United States Court of Appeals for the Federal Circuit

IN RE CELLECT, L.L.C.,

Appellant.

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

BRIEF OF AMICI CURIAE LANGUAGE TECHNOLOGIES, INC., PARUS HOLDINGS, INC., AND ROBOCAST, INC. IN SUPPORT OF APPELLANT'S PETITION FOR REHEARING EN BANC

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November 28, 2023

CERTIFICATE OF INTEREST

Counsel for Amici Curiae certify the following:

- 1. Full name of party represented by me is:
 - 1. Language Technologies, Inc.
 - 2. Parus Holdings, Inc.
 - 3. Robocast, Inc.
- 2. Name of real party in interest represented by me is:

Same as above

3. Parent corporations and publicly held companies that own 10% or more of stock in the party:

With respect to Language Technologies, Inc. ("LTI"), in 2008, Pearson Investment Holdings, Inc., an affiliate of Pearson PLC (traded on the NYSE as "PSO") acquired a 15% ownership stake in LTI. LTI believes that Pearson's current ownership stake is less than 10%. None with respect to amici 2 and 3.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

None

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. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

NA

6. 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.

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INTEREST OF THE AMICI CURIAE

Amici curiae are owners of United States patent portfolios reflecting substantial investment in development of innovative technologies across a range of subject matter. Amici curiae have an interest in ensuring a robust, equitable patent system that fairly compensates innovators for their contributions. Pursuant to the statutory mandate of 35 U.S.C. § 154, their portfolios include patent families with multiple members granted different periods of patent term adjustment ("PTA") due to PTO delays. The panel's decision in *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023), risks impacting the term and/or validity of one or more such patents in view of its conclusion concerning the interplay of PTA and the judge-made doctrine of obviousness-type double patenting ("ODP").

Appellant consents to the filing of this brief, and appellee does not oppose it.

No counsel for any party authored this brief in any part, and no party, counsel, or person other than amici made a monetary contribution to fund the preparation and submission of this brief.

INTRODUCTION

The panel's decision relies on a strained interpretation of 35 U.S.C. § 154(b) to justify its disparate treatment of the PTA statute from the Patent Term Extension ("PTE") statute applicable only to Hatch-Waxman patents. But neither the language of the PTA statute nor this Court's case law applying the PTE statute support the panel's decision, which transforms a law intended to "guarantee" diligent applicants a minimum effective 17-year patent term into a basis for invalidating patents properly awarded PTA. From an ODP perspective, there is no principled reason to treat delays caused by the USPTO in issuing a patent differently from delays in regulatory approval for drugs covered by Hatch-Waxman patents – both have the effect of shortening the effective period of exclusivity.

The panel's rationale based on the language of 35 U.S.C. § 101 limiting inventors to "a patent" for their inventions does not support its decision. This Court has held that ODP's roots in § 101 do not bar a patentee from owning two patentably indistinct patents with different expiration dates in two analogous scenarios: patents subject to the "happenstance" of an intervening change in law when the Unites States transitioned its patent system to measure patent term from priority date instead of issue date; and patents subject to the two-way test for ODP due to PTO delays in prosecution.

Consistent with the foregoing, this Court's precedent establishes that ODP is fundamentally an equitable doctrine that serves the purpose of preventing only "unjustified" time-wise extensions of patent term. But the panel swept aside the equitable underpinnings of the doctrine in concluding that a difference in patent term resulting solely from a proper award of PTA is necessarily unjustified, and supports invalidating the patent with the longer term.

This Court should grant rehearing en banc and reverse the judgments of the Patent Trial and Appeal Board.

ARGUMENT

I. PTA and PTE Serve the Same Purpose of Compensating for Loss of Patent Term Due to Administrative Delays, and Should be Consistently Applied vis-à-vis ODP.

The panel concluded that the statutory constructs of the PTE (35 U.S.C. § 156) and PTA (35 U.S.C. § 154) statutes mandate divergent treatment in the ODP analysis. *In re Cellect, LLC*, 81 F.4th 1216, 1226-29 (Fed. Cir. 2023). But both statues serve the same purpose – preventing the effective shortening of patent terms due to governmental delays outside the control of the patent owner. PTA targets administrative delays that became term-shortening after the Uruguay Round Agreements Act of 1994 ("URAA") took effect, which changed the term of a patent from 17 years after issuance to 20 years after the claimed priority date. H.R. Rep.

No. 106-287, pt. 1, at 50 (1999) (purpose of PTA was to "guarantee[] diligent applicants at least a 17-year term").

The panel's decision fails to reconcile this disparate treatment, which does not follow from this Court's precedent. In Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 1322-23 (Fed. Cir. 2007), this Court held that a terminal disclaimer filed to obviate an ODP rejection for a Hatch-Waxman patent did not negate PTE for that patent, finding that PTE was properly added to the term of the patent, as shortened by the terminal disclaimer. The court there rejected the argument that its holding "improperly uncouple[d]" a second, non-patentably distinct patent from its earlierexpiring counterpart. Id. at 1322-23. It explicitly noted that the purpose of the terminal disclaimer, i.e., to "prevent extension of patent term of subject matter that would have been obvious over an earlier filed patent" "remains fulfilled" because the PTE was added to the shortened term. *Id.* at 1323. The Court thus acknowledged that ODP does not foreclose a patentee from owning two patents for the same invention with different expiration dates.

There is no statutory, logical or equitable reason to treat PTA differently, yet that is the result of the panel's holding. In the case of a patent family with claims across multiple patents that are not patentably distinct, each of those multiple patents must have the same expiration date, notwithstanding that the statute mandates adjustments due to PTO delays. In its decision below, the Board relied on dicta in

Merck stating that "§ 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays." J.A. 35-38 (quoting Merck, 482 F.3d at 1323). The panel misconstrued this statutory language in concluding that it reflected Congress's intent that the ODP analysis be applied based on expiration dates including PTA. 81 F.4th at 1229. As petitioner notes, however, § 154(b)(2)(B) is simply a calculation rule governing how PTA awards are applied where term has been disclaimed. Petition (Dkt. 96) at 7-8.

The panel did not have the benefit of a fact pattern actually implicating § 154(b)(2)(B), *i.e.*, a patent that included a terminal disclaimer filed during prosecution. But the panel held that ODP applies based on post-PTA expiration dates regardless. A hypothetical fact pattern involving a terminal disclaimer illustrates how this section actually applies. Consider a first-filed, post-URAA application in a patent family that issues with 100 days of PTA. A second, continuation application in the family (claiming the same priority date) is filed and subject to a terminal disclaimer based on the first patent. The second patent then issues and is accorded 150 days of PTA. In this scenario, § 154(b)(2)(B) operates to reduce the 150 days of PTA for the second patent to 100 days, and thus the continuation (second) patent's term is coextensive with the parent (first) patent. This

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¹ As Petitioner notes, the statutory language is directed to "an existing disclaimer made during prosecution of the patent." Petition at 8.

scenario is expressly addressed by the language of § 154(b)(2)(B) that only bars adjustments "beyond the expiration date specified in the disclaimer." Thus, just as in *Merck*, the policy behind ODP is fulfilled, but the patentee also benefits from the mandatory statutory extensions awarded for PTO delays in issuing both patents.

Modifying the hypothetical, if the PTA for the continuation patent was instead only 50 days, § 154(b)(2)(B) would not reduce its extension, but its term would nonetheless be 50-days shorter than the parent patent. Under the panel's holding, in the absence of a terminal disclaimer for the *parent* patent disclaiming its additional 50-days of PTA, this difference in term attributable to different PTA extensions is grounds to invalidate any patentably indistinct claims in the first, later expiring patent.

But such a result does not serve the policy behind ODP, as the inventor clearly did not "secure a second, later-expiring patent for non-distinct claims," which the panel characterized as "[a] crucial purpose of ODP." 81 F.4th at 1226. Rather, it serves only to penalize patentees that seek to benefit from continuation practice by negating the statutory grant of additional PTA for the first patent (if the additional 50 days is terminally disclaimed), or worse, invalidating the patent if there is no terminal disclaimer filed, as in the panel's decision.

II. The Panel's Decision is Not Justified by the "a patent" Language of 35 U.S.C. § 101.

The panel's analysis provides no rationale for adopting a rule of law that penalizes patentees for obtaining continuation patents with shorter terms than a first filed/first issued parent patent. The panel noted that ODP "has its roots" in the "a patent" language of 35 U.S.C. § 101. *Id.* But unlike § 101, this Court's precedent establishes that ODP does not *necessarily* preclude a patentee from obtaining multiple patents on patentably indistinct inventions. In addition to the PTE example (*Merck*), the Court found this permissible where it was caused by the URAA change in patent term, *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1363-64 (Fed. Cir. 2018), and where the two-way test for ODP applies due to PTO delays during examination. *In re Braat*, 937 F.2d 589, 593-95 (Fed. Cir. 1991) ("[O]nly if the extension of patent rights is *unjustified* is a double patenting rejection appropriate.") (emphasis in original).

Nothing in § 154, including § 154(b)(2)(B), is tantamount to a statutory bar on multiple patents subject to differing amounts of PTA based on ODP. Indeed, Congress made clear that PTA is an "award" of additional term intended to "compensate applicants fully for USPTO caused administrative delays." H.R. Rep. No. 106-464, at 125 (Nov. 9, 1999) (Conf. Rep.). Under the panel's decision, it becomes a weapon used to invalidate patents.

The panel rationalized its decision by noting that the main reference patent in the Cellect family (the '036 patent) was not awarded any PTA, and that any extension past that date "constitutes an inappropriate time-wise extension for the asserted claims of the challenged patents." 81 F.4th at 1229. But the panel failed to explain why the later expiration dates for some family members attributable solely to statutorily mandated awards of PTA were "inappropriate." The panel asserted that "[t]o hold otherwise would, in effect, confer on the reference claims of the '036 patent PTA to which they were not entitled." *Id.* at 1230.

However, § 154 does not address the "effect[ive]" grant of PTA on other patents. And in *Novartis AG v. Ezra Ventures, LLC*, 909 F.3d 1367 (Fed. Cir. 2018), this Court acknowledged that in the context of PTE, although § 156 allows for the term of only one patent to be extended, in the case of a patent subject to a terminal disclaimer, "the term of patent protection afforded to the patentably indistinct patent to which the extended patent was terminally disclaimed is [] effectively extended because of a PTE granted pursuant to § 156." 909 F.3d at 1374 (cleaned up). The panel failed to point to any difference in the language of § 154 that requires a different outcome for PTA. That PTA for a given patent is limited by a terminal disclaimer under § 154(b)(2)(B) is not a statutory prohibition on the "effective" extension of reference claims in other patents.

III. The Panel Failed to Account for This Court's Precedent That ODP is an Equitable Doctrine That Applies Only to "Unjustified" Extensions of Patent Term

The panel quoted *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997) for the proposition that ODP "is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious variant." 81 F.4th at 1226. But again, controlling precedent has long recognized that ODP does not prohibit *all* situations where multiple patents for patentably indistinct inventions have different expiration dates. The language in *Lonardo* traces back to *In re Schneller*, 397 F.32 350, 354 (CCPA 1968), where the court framed the "fundamental reason for the rule" as "preventing *unjustified* timewise extension of the right to exclude." (emphasis modified).

The concept of an "unjustified," "improper," or "undue," time-wise extension of patent term as the premise for ODP has been carried forward in multiple subsequent decisions of this Court and its predecessor. *E.g.*, *In re Van Orum*, 686 F.2d, 937, 943-44 (CCPA 1982) (quoting *Schneller*); *In re Goodman*, 11 F.3d 1046, 1049 (Fed. Cir. 1993) (same); *In re Fallaux*, 564 F.3d 1313, 1318-19 (Fed. Cir. 2009) (reiterating "unjust time-wise extension" rationale for ODP); *Boehringer Ingelheim Intern. GmbH v. Barr Laboratories, Inc.*, 592 F.3d 1340, 1347 (Fed. Cir. 2010) (quoting *Schneller*); *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1216 (Fed. Cir. 2013) (noting use of terminal disclaimers to "overcome any

objection to improper term extension"); *Abbvie Inc. v. Mathilda and Terrence Kennedy Institute*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (framing ODP as preventing "undue patent term extension").

Consistent with this thread of decisions recognizing that ODP is not a rigid rule of law, this Court reaffirmed in *Immunex Corp. v. Sandoz, Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020), that ODP is an "equitable doctrine." The panel failed to address the equitable underpinnings of ODP raised by petitioner, and instead presumed that an extension of patent term due to PTO delay was necessarily "unjustified" if it resulted in two patentably indistinct patents with different expiration dates. In finding that gamesmanship during prosecution was not the only issue addressed by ODP, the panel appeared to agree with the Board that "it does not matter how the unjustified extensions are obtained," and "the mere presence of an unjustified extension is sufficient for the Board to find that claims are unpatentable under ODP." 81 F.4th at 1229.

The panel's break with precedent is highlighted by its failure to distinguish the "unjustified" extensions received by Cellect from the "justified" extensions this Court found in *Breckenridge* (due to the URAA transition statute) and *Braat* (due to PTO delays warranting application of two-way obviousness test), each of which also resulted in multiple, patentably indistinct patents with different expiration dates.

The panel's decision was influenced by the fact that the Board's decisions under review arose from ex parte reexamination proceedings. In response to petitioner's argument that it acted in good faith during prosecution of its patent, the panel stated that "there is no basis for an examiner to inquire into the intent of an applicant, or credit it." *Id.* at 1230. But ODP is most often raised as a defense in district court litigation, where courts are well equipped to judge gamesmanship and good faith based on a full factual record and arguments from both sides.

Two recent decisions from the District of New Jersey illustrate this. In *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F.Supp.3d 170, 213-14 (D.N.J. 2021), the court held that an earlier expiring patent could not be used as a double patenting reference against a patent that expired later solely due to properly granted PTA. Relying on this Court's decision in *Ezra*, the court noted that "there is no concern that MTPC 'sought to subsequently secur[e] a second, later expiring patent for the same invention' after the issuance of the [first] patent." *Id.* at 214 (quoting *Ezra*, 909 F.3d at 1375).

In *Amgen, Inc. v. Sandoz Inc.*, 2021 WL 5366800 (D.N.J. Sept. 20, 2021), the court similarly relied on *Ezra* to conclude that "[a] difference in expiration dates between two patents that arises solely from a statutorily authorized time extension" due to either PTA or PTE "cannot be the basis for an application of ODP." *Id.* at * 26. The *Amgen* court went further. Relying on this Court's

decisions in *Immunex*, *Breckenridge*, and *Braat*, the court held that even if the earlier expiring patent "were a proper ODP reference," the court "would exercise its equitable discretion not to apply the doctrine" because the difference in expiration dates "is not the result of prosecution gamesmanship or any improper conduct by [patentee]." *Id.* at *27.

The reexamination posture of the panel's decision is no reason to disregard decades of precedent mandating consideration of the reasons for the different patent terms. This Court should thus reject any interpretation of §154 that eviscerates district courts' "equitable discretion" in applying ODP. If the Court agrees with the panel that expiration dates for purposes of ODP include any PTA, then it should clarify that district courts nonetheless retain the discretion to reject an ODP defense where, *e.g.*, the court finds that the difference in expiration dates is not due to prosecution gamesmanship or any improper conduct, as in *Amgen*.

CONCLUSION

The petition for rehearing en banc should be granted.

Dated: November 28, 2023 Respectfully submitted,

/s/ Steven J. Rizzi

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CERTIFICATE OF SERVICE

I hereby certify that on the date indicated below, I caused the foregoing BRIEF AMICI CURIAE LANGUAGE TECHNOLOGIES, INC., PARUS HOLDINGS, INC., AND ROBOCAST, INC. IN SUPPORT OF APPELLANT'S PETITION FOR REHEARING EN BANC to be filed via CM/ECF with the Clerk of the Court, thereby electronically serving it on all counsel of record in this matter.

Dated: November 28, 2023 /s/ Steven J. Rizzi

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing BRIEF AMICI CURIAE LANGUAGE

TECHNOLOGIES, INC., PARUS HOLDINGS, INC., AND ROBOCAST, INC.

IN SUPPORT OF APPELLANT'S PETITION FOR REHEARING EN BANC:

1. Complies with the type-volume limitation of Fed. R. App. P. 35(g)(3).

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