

2022-1293, -1294, -1295, -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 *Ex Parte* Reexamination Control Nos. 90/014,453,
90/014,454, 90/014,455, 90/014,457.

**DIRECTOR'S RESPONSE TO CELLECT, LLC'S PETITION FOR
REHEARING EN BANC**

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Table of Contents

I.	Introduction.....	1
II.	Neither panel rehearing nor rehearing en banc is warranted.....	3
	A. The panel properly concluded that Collect’s challenged claims are unpatentable under ODP over its admittedly patentably indistinct reference claims	4
	B. The panel’s decision is consistent with this Court’s precedent	9
	C. The panel’s decision is also consistent with the policies underlying ODP and does not raise a question of exceptional importance	11
III.	Conclusion	14

Table of Authorities

	Page(s)
Cases	
<i>AbbVie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Tr.</i> , 764 F.3d 1366 (Fed. Cir. 2014).....	2, 9, 10, 13
<i>Boehringer Ingelheim Int’l GmbH v. Barr Labs., Inc.</i> , 592 F.3d 1340 (Fed. Cir. 2010).....	3, 9
<i>In re Collect</i> , 81 F.4th 1216 (Fed. Cir. 2023).....	<i>passim</i>
<i>In re Fallaux</i> , 564 F.3d 1313 (Fed. Cir. 2009).....	9
<i>Gilead Scis., Inc. v. Natco Pharma Ltd.</i> , 753 F.3d 1208 (Fed. Cir. 2014).....	10
<i>In re Lonardo</i> , 119 F.3d 960 (Fed. Cir. 1997).....	9
<i>Merck & Co. v. Hi-Tech Pharmacal Co.</i> , 482 F.3d 1317 (Fed. Cir. 2007).....	6, 7, 9, 10
<i>Novartis AG, et al., v. Ezra Ventures LLC</i> , 909 F.3d 1367 (Fed. Cir. 2018).....	<i>passim</i>
<i>Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.</i> , 909 F.3d 1355 (Fed. Cir. 2018).....	10
Statutes	
35 U.S.C. § 101.....	1
35 U.S.C. § 154.....	<i>passim</i>
35 U.S.C. § 154(b)(1)(B)	8
35 U.S.C. § 154(b)(1)(B)(i).....	8
35 U.S.C. § 154(b)(2)(B)	2, 5, 7, 8

35 U.S.C. § 156..... 6, 7, 8, 10, 11

Other Authorities

Fed. Cir. R. 35(b)(2) 4
Fed. Cir. R. 40(a)(5)..... 4
Fed. R. App. P. 35(a)..... 4
Fed. R. App. P. 40(a)(2)..... 4
H.R. Rep. No. 106-287(I)..... 10
Manual of Patent Examination and Procedure § 804(I)(B)(1) 12

I. Introduction

Nothing in this case warrants en banc rehearing. The panel’s affirmance of the Board’s obviousness-type double patenting (“ODP”) determination is correct and consistent with this Court’s prior precedent and the legal and equitable principles underlying the doctrine. Collect’s challenged patent claims, which admittedly recite obvious variants of Collect’s earlier-expiring reference patent claims, are unpatentable under ODP. And any patent term adjustment (“PTA”) on those challenged claims beyond the expiration of the reference claims, is an unjustified extension of patent term.

The Patent Act entitles an inventor to “a patent”—a single patent—for an invention. 35 U.S.C. § 101. Collect, however, owns several patents claiming patentably indistinct inventions that expired on different dates. Those facts are undisputed and present a textbook case of ODP, which is a judicially-created doctrine grounded in § 101 and public policy. The ODP doctrine prohibits an individual from obtaining more than one patent on essentially the same invention and is aimed at (1) preventing a patentee from receiving an unjustified timewise extension of their exclusive rights beyond the expected patent term for the claimed subject matter, and (2) protecting against split ownership of indistinct patents and harassment by multiple assignees. That the timewise extension results from PTA granted under 35 U.S.C. § 154 does not change these concerns. Indeed, as the panel explained, Congress understood that patent term cannot be extended for patentably indistinct inventions when it required

that any PTA be subject to a terminal disclaimer, a routine means to obviate an ODP challenge. *In re Collect*, 81 F.4th 1216, 1226-1229 (Fed. Cir. 2023); *see also* 35 U.S.C. § 154(b)(2)(B). The panel reiterated that ODP applies in situations where a patentee has later patents claiming indistinct subject matter that have received grants of PTA. *Collect*, 81 F.4th at 1226 (citing *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014)). To that end, the panel clarified that an ODP analysis is performed after any granted PTA is added to the expiration date of the challenged and reference claims. *Id.* at 1229. Because Collect owns several patents claiming essentially the same invention and, due to PTA, enjoyed an unjustified timewise extension of its ability to exclude the public from practicing that invention, the Court affirmed the Board's ODP determination. *Id.*

During the life of the reference claims, Collect never filed a terminal disclaimer tying its patents' expiration and ownership together. As the panel explained, such a terminal disclaimer would have avoided an ODP challenge and addressed the public policy concerns underlying the doctrine: namely, (1) preventing Collect from enjoying an unjust timewise extension of the right to exclude, and (2) avoiding the risk of split ownership and harassment by multiple assignees (should Collect assign or sell its patents to different owners).

Regarding the first policy concern, the panel found that the additional term Collect enjoyed due to PTA was unjust as extending the life of an invention that Collect admitted was patentably indistinct from its prior-expiring claims. *Id.* at 1229-

1230; *see also* *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347-1348 (Fed. Cir. 2010) (explaining that when a patentee does not terminally disclaim the later patent before the expiration of the earlier related patent, “the patentee enjoys an unjustified advantage—a purported time extension of the right to exclude from the date of the earlier patent.”). And the panel explained that no evidence of good faith before the USPTO, or lack of gamesmanship in prosecution of the patent, overcomes that determination. *Collect*, 81 F.4th at 1230. Regarding the second policy underlying ODP, the panel explained that even if *Collect*’s patents had expired on the same date, a terminal disclaimer would still be necessary to ensure common ownership of the patents claiming indistinct inventions. The panel noted that *Collect*’s promise not to divide ownership of the patents does not suffice, as “promises do not substitute for sound applications of rules of law.” *Id.*

Collect’s request for rehearing en banc repeats the legal and equitable arguments it raised before the panel and overlooks this Court’s precedent and its own concession that the patents claim patentably indistinct inventions. Because the panel issued a reasoned decision that is consistent with this Court’s precedent and does not present a question of exceptional importance, the Court should deny *Collect*’s request for rehearing en banc.

II. Neither panel rehearing nor rehearing en banc is warranted

A panel of this Court affirmed the USPTO’s decision, determining that *Collect*’s challenged claims are unpatentable under ODP because they recite

admittedly obvious variants of Collect's earlier expiring claims. *Collect*, 81 F.4th at 1229. The panel's decision neither conflicts with precedent nor presents an issue of exceptional importance warranting en banc review. *See* Fed. R. App. P. 35(a); Fed. Cir. R. 35(b)(2); Fed. R. App. P. 40(a)(2); Fed. Cir. R. 40(a)(5). On the contrary, in issuing its decision, the panel followed this Court's prior decisions and the principles underlying ODP.

A. The panel properly concluded that Collect's challenged claims are unpatentable under ODP over its admittedly patentably indistinct reference claims

The panel correctly concluded that the claims of Collect's patents are unpatentable on the basis of ODP because they are patentably indistinct from the claims of the reference patents and because, with the grant of PTA, Collect enjoyed an unjustified timewise extension of its ability to exclude the public from practicing its claimed inventions. *Collect*, 81 F.4th at 1229. The panel's decision is consistent with the statutory requirements established in Title 35 of the U.S. Code and with the policies that undergird them, as recognized by this Court's precedent. Collect's arguments to the contrary are without avail.

First, Collect and several amici argue that because any timewise extension was due to statutorily granted PTA, such an extension is not unjust without evidence of gamesmanship or bad faith. *See* Pet. at 4-5; *see also e.g.*, D.E. No. 151 at 7-9; D.E. No. 152 at 4. But as the panel explained, because Collect conceded that its challenged patent claims are obvious variants of its reference claims, any award of PTA past the

date of its reference claims constitutes an unjustified timewise extension of the invention. *Collect*, 81 F.4th at 1229-1230. For the panel “to hold otherwise would, in effect, confer on the reference claims . . . PTA to which they were not entitled.” *Id.* at 1230. In examining the statutory language of Section 154, the panel observed that Congress expressly provided that patent term should not be extended for patentably indistinct inventions when it required that any statutory award of PTA be subject to a terminal disclaimer, which is a routine means to obviate an ODP challenge. 35 U.S.C. § 154(b)(2)(B); 81 F.4th at 1226-1228 (“Given the interconnection of ODP and terminal disclaimers as ‘two sides of the same coin,’ . . . the statutory recognition of the binding power of terminal disclaimers in § 154(b)(2)(B) is tantamount to a statutory acknowledgment that ODP concerns can arise when PTA results in a later-expiring claim that is patentably indistinct.”). As the panel recognized, *Collect* did not file a terminal disclaimer and it “would frustrate the clear intent of Congress for patent applicants to benefit from their failure, or an examiner’s failure, to comply with established practice concerning ODP, which contemplates terminal disclaimers as a solution to avoid invalidation of patents claiming obvious inventions, as we have here.”¹ *Id.* at 1229.

¹ As discussed in the Director’s brief (D.E. No. 62 at 35), the Board also explained that even if *Collect*’s patents had the same expiration date, because the challenged patent claims recite obvious variants of the reference patent claims, the risk of harassment by multiple assignees would still exist and a terminal disclaimer would be necessary to ensure that the patents remained commonly owned.

Second, Collect asserts that it was under no obligation to have proactively filed a terminal disclaimer because the Examiner never rejected the claims on the basis of ODP. Pet. at 5. But the Examiner’s error does not absolve Collect from the consequences of seeking and obtaining multiple patents claiming admittedly patentably-indistinct inventions. As the panel explained, Collect did not have to wait for an ODP rejection to arise before filing a terminal disclaimer. *Collect*, 81 F.4th at 1231. Indeed, Collect could have filed a terminal disclaimer at any point before its reference claims expired.

Third, Collect complains that in determining that ODP depends on calculating expiration dates that include PTA, the panel improperly conflated “technical differences” between Sections 154 and 156, ignored the patent term guaranteed by Congress, and disregarded the plain language of Section 154. Pet. at 6-10. Several amici raise similar arguments. *See e.g.*, D.E. No. 151 at 6; D.E. No. 152 at 5; D.E. No. 156 at 2-5. But, it is Collect and the amici who are improperly equating Sections 154 and 156, misreading the guarantee by Congress, and misconstruing Section 154.

As the panel explained, consistent with this Court’s prior analysis of the plain language of these statutes in *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007) and *Novartis AG, et al., v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), Section 154 contains requirements that are separate and distinct from those in Section 156, indicating a congressional intent to speak to terminal disclaimers and ODP in the context of PTA, but not PTE. *Collect*, 81 F.4th at 1227. In particular,

Section 154 expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for delays caused by the USPTO beyond that disclaimed date, but no similar prohibition exists in § 156. *Id.* at 1227 (citing *Merck*, 909 F.3d at 1322); *see also* 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.”). Further, as noted by the panel, PTE is designed to extend the patent term for a single patent claiming an approved product that the patentee was prevented from practicing due to pre-market regulatory review, while PTA is designed to extend the term of patents for delays in the processing of the patent. *Collect*, at 1227. And there is nothing in the PTA statute indicating that application of ODP to PTA-extended term would be contrary to congressional design. *Id.* The panel correctly determined that these meaningful differences between how the two statutes are written and operate evince a clear congressional intent to constitute PTE and PTA as different statutory frameworks. *Collect*, at 1227. It is *Collect* who, under the guise of equitable arguments, distorts the plain language of Section 154(b)(2)(B) by trying to engraft a “gamesmanship” requirement thereon.

While *Collect* failed to file a terminal disclaimer in this case, the panel explained that Section 154’s provision regarding terminal disclaimers is still critical to the analysis because if *Collect* had (properly) filed one, the provisions of § 154(b)(2)(B) would have come into play and PTA would have been limited. *Id.* at 1228-1229. Thus, the panel properly concluded that the ODP analysis depends on the expiration

date of the patent after PTA has been added regardless of whether or not a terminal disclaimer is required or has been filed. *Id.*

Collect and several amici wrongly assert that the panel, in construing Section 154, ignored that Congress enacted the PTA statute guaranteeing patent applicants a “full” patent term. Pet. at 7-10; *see also e.g.*, D.E. No. 152 at 5-6; D.E. No. 161 at 2-3; D.E. No. 156 at 2; D.E. 169 at 8-9. There is no absolute guarantee of a 17-year patent term. Indeed, each of the “patent term guarantees” set forth in Sections 154(b)(1)(A)-(C) expressly state that they are “subject to the limitations under paragraph (2),” which includes the “disclaimed term” paragraph of Section 154(b)(2)(B). And the plain language of Section 154(b)(2) specifies that certain circumstances—such as overlapping delay periods, disclaimed term (as already discussed), or excess time to respond to Office actions—may reduce the amount of PTA and, thus, patent term.

Further, the attempt by Collect (Pet. at 6-8) and several amici to support their “guaranteed patent term” argument with legislative history falls short, because the cited history pertains to the technical calculation of PTA and merely states that “no patent applicant *diligently* seeking to obtain a patent will receive a term of less than the 17 years as provided under the preGATT standard. . . .” H.R. Rep. No. 106-287(I), at 49 (emphasis added). Under operation of the statute, while 35 U.S.C. § 154(b)(1)(B) provides a guarantee of no more than a 3-year application pendency and allows “B” delay to accrue when the USPTO fails to issue a patent within 3 years from the filing date, such “B” delay excludes, for example, time consumed by continued examination.

See 35 U.S.C. § 154(b)(1)(B)(i). Accordingly, an applicant who files a request for continued examination may not receive PTA for each day that an application is pending beyond three years and, thus, may not receive a patent with a “full” 17-year term. The additional legislative history to which Collect points (Pet. at 10), as supposedly requiring “purposeful manipulation” by the patent applicant to cut term, similarly relates to the calculation of so-called “applicant delay” under Section 154. These cited passages regarding calculation of “B” delay and applicant delay have no bearing on whether a terminal disclaimer was or should have been filed as a consequence of two patents claiming patentably indistinct inventions.

In short, none of Collect’s and the amici’s assertions of error by the panel—in concluding that, during the ODP analysis, PTA should be included in assessing the patent expiration date —pass muster and, more importantly, call for en banc rehearing.

B. The panel’s decision is consistent with this Court’s precedent

The panel’s decision is in harmony with this Court’s ODP precedent including, in particular, *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Tr.*, 764 F.3d 1366 (Fed. Cir. 2014), *Novartis AG, et al., v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007), *Boehringer Ingelheim Int’l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340 (Fed. Cir. 2010); *In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009); and *In re Lonardo*, 119 F.3d 960 (Fed. Cir.

1997). All of these cases support the panel's holding that Collect's challenged claims are unpatentable under ODP over its admittedly obvious reference claims, and that Collect received unjustified extensions of its right to exclude the public from that claimed subject matter through PTA.

Collect and a few amici assert that the panel's decision is in conflict with *Ezra* and *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355 (Fed. Cir. 2018) and thus en banc review is warranted. Pet. at 11-13; *see also* D.E. No. 152 at 7-8; D.E. No. 156 at 9. As to *Ezra*, Collect essentially repeats its merits argument and asserts that like PTE, the judge-made doctrine of ODP cannot cut PTA. But for the reasons discussed above, the panel's decision is entirely consistent with *Ezra* and this Court's prior decision discussing the differences between Sections 154 and 156 and their interplay with ODP: *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007). Similarly, there is no conflict with the *Breckenridge* decision. In *Breckenridge*, the Court found that the same type of concerns described in *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014) and *AbbVie* (as to post-URAA patents) were not present because one of the patents was a pre-URAA patent and thus the issuance date "serve[d] as a reliable guide for assessing whether a patent may serve as a double patenting reference against another patent." *Breckenridge*, 909 F.3d at 1366. The Court explained that the difference in the pre- and post-URAA patent terms was due to the happenstance of an intervening change in patent term law in the URAA. *Id.* at 1364. Thus, *Breckenridge* involved both a change in the law that unsurprisingly yielded a

different outcome and two patents that did not present the same equitable concerns at play here.

C. The panel’s decision is also consistent with the policies underlying ODP and does not raise a question of exceptional importance

Lastly, in a series of policy arguments, Collect asserts that en banc review is necessary because the panel’s decision “eviscerates” the equitable purpose of ODP. Specifically, Collect contends that the panel improperly: (1) equated PTA that extends the term of an invention with an unjustified term extension, (2) determined that a promise to keep the challenged patents commonly owned was insufficient to address concerns of potential litigation harassment, and (3) placed the onus on patent holders to determine whether their claims are patentably indistinct and file preemptive terminal disclaimers. Pet. at 13-16. Several amici raised similar issues in their briefs to the Court. *See e.g.*, D.E. No. 154 at 3-5; D.E. No. 151 at 7; D.E. No. 156 at 8; D.E. No. 169 at 6-8.

First, the panel was correct in determining that Collect received unjustified extensions of patent term through its PTA. *Collect*, 81 F.4th at 1229-1230. Noting that Collect does not dispute that the challenged claims are obvious variants of the reference claims, the Court reasoned that any grant of PTA past the expiration date of the reference claims constitutes an improper timewise extension of the claimed

invention.² *Id.* Indeed, as the Board explained, holding otherwise would be tantamount to granting PTA to the reference claims, which are not entitled to a statutory extension. *Id.* Further, as already discussed, evidence of good faith or lack of gamesmanship during prosecution does not entitle an applicant to a patent term that it otherwise would not be entitled to under Section 154. *Id.*

Second, the panel explained that the risk of potential harassment by multiple assignees continues to exist when a patentee merely promises not to divide ownership of the patent, but has not filed a terminal disclaimer. *Id.* at 1229-1230. The panel observed that the policy risk of separate ownership of patentably indistinct patents existed here and that a terminal disclaimer was required to ensure common

² Amici question whether *Collect* stands for the proposition that any PTA granted by § 154(b) is an unjustified timewise extension of rights, that ODP issues may arise only long after a family of patents has been prosecuted, and/or that parent applications may require terminal disclaimers against child applications. *See e.g.*, D.E. No. 152 at 9-10, 12-13; D.E. No. 155 at 6. First, here, the challenged claims are not themselves “parent” claims; rather they are “child” claims that claim priority to the same parent application, and thus the scenarios presented by amici are not implicated. Second, from an examinational standpoint, the claims of an application can only be rejected for ODP based on prior issued claims, or provisionally rejected over co-pending claims. Manual of Patent Examination and Procedure § 804(I)(B)(1). If both the application under examination and the reference application have the same patent filing date, the examiner maintains the provisional ODP rejection in each application until it is overcome, either by filing a terminal disclaimer or by arguing that the claim(s) subject to the rejection is patentably distinct. *Id.* Thus, in that situation, a terminal disclaimer may be required in both co-pending applications. Although the USPTO may not require a terminal disclaimer to be filed in an issued unexpired patent, a disclaimer may be required in the event that the claims are patentably indistinct from claims of a reference patent and there is an unwarranted extension of the period of exclusion of the claimed subject matter.

ownership because neither Collect's past conduct nor its promises not to divide the patents in the future sufficed to abrogate the potential future risk of multiple owners or assignees. *Id.* As the panel explained, "promises do not substitute for sound applications of rules of law." *Id.* And as already discussed, Collect could have proactively filed a terminal disclaimer at any point prior to the expiration of the reference claims.

Certain amici assert that the URAA mooted the unjustified timewise extension rationale underlying ODP and requiring disclaimers of patent term.³ D.E. No. 105 at 6-9; D.E. No. 169 at 10. But the Court in *AbbVie*, 764 F.3d at 1373 (Fed. Cir. 2014) already rejected that argument and confirmed that the problem of unjustified timewise extension of patent term still exists due to patent term adjustment and the continuing possibility that the term of patentably indistinct claims could extend beyond the term of the reference claims.

None of the issues that Collect or the amici raise a question of exceptional importance warranting en banc rehearing.

³ Mr. Armitage urges this Court to reassess the ODP doctrine and consider whether application of *res judicata* or a re-conception of the doctrine could eliminate the need for the doctrine as it currently exists. D.E. No. 105. But as long as applicants and patentees continue to file and obtain multiple patents with patentably indistinct claims, the doctrine still serves the same important purposes it historically has, namely (1) to prevent the unjust time-wise extension of the right to exclude, and (2) to protect against split ownership and harassment by multiple assignees. But the existence of the ODP doctrine does not foreclose a Court from also addressing these issues through *res judicata* principles, to the extent applicable.

III. Conclusion

The Director respectfully requests that this Court deny Collect's petition for patent rehearing and rehearing en banc.

Dated: December 14, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing
DIRECTOR'S RESPONSE TO COLLECT, LLC'S PETITION FOR
REHEARING EN BANC complies with the type-volume limitation required by the
Court's rule. The total number of words in the foregoing brief, excluding the table of
contents and the table of authorities, is 3,584 as calculated using the Word® software
program.

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