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

Before JOHN A. SQUIRES, *Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*, KALYAN K. DESHPANDE, *Chief Administrative Patent Judge*, and MICHELLE N. ANKENBRAND, *Acting Deputy Chief Administrative Patent Judge*.

SQUIRES, *Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*.

DECISION ON *SUA SPONTE* REHEARING

I. INTRODUCTION

This Appeals Review Panel ("ARP") was convened to review the Board's Decision on Appeal ("Dec." or "Appeal Decision") and Decision on Request for Rehearing ("Reh'g Dec." or "Rehearing Decision"), with particular focus on the Board's reversal of the Examiner's rejections of claims 1–18 for nonstatutory double patenting, also known as obviousness-

type double patenting ("OTDP"). We have jurisdiction under 35 U.S.C. § 6(b).

On review, we REVERSE.

II. BACKGROUND

A. Procedural History

On November 8, 2024, the Board issued an Appeal Decision reversing the Examiner's rejections for OTDP.[1] On January 3, 2025, the Examiner filed a Request for Rehearing ("Req. Reh'g") under MPEP § 1214.04. On December 18, 2025, the Board issued a Rehearing Decision, which included a dissenting opinion.

On March 5, 2026, I convened this Appeals Review Panel ("ARP")[2] and granted *sua sponte* rehearing to review the Board's Appeal Decision and Rehearing Decision. *See* ARP Order, dated Mar. 5, 2026 ("ARP Order"). In the ARP Order, we authorized further briefing from Appellant. ARP Order 2. We also permitted briefing from *amici curiae*. *Id.*

The ARP Order indicated that Appellant and *amici* should consider addressing the following three questions: (1) whether *Allergan USA, Inc. v.*

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[1] The Appeal Decision reversed six OTDP rejections based on each of the following reference patents or patent applications in combination with US 2009/0162359 A1 ("Klein"): (i) Patent 10,882,922 B2 ("the '922 patent"), (ii) Patent 11,186,649 B2, (iii) Patent 11,530,268 B2, (iv) Patent 11,613,576 B2, (v) Patent 11,192,960 B2, and (vi) Application 18/183,107 (now Patent 12,227,573 B2). Appeal Dec. 3–4, 11. The Appeal Decision focused on the rejection involving the combination of Klein and the '922 patent, and noted that all of the rejections involved the same determinative issue. *Id.* at 4. We likewise focus our discussion on the OTDP rejection involving the combination of Klein and the '922 patent.

[2] *See* Appeals Review Panel § 1, available at https://www.uspto.gov/patents/ptab/appeals-review-panel.

MSN Laboratories Private Ltd., 111 F.4th 1358 (Fed. Cir. 2024), applies to the facts of this appeal and what constitutes "first-filed" for OTDP purposes under facts different than presented in *Allergan*; (2) whether examiners should determine projected expiration dates when making rejections for OTDP 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. ARP Order 2.

The Office received Appellant's additional briefing ("ARP Brief" or "ARP Br.") on March 27, 2026, and received eleven briefs from *amici*, which were entered into the prosecution record on April 1, 2026.

On August 6, 2026, an Order changing the ARP panel was entered.

B. Undisputed Matters

The '529 Application at issue in this case was filed December 28, 2020. Appeal Dec. 6. The '529 Application, through intervening continuation applications, claims the priority benefit of a non-provisional application (US Application No. 13/433,033) filed March 28, 2012. *Id.* at 5. Thus, the term of any patent issued on the '529 Application will expire on March 28, 2032—twenty years from the patent term filing date[3]—absent other factors that may affect patent term.[4] Appeal Dec. 5–7.

[3] Patent term filing date refers to the filing date that begins the running of the term. This date generally is the filing date of the first U.S. application to which the patent claims priority (i.e., it excludes priority claims to foreign or provisional applications). 35 U.S.C. § 154(a)(2).

[4] Appellant has acknowledged that, in view of existing terminal disclaimers over two other patents, any patent issuing on the '529 Application could not expire later than March 28, 2032, the same as its natural term expiration. Appeal Br. 10–11.

The '922 patent, asserted here as an OTDP reference, has an actual and patent term filing date of April 13, 2017. The '922 patent issued January 5, 2021. Its twenty-year term ends April 13, 2037, and it received an additional 70 days for patent term adjustment.

The '529 Application and the '922 patent are, at present, commonly owned by Appellant Sanofi and share several common inventors (Christian Beil, Ercole Rao, Christian Lange, and Carsten Corvey).

The Examiner determined that "[t]here is no dispute regarding Appellant's analysis of the patent term filing date." Ans. 11.

The claims on appeal relate to an antibody-like binding protein with certain characteristics. Appeal Br. 50 (Claims Appendix). The Examiner found, with no counterargument from Appellant, that pending claims 1–18 would have been obvious over claims 1–39 of the '922 patent in further view of Klein. Ans. 3–4. Appellant argued and the Examiner acknowledged, however, that the claims of the '922 patent would not have been obvious over the '529 Application's disclosure (as published). Appeal Br. 16; Ans. 12.

C. Double Patenting History

To provide additional context for our decision, we first set forth a history of the prohibition against double patenting, which is grounded in statutory language extending back to the earliest patent statutes.

1. Statutory Basis of the Prohibition Against Double Patenting

The prohibition against double patenting is firmly rooted in the text of the Patent Act. Section 101 of the statute provides that applicants "may obtain *a patent*" on their inventions. *See* 35 U.S.C. § 101 (emphasis added). Similar language has existed in every patent statute in U.S. history. *See*

Patent Act of 1790, § 1, 1 Stat. 109, 110 (codifying "that *a patent* may be granted" on an applicant's invention) (emphasis added); Patent Act of 1793, § 1, 1 Stat. 318, 320 (same); Patent Act of 1836, § 6, 5 Stat. 117, 119 (authorizing the Commissioner of Patents to "grant *a patent*" on each new invention) (emphasis added); Patent Act of 1870, § 24, 18 Stat. 198, 201 (authorizing applicants to "obtain *a patent*" on an invention) (emphasis added). The use of the singular—"a patent"—signals that, by statute, only a single patent is allowed on each invention. Thus, the basic prohibition against double patenting has long been grounded in the text of our country's Patent Acts.

Importantly, the prohibition against double patenting has also long extended to prohibit multiple patents on trivial variations of the same invention. As the Supreme Court held in *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894), "no patent can issue for an invention actually covered by a former patent, especially to the same patentee, although the terms of the claims may differ." *See also McCreary v. Pa. Canal Co.*, 141 U.S. 459, 467 (1891) (stating that a second patent containing only a "colorable variation" from a first would be void because "a patentee cannot take out two patents for the same invention"). Thus, trivial variations of the claim language do not remove a patent from the prohibition on double patenting of the same invention.

That additional rule is, in modern caselaw, frequently and accurately described as a prohibition on "obviousness-type double patenting." While this rule has sometimes been called a judicially-created doctrine, the rule is also well-grounded in the statute. The statutory language in current § 101 of the Patent Act states that "a patent" may be awarded to "[w]hoever invents

or discovers" new technology. *See* 35 U.S.C. §101. Invention and discovery are expressly defined in the Patent Act to be synonyms, *see* 35 U.S.C. § 100(a) (defining "invention" to mean "invention or discovery"), and since at least 1793, some class of trivial variations are not considered to constitute a patentable invention or discovery. *See* Patent Act of 1793, § 2, 1 Stat. at 321 (declaring that "simply changing the form or the proportions of any machine, or composition of matter, in any degree, shall not be deemed a discovery" for purposes of patent law); *see also Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1851) (holding that technological changes reflecting merely "the skill and ingenuity . . . possessed by an ordinary mechanic acquainted with the business" lack "that degree of skill and ingenuity which constitute essential elements of every invention"). Ever since 1952, the class of trivial variations of existing technology that are not patentable are described as those "obvious" to a person having ordinary skill in the relevant art. *See* 35 U.S.C. § 103.

At its core, the longstanding doctrine against double patenting reflects the basic patent-law bargain: in exchange for a limited right to exclude, the inventor discloses the invention to the public, and the public receives the right to practice that invention when the patent expires. *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). Further, as the Supreme Court explained well over a century ago, "the power to create a monopoly is exhausted by the *first patent*, and . . . a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." *Miller*, 151 U.S. at 198 (emphasis added).

Although the ban on double patenting may have been viewed as absolute in the nineteenth and early twentieth century, Congress in the 1952

enacted § 253 of the Patent Act, which included a provision authorizing patentees to "disclaim" the "terminal" part of a patent term. Patent Act of 1952, § 253 66 Stat. 792, 809 (1952) (second paragraph); *see also* 35 U.S.C. § 253(b) (modern codification). Contemporaneous commentary read that provision as providing a potential "cure" for some double patenting problems, and such commentary can provide an indication of the original public meaning of the statute. Within a dozen years, the Federal Circuit's predecessor court, the Court of Customs and Patent Appeals ("CCPA"), permitted terminal disclaimers to overcome at least some double patenting objections raised during patent prosecution. *See In re Robeson*, 331 F.2d 610 (CCPA 1964). As the court noted, "when the right to exclude granted by a patent expires at the end of the patent term, the public shall be free to use the invention as well as obvious modifications thereof or obvious improvements thereon." *Id.* at 614. A terminal disclaimer could vindicate that policy by ensuring that any subsequent patents on obvious modifications of a first-issued patent expired at the same time as the first patent.

Since the early 1970s, to overcome an OTDP rejection, agency regulations have required a terminal disclaimer both to disclaim any term extending beyond the expiration of a related patent *and* to identify and maintain common ownership. *See* 37 C.F.R. § 1.321(c) (1971). Indeed, a "terminal disclaimer precludes any extension" of patent term because "the second patent expires simultaneously with the first, [and] the right to fully utilize the patented discovery at the expiration date remains unimpaired." *Robeson*, 331 F.2d at 614.

2. An Important Limitation on the Prohibition against Double Patenting

The Supreme Court in *Miller* also set forth a logical limitation on the prohibition on double patenting. The Court observed "that where the second patent covers matter described in the prior patent, essentially distinct and separable from the invention covered thereby, and claims made thereunder, its validity may be sustained." 151 U.S. at 198. This passage is correctly read as vindicating another fundamental part of the Patent Act: Any patentably distinct inventive "improvement" on basic technology is itself patentable in a subsequent patent. *See* 35 U.S.C. § 101 (expressly allowing patents on any "new and useful improvement").[5] A new patent on a nonobvious improvement on previously patented technology does not violate the prohibition against double patenting, and that remains true even if the inventors and owners of the first and second patents are the same. Encouraging nonobvious improvements on existing technology is an important part of the patent system, and the inventors of a basic technology are often well positioned to develop patentable improvements on that technology.

3. OTDP Before the Uruguay Round Agreements Act (URAA)

Before the URAA was enacted in 1994, a patent's term ran seventeen years from its issuance. URAA, Pub.L. 103–465, 108 Stat. 4809. Under that pre-URAA framework, issuance date and expiration date were closely

[5] Further to this point on improvements, the statutory definition of "process" means "process, art or method, and includes *a new use of a known* process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b) (emphasis added).

linked—a later-issued patent generally expired later. Courts, therefore, often framed OTDP concerns as arising from a "second" or "later-issued" patent because that "second" patent was ordinarily the one that threatened to extend the patentee's term of exclusivity already set by a first or earlier-issued patent.

The pre-URAA focus on issue date reflected the mechanics of patent term at the time. A later-issued patent on the same invention or an obvious variant could prolong the patentee's right to exclude after the first patent expired. Thus, the caselaw described OTDP as a doctrine aimed at preventing an unjustified timewise extension of patent rights due to the grant of a second-issued patent. For example, in *In re Schneller*, 397 F.2d 350, 354 (CCPA 1968), the court stated that "[t]he fundamental reason for the rule [of OTDP] is to prevent unjustified timewise extension of the right to exclude granted by a patent." The same rationale informed the Federal Circuit's early OTDP cases, where the central concern was an improper extension of exclusivity through claims that were not patentably distinct. *See, e.g.*, *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

4. OTDP After URAA

The URAA changed the patent-term framework by setting patent term to twenty years from the earliest effective filing date. 35 U.S.C. § 154(a)(2). After that change, issuance date no longer predicted expiration date. That is, a later-issued patent may expire earlier, and an earlier-issued patent may expire later. Nonetheless, in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1217 (Fed. Cir. 2014), the court recognized the continued importance of the OTDP doctrine post-URAA, and held that a later-issued, but earlier-expiring patent could serve as an OTDP reference against an

earlier-issued but later-expiring patent. Then, in *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1374 (Fed. Cir. 2014), the court made "explicit what was implicit in *Gilead*: the doctrine of [OTDP] continues to apply where two patents that claim the same invention have different expiration dates."

5. Modern OTDP Analysis

More recent Federal Circuit decisions show that expiration date plays a central role in the OTDP analysis, but does not operate as an absolute rule. The modern OTDP inquiry considers not only which patent expires first, but also why the patents have different expiration dates. For example, the court has treated patent term adjustment ("PTA") and patent term extension ("PTE") differently when analyzing OTDP. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018) (holding OTDP does not invalidate a validly obtained PTE); *In re Cellect*, 81 F.4th 1216, 1229 (Fed. Cir. 2023) (holding OTDP is based on patent expiration dates after PTA is added).

In 2024, the Federal Circuit's *Allergan* decision further refined the expiration-date inquiry behind OTDP, and cautioned against an overly mechanical analysis. In *Allergan*, the challenged patent was the first-filed and first-issued patent in a family, but due to PTA, it would expire after two later-filed continuation patents that were being asserted against the parent as OTDP. *Allergan*, 111 F.4th at 1363. The court 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.* at 1369. The court reasoned that "the first-filed, first-issued patent in its family . . . sets the maximum period of exclusivity for the claimed subject

matter and any patentably indistinct variants." *Id.* In other words, the parent patent received the full term to which it was statutorily entitled—it did not create an unjustified timewise extension of the monopoly, and the later-filed, earlier-expiring continuation patents, therefore, were not properly asserted as OTDP references against the parent patent. *Id.*

6. Two Rationales for OTDP

As discussed above, the primary and historically dominant rationale for OTDP is preventing unjustified timewise extension of a patent's term. Cases such as *AbbVie*, *Gilead*, and *Allergan* focused on whether the challenged patent improperly extended exclusivity beyond the point at which the public should be free to practice the invention and obvious variants.

The courts, however, also have recognized a second policy rationale behind OTDP: preventing harassment from separate lawsuits brought by multiple assignees asserting patents covering the same invention or obvious variants thereof (the "anti-harassment rationale"). *See, e.g.*, *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (stating that "there is a second justification for obviousness-type double patenting—harassment by multiple assignees"). We discuss this second rationale in more detail below because it plays a pivotal role in our decision.

The coexistence of the two recognized rationales for OTDP has produced tension in the doctrine. Some decisions describe prevention of unjustified term extension as the doctrine's primary purpose, while others invoke anti-harassment to sustain OTDP in circumstances where the term-extension concern is diminished or absent. *Compare Allergan*, 111 F.4th at 1369 (describing "fundamental purpose[]" of OTDP as avoiding improper timewise term extension), *with Fallaux*, 564 F.3d at 1318 (explaining

"unjustified patent term extension justification . . . has limited force in this case"). The rationales often point in the same direction when patents are commonly owned and have different expiration dates: a terminal disclaimer can align both terms. Yet in cases where there is no unjustified term extension, there remains a broader (and arguably unsettled) doctrinal question of whether anti-harassment should serve as an independent basis for OTDP. Having discussed the history, current application, and rationales for OTDP, we now turn to the case at hand.

III. ANALYSIS

A. Allergan Does not Apply to This Case

We asked Appellant and *amici* to address whether *Allergan* applies to the facts of this appeal and what constitutes "first-filed" for OTDP purposes under facts different than presented in *Allergan.* Appellant and most *amici* focus on the Federal Circuit's discussion in *Allergan* about the fundamental purpose of OTDP, i.e., to prevent patent applicants from effectively extending the life of a first patent and the relative filing dates of the patent applications involved in an OTDP analysis, in urging that *Allergan* applies broadly. *See, e.g.*, Response to Order Convening Appeals Review Panel and Granting *Sua Sponte* Rehearing, 1–3; Brief of *Amicus Curiae* Amgen Inc. in Support of Appellant, 2–5.

Although Appellant and the *amici* arguments are not without merit, we determine that the OTDP exception *Allergan* establishes does not apply to the facts here. The holding in *Allergan* was 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." *Allergan*, 111 F.4th at 1369. The "first-filed" prong refers to actual filing dates, as this

is the interpretation that makes best sense in view of the facts of *Allergan*—the challenged and reference patents had the same patent term filing date and there was no suggestion that the conflicting claims had different effective filing dates. In the present case, the "first-filed" prong is not satisfied because the '529 Application does not have the first actual filing in its family, as was the case for the challenged patent in *Allergan*. Nor does the '529 Application have an earlier actual filing date than the '922 patent. With respect to the "first-issued" prong, the claims of the '529 Application are not "first-issued" because the '529 Application is still pending. The "common priority date" prong refers to patent term filing dates, s*ee id.* at 1363 (explaining that each of the two reference patents "will expire on March 14, 2025, *i.e.*, twenty years from its priority date"), and this prong is not satisfied because the '529 Application and the '922 patent have different patent term filing dates. Thus, *Allergan*'s holding does not apply here.

B. The Board's Decision is Contrary to Binding Federal Circuit Precedents

We now turn to the Board's decision that the '922 patent could not serve as an OTDP reference against the claims on appeal. Appeal Dec. 9. The Board reached its decision not because the claims on appeal are nonobvious over the '922 patent's claims—it was undisputed that the appealed claims covered obvious variants of what is claimed in the '922 patent. *Id.* at 4, 9. Instead, the Board considered decisive that any claims issuing from the '529 Application on appeal "will have a term that cannot extend beyond March 28, 2032, which is well before the expiration of the '922 patent claims [in 2037]." *Id.* at 6–7. As the Board explained, in typical OTDP cases, "the reference patent claims ha[ve] an earlier filing date than the patent against which they were applied," but here "the Examiner is

applying . . . [reference] claims from a second, later-filed application that was earlier-issued, but would be later expiring than claims that would issue from the application on appeal." *Id.* at 8.

The Board in effect found the OTDP doctrine inapplicable where issuance of the claims on appeal would not raise term-extension concerns. Because it was undisputed that the earlier-filed, earlier-expiring claims on appeal would not, if issued, extend the life/term of the later-filed and later-expiring '922 patent claims, the Board reasoned that the underlying purpose of the OTDP doctrine was not implicated.[6] *Id.* at 7 (citing *Allergan*, 111 F.4th at 1369, for the proposition that the "purpose of the non-statutory double patenting 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'"); *see also* Reh'g Dec. 9 (same). According to the Board, the appealed claims will not produce "a second, later expiring patent for the same invention as the '922 patent, and as such do[] not extend a period of exclusivity on the claimed subject matter." Appeal Dec. 10. Thus, the Board concluded that "the '922 patent claims cannot serve as reference claims against the claims on appeal" and reversed the Examiner's OTDP rejection. *Id.* at 10.

Improper term extension, however, is not the only rationale underpinning the OTDP doctrine. As discussed above, the anti-harassment

[6] The filing dates referred to here by the panel are patent term filing dates under 35 U.S.C. § 154(a), which the panel also refers to in its decisions as "effective" filing dates. *See* Appeal Dec. 9; Reh'g Dec. 3–5. Such dates may be, but are not necessarily, an application's or patent's actual filing dates.

rationale is a second justification for the doctrine. As the Federal Circuit has recognized:

> There are two justifications for obviousness-type double patenting. The first is "to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *Van Ornum*, 686 F.2d at 943–44 (quotation and citation omitted). The second rationale is to prevent multiple infringement suits by different assignees asserting essentially the same patented invention. *Fallaux*, 564 F.3d at 1319 (recognizing that "harassment by multiple assignees" provides "a second justification for obviousness-type double patenting"); *see also* Chisum on Patents § 9.04[2][b][ii] ("The possibility of multiple suits against an infringer by assignees of related patents has long been recognized as one of the concerns behind the doctrine of double patenting.").

In re Hubbell, 709 F.3d 1140, 1145 (Fed. Cir. 2013).

Current Office guidance instructs examiners to consider both rationales when making OTDP rejections. *See* MPEP § 804(II)(B). As spelled out in that guidance, "[a] rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent." *Id.* (citing precedents). Moreover, the guidance states, "[a] double patenting rejection also serves public policy interests by preventing the possibility of multiple suits against an accused infringer by different assignees of patents claiming patentably indistinct variations of the same invention." *Id.* (citing precedents).

And, to address both rationales, when an applicant files a terminal disclaimer to overcome OTDP rejections, the Office's rules specify that such disclaimer must also include a common-ownership provision. 37 C.F.R. § 1.321(c). More specifically, the Office requires a terminal disclaimer to

include a provision that any patent granted on the subject application "shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting." *Id.* at § 1.321(c)(3); *see also In re Van Ornum*, 686 F.2d 937, 944–48 (CCPA 1982) (approving common-ownership requirement under 37 C.F.R. § 1.321); *In re Griswold*, 365 F.2d 834, 840 n.5 (CCPA 1966) (noting the common-ownership requirement was "an imaginative solution to one of the more theoretical objections to double patenting, split ownership of two patents and potential harassment").

The Examiner cited the risk of separate ownership and the anti-harassment rationale as support for the OTDP rejections on appeal, but the Board dismissed that rationale as immaterial. Final Act. 7–8; Reh'g Req. 10–12. According to the Board, "a risk of separate ownership . . . is immaterial where the '922 patent is not a proper nonstatutory double patenting reference." Appeal Dec. 10 n.6. In the Board's view, the anti-harassment rationale does not independently support an OTDP rejection and plays, at most, only a supporting role when the first rationale—improper term extension—is present. Reh'g Dec. 16–22 (rejecting proposition that the anti-harassment rationale "is a stand-alone justification" for upholding the OTDP rejections).

To demonstrate the real-world concern associated with the anti-harassment rationale, consider (for example) a hypothetical licensee to the '922 patent. Such a licensee might legitimately believe that it has the full permission of the patent owner to practice the technology disclosed and claimed in the '922 patent, but if the '529 Application should issue as a patent, such licensee will need to obtain a new license from the patent owner

of the '922 patent as that owner would also own the results of the '529 Application. Worse still, if the current owner of the '922 patent should sell the rights to the pending '529 Application, licensees of the '922 patent would have to negotiate with an entirely different entity.

We conclude that the Board erred in dismissing the anti-harassment rationale as inadequate to support the Examiner's OTDP rejections. The Federal Circuit has repeatedly recognized the anti-harassment rationale as a policy justification underpinning the OTDP doctrine and, applying that law here, we are compelled to reverse the Board and sustain the rejections for OTDP on appeal.

The Federal Circuit has invoked the anti-harassment rationale and endorsed the Office's rules designed to address it, even where there was no evident term extension concern. In *Fallaux*, for example, after remarking that "[i]t is true that the unjustified patent term extension justification for obviousness-type double patenting has limited force in this case," the court turned to "a second justification for obviousness-type double patenting—harassment by multiple assignees." *Fallaux*, 564 F.3d at 1318–19 (affirming the Board and OTDP rejections on appeal). Indeed, the court explained, the "harassment justification . . . is particularly pertinent here because the Fallaux application and the [reference] patents are not commonly owned," noting "this defect was of the applicant's creation" due to assignments that split ownership between different entities. *Id.* at 1319. The appealed claims in *Fallaux* had an earlier patent term filing date and earlier expiration date compared to the reference patent's respective patent term filing and expiration dates—much like the claims of the '529 Application and the

'922 patent at issue before us. *Id.* at 1315. Thus, as in this case, improper timewise extension of patent term was absent in *Fallaux*.

Four years later, the court revisited and "reaffirmed" the anti-harassment rationale as underpinning the OTDP doctrine. *Hubbell*, 709 F.3d at 1147 (explaining "in *Fallaux*, this court reaffirmed the multiple assignee harassment rationale and applied it to a situation where, as here, the patents were related to the application only by way of a common inventor"). Although the main dispute in *Hubbell* was whether OTDP rejections could be sustained where the application and reference patent were not commonly owned and shared only partial overlap in named inventors, the court repeatedly invoked the anti-harassment rationale in affirming the Board. *Id.* at 1147–48 (finding "if Hubbell's rejected application claims were to issue, the potential for harassment by multiple assignees would exist" because an infringer of the reference claims would also infringe the pending claims and, thus, "the multiple assignee harassment justification adopted in *Van Ornum* and reaffirmed in *Fallaux* applies here"). And, like *Fallaux*, improper term extension was not an identified concern given the respective patent term filing dates and apparent expiration dates for the appealed and reference claims. *See id.* at 1142–43 n.1–2.

More recently, in *Cellect*, the court identified the risk of separate ownership as a reason to uphold the Office's OTDP rejections. Indeed, the court seemingly accepted the Office's argument that a terminal disclaimer ensuring continued common ownership would have been required to overcome OTDP rejections "even if the patents had the same expiration date." *Cellect*, 81 F.4th at 1229. Although term extension issues were manifest in *Cellect* as the relevant patents did not share expiration dates, the

court "also agree[d] with the USPTO that the Board did not err in determining that a risk of separate ownership existed and, even in the absence of separate ownership, that a terminal disclaimer would have been required to ensure common ownership." *Id.* at 1230 (agreeing the risk of divided ownership and separate lawsuits existed despite patentee's argument that it had not and would not split ownership of the patents, explaining "[p]romises do not substitute for sound applications of rules of law"). Here again, the court recognized the anti-harassment rationale behind the OTDP doctrine. *Id.*

Given the foregoing precedents, we disagree with the Board's characterization of the anti-harassment rationale as "immaterial" and its attempt to brush aside decisions applying that rationale as mere "dicta." *See* Appeal Dec. 10 n.6; Reh'g Dec. 16–23. As explained above, in at least *Fallaux* and *Hubbell*, there was no apparent term extension concern and no asserted rationale based on it—the OTDP rejections were premised on *later-filed* and *later-expiring* reference patents.[7] Yet the Federal Circuit, citing

[7] The Board suggests improper term extension was at issue in *Hubbell*, but that is incorrect. Reh'g Dec. 17. According to the Board, "[i]n *Hubbell*, there was no dispute that the reference patent [with species claims], which was filed post-URAA, was filed prior to the application at issue [with genus claims]." *Id.* Thus, the Board concluded "there can be no dispute that the issuance of genus claim of the application would extend the term of the reference patent species claim." *Id.* The Board is mistaken. The flaw in the Board's reasoning is its reliance on and comparison of *actual* filing dates, not patent term filing dates for determining the terms. Comparing patent term filing dates, the term of the rejected genus claim (with an earlier patent term filing date) would end before the term of the reference species claim (with a later patent term filing date) and, therefore, the species claim's term was not extended. *Hubbell*, 709 F.3d at 1142–43 n.1, n.2.

the anti-harassment rationale, affirmed the Office's OTDP rejections all the same. Although we note the Board's (and Appellant's) attempts to dismiss *Fallaux* and *Hubbell*, the notion that the court's discussion of the anti-harassment rationale in those cases is dicta would mean that the rejections were affirmed for no underlying OTDP rationale at all. *See* ARP Br. 9–10; *see* Brief for Prof. Mark A. Lemley and Prof. Lisa Larrimore Ouellette as *Amici Curiae* in Support of Examiner, p. 5, Appeal 2024-002920 (PTAB Nov. 8, 2024).

If, contrary to our conclusion here, the Federal Circuit's precedents should not be read as permitting OTDP rejections based on the anti-harassment rationale where no term-extension concern is apparent, the Office would welcome that clarification from the court. Indeed, the issue is now before the court in *In re: Ablynx N.V.*, Appeal No. 26–1333 (*sub nom Ex parte Baumeister*). *See Ex parte Baumeister*, 2025 WL 3515282 at *10 (PTAB Nov. 20, 2025) (determining that *Van Ornum*, *Fallaux*, and related progeny supported the examiner's OTDP rejection, and rejecting appellant's argument that those precedents were "wrongly decided" because the "Board is not the proper venue to address this argument"); *see also id.* at *5 (determining that "*Fallaux* remains good law" and rejecting appellant's argument "that the reference patents do not qualify as [OTDP] references because they each have a later patent term filing date compared to the instant application and expires later than any patent issuing from the instant application").

C. A Future Framework for OTDP at the USPTO

We reverse the Board's determination and sustain the Examiner's rejections for OTDP for the reasons discussed above, applying existing

precedents as we understand them. Nonetheless, the ARP also takes this opportunity to provide our thoughts about the continued significance of examining for OTDP at the Office, and to propose a possible framework for an approach to OTDP that is reasonably administrable by examiners and more predictable to our stakeholders, should the Federal Circuit clarify that OTDP rejections cannot be based solely on the anti-harassment rationale. The proposed framework acknowledges the precedents and the policy justifications behind the OTDP doctrine while endeavoring to apply the doctrine in a way that avoids harm to existing and future innovation identified by *amici*.

1. Whether Examination for OTDP Remains Necessary

If the primary policy justification for the OTDP doctrine is the improper timewise extension of a first patent's term of exclusivity arising from a later-filed second patent covering obvious variants of the subject matter claimed in the first patent, it must be acknowledged that this policy justification plays a diminished role following the passage of the URAA. That law, effective June 8, 1995, changed patent term from seventeen years from a patent's issuance to a twenty-year patent term that begins to run from the patent's earliest claimed priority date. *See* 35 U.S.C. § 154(a). By tying the putative expiration date of related patents to a single common filing date, that change in the law curbed abuses in continuation practices where, previously, related applications claiming essentially the same subject matter might be filed seriatim with each newly-issued patent getting a new 17-year term—effectively extending the patent monopoly well beyond the original life of the first-issued patent. *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010) ("The doctrine of

obviousness-type double patenting is an important check on improper extension of patent rights through the use of divisional and continuation applications, at least for patents issued from applications filed prior to the amendment of 35 U.S.C. § 154 to create twenty-year terms running from the date of the earliest related application.").

The Federal Circuit has acknowledged that the URAA mitigated concerns about improper term extension as forming a basis for the rejection or invalidation of claims for OTDP. In *Fallaux*, for example, the court noted the "limited force" the patent term extension justification holds for post-URAA patents, explaining "this is surely true of many double patenting rejections today, in no small part because of the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing." *Fallaux*, 564 F.3d at 1318. So too in *Allergan*, where the court noted that "[i]n many cases . . . post-URAA, there is little risk of an unjustified extension of term subject to [OTDP] because all patents to an invention that share a priority date are expected to expire on the same day." *Allergan*, 111 F.4th at 1367.

At the same time, the court has also recognized that the OTDP doctrine is still important, even for post-URAA patents. *Abbvie*, 764 F.3d at 1373 ("Although this court has recognized that the doctrine of [OTDP] is less significant in post-URAA patent disputes, we have also recognized its continued importance."). OTDP "continues to apply where two patents that claim the same invention have different expiration dates." *Id.* at 1374. This may happen when the challenged claims and the reference claims are filed as part of different patent families with different patent term filing dates, such as in *Gilead*. *See Gilead*, 753 F.3d at 1210. There, the court held that an

earlier-filed and "earlier-expiring patent can qualify as an [OTDP] reference for a later-expiring patent" regardless of the patents' respective issue dates. *Id.* at 1214–1217 ("Looking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting.").

The court has also held that the OTDP doctrine may apply where a grant of PTA under 35 U.S.C. § 154(b) causes related patents to have different expiration dates. Indeed, the court has affirmed rejections for OTDP when, for instance, two related patents share the same patent term filing date but a later-issued patent claiming obvious subject matter has, by reason of awarded PTA, a longer term than an earlier-issued patent with less or no PTA. *See Cellect*, 81 F.4th at 1219–21 (comparing, e.g., the '742 patent's claims with claims of the '369 reference patent), 1226 (holding a "crucial purpose of [OTDP] is to prevent an inventor from securing a second, later-expiring patent for non-distinct claims," which "purpose applies equally to situations in which the later patents have received grants of PTA resulting from examination delays at the USPTO").[8] There are exceptions, however, as seen in *Allergan* where a first-filed, first-issued parent patent that received PTA was not invalidated for OTDP by its later filed and issued progeny patents that received no PTA. *Allergan*, 111 F.4th at 1363–64 (depicting filing, issue, and expiration timeline of related patents), 1369 ("We therefore hold that a first-filed, first-issued, later-

[8] Although OTDP may apply based on different expirations resulting from the grant of PTA, it cannot be based on different expiration dates arising from PTE under § 156. *Novartis*, 909 F.3d at 1372 (holding the "judge-made doctrine" of OTDP should not be used to "cut off a statutorily authorized time extension" for otherwise validly obtained PTE).

expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date.").

Although improper term extension concerns are less prevalent post-URAA, we heed the Federal Circuit's instruction that the OTDP doctrine is still needed. Accordingly, under the proposed framework, the Office would continue to review patent applications for potential OTDP. For reasons we discuss below, however, the ARP is of the view that the Office's review for OTDP should be more streamlined, predictable, and, to the extent possible, aimed at mitigating the term extension issues the court has flagged for post-URAA patents. Further, and to those ends, the Office's review should be based on facts of record known during examination—not speculation about matters unknown to the Office at that time.

2. Potential Harassment as a Freestanding Rationale for OTDP Rejections During Examination

Were the Office not bound by the Federal Circuit's precedents applying the OTDP anti-harassment rationale, this ARP would clarify that the risk of separate ownership and hypothetical harassment generally should not form a standalone basis for OTDP rejections during examination. This is so because, absent evidence that an applicant/patentee has engaged in splitting ownership to patents covering obvious variants of the same invention and that the public has been subject to separate lawsuits on such patent, the Office is just speculating. And such speculation encumbers patents with terminal disclaimers including an anti-alienation and anti-enforcement provision that is premised on contingencies that may never come to be. As Judge Rich presciently observed nearly sixty-years ago, the anti-harassment rationale is more theory than real. *In re Jentoft*, 392 F.2d

633, 641 (CCPA 1968) (remarking "we do not see the courts bogged down with harassment suits").

Further, the Office's grant of a patent without an OTDP rejection or terminal disclaimer to overcome the rejection would not immunize that patent from all future challenges. If, in fact, a patentee does split ownership of multiple patents and facilitate harassment lawsuits, the courts are empowered to adjudicate validity under the judge-made OTDP doctrine or to penalize the offending behavior as appropriate. *Jentoft*, 392 F.2d at 641 ("In those rare instances where there is a situation which a court can be persuaded amounts to harassment, it has means for dealing with it by inflicting the plaintiff with attorney's fees.").

There are also policy downsides to sustaining OTDP rejections based on a freestanding anti-harassment rationale. As many of the *amici* point out, allowing later-filed, later-expiring patents to invalidate earlier-filed, earlier-expiring patents based merely on the possibility of split ownership and separate infringement lawsuits, discourages follow-on and inter-company collaborative research and may ultimately harm future innovation. *See, e.g.*, Brief for Canon Inc. et al., as *Amici Curiae* in Support of Appellant, p. 6–10, Appeal 2024-002920 (PTAB Nov. 8, 2024) ("Canon Br."); Brief for Regeneron Pharma., Inc. et al. as *Amici Curiae*, in Support of Appellant, p. 8–10, Appeal 2024-002920 (PTAB Nov. 8, 2024). Once the OTDP doctrine is untethered from the term-extension rationale, patents covering improvements, even if filed years after a foundational patent or application, might be used to invalidate or reject those foundational innovations—disincentivizing the discovery and patenting of such improvements. *See* Canon Br. at 7 ("This creates a backwards-looking OTDP problem that is

entirely unprecedented" where "the mere act of continuing to innovate by filing new patent applications that stand on their own could retroactively threaten the validity of a company's *existing* patents."). If the rule is that possible harassment is a sufficient rationale on its own, there are few limiting principles to this OTDP regime. Indeed, where a broad seminal patent claim is obvious over a "reference" patent claiming an improvement on that technology (regardless of respective filing or expiration dates), and if the patents are commonly owned or share even one inventor in common, that could be enough to reject or invalidate the seminal claim for OTDP.

An example may help illustrate a problem with applying the OTDP doctrine in this way. Imagine a scenario where inventors Smith, Rogers, and Jones file a patent application claiming a foundational genus or platform technology (e.g., nucleic-acid vaccines), which application is assigned to their employer Acme Corp. Jones then leaves Acme, starts his own company (Beta Corp.), and two years later with the help of inventor Davis, develops a method of treating pancreatic cancer with an mRNA vaccine for which they file a patent application that is assigned to Beta. Assume, for purposes of this example, that the Acme application is still pending at the time the Beta application issues as a patent. And further assume the Acme application claims are obvious over the Beta patent claims, but the Beta claims are a true improvement and nonobvious over the Acme claims.

Under this example scenario, there is no apparent term-extension concern if Acme's patent were to issue—it has an earlier patent term filing date than Beta's patent. But, applying the anti-harassment rationale alone, the Office could properly reject the Acme claims for OTDP. While Acme may be able to overcome the OTDP rejection by filing a terminal disclaimer,

the common ownership language in the terminal disclaimer would preclude Acme from enforcing the patent unless Acme also acquired ownership of the Beta patent. One might alternatively suggest that Acme could amend its claims—a paradoxical (if not unfair) position that asks Acme to amend its foundational discovery to try to avoid a follow-on innovation and, therein, to give up broader claim scope that it might have otherwise been entitled to had Beta never filed a patent application on its later-developed technology. In short, the standalone anti-harassment rationale potentially sets a "trap" with no viable escape for at least some applicants. *See* Canon Br. at 8 (explaining "a later-expiring patent by a co-inventor at a different company could potentially invalidate an earlier patent, and the earlier patent holder would have no mechanism to cure the defect").[9]

3. Rubric for Examination of OTDP at the Office

Under the proposed framework, the Office would continue to examine for OTDP with an emphasis on the doctrine's fundamental purpose—"prevent[ing] an unjustified timewise extension of patent exclusivity beyond the life of a patent." *Allergan*, 111 F.4th at 1367 (describing the avoidance of improper term extension as the "doctrine's primary goal"). As discussed

[9] This hypothetical scenario is not far removed from the facts of *Hubbell*, where four inventors at CalTech filed an application claiming a genus of proteins with certain domains and two of the inventors subsequently left to join the faculty at the University of Zurich, where they developed follow-on technology and filed an application claiming species of the aforementioned proteins. *See Hubbell*, 709 F.3d at 1140, 1142–44. The ARP submits that the dissent in *Hubbell* seized on something important in recognizing, under facts such as these, that "[t]his court need not create a new protocol wherein the contributions of distinct entities and separate ownership are rejected for 'double patenting' instead of examined under the established rules." *Hubbell*, 709 F.3d at 1151 (Newman, J., dissenting).

above, the Federal Circuit has made clear that OTDP can still apply to post-URAA patents where two patents that claim obvious variants of the same invention have different expiration dates. *See, e.g.*, *Abbvie*, 764 F.3d at 1374.

Although examiners generally are not instructed to make predictions about the expiration dates for patents that may issue on the applications they are reviewing, they need not do so to examine for OTDP consistent with the doctrine's primary purpose. *See* Reh'g Req. 6–8 (arguing that predicting expiration dates involves speculation and is inconsistent with MPEP § 804). Rather, looking to patent term filing dates, which start the statutory clock on a patent's ordinary twenty-year term, can serve as a surrogate for expiration dates. And examiners already regularly consider and compare patent term filing dates as part of their review for possible anticipation or obviousness. The OTDP analysis would thus ask a simple question: Does a putative OTDP reference have a later patent term filing date than the patent term filing date of the application under examination? If the answer is "yes," the Office's OTDP analysis under a term-extension rationale for that alleged reference ends.[10] If, alternatively, the reference has an earlier patent term filing date, the analysis may proceed to a comparison of the claims and, as appropriate, a rejection for OTDP may be made.

[10] In limited instances, such as when the reference's term is shortened due to a known terminal disclaimer where the natural twenty-year term of the claims under examination would extend beyond the reference's term, the OTDP inquiry may proceed. When a patent has been granted PTA, thus extending its known expiration, that may also factor into the analysis. The focus, however, should be on using *known* facts of record, not speculation on unknown matters such as hypothetical future grants of PTA, possible withdrawal of terminal disclaimers, or potential priority benefit changes.

The analysis above would be appropriate for applications and/or patents from different patent families, but does not address what the Office should do to mitigate term-extension concerns and potential OTDP within a single family. *See generally Cellect*, 81 F.4th 1216 (affirming OTDP rejections between members of related family patents). Related patents and applications that share the same patent term filing date ordinarily should expire at the same time. However, as cases like *Cellect* and *Allergan* make clear, that is not always true. Applications and patents within the family that have later *actual filing dates* can be awarded PTA that extends their term beyond the term of earlier-filed patents or applications in the family. To the extent such later-filed applications or patents claim obvious variants of subject matter claimed in the earlier-filed ancestral applications or patents, the OTDP policy against improper timewise extension would be implicated.

On the other hand, first- or earlier-filed and issued patents within a family would not be subject to invalidation or rejection for OTDP by the later-filed progeny of those patents on the basis of improper term extension. As the Federal Circuit held in *Allergan*, "the first-filed, first-issued patent in its family . . . is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants." *Allergan*, 111 F.4th at 1369–70 (citing *Novartis*, 909 F.3d at 1374 (noting that "the traditional concern with obviousness-type double patenting" is not raised where "it is the earlier-filed, earlier issued . . . patent, not the later-filed, later-issued . . . patent, that has the later expiration date")). Thus, in keeping with the Federal Circuit's reasoning, when examining for OTDP within the same patent family, the Office would focus on *actual* filing dates (and issue dates, if known, as applicable). Applications with later actual filing dates

can be rejected for OTDP over their earlier-filed parent applications or patents within the family, but such rejections would not work in reverse. This approach would better ensure that later-filed patents will not have a term that extends longer than their parent patents claiming substantially the same innovation.[11]

Finally, we suggest that the standalone anti-harassment rationale should be, if not abandoned as part of examination at the Office as detailed above, at least circumscribed in some ways to mitigate unfairness to applicants and downstream harms to innovation. One option would be to require actual evidence of previous ownership splitting and harassment resulting from the conduct of a particular applicant before the anti-harassment rationale could be wielded on its own against that applicant as a basis for OTDP rejections. That an applicant might get caught facilitating such conduct and thereby suffer the consequences in future dealings with the Office would, we expect, act as a deterrent. Another option is requiring the examiner to establish the obviousness of the challenged claims and reference claims over each other—essentially a two-way test—before a standalone anti-harassment rationale could form the basis for OTDP at the Office. Historically, that test has been reserved for rare circumstances, especially aimed at pre-URAA patents, where the Office was solely responsible for delays that caused an applicant's follow-on patent to be issued before an earlier-filed application. *See In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir.

[11] Absent a change or clarification in the law by the Federal Circuit, if the anti-harassment rationale is sufficient on its own, the Office will continue to examine for OTDP across or within families of patents regardless of the respective actual or patent term filing dates.

1998). But it could be appropriate to address the departed inventor "trap" scenario discussed above and circumstances in which the reference claims and the challenged claims do not stem from common ownership or a complete overlap in inventors, giving applicants a fairer and more realistic means of overcoming the rejection. *See Hubbell*, 709 F.3d at 1152 (Newman, J., dissenting) (explaining that although OTDP has evolved, it has "never departed from the requirement of either common inventorship or common ownership, and never departed from the available remedy of terminal disclaimer"). In other words, the Office would ask whether a third-party application would issue as a patent under the same circumstances and, if so, would not reject the claims for OTDP. Whether the Office might pursue such options, however, is contingent on further guidance from the Federal Circuit about the reach of the anti-harassment rationale.

IV. CONCLUSION

For reasons discussed above, we reverse the Board's Appeal Decision and Rehearing Decision. The Examiner's rejections of record for obviousness-type double patenting, therefore, are affirmed.

V. GUIDANCE TO USPTO PERSONNEL ON APPLYING ALLERGAN

Finally, we take this opportunity to provide guidance to USPTO personnel on how the Office will apply *Allergan* at this time. USPTO personnel should continue to follow existing pre-*Allergan* OTDP practice discussed in MPEP § 804 unless a determination is made that the holding of *Allergan* applies because (1) the application (or patent under reexamination) and the OTDP reference are in the same family and have the same patent term filing date, and (2) the claims under examination are first-filed, first-

issued, and later-expiring. In this context, consistent with *Allergan*, a first-filed, first-issued claim is a claim present in a patent that has the first actual filing date and the first issue date of all the patents in that family. This can arise in reexamination of a patent or in an application for reissue. It will rarely, if ever, arise in original examination because a patent examiner will rarely, if ever, be in a position to determine that the claims under examination will be first-filed, first-issued, and later-expiring claims.

DECISION SUMMARY

Outcome of Decision on Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Denied	Granted
1–18		Nonstatutory Double Patenting: US Patent 10,882,922, Klein		1–18
1–4, 6–18		Nonstatutory Double Patenting: US Patent 11,186,649, Klein		1–4, 6–18
1–4, 6–18		Nonstatutory Double Patenting: US Patent 11,530,268, Klein		1–4, 6–18
1–4, 6–18		Nonstatutory Double Patenting: US Patent 11,613,576, Klein		1–4, 6–18
1–18		Nonstatutory Double Patenting: US Patent 11,192,960, Klein		1–18
1–18		Provisional Nonstatutory Double Patenting: US Patent Application 18/183,107, Klein		1–18
Overall Outcome				1–18

Final Outcome of Appeal after Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
1–18		Nonstatutory Double Patenting: US Patent 10,882,922, Klein	1–18	
1–4, 6–18		Nonstatutory Double Patenting: US Patent 11,186,649, Klein	1–4, 6–18	
1–4, 6–18		Nonstatutory Double Patenting: US Patent 11,530,268, Klein	1–4, 6–18	
1–4, 6–18		Nonstatutory Double Patenting: US Patent 11,613,576, Klein	1–4, 6–18	

1–18		Nonstatutory Double Patenting: US Patent 11,192,960, Klein	1–18	
1–18		Provisional Nonstatutory Double Patenting: US Patent Application 18/183,107, Klein	1–18	
Overall Outcome			1–18	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § l.136(a)(l)(iv).