IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Nicolas Baurin et al.
App. No	:	17/135,529
Filed	:	December 28, 2020
For	:	Dual Variable Region Antibody-Like Binding Proteins Having Cross-Over Binding Region Orientation
Examiner	:	Roark, Jessica Hope
Art Unit	:	1643
Conf No.	:	5010

AMICUS CURIE APPEAL BRIEF

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Dear Mr. Squires:

In response to your Order Convening Appeals Review Panel and Granting Sua Sponte Rehearing dated March 5, 2026, Amicus Curiae Michael O'Brien submits the following appeal brief.

I. Real party in interest

Michael O'Brien is a registered patent practitioner and published scholar in patent law and economics. His scholarship examines the intersection of continuation practice, patent term mechanics, and the empirical foundations of USPTO examination policy. He has no financial interest in the outcome of this proceeding and files this brief as a friend of the Panel. The three questions the ARP has presented rest on empirical premises about how the patent system operates in practice—premises that have been asserted by instinct and litigated by anecdote but not tested against system-wide data. This brief presents the results of an empirical study of approximately 3.1 million U.S. granted patents across eight technology classes, drawn from the USPTO's own

publicly accessible data on Google Patents Public Data (Google BigQuery), to provide the Panel with a data-grounded foundation for its decision, wherever that decision falls.

II. Summary of Argument

The Examiner's actual-filing-date rule for identifying the "first-filed" patent would misidentify the later-invented patent as the reference in a majority of same-assignee, cross-family patent pairs across every technology class the USPTO examines—not merely in life sciences. Empirical analysis of 3.1 million patents across eight technology classes confirms this misclassification is structural and technology-neutral, with a floor rate of 49.95%. The framework supported by Allergan and Gilead—effective filing dates and apparent expiration dates—is both required by the case law and workable in examination practice.

Examiners should determine apparent expiration dates. The Examiner's PTA-uncertainty objection is an upper-bound non-problem: only 4.44% of antibody patents have prosecution durations long enough to theoretically generate the PTA needed to close the relevant gap. The predicted administrative burden is a paper tiger—actual prosecution velocity increased in the decade following Gilead, not decreased.

Separate ownership risk is not an independent OTDP trigger. No court has ever applied the harassment rationale as a freestanding basis for rejection absent a valid reference patent. The observed data on family ownership splits reflect M&A activity and tax-driven IP assignment, not adversarial fragmentation. The two-way test's own structure confirms that term extension, not harassment, is OTDP's operative condition.

III. Proposed Governing Rule

A patent may serve as an obviousness-type double patenting reference only if it is temporally prior to the challenged claim and its later expiration would otherwise extend the effective exclusivity period of the claimed subject matter. In applying this standard, examiners should (1) compare effective filing dates under 35 U.S.C. § 154(a)(2) as the ex ante measure of temporal priority, and (2) assess apparent statutory expiration dates—the 20-year term from the § 154(a)(2) date, adjusted for any filed terminal disclaimers—to determine whether a risk of timewise extension exists. Exact prediction of patent term adjustment or patent term extension is not required; the apparent expiration date relies solely on information available in the prosecution record and is fully administrable during examination. Considerations of common ownership or

potential harassment do not independently establish a proper reference. They instead govern the conditions under which a terminal disclaimer is required once a valid reference has been identified under the foregoing standard.

IV. Argument

a. First-Filed" Means the Patent with the Earlier Effective Priority Date.

The ARP should hold that the Baurin application is "first-filed" for OTDP purposes because its § 154(a)(2) priority date—March 28, 2012—predates the priority dates of all six reference patents by five to eleven years. Under that standard, none of the six references is a proper OTDP reference and all six rejections must fall.

Allergan USA, Inc. v. MSN Labs. Private Ltd., 111 F.4th 1358, 1368 (Fed. Cir. 2024), holds that "a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim." The court grounded this holding in OTDP's fundamental purpose—preventing a patentee from obtaining "a second patent" to "effectively extend the life of a first patent." Id. Critically, Allergan stated that post-URAA patent term "is now measured from its effective filing, or priority, date." Id. at 1367. Gilead Sciences, Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1215 (Fed. Cir. 2014), established that "expiration dates are the controlling factor" for post-URAA OTDP. These cases support a rule that compares effective priority dates and apparent expiration dates. The patent that is earlier on both measures is protected; the patent that is later on both is the improper reference.

Where filing date and expiration date diverge due to patent term adjustment or a filed terminal disclaimer, the effective filing date provides the appropriate ex ante proxy for determining temporal priority during examination, while the apparent expiration date confirms whether a risk of timewise extension exists. This two-part approach reconciles Allergan and Gilead while preserving administrability: both inputs are available in the prosecution record at the time of examination.

Empirical analysis confirms both the doctrinal framework and its critical system-wide importance. The Office characterizes the Baurin application's approximately eight-year gap between its 2012 priority date and 2020 actual filing date as if it signals gamesmanship. The data do not support that characterization. Analysis of 39,773 U.S. granted antibody patents (CPC C07K16) shows that 29.1% have a priority-to-filing lag of five or more years, and 11.6% have a

lag matching or exceeding the Baurin application's gap. The Baurin configuration sits at the 90th percentile of the distribution—the normal upper range of platform-technology prosecution, not an anomaly warranting adverse inference.

The data demonstrate that the Office's actual-filing-date alternative produces systematic majority error. Among same-assignee, cross-family antibody patent pairs (n = 2,125,975 pairs), that rule designates the later-invented patent as "first-filed" in 20.5% of all pairs. Restricting to pairs with an unambiguous priority gap of two or more years—eliminating cases where temporal sequencing is genuinely ambiguous—the error rate is 14.1% across 1,567,186 pairs, with an average priority gap of 4.73 years among the inverted pairs.

Observed patterns indicate most importantly that this is not a life-sciences problem. Across eight technology classes representing 3.1 million granted U.S. patents—from Mechanical Engineering to Semiconductors—the Examiner's rule designates the later-invented patent as "first-filed" for a majority of same-assignee cross-family patent pairs held by large portfolio entities in every class examined without exception. The floor rate is 49.95% in Mechanical Engineering, the control class with the least continuation activity. Cross-technology regression confirms this near-uniform distribution is unexplained by continuation intensity ($R^2 = 0.07$, $p = 0.54$), prosecution duration ($R^2 = 0.01$, $p = 0.82$), or query parameterization differences across classes ($R^2 = 0.0002$, $p = 0.97$). These empirical results do not substitute for the doctrine derived from *Allergan* and *Gilead*—they confirm that the doctrinal rule is necessary to avoid systemic, technology-neutral error. See Panel B of the Figure below.

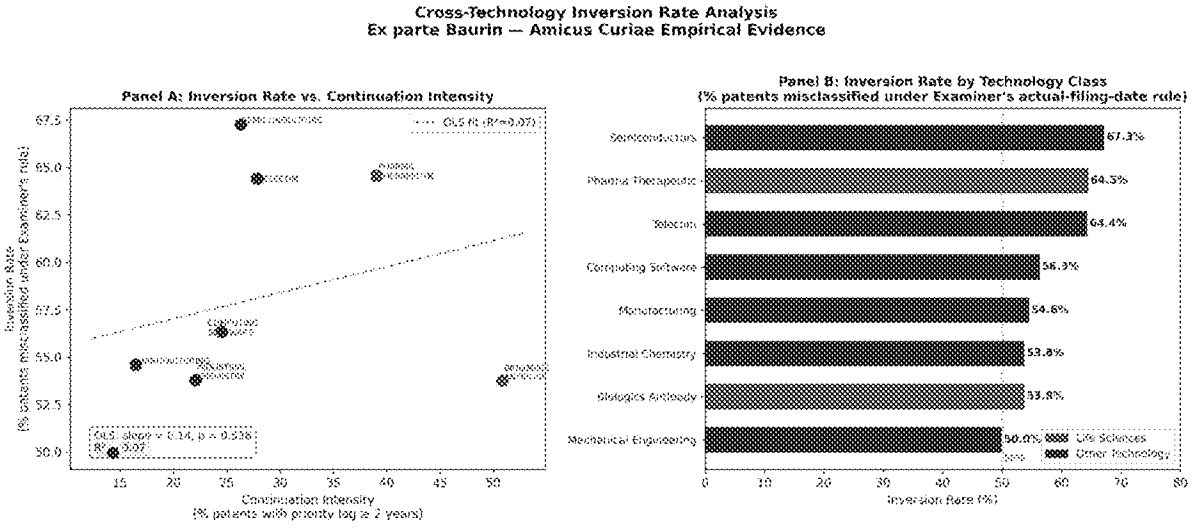

Figure. Panel A: inversion rate vs. continuation intensity by technology class (OLS fit, $R^2 = 0.07$). Panel B: patent-level inversion rate—the fraction of patents misidentified as "first-filed" under the actual-filing-date rule—by technology class. All eight classes exceed 49%. Red = life sciences; blue = other technology.

The Office's position would produce systemic majority misclassification. The Office argues that "first-filed" in *Allergan* refers to the first patent of the patent family based on actual filing dates, and that the Baurin application cannot qualify because its actual filing date of December 28, 2020 postdates the '922 Patent's actual filing date of April 13, 2017. *Request for Rehearing* at 2–4. This reading is textually unsupported: *Allergan* stated that post-URAA term "is now measured from its effective filing, or priority, date"—not its actual filing date. Using actual filing dates to define "first-filed" directly contradicts the measure of term the court identified as controlling. The Office's same-family limitation is similarly without basis in *Allergan*'s holding or reasoning: the operative question—does the application extend the exclusivity period on subject matter previously claimed?—is answered by comparing effective filing dates and expiration dates regardless of family membership. The Office's reliance on *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013), does not fill the gap. *Hubbell* addressed only whether OTDP applies when inventive entities partially overlap; reference validity was assumed without examination. Under the principle of party presentation, cited in *Allergan* at footnote 6, a court's silence on threshold reference eligibility is not precedent on that question.

Applicant's argument that a reference with a later § 154(a)(2) date cannot serve as an OTDP reference is correct, and the data confirm its systemic importance beyond the facts of this case. *Appeal Brief* at 9–12. The 29.1% of antibody patents with five-year-plus priority-to-filing lags represent the normal commercial development cycle of platform biotechnologies; the same structural pattern appears across all eight technology classes. Penalizing that structure system-wide would impose costs the data show are avoidable under the correct rule. **"**First-filed" means the patent with the earlier effective priority date. The data confirm that the alternative rule produces majority misclassification across every technology class the USPTO examines. All six rejections should be reversed.

b. Examiners Should Determine Apparent Expiration Dates, and Doing So Is Workable.

Examiners should determine apparent expiration dates based on the 20-year statutory term under § 154(a)(2), adjusted for any filed terminal disclaimers. Exact prediction of future patent term adjustment or patent term extension is not required. This approach relies entirely on information available in the prosecution record and is fully administrable. The Examiner's PTA-uncertainty objection is an upper-bound non-problem falsified by twelve years of post-*Gilead* prosecution data. MPEP § 804(I)(A) directs examiners to determine whether "the grant of a second patent would give rise to an unjustified extension" of patent rights. That determination cannot be made without comparing expiration dates. MPEP § 1701 provides an express examination exception permitting examiners to opine on expiration dates "to the extent necessary to carry out an examination of a non-reissue patent application where determination of the expiration date of a patent is necessary to conduct examination." *Gilead* makes that determination necessary. The MPEP cannot be read to prohibit what it simultaneously commands; in any event, the MPEP carries the force of guidance, not law—Federal Circuit precedent governs. Under *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007), PTA cannot extend patent term beyond the date set in a filed terminal disclaimer, eliminating the primary source of uncertainty the Office identifies.

The data demonstrate the workability of this standard. Prosecution duration is a conservative upper bound on PTA—actual PTA is always less than or equal to gross prosecution duration after applicant-caused delays are subtracted. All figures stated here therefore overstate the at-risk population; they are ceilings. Despite this generous framing, only 4.44% of C07K16 antibody patents have prosecution durations long enough to theoretically generate the PTA required to close the largest expiration gap in this case (approximately seven years). For the nearest reference gap (approximately four years, the '922 Patent), the upper-bound fraction is 35.48%—but that figure is legally irrelevant for applications with filed terminal disclaimers, which *Merck v. Hi-Tech* caps at the TD date. The Baurin application has filed TDs. The PTA concern approaches zero in any realistic scenario.

The predicted administrative burden is a paper tiger. If the Board's expiration-date framework created unworkable examination complexity, prosecution duration should have increased after *Gilead* (2014). The opposite occurred: mean prosecution duration in C07K16 fell from 3.82 years pre-*Gilead* to 3.39 years post-*Gilead*—a five-month reduction. This pattern holds

across seven of eight technology classes examined. Twelve years of actual examiner behavior provide no empirical support for the burden concern.

The Office's position would require predicting the unpredictable—a problem that does not exist in practice. The Office argues that MPEP § 804 does not authorize expiration-date comparisons in ordinary prosecution and that MPEP § 804.02(IV) requires a separate terminal disclaimer for each reference patent regardless of expiration analysis. *Request for Rehearing* at 7–9. The MPEP § 804 argument is self-defeating: the same provision commands the substantive inquiry (whether grant causes unjustified extension) while the Office reads it to prohibit the only information needed to conduct that inquiry. The Office further argues that even with filed TDs, the Baurin application could later withdraw them and accumulate PTA to push expiration past a reference. *Id.* at 8. This hypothetical fails legally—MPEP § 1409 states petitions to reopen a TD "have not been favorably considered," and withdrawal requires a showing of patentable distinctness that renders the underlying OTDP moot—and fails empirically: the record contains no documented case in which a TD was withdrawn and PTA then extended expiration past a reference patent's date.

Applicant correctly characterizes the Office's approach as a "just in case" rejection—refusing to assess how much its own prosecution delay has generated the PTA to which Applicant is statutorily entitled, then penalizing Applicant for that entitlement. *Appeal Brief* at 10–11. Twelve years of post-*Gilead* prosecution data corroborate that characterization: the predicted burden did not materialize. Examiners should determine apparent expiration dates. The standard is workable, legally required, and confirmed by a decade of post-*Gilead* prosecution data. The ARP should affirm it.

c. Separate Ownership Risk Is Not an Independent Basis for an OTDP Rejection.

Ownership concerns do not define whether a patent qualifies as an OTDP reference. They instead govern the conditions under which a terminal disclaimer is required once a proper reference has been identified. No court has ever applied the harassment rationale as a freestanding OTDP trigger absent a valid reference patent. The data confirm that the mechanism the rationale targets does not operate in practice in the manner the Office assumes. OTDP is a judge-made equitable doctrine whose "fundamental reason" is "unjustified timewise extension of the right to exclude." *In re Van Ornum*, 686 F.2d 937, 943 (C.C.P.A. 1982). *Allergan* reaffirmed this purpose: OTDP

prevents obtaining "a second patent" to "effectively extend the life of a first patent." 111 F.4th at 1368. The terminal disclaimer mechanism under 37 C.F.R. § 1.321(c) provides the tool for overcoming a properly made OTDP rejection. The TD's conditions of issuance do not define what makes a rejection proper in the first place.

Empirical analysis requires candor about what the data show, and then explains it. Analysis of 8,378 multi-member antibody patent families finds that 55.78% are fully consistent (single assignee throughout) at grant across all families, falling to 34.18% for large families with five or more members. At-grant consistency is a ceiling—post-grant transfers can only reduce it. The data do not support a narrative that ownership splitting never occurs, and this brief does not claim otherwise.

The data demonstrate, however, that the splits which do occur bear the empirical signature of M&A activity and tax-driven IP assignment—not adversarial fragmentation. Split families in the large-family cohort have an average time span of 8.17 years; consistent families average 5.21 years—a nearly three-year differential. Corporate transactions accumulate over time; families prosecuted and maintained within a single enterprise do not. This time-span differential is the expected result of portfolio ownership drift driven by mergers, acquisitions, and tax-motivated holding-entity assignments—structures in which enforcement decisions remain centralized within the corporate enterprise and present zero realistic harassment risk. The mechanism the Office's rationale requires—deliberate family fragmentation to enable coordinated assertion by multiple genuinely independent entities against a single accused infringer—is categorically distinct from this observed pattern. The Office has not identified a single documented instance of that mechanism operating in practice, and neither has Applicant. *Appeal Brief* at 16.

The Office's position would elevate dicta into doctrine without support. The Office argues that *Cellect*, *Hubbell*, *Van Ornum*, *Fallaux*, and MPEP § 804.02(VI) collectively establish separate ownership as a freestanding OTDP trigger. *Request for Rehearing* at 9–11. Each authority is distinguishable. In *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023), the court addressed whether a promise of non-alienation could substitute for a TD; *Allergan* itself stated *Cellect* "answered a different question." 111 F.4th at 1367 n.8. In *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013), reference validity was assumed without examination; only the overlapping-inventive-entity question was presented and decided. In *Van Ornum*, the court identified timewise extension

as OTDP's "fundamental reason" and addressed harassment only in validating the non-alienation requirement as a mechanism to *overcome* a properly made rejection—not to make one. In *In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009), reference validity was not disputed—flagged in footnote 1—so the harassment discussion arose as dicta with a conceded proper reference already in place. In every case the Office cites, threshold reference validity was already resolved or assumed before the harassment rationale appeared. As *Van Ornum* itself cautioned, precedents are valued "for what they decide," not for every sentence they contain. 686 F.2d at 946. The MPEP § 804.02(VI) argument fares no better: that provision addresses the content of a TD filed to overcome a rejection already properly made. As Applicant correctly observes, 37 C.F.R. § 1.321(c)(3) governs overcoming an OTDP rejection—it is silent on what creates one. *Reply Brief* at 5–6.

Applicant's position is correct, with one refinement. Applicant argues that the harassment rationale has no real-world evidentiary support and that courts have long been skeptical of it as an independent basis, citing *In re Jentoft*, 392 F.2d 633, 641 (C.C.P.A. 1968) (noting that harassment suits have not materialized for genus and species patents and that attorney's fee awards provide adequate deterrence). *Appeal Brief* at 18–19. The data corroborate that characterization: observed ownership splits reflect corporate lifecycle dynamics that present no realistic harassment risk. The refinement: the ARP need not find *Van Ornum* wrongly decided. The narrower, fully sufficient holding is that no court has *applied* the harassment rationale as a freestanding OTDP trigger absent a valid reference patent, and the data provide no basis for the ARP to be the first.

The structure of the two-way test is independently incompatible with an ownership-based trigger for OTDP. Under the two-way test, OTDP is inapplicable even when the application at issue is later-filed and under common ownership with the reference—precisely the configuration where, under the Office's theory, harassment risk would still be present. MPEP § 804 directs withdrawal of OTDP rejections under the two-way test without any harassment inquiry. If ownership alone were sufficient to trigger an OTDP rejection, the two-way test would require an ownership prong. It does not. The test's structure is structural proof that unjust term extension is OTDP's necessary condition; harassment prevention is a secondary benefit that terminal disclaimers serve once a valid rejection is properly established—not an independent trigger that can manufacture a valid rejection on its own. Separate ownership risk is not an independent OTDP

basis. The case law has never applied it as one; the data identify no evidentiary foundation for doing so now; and the two-way test's structure confirms it is not one. The ARP should so hold.

V. Conclusion

The Examiner's actual-filing-date rule is a paper tiger in reverse—it generates the precise harm OTDP was designed to prevent, misidentifying the later-invented patent as the reference in a majority of cases across every technology class examined. The predicted administrative burden of expiration-date comparison is the paper tiger: prosecution velocity increased in the decade following *Gilead*, not decreased. And observed ownership splits are byproducts of corporate lifecycle events—M&A and tax-driven assignments—not adversarial strategy; to hold that harassment risk provides a freestanding basis for rejection is to prioritize a theoretical litigation cost over the concrete deadweight loss of restricted patent asset liquidity.

The Board reached the right result on legally sound grounds. The empirical record now confirms that result is also correct on the facts of how the patent system operates in practice across all technology areas. The ARP should affirm the Board's decision and adopt the governing rule proposed in Section III: OTDP applies to earlier-filed, term-extending references; apparent expiration dates are the administrable examination standard; and ownership considerations are reserved for the remedial function of terminal disclaimers once a valid reference has been properly identified.

Respectfully submitted,

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