Bristol Myers Squibb™

February 1, 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

Dear Director Vidal,

Please find the attached Comments of Bristol Myers Squibb Company on the USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025)

Sincerely,

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Bristol Myers Squibb™

Comments of Bristol Myers Squibb Company on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025)

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

Bristol Myers Squibb Company (BMS) appreciates the opportunity to submit the following comments on the proposed initiatives described in the USPTO's October 4, 2022 request for comments (RFC) as "further promot[ing] robust and reliable patent rights across all technology areas,"[1] including the initiatives in the USPTO's July 6, 2022 letter to the FDA,[2] as well as the questions posed by six U.S. Senators in a June 8, 2022 letter to the USPTO.[3] BMS strongly supports the USPTO's stated "purpose of furthering the common good, incentivizing innovation, and promoting economic prosperity."[4] Unfortunately, many of the proposed initiatives would not bolster the robustness and reliability of patents. Indeed, some of these initiatives would have precisely the opposite effect with profoundly negative consequences for the innovation leadership, economic security, and public health objectives of the United States.

General Comments

BMS believes that our patent system should encourage innovation, job creation, global competitiveness, early filing, and robust examination to ensure high quality and enforceable patent rights. Robust and reliable patent rights have propelled the United States to the forefront of global innovation across all sectors of science and technology, incentivizing investments in high-risk scientific and technological endeavors that have led to the most creative and sophisticated inventions in the world. That is particularly true in the biopharmaceutical sector, where life-saving advances typically require years of research, development, and testing, as well as billions of dollars before a product ever reaches the market, assuming it even does.[5] Patents play a critical role in securing the funding for these efforts. Without confidence in a robust patent examination process and predictable enforcement mechanisms, investments in critical next-generation innovations

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[1] Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60,130 (Oct. 4, 2022).

[2] Letter from USPTO Director Katherine K. Vidal to FDA Commissioner Robert M. Califf, M.D. (July 6, 2022).

[3] Letter from U.S. Senators Patrick Leahy, John Cornyn, Richard Blumenthal, Susan M. Collins, Amy Klobuchar, and Mike Braun to the Honorable Kathi Vidal (June 8, 2022).

[4] 87 Fed. Reg. at 60,130.

[5] *See, e.g.*, Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 31 (2016) (concluding that the average cost of research and development per new drug is $2.6 billion (in 2013 dollars), including the costs related to laboratory research, clinical trials, and drugs that do not reach the market).

inevitably will decline.[6] BMS urges the USPTO to avoid unnecessary rules, costs, and bureaucratic barriers to the patent system, each of which can deter innovation.

At the outset, BMS observes that several of the questions propose changes in Office policy or procedure "to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents." While those are laudable goals, BMS is not aware of any reliable data or unbiased study suggesting that the current system impedes those aims. Within many of the ongoing patent policy debates, however, there are several misleading narratives based on misinformation. Therefore, BMS encourages the Office to conduct an independent study to ensure that any changes in policy are based on accurate, reliable, and replicable facts.[7] The Office should not disrupt longstanding policies and procedures without an unbiased assessment of the evidence.

Several of the initiatives described and questions posed in the RFC appear to reflect the mistaken perception that a single patent application can or should provide adequate opportunity to protect the full range of innovation reflected in a commercial product. They also appear to reflect misunderstandings regarding the nature of innovation and unwarranted skepticism regarding the importance of continuation practice to the Office, patent applicants, and the public.

The reality for most innovative products—regardless of technology sector—is that requiring a single patent application would prove unwieldy for both the applicant and the examiner. A single pharmaceutical product, for example, typically reflects an entire portfolio of innovations including not only the chemical composition of the active ingredients, but also inventive excipient formulations, delivery mechanisms, manufacturing methods, and treatment regimens, among other possibilities. The same is true across all industries; indeed, companies in the life sciences comprise only a fraction of the top 300 organizations granted U.S. patents in recent years—a list dominated by high-tech companies.[8] Even seemingly less complex products incorporate numerous patented inventions. A single golf club, for example, may be covered by hundreds of U.S. patents,[9] and the golf industry has generated more than 22,000 patents over the last several decades.[10]

The ability to engage with the USPTO on an iterative basis through continuation and divisional practice ensures careful consideration of each inventive aspect of such products and their uses without overwhelming examiners with unmanageable claim sets. It also facilitates the presentation and examination of claims specifically covering the full scope of one's inventive contributions, which has become particularly challenging in certain industries due to courts'

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[6] *See, e.g.*, Mark F. Schultz, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies*, USIJ Policy Report (July 2020), https://www.usij.org/s/USIJ-Executive-Summary_Final_2020.pdf.

[7] *See* Letter from U.S. Senator Thom Tillis to Commissioner of Patents Performing the Functions and Duties of the USPTO Director Drew Hirshfeld and FDA Commissioner Robert Califf, M.D. (Apr. 1, 2022).

[8] *See* IPO, Top 300 Organizations Granted U.S. Patents in 2021 (Jan. 6, 2022), https://ipo.org/wp-content/uploads/2022/01/2021-Patent-300%C2%AE-IPO-Top-Patent-Owners-List-FINAL.pdf.

[9] *See, e.g.*, TaylorMade, *TaylorMade Golf Patents*, https://www.taylormadegolf.com/about-us/pat.html?lang=en_US (last visited Jan. 22, 2023).

[10] National Golf Foundation, *Golf Is the No. U.S. Sport ... for Patents* (Apr. 13, 2018), https://www.ngf.org/golf-is-the-no-1-u-s-sport-for-patents/.

increased hostility to genus claims.[11] The availability of continuation and divisional practice also promotes early filing, which in turn results in earlier public dissemination of the teaching in the application and decreased risks of forfeiture due to pre-filing disclosures.

Furthermore, imposing a "single application" approach or rigid limitations on continuation practice would run counter to the very nature of innovation. Most innovations require time, testing, and real-world feedback before the safest, most effective, and most commercially viable embodiments can be identified and the benefits of the full inventive footprint realized. The patent system should incentivize these important ongoing research and development investments to identify and commercialize product improvements and new uses for existing products. Importantly, however, each patent remains subject to a limited period of exclusivity. The expiration of earlier-filed patents facilitates the introduction of generic pharmaceutical products, for example, in parallel with ongoing work that may culminate in separate inventions meriting protection for new indications, more efficacious formulations, or compliance-promoting methods of administration.

BMS also discourages the Office from disparaging patentable inventions as "minor," "incremental," or "follow-on." Many of the most valuable and innovative discoveries involve seemingly minor or incremental improvements with outsized impacts, such as Thomas Edison's identification of the most practical light bulb filament, clinical trials confirming new and life-changing indications for existing medications. Patent protections should be available for all inventions based on the rigorous and consistent application of the statutory criteria established by Congress, not on subjective perceptions.

While some critics have focused on the number of patents related to the same product with disparaging terms such as "patent thickets," so long as the claims of each patent meet the statutory conditions, these "thickets" actually reflect concentrated examples of multifaceted innovation. Moreover, because most continuation applications have not been capable of extending patent term since the 1990s,[12] there is little practical difference between a single patent with 80 claims and four coterminous patents with 20 claims each. And despite rhetoric regarding the burdens of challenging the validity of multiple patents, most real-world litigation turns on a handful of "representative claims" chosen either voluntarily or by direction of the court.[13]

The opportunity for a limited right to exclude in exchange for public disclosure is the fundamental *quid pro quo* of the patent system. Policies that would discourage broad and early disclosure, such as limiting the number of patents available for related inventions, would stifle innovation by not only discouraging inventors from pursuing the full scope of their inventions, but also preventing future innovators from understanding and building upon those contributions.

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[11] *See generally* Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 Harv. J. L. & Tech. 1 (2021).

[12] *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994) (amending 35 U.S.C. § 154 to limit patent terms to 20 years from the effective filing date rather than 17 years from the issue date).

[13] *See, e.g.*, Patricia E. Campbell, *Representative Patent Claims: Their Use in Appeals to the Board and in Infringement Litigation*, 23 Santa Clara Computer & High Tech. L.J. 55 (2006).

Comments on Specific Questions

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

"The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability."[14] Accordingly, BMS supports USPTO initiatives to leverage artificial intelligence, collaboration with international patent agencies, and other resources to ensure that examiners have efficient access to the full scope of the most relevant prior art.

As the Office emphasized in a recent Federal Register notice,[15] patent applicants and others involved in prosecuting patent applications have an affirmative duty to disclose "all information known to that individual to be material to patentability,"[16] which includes relevant prior art of any variety, including evidence of inventions having been "on sale" or "in public use" as described in 35 U.S.C. § 102. BMS is unaware of any impediments to such mandatory disclosures but conceptually supports efforts to facilitate efficient interactions between applicants and the Office.

[14] 37 C.F.R. § 1.56(a).

[15] Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45,764 (July 29, 2022).

[16] 37 C.F.R. § 1.56(a).

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

    a. ***require applicants to explain or identify the corresponding support in the written description for each claim, or claim limitation, upon the original presentation of the claim(s), and/or upon any subsequent amendment to the claim(s) (including requiring a showing of express or inherent support in the written description for negative claim limitations)?***

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

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

BMS agrees with the current MPEP guidance noted in the RFC,[17] and as a frequent patent applicant, BMS knows that identifying support for newly added or amended claims promotes efficient examination, ensures compliance with 35 U.S.C. § 112, and therefore serves its own interests as well as those of the Office and the public. Based on the text accompanying these initiatives in the RFC, BMS understands the Office to be considering something akin to the rule governing claim amendments in *ex parte* reexamination proceedings, 37 C.F.R. § 1.530(e), which requires such an identification of support. Should the Office pursue this approach, BMS cautions against the burdens and potentially unintended limiting effects of requiring exhaustive identification of every supportive disclosure in the relevant specification. Applicants could be required, for example, to provide exemplary citations subject to an examiner's request for additional support. BMS also notes that requiring applicants to identify support for the "original presentation of the claim(s)" referenced in subpart (a) would be superfluous, as the originally filed claims are part of the written description.[18]

[17] 87 Fed. Reg. at 60,132 (quoting MPEP 2163 II.A. ("With respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.")).

[18] *See, e.g., In re Benno*, 768 F.2d 1340 (Fed. Cir. 1985).

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

BMS has no comment on this proposal.

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?***

It is not clear precisely what the proposed "detailed analysis" might require, but BMS cautions against a rigid policy requiring a burdensome identification of support in the written description for "each species," as the amount of work required to compile such disclosures could far outweigh any benefit to the examiner, the applicant, or the public, particularly for a claimed genus encompassing a large number of species bearing significant known or common traits. In any event, the Office should not impose any burden greater than the statutory requirement of "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."[19]

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)?***

As an initial observation, "new matter" is permitted only in continuation-in-part (CIP) applications filed pursuant to 37 C.F.R. § 1.53(b). BMS believes that applicants should identify such new matter as a best practice, although modern technology should enable either the Office or the applicant to readily identify any changes between an original and a continuing application, and therefore a new requirement should not be necessary.

[19] 35 U.S.C. § 112(a). For purposes of assessing whether a new or amended claim is supported by the specification as filed, identification of words in the specification that either literally or inherently describe the inventive concept set forth in this claim should be sufficient to perform the necessary gate-keeping function.

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?***

BMS believes that every patent application should receive robust examination to ensure full compliance with all of the statutory criteria for patentability. Indeed, BMS relies on the USPTO's examiners to perform this critical vetting function as part of the collaborative examination process. BMS has no interest in securing claims on unpatentable subject matter, as it allocates resources, directs investments, and launches commercial products in reliance on the patent grant. Therefore, the USPTO should not discriminate among technologies, application types, or continuation status. The Office should hold all patent applicants and applications to the same standards of examination scrutiny. Consequently, BMS does not support "increasing the scrutiny given" to any subset of patent applications or RCEs any more than it would support "decreasing the scrutiny given" to any other application or RCE. Moreover, this proposed initiative raises significant questions about what "increasing . . . scrutiny" would entail.

It is also unclear how transferring an RCE to a different examiner would promote the stated aims of the proposal. Each examiner should apply the same criteria in an objective manner. To the extent the Office believes that different examiners would reach different results on the same application, that concern likely reflects internal training and quality control issues that should be addressed independently rather than attempting to mitigate them by shuffling RCE applications among different examiners. Furthermore, transferring applications to a different examiner based on an arbitrary number of RCEs has the potential to undermine the efficiencies of the iterative examination process. Transferring applications to different examiners will introduce unnecessary delay and likely not lead to better quality as the subsequent examiner would not be as familiar with the technology, the prior art, and the prosecution history as the original examiner.

Finally, the text accompanying this proposed initiative does not clearly identify the potential harm it seeks to address. Although the RFC states that applicants may pursue a "cycle" of RCEs "subject only to a finding of prosecution laches,"[20] RCEs do not extend the term of any patent that may issue from the underlying application, applicants must pay fees to cover the cost of the continued examination,[21] and pursuing an RCE can itself be characterized as inviting additional scrutiny of the proposed claims. For at least these reasons, BMS does not agree that the proposed changes to RCE practice would achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents.

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,***

[20] 87 Fed. Reg. at 60,132.

[21] *See* USPTO Fee Schedule, https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Misc%20Fee (last visited Jan. 7, 2023).

competition, and access to information through robust and reliable patents? Specifically, should the USPTO:

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

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

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

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?***

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

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?***

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?***

BMS does not support these proposed initiatives at this time. Although BMS believes that the applicant is typically in the best position to determine whether claims should be examined in a single application or split into separate divisional applications, the USPTO may disagree. In those situations, BMS is comfortable with the current restriction practice, which appears to balance the needs of the Office and applicants subject to safeguards designed to shield applicants from unjust double patenting rejections.[22] That said, BMS encourages the Office to evaluate whether the current approach to examiner assignments within the corps promotes efficiency in the context of related applications. BMS also cautions against imposing rigid timing requirements on divisional or rejoinder practice, as it is unclear what benefits flowing from such changes would outweigh the burdens and potential risks of forfeiture to applicants.

h. ***limit or change non-statutory double patenting practice, including requiring applicants seeking patents on obvious variations to prior claims to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer to obviate the rejection; rejecting such claims as not differing substantially from each other or as unduly multiplied under 37 CFR 1.75; and/or requiring a common applicant or assignee to include***

[22] *See* 35 U.S.C. § 121.

all patentably indistinct claims in a single application or to explain a good and sufficient reason for retaining patentably indistinct claims in two or more applications? See 37 CFR 1.78(f).

The judicially created doctrine of non-statutory or obviousness-type double patenting (OTDP) has long outlived its usefulness. It was designed to prevent unwarranted term extensions in the pre-GATT era,[23] and as previously noted, continuing applications now generally expire at the same time as the parent application. Therefore, extended continuation strategies typically limit the net term of any resulting patent. And to the extent an applicant files separate initial applications seeking obvious variations of claims in its own previously published applications, standard rejections under § 103 should serve to adequately police mischief. As such, the RFC's stated concern regarding patent owner trying "to obtain an unjustified timewise extension of patent rights" is obsolete.[24] Moreover, as correctly noted in the RFC, "compar[ing] the claims in these multiple patents and pending applications to determine if a non-statutory double patenting rejection is proper" imposes "a heavy burden on examiners."[25]

Instead of policing gamesmanship, OTDP has led to a notoriously complex and confusing body of case law subjecting patent owners to unpredictable and unreasonable forfeiture risks based on the doctrine's potentially inconsistent interplay with patent term extensions (PTE) due to FDA delays and patent term adjustments (PTA) due to USPTO delays.[26] And while divisional applications resulting from USPTO restriction requirement theoretically benefit from the statutory safe harbor of 35 U.S.C. § 121, the law has created traps for the unwary here as well.[27] More fundamentally, OTDP places original applicants in an inferior position to third-party applicants, who can apply for improvements on the originally claimed invention without being subject to the doctrine, which not only limits the patent's term, but also its alienability.[28]

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[23] "Double patenting is a basis of rejection grounded in public policy and primarily intended to prevent prolongation of monopoly." *In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967).

[24] 87 Fed. Reg. at 60,133.

[25] *Id.*

[26] *See, e.g.*, Scott A. McMurry, PhD & Ryan T. Babcock, *Does PTAB's Ex Parte Cellect Decision Endanger Biopharmaceutial Patent Terms?*, Mayer Brown (April 20, 2022), https://www.mayerbrown.com/en/perspectives-events/publications/2022/04/does-us-ptabs-ex-parte-cellect-decision-endanger-valuable-patent-terms-of-biopharmaceuticals.

[27] *See, e.g.*, Shoshana Marvin et al., *Has Ex Parte Sauerberg Gutted the Patent Act's Safe Harbor Provision?*, IPWatchdog (Aug. 2, 2021), https://ipwatchdog.com/2021/08/02/ex-parte-sauerberg-gutted-patent-acts-safe-harbor-provision/id=136163/.

[28] 37 C.F.R. § 1.321(c)(3) (providing that a terminal disclaimer filed to obviate judicially created double patenting must, among other things, "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting").

Terminal disclaimers are authorized by statute,[29] and—like the OTDP doctrine itself—were a judicially created means of overcoming an OTDP rejection.[30] As such, the USPTO does not have authority to eliminate either the OTDP doctrine or the practice of overcoming OTDP rejections with terminal disclaimers.[31] However, terminal disclaimers insulate patent applicants against the risk of adverse OTDP determinations to some extent, and unless and until Congress or the courts finally retire the OTDP doctrine, BMS would not alter the current practice as suggested in the three initiatives proposed in subpart (h).

Regarding the first proposal, requiring applicants to stipulate that claims are not patentably distinct from each other would impose a new substantive requirement not found in the statute or the case law. To the contrary, it would exceed the Office's authority by overruling Federal Circuit precedent "foreclos[ing] the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims," and holding that it "does not give rise to a presumption that a patent subject to a terminal disclaimer is patentably indistinct from its parent patents."[32] Moreover, claims appearing in multiple commonly owned and coterminous applications are materially similar to the same claims collectively appearing in a single application. Yet no such stipulations are required in that context, as validity is claim-specific.[33]

The second proposal likewise appears to contemplate a new substantive criterion for patentability by suggesting blanket rejections for claims otherwise subject to OTDP as "not differing substantially from each other" or "unduly multiplied" under 37 C.F.R. § 1.75(b), an unclear and rarely applied regulation rooted in clarity concerns related to § 112 rather than obviousness.[34] And to the extent that the Office proposes this approach to foreclose applicants' use of terminal disclaimers to obviate what would currently be framed as OTDP rejections, BMS believes it would exceed the agency's authority for the reasons explained above.

Finally, it is unclear how the third proposal purports to alter the status quo. The requirement that applicants provide a "good and sufficient reason" for retaining patentably indistinct claims in multiple applications is already provided in 37 C.F.R. § 1.78(f). Again, however, to the extent that the Office proposes this approach to foreclose applicants' use of terminal disclaimers to obviate

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[29] 35 U.S.C. § 253.

[30] *See* Sherry Knowles & Anthony Prosser, *Let's Do Something About the Unauthorized Doctrine of Non-Statutory Judicially Created Obviousness-Type Double Patenting*, IPWatchdog (Sept. 6, 2022), https://ipwatchdog.com/2022/09/06/lets-something-unauthorized-doctrine-non-statutory-judicially-created-obviousness-type-double-patenting/id=151271/ (discussing *In re Robeson*, 331 F.2d 610, 615 (C.C.P.A. 1964)).

[31] *See, e.g.*, *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (confirming that the USPTO does not have substantive rulemaking authority).

[32] *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-68 (Fed. Cir. 2018).

[33] *See, e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011).

[34] *See, e.g.*, *In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970) (referencing an examiner's rejection of patent claims "for undue multiplicity under 35 U.S.C. § 112").

what would currently be framed as OTDP rejections, BMS believes it would exceed the agency's authority for the reasons explained above.

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.***

BMS urges the USPTO to consider additional administrative reforms that would promote innovation, competition, and access to information through robust and reliable patent rights. For example, fluctuating Office policies related to inter partes review proceedings have introduced significant uncertainty undermining the reliability of patent rights.[35] BMS also encourages the Office to engage with Congress and the courts to clarify the law regarding patent-eligible subject matter under 35 U.S.C. § 101, which has likewise frustrated reliability through uncertainty.[36]

BMS supports many of the efforts identified in the July 6, 2022 USPTO letter, such as providing examiners with additional training and resources (2a), leveraging automation (2d), and promoting intra-agency communications and educational opportunities (2c). However, BMS has significant concerns regarding initiatives suggesting "applying greater scrutiny to continuation applications in large families and/or the use of declaratory evidence to overcome rejections" (2e) as articulated above in response to question #3. BMS also urges caution in revisiting OTDP practice (2f) for the reasons stated above in response to question #4(h). In particular, BMS is unaware of data supporting the suggestion that multiple patents "could potentially deter competition" or "delay resolution of ongoing district court litigation" as suggested in the letter. As explained above in the General Comments, most real-world litigation turns on a handful of "representative claims," and the availability of continuation and divisional practice promotes the broad and early invention disclosures at the heart of our patent system. As further explained in the General Comments, BMS urges the Office to probe the false narratives and misinformation underpinning many of the calls for changes in USPTO policies and procedures. Evidence-based policymaking requires an unbiased evaluation of objective facts, and BMS encourages the Office to study whether the current system achieves "the aims of fostering innovation, competition, and access to information."

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?***

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[35] *See, e.g.*, Katherine K. Vidal, *Updated Guidance on the Treatment of Statements of the Applicant in the Challenged Patent in Inter Partes Review Under § 311* (June 9, 2022); Katherine K. Vidal, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (June 21, 2022).

[36] *See, e.g.*, Riddhi Setty, *Clarity on Patent Eligibility Sought from Court, Congress, PTO*, Bloomberg Law (July 5, 2022), https://news.bloomberglaw.com/ip-law/clarity-on-patent-eligibility-sought-from-courts-congress-pto.

BMS incorporates by reference its response to question #4(h). This proposal would fundamentally upend continuing application practice in the United States and introduce significant inefficiencies and harmful unintended side effects. As discussed above, the USPTO permits applicants to pursue claims protecting the full scope of their inventions, so long as those claims comport with the statutory criteria for patentability. For the reasons previously described, presenting all such claims for examination in a single application poses both policy problems and logistical difficulties. For example, foreclosing the use of terminal disclaimers to obviate OTDP rejections would force applicants and examiners to compress the patent prosecution process into a single application, introducing significant inefficiencies and likely resulting in a net reduction of patent quality. In addition, applicants would be forced to balance the risks of delaying filing against potentially sacrificing the opportunity to capture the full scope of protections commensurate with their inventive contributions. The proposed change would likely result in unwieldy claim sets that would burden both patent applicants and the Office, as well as narrower disclosures and delayed filings that would not promote the public interest.

Furthermore, as discussed above in response to question #4(h), the USPTO lacks the authority to foreclose the use of statutory terminal disclaimers or alter the judicially created doctrine of obviousness type double patenting. As further discussed above, the OTDP doctrine has outlived its usefulness in the post-GATT era, and it poses the risk of serious inequities for patent owners, but these problems are most appropriately addressed by Congress and the courts.

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?***

BMS incorporates by reference its response to question #4(h). BMS strongly disagrees that the filing of a terminal disclaimer should serve as an admission of obviousness for the same reasons described above, including binding Federal Circuit precedent "foreclose[ing] the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims."[37] Furthermore, patent claims within the same patent do not stand or fall together, as validity and patentability are claim-specific.[38] To the extent the Senators' question reflects concerns about challenging claims in multiple patents, that concern would also apply to a single patent with a large number of claims, and in any event patent litigation typically focuses on a small subset of representative claims as discussed above.

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?***

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[37] *SimpleAir*, 884 F.3d at 1167.

[38] *See, e.g.*, *Therasense*, 649 F.3d at 1288.

As discussed above in its response to question #3, which BMS incorporates here by reference, BMS believes that every patent application should receive robust examination to ensure full compliance with all of the statutory criteria for patentability. The USPTO should not discriminate among technologies and should hold all patent applications to the same standards of examination scrutiny, including the requirements of § 112. BMS recognizes that the USPTO issues approximately 400,000 patents per year,[39] and mistakes are inevitable at that volume. Indeed, that fact motivated Congress to implement various post-grant review mechanisms, such as inter partes review in the Leahy-Smith America Invents Act of 2011 to provide a "second look" at issued patent claims. But that does not mean that the Office should discriminate among pending patent applications by applying inconsistent levels of scrutiny. Furthermore, BMS is unaware of data supporting the suggestion that continuation applications pose particular risks of double patenting or compliance with the requirements of § 112. As explained above in the General Comments, BMS urges the Office to probe the false narrative and misinformation underpinning many of the calls for changes in USPTO policies and procedures. Evidence-based policymaking requires an unbiased evaluation of objective facts. BMS also encourages the Office to consider the practical implications of requiring a "second look," particularly in view of the profoundly negative consequences flowing from the "second pair of eyes" review implemented 20 years ago.[40]

However, BMS would support a distinct form of examination scrutiny that would bolster the reliability of the patent grant. For some industries, reliable and robust patent protections are particularly critical to launching new products, and that is especially true in the bio-pharmaceutical field.[41] For BMS and similarly situated patent applicants, the risks of going to market with an improvidently granted patent are severe and may undercut critical research and development investments in the next wave of life-saving technology. Therefore, many applicants would welcome the opportunity for enhanced pre-issuance scrutiny to avoid the cancellation of claims after the patent has issued. BMS suggests that an option to submit otherwise allowable claims for such review (and pay appropriate fees for the examination and quality control) would be worthwhile provided that—if confirmed patentable and subsequently issued—they are not subject to a third, fourth, or even more additional reviews by the USPTO post-issuance.

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

As discussed above in its response to question #3, which BMS incorporates here by reference, BMS believes that every patent application should receive robust examination to ensure full compliance with all of the statutory criteria for patentability. The Office should hold all patent applicants and applications to the same standards of examination scrutiny, and the Office lacks authority to impose additional substantive requirements for claims presented in continuation

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[39] USPTO, *U.S. Patent Statistics Chart, Calendar Years 1963-2020*, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited Jan. 7, 2023).

[40] *See, e.g.*, Gene Quinn, *Alice Experts and the Return of Second Pair of Eyes to the PTO*, IPWatchdog (July 24, 2016), https://ipwatchdog.com/2016/07/24/alice-experts-second-pair-of-eyes/id=71185/ (noting that "[s]econd pair of eyes review . . . was one of the primary reasons patent pendency got out of control and the backlog of patent applications grew to well over 1 million unexamined patent applications," and that "second pair of eyes review nearly broke the Patent Office and crippled the U.S. patent system").

[41] *See* note 5, *supra*.

applications. Consequently, BMS does not support "heightened examination requirements" to any subset of patent applications any more than it would support "lowered examination requirements" for any other application. This proposal raises significant questions about what "heightened examination requirements" would entail, but to the extent they would raise the substantive criteria for patentability, the Office lacks the authority to implement them.[42] Furthermore, BMS is unaware of data supporting the suggestion that continuation applications pose particular risks of double patenting or compliance with the requirements of § 112. As explained above in the General Comments, BMS urges the Office to probe the false narratives and misinformation underpinning many of the calls for changes in USPTO policies and procedures. Evidence-based policymaking requires an unbiased evaluation of objective facts.

This question also appears to assume that "minor modifications" do not warrant patent protection, without defining that term and regardless of the real-world impact of objective indicia of non-obviousness associated with such claimed inventions. BMS disagrees with that perspective, as well as the question's presumption against multiple patents on related inventions, for at least the reasons stated in the General Comments above, which BMS incorporates here by reference.

10. ***The Patent Act requires the USPTO Director to set a "time during the pendency of the [original] application" in which continuation status may be filed. Currently there is no time limit relative to the original application. Can the USPTO implement a rule change that requires any continuation application to be filed within a set timeframe of the ultimate parent application? What is the appropriate timeframe after the applicant files an application before the applicant should know what types of inventions the patent will actually cover? Would a benchmark (e.g., within six months of the first office action on the earliest application in a family) be preferable to a specific deadline (e.g., one year after the earliest application in a family)?***

As explained in the General Comments above, which BMS incorporates here by reference, imposing arbitrary time limitations on continuation practice is problematic for several practical and policy-based reasons. Furthermore, because continuation applications no longer receive later expiration dates than their parent applications, ongoing prosecution typically results in shorter net patent terms for any patents issuing from such continuation applications. Perhaps more directly responsive to the question, however, the USPTO not only lacks substantive rulemaking authority to limit applicants' opportunity to file continuation applications pursuant to 35 U.S.C. § 120,[43] but the Federal Circuit previously rejected the USPTO's last attempt to unduly constrict the statutory continuation provisions. Although that decision was vacated for an en banc rehearing that never

[42] *See, e.g.*, *Merck*, 80 F.3d at 1549-50.

[43] *See, e.g.*, *Merck*, 80 F.3d at 1549-50.

occurred due to the settlement of the case,[44] BMS believes that the proposed limitations would exceed the Office's authority and conflict with the plain language of the statute.[45]

11. ***The USPTO has fee-setting authority and has set [fees] for filing, search, and examination of applications below the actual costs of carrying out these activities, while maintenance fees for issued patents are above the actual cost. If the up-front fees reflected the actual cost of obtaining a patent, would this increase patent quality by discouraging filing of patents unlikely to succeed? Similarly, if fees for continuation applications were increased above the initial filing fees, would examination be more thorough and would applicants be less likely to use continuations to cover, for example, inventions that are obvious variations of each other?***

BMS supports the current balance struck by the USPTO in setting fees. Shifting fees to the front end is unlikely to impact patent quality, although studies would be necessary to estimate the predicted revenue impacts of reduced maintenance fees, increased filing fees, and the potential decrease in applications filed. Moreover, shifting fees forward would reduce the cost of maintaining existing patents and may incentivize patent owners to maintain patents that would otherwise be abandoned. The question posed is correct in one regard, however, and that is the causal connection between increasing up-front fees and discouraging the filing of patent applications. Unfortunately, it is difficult to know which patent applications will "succeed" and which underlying inventions will prove most valuable in the marketplace, and that is particularly true for the least sophisticated inventors most likely to be deterred by increased costs and other barriers to seeking patent protection. The most likely result of raising upfront fees would be to undermine important agency initiatives designed to encourage broader participation in the patent system by historically underrepresented populations.[46] The pharmaceutical industry shoulders an outsized portion of net USPTO fees due to longer product lifecycles and different business models than many other industries. BMS is comfortable with this disparity in view of the benefits to our innovation economy of preserving a low cost of entry to the patent system and thereby harnessing the power of all innovators

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[44] *See* Sherry Knowles, *Note to Senators: U.S. Patent Office Remains Under a Permanent Injunction*, IPWatchdog (June 20, 2022), https://ipwatchdog.com/2022/06/20/note-senators-u-s-patent-office-remains-permanent-injunction/id=149690/ (addressing *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *reh'g en banc granted, opinion vacated*, 328 F. App'x 658 (Fed. Cir. 2009)).

[45] *See Transco Prod. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994) ("The plain and unambiguous meaning of section 120 is that ***any*** application fulfilling the requirements therein 'shall have the same effect' as if filed on the date of the application upon which it claims priority." (emphasis added)).

[46] *See, e.g.*, USPTO, *Patent Fees for Small and Micro Entities Reduced* (Dec. 30, 2022), https://www.uspto.gov/subscription-center/2022/patent-fees-small-and-micro-entities-reduced (remarks of USPTO Director Kathi Vidal noting the agency's "work to support small inventors, start-ups and those traditionally underrepresented in the innovation ecosystem," and further stating that with "lower fees, additional outreach and support, and the expanded ability to obtain pro bono counsel, we are positioned to make meaningful progress in 2023 by measurably lowering the barriers for those entering the innovation ecosystem").