No. 23-1231

In the Supreme Court of the United States

CELLECT LLC, PETITIONER

v.

KATHERINE K. VIDAL, DIRECTOR,
UNITED STATES PATENT AND TRADEMARK OFFICE

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The government acknowledges (Opp. 12-13) that the decision below "limits" statutorily "guaranteed" patent term adjustment (PTA). Though wrongly asserting that the rule against obviousness-type double-patenting (ODP) is statutory rather than judge-made, the government admits (*ibid.*) that the Federal Circuit limits the statutory guarantee by applying ODP against terms that are longer than reference patents' terms *only* because of the required adjustment.

Yet the government declines to defend what it admits the Federal Circuit has done. Instead, the government recasts the question presented as whether the PTA statute "displace[s]" the ODP doctrine. Opp. 9-10.

Petitioner has advanced no such displacement theory. All parties agree that the ODP doctrine *can* apply to patents with PTA-extended terms. Where a patent would run afoul of the ODP doctrine notwithstanding any PTA obtained in good faith, then nothing in the PTA statute "displaces" that result. But, where the doctrine would not apply to a patent *at all* unless the guaranteed, PTA-extended term is applied, the command that an eligible patent's term "shall be extended" leaves no room for ODP to displace the statutory instruction. By pretending that this case is about PTA displacing ODP—rather than about ODP displacing PTA—the government tacitly admits that the result below is indefensible.

To the limited extent the government tries to defend the nonsensical result reached below, it relies on Section 154's terminal-disclaimer caveat and the

"history" and "context" behind the PTA statute. Those slender reeds cannot support the Federal Circuit's massive and consequential rewrite of the statute. The government cannot explain, either, why diametrically opposite results should hold when a patent's term is longer than a reference patent's term because of patent-office delay, but not when that is so because of FDA delay. The settled principle that identical phrasing in like statutes should be construed *in pari materia* (Pet. 14-17) becomes, in the government's retelling, a mere "analogy" between two vaguely related statutes. Opp. 7, 9.

Finally, the government unpersuasively contends that the question presented lacks importance. The *eight* amicus briefs filed at the cert. stage–seven in support of a grant and one in support of denial–speak far louder than the government's self-serving speculation.

I. Duly Granted Patent Term Adjustment Cannot Cause Double-Patenting Invalidation

1. The government (Opp. 10-13), like the court of appeals (Pet. App. 21a-23a), relies on Section 154's caveat that "[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B). By "referencing terminal disclaimers" (which are often filed to avoid ODP), the government says, Congress "'acknowledged that obviousness-type double patenting concerns can arise when PTA results in a later-expiring claim that is patentably indistinct.'" Opp. 13 (quoting Pet. App. 22a) (alterations adopted).

True. But the government's counterintuitive next step has no basis in the text. The statute's caveat says *not* to add PTA past a patent's expiration date when a valid terminal disclaimer *has* been filed. That offers no guidance about how a patent should be assessed for ODP when a terminal disclaimer has *not* been filed. The government "read[s] into statutes words that aren't there." *Romag Fasteners, Inc* v. *Fossil, Inc.*, 590 U.S. 212, 215 (2020).

It is hard to see why Congress would have hidden a backdoor limitation on its statutory "guarantee" of PTA-extended patent term in a provision explaining that PTA shall *not* be applied in circumstances *that are the opposite* of the ones in this case. That is especially implausible because the proffered limitation can (as it did here) wholly *invalidate* a patent that has no terminal disclaimer. And it is doubly implausible that Congress would have been so cagey given the enormous significance of the government's reading of the statute. See Pet. 24-29; *infra* pp. 8-10. Congress, after all, "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *Am. Trucking Associations*, 531 U.S. 457, 468 (2001).

Petitioner has the better reading of the text Congress *did* enact. Consider a similar construct in an immigration statute: An alien who is subject to removal can request "voluntary departure" to avoid a final order of removal; but, if he fails to depart "within the time period specified," he becomes ineligible, for 10 years, for adjustment of status to lawful permanent resident. 8 U.S.C. § 1229c(d)(1)(B). Just as terminal disclaimers are often filed to obviate ODP, requests

for voluntary departure are typically made to avoid removal. Yet no one would read this provision as requiring or otherwise governing the removal of aliens who do *not* request voluntary departure.

Retreating further from the text, the government argues that there is "no plausible reason that Congress would have limited PTA when a terminal disclaimer *is* filed but adopted the opposite approach when a terminal disclaimer is *not* filed." Opp. 13. Whatever Congress's reasons, the text limits PTA only when a terminal disclaimer has been filed and states the PTA "shall be granted" when no terminal disclaimer is filed. That ends the inquiry: When ordinary meaning and structure "yield[] a clear answer, judges must stop." *Food Mktg. Inst.* v. *Argus Leader Media*, 588 U.S. 427, 436 (2019).[1]

2. Like the court of appeals, the government rejects reading Sections 154 and 156 *in pari materia* by arguing that "[a] critical textual distinction"—Section 154's reference to terminal disclaimers—"shows that Congress intended the two schemes to operate differently." Opp. 13. For support, the government cites *Novartis AG* v. *Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), which (correctly) held that a PTE-extended patent "is valid so long as the extended patent is otherwise valid without the extension." *Id.*

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[1] In any case, there are at least two reasons Congress would have intended this result. First, it puts the onus on the PTO to flag double-patenting issues during patent prosecution and prevents blindsiding inventors with a later invalidation. Second, whereas publicly filed terminal disclaimers allow the public to rely on a patentee's representation that a patent will have a specific end date, no such reliance interest exists where PTA is added in the absence of a terminal disclaimer.

at 1375. The government's upshot? For PTA, but not for PTE, "a judge-made doctrine * * * cut[s] off a statutorily-authorized time extension." *Ibid.* But the parallels between PTA and PTE are far more than a "proposed analogy" (Opp. 9); both statutes' "shall be extended" commands are identical. 35 U.S.C. §§ 154(b)(1)(A); 156(a).

So is the statutes' common purpose of guaranteeing an effective period of exclusivity against regulatory delay. The fact that Section 154 denies PTA to terminally disclaimed patents, and Section 156 does not do the same with PTE, has no bearing on patents that, in either case, have *not* been disclaimed. Under either statute, the question is the same: Should the ODP doctrine apply before taking the statutory extension into account or after? The government's focus on one circumstance in which the PTA statute does **not** apply gives no reason why PTA and PTE should not be read *in pari materia* when they **do** apply. See Opp. 13-14.

3. Nor do "history and context confirm" (Opp. 11-12) the court of appeals' reliance on the PTA statute's terminal-disclaimer caveat to limit that statute's explicit guarantee of extended patent term. Before the URAA's enactment, patent terms were measured from the issuance date rather than from the application date. So, the government says in a complete *non sequitur*, pre-URAA law "implicitly incorporat[ed] USPTO examining and processing times" in patent terms that were subject to invalidation for double-patenting. *Ibid.* Congress therefore must have intended—unless PTA "displaces" ODP (Opp. 9, 10, 11)—that express grants of PTA extensions, to

account for USPTO delays, would trigger ODP-based invalidations of the term-extended patents.

But that argument answers the wrong question (and incorrectly, to boot). The question is not whether PTA "displaced" any preexisting double-patenting principles established by the courts. No one disputes, for example, that PTA-extended patents *may* be invalidated for ODP, as when a patentee eschews continuation practice and "craft[s] a separate 'chain' of applications" for strategic advantage. *Novartis Pharms. Corp.* v. *Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1364 (Fed. Cir. 2018) (quoting *Gilead Scis., Inc.* v. *Natco Pharma Ltd.*, 753 F.3d 1208, 1210 (Fed. Cir. 2014)); see also *AbbVie Inc.* v. *Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014). In that scenario, unless the reference patent and the challenged patent applications are filed the same day, the challenged, PTA-extended patent will be invalidated for double patenting without accounting for the application of any PTA (rather than, as here, *because of* the PTA). And, although the facts of this case do not present the issue, a patentee that extracted PTA by "delay[ing] issuance of patent applications while pretending that it was the PTO's fault"[2] may fall within ODP's traditional rule against "split[ting] up [an] invention for the purpose of securing additional results, or of extending or of prolonging the life" of a patent. *Miller* v. *Eagle Mfg. Co.*, 151 U.S. 186, 201 (1894).

The government's "implicit[] incorporation" argument is also impossible to square with its seeming acceptance of *Novartis*'s holding that ODP is assessed

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[2] Br. of *Amicus Curiae* Inari Agriculture, Inc., at 15.

before—not after—applying any FDA-related PTE. See *supra* pp. 4-5. The government cannot explain why the patent law would implicitly incorporate longstanding bureaucratic delay by the patent office but not by the FDA.

In any event, even granting the government's framing, the fact that pre-URAA patents ran from the issuance date, yet were subject to ODP, is no ground on which to infer that the post-URAA guarantee of PTA extension nevertheless can trigger ODP invalidation. It is one thing to enlist background law as an interpretive guide in the face of ambiguity; it is quite another to use pre-URAA law to "justify a rule that denies statutory text its fairest reading." *Armstrong* v. *Exceptional Child Ctr., Inc.*, 575 U.S. 320, 329 (2015). Whatever may have been permissible under the pre-URAA statutory scheme, "[t]he starting point in discerning congressional intent is the existing statutory text, and not the predecessor statutes." *Lamie* v. *U.S. Trustee*, 540 U.S. 526, 534 (2004) (citation omitted).

4. The government's treatment of ODP's equitable roots also falls flat. In a halfhearted attempt to ground ODP in statutory text, the government points to an inventor's ability to "obtain *a patent*" for an invention. Opp. 14 (quoting 35 U.S.C. § 101). But ODP applies only when "the claims define *separate*, albeit patentably indistinct, inventions." *In re Kaye*, 332 F.2d 816, 819 (C.C.P.A. 1964) (emphasis added). There is no statutory obviousness bar as between a patentees' own inventions. Therefore, although ODP is based on the "policy reflected in the patent statute," *AbbVie*, 764 F.3d at 1372, it is nonetheless a "judicially created doctrine" that "prevent[s] the

extension of the term of a patent, even where an express statutory basis for the rejection is missing." *Boehringer Ingelheim Int'l GmbH* v. *Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010) (quoting *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)). That is why it's referred to as "non-statutory" double patenting. *Novartis Pharms. Corp.* v. *Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1362 (Fed. Cir. 2018). Indeed, the PTO's own regulations acknowledge that ODP is "judicially created." 37 C.F.R. § 1.321(c). Again, it speaks volumes that the Solicitor General, to attempt to defend the result below, feels she must contradict her own client.

As for the court of appeals' dispensing with the longstanding requirement that ODP be applied to patents only where there has been some gamesmanship in prosecution (see Pet. 23, citing *Thomson-Houston Elec. Co.* v. *Ohio Brass Co.*, 80 F. 712, 724, 726 (6th Cir. 1897) (Taft, J.)), the government nowhere explains why an extension mandated by Congress to guarantee patent term against regulatory delay is, without more, "unjustified." Opp. 15.

II. The Question Presented Is Exceptionally Important

The government tries to minimize the importance of the question presented. It observes that, after all, not every patent that receives PTA is at risk under the decision below, and patentees have always had some incentive to avoid double patenting. Those protestations ring hollow and fail to grapple with the contrary experiences of *amici* who know better. Nor has the court of appeals' recent decision in *Allergan USA, Inc.* v. *MSN Laboratories Private Ltd.*, No. 24-1061, 2024 WL 3763599 (Fed. Cir. Aug. 13, 2024), decreased the significance of the decision below—

rather, it demonstrates the ad hoc, unpredictable ODP doctrine that the decision below invites.

1. The government calls it "largely beside the point" that "approximately half of all granted patents have been awarded PTA"—urging that, even so, the question presented would not arise in connection with every such patent. Opp. 17. True enough, but that provides no comfort for patentees, like many in the pharmaceutical and biotechnology industries, for whom a single patent family may be the product of "more than a decade of time and billions of dollars."[3] The decision below creates uncertainty—and imposes attendant costs—for a vast set of patents previously understood to be safe from ODP challenges. It is *not* "largely beside the point" (Opp. 17) that many key stakeholders no longer know when each of the numerous patents in their portfolios expire.[4]

Indeed, the government tries to wave away the substantial costs associated with reviewing entire patent portfolios for ODP landmines, arguing that, "[u]nder th[e] status quo, patentholders *already* have an incentive to review their issued patents, so that they can file terminal disclaimers before those patents expire." Opp. 18. That hardly addresses inventors' concern that Congress's guarantee of patent term could threaten their portfolios "long after all of the patents in a family were prosecuted" and "enormous

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[3] Br. of *Amici Curiae* Pharmaceutical Research and Manufacturers of America And Biotechnology Innovation Organization at 5-6.

[4] Br. of *Amici Curiae* Sonos, Inc., et al. at 6.

investments" were made to pioneer those patents.[5] And a steady status quo is belied by the 50% increase in terminal-disclaimer filings from 2022 to 2023.[6] As *amici* have explained, the decision below has diverted time and resources away from innovation as patentees "scrambl[e] to evaluate their ODP risk."[7]

The government's answer to this chorus of objections—that "Congress allowed patentholders to file terminal disclaimers to mitigate the risk of such challenges" (Opp. 18)—is especially unavailing in light of a destabilizing PTO proposal. Under a new proposed rule, terminal disclaimers would be ineffective where "any claim" of another patent tied to the terminally disclaimed patent "has been finally held unpatentable or invalid as anticipated or obvious." 89 Fed. Reg. 92, at 40439. This would mean that, in exchange for an ODP-obviating terminal disclaimer, a patentee must "accept[ ] the risk that an entire patent's enforceability could hinge on the strength of a single claim in another patent."[8]

2. The government highlights the Federal Circuit's recent decision in *Allergan*, Opp. 17-18, but the

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[5] Br. of *Amici Curiae* Pharmaceutical Research and Manufacturers of America And Biotechnology Innovation Organization at 18.

[6] Br. of *Amicus Curiae* American Intellectual Property Law Association at 19 (citing 16 Dennis Crouch, Terminal Disclaimers: A Growing Concern in Patent Practice, PATENTLY-O (May 10, 2024), https://perma.cc/6PVV-6CLQ)).

[7] *Id.* at 17.

[8] *Id.* at 18-19 n.15 (quoting Dennis Crouch, Major Proposed Changes to Terminal Disclaimer Practice (and You are Not Going to Like it), PATENTLY-O (May 9, 2024), https://perma.cc/8593-GMDJ).

pretzel logic of that decision demonstrates the unpredictability that plagues the Federal Circuit's ODP cases and makes resolving the question presented more important, not less. The court of appeals there held that invalidating "a first-filed, first-issued parent patent having duly received PTA" by reference to "a later-filed, later-issued child patent with less, if any, PTA" would "run afoul of the fundamental purposes of ODP" and "effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA." 2024 WL 3763599, at *8.

The court of appeals got at least one thing right in *Allergan*—invalidating patents because of "duly received PTA" in fact *does* abrogate the benefit that Congress bestowed on patentees in Section 154. But, because in the decision below the Federal Circuit strayed from Section 154's command that a patent's term "shall be extended," the *Allergan* panel could provide no sound reason why forcing the disclaimer of PTA abrogates Congress's guarantee *only* when the subject patent was first-filed and first-issued, but not in other circumstances. See *ibid.* Such arbitrary line-drawing is to be expected when, as here, a court is attempting to apply a judge-made rule in derogation of controlling statutory text.

Indeed, the court of appeals' case law is now so far from any statutory mooring that each new case is an unpredictable gamble. *Allergan*, in particular, was a sharp departure from the court's earlier holding in *Gilead Sciences, Inc.* v. *Natco Pharma Ltd.*, which decided that "a patent that issues after but expires before another patent [can] qualify as a double patenting reference for that other patent" because, post-URAA, courts should look not to the date of

issuance but to "the earliest expiration date of all the patents." 753 F.3d 1208, 1211–12, 1216 (Fed. Cir. 2014). The *Allergan* court acknowledged that *Gilead* "appear[ed] to apply," but escaped its logic because it was "expressly limited" to its facts. 2024 WL 3763599 at *7. And the court of appeals distinguished the decision below on the ground that, though it too turned on expiration dates, it "d[id] not address * * * under what circumstances can a claim properly serve as an ODP reference." *Id.* at *6.

Ad hoc turnabouts like *Allergan* are the wages of ignoring the statutory text. Unless this Court nips the poisonous tree in the bud by reviewing and reversing the decision below, its tainted fruit will grow at the cost of both legitimate patent rights and sound statutory construction.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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