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The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and Director
United States Patent & Trademark Office
P.O. Box 1450
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Comments submitted via https://www.regulations.gov/

Re: Amgen's Comments in Response to the USPTO's Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025)

I. Introduction

Amgen submits these comments in response to the United States Patent and Trademark Office's (USPTO) Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60,130-60,134 (Oct. 4, 2022).

Amgen is the world's leading independent biotechnology company. We began as a venture capital startup in 1980, based in Thousand Oaks, California, and we have since grown into a company that employs over 24,000 people with operations in over 100 countries. Most importantly, we serve millions of patients with life-altering medicines. Amgen was a pioneer in the science of biotechnology—using living cells to make what are called "large molecule" medicines such as proteins and antibodies. We helped invent the processes and tools that built the global biotech industry—turning it into what is today the leading source of new therapies for patients.

Our mission is to serve patients by discovering and developing medicines that treat serious

illnesses, and we typically address diseases with significant unmet medical needs having no or limited treatment options. We have over two dozen products on the market that treat diseases as wide ranging as anemia, rheumatoid arthritis and post-menopausal osteoporosis and life-threatening illnesses like cardiovascular disease and cancer.

To be successful, Amgen must innovate across a broad range of disciplines: basic scientific research to understand disease mechanisms; clinical science to understand disease pathologies and patients' need; drug design and molecular architecture to create new and improved classes of drugs; and commercial scale manufacturing processes to ensure we have an adequate supply of safe, reliable medicines to treat every patient, every time. We are revolutionizing progress in these areas by leveraging new tools and technologies such as the extraordinary power of genomics and proteomics to understand disease processes at the level of individual patients and artificial intelligence/machine learning to exponentially increase the power, speed, and efficiency of drug discovery and development. Our commitment to innovation is the key and it comes at a high cost. Last year alone, Amgen invested almost $5 billion in research and development. Of that amount, we spent $1.78 billion in later-stage clinical programs.

Bringing medicines to market is a high risk, high cost, lengthy product development cycle process. No other industry faces challenges as daunting. Our business model requires strong, meaningful patent protection for the products that obtain the necessary FDA approval and we bring to market. In our industry, most of the product candidates we invest in will fail to ever reach the market. We pursue this risky innovation and rely on the protections of the patent and regulatory systems to allow us to recoup our investments on the products that succeed and all the ones that fail as well.

Because Amgen is a world leader in the manufacture of protein-based therapeutics, we

have applied our manufacturing and clinical development capabilities to bring biosimilar products to the market. Being a leader in both innovative large molecule therapeutics and biosimilars, Amgen has a unique perspective on the patent system and how it can be even more fair and more effective in driving innovation in this country.

With all the current talk about what is wrong with the U.S. patent system, Amgen is here to say what is right with it. Amgen's history shows what can happen with great science, great products, and a strong patent system. Amgen's scientists made the breakthrough inventions that resulted in new therapies, the USPTO examined and issued patents on those inventions, and Amgen was able to enforce those patents in the courts to keep competitors from misappropriating our inventions. And we continue to heavily rely on the patent system. We expect and need rigorous examination of patent applications, our own and others, so that there is more predictability in the system. We need strong, enforceable patents to encourage investment and bring new products to market. And it is not just Amgen or just the biopharmaceutical industry that relies on the U.S. patent system; our innovation driven economy is based on the protections afforded by patents. We applaud the central role that the USPTO has played and continues to play in ensuring that inventors receive the protections they deserve for their inventions and the resulting impact patents have on promoting tremendous advances across all technologies to the benefit of our society.

Work remains to be done, however, as there are still areas where improvements can be made. Quality of patent examination remains a concern, as, unfortunately, there are instances where the USPTO issued patents it should have rejected. Such patents are often challenged in post-grant proceedings. So many of the complaints about our patent system are addressed principally by improving the quality of patent examination. Most of the proposals to change

USPTO rules or processes are rendered unnecessary with improvements in patent quality. From our perspective, we see instances where the patent examiners fail to consistently apply the statutory requirements for patentability, and other cases where the examination was inadequate due to lack of sufficient time, understanding of the invention or the prior art, or simply lack of effort on the part of the examiner. Training examiners on the law, allowing sufficient time for a thorough examination, and internal checks on quality are key steps to improving the quality of patent examination. We support and encourage the Office to focus on the steps needed to better train its examiners to understand and consistently apply the statutory requirements for patentability.

Another concern we have is the current trend to unnecessarily narrow the scope of claims to be less than the scope of the patent disclosure. To be effective in incentivizing investments in innovation, patent claim scope must be meaningful. A patent applicant is entitled to protect her invention to the breadth of what her disclosure teaches those skilled in the relevant art. It rewards a patentee nothing for bringing forward her invention if the USPTO issues only narrow claims where the patent teaching is much broader thereby allowing a competitor to appropriate the disclosed invention and escape infringement of the narrow claims. A patent system that rewards inventors of breakthrough inventions with only narrow patent claims fails to provide the incentives to pursue such breakthroughs but instead channels investments into copying the work of others. So, the question is: what do we want our patent system to incentivize? Breakthrough innovations or copying? If we want to continue to see remarkable, breakthrough innovations to address the societal needs we face, be it in healthcare, climate change, or across the various technologies of our economy, then the patent system needs to reward such breakthroughs with patent claims commensurate in scope with the invention.

As you are aware, Amgen currently has a case pending before the United States Supreme

Court seeking to reverse the Federal Circuit's recent application of the enablement standard to invalidate patents that claim more than the specific embodiments disclosed in the patent specification even though the teaching of the patent disclosure enables so much more. The two patents involved in the case relate to Amgen's breakthrough invention of antibodies that dramatically lower levels of LDL cholesterol. The patents claim antibodies that bind to a small region on a target protein, PCSK9, and block the interaction of PCSK9 with the LDL receptor. The patents disclose 26 exemplary antibodies within the claims together with the methods that can be used to obtain all the antibodies within the claims. While the inventors selected 26 antibodies for further characterization, including amino acid sequencing, the patents indicate that the inventors isolated many more antibodies within the claims. The USPTO properly issued these patents and two juries have upheld them against multiple validity challenges. In our view, if the U.S. patent system is to "promote the progress of science" and encourage inventors to invest their time, effort, and limited resources to achieve such breakthroughs to the benefit of our society for decades to come, the USPTO needs to continue to issue patents with claims commensurate in scope with such breakthrough inventions, and the courts need to uphold them.

More than any other industry, the biotechnology industry relies on IP protection that is both strong and fair. The USPTO is our essential partner in the effort to keep our patent system as a main driver of innovation in this country. Currently, there is much confusion among the policy makers on how to achieve that goal. We submit that improving patent quality and issuing claims of meaningful scope are important steps to take. In addition, we would like to respond below to some of the questions posed in the Request for Comments and share our thoughts on several ways the USPTO can improve its initiatives to ensure the continued robustness and reliability of our patent system.

II. The USPTO Should Maintain its Current Continuation Application Practices (Questions 4(f), 8-10)

A. Continuation practice is beneficial to patent applicants, patent examiners, and the public by encouraging early and complete disclosure of inventions and efficient examination

Continuation applications provide important benefits to the USPTO, the public, and the inventing community for several reasons.

Patent examination is an iterative process. For most patent applications, the process of examination involves an exchange of viewpoints between the examiner and the applicant to come to an agreement on the language and format to use to claim and distinguish the invention over the prior art. The examiner and applicant may have different views on the scope of the invention, the teachings of the patent disclosure, the teachings of the prior art, and the words that can be used in a patent claim to describe the invention. Given the limitations on the examiner's time and resources, as well as the applicant's, agreement on all these points is rarely accomplished with the initial filing and examination. Rather, the process of coming to agreement requires a series of back-and-forth, iterative exchanges – Office Actions and responses – that help clarify and narrow how the claim language should capture the invention eventually resulting in an allowance of patent claims or a final rejection that an applicant can appeal.

Often, the invention disclosed in an application has various features that can be included or not in the patent claims, and an applicant may feel that a first set of allowed claims may not capture the full scope of her invention. Continuation practice allows this examination process to "continue" beyond a single patent filing and allowance of a single patent. Applicants and the USPTO continue to work cooperatively and iteratively to best define and delimit the inventions in an application. The practice of filing continuation applications permits a patent applicant to agree to one set of claims and then continue to pursue claims of different wording, scope, and variation

that were either not presented or were not agreed upon in the initial examination. Continuation practice promotes efficient patent examination because it removes agreed upon claims and allows them to issue as patents so that the areas that are not yet agreed upon become more focused in the examination of claims in a continuation application. Patents issue sooner thereby providing the public with clarity on the subject matter that is protected. Without continuation practice, the initial set of claims would be lengthy (or more likely, multiple applications would be filed on the same day) to capture all the variations on claiming the invention. Either alternative would greatly increase the burden on the USPTO. Continuation practice has proven to be a more effective and efficient way to allow the patent applicant to protect the full scope and variations of her invention in somewhat of a step-wise progression of patent prosecution.

Early and full disclosure of inventions. Continuation practice is also beneficial to the patent applicant, and ultimately the examiner, in the efficient drafting and preparation of a single patent application. Knowing that claims of different scope and including different features can be pursued in one or more continuation applications, an inventor describes her invention fully in a single application – in both broad and narrow terms to support claims of varying scope. As opposed to doing it in multiple fragmented patent filings, continuation practice provides the ability of an applicant to fully disclose her entire invention and related technologies in a single application. And it gives the public all it needs to understand an advancement in the field in a single document. Disclosing all aspects of an invention in a single patent application is more efficient and cost effective for the applicant and results in earlier, more fulsome patent filings.

On the other hand, limiting the number of continuations would force an applicant to divide inventions among different patent families to allow for flexibility in prosecution and claiming strategy. If limitations were placed on the number of continuation applications, applicants would

have to file multiple applications on the same day leading to increased costs for both the applicant and the USPTO. Such fragmented patent families would also harm the public by making it more difficult to conduct freedom-to-operate analyses as they will need to review multiple patent families instead of one.

Efficiency of examination and reliability of patents. The USPTO should maintain its current continuation practice because it promotes efficiency and consistent decision making. Under the current system, an examiner who is assigned a parent application typically is also assigned its continuation applications. As prosecution of the family advances, he or she becomes increasingly familiar with the family's subject matter and so can efficiently examine each new continuation application. A single examiner also ensures consistency in examination decisions across the patent family, promoting robustness and reliability of the patent rights. If continuation practice is limited, applicants will instead file multiple independent applications that may be assigned to different examiners. This would unnecessarily burden both the USPTO and the applicant, requiring multiple examiners to come up to speed on the same or closely related subject matter. It would also increase the likelihood of inconsistent decisions between similar applications creating uncertainty about the scope and validity of patents that are issued.

Serving business needs. Continuation applications allow an applicant to prioritize the timing and order of the issuance of patents covering its related inventions. This can be especially important for start-ups or small businesses with limited resources as obtaining early issuance of a patent claiming one aspect of an invention (while others can be pursued in subsequent continuation applications) can help them attract licensees or obtain funding from third-party investors to continue their research and development efforts. Continuation applications also give an applicant the flexibility to adapt her claiming strategy to changing priorities and circumstances.

For example, a parent application might be filed that discloses multiple related product candidates. At the time of filing, one of them might be the most promising candidate for commercialization and thus be the focus of prosecution for the parent application and its first few continuation applications. If it later emerges that one of the other candidates disclosed in the parent application is even more promising, the applicant can file continuation applications directed to it. If applicants are restricted in the number of continuation applications they can file, they will either file independent applications on each product candidate, if they can afford it, or be left with the risk of not being able to protect their ultimate commercial product.

B. Continuation applications must meet the statutory requirements for patentability and cannot be used to extend the term of a patent family and thus do not require special examination rules.

Continuation applications must meet the same statutory patentability requirements as original patent applications—including sufficiently disclosing and claiming an invention that is novel, and non-obviousness over the prior art. Therefore, there is no need to create a heightened examination requirement or special examination procedures for continuation patents.

There are several common misconceptions about continuation practice that the USPTO should dispel. First, continuation applications do not extend the patent term of any patents within the family. Subject to limited and statutorily authorized exceptions,[1] a patent issued from a continuation application expires twenty years from its parent application's filing date, regardless of when the continuation application is filed. Therefore, all the patents that issue from the parent application will expire on the same day, and continuations cannot be used to extend the term of a patent family.

[1] Patent term extension ("PTE") and patent term adjustment ("PTA") are mandated by the Patent Statute under 35 U.S.C. §§ 156 and 154, respectively, to provide extended patent terms beyond twenty years to account for the time needed to obtain FDA approval and USPTO delays.

Second, a continuation application cannot be used to claim an invention that was not disclosed in its parent application. The USPTO requires that the disclosure presented in the continuation must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application. See MPEP § 201.07. The parent application must provide written description and enabling support for the invention being claimed in the continuation application. 35 U.S.C. §112. This rule limits the scope of continuation patent claims to inventions that were already disclosed in the parent's specification.

Third, issuing multiple patents from a single, common patent disclosure achieves the worthy goal of ensuring that patent applicants receive the full patent protection for their inventions as permitted under the law. Why would we strive for anything less? For over two centuries, the U.S. patent system has driven innovation and technological breakthroughs because it allows an inventor to protect her inventions. As we review ways to improve the patent system, we should be discussing ways to enhance the ability to obtain such protection and continue to drive innovation instead of ways to limit protection and thereby hinder innovation.

C. Medicines are complex discoveries that often warrant continuation applications and later patent filings on new inventions.

Continuation practice is critically important to the pharmaceutical industry. On average, it takes more than a decade of research and development and roughly $2.6 billion to obtain approval to bring a medicine to market.[2] And this effort results in multiple inventions; some made at the early stages of research in creating the therapeutic molecule, and others made later as the product is tested in clinical trials and prepared for patient use. We should expect that all of this inventive activity should result in more than a single patent protecting a pharmaceutical product, its

[2] Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. HEALTH ECON. 20-33 (2016).

manufacture and uses.

Pharmaceutical patent applications are rich tapestries woven from sometimes disparate areas of scientific efforts. Numerous innovations may be disclosed within a single patent application. For example, a patent application disclosing a new potential therapeutic product will also typically disclose potential uses in treating certain classes of patients, ways to formulate and deliver the product to patients, and ways to make such product.[3] Indeed, Section 112 of the Patent Statute requires a patent disclosure to teach how to make and use the invention.

Current continuation practice allows an applicant to make a complete disclosure of her discoveries in a single document, allowing the public to learn how all aspects of the invention work together. Moreover, current continuation practice provides flexibility to applicants who are operating in a lengthy, expensive, and risky research and development process. As noted, continuations provide flexibility to companies to disclose several inventions in a single application with the option of adjusting their claiming strategy as they learn more through the lengthy research and development process. This is especially important in the pharmaceutical industry, as a company may determine during the research process that the safest, most effective, or most commercially viable variation or configuration of a pharmaceutical product was a candidate disclosed but not claimed in the parent application. As additional data becomes available during the development process, companies may find that a compound originally being pursued does not meet FDA approval standards, but an alternative compound disclosed in the original patent's specification is safer and/or more efficacious and should instead be pursued for development. Continuation applications allow for the inventor to focus first on what at the time seems most

[3] Patent applications on new therapeutics are filed before any public disclosure or clinical testing of the new therapeutic and many years before the product is shown to be safe and effective and receives FDA approval.

important to obtain patent protection on and then to pursue additional aspects of the invention or products that are disclosed in the parent application but were not the subject of the original claims.

To be clear, inventions continue to be made with respect to pharmaceutical products as the products move through clinical testing and are prepared for patients' use. These later inventions may be improvements on what was known and disclosed in the original compound patent and are filed as independent patent applications that are not continuations of the original application on the compound itself. If these later patent filings meet the patentability requirements and are issued, these improvement patents have their own twenty-year patent term. Such improvements may relate to the specifics of the product's uses, formulations, methods of commercial manufacture, etc. and must be novel and non-obvious over the prior art, including the disclosure of the compound patent in most instances, to be patentable. Many of these later inventions can represent important steps in making the product available to treat a variety of patients. Here again, we submit that any perceived problems with later filed patent applications on a pharmaceutical product are best addressed by the USPTO ensuring the quality of examination and a consistent application of the statutory requirements of patentability.

Given the rhetoric about some pharmaceutical patents "extending the patent term" on a product and statements made by commentators who should know better, it is important to clarify that these later separate patent filings do not extend the term of the original product patent, but they only protect the specific invention claimed therein—be it a new use, formulation, or method of manufacture. Competitors and the public are free to practice the original compound patent when it expires but must take steps to ensure that they avoid infringing any later filed improvement patents.

Amgen confronts the issues of continuation filings and later filed improvement patents both as an innovator and as a biosimilar manufacturer. Having these dual perspectives, we submit that instead of seeking to limit the number of continuation filings or adopt special examination processes for continuation applications or later improvement applications, the USPTO should focus on improving the quality of patent examination to ensure that the statutory requirements are met; the inventions are novel, nonobvious, and adequately described in the patent disclosure. If the patent claims meet the statutory requirements, then competitors must wait to use those claimed inventions or design around them. In this way, the patent system balances the need to incentivize innovation by providing valid patent rights for a limited time and will continue to be the driver of advances in science and technology.

D. Limiting the number of continuation applications will not reduce litigation costs in challenging patents.

Some critics of continuation practice assert that continuation applications lead to an increase in the number of patents which a competitor must challenge either in post-grant proceedings or in district court litigation with a corresponding significant increase in the cost of such challenges. We submit that limiting the number of continuation applications will not reduce the burden or expense of challenging a portfolio of patents.

As explained above, continuation applications are necessary to ensure that an inventor can secure patent protection for the full scope of her invention. Placing limits on the number or the timing of continuation applications would result in applicants filing multiple patent applications on the same day in order to preserve the ability to seek different claims from the same disclosure. In our view, imposing such limitations will result in more patents in a portfolio, not fewer, with equal or even higher burden and costs in challenging them.

Given that continuations share the same disclosure and prior art as the parent patent, litigation including more than one patent from a family does not typically result in a significant increase in costs because the work performed to litigate the parent patent often applies to the related continuations. For example, fact and expert discovery on the validity arguments are substantially the same across patents within the same family. The court may also seek to narrow the case through imposing limits on discovery and through summary judgment and other pre-trial motions. When it comes to trial, it is the number of claims that are presented and not the number of patents that is the driver of complexity and cost. District courts typically require the patent owners to narrow the number of claims asserted to a manageable number to reduce the burden on the parties and the court. So, whether the claims to be tried are presented in one or two patents or a dozen, the number of claims to be tried will likely be similar with no reduction in litigation costs. We submit that the current continuation practice has worked well for many decades, and the USPTO should defer to the courts to resolve any concerns or issues regarding the efficiency of litigating multiple patents in a single lawsuit.

III. The USPTO Should Abolish the Practice of Rejecting Claims Under the Non-Statutory Doctrine of Obviousness-type Double Patenting (Questions 4(h), 6-7)

A. Non-Statutory Obviousness-type Double Patenting ("OTDP") is a judicially created doctrine that no longer applies to examination of patent applications by the USPTO

In its Request for Comments, the Office asks several questions related to OTDP and terminal disclaimers, albeit with perhaps a different view in mind than what we propose, centering on whether the USPTO should stop its current practice of issuing OTDP rejections to related patent applications and allowing those rejections (typically cast as "provisional" rejections if the applications are co-pending) to be overcome by a terminal disclaimer. We agree that the USPTO should stop rejecting applications based on OTDP because there is no statutory basis for such

rejections and the USPTO has no authority to reject applications on such a non-statutory basis. Similarly, there is no statutory basis for requiring a patent applicant to disclaim patent term or pledge to maintain common ownership of patents to secure allowance and issuance of a patent. Whatever law the courts create on OTDP, sitting in equity and judging any specific set of circumstances to find an improper extension of patent term, gives no authority to the USPTO to adopt and employ the doctrine. Examination of patents by the USPTO and the requirements for patentability are governed by statute, not by principles of equity.

1. Same invention double patenting has a statutory basis under § 101

"Statutory" double patenting bars an inventor from having two patents with the same claim (or with claims that are effectively identical). The prohibition against statutory double patenting arises from 35 U.S.C. § 101, which allows an inventor to "obtain a patent." Because it arises from applying the statute, it is properly addressed in examination by the USPTO. As statutory double patenting requires the same claim in two patents, it is relatively easy to avoid by making claim amendments.

2. Obviousness-type double patenting has no statutory basis

In contrast, OTDP has no basis in any provision of the Patent Statute – it is "non-statutory."[4] As applied by the USPTO, "obviousness-type" double patenting bars an inventor from obtaining a patent with a claim that is obvious over a claim in another of the inventor's or her assignee's patents. But this practice has no basis in statutory law and was created by judges to address improper extensions of patent terms resulting from lengthy delays in prosecution at the

[4] Sherry Knowles, "Let's Do Something About the Unauthorized Doctrine of Non-Statutory Judicially Created Obviousness-Type Double Patenting," IPWatchdog.com (Sept. 6, 2022), available at https://ipwatchdog.com/2022/09/06/lets-something-unauthorized-doctrine-non-statutory-judicially-created-obviousness-type-double-patenting/id=151271/

USPTO under the prior seventeen-years-from-grant patent term law. *See In re Schneller*, 397 F.2d 350, 354 (CCPA 1968). Court decisions describe the dual purposes of OTDP as (i) preventing an inventor from extending the life of a first patent by obtaining a second patent claiming an obvious variation of the first patent and (ii) to protect third parties from harassment by multiple patent owners in connection with the same invention. But for purposes of the role of the USPTO in examining patent applications and issuing patents, OTDP is unnecessary to achieve either goal.

3. With the change to a twenty-years-from-filing-date patent term, examination proceedings in the USPTO can no longer result in "improper" extension of patent rights

When the courts created the doctrine of OTDP, U.S. patents expired seventeen years from their issue date. Courts developed the OTDP doctrine to prevent patent owners from extending their effective patent term beyond seventeen years after issuance of a first patent by purposely causing delay in the examination and/or issuance of a second, related patent. But patents granted on applications filed since June 1995 – when the statutory term changed in furtherance of U.S. law coming into agreement with the General Agreement on Tariffs and Trade (GATT) – are limited to a term that expires twenty years from their earliest priority filing date, regardless of when the patents are issued.[5] Thus, it is not possible to extend the term of a patent by delaying its issuance, and the primary purpose served by OTDP no longer exists.

i. Patents issuing from the same priority filing expire at the same time except for possible PTE and PTA which is statutory and thus not "improper"

Today, patents issuing from the same priority filing will expire on the same day, except where Congress has authorized a patent term extension under 35 U.S.C. § 156 or patent term

[5] The only exceptions are the two statutorily mandated patent term extensions (PTE) and patent term adjustments (PTA) addressed below.

adjustment under 35 U.S.C. § 154(b). These types of extensions are not the type of unjustified timewise extensions that OTDP was created to remedy[6]; rather, they are statutorily mandated, reflecting the legislature's decision to adjust the statutory term of a patent due to delays (whether in securing regulatory approval by the FDA under § 156 or the USPTO taking longer to issue a patent than contemplated under § 154(b)). PTA and PTE compensate for reductions in patent term that are beyond the patent owner's control and are not the fault of the applicant—the very opposite of an unjustified extension.

The Federal Circuit has held that a statutorily-mandated patent term extension under § 156 cannot give rise to OTDP. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018). Section 156 reflects the carefully tailored legislative decision to adjust the statutory term of a patent based upon a calculation of the time a product was in clinical testing and review by the FDA. *Cf. O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994) (courts should not "adopt a court-made rule to supplement federal statutory regulation that is comprehensive and detailed").

The same is true for Congressionally authorized patent term adjustments under 35 U.S.C. § 154(b). The text of the Act is clear and mandatory: when the Patent Office fails to meet certain statutory deadlines in examination, the "term of the patent *shall be extended* 1 day for each day" of Patent-Office delay. 35 U.S.C. § 154(b)(1)(A)(iv) (emphasis added). This patent term adjustment was introduced as a "patent term guarantee" to facilitate the transition from a seventeen-years-from-date-of-*issue* patent term to the current twenty-years-from-date-of-*filing* regime, where delays in prosecution at the USPTO would otherwise result in a shortened effective patent term. Using OTDP to deprive a patent of its patent term adjustment contravenes the very purpose of § 154(b).

[6] *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013).

ii. Patents issuing from later-filed priority applications are entitled to their own term

Section 154(a)(2) states that, once issued, a patent shall have a term that is twenty years from the earliest application to which it claims priority. 35 U.S.C. §154(a)(2). Thus, a later filed patent application, if issued, is entitled to its own twenty-year term from its earliest priority filing which cannot be shortened by OTDP or by requiring a terminal disclaimer. The Statute says nothing about shortening patent term for these reasons. Thus, a patent issuing on a second, later application filed by the same inventor of an earlier first application, or by a different inventive entity but assigned to the same assignee as the first application, is entitled to a patent with a full twenty-year term from its own priority date.[7] The Statute says nothing about using OTDP to prevent the issuance of the second patent even in view of the first. Only if the first application falls into one of the categories of prior art described in §102 can the second application be rejected over the first patent. Far from being "improper," this is the direct result of the plain language of the Patent Statute.

4. Later-filed patent applications are subject to the same statutory requirements for patentability as earlier-filed patent applications

Each patent application must be examined on its own merits and must meet the same statutory patentability requirements—including disclosing an invention that is new and useful, novel, and non-obviousness over the prior art and supported by a description of the invention and the manner and process of making and using it.[8] There is no statutory basis for denying an application satisfying these statutory requirements, regardless of when it was filed or whether it

[7] In *Gilead Sciences, Inc. v Natco Pharma Ltd*., 753 F.3d 1208 (Fed. Cir. 2014), however, the Federal Circuit permitted a later-filed, but earlier expiring patent to be used as an OTDP reference without consideration of the filing date or issue date. Again, the courts have the authority to decide cases based on non-statutory principles of equity, but the USPTO does not.
[8] *See* 35 U.S.C. §§101, 102, 103 and 112.

was filed as a continuation of an earlier filed patent application. The Patent Statute, 35 U.S.C. §101, makes plain that an inventor of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Section 102 states, "A person shall be entitled to a patent unless –" the invention lacks novelty as described in one of the subparagraphs of section 102. Section 103 adds the limitation that an invention cannot be obvious over the prior art as described in section 102. The Patent Statute sets the requirements to obtain a patent and OTDP is *not* listed as a bar to obtaining a patent. The USPTO does not have the authority to impose additional non-statutory patentability requirements such as OTDP.

5. There is no statutory basis for requiring common ownership for patent issuance

Requiring a patent applicant to submit a terminal disclaimer in order to obtain issuance of a patent is also not found in the Patent Statute. While the statute does allow a patent owner to voluntarily disclaim all or part of a patent term of an issued patent, 35 U.S.C. § 253, there is no provision requiring a terminal disclaimer to overcome an OTDP, or any other, rejection.

Moreover, the Patent Statute says nothing about "common ownership" of related patents as a requirement for patentability. 35 U.S.C. § 103(c) is the only provision that mentions common ownership, but it has nothing to do with OTDP or terminal disclaimers as it defines exceptions to certain categories of prior art under Section 102(e), (f), and (g) where "the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person." It does not create a requirement that two patents must be commonly owned to issue.

B. OTDP policy and equitable considerations are best left to the courts

OTDP was created by the courts under the prior patent term law in equity to address

gamesmanship by patent applicants who were unfairly extending the then seventeen years from issuance patent term by delaying issuance of a patent and seeking a string of multiple patents each with its own seventeen-year term. But patent examiners are not judges and they are not trained to decide matters of equity. And they have no ability to research or discover the facts required to make such determinations. Courts are better positioned than the USPTO to consider and decide such equitable issues that may be proven in court.

First, as explained above, non-statutory OTDP should find little, if any, application under the new term provided by the Patent Statute. If there are circumstances that still invoke OTDP and its equitable considerations, the courts are equipped to discover and evaluate the facts and determine whether the patent term has been "unjustly" extended through, e.g., misconduct by the patent applicant.

Second, the purported rationale for requiring "common ownership" of patents issuing from the same or related priority filings—to avoid "harassment" of infringers by multiple patent lawsuits by different patent owners -- lacks any real-world evidence that this problem ever existed. In fact, the "first-to-file" patent system that we now have allows the situation in which unrelated owners could each own a patent claiming the same or similar inventions. This would be the result of two separate inventors filing patent applications on the same day claiming the same or overlapping inventions. Under the provisions of the AIA revised Patent Statute, both inventors could obtain a patent on their inventions and could separately sue an infringer. If the Patent Statute allows this outcome from separate patent filings, why should two patents issuing from the same application be any different or of more cause for concern?

In the unlikely event that separate patents issuing from the same parent application are assigned to separate assignees who each bring a separate infringement action against an infringer,

any concerns about "harassment" are best addressed and remedied by a district court if such a scenario ever becomes real. A district court has procedures available to address any concern about harassment of an accused infringer by multiple assignees, for example, by requiring joinder of parties under the Federal Rules of Civil Procedure. By contrast, the USPTO has no basis for rejecting a patent application and requiring a blanket pledge of "common ownership" for the life of the patents on the remote possibility that at some future time the issued patent is transferred to a different entity and is used to harass some infringer via the filing of separate lawsuits. The courts are most qualified to sort that out if in fact it ever occurs.

C. OTDP terminal disclaimers should also be eliminated

The USPTO rules regarding OTDP terminal disclaimers are based on a C.C.P.A. decision, not on a statute.[9] In fact, in *In re Robeson*, 51 C.C.P.A. 1271 (1964), the C.C.P.A. admitted that whether a terminal disclaimer can be used to overcome objections to double patenting was not clear from the wording of 35 U.S.C. § 253, which provides that "any patent or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted." On its face, it's clear that this statute is voluntary—an applicant "may" disclaim some or all of her patent. This statute does not *require* applicants to terminally disclaim their patent term to overcome an OTDP rejection. Nonetheless, the court divined that Congress would not have wanted obviousness-type double patenting for a variety of reasons, and that the terminal disclaimer should be accepted to overcome it.

After the *Robeson* decision issued, the USPTO added 37 C.F.R. 1.321(c) to authorize

[9] Caitlin O'Connell, et al., "The CCPA's Influence on Obviousness-Type Double Patenting Jurisprudence," Finnegan Blog, available at https://www.finnegan.com/en/insights/blogs/prosecution-first/the-ccpas-influence-on-obviousness-type-double-patenting-jurisprudence.html; see also MPEP § 1490.

terminal disclaimers to obviate an obviousness-type double patenting rejection. The promulgation of this regulation thus did not arise through Congressionally authorized rulemaking, but through judicial rulemaking. And "there has been no clear delegation of authority under *Chevron U.S.A., Inc. v. Natural Resource Defense Council*, 467 U.S. 837 (1984) to the [the agency] to generate an entire body of regulatory law on obviousness-type double patenting and associated terminal disclaimers."[10]

D. Ending OTDP and terminal disclaimers will result in more focused examination and possibly fewer patents

The USPTO's guidance to examiners on OTDP is complicated and lengthy. Eliminating such rejections would allow the examiners to focus on the statutory requirements for patentability. OTDP is described in MPEP §804 which goes on for pages and pages, includes multiple flow charts to illustrate various scenarios that may or may not implicate OTDP, discusses the one-way and two-way tests applied in some court decisions, reviews principles of equity that may serve as the basis for an OTDP rejection and on and on it goes. For an examiner faced with making a possible OTDP rejection to study, comprehend and apply these pages of guidance could take hours – time that would be much better spent on examining the application and claims for compliance with the requirements of Sections 102, 103 and 112.

In many cases, it seems that examiners rely on OTDP to force the filing of a terminal disclaimer and then fail to conduct a thorough examination on the statutory requirements. Issuing

[10] Sherry Knowles, "Damage to Our Patent System by Failure to Honor the U.S. Legal Framework: Double Patenting," IPWatchdog.com (Aug. 27, 2019), available at https://ipwatchdog.com/2019/08/27/damage-patent-system-failure-honor-u-s-legal-framework-double-patenting/id=112629/#:~:text=Sherry%20Knowles%20August%2027%2C%202019%2C%2005%3A30%20PM%2010,doctrine%20is%20not%20authorized%20by%20a%20congressional%20statute

an OTDP rejection and withdrawing it in exchange for a terminal disclaimer offers an examiner a tempting but expedient alternative to a rigorous analysis of patentability against the prior art. Knowing this, patent applicants will often file more related applications, a practice that can ironically lead to the issuance of more patents from a patent family, not fewer. As a result, ending the practice of rejecting applications on OTDP could quite possibly result in fewer continuation applications and fewer patents.

E. European Patent Office ("EPO") practice shows that OTDP-style rejections and terminal disclaimers are unnecessary

Eliminating OTDP rejections and terminal disclaimers at the USPTO would help harmonize U.S. patent law with practices in other countries. Amgen routinely prosecutes applications in patent offices around the world, and in none of them have we encountered OTDP and terminal disclaimer rules like those in the US.

Prosecution practice in the EPO provides a useful case-in-point. While the EPO's Guidelines for Examination G-IV, 5.4 proscribe double-patenting of identical subject matter, like the U.S.'s statutory double-patenting law, the EPC does not have an equivalent to OTDP. The EPO will issue a patent on a second application having claims that overlap in scope with claims in a first application, should the second application otherwise meet the EPO's requirements for patentability. In these situations, an applicant is not required to disclaim any portion of the term of a patent issued from either application. This approach has not led to any of the problems imagined by proponents of the USPTO's current OTDP and terminal disclaimer practices.

Non-statutory OTDP is a court-made doctrine that arose in a prior era of patent practice that has no relevance to the examination of applications by the USPTO. Eliminating OTDP rejections and the associated filing of terminal disclaimers would allow examiners to focus more

on the statutory requirements for patentability and will likely result in better examination and fewer related patent filings.

IV. The Number of PTAB Challenges to Life Sciences Patents Fairly Reflects the Quality of USPTO Examination and the Availability of Statutory Litigation Pathways (Question 5)

The USPTO released a report in August 2021 providing data on post-grant petitions filed at the PTAB against Orange Book and biologic patents.[11] The report shows that such petitions represent only a small number of the petitions filed at the PTAB, namely 4% challenging Orange Book patents and 2% challenging biologic patents.[12] Some have questioned why the number of petitions remains low and why these patents survive post-grant challenges more often than patents in other technology sectors and are proposing changes to encourage more challenges to such patents. But there are rational explanations for why there are not more post-grant challenges of life science patents. First, given the potential importance of patents in life sciences, in most cases, the relevant prior art is disclosed by the applicant and considered by the examiner during examination. Second, despite the criticisms of some examination efforts described above, generally, examination of life science applications by the USPTO is rigorous and thorough. Third, the availability of statutorily defined litigation pathways – so-called ANDA litigation for Orange Book listed patents and BPCIA litigation for biosimilars – is a preferred route of challenge for many generic and biosimilar companies. For these reasons, there is no need to implement any measures attempting to increase the number of post-grant proceedings on life sciences patents.

A. Life sciences patents undergo more rigorous examination and have a higher likelihood of surviving invalidity challenges

[11] USPTO PTAB Orange Book Patent/Biologics Patent Study (June 2021 Update), available at www.uspto.gov/sites/default/files/documents/PTABOBbiologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf

[12] *See* footnote 12, *supra*.

Because it is understood that drug discovery and development is a long, costly, and high-risk process with many failures along the way, biopharmaceutical companies depend on strong patent protection throughout the period of exclusivity to recoup the investments made in the products that succeed and the products that fail. More than any other industry, the biopharmaceutical industry needs strong patent rights that can be relied upon for investment and bringing new innovations to market.

It is also understood by applicants that patents in the pharmaceutical and biotechnology space that protect commercial products are likely to be challenged in litigation by highly motivated generic or biosimilar manufacturers seeking marketing approval for a competing product. Because of their anticipated value and likelihood of being challenged, patent applicants in the life sciences have a great interest in a full and complete examination by the USPTO. Patent applicants are highly motivated to ensure that all the relevant prior art is disclosed during examination and considered by the examiner. Many applicants and their attorneys conduct searches of the prior art before drafting the patent application. The biopharmaceutical industry has generated a rich trove of journal publications, scientific literature, patent applications, and issued patents that can be readily searched. The relevant prior art located by such searching is disclosed and claims are drafted to be novel and non-obvious over the prior art. In addition, most patent applications in our industry are filed in many other countries as well as the U.S., and the prosecution of applications there provides more prior art to be cited in the U.S. prosecution. As a result, the examination of life science patent applications is generally more well informed as to the relevant prior art.

It is not surprising then, that parties seeking to challenge patents in the life sciences will be reluctant to bring a post-grant challenge based on prior art that was of record and considered by the examiner unless there is some reason to believe that the examiner simply misunderstood the

relevance of the prior art. It is also not surprising that the statistics show that life science patents survive validity challenges at a higher rate than patents in other industries. Patents claiming active ingredients have a 75% success rate in surviving invalidity changes, compared to approximately 41% across other industries.[13] Patents in our industry also fare better in post-grant challenges. They have lower institution rates than other technology sectors, and their claims are more often held to be patentable in final written decisions (59% of cases for Orange Book patents versus 44% for other technologies).[14] These statistics suggest that in most cases the USPTO does a good job examining and issuing patents in the life sciences. But the numbers also show that there is substantial room for improvement in the original examination to ensure that the requirements for patentability are met. Again, we submit that the USPTO should focus on providing robust original examination of applications to ensure that high quality patents are granted each and every time, rather than focusing on changes to the post-grant system to address IPR filing rates.

B. There are other statutory frameworks available to adjudicate the validity of life sciences patents.

With the passage of the Hatch-Waxman Act and the Biosimilars Price and Competition Act (BPCIA), Congress provided specific litigation pathways for challenging pharmaceutical patents. Both Congressional frameworks provide incentives to the patent challengers, for example, Hatch-Waxman provides a reward of 180-day exclusivity to the first applicant with a Paragraph

[13] Errol B. Taylor et al., "Focusing Only on Active Ingredient Patents Ignores Case Law Success Rates: Formulation and Method-of-Use Patents Provide Significant Protection for Medicines," Bloomberg Law (Oct. 27, 2011), available at https://news.bloomberglaw.com/pharma-and-life-sciences/focusing-only-on-active-ingredient-patents-ignores-case-law-success-rates-formulation-and-method-of-use-patents-provide-significant-protection-for-medicines

[14] https://www.finnegan.com/en/insights/articles/patent-trial-and-appeal-board-releases-updated-orange-bookbiologic-patent-study.html (reporting belove-average institution rates for Orange Book and biologic patents at 41% (excluding joined and pending petition) compared to 64% for other technologies).

IV certification. Likewise, a biosimilar applicant who has followed all the steps of the BPCIA controls the maximum number of patents that appear on each party's patent list, effectively limiting the scope of the litigation. By all accounts, the Hatch-Waxman and BPCIA pathways have successfully achieved the goals of facilitating generic and biosimilar entry. Today, 90% of all prescriptions dispensed in the United States are for generic pharmaceuticals.[15] As of January 2022, there were 33 FDA-approved biosimilars, 21 of which are now on the market, providing lower cost biosimilars to patients.[16]

Given that there are already established pathways to challenge biopharmaceutical patents that provide tangible benefits to the patent challengers, it is not surprising that the challengers elect to adjudicate validity of the biopharmaceutical patents via these pathways in federal district courts. And it is significant to note that a majority of the IPR and PGR filings on life science patents involve parties and patents that are already engaged in ongoing district court litigation. These duplicative post-grant proceedings result in increases in litigation costs without providing a significant benefit to the system.[17] Over two-thirds of IPRs filed on Orange Book-listed patents are filed after a generic manufacturer has been sued for infringement—resulting in parallel

[15] Institute Report, "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025," The IQVIA Institute (May 27, 2021), available at https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us

[16] Alexander Johnson, "How many biosimilars have been approved in the US?," Science Oxygen (Sept. 14, 2022), available at https://scienceoxygen.com/how-many-biosimilars-have-been-approved-in-the-us/#:~:text=Biosimilars%20are%20approved%20through%20an%20abbreviated%20FDA%20pathway%2C,available%20on%20the%20market.%20Table%20of%20Contents%20show

[17] Carlos Garcia et al., Ships in the night: Resolving administrative conflict between FDA and Patent-related legislation, 68 AM. U. L. REV. 1111 (2019), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3402656#

proceedings unlikely to resolve or simplify each other.[18] This is not surprising given the reward of the 180-day exclusivity for being the first ANDA filer, which incentivizes generic manufacturers to file an ANDA prior to filing an IPR or PGR petition at the PTAB. These duplicative proceedings are not what was contemplated by the statute, and we encourage the USPTO to continue to exercise its discretion to deny institution of petitions when there is a pending Hatch-Waxman or BPCIA litigation involving the same patent(s).

C. The number of AIA challenges to life sciences patents generally correlates with the number of Hatch-Waxman and BPCIA litigations

The number of AIA challenges to life sciences patents is not surprising because those numbers generally track the number of invalidity disputes that are raised in Hatch-Waxman and BPCIA litigation. The USPTO's updated Orange Book and biologics study demonstrates that the percentage of IPR petitions challenging Orange Book-listed patents dropped from a high of 7.9% in fiscal year 2015 to 0.2% in fiscal year 2021 through June 30, 2021.[19] The decline in AIA petitions challenging Orange Book-listed patents tracks the decline in ANDA case filings, which have fallen from a high of 479 case filings in 2015 to 102 in the first half of 2020.[20]

IPR petitions challenging biologic patents have also seen a downward trend from a high of 3.9% in fiscal year 2017 to a low of 1.6% for fiscal year 2021.[21] There has also been a decline in

[18] Jonathan J. Darrow et al., Will Inter Partes Review Speed U.S. Generic Drug Entry?, 35 NATURE BIOTECH. 1139, 1140 (2017), available at https://pubmed.ncbi.nlm.nih.gov/29220017/

[19] Amy C. Madl, et al., Patent Trial and Appeal Board Releases Updated Orange Book/Biologic Patent Study, Outsourced Pharma (Oct. 20, 2021), available at https://www.finnegan.com/en/insights/articles/patent-trial-and-appeal-board-releases-updated-orange-bookbiologic-patent-study.html

[20] *See* footnote 20, *supra*.

[21] *Id.*

new BPCIA case filings over those years.[22] While BPCIA litigation is not as closely correlated to PTAB challenges as ANDA litigation, with only 46% of biologic patents with an AIA petition in concurrent district court litigation between September 16, 2012, and November 30, 2018, "the downward trend observed in both forums suggests that PTAB challenges are neither displacing nor being displaced by district court litigation."[23] The numbers suggest that there was an initial surge of post-grant filings in the life sciences space when these actions became available only to decline as the number of ANDA and biosimilar litigations declined. Thus, there is no reason to believe that changes to the post-grant procedures are necessary to attract more challenges to life sciences patents.

V. CONCLUSION

While we do have some concerns, as outlined above, we acknowledge and appreciate the work that the USPTO and its examiners do in issuing patents that protect real inventions. We believe that the current system works well and there is no need to place limits on continuation applications or subject them to heightened scrutiny. And we submit that the USPTO should stop rejecting applications based on the non-statutory doctrine of obviousness-type double patenting and stop requiring terminal disclaimers to overcome such rejections for the reasons described above. We also recommend that the PTO continue to exercise its discretion to deny institution of IPRs of life sciences patents when there is a pending parallel Hatch-Waxman or BPCIA litigation. We would be happy to discuss these topics further with the Office or provide any additional information regarding these or other topics.

[22] Geoffrey D. Bielger, et al., Biosimilars 2022 Year in Review (Fish & Richardson Blog Jan. 17, 2023), available at Biosimilars 2022 Year in Review (fr.com) (Figure 2).
[23] *See* footnote 20, *supra*.

Respectfully submitted,

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