Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

United States Court of Appeals for the Federal Circuit

IN RE: CELLECT, LLC,
Appellant

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

CELLECT, LLC'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Cellect, LLC certifies the following:

1. The full name of every entity represented by us is:

   Cellect, LLC.

2. The name of the real party in interest for the entity. Do not list the real party if it is the same as the entity:

   Not applicable.

3. All parent corporations and any other publicly held companies that own 10 percent or more of the stock of the party or amicus curia represented by me are listed below:

   Cellect, LLC is a wholly-owned subsidiary of Micro Imaging Solutions LLC.

4. The names of all law firms, and the partners or associates that have not entered an appearance in the appeal, and (a) appeared for the entity in the lower tribunal; or (b) are expected to appear for the entity in this court:

   Not applicable.

5. Other than the originating case number(s), 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:

   - *In Re: Cellect, LLC*, No. 22-1292 (Fed. Cir.); and
   - *Cellect, LLC v. Samsung Electronics Co., Ltd., et al.*, No. 1:19-cv-00438 (D. Colo.).

6. All information required by Fed. R. App. P. 26.1(b) and (c) in criminal cases and bankruptcy cases.

   None.

Dated: November 13, 2023

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1) Whether the statutory language and legislative history of the patent term adjustment statute, 35 U.S.C. § 154(b), as well as this Court's precedent, instruct that it should be interpreted consistent with the patent term extension statute, 35 U.S.C. § 156, for purposes of determining the expiration date for an obviousness-type double patenting analysis.

2) Whether the Panel's decision overlooked the policy grounds underlying the judicially created obviousness-type double patenting doctrine in a manner that usurps Congress' legislative function.

Based on my professional judgment, I believe the Panel decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedent(s) of this Court: *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018); *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355 (Fed. Cir. 2018); *Merck & Co. v. Hi-Tech Pharmacal Co.,* 482 F.3d 1317 (Fed. Cir. 2007); *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366 (Fed. Cir. 2014); *Gilead Scis., Inc. v. Natco Pharma Ltd.,* 753 F.3d 1208 (Fed. Cir. 2014).

Dated: November 13, 2023

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ARGUMENT

This case warrants en banc review because it involves the precedent-setting question of whether two statutes that share the common purpose of compensating a patent owner for time lost due to Patent Office or regulatory delays should be interpreted consistently for purposes of an obviousness-type double patenting ("OTDP") analysis. The statutory text, legislative history and governing precedent regarding 35 U.S.C. § 154(b) compel that the answer to this question is yes.

This case involves the intersection of three concepts: (i) the OTDP doctrine, which is a judicially created equitable doctrine meant to prevent unjustified patent term extensions and/or harassment by multiple assignees; (ii) a statutory award of patent term adjustment ("PTA") due to Patent Office delays during patent prosecution pursuant to 35 U.S.C. § 154(b); and (iii) this Court's decision in *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018) ("*Novartis-Ezra*") regarding the expiration date that should be applied for purposes of the OTDP analysis when a patent receives statutory patent term extension ("PTE") pursuant to 35 U.S.C. § 156 due to delays in the regulatory review process before a product can be commercially marketed.

The Panel adopted an erroneous statutory interpretation of § 154(b) to conclude that PTA and PTE should be treated differently when determining whether claims are unpatentable due to OTDP. Specifically, the Panel concluded

that while the expiration date used for an OTDP analysis where a patent term received PTE is the expiration date ***before*** PTE is added, the expiration date used for the OTDP analysis where a patent received PTA is the expiration date ***after*** PTA is added. *In re: Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023).

The statutory text, scheme and legislative history of the PTA statute indicate that Congress spoke directly to how existing terminal disclaimers affect PTA and that, like PTE, the correct patent expiry date for the analysis is the expiration date before PTA is added. In particular, § 154(b)(2)(B)'s reference to "disclaimers" indicates that Congress specifically considered the term-cutting effect of disclaimers and adopted a provision limiting the award of PTA to any existing disclaimer. The Panel erred by interpreting § 154(b) inconsistent with Congressional intent expressed in this statutory language.

In addition, the Panel misapprehended the effect of the *Novartis-Ezra* decision, which explained how the judicial OTDP doctrine cannot trump a statutory award of additional patent term. *Novartis-Ezra*, 909 F.3d at 1375. Indeed, the Panel's decision disregards both equitable prongs of the OTDP doctrine to find that statutory patent term adjustment due to Patent Office delays is "unjust." By so doing, the Panel improperly adopted an overreaching interpretation of its OTDP precedent that permits a judicially created equitable doctrine to supersede a statutory award of additional patent term.

I. EN BANC REVIEW IS NECESSARY TO MAINTAIN UNIFORMITY AMONG STATUTORY INTERPRETATION AND THIS COURT'S PRECEDENT REGARDING THE OTDP DOCTRINE

Rehearing en banc is necessary regarding this case of first impression because the Panel incorrectly interpreted § 154(b) to find that the patent expiry date for purposes of the OTDP doctrine is the date after PTA is added. According to the statutory language, legislative history and this Court's precedent, the proper date is the expiration date before PTA is added, as this Court found in *Novartis-Ezra* with respect to PTE. The Panel would not have invalidated the Challenged Claims based on OTDP if it applied the correct patent expiration date.

A. The Challenged Claims Share a Common Expiration Date But-For the Statutorily Authorized PTA Grant

Certain undisputed facts are critical to this appeal and demonstrate the need for en banc review of the precedent-setting issue raised herein. Indeed, the Panel itself recognized both that this is a case of first impression, and that the Panel's statutory interpretation of the PTA statute (35 U.S.C. § 154(b)) is diametrically opposed to its statutory interpretation of the PTE statute (35 U.S.C. § 156) and interplay with OTDP. *In re: Cellect,* 81 F.4th at 1227 ("For the first time, here, we address how another statutorily authorized extension, PTA, interacts with ODP."); *id.* at 1226 ("[W]e 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.") ‼

First, each of Cellect's Challenged Patents would have expired on the same date but-for receiving statutorily authorized patent term adjustment due to delays at the Patent Office pursuant to 35 U.S.C. § 154(b). The Board rejected each of the Challenged Patents using other Cellect patents, which had no PTA, that claimed the same effective filing date as the Challenged Patents. Thus, but-for statutory PTA, both the Challenged Patents and the invalidating Cellect patents would have had identical expiration dates. It is only because the previously issued and related Cellect patents did not have their terms adjusted, that they were transformed into invalidating references against related patents with PTA. This result is antithetical to Congress' intent in enacting § 154(b) to ***add*** to the term of the patent whose examination was delayed, not to invalidate it.

Second, there is no allegation, evidence or finding of any gamesmanship or bad faith on the part of Cellect in obtaining the statutorily authorized PTA. This Court and district courts have long distinguished between application of the equitable OTDP doctrine to cases where there is evidence of misconduct in patent prosecution and cases, like here, where there is a complete absence of gamesmanship. *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1367 (Fed. Cir. 2018) ("*Novartis-Breckenridge*") (finding it "critical[]" that patent owner did not engage in gamesmanship to extend the term of his patent); *Amgen, Inc. v. Sandoz Inc.,* No. 18-11026 (MAS) (DEA), 2021 WL 5366800, at

*27 (D.N.J. Sept. 20, 2021) ("[T]he Court would exercise its equitable discretion not to apply the doctrine of [OTDP]" in absence of gamesmanship) (citing *Immunex Corp. v. Sandoz, Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (noting that OTDP is an "equitable doctrine")); *cf. Gilead Scis., Inc. v. Natco Pharma Ltd.,* 753 F.3d 1208, 1210 (Fed. Cir. 2014) (applying OTDP when the patentee engaged in prosecution gamesmanship by structuring priority claims).

Third, Cellect did not file a terminal disclaimer during prosecution, nor had any reason to believe it needed to do so, because the Examiner did not issue an OTDP rejection. The Panel noted that it was "perhaps the obligation" ***of the Examiner*** to reject certain claims if OTDP existed, ***not*** Cellect's obligation to proactively file a terminal disclaimer to avoid a potential rejection during reexamination. *In re: Cellect*, 81 F.4th at 1228. The Examiner issued no such rejection. *Id.*

B. The Statutory Language and Legislative History Confirm the OTDP Doctrine Cannot Re-Write § 154(b)

Congress enacted the PTA and PTE statutes as two statutory frameworks to accomplish a common goal – namely, to "restore the value of the patent term that a patent owner loses during the early years of the patent." *Novartis-Ezra*, 909 F.3d at 1369; *see also* H.R. Rep. No. 106-287(I), at 49-50 (1999). Importantly, both statutory schemes are intended to act as "technical term adjustment provisions" that restore patent term lost to different types of administrative delay. *See* H.R.

Rep. No. 106-287(I) at 51 ("coordinat[ing]" adjustments and extensions). The Panel was dismissive of this context. *In re Cellect*, 81 F. 4th at 1226 ("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 Cellect argues, is an unjustified attempt to force disparate statutes into one.").

The Panel improperly conflated technical differences between PTA and PTE with how a statute takes precedence over a judicial doctrine. Further, the Panel's decision ignores that the PTA statute (*i.e.*, § 154(b)(2)(B)) includes a calculation rule that sets forth how much lost patent term due to delays at the Patent Office a patent owner should be given back when a disclaimer already exists. The Panel instead weaponized statutory PTA by relying on this calculation rule as the basis that an otherwise valid patent is deemed unpatentable ***for the entire patent term***.

The intent of Congress in enacting these statutory frameworks is reflected in the statutory text and legislative history. For example, Congress enacted the current PTA statute under the "patent term guarantee" of the American Invents Act of 1999 ("AIA"). The specific problem that the AIA's "patent term guarantee" addressed is that a 1994 intervening change in law regarding how to calculate a patent term resulted in some patent terms being cut short by operation of the new law.

Congress enacted the PTA statute with the intent of "promis[ing] patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO." *Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010); H.R. Rep. No. 106-287(I), at 49-50. "This promise took the form of three distinct 'guarantees,'" that dictated how to calculate time to be added to the end of a patent term to compensate for time lost due to Patent Office delays. *Wyeth*, 591 F.3d at 1366 (citing 35 U.S.C. § 154(b)(1)).

The text of the PTA statute is unequivocal and mandates that if the Patent Office fails to meet statutory deadlines during examination, the "term of the patent ***shall be extended*** for 1 day for each day" of the delay. 35 U.S.C. § 154(b)(1)(A)(iv) (emphasis added). Similarly, the PTE statute provides that the patent term for patents covering subject matter that requires regulatory review "***shall be extended***" up to five years, upon patent owner's application and the satisfaction of various conditions. 35 U.S.C. §§ 156(c), 156(g)(6). Thus, both statutes reflect Congressional intent to compensate patent owners for lost patent term due to administrative delays beyond the patent owner's control.

The Panel hinged its statutory analysis on the PTA statute's limitation on the mandatory term adjustment, specifically:

> 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.

35 U.S.C. § 154(b)(2)(B) (emphasis added). This is a straightforward calculation rule for PTA awards when term has been disclaimed already and ensures that the PTA award does not extend term beyond the existing disclaimed date of the patent.

The Panel admits that this provision is not "directly applicable" to this case because no terminal disclaimers were filed ***because the Patent Office did not issue an OTDP rejection*** despite having an obligation ("perhaps") to do so if it thought such a concern existed. *In re: Cellect*, 81 F.4th at 1228. Nor did the Panel dispute that the statutory language speaks in terms of an existing disclaimer made during prosecution of the patent, as Cellect pointed out in its Opening Brief. Dkt. No. 22 at 26-27. Thus, § 154(b)(2)(B)'s limitation does not apply under the statute's plain language because no patent term was disclaimed.

The Panel disregarded this plain language and presumes that Congress wrote the PTA statute using some secret code. In particular, the Panel reasoned that the word "disclaimed" in § 154(b)(2)(B) does not require an actual terminal disclaimer filed during prosecution. *In re: Cellect*, 81 F.4th at 1229 ("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*** . . . ."") (emphasis added). Rather, according to the Panel, Congress used veiled reference to a "disclaimer" to sweep within the PTA statute the entire breadth of the terminal disclaimer doctrine. The Panel could not and did not base its conclusion in statutory text and, instead, was

left to simply equate "disclaimers" as "tantamount" to a Congressional recognition of OTDP concerns for purposes of its statutory interpretation analysis. *Id*. at 1228-29.

Such a strained deciphering of the PTA statute is incorrect. The Panel strays from the text to reason that Congress, by stating "disclaimed," meant to include the ***possibility*** that a terminal disclaimer ***might have needed to be filed*** (which presumes a mistake by the Examiner in failing to perform its ***possible*** obligation to issue an OTDP rejection during prosecution) and, ***if a terminal disclaimer had been filed***, then § 154(b)(2)(B) would have come into play. *Id.* at 1228 ("If terminal disclaimers had been filed in this case, the provisions of § 154(b)(2)(B) would have come into play.").

The Panel's outcome is not what the statute states or what Congress intended. *Novartis-Ezra*, 909 F.3d at 1372 ("[C]ourts 'ordinarily resist[] reading words into a statute that do not appear on its face.'") (citation omitted). To the contrary, § 154(b)(2)(B)'s reference to a disclaimer confirms that the patent term expiration date for an obviousness-type double-patenting analysis is ***before*** PTA is added.

In particular, under § 154(b)(2)(B)'s statutory text, the length of the terminal disclaimer controls the available amount of PTA. § 154(b)(2)(B) (the patent term may not be adjusted beyond the date specified in the disclaimer). The Panel's interpretation flips this language so that it is the amount of PTA that controls

whether a terminal disclaimer ***should have been*** filed, creating this illogical scenario: Patent Office delays trigger PTA; this PTA would then trigger the need for a terminal disclaimer; and that terminal disclaimer then triggers a limitation on the PTA. *See* Dkt. No. 31 at 3 (*Amicus Curiae* Br. of Biotechnology Innovation Org.). There is no basis for this circular reasoning. Rather, because the disclaimers referenced in § 154(b)(2)(B) arise during the course of prosecution, any such disclaimer cannot be based on PTA that itself is not determined or awarded until prosecution is complete

The PTA statute's language is straightforward: the amount of available PTA is dependent on the presence of any existing disclaimer. § 154(b)(2)(B). Thus, the conditions that necessitate a terminal disclaimer, such as OTDP concerns, must be analyzed before any PTA is awarded.

The Panel cites nothing in the legislative history to support that Congress, by enacting a provision to offset Patent Office delays that diminished the patent owner's rightful term, meant to provide a weapon by which a patent's ***entire patent term*** can be eviscerated by virtue solely of such a statutory band-aid. H.R. Rep. 106-287(I) (1999) at 48-49 (stating "***[o]nly*** those who ***purposely manipulate*** the system to delay the issuance of their patents will be penalized under [this title]") (emphasis added).

II. EN BANC REVIEW IS NECESSARY TO ENSURE UNIFORMITY AMONG PRECEDENT AND PREVENT A JUDICIAL DOCTRINE BASED ON EQUITY TO OVERRIDE A STATUTORY GRANT OF PTA

Rehearing en banc is necessary to ensure uniformity among this Court's opinions that the "judge-made doctrine" of OTDP cannot "cut off a statutorily-authorized time extension," whether it be PTA or PTE. *Novartis-Ezra*, 909 F.3d at 1375.

This Court previously held that a statutorily-mandated PTE cannot give rise to OTDP. *Id.* at 1373. In so holding, this Court explicitly declined to allow "a judge-made doctrine [of OTDP to] cut off a statutorily-authorized time extension." *Id.* at 1375. Indeed, this Court explained in *Novartis-Ezra*, following a detailed evaluation of both PTA and PTE, that a patent should not be at risk of invalidation for double patenting just because "the term extension it received causes the [extended] patent to expire after [another] allegedly patentably indistinct . . . patent." *Id.* at 1373. The Court acknowledged the differences between PTA and PTE, but also explained that they both exist to "restore the value of the patent term that a patent owner loses during the early years of the patent . . . ." *Id.* at 1369; *see also* H.R. Rep. No. 106-287(I) at 49-50. Thus, the *Novartis-Ezra* holding that "a judge-made doctrine" should not "cut off a statutorily-authorized time extension" applies equally to PTA and PTE. *Novartis-Ezra*, 909 F.3d at 1375.

Similarly, this Court further declined to permit this judge-made doctrine to cut short a statutory term mandated due to the URAA change in patent term. *Novartis-Breckenridge*, 909 F.3d at 1361-62. In particular, this Court in *Novartis-Breckenridge* found two patents with concededly patentably indistinct claims were not invalid based on OTDP because the cause of the extended term and different expiration dates was a statutory change. *Id.* at 1363–64 (finding patent owner had not "improperly captured unjustified patent term").

Rather than apply these holdings to PTA, the Panel reached the exact opposite result. The Panel did so despite acknowledging (although ultimately ignoring) that the PTA and PTE statutes serve a common purpose and share similar language (as explained above). *In re: Cellect*, 81 F.4th at 1226, 1228.

Notably, the Panel reached this contradictory result while purporting to rely on the exact same precedent it used in *Novartis-Ezra* – namely, *Merck*[1], *Gilead*[2] and *AbbVie*.[3] *Id*. The same precedent analyzing similar statutory text with common purposes should not yield diametrically opposed results, as is the case here.

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[1] *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007)

[2] *Gilead*, 753 F.3d at 1211-12, 1217.

[3] *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1373-74 (Fed. Cir. 2014)

Moreover, the Panel failed to address the dispositive reasons that this Court's holdings in *Gilead* and *AbbVie*, which predate *Novartis-Ezra* and do not address PTA, are not controlling. *See, e.g.*, Dkt. No. 22 at 25, 37-39, 43; Dkt. No. 63 at 7-12. In particular, both these cases dealt with ***unrelated*** patents with ***different*** priority dates and possible gamesmanship through filing unrelated patent applications on the same subject matter. *Id.* Here, unlike in *Gilead* and *Abbvie*, all of Cellect's Challenged Patents claim the same priority date and there are no allegations of gamesmanship, yet the Board and the Panel used Cellect's related continuation patents against their relatives. Moreover, the language in the *AbbVie* opinion is dicta that must be revisited in view of the later *Novartis-Ezra* statement of the law. *Howes v. Fields*, 565 U.S. 499, 505 (2012) (reiterating that "clearly established law" signifies "the holdings, as opposed to the dicta, of [a] Court's decisions" (quoting *Williams v. Taylor*, 529 U.S. 362, 412 (2000)).

Thus, rehearing en banc is necessary to ensure uniformity in this Court's precedent that a judge-made doctrine, like OTDP, cannot cut short a statutory award of PTA (or PTE).

III. EN BANC REVIEW IS NECESSARY BECAUSE THE PANEL'S DECISION ELIMINATES THE POLICY GROUNDS UNDERLYING THE OBVIOUNESS-TYPE DOUBLE PATENTING DOCTRINE

En banc review is necessary because the Panel's decision eviscerates the equitable purpose of the OTDP doctrine in a manner that amounts to usurping the

legislative function. OTDP is a judicially created doctrine based in equity and meant to prevent (i) a patent owner from obtaining an ***unjust*** patent term extensions or (ii) harassment from multiple suits. *Immunex Corp.*, 964 F.3d at 1059. Here, the Panel equated statutorily authorized PTA with an unjust patent term extension. This was an error.

Not every patent term adjustment is "unjustified" – even where patent claims are alleged and/or found to be patentably indistinct. Rather, the reasons (*i.e.*, the equities) matter to an OTDP analysis.

For example, this Court in *Novartis-Ezra* found no evidence of an unjustified timewise extension of patent term, even where the claims were patentably indistinct. Rather, the challenged extension term resulted from Congress's "statutorily-allowed" PTE. 909 F.3d at 1374. This Court therefore explicitly declined to apply the equitable OTDP doctrine despite that the PTE "cause[d] the [challenged patent] to expire after Novartis's allegedly patentably indistinct [reference] patent. *Id.* at 1373.

Here, the Panel went even further and ruled that equities simply do not matter at all. Indeed, the Panel explicitly stated that an applicant's good faith is irrelevant – a double patenting rejection based solely on the statutory award of PTA to allegedly indistinct claims will issue regardless of the equities. "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." *In re: Cellect*, 81 F.4th at 1230. According to the Panel, the award of statutorily mandated PTA in this scenario was unjust merely because there was a finding that the patent claims were indistinct – notwithstanding that these exact same facts (including patentably indistinct claims) did not give rise to a finding of an unjust extension in the PTE context in *Novartis-Ezra* (909 F.3d at 1373), nor due to a change in the patent term statute in *Novartis-Breckenridge* (909 F.3d at 1357-58).

Nor did it matter to the Panel that Cellect submitted a declaration, as part of the intrinsic record of the Patent Office, affirming that it always has and will keep the Challenged Patents commonly owned. Appx1753 (Adair Decl.), ¶ 24. Rather, the Panel found that a speculative risk, that contradicts actual facts and history of Cellect's ownership of Cellect's patents, was enough to meet the equitable prong of OTDP for multiple assignees. *In re: Cellect,* 81 F.4th at 1230. Thus, the Panel's decision here again eviscerates the equitable purpose of the OTDP doctrine so that it applies to PTA where claims are alleged to be patentably indistinct regardless of the equities.

En banc review is further necessary because the Panel's decision amounts to improper legislating by judicial ruling. The Panel effectively re-writes §

154(b)(2)(B) so that it applies in circumstances where a terminal disclaimer has not been filed, which is contrary to the statutory text. § 154(b)(2)(B).

Moreover, the Panel's decision imposes an obligation on a patent owner to file a preemptive terminal disclaimer, even in instances where the Examiner issues no rejection based on OTDP, to protect against a possible future rejection on this basis. Nothing in Title 35, 37 C.F.R, or the MPEP requires patent applicants to re-examine double patenting based purely on term adjustment through no fault of the patent owner, even though a patent has already been allowed and the patent owner has already paid the issue fee. Rather, the MPEP places the obligation on the Patent Office to issue rejections during the course of prosecution. *See* M.P.E.P. § 706.

The Panel's decision should be reconsidered as it transforms PTA, which is intended to compensate patent owners for lost patent term, into the very reason that a patent owner loses its patent rights altogether. This serves no equitable purpose.

CONCLUSION

For the foregoing reasons, Cellect respectfully requests rehearing en banc.

Respectfully submitted,

Dated: November 13, 2023

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ADDENDUM – TABLE OF CONTENTS

Tab 1

United States Court of Appeals for the Federal Circuit

IN RE: CELLECT, LLC,
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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

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

LOURIE, *Circuit Judge*.

Cellect, LLC ("Cellect") 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

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 Cellect LLC*, Appeal 2021-005302 (P.T.A.B. Feb. 17, 2020), J.A. 27–49; *Ex parte Cellect LLC*, Appeal 2021-005046 (P.T.A.B. Feb. 18, 2020), J.A. 51–73; *Ex parte Cellect LLC*, Appeal 2021-005258 (P.T.A.B. Feb. 19, 2020), J.A. 76–97; *Ex parte Cellect LLC*, Appeal 2021-005303 (P.T.A.B. Feb. 16, 2020), J.A. 2–24.[1] For the reasons provided below, we affirm.

BACKGROUND

Cellect 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

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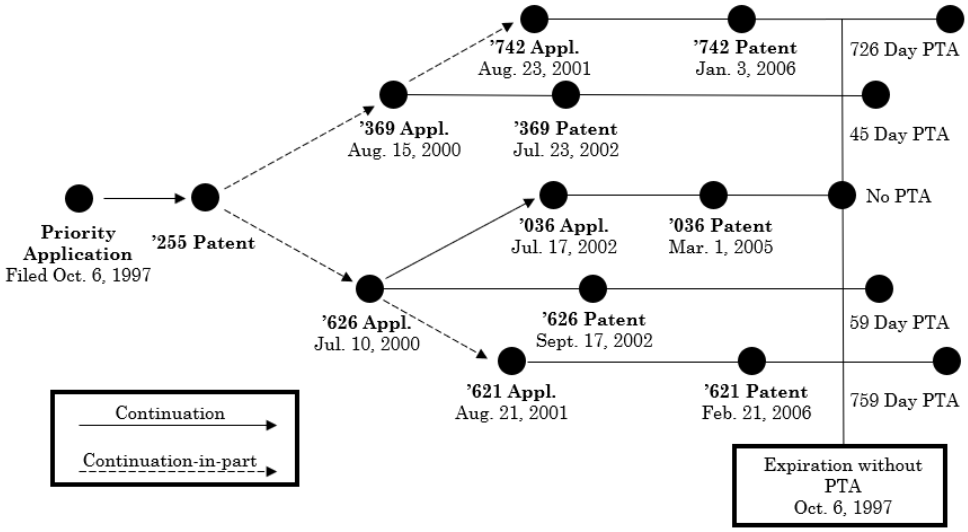
[1] The four appeals for *ex parte* reexamination issued by the Board essentially contain the same language and analysis. We treat Appeal 2021-005302 as representative.

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.



Cellect 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 Cellect'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.

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.

Cellect appealed the rejection of the claims of the challenged patents to the Board. Cellect noted that under *Novartis 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, Cellect argued that determining unpatentability under ODP should be based on the expiration dates of the patents before any PTA is added to the term.

Cellect 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. Cellect 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, Cellect contended, abrogated the risk of harassment by multiple owners or assignees. Cellect 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

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 Cellect'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 Cellect did not dispute that fact. J.A. 43. Cellect instead focused its argument on whether or not ODP could cut short a grant of PTA. The Board also found that Cellect 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 Cellect'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 Cellect-owned patents, or his willingness to issue ODP rejections in the prosecution of other Cellect-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 Cellect appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Cellect raises three challenges on appeal. First, Cellect 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, Cellect contends that the Board erred in failing to

consider the equitable concerns underlying the finding of ODP in the *ex parte* reexamination proceedings. Third, Cellect 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 Cellect'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],

> 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).

Cellect 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

PTA or PTE. Cellect alleges that our precedent, legislative intent, and the statutory language all dictate this outcome. First, Cellect 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, Cellect 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, Cellect argues that PTA and PTE have similar statutory limitations. Cellect 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). Cellect 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, Cellect asserts, would be incompatible with and would fundamentally change continuations practice.

In addition, Cellect 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. Cellect 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").

Cellect 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.

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 Cellect 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 Cellect, 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.

Cellect 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, Cellect's interpretation of the PTA statue 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

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'ys, 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

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 Cellect'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.

Cellect 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. Cellect asserts that the Board cannot and does not point to any evidence that Cellect has purposely manipulated the system to delay the issuance of the challenged patents to improperly extend their term. Cellect 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. Cellect 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 Cellect 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 Cellect's declaration not to assign the patents insufficient.

We agree with the USPTO that the Board did not err in determining that Cellect received unjustified extensions of patent term. Neither Cellect 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 timewise 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

expired fewer than six years ago, so the risk remains for multiple assignees to seek past damages. While Cellect 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.

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

Cellect argues that there was no substantial new question of patentability present in the underlying reexaminations, so the reexaminations were improper. In particular, Cellect 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 Cellect-owned applications that he examined. Cellect asserts that the Board artificially created a substantial new question of patentability by second-guessing the examiner's judgment.

Cellect 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 Cellect'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. Cellect'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 Cellect-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

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 Cellect 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 Cellect 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. Cellect 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 Cellect the opportunity to benefit from terminal disclaimers that it never filed.

CONCLUSION

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

AFFIRMED

Tab 2

United States Code Annotated
Title 35. Patents (Refs & Annos)
Part II. Patentability of Inventions and Grant of Patents (Refs & Annos)
Chapter 14. Issue of Patent

35 U.S.C.A. § 154

§ 154. Contents and term of patent; provisional rights

Effective: May 13, 2015

Currentness

(a) In General.--

(1) Contents.--Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) Term.--Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, 365(c), or 386(c), from the date on which the earliest such application was filed.

(3) Priority.--Priority under section 119, 365(a), 365(b), 386(a), or 386(b) shall not be taken into account in determining the term of a patent.

(4) Specification and drawing.--A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(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) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after--

(I) the date on which an application was filed under section 111(a); or

(II) the date of commencement of the national stage under section 371 in an international application;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Patent Trial and Appeal Board under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied,

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) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

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) a proceeding under section 135(a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Patent Trial and Appeal Board or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability,

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.--

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(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 under paragraph (1) 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.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

(3) Procedures for patent term adjustment determination.--

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall--

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination no later than the date of issuance of the patent; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

(D) The Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.

(4) Appeal of patent term adjustment determination.--

(A) An applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph

(3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

(B) The determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent.

(c) Continuation.--

(1) Determination.--The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) Remedies.--The remedies of sections 283, 284, and 285 shall not apply to acts which--

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) Remuneration.--The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)).

(d) Provisional Rights.--

(1) In general.--In addition to other rights provided by this section, a patent shall include the right to obtain a reasonable royalty from any person who, during the period beginning on the date of publication of the application for such patent under section 122(b), or in the case of an international application filed under the treaty defined in section 351(a) designating the United States under Article 21(2)(a) of such treaty or an international design application filed under the treaty defined in section 381(a)(1) designating the United States under Article 5 of such treaty, the date of publication of the application, and ending on the date the patent is issued--

(A)(i) makes, uses, offers for sale, or sells in the United States the invention as claimed in the published patent application or imports such an invention into the United States; or

(ii) if the invention as claimed in the published patent application is a process, uses, offers for sale, or sells in the United States or imports into the United States products made by that process as claimed in the published patent application; and

(B) had actual notice of the published patent application and, in a case in which the right arising under this paragraph is based upon an international application designating the United States that is published in a language other than English, had a translation of the international application into the English language.

(2) Right based on substantially identical inventions.--The right under paragraph (1) to obtain a reasonable royalty shall not be available under this subsection unless the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application.

(3) Time limitation on obtaining a reasonable royalty.--The right under paragraph (1) to obtain a reasonable royalty shall be available only in an action brought not later than 6 years after the patent is issued. The right under paragraph (1) to obtain a reasonable royalty shall not be affected by the duration of the period described in paragraph (1).

(4) Requirements for international applications.--

(A) Effective date.--The right under paragraph (1) to obtain a reasonable royalty based upon the publication under the treaty defined in section 351(a) of an international application designating the United States shall commence on the date of publication under the treaty of the international application, or, if the publication under the treaty of the international application is in a language other than English, on the date on which the Patent and Trademark Office receives a translation of the publication in the English language.

(B) Copies.--The Director may require the applicant to provide a copy of the international application and a translation thereof.

CREDIT(S)

(July 19, 1952, c. 950, 66 Stat. 804; Pub.L. 89-83, § 5, July 24, 1965, 79 Stat. 261; Pub.L. 96-517, § 4, Dec. 12, 1980, 94 Stat. 3018; Pub.L. 100-418, Title IX, § 9002, Aug. 23, 1988, 102 Stat. 1563; Pub.L. 103-465, Title V, § 532(a)(1), Dec. 8, 1994, 108 Stat. 4983; Pub.L. 104-295, § 20(e)(1), Oct. 11, 1996, 110 Stat. 3529; Pub.L. 106-113, Div. B, § 1000(a)(9) [Title IV, §§ 4402(a), 4504], Nov. 29, 1999, 113 Stat. 1536, 1501A-557, 1501A-564; Pub.L. 107-273, Div. C, Title III, §§ 13204, 13206(a)(8), Nov. 2, 2002, 116 Stat. 1902, 1904; Pub.L. 112-29, §§ 3(j)(1), (2)(B), 9(a), 20(j)(1), Sept. 16, 2011, 125 Stat. 290, 316, 335; Pub.L. 112-211, Title I, § 102(6), Dec. 18, 2012, 126 Stat. 1531; Pub.L. 112-274, § 1(h), Jan. 14, 2013, 126 Stat. 2457.)

Notes of Decisions (549)

35 U.S.C.A. § 154, 35 USCA § 154
Current through P.L. 118-3. Some statute sections may be more current, see credits for details.

End of Document

Tab 3

KeyCite citing references available

United States Code Annotated
Title 35. Patents (Refs & Annos)
Part II. Patentability of Inventions and Grant of Patents (Refs & Annos)
Chapter 14. Issue of Patent

35 U.S.C.A. § 156

§ 156. Extension of patent term

Effective: November 25, 2015

Currentness

(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) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which--

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended--

(1) in the case of a patent which claims a product, be limited to any use approved for the product--

(A) before the expiration of the term of the patent--

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product--

(A) before the expiration of the term of the patent--

(i) under any provision of law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make--

(A) the approved product, or

(B) the product if it has been subject to a regulatory review period described in paragraph (1), (4), or (5) of subsection (g).

As used in this subsection, the term "product" includes an approved product.

(c) 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--

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) 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; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use, or in the case of a drug product described in subsection (i), within the sixty-day period beginning on the covered date (as defined in subsection (i)). The application shall contain--

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Director to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Director may require.

For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.

(2)(A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Director shall notify--

(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Director, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination, and shall publish in the Federal Register a notice of such determination.

(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Director[1] of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Director of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term “due diligence” means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.

(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days, before such

term is due to expire. The application shall contain--

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Director to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Director may require.

(B) If the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period the applicant notifies the Director of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section--

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension--

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e)(1) A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term “product” means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of--

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151-158).

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y)[2] of the Federal Food, Drug, and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) The term "date of enactment" as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8) The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of--

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of--

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of--

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of--

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of--

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(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 the 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) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,

before such date for 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.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Director may establish such fees as the Director determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to

recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to--

(A) have been approved or indexed under the relevant provision of the Public Health Service Act or Federal Food, Drug, and Cosmetic Act; and

(B) have permission for commercial marketing or use.

(2) In this subsection, the term "covered date" means the later of--

(A) the date an application is approved--

(i) under section 351(a)(2)(C) of the Public Health Service Act; or

(ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;

(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

(C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or

(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.

CREDIT(S)

(Added Pub.L. 98-417, Title II, § 201(a), Sept. 24, 1984, 98 Stat. 1598; amended Pub.L. 100-670, Title II, § 201(a) to (h), Nov. 16, 1988, 102 Stat. 3984; Pub.L. 103-179, §§ 5, 6, Dec. 3, 1993, 107 Stat. 2040; Pub.L. 103-465, Title V, § 532(c)(1), Dec. 8, 1994, 108 Stat. 4987; Pub.L. 105-115, Title I, § 125(b)(2)(P), Nov. 21, 1997, 111 Stat. 2326; Pub.L. 106-113, Div. B, § 1000(a)(9) [Title IV, §§ 4404, 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A-560, 1501A-582; Pub.L. 107-273, Div. C, Title III, § 13206(a)(9), (b)(1)(B), Nov. 2, 2002, 116 Stat. 1904, 1906; Pub.L. 112-29, § 37(a), Sept. 16, 2011, 125 Stat. 341; Pub.L. 114-89, § 2(c), Nov. 25, 2015, 129 Stat. 700.)

Notes of Decisions (46)

Footnotes

1 So in original. Probably should be “Commissioner”.

2 Section 201(y) of the Federal Food, Drug, and Cosmetic Act, which was classified to 21 U.S.C.A. § 321(y), was subsequently amended, and as amended subsec. (y) no longer defines the term “informal hearing”, however, such term is defined elsewhere in that section. See References in Text note set out under this section.

35 U.S.C.A. § 156, 35 USCA § 156
Current through P.L. 118-3. Some statute sections may be more current, see credits for details.

End of Document

CERTIFICATE OF COMPLIANCE WITH FED. CIR. R. 32

1. The foregoing filing complies with the type-volume limitation of Fed. R. App. P. 35(b)(2) because this brief contains 3,696 words exclusive of the parts of the filing as exempted by Fed. Cir. R. 32(b)(2).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: November 13, 2023

/s/ Paul J. Andre
Paul J. Andre