

No. 24A-_____

IN THE
Supreme Court of the United States

IN RE: COLLECT, LLC,

Applicant.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

**APPLICATION FOR EXTENSION OF TIME TO FILE A PETITION FOR
A WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

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April 2, 2024

Corporate Disclosure Statement

Pursuant to Rule 29.6, Applicant states as follows:

Applicant Collect, LLC, is a wholly owned subsidiary of Micro Imaging Solutions LLC.

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

Pursuant to 28 U.S.C. § 2101(c) and Rules 13.5, 22, and 30 of the Rules of this Court, Applicant Collect, LLC respectfully requests an extension of time, to and including May 20, 2024, in which to file a petition for a writ of certiorari. Unless an extension is granted, Applicant's deadline for filing the petition will be April 18, 2024. This application is timely because it is made at least ten days before the petition would be due. No prior application has been made in this case. In support of this request, Applicant states the following:

1. The United States Court of Appeals for the Federal Circuit issued a published opinion and entered judgment on August 28, 2023 (Exhibit A). On January 19, 2024, the court denied Respondents' timely petition for rehearing.

2. This Court has jurisdiction under 28 U.S.C. § 1254(1).

3. This case arises from the *ex parte* reexamination and invalidation of four of Applicant's patents. Applicant sued Samsung Electronics, Co. for infringing those patents; Samsung then requested *ex parte* reexamination, arguing that the patents were invalid under the judge-made doctrine of "obviousness-type double patenting," ("ODP") which operates to invalidate commonly owned, non-distinct patents in some circumstances. The patent examiner below issued a Final Office Action invalidating the patents, which the Patent Trial and Appeal Board affirmed.

4. The Federal Circuit also affirmed, rejecting Applicant's arguments that "Patent Term Adjustment" should be interpreted consistently with "Patent Term

Extension” in determining the expiration dates of commonly owned patents. The Federal Circuit held that, “while the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added, the expiration date used for an ODP analysis where a patent has received PTA is the expiration date after the PTA has been added.” Slip op. Exhibit A, at 15-16.

5. The statute governing Patent Term Adjustment provides that “the term of the patent shall be extended 1 day for each day” of delay in issuing a patent that is attributable to the Patent Office. 35 U.S.C. § 154(b)(1)(A) (emphasis added). 35 U.S.C. § 156. Patent Term Extension operates similarly, accounting for delay in FDA approval of products governed by the Federal Food, Drug, and Cosmetics Act. That provision provides that “[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b).” *Id.* § 156(a). The petition for a writ of certiorari will argue (among other things) that the two statutes should be construed *in pari materia*. The issue is of great economic significance as reflected in the fact that 13 *amicus curiae* briefs were filed in support of *Collect* in the Federal Circuit at either the merits stage, the rehearing stage, or both. A similar number are expected in this Court.

6. There is good cause for the requested extension. This case presents complex and important legal issues that implicate the validity of numerous valuable patents backed by significant investments, as well as the viability of well-settled

continuation practice before the Patent Office as authorized by statute, 35 U.S.C. § 120.

7. Furthermore, Applicant's counsel have substantial obligations in the interim period. Supreme Court counsel Roy Englert, for example, has been working on a brief due in the Second Circuit on April 2, 2024, in a case in which the government is appealing from a post-conviction judgment of acquittal of Kramer Levin's client, and is involved in numerous matters in this Court – most prominently, the expedited case of *Harrington v. Purdue Pharma L.P.*, No. 23-124 (argued Dec. 4, 2023), and the cases of *Highland Capital Management, L.P. v. NexPoint Advisors, L.P.*, No. 22-631, and *NexPoint Advisors, L.P. v. Highland Capital Management, L.P.*, No. 22-669 (view of Solicitor General requested in both cases May 15, 2023) – in which action by this Court could come at any time and could necessitate substantial and immediate additional work in this Court, the lower courts, or both. By the nature of this patent case, Mr. Englert necessarily consults extensively with lead counsel in the court and agencies below, Paul Andre. Mr. Andre is involved in preparing briefs and argument in several Federal Circuit appeals, including cases recently scheduled for oral argument on May 8, 2024 (*CUPP Computing AS v. Vidal*, No. 23-1129) and May 10, 2024 (*Midwest Athletics and Sports Alliance LLC v. Xerox Corp*, No. 23-1077).

8. Applicant requests the extension to prepare a petition that will best assist the Court's consideration.

WHEREFORE, for the foregoing reasons, the application should be granted and the time for filing a petition for writ of certiorari should be extended by 30 days, to and including May 20, 2024.

Respectfully submitted.

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Exhibit A

United States Court of Appeals for the Federal Circuit

IN RE: CELLECT, LLC,
Appellant

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

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.

Decided: August 28, 2023

PAUL J. ANDRE, Kramer Levin Naftalis & Frankel LLP, Redwood Shores, CA, argued for appellant. Also represented by JAMES R. HANNAH, LISA KOBIALKA; JONATHAN CAPLAN, JEFFREY PRICE, New York, NY.

KAKOLI CAPRIHAN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for appellee Katherine K. Vidal. Also represented by THOMAS W. KRAUSE, AMY J. NELSON, BRIAN RACILLA, FARHEENA YASMEEN RASHEED.

JEREMY LOWE, Leydig, Voit & Mayer, Ltd., Chicago, IL, for amicus curiae Alvogen PB Research & Development LLC. Also represented by KEELIN BIELSKI, STEVEN H. SKLAR.

KURT A. MATHAS, Winston & Strawn LLP, Chicago, IL,

for amicus curiae Association for Accessible Medicines. Also represented by CLAIRE A. FUNDAKOWSKI, Washington, DC.

KEVIN EDWARD NOONAN, McDonnell Boehnen Hulbert & Berghoff LLP, Chicago, IL, for amicus curiae Biotechnology Innovation Organization. Also represented by AARON VINCENT GIN, ALEXA L. GIRALAMO, DANIEL GONZALEZ, JR., DONALD LOUIS ZUHN, JR.; HANSJORG SAUER, Biotechnology Innovation Organization, Washington, DC.

PAUL BERGHOFF, McDonnell Boehnen Hulbert & Berghoff LLP, for amicus curiae Intellectual Property Owners Association. Also represented by HENRY HADAD, Bristol Myers Squibb, Lawrenceville, NJ.

JEFFREY PAUL KUSHAN, Sidley Austin LLP, Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America. Also represented by STEVEN J. HOROWITZ, Chicago, IL; DAVID EVAN KORN, Pharmaceutical Research and Manufacturers of America, Washington, DC.

DOUGLAS HALLWARD-DRIEMEIER, Ropes & Gray LLP, Washington, DC, for amici curiae Samsung Electronics Co., Ltd., Samsung Electronics America, Inc. Also represented by SCOTT ANTHONY MCKEOWN; JAMES LAWRENCE DAVIS, JR., East Palo Alto, CA; ALEXANDER E. MIDDLETON, New York, NY.

Before LOURIE, DYK, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Collect, LLC (“Collect”) appeals from four *ex parte* reexamination decisions of the United States Patent and Trademark Office (“USPTO”) Patent Trial and Appeal Board (“the Board”) affirming the unpatentability of: (1) claims

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22, 42, 58, and 66 of U.S. Patent 6,982,742 (“the ’742 patent”); (2) claims 1, 17, 19, 21, 22, 27, 49, 55, and 61 of U.S. Patent 6,424,369 (“the ’369 patent”); (3) claims 1, 5, 11, 33, 34, 58, and 64 of U.S. Patent 6,452,626 (“the ’626 patent”); and (4) claims 25–29 and 33 of U.S. Patent 7,002,621 (“the ’621 patent”) for obviousness-type double patenting (“ODP”). *Ex parte Collect LLC*, Appeal 2021-005302 (P.T.A.B. Feb. 17, 2020), J.A. 27–49; *Ex parte Collect LLC*, Appeal 2021-005046 (P.T.A.B. Feb. 18, 2020), J.A. 51–73; *Ex parte Collect LLC*, Appeal 2021-005258 (P.T.A.B. Feb. 19, 2020), J.A. 76–97; *Ex parte Collect LLC*, Appeal 2021-005303 (P.T.A.B. Feb. 16, 2020), J.A. 2–24.¹ For the reasons provided below, we affirm.

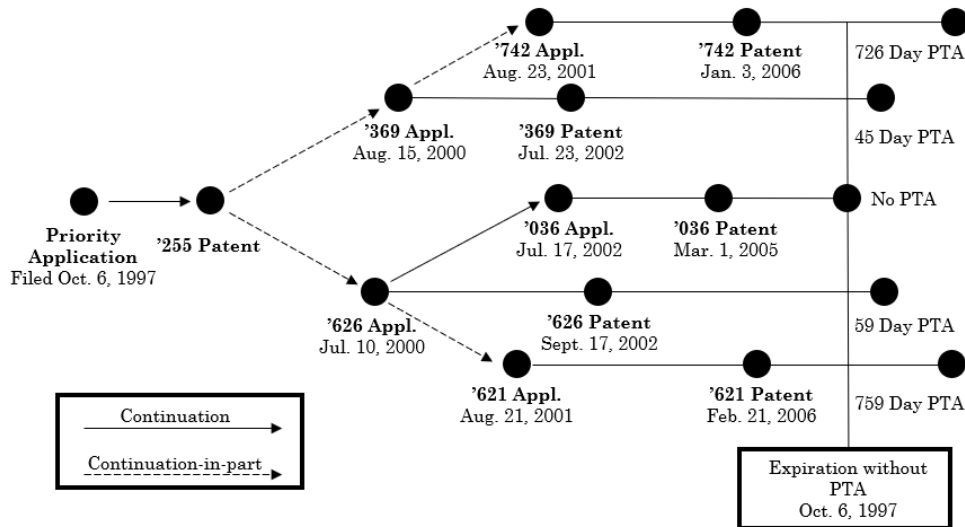
BACKGROUND

Collect owns the ’742, ’369, ’626, and ’621 patents (“the challenged patents”), each of which is directed to devices (*e.g.*, personal digital assistant devices or phones) comprising image sensors. The challenged patents are all interrelated, each claiming priority from a single application that issued as U.S. Patent 6,275,255 (“the ’255 patent”). The ’369 and ’626 patents are continuations-in-part of the ’255 patent. The ’742 patent is a continuation-in-part of the ’369 patent, and the ’621 patent is a continuation-in-part of the ’626 patent. U.S. 6,862,036 (“the ’036 patent”), another member of this family, is a continuation of the ’626 patent.

Each of the challenged patents was granted Patent Term Adjustment (“PTA”) for USPTO delay during prosecution pursuant to pre-AIA 35 U.S.C. § 154(b). Because each family member patent claims priority from the same application, each would have expired on the same day but for the individual grants of PTA. None of the patents was

¹ The four appeals for *ex parte* reexamination issued by the Board essentially contain the same language and analysis. We treat Appeal 2021-005302 as representative.

subject to a terminal disclaimer during prosecution, and the challenged patents are all expired, even after factoring in the grants of PTA. The relationship of the applications and issued patents, including the individual grants of PTA, is indicated in the figure



Collect sued Samsung Electronics, Co. (“Samsung”) for infringement of the challenged patents in the United States District Court for the District of Colorado. Samsung then requested the underlying *ex parte* reexaminations, asserting that the patents were unpatentable based on ODP, which was not raised by the examiner during prosecution. In each reexamination proceeding, the examiner issued a Final Office Action determining that the challenged claims were obvious variants of Collect’s prior-expiring reference patent claims. For the four *ex parte* reexamination proceedings, the asserted claims and ODP invalidating reference patents are indicated in the table, with representative claims indicated in bold.

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Patent	Claims	ODP Reference Patent
'742	22, 42, 58, and 66	'369
'369	1, 17, 19, 21, 22, 27, 49, 55, and 61	'036
'626	1, 5, 11, 33, 34, 58, and 64	'369
'621	25, 26, 27, 28, 29, and 33	'626

The invalidation of all claims under ODP can be traced back to the '036 patent, which is the only family member that did not receive a grant of PTA and thus retained an expiration date twenty years after the filing of the priority patent application. Specifically, the '621 patent claims were found to be unpatentable over the '626 patent claims, which were found to be unpatentable over the '369 patent claims. The '742 patent claims were also found to be unpatentable over the '369 patent claims. The '369 patent claims were themselves found to be unpatentable over the '036 patent claims. Thus, although the ODP invalidating reference patents form a network across the four *ex parte* reexamination proceedings, all invalidated claims can be traced back to the single family member patent that did not receive a grant of PTA: the '036 patent.

Collect appealed the rejection of the claims of the challenged patents to the Board. Collect noted that under *No-vartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), ODP does not invalidate a validly obtained Patent Term Extension ("PTE") under 35 U.S.C. § 156, and argued that the Board should similarly hold that ODP cannot negate a statutory grant of PTA. That is, Collect argued that determining unpatentability under ODP should be based on the expiration dates of the patents before any PTA is added to the term.

Collect further argued that an ODP rejection is not proper under the equitable principles underlying ODP, including (1) preventing the receipt of an improper timewise extension of a patent term, and (2) preventing split ownership of related patents and subsequent potential harassment by multiple owners or assignees. Collect asserted

that no terminal disclaimer could be filed to cure the rejection since the patents had expired, but that it had promised not to sell its expired patents. That, Collect contended, abrogated the risk of harassment by multiple owners or assignees. Collect also argued that the *ex parte* reexamination requests were not properly granted because the examiner had allegedly considered ODP during prosecution of the challenged patents, and so none of the requests presented a substantial new question of patentability, a requirement for a proper *ex parte* reexamination.

In each of the four appeals from *ex parte* reexamination, the Board sustained the examiner's determinations that the asserted claims of the challenged patents were unpatentable under ODP. The Board further considered whether or not an ODP analysis on a patent that has been granted PTA should be based on the expiration date of the patent with PTA or without PTA. First, the Board compared the cases on appeal for reexamination to that in *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007), a case in which a patent owner had filed a terminal disclaimer to overcome an ODP rejection, after which that patent was awarded PTE. There, as the Board noted, we held that "a patent term extension under [35 U.S.C.] § 156 is not foreclosed by a terminal disclaimer." *Id.* at 1322; J.A. 33. Stated otherwise, the Board noted that a "patent term extension is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer." *Merck*, 482 F.3d at 1322–23; J.A. 33.

The Board also compared the cases on appeal to that in *Novartis*, a case in which we addressed the interaction between ODP and PTE in the absence of a terminal disclaimer. 909 F.3d at 1367. There, as the Board noted, we held that, "as a logical extension of [the] holding in *Merck & Co. v. Hi-Tech*," ODP should be considered from the

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expiration date of the patent before the addition of PTE. *Id.* at 1373–74.

In the four underlying appeals for *ex parte* reexamination, the Board framed the issue as a question of how PTA affects an ODP analysis and whether an ODP analysis should be based on the expiration date of a patent with or without any granted PTA added. J.A. 35–38. The Board concluded that Collect’s argument that a judge-made doctrine (*i.e.*, ODP) cannot cut off a statutorily authorized time extension (*i.e.*, PTA) was unpersuasive because it ignored the text of § 154 and the holding of *Novartis*. J.A. 35. First, the Board concluded that the reasoning in the precedent, including *Merck*, was based on differences between the statutory language in § 156 and § 154. J.A. 35–36. Second, the Board found that the statutory language in § 154(b)(2)(B) makes clear that any terminal disclaimer should be applied after any PTA is granted or, in other words, that a PTA cannot adjust a term beyond the disclaimed date in any terminal disclaimer. J.A. 36–37. It therefore concluded that, unlike PTE, a grant of PTA shall not extend the term of a patent past the date of a terminal disclaimer. J.A. 38.

The Board also reasoned that terminal disclaimers arise almost exclusively in situations to overcome ODP rejections, and so Congress, by addressing terminal disclaimers in § 154, effectively addresses ODP. JA. 37. The Board further reasoned that this court has stated that ODP “prevent[s] an inventor from securing a second, later expiring patent” for an invention covered by a patent that was filed at the same time but that has a different patent term due to a grant of PTA. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014); J.A. 38. It found that this rationale applied. J.A. 38.

Based on those findings and reasoning, the Board held that both ODP and terminal disclaimers should be

considered after any PTA. J.A. 38. That is, any ODP analysis or determination, whether or not a terminal disclaimer is required, should be based on the adjusted expiration date of the patent.

The Board further found that the asserted claims would have been obvious in view of the respective invalidating ODP references and noted that Collect did not dispute that fact. J.A. 43. Collect instead focused its argument on whether or not ODP could cut short a grant of PTA. The Board also found that Collect received an unjustified timewise extension of patent term for the asserted claims of the challenged patents and that a risk of divided ownership, and subsequent harassment by multiple assignees, remained active. J.A. 44–46. Finally, the Board found that ODP was a substantial new question of patentability and that Collect’s arguments that the examiner had considered ODP during prosecution lacked merit. J.A. 46. In particular, the Board determined that there was no indication that the examiner had considered ODP during prosecution of the challenged patents. J.A. 46. Further, the Board concluded that the examiner’s knowledge of other Collect-owned patents, or his willingness to issue ODP rejections in the prosecution of other Collect-filed applications, did not amount to a finding that the examiner had considered ODP in the prosecution of the challenged patents. J.A. 46.

The Board sustained the finding of unpatentability of the claims under ODP, and Collect appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Collect raises three challenges on appeal. First, Collect contends that the Board erred in determining that whether or not a patent is unpatentable for ODP is determined based on the date of expiration of a patent that includes any duly granted PTA pursuant to 35 U.S.C. § 154. Second, Collect contends that the Board erred in failing to

consider the equitable concerns underlying the finding of ODP in the *ex parte* reexamination proceedings. Third, Collect contends that the Board erred in finding a substantial new question of patentability in the underlying *ex parte* reexaminations, and thus that the reexamination proceedings were improper. We address each argument in turn.

We may not set aside the Board's decisions unless they were "arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or otherwise not in accordance with law." *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004); 5 U.S.C. § 706(2)(A). ODP is a question of law that we review *de novo*. *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997). Whether or not a substantial new question of patentability exists is a question of fact that we review for substantial evidence. *In re Swanson*, 540 F.3d 1368, 1375, 1381 (Fed. Cir. 2008). "Substantial evidence is more than a mere scintilla and means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Celgene Corp. v. Peter*, 931 F.3d 1342, 1349 (Fed. Cir. 2019) (quotation marks and citations omitted).

I

We first consider Collect's challenge to the Board's determination that the unpatentability of claims under ODP must be based on the date of expiration of a patent that includes any duly granted PTA pursuant to 35 U.S.C. § 154. That statute, in relevant part, reads as follows:

Contents and term of patent; provisional rights.

(b) Adjustment of Patent Term.—

(1) Patent term guarantees.—

(A) Guarantee of prompt patent and trademark office responses.—Subject to the limitations under paragraph (2), if the issue of an original

patent is delayed due to the failure of the Patent and Trademark Office to—

(i)–(iv) [providing for appropriate notifications and USPTO response times],

the term of the patent *shall* be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) Guarantee of no more than 3-year application pendency.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including—

(i)–(iii) [providing for timing exceptions],

the term of the patent *shall* be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) Guarantee of adjustments for delays due to derivation proceedings, secrecy orders, and appeals.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i)–(iii) [providing for delay conditions related to derivation proceedings, secrecy orders, and appeals],

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the term of the patent *shall* be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(2) Limitations.—

(B) Disclaimed term.—

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.

(C) Reduction of period of adjustment.—

(i) The period of adjustment of the term of a patent . . . shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

35 U.S.C. § 154(b) (emphases added).

Because the arguments in this case involve comparison between § 154 and § 156, we also set forth the relevant text of § 156.

Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product *shall* be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1)–(5) [providing requirements for a grant of PTE]

(c)(3) The term of a patent eligible for extension under subsection (a) *shall* be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that . . . if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years;

(g)(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and—

(i)–(iii) [providing for exceptions pertaining to exemptions, major health or environmental health effects tests, or clinical investigations before such date of the approved product], . . .

the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

35 U.S.C. § 156(a), (c)(3), (g)(6) (emphases added).

Collect argues that PTA and PTE should be factored into an ODP analysis in the same way, *i.e.*, determining whether or not claims are unpatentable under ODP based on their expiration dates before the addition of any granted

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PTA or PTE. Collect alleges that our precedent, legislative intent, and the statutory language all dictate this outcome. First, Collect asserts that *Novartis* holds that a statutorily authorized extension of patent term (*i.e.*, PTE) cannot be terminated by a judicial doctrine, here ODP. 909 F.3d at 1375. Because PTA and PTE are both statutorily authorized extensions of term, Collect contends that ODP cannot cut off PTA and that whether or not claims are unpatentable under ODP should be based on the expiration date that does not include the addition of any duly granted PTA.

Further, Collect argues that PTA and PTE have similar statutory limitations. Collect asserts that PTE is limited in that the patent owner must choose one patent to receive a term extension and that PTA is limited in that a grant of PTA cannot cause the patent's term to exceed the expiration date specified in a terminal disclaimer, pursuant to § 154(b)(2)(B). Collect further asserts that, under the Board's interpretation of § 154(b), any adjustment to related patents would invalidate them under ODP, and the only way to avoid wholesale invalidation of related patents would be to file preemptive terminal disclaimers. That, Collect asserts, would be incompatible with and would fundamentally change continuations practice.

In addition, Collect argues that legislative intent illustrates that PTE and PTA were meant to be mandatory term adjustment and extension provisions that restore patent term lost to different administrative delays. Collect notes that each statutory provision states that the extension "shall" be granted when particular conditions are met. 35 U.S.C. § 156(a) (stating that an extension "shall" be granted), 35 U.S.C. § 154(b)(1)(A), (b)(1)(B), and (b)(1)(C) (stating that "the term of the patent shall be extended").

Collect is supported by *amici* representing Biotechnology Innovation Organization and Pharmaceutical Research and Manufacturers of America ("PhRMA"). Intellectual Property Owners of America, writing in

support of neither party, also urges reversal of the Board's decision.

The USPTO responds that, as a threshold matter, Cellect does not dispute that the challenged and reference patents are commonly owned, that the challenged patents expire after the reference patents, or that all challenged claims are patentably indistinct over claims in the reference patents.

The USPTO further responds that statutory language and precedent clearly illustrate that PTA and PTE should be considered differently from each other when determining whether or not claims are unpatentable under ODP. In particular, the USPTO argues that, while an extension pursuant to PTE is added to the patent term after a consideration of ODP, *see Novartis*, 909 F.3d at 1375, an adjustment pursuant to PTA should be added to the patent term before a consideration of ODP. The USPTO argues that our precedent and the statutory language are clear that PTE and PTA should be considered differently when analyzing ODP.

The USPTO argues that precedent does not hold that ODP does not apply to patents with PTA. Citing *AbbVie*, the USPTO asserts that, when a situation arises where related patents filed at the same time claim overlapping subject matter yet have different expirations due to PTA, ODP still applies to ensure that the applicant does not receive an unjust timewise extension of patent term. *AbbVie*, 764 F.3d at 1373. Further, the USPTO asserts that *Novartis's* statement that a judge-made doctrine such as ODP cannot be used to cut off a statutorily granted term extension cannot be viewed in a vacuum, and it is limited to the application of ODP to a patent with PTE. There is nothing in that case, the USPTO asserts, that suggests that it should be extended to hold that patents with extended terms due to PTA cannot be subject to ODP rejections.

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The USPTO also argues that the statutory language is clear that terminal disclaimers cut short PTA but not PTE. In particular, the USPTO notes that § 154 mentions terminal disclaimers, but § 156 does not.

The USPTO further notes that while both statutory provisions indicate that an extension or adjustment “shall” be granted if various conditions are met, 35 U.S.C. § 156(a); 35 U.S.C. § 154(b)(1)(A), (b)(1)(B), and (b)(1)(C), the required conditions are limited by the presence of a terminal disclaimer in PTA but not PTE, 35 U.S.C. § 154(b)(2)(B). That statutory difference, the USPTO contends, indicates that Congress intended to treat the two frameworks differently from each other. The USPTO asserts that differential treatment was confirmed in *Merck*.

The USPTO’s position is supported by *amici* representing Alvogen PB Research & Development LLP, the Association for Accessible Medicines, and Samsung Electronics (Samsung Electronics Co., Ltd. and Samsung Electronics America, Inc.). We appreciate the several *amicus* briefs and have considered the views they expressed.

First, we note that an ODP determination depends on an assessment of obviousness, *i.e.*, whether the claims of a later-expiring patent would have been obvious over the claims of an earlier-expiring patent owned by the same party. If so, absent a terminal disclaimer, the later-expiring claims are invalid. Application of that determination requires determining which is the later-expiring patent, which is why the date when PTA or PTE is applied matters.

Proceeding to the merits, we agree with the USPTO that PTA and PTE should be treated differently from each other when determining whether or not claims are unpatentable under ODP. PTA and PTE are dealt with in different statutes and deal with differing circumstances. We conclude that, while the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added, the expiration

date used for an ODP analysis where a patent has received PTA is the expiration date after the PTA has been added. To say that PTA and PTE should be factored into an ODP analysis in the same manner merely because they both provide statutorily authorized time extensions that restore patent term due to various administrative delays, as Collect argues, is an unjustified attempt to force disparate statutes into one.

ODP is a judicially created doctrine that has its roots in 35 U.S.C. § 101, which states that an inventor may obtain “a patent” (*i.e.*, a single patent) for an invention. *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). ODP “is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof” and prevents an inventor from claiming a second patent for claims that are not patentably distinct from the claims of a first patent. *Id.* A crucial purpose of ODP is to prevent an inventor from securing a second, later-expiring patent for non-distinct claims. This purpose applies equally to situations in which the later patents have received grants of PTA resulting from examination delays at the USPTO. *AbbVie*, 764 F.3d at 1373. Terminal disclaimers, which may be filed to overcome an ODP rejection assuming that the first patent has not yet expired, are provided for in 35 U.S.C. § 253 and 37 C.F.R. § 1.321. No terminal disclaimers were filed by Collect, and the patents at issue have all expired, precluding any late filings of terminal disclaimers.

Our case precedent has clearly delineated how a patent that has received PTE, a statutorily authorized extension, interacts with ODP, a doctrine that limits the term of a patent or, at least, ties later-filed, commonly owned, obvious variations to the expiration date of an earlier-filed reference patent. In *Merck*, we held that PTE is not foreclosed by a terminal disclaimer. 482 F.3d at 1322, 1324. That holding was based on the fact that, while § 156 does not expressly reference terminal disclaimers, it provides for

other requirements that must be met to obtain a PTE and that the extension “shall” run from the expiration date of the patent, as adjusted under § 154(b) to account for any USPTO delays. *Id.* at 1321–22. We noted that § 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment beyond that disclaimed date for delays caused by the USPTO, but that no similar prohibition existed in § 156. *Id.* at 1322. We therefore concluded that the calculation of a grant of PTE on a patent that has a terminal disclaimer “is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer.” *Id.* at 1322–23.

The holding in *Merck* is premised on the fact that § 154 contains requirements separate and distinct from those in § 156 that indicate a congressional intent to speak to terminal disclaimers and ODP in the context of PTA. We extended this logic in *Novartis*, where we held that ODP does not invalidate a validly obtained PTE. 909 F.3d at 1373. There, we noted that, “if a patent, under its original expiration date without a PTE, should have been (but was not) terminally disclaimed because of [ODP], then this court’s [ODP] case law would apply, and the patent could be invalidated,” but that “if a patent . . . is valid under all other provisions of law, then it is entitled to the full term of its PTE.” *Id.* at 1374

Together, *Merck* and *Novartis* establish that ODP for a patent that has received PTE should be applied based on the expiration date (adjusted to a disclaimed date if a terminal disclaimer has been filed) before the PTE is added, so long as the extended patent is otherwise valid without the extension. For the first time, here, we address how another statutorily authorized extension, PTA, interacts with ODP. Even though both PTA and PTE are statutorily authorized extensions, and each serves to recover lost term,

each has its own independent framework established through an independent statutory schema.

Collect relies heavily on *Novartis* for its argument that any statutorily mandated extension, including PTA and PTE, cannot be cut short by a judge-made doctrine like ODP. But that is not an accurate reading of that holding. In *Novartis*, we held that the presence of ODP would not cut off a duly granted PTE under § 156. Stated otherwise, whether or not claims are unpatentable for ODP is determined in view of the expiration date of the patents before any PTE is added. In *Novartis*, we merely “decline[d]” to allow “a judge-made doctrine [to] cut off a statutorily-authorized time extension.” *Novartis*, 909 F.3d at 1375. But there is no conflict between ODP and § 154. The PTE and PTA statutes have quite distinct purposes. PTE is designed to effectively extend the overall patent term for a single invention due to regulatory delays in product approval. PTA is designed to extend the term of a particular patent due to delays in the processing of that patent. There is nothing in the PTA statute to suggest that application of ODP to the PTA-extended patent term would be contrary to the congressional design. Indeed, Collect’s interpretation of the PTA statute would effectively extend the overall patent term awarded to a single invention contrary to Congress’s purpose by allowing patents subject to PTA to have a longer term than the reference patent. The USPTO’s approach merely recognizes the distinct purposes and interpretation of the two statutes. It does not allow a judge-made doctrine to restrict the scope of the PTA statute.

As the USPTO argues, our case law and the statutory language dictate an outcome where an ODP analysis must be performed on patents that have received PTA based on the expiration date including PTA. In *AbbVie*, we held that ODP continues to apply where two patents that claim the same invention have different expiration dates, including where the different expiration date is due to a grant of PTA. 764 F.3d at 1373–74. Here, we have related patents that

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claim priority from the same application that, as conceded by Cellect, claim overlapping subject matter and that have different expiration dates only because of PTA. Thus, under *AbbVie*, ODP still applies to ensure that the applicant is not receiving an unjust extension of time.

While *Merck* and *Novartis* do not directly govern this case because they address PTE, they inform our analysis because they recognize the differences between PTA and PTE.

In *Merck* and *Novartis*, the holdings were premised on meaningful and substantive differences evincing a clear congressional intent to constitute PTE and PTA as different statutory frameworks. In particular, those cases set forth how § 154 clearly states that PTA “shall” be granted when certain requirements are met. 35 U.S.C. § 154(b)(1)(A), (b)(1)(B), and (b)(1)(C). But those requirements include limitations that are separate and distinct from those in the PTE framework, including the inability to extend a term past any date in a filed terminal disclaimer. Compare 35 U.S.C. § 154(b)(2)(B) with 35 U.S.C. § 156(c)(3), and (g)(6) (providing for statutory limitations on length of PTE and number of patents that can be extended).

In addition, while § 154(b)(2)(B)’s provision regarding terminal disclaimers is not directly applicable to the present case since none were filed, it remains critical in our analysis of the statute. Section 154(b)(2)(B) provides that “No patent the term of which has been disclaimed [pursuant to 35 U.S.C. § 253] beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.” Cellect had the opportunity to file terminal disclaimers in this case during both prosecution and *ex parte* reexamination. And, of course, the examiners had the opportunity, and perhaps the obligation, to reject certain of the pending claims, but they did not do so.

Terminal disclaimers are provided for in 35 U.S.C. § 253(a), which, in relevant part, provides that “A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent.” Title 37 of the Code of Federal Regulations, § 1.321 includes information on what a terminal disclaimer must include to be effective. 37 C.F.R. § 1.321. In particular, the regulation provides that a patentee may disclaim any complete claim or claims in a patent, *id.* § 1.321(a), or may disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted, *id.* § 1.321(b), (c).

Terminal disclaimers are almost always filed to overcome an ODP rejection, so terminal disclaimers and ODP remain inextricably intertwined. *See Boehringer Ingelheim Int’l GmbH v. Barr Lab’s, Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010). As the Board stated, ODP and terminal disclaimers are “two sides of the same coin: the problem and the solution.” J.A. 37. Given the interconnection of ODP and terminal disclaimers as “two sides of the same coin,” J.A. 37, the statutory recognition of the binding power of terminal disclaimers in § 154(b)(2)(B) is tantamount to a statutory acknowledgement that ODP concerns can arise when PTA results in a later-expiring claim that is patentably indistinct.

Terminal disclaimers were the solution to the problems created by the multiple challenged patents. If terminal disclaimers had been filed in this case, the provisions of § 154(b)(2)(B) would have come into play. Congress intended that, when a terminal disclaimer has been entered in a patent subject to PTA, no patent (or claim) may be extended beyond the disclaimed expiration date. Accordingly, in the absence of such disclaimers, it would frustrate the clear intent of Congress for applicants to benefit from their failure, or an examiner’s failure, to comply with established practice concerning ODP, which contemplates

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terminal disclaimers as a solution to avoid invalidation of patents claiming obvious inventions, as we have here.

We thus conclude that ODP for a patent that has received PTA, regardless whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent after PTA has been added. We therefore further conclude that the Board did not err in finding the asserted claims unpatentable under ODP.

II

We next consider Collect's challenge to the Board's determination that equitable concerns underlying ODP, including an improper timewise extension of a patent term and potential harassment by multiple assignees, are present in this case.

Collect argues that the equitable concerns underlying ODP, including an improper timewise extension of a patent term and potential harassment by multiple assignees, do not exist in this case. Collect asserts that the Board cannot and does not point to any evidence that Collect has purposely manipulated the system to delay the issuance of the challenged patents to improperly extend their term. Collect further asserts that it has never and will never split its patents among multiple owners, and thus the risk of claim splitting or harassment by multiple litigants is entirely speculative. Collect contends that the use of ODP to invalidate related patents with shared expiration dates based on an alleged nonexistent risk of divided ownership is improper.

The USPTO responds that the Board's decision is properly grounded in the public policy surrounding ODP. The USPTO asserts that the Board did not err in determining that Collect received an unjustified timewise extension of its patent terms and that it does not matter how the unjustified extensions are obtained. The USPTO further asserts that gamesmanship is not the only issue, and that the

mere presence of an unjustified extension is sufficient for the Board to find that claims are unpatentable under ODP. The USPTO further asserts that the Board did not err in determining that a risk of separate ownership existed (from, for example, creditors dividing the patents after a potential bankruptcy proceeding), or in determining that a terminal disclaimer would have been required to ensure continued common ownership even if the patents had the same expiration date. The USPTO also asserts that the Board did not err in finding Collect's declaration not to assign the patents insufficient.

We agree with the USPTO that the Board did not err in determining that Collect received unjustified extensions of patent term. Neither Collect nor the USPTO disputes that the asserted claims in the challenged patents would have been obvious variations of the respective claims in the invalidating ODP references. The obviousness of the asserted claims in each of the challenged patents can be traced back to the '036 patent. That is the only patent in the family that did not receive a grant of PTA and that expired on October 6, 2017, twenty years from the date on which the priority application was filed. Therefore, any extension past that date constitutes an inappropriate time-wise extension for the asserted claims of the challenged patents. To hold otherwise would, in effect, confer on the reference claims of the '036 patent PTA to which they were not entitled. We do, however, note that the non-asserted claims in the challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of earlier-filed, commonly owned claims. We have no basis for consideration of that issue here.

We also agree with the USPTO that the Board did not err in determining that a risk of separate ownership existed and, even in the absence of separate ownership, that a terminal disclaimer would have been required to ensure common ownership. As the Board found, the patents

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expired fewer than six years ago, so the risk remains for multiple assignees to seek past damages. While Collect has not engaged in actions that resulted in divided ownership in the past, and it has promised that it will not do so in the future, neither fact suffices to abrogate the potential future risk of multiple owners or assignees. Promises do not substitute for sound applications of rules of law.

Collect argues that, because it acted in good faith and because the grant of PTA takes into account any actions on the part of the applicant that may exacerbate the USPTO's delay, 35 U.S.C. § 154(b)(2)(C), it should not lose out on the grant of extra term that is required by statute. But there is no basis for an examiner to inquire into the intent of an applicant, or credit it. The ability of the applicant to show good faith during prosecution does not entitle it to a patent term to which it otherwise is not entitled. 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 of term.

III

We finally consider Collect's challenge to the Board's determination that the *ex parte* reexamination proceedings raised a substantial new question of patentability.

Collect argues that there was no substantial new question of patentability present in the underlying reexaminations, so the reexaminations were improper. In particular, Collect asserts that the same examiner analyzed all the challenged and reference patents, and was therefore aware of them, yet did not issue any ODP rejections during prosecution, despite issuing ODP rejections during the prosecution of other Collect-owned applications that he examined. Collect asserts that the Board artificially created a substantial new question of patentability by second-guessing the examiner's judgment.

Collect further argues that, even if we affirm the Board's holding that an ODP analysis for a patent that has received PTA is based on the expiration date including PTA, only the adjustment period, not the entire patent term, should be considered for invalidation.

The USPTO responds that the Board correctly determined that the reexamination requests raised a substantial new question of patentability because there is no indication that the examiner raised ODP as a relevant issue during the prosecution of the challenged patents. The USPTO further contends that the examiner's knowledge of the reference patents and ODP rejection in other applications is not sufficient to find that ODP was actually considered and decided by the examiner during prosecution of the challenged patents.

The USPTO also responds that Collect's request only to invalidate any granted adjustment period rather than the entire patent term was waived, as it was not raised before the Board. Even if it was not waived, the USPTO asserts that invalidating only the adjustment would be tantamount to issuing a retroactive terminal disclaimer, which would be improper.

We agree with the USPTO that the Board's determination that the reexamination requests raised a substantial new question of patentability was supported by substantial evidence. Collect's arguments lack merit and amount to little more than attempting to prove a negative. The examiner's willingness to issue ODP rejections of claims in other Collect-owned patent applications but not in the challenged patents and his knowledge of the reference patents do not affirmatively indicate that he considered ODP here. Further, "[t]he existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the [USPTO] or considered by the [USPTO]." 35 U.S.C. § 303(a). And, as the Board notes, neither party points to

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anything in the prosecution history that affirmatively indicates that the examiner considered whether or not an ODP rejection should be made. We thus conclude that the Board's findings were supported by substantial evidence and that a substantial new question of patentability was present in the underlying *ex parte* reexaminations.

A substantial new question of patentability requires just that—a substantial new question. Here, where Collect itself does not indicate a single portion of the prosecution history explicitly showing that the examiner considered ODP, the threshold for showing a substantial new question has been met. The fact that this case is before us here without terminal disclaimers having been required itself strongly suggests that the examiner did not consider the issue.

We also agree with the USPTO that the question of invalidation of only the adjustment period raised by Collect on appeal is forfeited, as it was not raised before the Board. We further agree with the USPTO that, even if not forfeited, invalidation of only the adjustment would be tantamount to granting a retroactive terminal disclaimer, tying the expiration of the later-filed claims to the earlier-filed reference claims. A terminal disclaimer is not an escape hatch to be deployed after a patent expires. Collect had the opportunity to file terminal disclaimers during prosecution, even in the absence of an ODP rejection, yet it declined to do so. Now the challenged patents have expired, and the opportunity has passed. Invalidating only the adjusted term would in effect give Collect the opportunity to benefit from terminal disclaimers that it never filed.

CONCLUSION

We have considered Collect's remaining arguments but find them unpersuasive. For the foregoing reasons, the decision of the Board is affirmed.

AFFIRMED