

No. 22-1293, -1294, -1295, -1296

**United States Court of Appeals
for the Federal Circuit**

IN RE CELLECT LLC,

APPELLANT.

*Appeal from the Patent Trial and Appeal Board in
Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457*

**BRIEF FOR NEW YORK INTELLECTUAL PROPERTY LAW
ASSOCIATION
AS AMICUS CURIAE IN SUPPORT OF REHEARING *EN BANC*,
BUT IN SUPPORT OF NO PARTY**

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United States Court of Appeals
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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 29 and 47.4, counsel for amicus curiae New York Intellectual Property Law Association certifies the following:

1. The full names of every party or *amicus* represented by me are:

New York Intellectual Property Law Association

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

New York Intellectual Property Law Association

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Not applicable

4. The names of all law firms and the partners or associates that appeared for any of the parties or amicus now represented by me in trial court or agency or are expected to appear in this Court are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are:
 - A. *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023)
 - B. *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 2023 U.S. Dist. LEXIS 172641, at *58-61 (D.Del. Sept. 27, 2023)
6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable.

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This case is a poster child for the oft-quoted truism that some *guarantees are not worth the paper they were written on*. At issue are Congressionally mandated “patent term guarantees” embodied in the Patent Term Adjustment (“PTA”) of 35 U.S.C. §154(b). PTA “compensates patentees for PTO-caused delays during prosecution,” ensuring patentees receive “a full patent term adjustment for any delay during prosecution caused by the PTO.” *Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010) (emphasis added). The current panel decision seemingly makes those guarantees worthless at best; in reality, it makes them a detriment.

As set out below, the New York Intellectual Property Law Association (“NYIPLA”) believes the panel’s decision:

- A.** fundamentally misapplies the equitable, judicially-created doctrine of Obviousness-Type Double Patenting (“ODP”), by
 - 1. applying the wrong legal test for evaluating patents whose expiration dates differ solely due to prosecution delays caused by the US Patent & Trademark Office (“PTO”), and
 - 2. ignoring the equities underlying ODP;
- B.** improperly vitiates patent term guarantees enacted by Congress to compensate patentees on a day-for-day basis (35 U.S.C. §154(b)(1)(A)(iv)) for a change in calculating patent term; and

C. reflects unsound policy that (1) significantly, adversely impacts innovation, particularly for smaller and less-well funded entities, (2) upsets the patent system, and (3) undermines long-established expectations of patent owners and licensees.

The panel decision clarified what had been an open issue of patent law. 81 F.4th 1216, 1227 (“For the first time, here, we address how another statutorily authorized extension, PTA, interacts with ODP.”); *see Sight Sciences, Inc. v. Ivantis, Inc.*, 1-21-cv-01317 (D.Del. Nov. 7, 2023) (law “was, at the least, unclear prior to the Federal Circuit’s recent holding.”) Respectfully, the panel did so incorrectly.

Accordingly, this is a question of exceptional importance, and NYIPLA urges this Court to grant the instant Petition for Rehearing *En Banc* (the “Petition”). While NYIPLA believes the petition should be granted, as set out herein, it takes no position on the underlying merits of the dispute and therefore submits this amicus curiae brief in support of no party.

I. INTERESTS OF AMICUS CURIAE

NYIPLA is a preeminent, regional bar association of attorneys who practice in the area of patent and other intellectual property areas (“IP”) law. Its members include both in-house counsel and private practice attorneys. Members represent IP owners and their adversaries (many of whom own IP), who are inventors, entrepreneurs, businesses, universities, and industry/trade associations. Members

actively participate in patent prosecution, licensing, and litigation, representing applicants, challengers, licensors, and licensees, and do so in the marketplace, PTO, and courts. NYIPLA therefore brings the well-rounded perspective of stakeholders in the present issues.

No party or party's counsel authored any part of this brief. No person other than amicus curiae, its members, or its counsel contributed money to fund preparing or submitting this brief. An absolute majority of NYIPLA's officers and Board of Directors (including any who did not vote, including recusal) approved the arguments set forth herein, but the arguments do not necessarily reflect the views of a majority of the NYIPLA's members or their firms/employers. After reasonable investigation, NYIPLA believes that no officer, director, or member of the Committee on Amicus Briefs who voted in favor of filing this brief, nor any attorney associated with them in any law or corporate firm, represents a party in this litigation.

II. THE PANEL DECISION AND PETITION QUESTIONS PRESENTED

On August 28, 2023, a panel of this Court affirmed a PTAB decision that commonly-owned patent family members were invalid based upon the judicially-created doctrine of ODP over family members that had no or less PTA. 81 F.4th at 1229. That decision allows the PTO to negate Congress's guarantees, holding that ODP is "based on the expiration date of the patent *after* PTA has been added," not before. *Id.* (emphasis supplied).

Cellect argued that PTA should be treated the same as Patent Term Extension (“PTE”) under 35 U.S.C. §156—this Court has already held PTE cannot be the basis of ODP. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018) (relying on the same cases as the panel). *See* Appellant’s Opening Brief at 22 (May 16, 2022) (citations omitted). Cellect also argued that the decision fails to analyze the equities. *Id.* at 41. The panel holding, however, treats PTE and PTA differently for ODP based upon how §154 and §156 are worded (81 F.4th at 1226), and rejects ODP’s equitable lens, stating “good faith during prosecution does not entitle it to a patent term to which it otherwise is not entitled.” *Id.* at 1230.

On November 13, 2023, Cellect filed a Petition for Rehearing *En Banc*, arguing (1) statutory language, legislative history, and this Court’s precedent dictate that PTA should be treated the same as PTE and (2) the panel overlooked the equities underlying ODP. In addition to supporting *en banc* review based upon Cellect’s Petition grounds, NYIPLA submits that the panel—like PTAB—improperly applied a one-way ODP analysis (*e.g.*, 81 F.4th at 1220, summarized in n.2 below) instead of two-way test; definitionally, the PTO only awards PTA for prosecution delays where the PTO is responsible (35 U.S.C. §154(b)(1)(A)(iv); *Wyeth*) and a two-way test is mandated where “the PTO is solely responsible for the delay.” *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998) (applying one-way test); *see In re Braat*, 937

F.2d 589, 593-94 (Fed. Cir. 1991) (Board erred with one-way test when PTO caused prosecution delays).

III. THESE ISSUES SHOULD BE ADDRESSED ON REHEARING

Rehearing *en banc* is appropriate when the merits panel has failed to follow existing precedent, *i.e.*, where necessary to secure or maintain uniformity of decisions; for questions of exceptional importance; or if needed to overrule a precedential prior holding. Fed. R. App. P. 35; Fed. Cir. IOP #13 (Nov. 14, 2008).

NYIPLA submits rehearing *en banc* is appropriate for each of these reasons.

A. The PTAB and Panel Erred

1. The Decisions Applied the Wrong Legal Test

A one-way ODP analysis—asking whether a claim is an obvious variant of a reference claim—is used unless the delay is “solely” the PTO-delay, in which case precedent requires a two-way test. *See Berg*, 140 F.3d at 1437; *see also Braat*, 937 F.2d at 593-94.¹ A two-way analysis often “is necessary because a later-filed improvement patent may issue before an earlier-filed basic invention,” *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993), such as occurred here. *See* 81 F.4th at 1219.

¹ Application of ODP is a question of law reviewed *de novo*. *See Berg*, 140 F.3d at 1432; *see also Texas Instrs. Inc. v. ITC*, 988 F.2d 1165, 1179 (Fed. Cir. 1993).

By statute, a PTA award means the PTO was responsible for prosecution delays; the award is based on the amount of PTO-caused delay. *Wyeth*, 591 F.3d at 1367 (summarizing PTA grounds); *see Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1353 (Fed. Cir. 2019) (PTA is for PTO delays reduced by applicant-caused delays); *see also* MPEP §§2731-2734 (how PTO calculates PTA). Accordingly, since PTA only is for PTO-delay, a two-way test is required. Only a one-way ODP test was applied,² which is legally incorrect. *See Braat*, 937 F.2d at 593.

Therefore, rehearing is necessary to clarify application of the proper ODP test in order to secure/maintain uniformity of decisions. *See* Fed. Cir. IOP #13.

2. The Panel and PTAB Decisions Ignore ODP’s Equities

The panel decision explicitly divorced ODP from equity, contrary to precedent. Respectfully, this must be corrected.

ODP is rooted in equity to prevent “improper” patent term extensions. *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985); *see Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (“...equitable doctrine of obviousness-type double patenting ...”); *Novartis-Ezra*, 909 F.3d at 1374-75 (accord); *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014) (accord); *In re Schneller*, 397 F.2d 350, 354 (CCPA 1968) (prevent “unjustified timewise extension

² *E.g.*, 81 F.4th at 1220 ('621 claims unpatentable over '626 claims, themselves unpatentable over the '369 claims; and '742 claims unpatentable over the '369 claims, themselves unpatentable over the '036 claims—without a reverse analysis).

of the right to exclude”). The doctrine is meant to address improper extensions of patent term resulting from a patentee’s “gamesmanship.” *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355, 1364 (Fed. Cir. 2018) (ODP inapplicable when expiration difference was due to “intervening change in patent term law,” not “gamesmanship”); *see Abbott Labs. v. Lupin Ltd.*, 2011 U.S. Dist. LEXIS 53846, at *26-27 (D.Del. 2011) (ODP addresses unjustifiable extensions from gamesmanship). Precedent therefore requires considering the equities of ODP on this case’s facts.

Inherently, the two-way test also is equitably-rooted. This Court in *Berg*, for instance, considered an applicant’s gamesmanship to stagger patent issuances, thereby extending patent term, and excluded the two-way test. 140 F.3d at 1434-35. Here, there was no equitable analysis by the panel or PTAB, *i.e.* asking if there was gamesmanship. In fact, the panel applied ODP as a strict liability doctrine, 81 F.4th at 1230 (“[G]ood faith during prosecution does not entitle [Cellect] to a patent term to which it otherwise is not entitled.”), a jurisprudential deviation already recognized by at least one district court. *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 2023 U.S. Dist. LEXIS 172641, at *58-61 (D.Del. Sept. 27, 2023) (“*Cellect* … [held] **ODP** depends solely on patent expiration dates and **should not [be] influenced by equitable concerns.**”).

NYIPLA respectfully submits that the precedent establishing ODP as equitable should be followed; courts should not divorce equities from a judicially-created equitable doctrine like ODP, consistent with the Supreme Court's admonishment not to rigidly apply flexible doctrines. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 419 (2x), 421, 422, 428 (2007). As such, NYIPLA supports rehearing to apply ODP equitably, maintain uniformity of decisions, and follow precedent.

B. The Panel Vitiated Congress's Guaranteed Patent Term

1. The Panel Decision Allows The PTO to Side-Step Deadlines

In 1995, Congress enacted the Uruguay Round Agreements Act (URAA), P.L. 103-465, amending 35 U.S.C. §154 such that patents would expire 20 years from the earliest claimed filing date; replacing the prior 17-years from grant term.³ Congress, however, recognized that this change could cause unfairness—any PTO-caused prosecution delay would reduce a patent's effective life—so Congress created a guarantee of timely PTO application handling: diligent patentees *must* be compensated for PTO-caused delays by an award of PTA based upon the delays. 35 U.S.C. §154(b); *Wyeth*, 591 F.3d at 1366; *Supernus Pharms.*, 913 F.3d at 1358; *see*

³ This change related to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, Uruguay Rounds of the General Agreement on Tariffs and Trade (GATT).

H.R. Rep. No. 106-287, pt. 1, at 50 (1999) (Congress enacted PTA to “protect patent term”).

The effect of the instant panel decision, however, is to eliminate Congress’s delay-offsetting compensation. *Cf. Murphy v. NCAA*, 138 S.Ct. 1461, 1483 (2018) (resulting scheme of court holding should not differ sharply from what Congress contemplated). Applying ODP *after* PTA instead of before, therefore, abrogates the guaranteed patent term and *shortens* (or, as here, entirely negates) PTA. This nullification violates a core Constitutional principle—judge-made law cannot usurp Congress’s legislative role. *See U.S. v. Rutherford*, 442 U.S. 544, 555 (1979) (“Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy.”); *Henry Schein, Inc. v. Archer & White Sales, Inc.*, 139 S.Ct. 524, 528 (2019) (“[t]he short answer is that the [Act] contains no [such] exception, and we may not engraft our own exceptions onto the statutory text.”), and 531 (“... we may not rewrite the statute simply to accommodate [a recognized] policy concern.”).

Respectfully, NYIPLA submits that rehearing also is necessary on this ground to address whether the judicially created doctrine of ODP can trump clear Congressional intent—a “question of exceptional importance.”

2. ODP Is Not Generally Necessary Post URAA

NYIPLA submits that URAA made the expiration-portion of ODP obsolete, a vestige of patent term computed from issuance (causing concerns including so-called “submarine patents”). After URAA, ODP should apply, at most, in situations where obvious variant patents from the same family are separately owned—this would avoid risk of harassment by multiple assignees. *See In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009) (limited application of ODP post-URAA, but declining to hold that ODP was no longer a required doctrine). Post-URAA there is no risk of the “unjustified timewise extension of right to exclude” that necessitates disclaiming patent term amongst family members, which was the impetus for courts creating ODP. *See Schneller*, 397 F.2d at 354.

Under current law, a later-issuing patent expires at the same time as an earlier-issued patent from the same family unless there is a Congressionally awarded term extension – either PTE or PTA, based upon FDA or PTO delay (the reasons for PTE and PTA term additions, respectively). Simply, post-URAA there cannot be an “*improper* timewise extension of the patent right,” *Braat*, 937 F.2d at 592 (emphasis original; citation omitted)—*i.e.*, what ODP is meant to “prevent,” *id.*—since these term additions are *proper* under Congress’s mandate and guarantees. There is nothing “*improper*” about PTA that justifies ODP, just as there is nothing “*improper*” about PTE that justifies ODP. *Novartis-Ezra*, 909 F.3d at 1374 (“This

case does not raise the traditional concern with obviousness-type double patenting of a patent owner ‘extending his exclusive rights to an invention’...” by PTE).

Thus, there is no need, post-URAA, for ODP to prevent an unjust extension of patent life. (NYIPLA recognizes policy reasons exist to require common ownership of patents in the same family, but that is not at issue here so NYIPLA limits its arguments to the issue of disclaiming term for ODP. *See Abbvie Inc. v. Mathilda & Terence Kennedy Inst.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (discussing ODP post-URAA). Accordingly, NYIPLA submits that the full *en banc* court should use this opportunity to reexamine ODP’s place and purpose and look at the “[n]ecessity of overruling” prior decisions concerning ODP.

C. The Panel Decision Significantly Adversely Impacts Innovation

The panel’s inequitable application of the equitable ODP doctrine has severe implications for the innovation economy, particularly small businesses. It is common for applicants to quickly seek patent protection covering a new invention/product and then file continuations to cover additional commercially relevant aspects—that is particularly true for small businesses that are not well-funded. With the panel decision, however, companies may not pursue such strategy, and inventions that add to prior patented work may be lost in fear that a subsequent patent may invalidate or devalue the first.

The panel’s suggestion that parties should “file terminal disclaimers during prosecution” prophylactically (81 F.4th at 1231) is no solution. The panel’s “solution” has challenged patent owners, many are small businesses and individual inventors, to *roll the proverbial dice* by predicting whether their claims run afoul of ODP. It invites them to preemptively cut their guaranteed patent term short and also, post-issuance, further burdens them to examine patent portfolios—lest ODP destroy valuable patent families in toto. Indeed, this has already occurred in light of the panel’s decision. *See Allergan*, 2023 U.S. Dist. LEXIS 172641, at *58-61 (applying ODP without any equitable analysis). Accordingly, this clearly is a question of “exceptional importance” that the Court should consider.

IV. CONCLUSION

For the foregoing reasons, NYIPLA respectfully urges the Court to grant Cellect’s Petition for Rehearing *en banc*.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

Pursuant to Federal Rule of Appellate Procedure 29, I certify that the foregoing Amicus Curiae Brief complies with the applicable type-volume limitations. Excluding those portions exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b), this brief contains 2,486 words. This certificate was prepared in reliance on the word count of the word-processing system used to prepare this brief.

This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft 365 Word in 14-point Times New Roman font.

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