2022-1293, 2022-1294, 2022-1295, 2022-1296

United States Court of Appeals For the Federal Circuit

IN RE: CELLECT, LLC,
Appellant

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457

BRIEF OF AMICUS CURIAE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF APPELLANT'S PETITION FOR REHEARING EN BANC

SALVATORE ANASTASI
First Vice President
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
BARLEY SNYDER
2 Great Valley Parkway, Suite 110
Malvern, PA 19355
Tel.: (610) 722-3899
sanastasi@barley.com

SOPHIE F. WANG
MARINA PULLERITS
DANIEL A. KLEIN
CHOATE, HALL & STEWART LLP
Two International Place
Boston, MA 02110
Tel.: (617) 248-5000
Fax: (617) 248-4000
swang@choate.com

Counsel for Amicus Curiae American Intellectual Property Law Association

November 22, 2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1293

Short Case Caption In re: Cellect, LLC

Filing Party/Entity American Intellectual Property Law Association

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 11/22/2023

Signature: /s/ Sophie F. Wang

Name: Sophie F. Wang

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
American Intellectual Property Law Association		

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☑ None/Not Applicable ☐ Additional pages attached

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☒ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

STATEMENT OF INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association representing the interests of approximately 7,000 members engaged in private and corporate practice, government service, and academia. AIPLA's members represent a diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trade secret, trademark, and copyright law, as well as other fields of law relating to intellectual property. AIPLA's members represent both owners and users of intellectual property. AIPLA's mission includes providing courts with objective analyses to promote an intellectual property system that stimulates and rewards invention, creativity, and investment while accommodating the public's interest in healthy competition, reasonable costs, and basic fairness. AIPLA has no stake in either of the parties to this litigation or in the result of this case. AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues.[1]

SUMMARY OF ARGUMENT

Appellant's Petition for Rehearing En Banc presents an opportunity for the Court to reconsider the legal basis for, and the unintended consequences of, its growing body of jurisprudence expanding the judicially-created doctrine of non-

[1] No person, party, or party's counsel, other than AIPLA or its counsel, authored this brief in whole or in part, or contributed money that was intended to fund preparing or submitting this brief.

statutory obviousness-type double patenting ("ODP") well beyond its policy-based roots. Significant changes to the U.S. patent system, particularly in calculating patent terms, have diminished ODP's role in curbing "unjust" extensions of patent term. Nevertheless, the panel's decision makes clear that ODP today wields even greater power than it did at its inception. The panel's decision thus departs from its prior exercise of judicial restraint to refuse to allow a "judge-made doctrine" to "cut off a statutorily authorized time extension." *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 (Fed. Cir. 2018). Because the panel's decision (i) has created a bright-line rule having a significant impact on countless existing patents with duly-issued patent term adjustments ("PTA"), and (ii) relies on a finding of implied congressional intent to override express grants of patent term, this case presents a question of exceptional importance warranting en banc review.

ARGUMENT

I. The Panel's Decision Improperly Expands a Judicially-Created Doctrine to Override Statutorily-Authorized PTA.

Congress has never codified ODP. Nevertheless, the panel held that a narrow provision in 35 U.S.C. § 154(b)(2)(B) relating to the "binding power of terminal disclaimers" was "tantamount to a statutory acknowledgment that ODP concerns can arise when PTA results in a later-expiring claim that is patentably indistinct." *In re Cellect*, 81 F.4th 1216, 1228 (Fed. Cir. 2023). Although the panel acknowledged that this provision "is not directly applicable to the present case," since no terminal

disclaimers were actually filed, it nonetheless found the provision "critical" and indicative of the "clear intent of Congress" that the judge-made doctrine of ODP can invalidate patents based on their PTA-extended terms in the absence of a terminal disclaimer. *Id.* at 1228-29. The panel's analysis does not justify these conclusions.

Section 154(b)(2)(B) does not mention ODP. Rather, the plain language of the statute simply refers to how an applicant's disclaimer of term affects the grant of PTA. *See* 35 U.S.C. § 154(b)(2)(B) ("No 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") (emphasis added). Thus, Section 154(b)(2)(B) provides only that *if* a terminal disclaimer has been filed, PTA cannot extend a patent's expiration beyond the date specified in the disclaimer. *Id. See Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1321 (Fed. Cir. 2007) ("As in any case of statutory construction, our analysis begins with the language of the statute. And where the statutory language provides a clear answer, it ends there.") (quotations omitted).

The panel's decision ignores this simple explanation for the provision: eliminating any doubt over what effect a terminal disclaimer might have on PTA. Instead, it derives from this otherwise straightforward provision a "clear intent of Congress" to prevent applicants from "benefit[ing] from their failure, or an examiner's failure, to comply with established practice concerning ODP." *Cellect*,

81 F.4th at 1229. The panel reasoned that since PTA could not be awarded to extend term if a terminal disclaimer was filed, Congress necessarily intended that the *absence* of a terminal disclaimer should expose a patent with PTA-extended term to invalidation under ODP. *See id.*

This rationale is unsound for several reasons. As a preliminary matter, had Congress intended to (i) codify ODP or (ii) allow ODP to cut off term extended by PTA, Congress could have done so expressly. *Cf. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 634 (2019) (merely adding a catchall phrase "would be a fairly oblique way of attempting to overturn" settled law, and thus "is simply not enough of a change for us to conclude that Congress intended to alter the meaning of" a statute); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 109-10 (2011) ("[H]ad Congress intended to drop the heightened standard of proof . . .[,] we assume it would have said so expressly."). Congress logically could have done so in Section 101 itself (the purported statutory hook for ODP, *see In re Robeson*, 331 F.2d 610, 614 (C.C.P.A. 1964)), rather than in an ancillary statute relating to PTA. It did not.

Indeed, it was not Congress that tied terminal disclaimers with ODP. In *Robeson,* this Court's predecessor court first addressed "[w]hether a terminal disclaimer can overcome the objections to double patenting." *Id.* at 613. The court acknowledged that "35 U.S.C. 253, providing for a terminal disclaimer, was first enacted in 1952 and has no known antecedent in the earlier patent statutes. The

legislative history and the Reviser's Notes shed little light on exactly why Congress enacted that particular provision." *Id.* at 613-14. The court further cited the commentary of a congressional staffer, who likewise noted that there was no specific reason for Section 253 in the record but surmised that "its proponents contemplated that it might be effective in some instances, in combatting a defense of double patenting." *Id.* at 614 n.4. Based on this, the court concluded that "[t]he terminal disclaimer, which Congress has expressly provided," could overcome an ODP rejection. *Id.* at 615. This conclusion has been subsequently cited, repeated, and expanded in this Court's jurisprudence, eventually leading to the panel's statement in this case that "terminal disclaimers and ODP remain inextricably intertwined." *Cellect*, 81 F.4th at 1228. But this intertwining is of the Court's own making; it does not justify a conclusion that Congress intended ODP to invalidate PTA-extended patents in the absence of a terminal disclaimer.

It is a well-established canon of statutory construction that courts should not rewrite statutes to cover matter that is not expressly covered. *See Iselin v. United States*, 270 U.S. 245, 251 (1926) ("What the Government asks is not a construction of a statute, but, in effect, an enlargement of it by the court, so that what was omitted, presumably by inadvertence, may be included within its scope. To supply omissions transcends the judicial function."); *see also* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 93 (2012). By interpreting

Section 154(b)'s narrow limitation on PTA as "tantamount to" congressional intent to adopt ODP, the panel violates these principles.

Moreover, Congress could not have had such a "clear intent" for the ODP doctrine to apply to PTA, since the doctrine in its current form did not exist when Congress enacted Section 154(b) in 1999. Indeed, it was not until this Court's decision in *Gilead*—fifteen years later—that the application of ODP became focused on the *expiration* date of a patent instead of its *issuance* date. *See Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1218 (Fed. Cir. 2014) (Rader, C.J., dissenting) (the court "craft[ed] a new rule" making the "expiration dates of the patents govern the [ODP] inquiry irrespective of filing or issue dates"); *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985). It cannot be fairly said that a provision in Section 154(b) concerning the impact of a terminal disclaimer on PTA, which was enacted well before *Gilead*, evidences congressional intent to apply post-*Gilead* ODP to invalidate patents with later expiration dates due solely to PTA. Thus, no support exists in the plain language or legislative history of Section 154(b) for the panel's finding of congressional intent.

Additionally, comparisons of Sections 156 and 154 (as also described in *Novartis* and *Merck*) do not establish the purported congressional intent. There is no dispute that Congress intended both statutes to provide ways of making up patent term that was lost solely due to factors outside of the applicant's control—in the case

of PTE, regulatory delays, and in the case of PTA, USPTO delays. However, the fact that two statutes have differences (e.g., Section 156 does not include a provision about the effect of a terminal disclaimer on PTE) does not mean those differences amount to congressional intent for a bright-line rule applying ODP affirmatively against PTA. The reliance of the panel's expansion of the ODP doctrine on a limited analysis of portions of ancillary statutes warrants en banc reconsideration.

II. The Panel's Decision Represents Yet a Further Departure from the Equitable Underpinnings of ODP.

The panel's creation of a bright-line rule that ODP can invalidate a patent whose later expiration date is based *solely* on statutorily-mandated PTA is also inconsistent with the doctrine's underlying purpose.

There can be no dispute that ODP was founded on equitable principles. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1056, 1059 (Fed. Cir. 2020). In *Novartis*, this Court specifically noted that "the concerns that drove recent decisions of this court" concerning ODP include the risk of "potential gamesmanship . . . through structuring of priority claims"—e.g., by filing serial patent applications with different priority dates and strategically responding to prosecution deadlines such that the application claiming the latest filing date issued first—which would allow inventors to "routinely orchestrate longer patent-exclusivity periods." 909 F.3d at 1374-75 (citing *Gilead*, 753 F.3d at 1215). Where no such tactics were identified and where the challenged patent would have expired earlier "[b]ut for" the statutory

extension, however, this Court declined to apply ODP. *Id.* at 1375. The same facts apply here, yet the Court reached the opposite conclusion. *See Cellect*, 81 F.4th at 1228. In doing so, the panel did not simply distinguish between Sections 156 and 154. Instead, the panel went further, holding that despite its equitable origins, the doctrine of ODP now applies *regardless* of whether a party acts in good faith. *See id.* at 1230 ("An applicant's ability to show that it did not engage in gamesmanship in obtaining a grant of PTA is not sufficient to overcome a finding that it has received an unjust timewise extension."). This sweeping statement has already had significant consequences.

For example, the District of Delaware recently relied upon the panel's decision in holding that a first-filed patent was nonetheless rendered invalid under ODP by a later-filed patent simply because the first-filed patent expired later solely because of PTA. *See Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd*., 2023 U.S. Dist. LEXIS 172641, at *60 (D. Del. Sept. 27, 2023) (interpreting the panel's decision as holding "that ODP depends solely on patent expiration dates *and should not [be] influenced by equitable concerns. Any extension* past the ODP reference patent's expiration date constituted an inappropriate timewise extension for the asserted claims of the challenged patents.") (emphasis added) (citations omitted). In doing so, the district court found that traditional equitable concerns have no place in the analysis because "*Cellect* recognizes no exception to the rule it announced, whether

for first-filed, first-issued claims or otherwise." *Id*. *But see Novartis*, 909 F.3d at 1374 (expressly relying on the fact that the traditional concern regarding obtaining unjust extensions of time "through claims in *a later-filed* patent that are not patentably distinct from claims in *the earlier filed* patent" did not apply because "[h]ere, it is the *earlier-filed, earlier-issued* '229 patent, not the later-filed, later-issued '565 patent, that has the later expiration date, *due to a statutorily-allowed term extension*") (emphases added).

Chief Judge Rader's dissent in *Gilead* cautioned that "courts should be reluctant to create or expand judge-made exceptions to statutory grants." 753 F.3d at 1218 (Rader, C.J., dissenting). This is particularly true where, as here, an expansion is inconsistent with the equitable principles that gave rise to the judicially-created doctrine in the first place. En banc review is necessary to determine the limits that ODP may impose on codified rights in the absence of congressional approval.

III. The Panel's Decision Has Created Great Uncertainty, Upset Settled Expectations, and Will Disincentivize Innovation.

The panel's broad expansion of ODP doctrine in this case has created great uncertainty regarding the status of innumerable patents that have received the benefit of PTA to offset, in many cases, significant USPTO delays. Companies rely heavily on knowing the exact duration of their patent exclusivities when entering collaborations, negotiating licenses, and investing in future research and

development. Following the panel's decision, companies face the need to reevaluate their entire patent portfolios on a claim-by-claim basis[2] to determine whether their prior acceptance of Congress's "fix" for USPTO delays (via PTA) has now endangered their patents under ODP. The panel's decision effectively forces patent owners to file terminal disclaimers even where no ODP rejection was made during prosecution, thus giving up duly-awarded PTA. Otherwise, patent owners face real risk that even first-filed, foundational patents may be rendered invalid. The effect of suddenly losing years of term could be devastating to patent owners, particularly in the life sciences industry where patent protection is a critical factor in driving research and drug development.

Moreover, the U.S. patent system benefits from, and expressly provides a means for, applicants to obtain continuation patents to ensure protection of the full scope of their inventions. *See* 35 U.S.C. § 120. Such a practice is routine, lawful, and puts the public on notice of the full scope of the invention while incentivizing continuing improvements and allowing for efficient prosecution of patents. The panel's decision, however, may motivate applicants to file a single application having all potential claims for fear of losing patent term allotted to a related

[2] Because ODP is evaluated on a claim-by-claim basis, while a terminal disclaimer limits term for the entire patent (*see Cellect*, 81 F.4th at 1231), the analysis of whether to file terminal disclaimers preemptively to avoid ODP is a complicated and unduly burdensome task involving a claim-by-claim assessment.

application. These all-encompassing applications will exponentially increase the burden on the USPTO, potentially lead to additional delays (the exact opposite of what Congress intended by allowing for both continuation applications and PTA), and may prove significantly more costly and difficult to pursue. *See also, e.g.*, 37 C.F.R. § 1.16; 37 C.F.R. § 1.75(b). This, and myriad other issues, present the types of unintended consequences brought about by the panel's far-reaching decision.

In enacting Section 154, Congress could not have intended to give a benefit to patent owners to make up for lost term, and, within the same statute, penalize patent owners for accepting that benefit by allowing a judge-made doctrine to thereafter invalidate PTA-extended patents. En banc review is necessary to determine whether the panel's reasoning is sufficient to sustain the serious and unjust consequences of its new expansion of the ODP doctrine, which deprive patent owners of Congress's statutory grant of term.

Dated: November 22, 2023

Respectfully submitted,

AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

By its attorneys,

/s/ Sophie F. Wang
SOPHIE F. WANG
MARINA PULLERITS
DANIEL A. KLEIN
CHOATE, HALL & STEWART LLP

2 International Place
Boston, MA 02110
Tel.: (617) 248-5000
Fax: (617) 248-4000
swang@choate.com

SALVATORE ANASTASI
First Vice President
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
BARLEY SNYDER
2 Great Valley Parkway, Suite 110
Malvern, PA 19355
Tel.: (610) 722-3899
sanastasi@barley.com

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 22-1293

Short Case Caption: In re: Cellect, LLC

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 2,600 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 11/22/2023

Signature: /s/ Sophie F. Wang

Name: Sophie F. Wang