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First Named Inventor: Nicolas Baurin
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Application No.: 17/135,529
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For: DUAL VARIABLE REGION ANTIBODY-LIKE BINDING
PROTEINS HAVING CROSS-OVER BINDING REGION
ORIENTATION
Examiner: J. H. Roark
Art Unit: 1643

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Dated: March 27, 2026

Electronic Signature for Janet S. O'Connor: /Janet S. O'Connor/

**RESPONSE TO ORDER CONVENING APPEALS REVIEW PANEL AND GRANTING
SUA SPONTE REHEARING**

Appeals Review Panel
US Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22313-1450

Dear Director:

This paper is submitted in response to the Order Convening Appeals Review Panel and Granting *Sua Sponte* Rehearing mailed on March 5, 2026 (hereinafter: “Order”), following the Decision on Request for Rehearing dated December 18, 2025 (hereinafter: “Rehearing Decision”) in which the Board denied the Examiner’s Request for Rehearing and declined to modify the Original Decision on Appeal dated November 8, 2024 (hereinafter: “Original Decision”). Appellant addresses the points noted on page 2 of the Order in turn below.

1A. The Reasoning of *Allergan* Applies to the Facts of this Case

The Board correctly concluded that the reasoning in Allergan – for determining whether a reference qualifies as a proper obviousness-type double patenting (“OTDP”) Reference against a

target patent/application – is applicable to the facts of the instant case.¹ See Rehearing Decision, page 3. In Allergan, the Federal Circuit reaffirmed that the *fundamental purpose* of the OTDP doctrine is to prevent an unjustified extension of patent term. See 111 F.4th at 1369 (“**[T]he purpose** of the ODP doctrine ... 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”) (emphasis in bold added). The Federal Circuit arrived at the holding in Allergan by applying the fundamental purpose of the OTDP doctrine to the material facts at issue:

Applying the fundamental purposes of ODP to these undisputed facts, the claims of the ’356 patent do not ‘extend or prolong the monopoly [on eluxadoline] beyond the period allowed by law,’ ... and therefore are not subject to ODP over the ’011 and ’709 patents. Put otherwise, the fact that the ’356 patent expires later is of no consequence here because it is not a ‘*second*, later expiring patent for the same invention.’ Abbvie, 764 F.3d at 1373.

Id. (emphasis in bold added); see also id., 1371 (“To hold otherwise ... **would ... run afoul of the fundamental purposes of ODP ...**” (emphasis added)). The Federal Circuit did not state or suggest that the reasoning in Allergan – for determining whether an asserted reference qualifies as an OTDP Reference – is limited to the facts (and question) at issue in that case.

Indeed, the Federal Circuit has consistently used the fundamental purpose of the OTDP doctrine to guide its conclusions in other cases having facts (and questions) at issue distinct from those of Allergan. See e.g., Application of Schneller, 397 F.2d 350, 354 (C.C.P.A. 1968) (using the “**fundamental reason**” for the OTDP doctrine (emphasis added)); In re Van Ornum, 686 F.2d 937, 943 (C.C.P.A. 1982) (using the “**fundamental reason**” for the OTDP doctrine (emphasis added)); Gilead Scis., Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1214 (Fed. Cir. 2014) (using the “**bedrock principle**” of the OTDP doctrine (emphasis added)); Abbvie Inc. v. Mathilda &

¹ For simplicity, this brief refers to reference applications/patents and target applications/patents rather than the claims of those patents/applications.

Terence Kennedy Inst. of Rheumatology Tr., 764 F.3d 1366, 1373 (Fed. Cir. 2014) (using the “*crucial purpose* of the [OTDP] doctrine” (emphasis added)). Thus, there is no reason why the fundamental purpose of the OTDP doctrine would not serve as the guiding principle for determining whether the asserted references qualify as OTDP References on the facts here.

When the fundamental purpose of the OTDP doctrine that proved dispositive in Allergan is applied to the undisputed facts of this case, the asserted references do not qualify as OTDP References for two independent reasons: (1) the instant application has an *earlier* patent-term filing date, *i.e.* it is “*first-filed*,” relative to the asserted references (see § 1B) and (2) the instant application, if issued, would *not* “*effectively extend the life of*” the asserted reference patents because it would expire first (see §§ 2-3).

1B. When a Target Application Has an Earlier Patent-Term Filing Date Than a Reference Patent/Application, the Target Application is “First-Filed”

The Board correctly concluded that patent-term filing dates² should be compared in view of Allergan to determine whether the asserted references are proper OTDP References on the instant facts. See Rehearing Decision, page 3-5. In Allergan, the Federal Circuit used the fundamental purpose of the OTDP doctrine (*i.e.*, to prevent an *unjustified extension* of patent term) to guide the court’s determination of whether the asserted references were proper OTDP References. See 111 F.4th at 1369. In doing so, the Federal Circuit reviewed expiration dates (to assess whether the target patent would effectively extend the term of the asserted reference patents) *and* filing dates (to assess whether an extension of term, if found, was unjustified). See id., 1363-1364; see also id., 1369 (rebutting an assertion that expiration dates alone (without a

² For patents that issued from an application filed after the URAA, the patent term is 20 years from the filing date of the earliest United States or Patent Cooperation Treaty (PCT) application to which it claims priority, excluding provisional applications (“patent-term filing date”). Gilead, 753 F.3d at 1211. The Board used the term “effective filing date” as opposed to “patent-term filing date.” See e.g., Rehearing Decision, page 5.

consideration of filing dates) are controlling and stating that this position is “antithetical to the principles of ODP”).

Regarding expiration dates, the Federal Circuit found that the target patent (the ’356 patent) was “later-expiring” relative to reference patents (*i.e.*, there was an extension of patent term). See id. Regarding filing dates, the Federal Circuit found that the target patent and the asserted references had a common patent-term filing date³ and that the target patent had an earlier actual filing date relative to the asserted reference (*i.e.*, the target patent was “first-filed” in this sense). See id. Ultimately, the court concluded that the extension of patent term ***was not unjustified*** because the target patent was a “first” patent; it was not a “second” patent claiming the same invention. See e.g., id. 1369 (“[T]he fact that the ’356 patent expires later is of no consequence here because it is not a ‘*second*, later expiring patent for the same invention’” (citing to Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr., 764 F.3d 1366, 1373 (Fed. Cir. 2014))).

The Federal Circuit’s reasoning in Allergan supports that when a target application has an earlier patent-term filing date than a reference patent/application, the target application is “first-filed.” The Board understood this as well. See id.; see also id., pages 9-10. In particular, the Board stated:

While the facts of *Allergan* are somewhat different than here ... , we find the reasoning compelling. The application at issue here was filed before the application leading to the ’922 patent, and was published well before the earliest effective filing date of the ’922 patent. (Appeal Br 15-16.) The Examiner allowed the claims of the ’922 patent over this publication, thus determining that the ’922 claims are not obvious from that disclosure... In other words, the claims at issue

³ In Allergan, the Federal Circuit used the term “priority date” as opposed to “patent-term filing date.” It is clear from the context of the opinion that “priority date” refers to the patent-term filing date, not the earliest effective filing date for establishing novelty and/or nonobviousness. See 111 F.4th at 1363.

would be a first patent ... It is not a second, later expiring patent for the same invention as the '922 patent ...

Id., pages 9-10 (emphasis added).

Indeed, courts have compared filing dates to help assess whether an extension of patent term was unjustified prior to Allergan, even under pre-URAA law when patent term was measured from issuance date. For example, in Application of Stanley, the Federal Circuit's predecessor court overturned an examiner's OTDP rejection of a target application claiming a generic method in view of a commonly-owned asserted reference (the earlier-issued and, therefore, earlier-expiring Truitt patent), which claimed an improvement to that method. See 214 F.2d 151 (C.C.P.A. 1954). As such, like Allergan (and in contrast to the instant case), it was clear that there was (or would be upon issuance of the target application) an extension of patent term. Nonetheless, the court emphasized that the target application had an *earlier* filing date relative to the asserted reference patent (*i.e.*, it was "first-filed"). See id., 958-959. In fact, the filing date of the asserted reference patent (corresponding to its earliest priority date⁴) was more than *two years later* than the filing date of the target application. See id. The court's holding and reasoning in Application of Stanley support using a comparison of filing dates (and, in particular, patent-term filing dates in the context of post-URAA law, as in the instant case) to guide the analysis of whether an extension of patent term is unjustified.⁵

⁴ This filing date would have also been its patent-term filing date if the application were under post-URAA law.

⁵ The court in Application of Stanley reasoned that:

We are of the opinion that the generic invention *is not* rendered unpatentable by the fact that a prior patent has been issued on a distinct improvement of that invention... Further, we think that the appellants should not be denied a patent for their invention because of the specific improvement patent to Truitt merely on the basis of the common assignee.

Id., 158-59 (emphasis added). The court later commented on the Application of Stanley decision, stating:

Thus, the Board correctly concluded that patent-term filing dates should be compared to determine whether the asserted references are proper OTDP References on the instant facts.

2. Examiners Should Determine Whether the Application Will Expire Before a Potential OTDP Reference

Whether a reference qualifies as an OTDP Reference is a threshold issue in an OTDP analysis. See Allergan, 111 F.4th at 1371; see also Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367, 1375 n.4 (Fed. Cir. 2018). The determination of whether a reference qualifies as an OTDP Reference during prosecution *requires* that an examiner consider expiration dates (as well as patent-term filing dates, as discussed in 1B above), because if a patent issuing on a pending application would expire *before* the potential OTDP reference expires, as is the case here, that reference is not a proper OTDP Reference against the application.

Determining expiration dates in an OTDP analysis is consistent with the M.P.E.P. See Rehearing Decision, page 11-12. M.P.E.P. § 804 expressly states that “[when] the inventor/applicant/patent owner has already secured the issuance of a first patent, the examiner *must determine* whether the grant of a second patent would give rise to an *unjustified extension* of the rights granted in the first patent.” (emphasis added). M.P.E.P. § 1701 makes clear that an examiner can review expiration dates “to the extent necessary to carry out . . . examination of a non-reissue patent application where determination of the expiration date of a patent is necessary

In Stanley, this court sanctioned, in 1954, the issuance of a dominating patent to the owner of the improvement patent which had issued in 1950, notwithstanding the owner's protection would thereby be extended beyond the expiration of the improvement patent by several years. We see, therefore, that *as a matter of law the extension of protection objection is not necessarily controlling*.

Application of Borah, 354 F.2d 1009, 1017 (C.C.P.A. 1966) (emphasis added). See also Allergan, 111 F.4th at 1369 (rebutting an assertion that expiration dates alone are controlling and stating that this position is “antithetical to the principles of ODP”). Thus, in both Application of Stanley and Allergan, comparisons of filing dates (*not just expiration dates*) were needed to guide the court's analysis and ultimate holding.

to conduct examination” (e.g., to examine claims for compliance with the OTDP doctrine).

Moreover, the initial burden of proof for rejections lies with the Office, and this burden requires that examiners show, by a preponderance of the evidence, that there will be an unjustified extension of term (according to the fundamental purpose of the OTDP doctrine).

Thus, examiners should determine whether a patent issuing on a pending application would expire before the potential OTDP Reference expires. If that question is answered affirmatively, there is no extension of time and no OTDP.⁶

3. The Alleged Risk of Harassment from Separate Ownership Does Not Provide an Independent Basis for Establishing a Reference as a Proper OTDP Reference

The Board correctly concluded that the alleged risk of harassment from separate ownership does not provide an independent basis for upholding the asserted OTDP rejections. See Rehearing Decision, pages 16-23. This is supported by: (A) the existence of the two-way test for assessing OTDP; and (B) case law discussing the alleged risk of separate ownership.⁷

A. *The Existence of the Two-Way Test Proves that the Risk of Harassment from Separate Ownership Cannot Stand as the Sole Basis for an OTDP Rejection*

Case law and M.P.E.P. guidance make clear that once it is determined that an asserted reference does not qualify as a proper OTDP Reference in view of the two-way test, the inquiry ends and any concerns over separate ownership are no longer at issue (even in the absence of a terminal disclaimer or other statement requiring common ownership).

⁶ Determining (and comparing) expiration dates in the instant case is straightforward. The expiration date of any patent granting on the instant application is limited to the 20-year patent term in view of previously filed terminal disclaimers, and the later expiration dates of the asserted reference patents likewise can be readily calculated. See Rehearing Decision, 14-15. Since there is no extension of patent term in the instant case, much less an unjust one, there can be no OTDP on this basis alone.

⁷ This position is even supported statutorily in view of 35 U.S.C. § 121, in which certain patents issuing from divisional applications (as well as the patent issuing from the application that received the restriction requirement) are shielded from double patenting, notwithstanding potential concerns regarding the possibility of separate ownership.

The Federal Circuit and its predecessor court, as far back as 1938, have upheld the availability of the two-way test. See e.g., In re Berg, 140 F.3d 1428, 1432 (Fed. Cir. 1998); see also In re Calvert, 97 F.2d 638 (C.C.P.A. 1938). In In re Braat, the Federal Circuit applied the two-way test and overturned a Board decision affirming an examiner's OTDP rejection. See 937 F.2d 589, 590 (Fed. Cir. 1991). The Federal Circuit acknowledged that its holding would effectively result in the extension of patent term; nonetheless, the Court determined that this extension of term **was not unjustified**. Id. at 594 (“Thus, only if the extension of patent right is **unjustified** is a double patenting rejection appropriate. There are situations where the extension is justified... This case presents such a situation.”) (emphasis added). Because the conditions of the two-way test were met, a terminal disclaimer **was not** required. It logically follows from the existence of the two-way test (and related Federal Circuit and C.C.P.A. precedent) that the possibility of separate ownership cannot serve as the sole basis to find an asserted reference is a proper OTDP Reference – the possibility of separate ownership **will always exist** in instances where the two-way test is met, because maintenance of common ownership is not required.⁸

Furthermore, M.P.E.P. guidance instructs examiners to withdraw OTDP rejections in instances when the two-way test is met – without considering concerns over separate ownership and without requiring the filing of a terminal disclaimer. See M.P.E.P. § 804 II.B.5.

Thus, the existence of the two-way test proves the point that the risk of harassment from separate ownership does not provide an independent basis for establishing a reference as a proper OTDP Reference.

B. Federal Circuit Case Law Does Not Support that the Risk of Harassment from Separate Ownership is an Independent Basis for an OTDP Rejection

⁸ The filing of a terminal disclaimer (or other document requiring common ownership) would obviate this concern. However, the Federal Circuit has not required the filing of a terminal disclaimer when the conditions of the two-way test are met. See In re Braat, 937 F.2d at 590.

The holdings (and precedent) established in prior Federal Circuit decisions in which the court addressed the question of whether references qualify as OTDP References do not support that a concern over separate ownership (or preventing potential harassment by separate owners of claims to obvious variants of an invention) is an independent basis for an OTDP rejection.

In Allergan, the Federal Circuit reasoned that the asserted reference patents did not qualify as OTDP References against the target patent because “[t]hat [was] the *only conclusion consistent with the purpose* of the [OTDP] doctrine.” See 111 F.4th at 1369 (emphasis added). Once it was determined that the asserted reference patents did not qualify as OTDP References, that analysis ended, and no terminal disclaimer was needed. The Federal Circuit held and reasoned likewise in Ezra, 909 F.3d, 1375 n.4 (“Because we find that the ’565 patent is not a double patenting reference for the ’229 patent, we need not address Ezra’s arguments as to whether the ’229 patent is patentably indistinct from the ’565 patent.”) and in Novartis Pharms. Corp. v. Breckenridge Pharm. Inc., 909 F.3d 1355, 1358 (Fed. Cir. 2018)(“[T]he ’990 patent is not a proper double patenting reference for the ’772 patent. Accordingly, we reverse.”).

It logically follows from the precedent established in Allergan, Ezra, and Breckenridge that concerns over separate ownership cannot serve as the sole basis for upholding an OTDP rejection. The possibility of separate ownership *existed* in Allergan, Ezra, and Breckenridge; nonetheless, the Federal Circuit found that the asserted references did not qualify as OTDP References.

Appellant acknowledges that in cases such as In re Fallaux, 564 F.3d 1313 (Fed. Cir. 2009), In re Hubbell, 709 F.3d 1140 (Fed. Cir. 2013), and In re Collect, 81 F.4th 1216 (Fed. Cir. 2023), the Federal Circuit has discussed a concern over separate ownership (or preventing potential harassment by separate owners of claims to obvious variants of an invention).

However, unlike Allergan (and the instant case), none of Fallaux, Hubbell, or Cellect involved a dispute as to whether an asserted reference qualified as an OTDP Reference.⁹ Indeed, in Allergan, the Federal Circuit explicitly stated that Cellect did not address whether the reference patents used to invalidate the asserted patents were proper OTDP References. See 111 F.4th at n. 6. The Board correctly concluded that these cases do not support that the possibility of separate ownership is an independent basis for an OTDP rejection. See Rehearing Decision, pages 16-23.

Thus, the *fundamental purpose* of the OTDP doctrine (*i.e.*, preventing an unjustified timewise extension of a patentee's monopoly) – not the possibility of separate ownership – is the guiding principle for determining whether a reference qualifies as an OTDP reference.

Conclusion

In view of the foregoing, Appellant respectfully submits that the Board held correctly in the Rehearing Decision on Request for Rehearing Appeal and the Original Decision on Appeal.

Dated: March 27, 2026

Respectfully submitted,

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⁹ The question in In re Fallaux was whether the applicant could rely on the two-way test to overcome an OTDP rejection; the questions in In re Hubbell were whether common ownership is a requirement for OTDP and whether certain alternatives to OTDP were available under equity; and the question in In re Cellect was what expiration date applies to OTDP on a patent that has received Patent Term Adjustment.