BEFORE THE APPEALS REVIEW PANEL

OF THE PATENT TRIAL AND APPEAL BOARD

UNITED STATES PATENT AND TRADEMARK OFFICE

Ex parte NICOLAS BAURIN, et al.

Appeal No. 2024-002920

Application No. 17/135,529

Technology Center 1600

AMICUS CURIAE BRIEF OF THE JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION (JPMA)

Dated March 27, 2026

I. INTRODUCTION

On March 5, 2026, the Director of the U.S. Patent and Trademark Office convened an Appeals Review Panel ("ARP") and granted sua sponte rehearing to review the Patent Trial and Appeal Board's reversal of obviousness-type double patenting ("OTDP") rejections of claims 1–18 in this ex parte appeal. The Order further authorized amicus curiae briefing limited to OTDP issues, and requested briefing on three questions concerning: (1) the applicability of *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024) and what constitutes "first-filed" for OTDP; (2) whether examiners should determine projected expiration dates during prosecution to support OTDP rejections; and (3) whether separate-ownership/harassment risk is an independent basis supporting an OTDP rejection during prosecution.

JPMA respectfully submits that the ARP should clarify a narrow, administrable OTDP framework that:

(i) remains anchored to OTDP's core temporal purpose—preventing an unjustified timewise extension of exclusivity through a "second patent";

(ii) avoids reliance on speculative "projected" expiration calculations during prosecution; and

(iii) does not elevate hypothetical separate-ownership concerns into an independent OTDP rejection basis, particularly where the Office already provides targeted tools (e.g., terminal disclaimers) to address enforceability/ownership concerns.

II. STATEMENT OF INTEREST

The Japan Pharmaceutical Manufacturers Association ("JPMA") is a voluntary association comprising 68 research-oriented pharmaceutical companies (as of January 1, 2026). JPMA aims to contribute to the improved health and medical care in Japan and worldwide through the development of innovative and highly useful pharmaceuticals and the sound development of the pharmaceutical industry. In the pharmaceutical sector, long regulatory review periods are a

well-recognized reality, and Congress has provided a statutory mechanism—patent term extension ("PTE") under 35 U.S.C. §156—to partially restore time lost during regulatory review.
Accordingly, JPMA has a strong interest in ensuring that OTDP is applied consistently with its intended purpose and in a manner that preserves predictability during prosecution and respects Congress's statutory term framework.

III. SUMMARY OF ARGUMENT

(1) "First-filed" for OTDP should be tied to the statutory patent-term system. For post-URAA utility patents, Congress measures patent term from the earliest U.S. filing date that determines term and expressly provides that certain priority claims are not taken into account in determining term.
As used in this brief, "patent-term filing date" means the U.S. filing date from which patent term is measured under 35 U.S.C. § 154(a)(2)—i.e., the actual U.S. filing date of the application or, where applicable, the filing date of the earliest U.S. application specifically referenced under 35 U.S.C. §§ 120, 121, 365(c), or 386(c)—excluding any priority claim under 35 U.S.C. §§ 119, 365(a), 365(b), 386(a), or 386(b), consistent with 35 U.S.C. § 154(a)(3).
Consistent with the reasoning and principles articulated in *Allergan*—and applying that reasoning to factual scenarios beyond those presented there—"first-filed" for OTDP purposes should mean the application or patent having the earliest U.S. patent-term filing date that determines term under 35 U.S.C. §154(a)(2), without importing priority concepts that Congress expressly excluded from patent-term determination.
JPMA further respectfully submits that OTDP references should be limited to "proper references" consistent with OTDP's core temporal rationale—namely, preventing an unjustified timewise extension of exclusivity through the issuance of a second patent with patentably indistinct claims—and that examination practices that invoke later-filed applications or patents as OTDP references in a manner contrary to that purpose should not be adopted.
(2) Examiners should not be required to determine "projected expiration dates" during prosecution to support OTDP rejections. "Projected" expiration depends on uncertain future events (including PTA determinations and their interaction with terminal disclaimers) and cannot be calculated with sufficient uniformity or reliability during examination. The Office already provides administrable tools—particularly terminal disclaimers—to address genuine OTDP issues without speculative projections. To the extent examiners consider expiration dates at all during prosecution, such consideration should be limited to straightforward, objectively determinable calculations based on the standard 20-year patent term under 35 U.S.C. §154(a)(2) (i.e., based on patent-term filing dates), and should not require speculation regarding any potential PTA, or their interaction with terminal disclaimers. JPMA's position is not that expiration dates are wholly irrelevant, but rather that any expiration-based analysis during prosecution should be confined to objectively

determinable facts on the prosecution record and should not extend to speculative projections.

(3) Separate-ownership/harassment risk should not be an independent basis for OTDP rejections during prosecution. Where OTDP is otherwise properly established during prosecution, ownership-related concerns can be addressed through terminal disclaimer practice. The Office's rules and guidance already require that a terminal disclaimer used to obviate judicially created OTDP include an enforceability-only-during-common-ownership condition, directly addressing separate-ownership concerns where OTDP is otherwise properly established. (*See* 37 C.F.R. §1.321(c)(3))

Accordingly, separate-ownership risk should not be used to expand OTDP beyond its temporal core in the absence of a proper OTDP reference and an actual unjustified extension scenario. JPMA does not seek to eliminate OTDP as a doctrine, but rather to ensure that it is applied consistently with its core temporal purpose and does not expand into a broad prophylactic restraint based on speculative concerns.

IV. ARGUMENT

A. OTDP must remain a narrow temporal doctrine focused on unjustified extension by a "second patent"

USPTO guidance explains that the judicially created doctrine of obviousness-type double patenting is intended primarily to prevent an unjustified timewise extension of exclusivity by issuance of a second patent with claims that are not patentably distinct from claims in a first patent. USPTO guidance also recognizes a related concern that separately owned patents with patentably indistinct claims could be asserted to subject an accused infringer to multiple suits. These purposes confirm that OTDP should be applied narrowly and in a manner tethered to actual risks the doctrine is meant to prevent. (MPEP §804; see also 37 C.F.R. §1.321(c)(3))

A proper prosecution-stage OTDP regime must therefore identify (i) a proper OTDP reference (i.e., a "proper reference") and (ii) a real and material risk of unjustified timewise extension, rather than expanding OTDP based on speculative forecasts or hypothetical policy concerns.

JPMA does not propose that OTDP concerns be deferred until after issuance; rather, JPMA proposes that OTDP rejections during prosecution should be grounded in proper references and objectively determinable facts, without speculation as to projected expiration.

This is particularly important in post-URAA practice, where Congress intentionally moved to a filing-date-based term and expressly excluded certain forms of priority from the term calculation. An OTDP framework that routinely requires projected expiration forecasts (i.e., projected expiration dates) would undermine Congress's term structure and create unnecessary unpredictability.

B. Question (1): "First-filed" should be defined by the earliest patent-term filing date, consistent

with 35 U.S.C. §154

For post-URAA utility patents, 35 U.S.C. §154(a)(2) states that the patent term ends 20 years from the date the application was filed in the United States, or (where specified) from the filing date of the earliest earlier-filed U.S. application under enumerated sections; and §154(a)(3) further provides that specified priority claims "shall not be taken into account" in determining patent term. The reasoning articulated in *Allergan* should inform the analysis even where the applications do not share a common priority date.

Accordingly, and consistent with the reasoning articulated in *Allergan*, JPMA respectfully submits that the ARP should define "first-filed" in an OTDP analysis as follows:

Proposed definition: For OTDP purposes, "first-filed" should mean the application/patent having the earliest **U.S. patent-term filing date** that determines term under §154(a)(2), without importing excluded priority concepts into the term analysis.

This definition (i) aligns OTDP's temporal focus with Congress's term framework, (ii) is objectively determinable on the prosecution record, and (iii) avoids transforming "first-filed" into a moving target dependent on future administrative adjustments.

C. Question (2): Examiners should not be required to determine "projected expiration dates" during prosecution

The ARP specifically asked whether examiners should determine projected expiration dates to support OTDP rejections during prosecution. (See ARP Order dated Mar. 5, 2026) JPMA submits the answer should be **no**.

1. "Projected" expiration is not reliably knowable during prosecution.

Expiration can be affected by patent term adjustment ("PTA") under 35 U.S.C. §154(b), and PTA-related consequences may not be finalized at the time of examination.

2. A projected-expiration requirement would risk over-rejection and encourage premature terminal disclaimers.

If examiners must forecast projected expiration to support OTDP, the rational institutional response will be to err on the side of issuing OTDP rejections, increasing prosecution costs, prolonging pendency, and encouraging applicants to file terminal disclaimers earlier than necessary.

3. The USPTO already provides a concrete, administrable mechanism to address genuine OTDP concerns without speculative forecasts.

A terminal disclaimer practice exists to obviate nonstatutory OTDP rejections, and the Patent Act specifically provides that no patent the term of which has been disclaimed beyond a specified date may be adjusted beyond the expiration date specified in the disclaimer. (See 35 U.S.C. §154(b)(2)(B))

Therefore, where OTDP is properly established on record facts, the applicant can address any

genuine temporal concern through established mechanisms, without requiring the examiner to compute speculative projected dates.

Requested ARP guidance: An OTDP rejection during prosecution should not be premised on an examiner's projected expiration forecast; rather, it should require a proper OTDP reference and record-based facts demonstrating a non-speculative, objectively identifiable timewise extension concern.

D. Question (3): Separate-ownership/harassment risk is not an independent basis for OTDP rejections during prosecution

The ARP asked whether the risk of separate ownership and preventing potential harassment by separate owners is an independent basis supporting an OTDP rejection during prosecution. (See ARP Order dated Mar. 5, 2026) JPMA submits the answer should be **no**.

1. Separate-ownership risk is inherently speculative during prosecution and would expand OTDP beyond its temporal core.

A rule that treats potential future ownership changes as a standalone OTDP basis would turn OTDP into a broad prophylactic restraint, untethered from OTDP's core temporal purpose.

2. The Office already addresses separate-ownership concerns through terminal disclaimer enforceability conditions.

USPTO guidance recognizes the "multiple suits by different assignees" concern and explains that a terminal disclaimer submitted to overcome a double patenting rejection includes a provision that the resulting patent is enforceable only during such period that it is owned by the same party as the other identified patents/applications.

This enforceability condition is also reflected in the governing terminal disclaimer rule, which requires that a terminal disclaimer include a provision that any patent granted "shall be enforceable only for and during such period" that it is commonly owned with the application or patent forming the basis for judicially created double patenting. (See 37 C.F.R. §1.321(c)(3))

Thus, where OTDP is otherwise properly established, the existing terminal disclaimer mechanism provides a targeted, administrable solution to ownership-based concerns—without making speculative ownership risk a free-standing rejection basis.

Requested ARP guidance: Separate-ownership/harassment risk should not be recognized as an independent OTDP rejection ground during prosecution. Such concerns, when relevant, are appropriately handled through terminal disclaimer conditions (including the common-ownership enforceability requirement) where OTDP is otherwise properly established.

E. Statutory PTE (35 U.S.C. §156) must be respected; OTDP should not be expanded in ways that chill PTE policy objectives

Congress enacted PTE (35 U.S.C. §156) as a statutory extension mechanism that is particularly important in regulated industries. (See 35 U.S.C. §156)

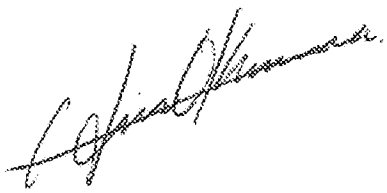
JPMA submits that an OTDP framework that turns on speculative projected expiration calculations during prosecution, or that expands OTDP based on hypothetical policy concerns, would increase uncertainty and litigation risk around patent term—thereby discouraging applicants from confidently relying on Congress's statutory PTE framework and undermining predictability in regulated-product patent portfolios.

V. CONCLUSION

For the foregoing reasons, JPMA respectfully requests that the ARP clarify that:

1. For OTDP purposes, "first-filed" should be defined by the earliest **U.S. patent-term filing date** that determines term under 35 U.S.C. §154(a)(2), consistent with §154(a)(3)'s exclusion of specified priority concepts from term determination;
2. Examiners should not be required to determine "projected expiration dates" during prosecution to support OTDP rejections; rather, OTDP rejections should rest on proper references and record-based facts showing a real and material unjustified timewise extension scenario; and
3. Separate-ownership/harassment risk should not be treated as an independent basis for OTDP rejections during prosecution, particularly given that terminal disclaimer practice already addresses enforceability/ownership concerns where OTDP is otherwise properly established. (See 37 C.F.R. §1.321(c)(3))

Respectfully submitted,



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