January 31, 2023

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

Re: LES Response to RFC on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights;
USPTO Docket No. PTO-P-2022-0025

Dear Director Vidal:

On behalf of the Licensing Executives Society (USA & Canada), Inc. ("LES"), we respond to your request for comment on USPTO initiatives to ensure the robustness and reliability of patent rights (RFC). LES commends your efforts to ensure robustness and reliability in U.S. patent protection, and we appreciate the opportunity to comment on preserving the rights of inventors in their contributions to the useful arts. Such protections are critical to innovation, the health of our economy, and our national security.

LES represents the entire innovation ecosystem. It is an independent, non-profit, non-partisan, professional association devoted to the global commercialization of intellectual property through education, networking, standards development, and certification. It is the leading professional organization devoted to the industry of licensing -- that is, technology-related commercial transactions involving patents, trade secrets, know-how, trademarks, and copyrights. Our members come from all quarters of the economy, and represent diverse industries from life sciences and healthcare to high technology and communications. Our members are business executives, lawyers, technology transfer professionals, IP valuation experts, entrepreneurs, and inventors.

I. Executive Summary

The RFC initiatives are couched in terms of a specific industry sector, healthcare and pharmaceuticals; however, the initiatives would affect the entire innovation ecosystem, regardless of industry. Such wide-ranging changes to the U.S. patent system must be considered carefully, and undertaken, if at all, cautiously and incrementally. The initiatives would have a wide-ranging effect on innovation in America, and so the case for making such changes must be clear, compelling, fact-based, and focused.

No legal regime is perfect, including the U.S. patent system. LES applauds the USPTO's dedication to the principles of continual improvement and quality management. In particular, we support the USPTO's proposals for improved quality of services through examiner training and access to the best possible search tools and other resources. We fully support calls to ensure the USPTO's access to the entirety of its fee revenue to fund those and other worthy initiatives.[1]

We commend the USPTO on its longstanding practice of transparency and public engagement in pursuit of those principles. We urge you to continue those practices by soliciting public input as to areas of greatest concern for improvement. We submit that would produce input urging a focus on, among other things: the administration of the Patent Trial and Appeal Board (PTAB) to ensure the due process protections of patent holders, and consistency relative to the work of Article III courts; as well as collaboration with Congress to clarify patent eligible subject matter, and the right to injunctive relief; international outreach to promote respect for IP rights globally; and initiatives to enhance diverse representation among inventors and patentees.

Regrettably, however, the RFC does not follow that practice. It does not provide facts or findings sufficient to support or justify the various initiatives; and it does not appear to be responsive to any consensus of deficiencies or areas in need of improvement. Indeed, it seems to be responsive only to unsupported assertions made by six Senators in a June 8, 2022 letter to the USPTO. For this reason, LES is of the view that these initiatives are not justified, and should not be implemented at this time, or on this record.

It may be that public input offers evidence of a need for initiatives described in the RFC; and, if so, that evidence should be acted upon with proposals carefully tailored to correspond to the consensus for needed improvement. Then, and only then, will the user community be in a position to comment meaningfully on any such proposed changes to our system for protecting and encouraging American innovation.

II. The U.S. Patent System Is Fulfilling the Constitutional Mandate to Promote the Progress of the Useful Arts

The U.S. Constitution directs Congress to promote the progress of the useful arts by securing for limited times to inventors the exclusive right to their discoveries.[2] Since the first Patent Act of 1790, Congress has consistently done so, culminating in today's Title 35 U.S.C. Over time, the four pillars of patentability have evolved: utility, novelty, non-obviousness, and written description. Through carefully wrought legislation, and painstaking jurisprudence, American inventors

[1] B. O'Shaughnessy, "Diversion of USPTO fees is a tax on innovation," May 17, 2016, at https://ipwatchdog.com/2016/05/17/diversion-uspto-user-fees-tax-innovation/id=69070/

[2] U.S. Constitution, Art. I, Sect. 8, cl. 8.

now have a sophisticated and robust understanding as to what constitutes a patentable invention, and what it takes to secure their limited, exclusive right.

While no system is perfect, ours is a system built on sound democratic principles, with all the corresponding attributes of transparency, continuity, and public confidence. The principles by which patentability is assessed in the U.S., both administratively and judicially, is generally reliable and predictable. Throughout its development, the U.S. patent system has been at the forefront of regimes protecting property rights founded on equitable principles that serve both the private rights of individuals and the public good.[3]

We should not blithely change that system for perceived, but unsupported, shortcomings or abuses.

Throughout its history, the U.S. patent system has proven to be the gold standard for fostering innovation, and as the birthplace of groundbreaking new markets and industries that benefit all of us, everywhere.[4] Generally, throughout our history as a nation, others have looked to our system of patent protection to stimulate innovation and the growth of their own economies, and rarely has it gone the other way.

This is supported by the enviable rankings that the U.S. continually achieves in the strength and reliability of its IP protection regime, particularly as to patents.[5] Notwithstanding, the U.S. patent system has had its challenges, creating uncertainties in, *e.g.*, patent eligible subject matter[6] and the right to injunctive

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[3] Madison, J., Federalist No. 43 ("The Fourth class comprises the following miscellaneous powers: 1. A power 'to promote the progress of science and useful arts, by securing, for a limited time, to authors and inventors, the exclusive right to their respective writings and discoveries.' The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors.").

[4] *See, e.g*., Adam Mossoff, "The Constitutional Protection of Intellectual Property," The Heritage Foundation, (March 8, 2021) at https://www.heritage.org/economic-and-property-rights/report/the-constitutional-protection-intellectual-property at 2/9 ("The First Congress immediately enacted the first patent and copyright laws in 1790. As these and subsequent statutes were interpreted and enforced by the courts, innovators and creators were provided reliable and effective property rights in the fruits of their productive labors. These intellectual property rights spurred the explosive growth in the U.S. innovation economy from the 19th century through today. By the end of the 19th century, U.S. institutions and legal rules securing patents as property rights in technological innovations had become the 'gold standard' for the rest of the world." citations omitted).

[5] *See, e.g.,* U.S. Chamber of Commerce, Global Innovation Policy Center, International IP Index (9th ed., 2021).

[6] *Id.*, at 46 ("As noted in previous editions, the patenting environment in the United States continues to be held back by uncertainty over what constitutes patentable subject matter and patent nullity proceedings through the inter partes review (IPR), which occurs before the specialized Patent Trial and Appeals Board (PTAB) within the USPTO. Since the Supreme Court decisions in the Bilski, Myriad, Mayo, and Alice cases, there has been a high and sustained level of uncertainty as to which inventions are patentable in the United States.").

relief.[7] Uncertainty in our patent system harms innovation and diminishes investment, which risks depriving our citizens of new cures and therapies, as well as other life enhancing developments.

Our patent system, by providing appropriate incentives for innovation, improves lives, not only for the people of this country, but all of humanity. We must be careful to construct it, and implement it, for maximum benefit for all.

III. There is No Evidence Supporting a Need for the Proposed Initiatives

The RFC responds to a June 8, 2022 letter from six U.S. Senators to the USPTO.[8] The letter is premised upon the unsupported assertion that competition is being stifled by "large numbers of patents that cover a single product or minor variations on a single product, commonly known as patent thickets"; and, that these thickets "are primarily made up of continuation patents." The letter cites no example, much less any comprehensive body of evidence or data, to show that any of those assertions are true.

Notably, those assertions are similar to those made by the Initiative for Medicines, Access and Knowledge (I-MAK). However, as has been shown by Professor Adam Mossoff, I-MAK's purported "facts" and findings are "infected with serious questions of reliability and accuracy."[9]

Senator Thom Tillis wisely warned against making changes to our patent system based on dubious assertions unsupported by any fact-based evidence. Senator Tillis sent a letter to I-MAK requesting that it explain the data it was relying on in making assertions similar to those of the June 8 Senate letter, and specifically relating to "the number of patents on pharmaceutical products and the years of exclusivity drugs receive from patents."[10] Among other things, Senator Tillis asked I-MAK to provide a detailed explanation of its methodology, and to explain why its numbers differ so dramatically from public sources. Senator Tillis's

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[7] Kirti Gupta, Jay Kesan, "Studying the Impact of eBay on Injunctive Relief in Patent Cases, Hoover Institution, January 10, 2017, at 39, available at https://www.hoover.org/sites/default/files/ip2-wp17004-paper.pdf ("our extensive analysis with a significant dataset involving thousands of patent cases both pre- and post- eBay shows that the eBay decision has reduced, rather dramatically, both the level at which injunctive relief is sought in patent cases and the rate at which they are granted, particularly for preliminary injunctions.").

[8] https://www.collins.senate.gov/imo/media/doc/patent_letter.pdf

[9] Adam Mossoff, "Unreliable Data Have Infected the Policy Debates Over Drug Patents," Hudson Institute (January 2022) https://s3.amazonaws.com/media.hudson.org/Mossoff_Unreliable%20Data%20Have%20Infected%20the%20Policy%20Debates%20Over%20Drug%20Patents.pdf.

[10] Sen. Thom Tillis January 31, 2022 letter to I-MAK, available at http://s3.amazonaws.com/media.hudson.org/1.31.2022-%20LTR%20from%20Senator%20Tillis%20to%20IMAK%20re%20Patent%20Data%20Sources.pdf

request to I-MAK for a detailed explanation went unanswered.[11] In effect, I-MAK merely reiterated the same assertions, saying that it stands by its data, facts, and findings.

Senator Tillis repeated his concerns in a letter to the USPTO of April 1, 2022.[12] Specifically, he expressed concern with the reliability and reproducibility of I-MAK's facts and findings, and warned against making any substantive policy changes based on flawed and misleading information. He expressed his intention to "ensure that policymaking in this critical area is based on accurate, reliable, and replicable facts and evidence."

We agree with Senator Tillis. The USPTO should not revise its regulations and practices without reliable, fact-based evidence showing a need for such revision, and appropriate public comment in response to that evidence. The June 8 Senate letter, and the I-MAK "facts" and findings, fail to provide any evidence, and thus fail to make such a showing. Indeed, the assertions of that letter are deserving of well-reasoned skepticism.

Further, the June 8 Senate letter overlooks the fact that our laws, precedent, and regulations have already built a well-established regime for addressing the very issues purportedly underlying the RFC. For example, the USPTO has a longstanding practice, based on well-settled laws and regulations, for Restriction practice.[13] Where multiple inventions are disclosed in a singular patent application, they are subject to Restriction, and the applicant is required to elect one of the enumerated claimed inventions for further examination.[14] The unelected inventions, or other disclosed and unclaimed inventions, may properly be pursued in Divisional or Continuation applications. Similarly, the USPTO's practice of addressing "double patenting" prevents the improper temporal extension of a patent grant for a modest modification of a claimed invention by way of a Continuation or other related application.[15]

IV. The Proposed Initiatives Will Burden Inventors and Diminish Innovation

Current laws, jurisprudence, and regulations have crafted a generally sound and equitable balance between the property rights of the individual inventor and the public good. The law of written description and particularity of claim language is

[11] I-MAK letter of March 9, 2022 to Senator Tillis, available at www.i-mak.org/wp-content/uploads/2022/03/Letter-to-Senator-Tillis-re-I-MAK-Patent-Data-9-March-2022-1.pdf

[12] Senator Thom Tillis Letter to US FDA and USPTO of April 1, 2022 available at https://ipwatchdog.com/wp-content/uploads/2022/04/4.1.2022-TT-Ltr-to-USPTO-FDA-re-IMAK-patent-data-Final.pdf

[13] USPTO, Manual of Patent Examining Procedure ("MPEP") (June 2020), § 802.

[14] *See, e.g.*, USPTO, MPEP § 803 *et seq.*

[15] USPTO, MPEP § 806.

well understood, and supported by duly enacted laws, decades of judicial interpretation, and corresponding regulations and USPTO practices.

Nonetheless, the RFC queries whether the USPTO should change its regulations or practices with regard to: identifying supporting disclosure within an application or subsequent related application; continuation practice; RCE practice; and restriction, divisional, rejoinder, and/or non-statutory double patenting to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents.

The RFC offers no evidence, or any explanation, as to how current practices are deficient, or are contrary to either the public interest or the rights of individual inventors. Indeed, many of the changes proposed would be prejudicial to the individual inventor with no apparent or offsetting benefit to the public good. It is the view of LES that such changes would be premature, and should not now be implemented.

As discussed above, any substantial change to the U.S. patent system must be supported by compelling fact-based evidence in support of such change; and, any changes proposed must be carefully and narrowly tailored to remediate any practices shown to be in need of improvement. The RFC is completely silent as to where a problem resides with respect to written description support for a claimed invention, or any defect in our patent system associated with Continuation practice or Restriction practice.

A. Written Description, Enablement, and Continuation Practice

Generally, the law associated with written description and enablement is well developed, sophisticated, and balanced. The system as it currently exists properly places the burden on the USPTO to first identify a written description issue. It must do so on a case-by-case basis as a matter of fact; and if the USPTO determines there to be a good faith basis for a corresponding rejection, the USPTO has ample opportunity to demand evidence to overcome the rejection.[16] In many instances, the support is self-evident, and the examiner may easily locate it within a carefully crafted specification. The proposal that suggests placing the burden on the inventor to do so preemptively cuts squarely against the Patent Act's premise that an inventor is entitled to a patent unless certain statutory

[16] USPTO, MPEP (June 2020) § 2163.04 ("The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *** A simple statement such as 'Applicant has not pointed out where the new (or amended) claim is supported, nor does there appear to be a written description of the claim limitation '____' in the application as filed.' may be sufficient where the claim is a new or amended claim, the support for the limitation is not apparent, and applicant has not pointed out where the limitation is supported.").

requirements are not met.[17] This is entirely consistent with the vision of our nation's founders that government exists to preserve the rights of the individual.[18]

The premise of our patent system is a *quid pro quo* between inventor and the public. The individual inventor provides a complete and thorough description of the invention sufficient to enable one of ordinary skill in the art to make and use the invention; and, in return, we recognize the inventor's limited exclusive right to each and every invention so disclosed and claimed. The inventor is entitled to protection for all that is so disclosed and properly claimed. That which is disclosed but not claimed is deemed dedicated to the public domain. To deny an inventor the ability to claim all that is disclosed would be cheating the inventor out of the fundamental bargain upon which our patent system is based.

Moreover, such an approach would encourage workarounds that would only add to the work of the USPTO and/or result in a diminishment of the disclosure, which otherwise would inure to the public benefit. For example, if there were arbitrary limitations placed on continuation practice – without any regard to the merits or the content of a particular disclosure – applicants would tend toward reducing disclosures, and filing more discrete, focused applications. This would increase burden and cost on both the USPTO and the individual inventor, and with no apparent advantage to the public.

It would also encourage our inventors to disclose less rather than more, thus depriving society of the benefits of additional disclosure that might fuel additional non-infringing or patentably distinct improvements, which the public would otherwise be free to exploit. The purpose of our patent system is to promote transparency and disclosure. This approach would encourage the opposite.

At bottom, the issue of written description and continuation practice are one and the same; and they are adequately addressed by the law as it exists, and as it is implemented. Either a claimed invention is adequately described and enabled or it is not. The current system fully empowers the USPTO to carefully assess that fact, and to take appropriate action on a case-by-case basis (*e.g.*, by rejecting the claim). There is no evidence, or even a reasonable postulate, that our patent system is currently deficient in this regard or somehow in need of remodeling. Just as every invention is, by definition, unique, so too every initial patent application is unique (though it might disclose more than one invention). To

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[17] 35 U.S.C. § 102 ("A person shall be entitled to a patent unless - …."); *see also* 35 U.S.C. § 112, and MPEP § 2163.04 ("A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.").

[18] Adam Mossoff, "*The Constitutional Protection of Intellectual Property,*" The Heritage Foundation, (March 8, 2021) at 2/9, https://www.heritage.org/economic-and-property-rights/report/the-constitutional-protection-intellectual-property ("Consistent with the understanding at the time that the role of the government is to define and secure individual rights, Congress is authorized here to secure a right of individual inventors and authors." at 2/9 (citations omitted)).

suggest that we could or should place arbitrary limits on the number of inventions that can be disclosed and claimed in a particular application is not supported by the evidence, or any sound public policy.

The various proposals and initiatives relating to both written description and continuation practice would unduly burden inventors, and would cut squarely against "the unique commitment in our political and legal institutions to natural rights and the rule of law as secured by a government of limited powers."[19]

B. RCE Practice

LES sees no need for altering current practice with respect to RCEs. As with Continuation applications, an applicant may have myriad reasons for resorting to a RCE. The proposition that the filing of multiple RCEs is suspect or deserving of greater scrutiny, if not outright prejudicial treatment, is unsupported by any evidence. As discussed above, the principal threat of such RCEs resides in the potential for a temporal extension of the patent grant; however, existing laws, regulations and procedures pertaining to double patenting have not been shown to be deficient, or prejudicial to the public interest. Unless and until there is ample and compelling evidence of a systemic problem clearly showing that RCE practice is either being abused, or is somehow contrary to the public interest, there should be no change to longstanding regulation and practice.

C. Restriction, Divisional, Rejoinder, and/or Non-statutory Double Patenting

As above, the proposed initiatives are not aligned with any comprehensive evidence, collection of data, or consensus as to existing deficiencies or areas needing improvement. We urge caution in implementing change without such support. In particular, we oppose the suggestion that innovation would be better fostered by disposing of the longstanding and well-settled Restriction practice in favor of a unity of invention approach. This would be a substantive change to U.S. patent practice that would increase uncertainty without any showing of a compelling need or benefit.

We oppose changes to Divisional practice that would prejudice inventors by limiting their ability to comprehensively and strategically secure their rights in their discoveries. The proposed limitation on Divisional filings risks shortchanging our inventors, and offers no explanation as to how the public interest is compromised under current practice, or would be better served under the proposed practice. As such, we oppose such changes.

Likewise, in the interest of continuity and predictability, and securing inventors' rights in their discoveries, we submit that it is premature to pursue changes to

[19] *Id.* at 1/9.

Rejoinder, and Non-statutory Double Patenting practice without a clear and compelling case for doing so.

D. Terminal Disclaimers & "Second Look"

We see no need for altering existing terminal disclaimer practice. As above, there is no showing that inventors are prejudiced or that the public is not well served under existing practice.

Likewise, the proposal for a "second look" relating to continuation applications, as discussed above, appears to assume that a continuation application is somehow suspect, or less worthy than an original or parent application. There is no evidence to support that supposition.

Such a "second look" also suggests a heightened level of scrutiny that is not supported by statute. There is nothing in the patent statute, and particularly 35 U.S.C. § 112, that suggests that any of the requisites for perfecting the inventor's exclusive right by patent should be imposed more rigorously against a Continuation or any other related application. Such a prejudicial approach finds no support in law or any well-reasoned policy.

Such a prejudicial approach would place a greater administrative burden on the USPTO. It would increase costs to the inventor in securing the very rights that our Constitution guarantees. Moreover, such a second look would necessarily complicate examination, delay allowance, and thus cause a diminution of the inventor's patent term. Thus, we oppose such an approach.

In the absence of evidence or explanation in support of these initiatives, the aims of fostering innovation, competition, and access to information through robust and reliable patents will best be served by maintaining the *status quo*, and deferring further consideration of these initiatives until an appropriate case can be made in support of their implementation.

V. Conclusion

The RFC presents good and worthy general proposals for continual improvement and enhancing the quality of services provided by the USPTO. Notably, LES supports enhanced examiner training and access to resources to ensure that both inventors and the public have trust and confidence in the rights secured by a U.S. patent. However, the more specific changes to our patent system proposed in the RFC are not shown to be supported by any comprehensive body of evidence or consensus among either the inventor community or the public at large. Nor is there any showing how the proposed specific changes to U.S. patent practice would address even perceived deficiencies in our patent system. In the absence of such showing or explanation, LES opposes the various changes to USPTO patent

practice, and specifically those of Questions for Public Comment numbers 2 through 4, and 6 through 10.

We encourage you to call on us to assist you in your ongoing efforts toward continual improvement of USPTO services to the public, and particularly in its regulations and practices.

Sincerely,

Karthika Perumal
President and Chair of the Board
LES USA & Canada, Inc.

Brian P. O'Shaughnessy
Sr. V.P., Public Policy
LES USA & Canada, Inc.