Genentech
A Member of the Roche Group

Comments on USPTO Initiatives
Docket No. PTO-P-2022-0025
February 1, 2023

Genentech appreciates the opportunity to respond to the questions that the USPTO posed in its Federal Register Notice dated October 4, 2022. Genentech shares the USPTO's goal of ensuring issuance of robust and reliable patents. Strong patents that reflect inventors' contributions to the art are the economic engine that drives innovation, and are especially important to the biopharmaceutical industry given the high cost and risk involved in drug discovery and development.

After briefly addressing the issue of drug pricing, Genentech's comments focus on two specific topics: continuation applications and terminal disclaimers.

Genentech

Founded more than 45 years ago, Genentech, a member of the Roche Group, is a leading biotechnology company that pursues groundbreaking science to discover and develop innovative medicines for people facing serious and life-threatening diseases. Our transformational discoveries include the first targeted antibody for cancer and the first medicine for primary progressive multiple sclerosis.

Today, we have more than 40 medicines on the market, 85 new investigational medicines in clinical development, and have received 39 Breakthrough Therapy Designations. Over the last twelve years, we have launched 23 groundbreaking medicines in areas of great need for innovation, including cancer, neuroscience, respiratory and ophthalmology diseases, as well as devastating rare diseases like hemophilia and spinal muscular atrophy. Additionally, over the lifecycle of a medicine, we are committed to investing in research to generate continuous clinical data.

In 2021 alone, Roche and Genentech combined invested $15 billion globally in R&D – more than any other healthcare company in the world. Over the past five years, we have invested more than $60 billion globally in R&D.

Today, Genentech is committed to finding treatments for life-threatening and difficult-to-treat conditions such as cancer, autoimmune conditions, neurological disease, infectious disease, and retinal disorders such as geographic atrophy and diabetic macular edema. We have 13,500 employees working to solve some of the most complex biomedical problems in the history of humankind, always with the goal of putting patients first. The life-changing work of our scientists depends on a stable and predictable patent system that rewards innovation. Genentech's commitment to innovation is reflected in the more than 20,000 patents we have received worldwide.

Comments

I. DRUG PRICING AND THE PATENT SYSTEM

Before turning to the details of the USPTO's questions regarding continuation applications and terminal disclaimers, Genentech would like to address a threshold issue—namely, the tenuous connection between the various initiatives in the USPTO's notice and the Biden Administration's stated goal of promoting access to prescription pharmaceuticals. Historically, the best way to ensure that prescription pharmaceuticals are available to meet patient needs has been to maintain a robust patent system that creates incentives to invent and develop new medicines, new methods of treatment, and new techniques for manufacturing drugs safely and at scale. The public will have no access to drugs that are never invented in the first place. Thus, it is important that any effort to reduce drug prices not risk undermining the long-term incentive to innovate.

As a company with a long history of pursuing ground-breaking science to bring innovative medicines to patients, Genentech strives to ensure that anyone who is prescribed one of our potentially life-changing medicines can get it, regardless of their ability to pay. Over the past 30 years, Genentech has helped more than 2.8 million people through patient assistance programs such as Genentech Access Solutions and the Genentech Patient Foundation.

Adjusting basic patent principles in the name of attempting to influence drug prices, however, is a particularly indirect and ineffective way to achieve the objective, and one fraught with unintended consequences. Drug pricing is a complicated topic affected by many factors, and it is not an issue limited to patented medicines. A productive public policy discussion about drug prices should instead focus directly on drug prices. That discussion should include an examination of the role of pharmacy benefit managers, the middlemen who negotiate discounts from manufacturers but often fail to pass those discounts along to consumers. It should include a discussion of the drug pricing measures already passed in the Inflation Reduction Act of 2022. And it should include a discussion of the many other inputs that affect the cost of medical care.

The patent system serves a vital purpose in the life and competitiveness of the nation. It functions best when it focuses on that core purpose and is not altered to serve other ends.

II. CONTINUATION APPLICATIONS

A. Continuation Applications Serve Important Purposes

Several of the discussion questions from the PTO and from the six Senators who wrote to the PTO relate to the use of continuation applications. The implicit assumption in some of the questions seems to be that continuation applications are problematic and need to be restricted. To the contrary, continuation applications serve important purposes.

First, continuation applications allow an inventor to get some claims issued while continuing to pursue the full scope of protection to which the inventor is entitled based on its disclosure. If a company could not pursue patent claims in batches by using continuing applications, it would face an untenable choice in which it might have to sacrifice claims to which it should have been entitled in the interest of securing prompt issuance of a patent. Conversely, if the company decided to pursue all the claims to which it is entitled in a single application, prosecution would slow down, because no patent could issue until the Examiner considered all claims ready for

issuance. This would lead to longer periods of Patent Term Adjustment under 35 U.S.C. § 154(b) due to the delays in the PTO. Limiting the use of continuation applications or subjecting them to heightened requirements could thus have the unintended effect of *delaying* the expiration of patent protection.

Second, continuation applications encourage early disclosure. Under current law, an applicant is encouraged to disclose as much as possible in its earliest priority application, knowing that in a series of applications, it can seek patent protection for what it originally disclosed. This early disclosure allows the public to start building on the applicant's contribution as soon as the priority application publishes. In contrast, without continuation applications, an applicant may be less willing to disclose so much so early. Instead, the applicant might delay making any disclosures until it is in a position to seek the full scope of the protection to which it is entitled, or it might make piecemeal disclosures in separate applications. The effect would be to delay public access to the inventor's disclosures, and to delay the follow-on innovation that such disclosures can support.

Third, there are already built-in checks on the misuse of continuation applications. A continuation application cannot add new matter or claim a new invention that was not previously disclosed. Under 35 U.S.C. § 112, the specification must contain "a written description of the invention" and enable a person skilled in the art to make and use the invention. Accordingly, a continuation application can claim only an invention that was already described and enabled in the priority application, and cannot be used to capture later developments that were not part of the original disclosure.

Relatedly, an inventor does not secure additional patent term just by filing a continuation application. The expiration date of a patent issuing from a continuation application is calculated based on the filing date of the earliest application to which it claims priority. 35 U.S.C. § 154(a)(2). A patent that issues from a continuation application will thus generally expire on the same date as any patent that issued from the priority application, and an applicant that unduly delays prosecution is not extending the overall period of protection but rather burning effective patent life. Moreover, even if the patent receives Patent Term Adjustment to compensate for delays by the USPTO, continuation applications decrease the overall need for Patent Term Adjustment for the reasons discussed above.

Concerns about continuation applications wearing down Examiners are also misplaced. Continuation applications allow Examiners to make decisions about smaller batches of claims on their own merits, which can be less burdensome than reviewing numerous claims all at once in a single omnibus application.

Fourth, continuation applications allow an inventor to determine if a technology is important to its business before deciding which of the inventions it previously disclosed will be claimed. Companies often make multiple inventions as they explore different paths and products. As long as the company has disclosed what it invented, continuation applications give it time to decide which of the disclosed inventions it wants to patent and which it wants to dedicate to the public through its unclaimed disclosure. In contrast, if the company had to decide at the outset exactly what to claim, it might seek more patent protection than it ultimately needs to protect its commercial interests. Continuation applications can thus reduce risk-averse decision-making, potentially placing more inventions in the public domain.

Fifth, continuation applications allow companies to defer costs. Patent prosecution can be a significant expense, especially for small companies, research institutions, and individual inventors. An inventor may wish to obtain patents on some aspects of an invention to attract initial investment, and then use that investment to fund its efforts to secure full protection. In addition, it is less expensive to file a continuation application than to file a new application, and examination is more efficient because the Examiner is already familiar with the patent family.

Sixth, continuation applications can be used to obtain patents that expire at the same time but have claims with different scope. This facilitates flexibility in enforcing and licensing patents. For example, a patent owner might choose to retain exclusivity on a patent with narrower claims while licensing a related patent that contains broader claims as part of a cross-license with a competitor.

Seventh, under current law, a patent can only claim one invention. Divisional and continuation applications are thus necessary in some cases to ensure that an inventor who discloses more than one invention can claim the full range of what was invented. Genentech appreciates that the USPTO is considering whether to change divisional practice, but for now, filing continuation or divisional applications is necessary for breakthroughs that result in multiple, distinct inventions.

Eighth, continuation applications allow companies to respond to changes in the law that are beyond their control. In the past 20 years, the Supreme Court has substantially changed patent law in unexpected ways, including the legal doctrines that apply to patent-eligible subject matter, indefiniteness, obviousness, and other basic principles. An inventor who has made a genuine breakthrough should not lose all patent protection due to an unexpected shift in the law. A continuation application allows the inventor to obtain new claims, within the footprint of its original disclosure, to ensure that it does not lose effective protection based on fixable issues.

B. Continuation Applications Should Not Be Subject To Special Or Heightened Burdens

Turning to some of the specific questions posed in the USPTO's notice, Genentech is particularly concerned by the suggestion that a continuation application should be subject to special procedures, such as "heightened examination requirements" or "a second look, by a team of patent quality specialists." 87 Fed. Reg. 60134. Continuation applications are already subject to all the requirements of patentability established by Congress. Those requirements are sufficient to ensure that inventors receive no more—and no less—than they are entitled to under the law. Imposing a heightened standard would improperly bias the process against granting patent protection even when an application meets all the statutory requirements for receiving a patent.

The PTO does not have authority to impose heightened requirements. Congress provided that continuation applications "shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application." 35 U.S.C. § 120. Congress's clear intent was to treat continuation applications the same as earlier-filed priority applications. Congress has not granted the USPTO substantive rulemaking authority, but even if it had, the USPTO could not disregard this clear congressional command.

Moreover, requiring "a second look" before a patent issues from a continuation application could have unintended consequences. If the second look slows down prosecution, it could increase the period of Patent Term Adjustment Congress created to compensate for delays in the PTO, thereby delaying the patent's expiration date. It might also be interpreted as a signal that Examiners are not trusted to get things right the first time, which could impact Examiner morale.

Genentech also opposes imposing new time limits on how soon after an original application a continuation application must be filed or how soon after a restriction requirement a divisional application must be filed. Imposing arbitrary time limits on continuation and divisional applications would discourage their use in a way that could delay patent expiration, discourage early disclosure, force inventors to forgo protection to which they are entitled, and impose a substantial burden on small companies, research institutions, and individual inventors.

The short time limits mentioned in the Senate-inspired questions, such as six months after the first office action or one year after the earliest application in a family, are especially concerning. A short time limit would impede the use of continuation applications, depriving patent owners, the USPTO, and the public of the many benefits those applications provide. *See supra* II.A. Moreover, the question whether these time limits would give an inventor enough time to "know what types of inventions the patent will actually cover," 87 Fed. Reg. 60134, starts from the wrong premise. Because a continuation application cannot add new matter, an inventor must disclose anything it is going to later claim at the time of its earliest priority application. From that point forward, prosecution involves a dialogue with the PTO, and until an applicant knows what claims are going to issue on an earlier application, it cannot know whether prosecution is complete or whether further proceedings on a continuation application are needed to get the full range of protection to which it is entitled based on its original disclosure.

Congress set the appropriate time limit for filing a continuation application, requiring only that it be "filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application." 35 U.S.C. § 120. The PTO should not—and likely lacks authority to—deviate from the judgment made by Congress that continuation applications are appropriate up until the abandonment or termination of proceedings on the preceding link in the chain of priority.

III. TERMINAL DISCLAIMERS

Genentech respectfully opposes the suggestion that terminal disclaimers should be "eliminat[ed]." 87 Fed. Reg. 60134. Terminal disclaimers provide an important safety valve to mitigate the potential harshness of the doctrine of obviousness-type double patenting (OTDP). OTDP is a judge-created doctrine designed to prevent the unwarranted timewise extension of patent protection. Without terminal disclaimers, OTPD would overshoot that objective by outright invalidating claims to which an applicant should be entitled before they have any effect on the overall length of patent protection. With terminal disclaimers, the public receives the benefit of preventing a timewise extension of the overall period of patent protection without overshooting the goal.

An example illustrates the importance of terminal disclaimers. Imagine that an innovator invents a new class of drugs for treating a medical condition. The PTO may be prepared to promptly issue one or more patents that cover individual molecules within the genus that was invented.

But it may take more time to prosecute any genus claims to which the applicant is entitled, both because there may be more prior art to consider and because the Examiner may need to consider objective indicia of non-obviousness. Because the genus claim may cover one or more of the species claims that issued quickly, the genus claim may be considered patentably indistinct from the earlier claim. But that does not mean there is no difference. To the contrary, the genus claim would better reflect the full scope of what the applicant invented and disclosed in the original application. Without a terminal disclaimer, the applicant would risk losing all protection from the genus claim, even during the life of the species claim. The doctrine of OTDP would thus deprive the inventor of protection for something it actually invented and disclosed.

As another example, imagine the same scenario but this time the genus claim issues first, because the applicant decides that it will only obtain a narrow patent on one of the disclosed species once it has determined which species it will use in its commercial product. Applying OTDP to the species patent would discourage the applicant's selectivity and encourage risk-averse decisions to seek more claims overall in a single application.

A terminal disclaimer provides a solution to these dilemmas. It resolves any concern about whether the inventor is somehow using the later-issued patent to extend the period of patent protection (assuming that were even possible under current law), while allowing the inventor to have protection for both the genus and species inventions during the lifetime of the earlier-expiring patent.

Eliminating terminal disclaimers would have several negative consequences. It would deprive applicants of patent protection for otherwise novel and non-obvious inventions that they disclosed. It would discourage continuation applications, which as discussed, could have the opposite of the desired outcome by slowing down prosecution and extending the expiration date of the resulting patents. It could lead some applicants to delay making disclosures, which as discussed would deprive the public of early access to that information. And it would acutely impact individual inventors and small entities who have fewer resources.

Genentech also opposes the suggestion that an applicant should have to "stipulate" that its "claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer." 87 Fed. Reg. 60134. Current Federal Circuit precedent "foreclose[s] the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims." *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018). That is the correct approach. An applicant may disagree with an Examiner's assessment that claims are not patentably distinct, but nonetheless file a terminal disclaimer to moot the issue and keep prosecution moving. This is in the interest of the patent system and the USPTO because it encourages efficiency. A contrary rule that forced applicants to make a binding concession to file a terminal disclaimer could delay prosecution by discouraging continuation applications. It could also encourage more applicants to engage in a protracted fight over whether there is actually an OTDP problem that would necessitate a terminal disclaimer. Transforming a terminal disclaimer into a binding concession could thus have the unintended consequence of extending prosecution and reducing the use of terminal disclaimers.

Changing terminal disclaimers is particularly unnecessary and inadvisable at this time because the issue of longer patent terms based on the issue date of a patent, which the doctrine of OTDP was intended to address, has largely been rendered obsolete by the United States' switch to a 20-

year patent term running from the earliest claimed priority date. OTDP is a judge-made doctrine created at a time when a patent's term lasted for seventeen years from the patent's date of issuance. Under that system, an applicant could use successive continuation applications to try to claim features of an invention many years after the filing of the original patent application and obtain successive patents with terms that ran from the date of issuance. The concerns that motivated the creation of the doctrine substantially diminished after Congress amended the Patent Act to adopt a twenty-year patent term measured from the date of the earliest application to which the patent claims priority. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994). Now when an applicant files a continuation application with the same effective filing date as its parent, the patents will normally expire on the same date.

The USPTO nonetheless regularly enters provisional OTDP rejections during prosecution. In addition, although the Supreme Court has not addressed the issue, the Federal Circuit has held that OTDP can still apply to post-URAA patents in limited circumstances. *Gilead Sciences, Inc. v. Natco Pharma Ltd*., 753 F.3d 1208 (Fed. Cir 2014). Terminal disclaimers provide an efficient way to resolve these issues, and the USPTO should not make changes that would give more force to a judge-made doctrine that originated in a different era.

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Genentech appreciates the opportunity to comment, and welcomes an ongoing dialogue with the Office on these important issues.