abbvie

February 1, 2023

The Honorable Kathi Vidal
Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

**RE: Docket No. PTO-P-2022-0025: Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights**

Dear Director Vidal:

AbbVie appreciates the opportunity to respond to the USPTO's Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (RFC). AbbVie is a global, research-based biopharmaceutical company. Since our launch in 2013, we have invested about $50 billion in research to discover, develop and deliver new medicines. Today, we employ approximately 50,000 employees around the world and focus on discovering and delivering transformational medicines and products in key therapeutic areas. Our mission is to discover and deliver innovative medicines and products that solve serious health issues and enhance people's lives today and address the medical challenges of tomorrow.

Innovation is the lifeblood of our company, and the patent system is the foundation for innovation. Patents incentivize innovation by granting exclusive rights to inventors for limited times, while requiring inventors to publicly disclose their inventions. This enables competitors to improve upon these inventions to develop better products, and also allows generic manufacturers and the public to freely exploit these inventions after patent protections expire. The United States has the most effective, robust and balanced patent system in the world, which has been the key to the success of our innovation-driven economy and long recognized as such by both Democratic and Republican administrations and leaders.[1]

[1] *See, e.g., U.S. Patent and Trademark Office: the America Invents Act and Beyond, Domestic and International Policy Goals: Hearing Before the Subcomm. on Courts, Intellectual Property, and the Internet*, 113 Cong. (2014) (statement of Rep. John Conyers, Jr., D-Mich) ("Our intellectual property system is the envy of the world because it forms the foundation for our inventiveness and dynamic business culture. It is clear that the protection and enforcement of intellectual property is vital to maintaining our competitiveness globally.") (https://www.govinfo.gov/content/pkg/CHRG-113hhrg88922/html/CHRG-113hhrg88922.htm, accessed on January 9, 2023); and Press Release, *Tillis Introduces Landmark Legislation to Restore American Innovation* (2022) (statement of Sen. Thom Tillis, R-NC) ("I have long said that clear, strong, and predictable patent rights are imperative to enable investments in the broad array of innovative technologies that are critical to the economic and global competitiveness of the United States, and to its national security") (https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation, accessed on January 23, 2023).

Abbvie applauds the work of the USPTO to launch initiatives that improve patent quality and reliability. We support the USPTO introducing more examination time for each patent application, providing more training and resources to patent examiners, enhancing communication between patent examiners and the PTAB, and encouraging disclosure of relevant material information to the examiners. We believe these initiatives will likely help improve patent quality and reliability, promote innovation, and foster competition.

We are concerned, however, about certain narratives in the RFC regarding continuing applications and obviousness-type double patenting (OTDP). We believe that those narratives are misguided and not supported by sound evidence. We also believe that the current continuing and OTDP practices strike the right balance between different policy considerations, are crucial to American innovation, and should not be restricted.

## 1. Continuing Applications Are Crucial to the Effectiveness and Robustness of the US Patent System

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

The existing patent infringement law alone does not help protect subject matters that are disclosed but not claimed. Specifically, the disclosure-dedication doctrine bars a finding of infringement if an infringer copies an embodiment/element that is disclosed but not claimed.[2] This doctrine applies even if the copied embodiment/element is an obvious variant but falls outside the literal scope of the initially granted claim due to the semantic limitations of language.[3] Continuing applications help ensure that each inventor can properly protect the entire scope of her disclosed

[2] *See, e.g.*, *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1175 (Fed. Cir. 2020) ("The disclosure-dedication doctrine bars application of the doctrine of equivalents").

[3] *See, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 731 (2002) ("Unfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application"); and *Graver Tank & Mfg. Co. v. Linde Air Products Co*., 339 U.S. 605, 607 (1950) ("Such a limitation would leave room for – indeed encourage – the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent ... It would deprive [the inventor] of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system.")

invention and, therefore, are crucial to the advancement of the quid pro quo principle of patent disclosure.

Continuing applications also promote innovation by encouraging the public to design around or improve upon what is disclosed.[4] The initially granted patent claims often do not fully capture what is disclosed in the patent specification. However, third parties recognize not only what is claimed, but also what is not claimed but can be protected through continuing applications. As a result, continuing applications help discourage unscrupulous copying of what is disclosed but not yet claimed, and encourage third parties to improve beyond the patent disclosure. Simply copying what has been disclosed but not yet claimed does not help promote science or innovation.

Moreover, continuing applications facilitate patent examination and help improve patent quality. Continuing applications allow inventors to pursue different inventions or embodiments in different applications, thereby helping reduce the total number of claims in each application and making the patent prosecution process more efficient for both applicants and the USPTO. In contrast, if continuing applications are limited, inventors would have to prosecute a large number of claims in a single application in order to adequately protect different inventions/embodiments; and this would make patent examination more complex and difficult, causing unnecessary delays and potentially leading to lower-quality patents and prolonging patent exclusivity due to examination delays.

For the above reasons, we urge the USPTO not to limit the current continuing application practice that has been crucial to the effectiveness and robustness of the US patent system.

**2. Current Obviousness-Type Double Patenting and Terminal Disclaimer Practices Strike the Right Balance between Different Policy Considerations**

We urge the USPTO not to restrict current obviousness-type double patenting (OTDP) and terminal disclaimer practices. We believe that the restrictions on terminal disclaimers, as proposed in the RFC, will likely compromise overall patent quality, raise serious questions of fairness and due process, and do not meaningfully address any valid policy concerns. We also believe that the Federal Circuit's approach on the effect of terminal disclaimers on related patents strikes the right balance between different policy considerations.

[4] *See, e.g.*, *WMS Gaming Inc. v. International Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999) ("the patent law encourages competitors to design or invent around existing patents").

OTDP is a judicially created doctrine grounded in public policy.[5] The use of the statutory terminal disclaimer to overcome ODTP is a judicially created remedy in response to OTDP rejections.[6] By filing a terminal disclaimer, a patent applicant surrenders the terminal part of the statutory term of her patent that would go beyond the expiration date of the reference patent, and also agrees that her patent is enforceable only for and during the period that it and the reference patent are commonly owned. Terminal disclaimers therefore serve an important public interest which "encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public".[7]

Patent applicants often file terminal disclaimers to overcome OTDP for reasons not related to the merits of the OTDP rejections.[8] For example, terminal disclaimers are often filed for convenience in continuation applications when these applications are expected to have the same ownership and expire at the same time as, or even earlier than, the reference parent patent (e.g., if the parent patent has a longer patent term adjustment). Terminal disclaimers have also been filed to avoid additional prosecution costs, or get patents issued quickly to help obtain finance or attract investment.

Restrictions on the use of terminal disclaimers to overcome OTDP are unlikely to help improve patent quality. These restrictions will likely force patent applicants to contest, and oblige the USPTO to defend, the merits of the OTDP rejections. This would increase patent prosecution costs for all sizes of applicants, cause unnecessary prosecution delays, and waste valuable resources at the USPTO. If the OTDP rejections are successfully overcome by patent applicants on the merits, it could lead to later patent expiration dates, thereby prolonging patent exclusivity.

---

[5] *See, e.g.*, *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012) ("Nonstatutory double patenting is a judicially created doctrine grounded in public policy that prevents the extension of the term of a patent, even where an express statutory basis for the rejection is missing, by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent.") (cleaned up).

[6] *See, e.g.*, *In re Kaye*, 332 F.2d 816, 819 (CCPA 1964) ("this court had occasion to consider the effect of a terminal disclaimer in overcoming a double patenting rejection" and "we held that where, as here, the claims define separate, albeit patentably indistinct, inventions, the filing of a terminal disclaimer may obviate a double patenting rejection.").

[7] See *In re Berg*, 140 F.3d 1428, 1436 (Fed. Cir. 1998). *See also In re Wright*, 393 F.2d 1001, 1008 (CCPA 1968) (Smith, concurring) ("it seems to me the public interest is better served by the terminal disclaimer provisions since the disclosure of the first patent can be made public at an earlier instance than if prosecution is protracted to permit prosecution of all the claims to which an applicant may be entitled. It is generally conceded that early publication of patents is in the public interest, hence any procedure which facilitates this end should be encouraged.")

[8] *See, e.g.*, *Wooster Brush Co. v. Newell Operating Co*, 2000 U.S. App. LEXIS 14132 (Fed. Cir. 2000) ("There are many reasons to file a terminal disclaimer, and it is not up to us to say, in this case where no reason was given, that Sekar filed such a disclaimer because he concluded that the patent would not otherwise issue, rather than because he was in financial difficulty (as he admitted), and could not afford to argue further with the Patent Office, or wait longer for his patent.")

Moreover, these restrictions will likely encourage patent applicants to include more claims in a single application, which would make patent examination more complex and difficult, potentially leading to lower-quality patents and longer patent terms. Accordingly, we believe that restrictions on the use of terminal disclaimers to overcome OTDP will likely compromise overall patent quality rather than improve it.

In addition, restrictions on terminal disclaimers, as proposed in Questions 4(h) and 7 of the RFC, do not address any policy concerns underlying OTDP – namely, preventing unjustified patent term extensions and harassment from multiple suits by different assignees. Nor do they help promote additional disclosure and earlier patent expiration, a main policy reason why courts developed the use of terminal disclaimer to overcome ODTP in the first place. Instead, these restrictions appear to be designed to address an entirely different policy concern (namely, that a large number of purportedly obvious-variant patents allegedly delay generic and biosimilar competition) which has never been considered by courts as relevant to OTDP and is not supported by sound evidence.[9]

Moreover, deeming the filing of a terminal disclaimer as an admission of obviousness, or requiring patents that are subject to terminal disclaimers to stand and fall together, could raise serious questions of fairness and due process. [10] A patent claim may be found invalid/unpatentable for a variety of reasons. If one claim in the reference patent is invalidated, there should be no reason to infer that the claims in the terminally disclaimed patent must also be invalid. Afterall, within a single patent, each claim of a patent "shall be presumed valid independently of the validity of other claims".[11]

Furthermore, the Federal Circuit has already developed an effective approach to address the impact of terminal disclaimers on related patents. Specifically, the Federal Circuit found that a terminal disclaimer, although not conclusive or a presumption, was a strong clue that the relevant

[9] As an example, it is wrongly alleged that Imbruvica, a life-saving anti-cancer drug, has a "patent wall" of 88 granted patents. *See* https://www.i-mak.org/imbruvica (accessed on 10/25/2022). However, in the ANDA litigation between the patentee and the generic company Alvogen, only 5 claims selected from 4 patents were actually adjudicated. Alvogen could enter the market with its specific generic product at issue upon finding of non-infringement or invalidity of these 5 claims, instead of challenging and overcoming each and every patent in the alleged "patent wall". The district court upheld the validity of these 5 claims and found Alvogen infringed all of them, and the Federal Circuit affirmed. *See Pharmacyclics LLC v. Alvogen, Inc*., 2022 U.S. App. LEXIS 31479 (Fed. Cir. 2022).

[10] See, e.g., *Blonder-Tongue Labs. v. University of Illinois Found*. 402 U.S. 313, 329 (1971) ("[Some litigants] have never had a chance to present their evidence and arguments on the claim. Due process prohibits estopping them despite one or more existing adjudications of the identical issue which stand squarely against their position.").

[11] 35 USC §282(a)

claims in a continuation patent may lack a patentable distinction over the parent.[12] This approach discourages patentees from asserting a terminally disclaimed patent that is truly obvious over the reference patent that has been finally decided to be unpatentable or invalid due to prior art. This well-established approach has proven to be effective in helping streamline the resolution of patent disputes involving obvious-variant patents. We believe that the Federal Circuit's approach – considering terminal disclaimers relevant but not conclusive – strikes the right balance between different policy considerations and should be adequate to address the policy objective that the USPTO attempts to achieve through the proposed restrictions.

Accordingly, we urge the USPTO to reconsider its proposed restriction on terminal disclaimers.[13] We also encourage the USPTO to investigate the factual basis for the narrative that a large number of "obvious-variant" patents unreasonably delay generic and biosimilar entry (which we believe is not supported by sound evidence), and consider whether the Federal Circuit's approach on terminal disclaimers would adequately address the USPTO's concerns.

### 3. Increased Scrutiny Should Apply to All Types of Patent Applications

We welcome "increased scrutiny" and "heightened examination requirements" for all types of applications to the extent the USPTO has good reason to believe these standards are not currently being applied/adhered to. We believe that greater scrutiny under the preponderance of evidence standard will likely help improve patent quality, reliability and predictability. However, we are concerned that the RFC proposals appear to limit increased scrutiny to only certain types of patent applications, particularly continuation applications. We believe that this would raise the question of whether the USPTO would apply a different evidentiary standard, other than the preponderance of evidence standard, to the examination of continuation applications. It also raises the question of whether other patent applications would be subject to less scrutiny and therefore potentially result in less patent quality. We believe that the USPTO should apply the same

[12] *See SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018) ("a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent. But as our precedent indicates, that strong clue does not give rise to a presumption that a patent subject to a terminal disclaimer is patentably indistinct from its parent patents.")

[13] We also question whether the USPTO has the necessary statutory power to expand or modify the judicially created remedy of using statutory terminal disclaimers to overcome judicially created OTDP rejections. In addition, certain proposals (e.g., the stipulation and the expanded use of 37 CFR 1.78(f) proposed under Question 4(h)) could contradict Federal Circuit case law or the governing statutes. *See, e.g.*, *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018) ("our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims."); and 35 USC §120.

evidentiary standard and the same level of heightened scrutiny to all types of patent applications.

AbbVie appreciates the opportunity to submit comments. We look forward to continued dialogue with the agency and other stakeholders on these issues. If you require further clarification on any comments provided above, please do not hesitate to contact us.

Respectfully submitted,

AbbVie Inc.
1 North Waukegan Road
North Chicago, Illinois 60064