time a decision on a petition is reached, it may no longer be relevant.

AIPLA is concerned that the current methods of establishing burden allows for restriction between inventions that could and should be examined in the same application. Currently, classification in different classes is sufficient to establish sufficient burden and justify restriction. Classification, however, is fluid and virtually any two claims, no matter how closely related, can be placed in separate classes.

Classification for establishing search burden is an artifact of pre-computer searching. Examiners used to physically go to different locations to sort through physical patent documents. Now, database searches of both patent and non-patent literature can be done concurrently.

On the other hand, if too many patentably distinct inventions are present, such as when there are claims to numerous embodiments, an examiner could be overwhelmed by the amount of literature to review, which is continually expanding.

Objective criteria should be established to strike a better balance and achieve consistent application of the standard. For example, a serious search burden can currently be established by: (1) separate classifications; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. Establishing more detailed criteria at the group art unit level for what is required to establish a serious search burden in each of the categories may result in more predictable and appropriate application of the standard. It may also be useful for supervisory staff to review restriction requirements.

4.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?

AIPLA Response

AIPLA supports greater involvement and cooperation between applicants and examiners. The applicant may be in the best position to help guide the search.

AIPLA is concerned, however, that if an applicant is perceived to have influenced the Office's search strategy, it may create unnecessary or inappropriate file wrapper estoppel issues. While applicant has a duty of candor, it is the examiner's responsibility to search. Further, applicants' involvement in formulating the search strategy may expose applicants to claims of inequitable conduct (perceived or real).

Provided applicants' assistance in developing search strategies is optional, applicants might be more inclined to assist the examiner.

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

AIPLA Response

AIPLA has long supported a unity of invention standard. A unity of invention standard could provide a more objective basis for determining which claims should be examined in the same application. Examiner burden would no longer be the prime consideration. This would also avoid the complexities of determining whether patentably distinct inventions are being claimed. The Office is already applying a unity of invention standard in U.S. national stage filings from PCT applications. Greater consistency across art units would be beneficial.

4.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?

AIPLA Response

AIPLA is unclear what the Office is proposing. As understood, this proposal raises several concerns.

Under current law, all applications claiming the same priority date will normally[3] expire 20 years from their earliest effective filing date. Serial filing of divisional applications will not extend the period of exclusivity for inventions maturing from the same first filing. Delays in filing divisional applications have no effect on patent term extension.

As the examiner determines whether to restrict examination, the Office already has some control over the number of divisional applications that can be filed.

If applicants are required to file divisional applications in a shortened time period, it will accelerate and possibly increase the financial burden on applicants. If the number of restricted inventions is high, the burden on the applicant could also be high.

A surge of applications before the deadline would likely put a substantial burden on the Office and create examination delays that would result in patent term extensions.

Forcing the filing of divisional applications by a deadline could result in additional applications being filed that an applicant might have chosen not to file. This would waste both applicant and Office resources. Filing divisional applications sequentially allows the applicant to balance prosecution costs against financial and business development realities.

Shortening the period within which to file divisional applications would also likely have a more substantial effect on micro, small, and medium entities, whose resources are more limited.

Setting a time limit for filing divisional applications could also encourage applicants to limit the number of inventions disclosed in an application. This could delay filing applications on some inventions or incentivize keeping inventions secret.

The current system encourages applicants to file early. Early filing benefits not only the applicant under a first-inventor-to-file system, but also the public because information about the invention will become public sooner. Using a single application to make a broad disclosure containing multiple inventions saves money, encouraging earlier disclosure. These disclosures, while making more information available to the public earlier, also start the statutory patent term clock for the disclosed inventions.

AIPLA requests that the Office share any data showing that serial filing of divisional applications places undue demands or burdens on examination resources, as well as information on how many divisional applications *might* be filed based upon restriction requirements versus the number that are *actually* filed. In other words, how many restricted embodiments that were withdrawn from consideration were *not* filed as divisional applications.

[3] The notable exception is that patents issuing on such related applications not subject to terminal disclaimer may have independent term adjustment.

To the extent that these concerns are based upon restriction practice, the examiner controls restriction. If the Office limits restrictions, more inventions would be examined without the need for divisional applications.

AIPLA is concerned how the Office would manage the proposed practice. In the near term, bulk filing will likely cause a spike in filings akin to those seen in 1995 and 2011, when GATT and the AIA were implemented, respectively. These spikes in pendency took years to resolve.

In the longer term, AIPLA is concerned about the number of inventions that will be kept secret because of a time limit on filing divisional applications. If inventors choose trade secret protection rather than patents, will there be fewer inventions? Will this inhibit implementation of patentably distinct inventions because applicants will be unable to obtain IP for many of their innovations based on resource limitations?

4.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?

AIPLA Response

AIPLA would support more flexibility in administration of rejoinder practice. Currently, it is necessary to concurrently amend both product and method claims, while patentability is being established. Examiners are often reluctant to provide latitude for rejoinder because it involves additional administrative work and raises potential questions under 35 U.S.C. § 112(a) and (b).

AIPLA proposes that, once allowable claims are identified, applicant be given time to identify "rejoinable" claims and, the opportunity to interview and discuss any issues with the examiner.

4.h. limit or change non-statutory double patenting practice, including —

(i) 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;

AIPLA Response

From an applicant's perspective, terminal disclaimers are an economically efficient response to address an obviousness-type double patenting rejection. Modifying the standard to require an applicant to stipulate that there is no patentable distinction would in many instances force longer prosecution with more costs spent by the applicant and the Office debating the relative merits of claims that all parties have agreed are patentable over the existing prior art.

Further, requiring such a statement when claims have been restricted is contrary to 35 U.S.C. § 121 that provides: "A patent issuing on an application with respect to which a requirement for

restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application."

In an original application there is no statutory requirement to stipulate that all the independent and corresponding dependent claims are not patentably distinct from one another. The question proposes such stipulations should be required in continuing or divisional applications or to later applications that the Office has identified as related by requiring a terminal disclaimer.

AIPLA opposes applying in subsequent applications standards different from the standards applied in original applications. AIPLA believes such a change would increase costs and burdens on applicants. It would also impose a different examination standard, with a higher burden for continuing applications, not contemplated by the statutes.

(ii) rejecting such claims as not differing substantially from each other or as unduly multiplied under 37 CFR 1.75; and/or

AIPLA Response

The undue multiplicity provision of 37 C.F.R. § 1.75(b) applies only to claims presented in the same application. When claims are presented in separate applications and there are no substantial differences between them, double patenting rejections under 35 U.S.C. § 101 can be made. Therefore, AIPLA opposes rejecting claims in separate applications as being unduly multiplicative.

Further, an applicant is entitled to claim their invention as they desire so long as it meets the patentability requirements. In rare instances where it is objectively evident that the same invention is being claimed many times in a single application, an undue multiplicity rejection may be warranted, but great caution should be exercised to avoid limiting the applicant's right to claim what they consider as their invention(s).

(iii) 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).

AIPLA Response

Where claims in a first application are not patentably distinct from claims pending in a second application, 37 C.F.R. § 1.78(f) allows the Office to require that an applicant move the claims to the other application. This allows the Office to coordinate examination more efficiently, without

adversely affecting the applicant's rights.

AIPLA does not interpret this rule to permit the Office to require an applicant to cancel claims from an application if they cannot be presented in another, pending application of the same applicant, or owned by the same assignee.

AIPLA would oppose a rule that would force applicants to cancel claims to inventions that are not distinct from inventions already claimed in a patent granted on an earlier filed application.

As a result of current compact prosecution practice and current restriction practice, applicants are frequently faced with a choice of accepting allowable subject matter or paying an RCE fee. This fee can be as much or more than the cost of a continuing application or issuing the allowable claims into a first patent and continuing prosecution of, or ultimately appealing, the rejected claims.

Similarly, applicants are frequently faced with restriction requirements to prosecute their applications separately.

Finally, innovation in its healthiest form is not a static endeavor. As an idea moves to market and continues to develop, there are continuous improvements and modifications to the product. Currently, continuation-in-part applications or new applications may be filed disclosing new insights and distinctions.

For all the above reasons, the ability to file additional applications provides economic efficiency and provides fair opportunity and incentive for inventors to develop and disclose new innovations. Double patenting doctrines (statutory and court-created) protect the public from any undeserved extension of patent term.

Additionally, AIPLA is concerned that these proposals force an applicant to assess and determine distinctiveness of a claimed invention without knowledge of the art or how a claim might be interpreted. An applicant cannot know about "secret" prior art that might become available during the examination of a later application. Forcing an early determination also deprives an applicant of the benefits of insight gleaned from further work on their invention. This insight can be important to a cost-effective protection strategy for independent inventors, start-ups, and SMEs.

Finally, depending on what the Office is proposing, the Office's authority to make these changes must be established. One issue is whether requiring a "good and sufficient" showing to retain claims in a continuation application deprives an applicant of its statutory right to a patent.

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.

AIPLA Response

Additional input relating to Questions 2(a)-2(i)

AIPLA believes that tools exist or could be developed that could identify new matter and written description support issues. Access and training on these systems would advance the Office's goal of robust and reliable patents.

Systems that automatically identify differences between a new application and earlier-filed applications would assist an examiner in identifying new matter. Systems could also identify in earlier-filed applications the passages that correspond to claim limitations based on literal or conceptual comparisons.

Additional input relating to Question 3 on RCEs

AIPLA proposes that the Office review the current compact prosecution practice. Circumstances have changed since compact prosecution was implemented. Applications have generally become longer and more comprehensive. Technology has become more complex and challenging. Applicable legal standards have become more complicated.

The current compact prosecution model might be inefficient and contribute to more RCEs being needed. It may also give inadequate consideration to claim interpretation, support, written description, clarity or definiteness of claims, and hinder development of a clear examination record.

AIPLA proposes that the compact prosecution model be expanded to allow the Office to issue an initial Office Action focused on claim interpretation and scope alone. This could improve search efficiency and prior art-based rejections.

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?

AIPLA Response

All patents on obvious variants owned by the same patentee should expire at the same time, the end of the statutorily authorized term (subject to any extensions permitted by statute).

Permitting an applicant to claim non-obvious variants in a continuing or later-filed application

contributes to better examination. Continuation applications are sometimes necessitated by the tight constraints of compact prosecution. When an applicant and examiner cannot agree on the patentability of all the claims presented, applicant can choose to cancel rejected claims and present them in a continuing application. This reduces the need to go through an RCE or appeal. The availability of continuation applications to prosecute claims that were not restricted improves examination quality. Claims of narrower or immediate scope are less likely to receive scrutiny if considered together with broad genus claims. By allowing them to be examined in separate applications, even if they are obvious variants, they are likely to receive more attention than they would have otherwise received.

More importantly, eliminating terminal disclaimer practice while maintaining obviousness-type double patenting doctrines would force substantial changes in examination practice. It would disrupt settled expectations, cause greater uncertainty, and increase burdens and costs on applicants and the Office. Instead of improving quality, it would likely have the opposite effect.

Were terminal disclaimers to be eliminated, AIPLA submits applicants might be motivated to present more claims in the first application filing to mitigate the risk of loss of rights. Presenting every conceivable claim at the outset will be necessary to receive the benefit of the safe harbor under Section 121, and thus mitigate the risk of obviousness-type double patenting. It will also be necessary to reduce the risk of loss of rights to disclosed subject matter that might be considered an obvious variant.

As a result, applicants will be encouraged to spend more time and money up front to prepare and file more claims. Resources will be wasted on presenting claims that are restricted and presenting and examining claims that, in retrospect with time, an applicant might have chosen never to present.

Examiners might have to consider more claims at the outset and make extensive restrictions, thereby restricting more than necessary simply to reduce the number of claims to be considered. Although applicants might accept these restrictions, many restrictions are more likely to be challenged. In continuation applications, applicants will be forced to fight obviousness-type double patenting rejections. More RCEs, appeals, reissues, or *ex parte* reexaminations would be expected.

Drafting and examining more claims usually means less attention is given to each claim. Time and money -- that could have been better spent on writing a higher quality specification and claims -- will, instead, be diverted to writing more claims, paying higher filing fees, responding to obviousness-type double patenting rejections, and filing more RCEs and appeals.

Eliminating terminal disclaimers will likely impact individuals, start-ups, and SMEs the hardest. These groups likely have fewer resources to protect their interests and mitigate loss of rights.

Finally, AIPLA anticipates challenges to obviousness-type double patenting doctrines as contrary to AIA Sections 102 and 103. Such challenges would lead to years of uncertainty for all and actions by applicants to preserve options that will likely increase costs, delay issuance, and further burden the Office.

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?

AIPLA Response

AIPLA opposes requiring applicants to admit obviousness as a condition to submitting a terminal disclaimer.

When reviewing multiple patents (or even claims within a patent), each claim must be separately assessed. Double patenting is judged on a claim-by-claim basis. Thus, if an examiner finds that just one out of twenty claims in a second application is not patentably distinct over just one claim in another application or patent, a non-statutory double patenting rejection is appropriate, and a terminal disclaimer may be used.

Any requirement to do a claim-by-claim analysis would involve a substantial undue burden.

Applicants may accept terminal disclaimers for various reasons other than the lack of patentable distinction.

AIPLA understands the concern apparently prompting this proposal is that separate validity challenges to multiple patents significantly increase the cost to challenge compared to the cost to challenge a single patent (even with the same number of claims). This may be true where significant fees are assessed for each patent being challenged and the challenges are heard in separate proceedings.

If the critical issue is the cost of post grant reviews, fees could be established so that patents under a terminal disclaimer could be reviewed in a single post grant proceeding based on the number of claims rather than the number of patents. Assuming the patentability of each claim is considered independently, this could provide a viable approach to this issue.

Finally, obviousness-type double patenting involves issues of art and claim interpretation fundamentally different from those involved in invalidity analysis. A proper obviousness-type double patenting rejection may be made where the prior art renders one of the two claims invalid but not the other.

For example, an element may meet a structural limitation but not suggest the function associated with that structure. It may involve two materials viewed as interchangeable for one purpose but not another. For these reasons, it is unreasonable to propose that patents subjected to an obviousness-type double patenting rejection should naturally stand or fall together based on the obviousness of one of the claims.

AIPLA opposes using a decision of invalidity of the claims in a first patent to invalidate *as a matter of law* all the claims of a second patent (even ones linked by terminal disclaimer to the invalidated claims) without individually reviewing each of the claims of the second patent.

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?

AIPLA Response

To the extent that examination quality is limited by failure to adequately examine for compliance with 35 U.S.C. § 112(a) and (b), AIPLA believes other options could provide more efficient use of resources. These include the options discussed above or providing more training on § 112(a) and (b) compliance with specific guidance on what should be reviewed and how it should be reviewed during examination.

If the Office's quality review program has found that first action allowances (whether in new or continuing applications) lack a full, high-quality examination, a second look might be appropriate. AIPLA encourages that this be done across all applications, not just in any specific art or technology sector.

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

AIPLA Response

Many of the above comments in response to Questions 2, 3, 4, and 6 apply here as well.

Fundamentally, a continuation application should be examined in the same manner as any other application. "Heightened examination requirements" of continuations implies that less attention be paid to examining the parent application.

AIPLA has concerns as to what is meant by a "minor" modification of an invention. If a modification is patentably distinct or was restricted and meets the statutory requirements, it is entitled to receive a patent, regardless of whether it is characterized as "minor." If the "minor"

modification is not patentably distinct, an obviousness-type double patenting rejection and terminal disclaimer would be appropriate. Applicant is, nonetheless, entitled to receive a patent. AIPLA is aware of no statutory basis for refusing to grant a patent on the basis that it is characterized as "minor." Rather, all patent applications should be treated equally regardless of technology or continuation status.

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.

10.a. Can the USPTO implement a rule change that requires any continuation application to be filed within a set timeframe of the ultimate parent application?

AIPLA Response

The simple answer is no, the Office does not have statutory authority. AIPLA respectfully suggests that the foundational assumption of this question is mistaken. The quoted portion of 35 U.S.C. § 120 (the second sentence) reads:

> No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director.

If the statute had been intended to mean during the pendency of "the *original* application" it would have referred to it as the "earlier filed application" as it does elsewhere in the sentence. It is instead addressing a time frame during the pendency of the application that seeks to benefit from the filing date of the earlier filed application.

Section 120 of Title 35 authorizes filing of continuation applications "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 and if it contains or is amended to contain a specific reference to the earlier filed application." Section 120 does not provide the Director statutory authority to prescribe time limits for filing continuation applications. A regulation or action of the Director that would limit filing of a continuation application based on something other than the co-pendency and amendment requirements provided in Section 120, would be inconsistent with Section 120.

10.b. 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?

AIPLA Response

AIPLA is unclear what is being asked or what is meant by "types of inventions the patent will actually cover."

If the question is asking when, during examination, an applicant should know what a patent granted on the application would cover, applicant might have some idea what the patent might cover after the first action. But it will not know with confidence until a notice of allowance issues. And it will not know with any reasonable certainty until the patent is issued and has been fully litigated.

When an applicant *files* a patent application, the claims are presumed patentable.

When the Office reviews that application, patentability questions may arise, most often under one or more of 35 U.S.C. §§ 101 (subject matter/utility), 102 (novelty), 103 (obviousness), and 112 (written description, enablement, best mode, and clarity). In response, applicants may amend the claims, which often means changing subject matter for which a patent is sought.

The *timing* of when an applicant *should know* what their patent will cover is uncertain. Action by the Office affects *when* the applicant *will know* whether the presented claims are patentable.

10.c. 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)?

AIPLA Response

While a "benchmark" is better than a "deadline," neither is appropriate for the reasons explained above. No time frame can be identified or determined that would cover all applications, much less all technologies. Nor would it be prudent to attempt to set such a benchmark for the reasons provided in answers to previous questions. AIPLA submits that any deadline or other action taken that would bar presenting continuing applications could have many negative consequences. Any legislative initiatives to impose a benchmark or deadline would be, in our view, misguided and detrimental to the patent system and innovation as a whole.

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.

11.a. 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?

AIPLA Response

The Office's current revenue model back-end loads fee collection. The up-front costs of patent examination are supplemented by post-grant fees including maintenance fees. Thus, patent filing and examination costs are minimized, fostering access to patents, especially for those with limited funds.

The Senate letter asks about the impact of altering this funding model so that up-front fees more closely match their actual costs. AIPLA believes that this will impede access for fund-limited applicants, particularly micro and SME innovators.

Redistribution of fees might change patenting activity based on an applicants' access to financial resources. Making patent application filing and examination more expensive would divert funds and resources from drafting quality patent disclosures. One benefit of the current model of increased maintenance fees during the later stages of the patent life is that it encourages disclosing technology to the public more quickly–a key element of the patent *quid pro quo*.

The current funding model helps maximize inventors' access to the IP system, while financially successful patentees off-set entry costs. Greater expenses early in the patent application process will most affect those with limited resources, such as SMEs – the very same group that is typically considered to drive US innovation.

11.b. 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?

AIPLA Response

Here, again, AIPLA has all the concerns laid out in other responses.

The question presumes that applicants intentionally file multiple patent applications on obvious variations. While applicants are permitted to do so, the Office can control overlapping filings by applying appropriate measures including enforcing double patenting proscriptions.

The proposal in this question directly counters the fee-for-service model. A continuing

application on a "minor variation" would have lower examination cost than the original or one on a major variation.

Increasing fees would affect all patent applicants, including the majority of which either do not file continuations or file only a small number. This takes away from application preparation throughout the system, which would likely decrease the quality of applications and, in turn, patent quality.

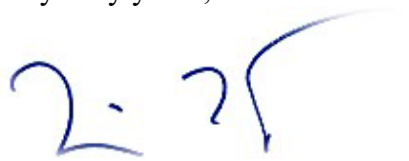
Concluding Remarks

AIPLA lauds the Office's community engagement in considering changes in the patent examination process. Patent quality and the patent examination processes can always be improved.

While some of the possible initiatives could have some positive effects, AIPLA worries that many of the possible initiatives would lower patent quality and unduly burden applicants without any assurances of achieving any of the desired effects. Office resources might be better spent developing clearer and more precise expectations for the patent examination process.

AIPLA gratefully acknowledges the efforts by the Office to improve and revisit the patent examination process. We thank you for the opportunity to provide such comments and are happy to discuss further.

Very truly yours,



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