UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE APPEALS REVIEW PANEL OF THE
PATENT TRIAL AND APPEAL BOARD

Ex parte NICOLAS BAURIN, CHRISTIAN BEIL, CARSTEN CORVEY, CHRISTIAN LANGE, DANXI LI, VINCENT MIKOL, ANKE STEINMETZ, and ERCOLE RAO

Appeal 2024-002920
Application 17/135,529
Technology Center 1600

BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INNOVATION ORGANIZATION

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I. INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. Many of BIO's members are small companies that have yet to bring products to market or to attain profitability. These members rely heavily on venture capital and other private investment, based on and protected by strong intellectual property rights. BIO submits this brief to assist the Patent Trial and Appeal Board's Appeals Review Panel ("ARP") as it considers how best to clarify the proper application of obviousness-type double patenting ("OTDP") rejections during prosecution. BIO has a strong interest in ensuring that the application of OTDP remains consistent with the purpose of the doctrine, as well as the settled expectations and practices of its members.

II. INTRODUCTION

This Brief addresses all three questions set forth by Director Squires in the March 5, 2026 Order Convening Appeals Review Panel and Granting *Sua Sponte* Rehearing:

1. The applicability, if any, of *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024), to the facts of this appeal, and consideration of what constitutes "first-filed" for OTDP purposes under facts different than those presented in *Allergan*;

2. Whether examiners should determine projected expiration dates to support OTDP rejections during prosecution; and

3. Whether the risk of separate ownership and preventing potential harassment by separate owners of claims to obvious variants of an invention is an independent basis that supports an OTDP rejection during prosecution.

As explained below, the panel in *Ex parte Baurin* correctly applied *Allergan* to the facts of that case. Moreover, *Allergan* should apply to similar cases involving first-filed applications facing possible OTDP rejections based on later-filed patents. Additionally, examiners should not speculate or assume that there may be patent term adjustment ("PTA") or otherwise "project" *possible* expiration dates to support OTDP rejections. Finally, separate ownership should not serve as an independent basis for an OTDP rejection. Doing so would improperly elevate dicta and a secondary consideration over OTDP's primary purpose and risks undermining future inventions and innovations.

By adopting the correct application of OTDP under *Allergan* and *Ex parte Baurin*, the ARP would preserve patent term of earlier-filed applications, promote predictability, and ensure strong protections for novel, breakthrough technologies that emerge from the biotechnology industry.

III. ARGUMENT

A. *Allergan* Correctly Applies to the *Ex parte Baurin* Appeal and Similar Fact Patterns Involving "First-Filed" Applications.

The fundamental purpose of the judicially-created doctrine of OTDP "is to prevent an unjustified timewise extension of patent exclusivity beyond the life of a patent." *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 111 F.4th 1358, 1367 (Fed. Cir. 2024) (emphasis added). The doctrine "preserve[s] [the] bargained-for right held by the public," because "[i]f an inventor could obtain several sequential patents on the same invention, he could retain for himself the exclusive right to exclude or control the public's right to use the patented invention far beyond the term awarded to him under the patent laws." *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014); *see also Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) ("The ban on double patenting ensures that the public gets the benefit of the invention *after the original period of monopoly expires*.") (emphasis added).

Accordingly, the purpose of OTDP is to prohibit a patentee from obtaining multiple patents on patentably indistinct inventions or variants that would effectively extend the life of the "first-filed" patent. *See Allergan*, 111 F.4th at 1369; *In re Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023). Given this purpose, post-URAA, the "first-filed" patent is necessarily the patent that establishes the earliest patent-term filing date for the subject matter, and thereby sets the "original period of monopoly" for that invention. *See Abbvie*, 764 F.3d at 1373. This principle applies regardless of whether the patents share a common owner or common priority date.

In *Cellect*, the Federal Circuit held that statutorily-mandated PTA could be considered in determining whether a later-expiring patent could be invalidated under OTDP. The decision by Judges Lourie, Dyk, and Reyna drew significant concern from many in the legal community, particularly where it appeared to have profound implications for first-filed patent applications to foundational technology, which—through no fault of the patentees—resulted in adjusted term based on PTA. *See* Brief of PhRMA and BIO as *Amici Curiae* in Support of Petitioner, *Cellect, LLC, v. Vidal*, No. 23-1231 (U.S. 2024); Brief of AIPLA as *Amicus Curiae* in Support of Certiorari, *Cellect, LLC, v. Vidal*, No. 23-1231 (U.S. 2024).

Less than a year later, the same panel of the Federal Circuit returned in *Allergan* to right the ship. Specifically, *Allergan* clarified that *Cellect* did not eviscerate the protections offered to foundational innovations, because "*Cellect* does not address, let alone resolve, any variation of the question presented here—namely, under what circumstances can a claim properly serve as an ODP reference[.]" *Allergan*, 111 F.4th at 1368-69. That question, the Federal Circuit decided, must be answered "consistent with the purpose of the ODP doctrine, which is to prevent patentees from obtaining a *second* patent on a patentably indistinct invention to effectively extend the life of a *first* patent to that subject matter." *Id.* at 1369 (emphasis in original) (citing *Miller v. Eagle Mfg.*

Co., 151 U.S. 186, 198 (1894)). As such, the Federal Circuit held that "a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date." *Id.* The court further explained that the fact that the earlier-filed claim expired later "[was] of no consequence" because it was not a "*second*, later expiring patent for the same invention." *Id.* (emphasis in original) (quoting *Abbvie*, 764. F.3d at 1373).

The Federal Circuit's decision is both legally and logically sound. First-filed patents, like in *Allergan*, are entitled to the benefit of their full, congressionally guaranteed patent term. *See id.* at 1371; *see also* 35 U.S.C. § 154(b); *Cellect*, 81 F.4th at 1230 ("We do, however, note that the non-asserted claims in the challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be *later-filed* obvious variations of earlier-filed, commonly owned claims.") (emphasis added). Allowing later-filed patents to serve as OTDP references to reduce the term of a first-filed application "would not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA," thus leading to an "untenable" result. *Allergan*, 111 F.4th at 1371.

Although *Allergan* involved patents that shared the same priority date, its reasoning is not limited to only first-filed patents in the same family. The PTAB panel in *Ex parte Baurin* properly applied *Allergan* in rejecting the use of a later-filed patent (i.e., a patent with a later patent-term filing date relative to the application at issue) as an OTDP reference. *See* No. 2024-002920, at 9-10 (P.T.A.B. Nov. 8, 2024). The *Baurin* panel correctly recognized that the claims of the challenged application would be the *first* patent to cover the invention and not a *second*, later-expiring patent that unjustly extended the exclusivity period on the claimed subject matter. *Id.* *Baurin* thus reinforces the correct approach to OTDP references.[1]

[1] *Ex parte Baumeister*, now on appeal to the Federal Circuit, involved a similar fact pattern to the *Baurin* appeal: a patent with a later patent-term filing date was used as an OTDP reference against a first-filed application with an

As *Baurin* illustrates, when the application and potential OTDP patent are not in the same family and do not share the same patent-term filing date, the "first-filed" patent is the one that establishes the earliest patent-term filing date for the relevant subject matter. The patent with (i) a later patent-term filing date, and (ii) claims an indistinct variant of the subject matter is the later-filed patent for OTDP purposes; it should not be considered an appropriate OTDP reference. In circumstances when two patents share the same patent-term filing date, as in *Allergan*, the earlier of their *actual* filing dates determines which is considered "first-filed." These definitions of "first-filed" patent ensure that the OTDP doctrine continues to serve its core purpose of preventing *unjustified* extensions of patent exclusivity, rather than invalidating first-filed patents covering initial inventions.

B. Examiners Should Not "Project" PTA for Pending Applications

To the extent the ARP's question addresses the propriety of examiners "projecting," i.e., estimating expiration dates to support OTDP rejections, including by estimating or assuming PTA, examiners should not do so. Although USPTO guidance requires examiners to consider issues of OTDP during examination (e.g., MPEP § 804), when examiners issue OTDP rejections in anticipation that an application *might* accrue PTA due to potential USPTO delays, the results lead to speculative and unsupported rejections. PTA is not determined until issuance, and it fluctuates throughout prosecution based on USPTO and applicant delays. Because the full amount of PTA cannot be known in advance, relying on hypothetical future adjustments should not support an

earlier patent-term filing date owned by a different party. No. 2026-000193, at 5 (P.T.A.B. Nov. 21, 2025). There, the panel reached the wrong conclusion, finding that *Allergan* was inapplicable because it involved applications with common priority dates. *Id.* at 7. Instead, the panel relied on *In re Fallaux*, an older case pre-dating *Gilead*, *Cellect,* and *Allergan*, which also did not address the question of whether it was appropriate to use an OTDP reference with a later patent-term filing date against a first-filed application. The panel additionally declined to consider *Baurin* because the request for rehearing was still pending. *Id.* at 17. That has since resolved, as the *Baurin* panel ultimately denied rehearing on the same grounds as its initial decision, correctly reaffirming the principle that a later-filed patent cannot serve as an OTDP reference against an earlier-filed application. Such result should have governed *Baumeister*.

OTDP rejection during examination. If PTA information is available for a granted reference patent, the examiner should assess whether and explain the basis for why PTA affects the OTDP analysis.

C. Separate Ownership Should Not Serve as an Independent Basis for OTDP Rejections.

As previously discussed, the central inquiry in assessing an OTDP rejection is whether a patentee would receive an *unjust* patent term extension of an earlier patent through a later, patentably indistinct patent. Under the MPEP, OTDP rejections may arise between an application and an issued patent that share a common inventive entity, common owner or assignees, or separate owners with at least one common inventor. MPEP § 804(I)(A). Separate ownership, however, does not change the facts of which is a "first filed" patent. Thus, allowing separate ownership to serve as an independent basis for OTDP would improperly elevate such secondary concerns over the doctrine's core purpose, and in doing so, frustrate that very purpose.

Consistent with this view, courts have not characterized ownership to be the threshold issue in analyzing OTDP. Rather, separate ownership concerns are often dicta, and at best, a noted equitable consideration *after* determining that the asserted OTDP rejection is appropriate. *See, e.g.*, *In re Hubbell*, 709 F. 3d 1140, 1145 (Fed. Cir. 2013) ("The *second* rationale [for OTDP] is to prevent multiple infringement suits by different assignees asserting essentially the same patented invention.") (emphasis added); *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (recognizing that "there is a *second* justification for obviousness-type double patenting--harassment by multiple assignees.") (emphasis added). This sequencing reflects courts' prior practices and reinforces that separate ownership, on its own, should not serve as a basis for an OTDP rejection. Moreover, that an accused infringer may have to litigate at least two lawsuits for similar inventions is not necessarily improper harassment, but simply a reality of modern patent litigation. Alleged infringers, particularly in competitive fields, often already defend multiple lawsuits against

companies with patents on related or similar technologies. Given these realities, concerns about possible risk of harassment should not justify treating separate ownership as an independent basis for OTDP.

Moreover, rejecting a separate ownership OTDP-based rule does not leave litigants without recourse when abuse does occur. Courts already have discretion to issue attorneys' fees and sanctions to address and deter improper conduct. For example, true litigation harassment by multiple assignees or owners is likely the type of conduct meant to be addressed by the "exceptional case" standard under 35 U.S.C. § 285. *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 555 (2014) ("[A] district court may award fees in the rare case in which a party's unreasonable conduct . . . [is] so 'exceptional' as to justify an award of fees."). These remedies, which provide fair and just solutions, directly target misconduct in specific circumstances without creating sweeping assumptions and distorting the purpose of OTDP. Relying on well-established judicial tools ensures the proper application of remedies without creating new OTDP rules that may unnecessarily risk diminishing patentees' rights.

Finally, allowing the risk of separate ownership and preventing potential harassment as an independent basis that supports an OTDP rejection during prosecution could disincentivize collaboration between companies. Biotech companies often rely on collaboration to combine technical expertise and resources; moreover, inventors often move between organizations. As part of these collaborations, companies frequently must structure their agreements to set forth patent ownership rights. Allowing examiners to issue OTDP rejections based solely on separate ownership would introduce yet another risk to the validity of patent claims, particularly because separate owners generally cannot file terminal disclaimers, except in narrow circumstances. *See* 37 C.F.R. § 1.321(d); MPEP § 2156. Many collaborators would thus be left without the option to

preserve their claims using terminal disclaimers. As a result, companies may be hesitant to collaborate if the risk of an OTDP rejection based on separate ownership could disrupt the protection of their respective novel technologies. Such a result would gravely impact the ability of many companies, particularly smaller ones who rely on collaborations as well as robust patent rights, to bring their innovations to the public.

D. Correct Application of the OTDP Doctrine Under *Allergan* and *Ex parte Baurin* Protects Innovation in the Biotechnology Industry.

The correct application of OTDP is critical for the biotechnology industry because misapplication can undermine incentives to pursue improvement technologies, follow-on patents, and continuation applications. As the *Allergan* court recognized, earlier-filed applications often undergo lengthy prosecution, particularly when they claim novel technologies. *See* 111 F.4th at 1371. To protect these innovations, applicants often plan to secure comprehensive patent protection by filing multiple related applications, which could end up with varying expiration dates. While it is equitable and consistent with the purpose of OTDP to use *earlier*-filed patents as references against *later*-filed patents—thereby ensuring that a patentee does not get a *second* patent on a patentably indistinct invention to effectively extend the life of a *first* patent to that subject matter—doing the opposite would create substantial uncertainty about whether subsequent improvements could endanger foundational inventions. In a world where patentees cannot rely on their first-filed patents receiving their full term, they will be forced to reevaluate entire patent portfolios and may reduce filing subsequent applications. Courts could not have intended OTDP to erode congressionally granted rights or force patentees into choosing between foundational and improvement patents. Adopting the correct application of *Allergan* to *Baurin* and its ilk avoids such outcomes.

Moreover, in the time since the *Allergan* and *Baurin* decisions issued, the biotechnology industry has already cited and relied upon their holdings in ongoing prosecution strategy. Upending the correct application of *Allergan* now would risk disrupting settled expectations as well as limiting existing and future patent terms of foundational technologies. As the Supreme Court has emphasized, "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community," *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). The ARP should exercise similar caution here. Biotech companies invest significant time and resources to support long-term innovation. Because the loss of patent term on the early foundational patents is especially devastating to further research and drug development, these companies rely on a predictable patent system that provides strong patent protection for these early, breakthrough technologies.

IV. CONCLUSION

For these reasons, the ARP should adopt an interpretation of OTDP's application consistent with *Allergan* and *Baurin* that protects patent term, ensures predictability, and preserves the incentives for innovation in the biotechnology industry.

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Respectfully submitted,

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