

No. 23-1231

IN THE
Supreme Court of the United States

CELLECT, LLC,

Petitioner,

v.

KATHERINE K. VIDAL, UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR, UNITED STATES PATENT
AND TRADEMARK OFFICE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED
STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**BRIEF OF THE NEW YORK INTELLECTUAL
PROPERTY LAW ASSOCIATION AS *AMICUS
CURIAE* IN SUPPORT OF CERTIORARI**

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QUESTIONS PRESENTED

1. Can the judicially created obviousness-type double patenting (“ODP”) doctrine vitiate Congressional guarantees of timely patent examination—as set out in the Patent Term Adjustment provisions of 35 U.S.C. §154(b) (“PTA”)—thereby allowing the U.S. Patent & Trademark Office (“PTO”) and courts to use those guarantees to invalidate patents solely based upon the mandatory PTA?

2. Did a panel decision of the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) err when it created a rigid rule, eliminating all equitable considerations from the judicially created ODP analysis, disregarding the reasons for ODP’s creation, and ignoring binding precedent?

3. Was the judicially created ODP doctrine, established at a time when a patent’s term was measured from patent issuance, abrogated when Congress changed how patent term is measured such that all patents sharing a common priority application expire on the same day unless a Congressionally mandated extension applies, such as where those patents expire on different days solely because the PTO was required to award PTA due to PTO’s delays in violation of statutory guarantees for prompt examination?

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I. INTEREST OF THE *AMICUS CURIAE*¹

The New York Intellectual Property Law Association (“NYIPLA”) is a preeminent, regional bar association of attorneys who practice in the area of intellectual property (“IP”) law, such as patent law. Its members include both in-house and private practice attorneys, who represent IP owners and their adversaries, inventors, entrepreneurs, businesses, universities, and industry/trade associations. Members participate in patent prosecution, licensing, and litigation on behalf of applicants, challengers, licensors, and licensees. NYIPLA therefore brings the well-rounded perspective of stakeholders in the present issues.

NYIPLA believes the Court should grant the *Petition for Certiorari* because of the extreme importance of the issues presented. NYIPLA takes no position, however, on the underlying merits and has no view on whether the patents-at-issue are or are not otherwise valid.

1. This brief is filed more than 10 days before its due date, in compliance with Sup. Ct. R. 37.2.

NYIPLA’s identified counsel authored this brief; no party or party’s counsel authored any part. Only NYIPLA, its members, and its counsel funded preparing or submitting this brief. These arguments were approved by an absolute majority of NYIPLA’s officers and Board (including any who did not vote and recusals), but 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 NYIPLA officer, director, or member who voted in favor of filing this brief, nor any attorney associated with them in any firm or corporate department, represents a party in this litigation.

II. SUMMARY OF ARGUMENT

This case is about PTA and ODP. Half of all US patents receive PTA,² making this a very important matter for the innovation and patent community.

2. Based upon full year data for all patents issued 2016-22 and 2023 through mid-June, according to the PTO's Patent Examination Research Dataset (PatEx) | USPTO. www.uspto.gov/ip-policy/economic-research/research-datasets/patent-examination-research-dataset-public-pair:

Year	Total Patents	Patents with PTA	Share with PTA	Average PTA (days)
2016	333,582	176,673	53%	373
2017	351,403	168,708	48%	346
2018	339,992	158,827	47%	309
2019	391,097	186,543	48%	287
2020	388,847	181,834	47%	262
2021	362,029	168,471	47%	245
2022	358,661	186,665	52%	271
2023*	144,054	77,358	54%	297
Total:	2,669,665	1,305,079		
Overall Average:			49%	299

PTO data from 2005 to 2022 shows that the PTO had to award PTA to between about 48% and 84% of utility patents each year (only utility patents are reported), and that the average PTA ranged from 6.5 months to 22 months. www.patentlyo.com/patent/2022/11/prosecution-delays-adjustment.html; *see* www.patentlyo.com/patent/2011/07/pta.html (data for 2005-11).

In *In re Collect*, the Federal Circuit (and PTO) ran roughshod over statutory guarantees requiring that the PTO timely examine patent applications or extend the resulting patent's life for the undue delays. To do so, *Collect* ignored binding precedent; misapplied an equitable doctrine as a rigid, strict liability standard; and explicitly stated that equities do not matter.

It has been almost a century since the Court substantively addressed double patenting,³ and in the interim Congress has significantly amended the Patent Code at least five times. Accordingly, NYIPLA respectfully urges the Court to grant the Petition for Certiorari to consider double patenting for the following reasons:

1. *Collect's Widespread Impact*. The PTO unduly delayed about half of all US patents, by about 10 months on average (note 2 above), meaning it was statutorily required to award PTA (35 U.S.C. §154) for those patents. Many of these patents are part of a multi-patent family, *i.e.*, they share a common priority application, so they now risk invalidity at no fault of the patentee **because of** the PTO's undue delays, unless the *Petition for Certiorari* is granted and the Court cures the situation. In 2023 the number of patents issuing with a terminal disclaimer—a surrender of rights that can obviate ODP (*see* §III.C below)—increased significantly. patentlyo.

3. *De Forest Radio Co. v. General Elect. Co.*, 283 U.S. 664 (1931); *but see Milcor Steel Co. v. George A. Fuller Co.*, 316 U.S. 143 (1942) (which addressed disclaimers but arguably double patenting); and *Elec. Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 21 (1939) (stating “no double patenting involved” where “both expired on the same day” so “no extension of the monopoly...”).

com/patent/2024/05/terminal-disclaimers-practice.html (for 2023 “almost 60,000 utility patents were bound by a terminal disclaimer.”). This shows *Collect*’s impact.

NYIPLA believes the Federal Circuit’s *Collect* decision destroys “patent term guarantee[s]” that Congress enacted to ensure prompt PTO examination, so patentees get a full patent term.⁴ Given its importance and widespread impact, this is an urgent issue for the Court to consider.

4. The House Report for the 1999 American Inventors Protection Act (Pub. L. 106-113) on §154 explains that PTA ensures at least 17 years of exclusivity (premised upon up to 3 years for PTO examination):

“Title III--Patent Term Guarantee

... Title III amends the provisions in the Patent Act that compensate patent applicants for certain reductions in patent term that are not the fault of the applicant. ... [Title III] adds a new provision to **compensate applicants fully for PTO-caused administrative delays**, and, for good measure, includes a new provision **guaranteeing diligent applicants at least a 17-year term** by extending the term of any patent not granted within three years of filing. Thus, **no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years Only those who purposely manipulate the system to delay the issuance of their patents will be penalized** under Title III, a result that the Committee believes entirely appropriate.”

H.R. Rep. No. 106-287, pt. 1 (1999) (emphasis added); *see* Kazhdan, *Obviousness-Type Double Patenting: Why It Exists And When It Applies*, 53 Akron L. Rev. 1017 (2019) (“ODP Why/When”), at 1020-21 (explaining PTA gives “the same term-[of] 17 years ... as before.”).

2. *Collect Negates Congress's Guarantees.* The Uruguay Round Agreements Act ("URAA"), P.L. 103-465, set a patent's term as 20 years from first application, so undue PTO delays shorten the period a patent protects the invention. Congress therefore created PTA to "compensate[] 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). *Collect* not only makes those guarantees worthless; it makes PTA a risk to patent validity.

3. *Collect Improperly Ignores the Equities.* ODP is a judge-made, equitable doctrine addressing patentee "gamesmanship." *Collect*, however, ignores precedent by rejecting all equities and applying ODP as a strict legal doctrine.

4. *It is Time to Retire ODP.* *Collect* highlights why ODP has outlived its usefulness; post-URAA, it is a solution in search of a problem. *Collect* applied ODP to patents in the same family that have different expiration dates *only because of* PTO's delays and mandatory PTA. This (i) significantly, adversely impacts innovation, particularly for smaller and less-well funded entities; (ii) upsets the patent system; and (iii) undermines long-established expectations of patent owners and licensees.

* * *

Accordingly, the Petition presents questions of exceptional importance. NYIPLA urges the Court grant *certiorari*.

III. ARGUMENT

In *Collect*, the Federal Circuit affirmed the PTO’s Patent Trial and Appeal Board (“PTAB”) invalidating commonly-owned patent family members under ODP because some patents had received different PTA than other patent-family members, since the PTO delayed some more than others. ODP, it said, must be analyzed “based on the expiration date of the patent *after* PTA has been added,” not before, regardless of why PTA was awarded. *In re Collect*, 81 F.4th 1216, 1220 (Fed. Cir. 2023) (emphasis added). That decision misapplies ODP and negates Congress’s “Patent Term Guarantee.” See note 4 above.

This differs from the Federal Circuit’s treatment of another Congressional guarantee adding patent term. In *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018) (“*Novartis-Ezra*”), it considered Patent Term Extension (“PTE”) under 35 U.S.C. §156, a Congressional guarantee compensating for time taken for the Food & Drug Administration (“FDA”) review process. *Novartis-Ezra* equitably found PTE does not result from gamesmanship, correctly holding that ODP is analyzed based on the patent expiration *before* PTE. Here, however, *Collect* explicitly ignored gamesmanship/equities, treating PTA’s impact on ODP differently, based upon statute wording subtleties. 81 F.4th at 1226; *cf.* 35 U.S.C. §156(a) (PTE statute cross-referencing §154 PTA).

In doing so, the Federal Circuit rejected ODP’s historical, *equitable* roots when patent term was measured from a patent’s issue date and ODP was needed to prevent applicant “gamesmanship” to unduly extend

patents. *Novartis Pharm. Co. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1362 (Fed. Cir. 2018) (“*Novartis-Breckenridge*”); *see id.* at 1364 (ODP inapplicable when expirations differ due to “intervening change in patent term law,” not “gamesmanship”). Congress recognized this in its PTA “Patent Term Guarantee,” noting “those who purposely manipulate the system to delay the issuance of their patents” are not entitled to a full patent term. H.R. Rep. No. 106-287, pt. 1 (1999) (fuller quote in note 4 above). PTA is only awarded for PTO-caused delays exceeding applicant-caused delays.⁵ Accordingly, PTA was designed to nullify attempted gamesmanship.

Collect, however, rejected equitable considerations, stating “good faith during prosecution does not entitle [an applicant] to a patent term to which it otherwise is not entitled” (81 F.4th at 1230), disregarding that Congress decided applicants *were entitled* to PTA based upon the PTO’s undue delays that caused patent-term loss. This fundamental change had an immediate effect; as one decision summarized it: “*Collect* ... [held] **ODP** depends **solely** on patent **expiration dates** and **should not [be] influenced by equitable concerns.**” *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 2023 U.S. Dist. LEXIS 172641, at *58-61 (D. Del. Sept. 27, 2023) (emphasis added).

5. 35 U.S.C. §154(b)(2)(C) (PTA “reduced” for applicant delays, such as when “the applicant failed to engage in reasonable efforts to conclude prosecution of the application.”); *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* Manual of Patent Examining Procedures (“MPEP”) §§2731-2734 (how PTO calculates PTA).

A. The Federal Circuit Usurped Congress's Authority

The Constitution assigns Congress the power to set patent and copyright term. U.S. CONST. ART. I, §8, CL. 8 (“[The Congress shall have Power ...] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”). As this Court has made clear, “Congress [is empowered] to prescribe ‘limited Times,’” which “is a rational exercise of the legislative authority conferred by [Art. I, §8, Cl. 8]. On this point, **the Court defers substantially to Congress.**” *Eldred v. Ashcroft*, 537 U.S. 186, 199 (2003) (emphasis added, citation omitted) (copyright term); *Bate Refrigerating Co. v. Sulzberger*, 157 U.S. 1, 43 (“It is the province of the legislative branch of the government to say when a patent to an inventor shall expire, ...”). This “judicial deference” to Congress is “but a corollary to the grant to Congress of any Article I power.” *Eldred*, 537 U.S. at 192 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966)). The *Collect* decision, however, defies Congressional legislative authority and it fails to show any deference to Congress’ intent, demonstrating why *certiorari* should be granted.

B. ODP’s Origins

The history of ODP is tied to how Congress set patent term prior to the URAA. Commentators often associate the Court’s double patenting jurisprudence to *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894), although other decisions date from the mid-19th Century.⁶

6. Justice Story arguably set the stage earlier when riding the circuit in 1819, at a time that patent applications were not

See Walterscheid, *Historical Development of the Law of Double Patenting Up Through The 1952 Act*, 4 APLA Q.J. 243 (1975) (“Historical Development”), at 249 (“... no other opinion has been so influential in the law of double patenting”).⁷ *Miller*, which the Court heard in equity, considered two patentably distinct cultivators with lifting springs: an 1881 lifting spring patent and an 1879 patent that required the spring be both lifting and depressing. *See id.* at 250. In doing so, the Court summarized its

substantively examined. *See Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (1819) (“It cannot be, that a patentee can have in use at the same time two valid patents for the same invention ... I hold it to be the necessary conclusion of law, that the inventor can have but a single valid patent for his invention ...”); *see Barrett v. Hall*, 2 F. Cas. 914, 924 (C.C.D. Mass. 1818) (Story, J.) (accord).

7. Nonetheless, many trace ODP’s specific origins to Judge Giles Rich’s concurrence in *In re Zickendraht*, 319 F.2d 225 (CCPA 1963). While the *Zickendraht* majority found double patenting, stating there was one invention (*i.e.*, §101 “same invention” double patenting (“§101 DP”)), Judge Rich said there were two inventions and the second *also* should be unpatentable for double patenting.

Where there are in fact two inventions, ... [§101] would seem to be inapplicable and the second patent has to be denied ... on some other ground. ... But since the patented invention is not prior art, the basis for denial is not a statutory basis; rather **it is a caselaw development.**

319 F.2d at 231 n.4 (emphasis added); *see id.* at 233 (Smith, J. joining in the concurrence); *see also* Lewis, *Curing Double Patenting During Prosecution and After Issuance: When Once is Never Enough and Twice is Too Much*, 21 AIPLA Q.J. 34 (1993) (“Curing DP”), at 36 (double patenting applies even if reference not prior art).

prior decisions,⁸ which seemingly focused on what became known as same invention §101 DP but extended that doctrine to cover the patentably distinct springs:

that 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; that the second patent, although containing a broader claim, more generical in its character than the specific claims contained in the prior patent, is also void; but 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.

Miller, 151 U.S. at 198. Thus, *Miller* “made clear that a mere distinction—without more—in the breadth or scope of the claims of the patents would not avoid double patenting.” Historical Development at 251.

8. For instance, *Miller* quoted *McCreary v. Penn. Canal Co.*, 141 U.S. 459, 467 (1891), as deciding:

that where a party owned two patents, showing substantially the same improvement, the second was void, the court saying: “It is true that the combination of the earlier patent in this case is substantially contained in the later. If it be identical with it, or only a colorable variation from it, the second patent would be void, as a patentee cannot take two patents for the same invention.”

151 U.S. at 197-98.

As the law evolved, double patenting separated into two doctrines as Judge Rich's *Zickendraht* concurrence (note 7 above) suggested: (i) same invention §101 DP, a statutory prohibition preventing patents to the same patentee claiming "identical" inventions under 35 U.S.C. §101; and (ii) ODP, a judicial doctrine preventing patents for "colorable variations" to the same patentee. *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998); *see* Curing DP 35-36 ("double patenting' ... encompasses two different invalidity doctrines ... intended to prevent the extension of a patent monopoly beyond the statutory limit ..."). Congress also created a safe harbor in 35 U.S.C. §121 where ODP is not applicable if multiple patents issued from a common priority application because of a PTO "requirement for restriction." *Id.* at 37-38 & nn.14-15.

C. The Federal Circuit's *Collect* Decision Rejected ODP's Equities

While courts have found §101 DP rooted in statute, ODP is not – it is intended to equitably prevent "improper" patent term extensions.⁹ As such, potential ODP invalidity usually can be cured by a "terminal disclaimer" – which (i) disclaims, or dedicates to the public, the end portion of the later-expiring patent's life that extends beyond that of the earlier-expiring patent; and (ii) also requires the patents to have common ownership in order to be

9. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (describing it as an "equitable doctrine"); *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 of the right to exclude"); *see also* Curing DP at 36.

enforceable. *Id.* at 41-44 (it is known as a terminal disclaimer “because the end portion of the patent’s life is disclaimed”); *see* MPEP §1490 (discussing statutory and regulatory terminal disclaimer provisions).¹⁰

ODP was created to prevent a patentee’s **improper** timewise extension of a patent, *i.e.*, “gamesmanship.” *Novartis-Breckenridge*, 909 F.3d at 1364 (ODP inapplicable when extension 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.) (ODP prevents gamesmanship). Precedent thus **requires** that any court consider the equities in light of the case’s facts. In *Berg*, for instance, the Federal Circuit considered staggered patent issuances that extended pre-URAA patent term (which was then measured from patent issuance date), and applied ODP equitably. 140 F.3d at 1434-35.

Prior to URAA, courts did not apply ODP as a strict issue of the timewise extension of right to exclude, as the Court of Customs and Patent Appeals (“CCPA”) phrased it in *Schneller*, 397 F.2d at 354. For example, the CCPA, a predecessor court to the Federal Circuit whose precedent binds the Federal Circuit (*South Corp. v. U.S.*, 690 F.2d 1368, 1370-71 (Fed. Cir. 1982) (*en banc*)), summarized its ODP jurisprudence stating:

In *Stanley*, [214 F.2d 151 (CCPA 1954),] this court sanctioned ... the issuance of a dominating

10. A terminal disclaimer cannot be used to overcome statutory §101 DP. MPEP §1490; Curing DP at 41, 44; *see* note 17 below (example where terminal disclaimer cannot overcome ODP).

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

In re Borah, 354 F.2d 1009, 1017 (CCPA 1966) (emphasis added).

The *Collect* decision *explicitly* discards equities – holding “gamesmanship” irrelevant and treating ODP as a strict liability doctrine. 81 F.4th at 1230 (“[G]ood faith during prosecution does not entitle [Collect] to a patent term to which it otherwise is not entitled.”); *see Allergan*, 2023 U.S. Dist. LEXIS 172641, at *59 (stating that *Collect* decision held ODP “should not [be] influenced by equitable concerns.”).¹¹

Such conflicting positions are ripe for review. NYIPLA supports the Court granting *certiorari* to determine whether ODP should be confirmed as an equitable doctrine as precedent requires.

D. The Federal Circuit Improperly Abrogated Congress's Guarantees

URAA changed how patent expiration dates are calculated. Post-URAA, patents expire 20 years from the

11. The Court has admonished the Federal Circuit against rigidly applying flexible doctrines. *See, e.g., KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 419 (2x), 421, 422, 428 (2007).

earliest-claimed U.S. or international filing date, instead of 17 years from issuance. Congress recognized, however, that with this change any PTO-caused prosecution delays would reduce a patent’s effective life, so it simultaneously guaranteed timely application examination and provided a mandatory guaranteed adjustment—PTA—of “1 day for each day” of PTO delay. 35 U.S.C. §154(b)(1); *Wyeth*, 591 F.3d at 1366; *Supernus Pharms.*, 913 F.3d at 1358; see H.R. Rep. No. 106-287, pt. 1 (Congress enacted PTA to “protect patent term.”) (quoted at note 4 above).

The *Collect* decision wrongly overrode this Congressional safeguard by analyzing for ODP based upon patent expiration *after* PTA is added, instead of before, and **explicitly** declaring Congressionally mandated PTA as an “improper” unjustified patent extension. 81 F.4th at 1229. Thus, under *Collect*, patents may be **invalid** simply because the PTO has improperly delayed their issuance requiring it to add PTA as a result. Courts historically have sought to avoid such “hard” double patenting consequences. See, e.g., *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 724 (6th Cir. 1897) (“where the delay in the issuing of the patent ... cannot be charged to the laches or fraud of the patentee, [a rule invalidating a late issuing patent] would be a hard one”).

Judicial nullification of an otherwise legal statute violates a core Constitutional principle: administrative agencies and courts may not usurp Congress’s legislative role.¹² The Constitution gives Congress authority to set

12. *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

patent terms. *Eldred*, 537 U.S. at 199. As the Court made clear in *Eldred*, courts should defer to Congress when Congress engages in “a rational exercise of the legislative authority conferred by” the Constitution such as setting, or guaranteeing its legally-set, patent term. *Id.*

Certiorari is necessary to address whether the judicially created doctrine of ODP, as applied, may override the clear statutory award of PTA that Congress enacted pursuant to its Constitutional mandate. NYIPLA submits that it may not.

E. ODP Is Not Necessary Post-URAA

ODP long-predates URAA – it comes from a time when gamesmanship could result in improper extensions

own conceptions of prudent public policy.”) and 559 (“Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.”); see *Henry Schein, Inc. v. Archer & White Sales, Inc.*, 586 U.S. --, 139 S.Ct. 524, 528 (2019) (“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.”); *R.R. Ret. Bd. v. Alton R.R.*, 295 U.S. 330, 362 (1935) (“we cannot rewrite a statute and give it an effect altogether different from that sought by the measure viewed as a whole”); *Murphy v. NCAA*, 584 U.S. 453, 482-83 (2018) (courts should not differ sharply from what Congress contemplated); see also A. Hamilton, *The Federalist Papers*, No. 78, *The Judiciary Department* (“**It can be of no weight to say that the courts, on the pretense of a repugnancy, may substitute their own pleasure to the constitutional intentions of the legislature.**” (emphasis added)), and No. 81, *The Judiciary Continued, and the Distribution of Judicial Authority* (addressing the “danger of judiciary encroachments on the legislative authority” and how the Constitutional balance minimizes the risks).

of patent term. *See Novartis-Breckenridge*, 909 F.3d at 1364. However, “the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing” means that concerns over “the unjustified patent term extension” have “limited force.” *In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009), quoted in *Abbvie Inc. v. Mathilda & Terence Kennedy Inst.*, 764 F.3d 1366, 1373-74 (Fed. Cir. 2014) (“*Kennedy Inst.*”) (discussing ODP’s role post-URAA); *see* ODP Why/When at 1019. NYIPLA therefore submits that the URAA made at least the expiration portion of ODP obsolete,¹³ a vestige of when patent term was computed from issuance that is no longer necessary. *Cf. Kennedy Inst.*, 764 F.3d at 1373-74 (discussing Federal Circuit’s reasons to keep ODP).

Moreover, counsel is aware of situations where ODP has stifled innovation. In one instance, two research-based companies developed foundational tools, and each patented its advance. The two considered combining those tools into what they anticipated would be a groundbreaking medical treatment but did not do so – they did not invest in a joint research project because of the likelihood that ODP based upon their two basic patents would undermine any patents resulting from their combined efforts.

13. After URAA, some argue, ODP should apply, at most (if at all), in situations where obvious variant patents from the same family are separately owned—this would avoid risk of harassment by multiple assignees (although, as previously noted, Congress has exempted the situation from ODP where the multiple patents issued based upon PTO restriction requirements). *See Fallaux*, 564 F.3d at 1318. That, however, is not the issue presented in the instant Petition and so NYIPLA limits its arguments to ODP in the context of PTA, although the safe harbor provisions of 35 U.S.C. §121 do allow such separate patents to *not* be commonly owned.

Post-URAA there is no risk of the “unjustified timewise extension of right to exclude” that necessitates disclaiming patent term amongst family members that share a common filing date, which was the impetus for courts creating ODP. *See Schneller*, 397 F.2d at 354; *see also* Bullinger, *Double Patenting and the 1952 Act*, 10 Pat. Trademark & Copy. J. Res. & Ed. 389 (1967) (“DP & 1952 Act”) 389, 398-99 (discussing impetus). This can be further appreciated in light of this Court’s early §101 DP decisions such as *Suffolk v. Hayden*, 70 U.S. (3 Wall) 315, 319 (1865), and *Barbed Wire Patent* case, 143 U.S. 275 (1892), which focused on the date of patent issuance. *See* Historical Development at 244-45.

Under current law, a later-issuing patent expires at the same time as an earlier-issued patent from the same family claiming the same priority date *unless* there is a Congressionally awarded term extension – *e.g.*, either PTE or PTA based upon FDA or PTO delay, respectively. There is nothing *improper* about PTA that justifies invalidating a patent with PTA, just as there is nothing *improper* about PTE. *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). If PTA is considered improper, then “the logic and purpose of [ODP] is flipped on its head.” *ACADIA Pharm. Inc. v. Aurobindo Pharma Ltd.*, 2023 U.S. Dist. LEXIS 221663, at *21 (D. Del. 2023). ODP is meant to “prevent” an “*improper* timewise extension of the patent right” (*Braat*, 937 F.2d at 592 (emphasis original; citation omitted)), and since Congress mandated PTA to guarantee patent term, it cannot be improper by definition – yet that is what the *Collect* decision held (81 F.4th at 1229).

Whether ODP has outlived its usefulness goes further than the PTA Congressional guarantees. Surprisingly, the Federal Circuit did not find URAA as a reason to confine (or even eliminate) ODP; it used URAA's enactment as an opportunity to *expand* the double patenting doctrine, notwithstanding binding precedent and statute.

In *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214-15 (Fed. Cir. 2014), *cert. denied*, 135 S.Ct. 1530 (2015), a divided Federal Circuit panel held that URAA allowed it to deviate from precedent. *See* 753 F.3d at 1217 (Rader, C.J., dissent) (“Today the court expands the judicially-created doctrine of obviousness-type double patenting . . . Because this expansion is unwarranted, I respectfully dissent.”); *see also Novartis-Breckenridge*, 909 F.3d at 1362 (“URAA altered the analytic inquiry . . .”). As PTO Associate Solicitor Kazhdan’s summarized *Gilead* in ODP Why/When (at 1038), “[t]he majority recognized that [*before* URAA] the Supreme Court held that an earlier-issued patent could not be challenged based on a later-issuing patent,” *i.e.*, courts could use the patent application date but not the issuance date to determine double patenting, but *after* URAA “only the expiration date mattered.”

In *Kennedy Inst.*, 764 F.3d at 1373-74, the Federal Circuit also discussed ODP in the post-URAA environment and held that the doctrine should continue in order to (i) prevent so-called *submarine patents*, where an applicant uses continuation applications to patent unclaimed features of an invention long after the original application (no longer a concern now that pending applications are published¹⁴);

14. Concern over *submarine patents* was also addressed by courts applying patent prosecution laches, which itself is

and (ii) to address where an “applicant chooses to file separate applications for overlapping subject matter and to claim different priority dates for the applications, [such that] the separate patents will have different expiration dates since the patent term is measured from the claimed priority date.” *Id.* at 1373, *see* DP & 1952 Act at 397-98 (listing basis for double patenting). The *Kennedy Inst.* panel, however, did not focus on whether that patentee committed “gamesmanship.”¹⁵ *See Kennedy Inst.*, 764 F.3d at 1373-74 & n.2; *see also* ODP Why/When at 1040 (panel “recognized that the *patentee* might have abused the system ... [but its] holding was not premised on that possibility.” (emphasis original)).

While, seemingly, *Kennedy Inst.* shows that the Federal Circuit agreed ODP is no longer necessary to address the submarine patent example, it held ODP should continue to address the second example of gamesmanship because “[w]hen such situations arise, the doctrine of [ODP] ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension.” *Id.* This second example, however, is limited to applications that “claim different priority dates” and, therefore, does not apply to patents and applications in the same family, which have the same priority date (as is at issue in the instant case).

an “equitable and flexible doctrine” that renders such patents unenforceable where appropriate. *E.g.*, *Personalized Media Comm., LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (2023) (citation omitted).

15. The *Kennedy Inst.* facts are unusual. The patentee selectively did not designate its earliest available application date for priority, which was pre-URAA, but chose only to rely on a post-URAA application (which could no longer occur).

NYIPLA submits that *certiorari* is appropriate to address whether and if so how the ODP doctrine should survive – as a **rigid, strict legal doctrine** or as an equitable one – in light of the Federal Circuit’s decision.

F. *Collect* Significantly Adversely Impacts Innovation

Patents are meant “[t]o promote the Progress of ... Science and useful Arts” encouraging innovation, U.S. CONST. Art. I, §8, Cl. 8, and this Court has cautioned against “changes that disrupt the settled expectations of the inventing community.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (citation omitted). But *Collect*’s brute-force application of ODP harms the innovation economy, particularly small businesses, by disrupting those settled expectations.

NYIPLA members, as discussed above, represent all aspects of IP and those impacted by it. It is common for applicants to quickly seek patent protection covering a new invention/product and then file additional applications within the same patent family to claim additional commercially relevant aspects (without seeking additional term). This is a routine strategy across all technology-focused companies, but is particularly relevant for small businesses and early-stage innovators (where resources are restricted) whose IP strategy may need to be flexible to respond to volatile market conditions.

One example of where this decision can create problems is that it is common for the first application in a patent family to issue having the broadest claims and receive PTA because of PTO delays associated with

examining the broadest claims; under the *Collect* decision, the issuance of additional patents in the family may render the first patent invalid, *e.g.*, if those later and narrower patents do not receive PTA. Thus, companies may hesitate to seek additional patents to round out their portfolio, and inventions that add to prior patented work may be lost in fear that a subsequent patent may invalidate or devalue an earlier one.

The Federal Circuit’s suggestion that the solution is for parties to prophylactically “file terminal disclaimers during prosecution” (81 F.4th at 1231) is no antidote.¹⁶ Not only is it impossible in some scenarios,¹⁷ but this “solution” challenges patent owners, many of whom are small businesses and individual inventors, to *roll the proverbial dice* by guessing whether their claims “might” run afoul of ODP in situations where a patent examiner has not raised an ODP rejection. As the example in Section III.E above shows, some innovators chose not to roll those dice rather than give up their statutory patent term.

16. Notably, the PTO seems to have accepted that invitation in a recent Notice of Proposed Rulemaking, *Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting*, 89 Fed. Reg. 40439-49 (May 10, 2024).

17. Other Federal Circuit precedent has created exceptions that also prove why this “solution” is unworkable. For instance, in *In re Hubbell*, 709 F.3d 1140, 1146 (Fed. Cir. 2013), it applied ODP between patents invented by different inventor groups if there is a common inventor, even if not commonly owned, and held that a terminal disclaimer – the tool used to overcome ODP – is not available if patents are not commonly owned. *Id.* at 1148-49; *Fallaux*, 564 F.3d at 1319 n.5.

Under *Collect* it is possible for a patent having PTA to become invalid after issuance, such as in instances where a later-filed application in the same family issues with no PTA, thus creating a double patenting reference where none existed before. *E.g., Collect*, 81 F.4th at 1229 (‘369 patent issued 7/23/02 with 45-day PTA invalid over ‘036 patent issued 3/1/05 without PTA). This creates a new burden: reconsidering already-issued patent portfolios, lest ODP destroy valuable patent families. Hence, under *Collect* patentees must continuously monitor the need for terminal disclaimers for the entire lifetime of each patent. It forces the patentee to be responsible for delays *caused exclusively* by the PTO.

The *Collect* decision presents a patentee with an unpalatable choice. If the PTO processes their broader application claims slowly (resulting in PTA), the options are to forgo filing any continuations (even if a separate, narrower set of claims would move through the PTO more quickly), or to file a continuation but jeopardize either patent term (*i.e.*, PTA-ODP) or the validity of the broader patent/application. The PTO’s tardiness leaves the patentee worse off no matter which of these bad choices they opt for. This is manifestly inequitable, because the PTO’s delay is outside the control of the patentee and will impact some patentees but not others. Congress created PTA to reduce the negative impact on patent term resulting from the PTO’s lag in processing applications, not to create a lottery for patentees.

These impacts, too, support this Court granting the Petition.

IV. CONCLUSION

The Federal Circuit’s decision provides compelling reasons for the Court to exercise its judicial discretion to grant the *Petition for Certiorari*. The Petition does not merely issue present an erroneous factual finding or the misapplication of a properly stated rule of law. Rather, as set out in Sup. Ct. R. 10(a) & (c), the Federal Circuit has “entered a decision in conflict with” its own decisions on an important question in a way that has “sanctioned” lower courts to depart from precedent, such that the Court should exercise its supervisory power; and did so, on an important issue of federal law, in a way that conflicts with relevant decisions of this Court.

Therefore, for the foregoing reasons, NYIPLA respectfully urges the Court to grant the *Petition for Certiorari*.

Respectfully submitted,

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