Navigating Patent Term Adjustment and Double Patenting After In re Cellect

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An Article discussing the US Court of Appeals for the Federal Circuit's August 28, 2023 *In re Cellect* decision, which held that patents awarded Patent Term Adjustment (PTA) under 35 U.S.C. § 154(b) can be invalidated under the doctrine of obviousness double patenting (ODP) based on earlier-expiring patents in the same family. It discusses the uncertainty created by two district court decisions that interpreted *Cellect* differently, the Federal Circuit's effort to clarify *Cellect* in its August 13, 2024 *Allergan USA, Inc. v. MSN Laboratories Private Ltd*. decision, and Cellect LLC's petition to the Supreme Court for a writ of certiorari. The Article includes background on PTA, ODP, and practice considerations and tactics for patent applicants and owners seeking to navigate the issues created by these decisions.

On August 28, 2023, the **US Court of Appeals for the Federal Circuit** decided *In re Cellect*, which affirmed the **US Patent and Trademark Office**'s (USPTO) determination that patents awarded statutorily mandated **Patent Term Adjustment** (PTA) can be invalidated under the doctrine of obviousness **double patenting** (ODP) based on earlier-expiring patents in the same family (*In re Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023); see Legal Update, Federal Circuit Clarifies Obviousness-Type Double Patenting's Application to Patents Extended Through PTA). On May 20, 2024, Cellect LLC filed a petition for writ of **certiorari** to the US Supreme Court.

PTA under 35 U.S.C. § 154(b) is awarded for USPTO delays in examining a patent application (see Practice Note, Patent Term Adjustment). When issued, the Federal Circuit's *Cellect* decision upended the expectations of many patent owners who believed their patents were entitled to their full term, including any awarded PTA. Of particular concern was the risk to PTA awarded to the first patent in a family if additional patents were pursued through continuation applications which may issue with earlier expiration dates. For the biotechnology and pharmaceutical industries, which depend on patent-based exclusivity to incentivize substantial investments in research and development, the potential loss of PTA poses significant consequences, especially because the terminal portion of the patent term may have the greatest value.

This Article discusses the Federal Circuit's *Cellect* decision, its practical implications, key considerations, and tactics for patent applicants and owners seeking to minimize the decision's impact. It also discusses Cellect's pending US Supreme Court certiorari petition and two conflicting decisions of the US District Court for the District of Delaware applying *Cellect*, which were both appealed to the Federal Circuit. In one of these appeals, the Federal Circuit recently issued a decision seeking to clarify the scope of its holding in *Cellect* (*Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 2024 WL 3763599, at *6-7 (Fed. Cir. Aug. 13, 2024)).

For information on:

- PTA, see Practice Note, Patent Term Adjustment.
- ODP, see Practice Note, Double Patenting: Obviousness-Type Double Patenting.

Obviousness Double Patenting, Patent Term Adjustment, and Patent Term Extension

Understanding *In re Cellect* and its implications requires knowledge of the basics and the interplay among PTA, a different statutory extension called a **Patent Term Extension** (PTE), and ODP.

Obviousness Double Patenting and Terminal Disclaimers

The doctrine of double patenting is rooted in 35 U.S.C. § 101, which states that an inventor may obtain "a patent" for an invention. This provision has been interpreted as a prohibition against obtaining more than a single patent claiming the "same" invention and is known as "statutory" or "same invention" double patenting. Statutory double patenting rarely arises because it is essentially limited to situations in which an inventor or assignee files separate applications with identical (or practically identical) claims. It is strictly applied so that two patents with identical claims cannot be granted to the same inventor or assignee. For more information on statutory double patenting, see Practice Note, Double Patenting: Statutory Double Patenting.

Far more common is the judicial doctrine of ODP, which is intended to prevent an inventor or assignee from obtaining or owning a second, later expiring patent that claims only an obvious variant of a first patent. (See *Eli Lilly & Co v. Barr Lab'ys, Inc.*, 251 F.3d 955, 967-68 (Fed. Cir. 2001); *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997); Practice Note, Double Patenting: Obviousness-Type Double Patenting.)

ODP often arises when a patent applicant files a **continuation** application to claim additional aspects of an invention, and the patent examiner concludes that the continuation application claims an obvious variant of the subject matter claimed in the earlier application. In contrast, if the examiner concludes that the application claims more than one patentably distinct invention, the examiner can issue a **restriction requirement** that forces the applicant to pursue coverage of each distinct invention in a separate **divisional** application. In this situation, subsequently filed divisional applications may be accorded a statutory safe harbor against an ODP challenge. (35 U.S.C. § 121; see Practice Note, Patent Prosecution: Restriction Requirements (Chemical and Life Sciences Inventions).)

Courts have expressed two justifications for ODP:

- The public's right to use an invention and its obvious variants after the patent term expires (*In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982) ("to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about")).

- The avoidance of multiple suits from multiple patent owners should patent ownership subsequently be divided (*In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (recognizing that "harassment by multiple assignees" provides "a second justification for [ODP]")).

Therefore, a "key purpose" of ODP is to "prevent a patent owner from extending the exclusivity rights over his invention beyond a full patent term," for instance where a patent applicant attempts to extend its patent monopoly by obtaining multiple patents with different expiration dates that claim obvious variants of each other (*Novartis AG v. Ezra Ventures, LLC*, 909 F.3d 1367, 1374 (Fed. Cir. 2018); *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1362 (Fed. Cir. 2018)).

In an ODP analysis, the challenged patent is assessed with reference to another patent (the reference patent) where the two patents are commonly owned or share at least one common inventor. The Federal Circuit has expanded the scope of the reference patent so that an earlier-filed, earlier-expiring, but later issued patent may serve as a reference patent to reject a later-filed, later-expiring, but earlier-issued patent (*Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1216 (Fed. Cir. 2014) ("Permitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA . . . preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires.")). (See Practice Note, Double Patenting: Reference Patent Requirements.)

Unlike statutory double patenting, a patent applicant or owner can overcome ODP by filing a terminal disclaimer (35 U.S.C. § 253; 37 C.F.R. § 1.321(c)). It disclaims the affected patent's term that extends beyond the expiration of the reference patent and includes an obligation that the two patents will only be enforceable while they are commonly owned. As discussed above, the latter requirement serves to prevent vexatious multiple infringement actions by different owners of patents claiming essentially the same invention. To be effective, a terminal disclaimer must be filed before the reference patent expires. (See MPEP § 1490(VI)(A); see also *Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys*, 592 F.3d 1340 (Fed. Cir. 2010).) For more information on terminal disclaimers, see Practice Note, Patent Correction: Statutory and Terminal Disclaimers, Certificates of Correction, and Inventorship: Using Terminal Disclaimers to Limit the Patent Term.

Patent Term Adjustment Under 35 U.S.C. § 154(b)

A US patent's term is governed by 35 U.S.C. § 154. In 1994, Congress enacted the Uruguay Round Agreements Act (URAA), amending Section 154 to provide for a patent term of 20 years from the earliest effective US filing date, eliminating the prior patent term of 17 years from the issue date (see URAA, Pub. L. No. 103-46, 108 Stat. §§ 4809, 4984 (1994)). In 1999, Congress further amended Section 154 as "Patent Term Guarantees" to provide for PTA to compensate applicants for USPTO prosecution delays. Under Section 154(b), if the USPTO does not act within certain specified time periods, the statute provides a formula for calculating PTA based on USPTO delay reduced by any applicant delay (see Practice Note, Patent Term Adjustment: Accruing and Calculating Patent Term Adjustment). Relevant to the Federal Circuit's reasoning in its *Cellect* decision, Section 154(b)(2)(B) limits PTA, so that "[n]o 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."

Patent Term Extension Under 35 U.S.C. § 156

In 1984, as part of the **Hatch-Waxman Act** providing for approval of generic versions of branded drug products, Congress also provided for PTE as codified in 35 U.S.C. § 156. PTE compensates patent owners with products subject to approval by the US

Food and Drug Administration (FDA), such as drugs and medical devices, by providing for an extension of patent term based on delays due to FDA regulatory review.

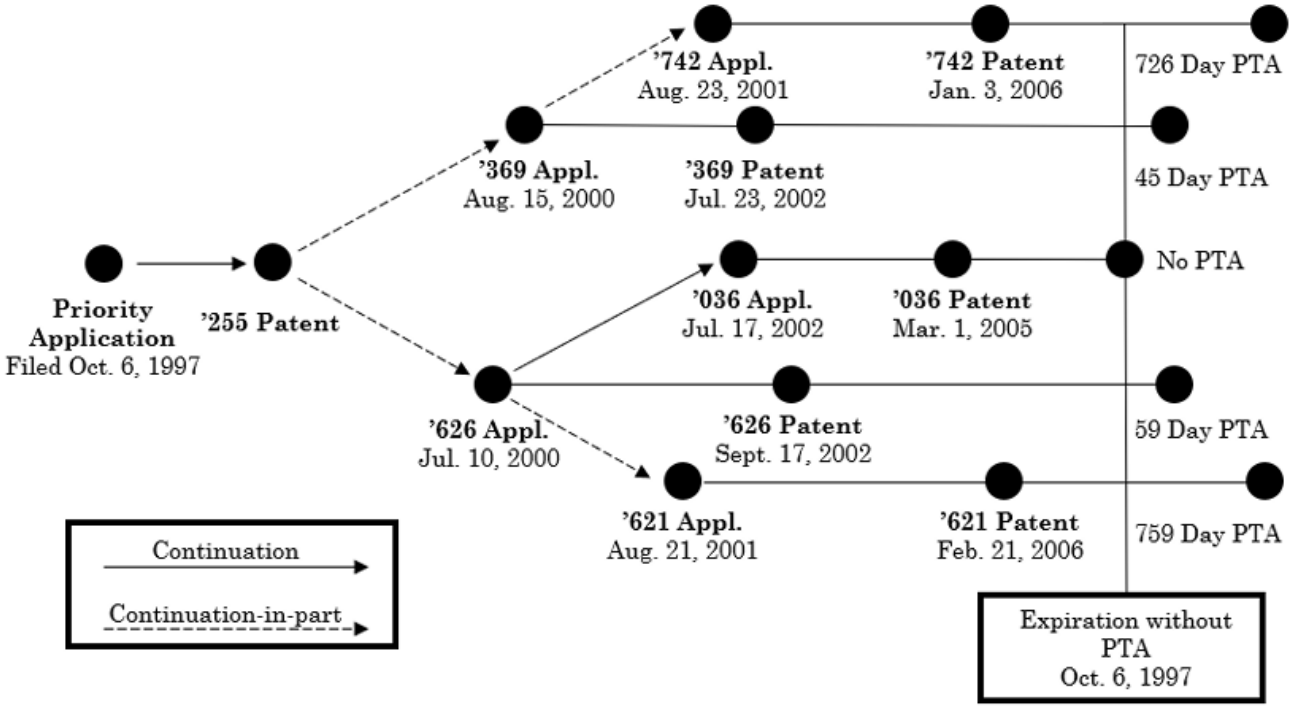
PTE can extend the term of one patent claiming an approved product or a method of using the product based on a statutory formula that factors in delays due to clinical trials and FDA review of the application for marketing approval. PTE is subject to a maximum of five years and the total patent term cannot exceed 14 years from the date of product approval (35 U.S.C. § 156). Patent owners carefully select the patent that should be awarded PTE because PTE is integral to protecting pharmaceutical and medical device product exclusivity, the approved product may be covered by multiple patents, and PTE must be applied for soon after FDA approval.

The Federal Circuit has held that additional patent term awarded under the PTE statute cannot form the basis of an ODP challenge (see *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007); *Novartis AG*, 909 F.3d at 1373-74). If a patent is entitled to both PTA and PTE and the total of the two extensions exceeds 14 years from FDA approval, the patent owner may decide to maximize the amount of PTE by terminally disclaiming enough days of PTA so that the PTE fits within the 14 year cap (see Obviousness Double Patenting and Terminal Disclaimers).

The Federal Circuit first addressed whether ODP can be based solely on the additional statutory term accorded a patent by PTA in *Cellect*.

The Federal Circuit's In re Cellect Decision Brings PTA Into the ODP Analysis

In re Cellect stemmed from a patent reexamination proceeding in which the USPTO determined that claims of four patents owned by Cellect were invalid based on ODP. The USPTO had granted each of the patents having challenged claims PTA under 35 U.S.C. § 154(b), as shown in the figure below. Because none of the challenged patents had been rejected for ODP during their original prosecution, no terminal disclaimers had been filed. In addition, each of the challenged patents had expired before reexamination.



US Patent No. 6,862,036 (the '036 patent) was identified as the reference patent. The '036 patent issued March 1, 2005, without any PTA, from an application filed July 17, 2002. The challenged claims were:

- Issued in patents filed earlier than the '036 patent, but would expire later because each was awarded varying amounts of PTA.

- Found invalid based on ODP, directly or indirectly, over the '036 as reference patent.

Cellect first appealed to the **Patent Trial and Appeal Board** (PTAB), which ruled that ODP is based on the expiration date of the challenged patent including term added by PTA. The PTAB, therefore, found that each of the challenged claims of the subject patents was invalid due to ODP because each of the patents expired later than the '036 patent due to PTA. The PTAB found support for its decision in Section 154(b)(2)(B), concluding that by linking PTA to the filing of a terminal disclaimer, the statute contemplated that the award of PTA was subject to ODP, unlike PTE under Section 156, which does not have a comparable provision.

On appeal to the Federal Circuit, Cellect argued that the PTAB erred in basing ODP on the expiration date of a patent after adding PTA, and that patents awarded PTA should be treated in the same way as patents awarded PTE because both are statutorily mandated additions to patent term. The Federal Circuit, however, in an opinion by Judge Lourie and joined by Judges Dyk and Renya, affirmed the PTAB's findings on all grounds, pointing out that the statutory provisions for PTE and PTA have different rationales. (See Legal Update, Federal Circuit Clarifies Obviousness-Type Double Patenting's Application to Patents Extended Through PTA.)

The Federal Circuit concluded 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." The court further distinguished PTA from PTE, both having an "independent framework established through an independent statutory schema," finding that "nothing in the PTA statute to suggest that application of ODP to the PTA-extended patent term would be contrary to the congressional design." (*In re Cellect*, 81 F.4th at 1226-27.)

Although the USPTO examiner of Cellect's patent applications had not issued any ODP rejections during prosecution (and therefore no terminal disclaimers had been filed), the Federal Circuit held that ODP is determined based on a patent's expiration date after PTA has been added. The court placed the onus on patent applicants to anticipate ODP even when the patent examiner does not raise it: "Cellect had the opportunity to file terminal disclaimers during prosecution, even in the absence of an ODP rejection, yet it declined to do so." (*In re Cellect*, 81 F.4th at 1231.)

The Federal Circuit was also not persuaded by Cellect's argument that there was no "gamesmanship" on its part, noting the USPTO's position with apparent agreement that "the mere presence of an unjustified extension is sufficient for the Board to find that claims are unpatentable under ODP." The court observed that the '036 patent was "the only patent in the family that did not receive PTA" and that "any extension past" the expiration of the '036 patent "would, in effect, confer on the reference claims of the '036 patent PTA to which they were not entitled." The court made a further observation 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." (*In re Cellect*, 81 F.4th at 1229-30.)

Despite **amicus** support for Cellect's petition for full Federal Circuit review of the initial panel decision, the court denied en banc rehearing on January 19, 2024. On May 20, 2024, Cellect filed a petition for a writ of certiorari with the US Supreme Court (Petition for a Writ of Certiorari, *Cellect LLC v. Katherine K. Vidal, Director, USPTO*, No. 23-1231, 2024 WL 2379649 (May 20, 2024)).

Cellect's certiorari petition principally argued that the Federal Circuit had "turned a congressional 'guarantee' of a minimum effective patent term on its head by converting that guarantee into a threat to the validity or term of countless continuation patents." (Petition, *Cellect LLC*, 2024 WL 2379649, at *12). The question presented to the Court was "[w]hether a patent procured in good faith can be invalidated on the ground that statutory Patent Term Adjustment, which requires lengthening a patent's term to account for time lost to Patent and Trademark Office delays, can trigger a judge-made patent invalidation doctrine" (Petition, *Cellect LLC*, 2024 WL 2379649, at *1). Seven amicus briefs from companies, industry groups, and bar associations have supported Cellect's certiorari petition.

The USPTO responded on August 21, 2024, following the Federal Circuit's August 13, 2024 *Allergan* decision, and was supported by one amicus brief filed by a company (Brief for Respondent in Opposition, *Cellect LLC*, No. 23-1231, 2024 WL 3914202 (Aug. 21, 2024)).

District Court Decisions in Allergan and Acadia Interpreting In re Cellect

Since the *Cellect* decision, two judges in the US District Court for the District of Delaware have interpreted it differently concerning whether an earlier-filed patent application that receives PTA can be invalidated by a later-filed continuation application that will expire earlier because it receives less or no PTA.

In *Allergan USA, Inc.*, Judge Andrews held that a first-filed patent having PTA was invalid for ODP based on later-filed continuation patents set to expire earlier because they did not receive PTA. The patent owner, Allergan, argued that the case was distinguishable from *Cellect* because the patent having PTA was the first-filed, first-issued patent. However, Judge Andrews read *Cellect* as "holding that ODP depends solely on patent expiration dates and should not [be] influenced by equitable concerns. 'Any extension past [the ODP reference patent's expiration] date constituted an inappropriate timewise extension for the asserted claims of the challenged patents.'" The court further found that "*Cellect* recognizes no exception to the rule it announced, whether for first-filed, first-issued claims or otherwise." (*Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd*, 694 F. Supp. 3d 511, 540 (D. Del. 2023).) On appeal, the Federal Circuit reversed (see The Federal Circuit's Allergan Decision Provides Some ODP Protection).

By contrast, in *Acadia Pharm. Inc.*, Judge Williams found that "the purpose of [the obvious-type double patenting ("OTDP")] doctrine is to 'prevent a patent owner from extending his exclusive rights to an invention through claims in a later-filed patent, that are not patentably distinct from claims in the earlier-filed patent'" (*Acadia Pharm. Inc. v. Aurobindo Pharm. Ltd.*, 2023 WL 8803448, at * 7-8 (D. Del. Dec. 13, 2023) (citing *Procter & Gamble Co. v. Teva Pharms USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009))).

The court granted patent owner Acadia's motion for summary judgment that its US Patent No. 7,601,740 (the '740 patent) was not invalid for ODP. It denied defendant's corresponding summary judgment motion of invalidity on two alternative grounds:

- The later-filed, earlier-expiring patent asserted as the basis for ODP was not a proper reference patent against the earlier-filed, later-expiring '740 patent.
- The statutory safe harbor of 35 U.S.C. § 121 applied.

Regarding ODP, Judge Williams found that "[i]f a later-filed patent is used as a reference, the logic and purpose of OTDP is flipped on its head: rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent" (*Acadia Pharm. Inc.*, 2023 WL 8803448, at * 11).

Judge Williams acknowledged Judge Andrews's *Allergan* decision, recognizing that "another court in this district has interpreted *Cellect* to cut off OTDP even for first-filed, first-issued patents." However, the court concluded that "the *Allergan* Court had

not taken into proper consideration the language in *Cellect* stating that "[w]e 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." Accordingly, Judge Williams wrote that "the Court does not find itself persuaded by *Allergan*." (*Acadia Pharm. Inc.*, 2023 WL 8803448, at * 7.)

Acadia raises the additional complexity that the '740 challenged patent had both PTA and PTE. The USPTO had granted the '740 patent 980 days of PTA due to USPTO delays during examination and, in addition, 1,315 days of PTE due to FDA delays in approving Acadia's Nuplazid® drug product. The combination of PTA and PTE resulted in an expiration date of April 29, 2030, compared with the reference patent's January 15, 2024, expiration date.

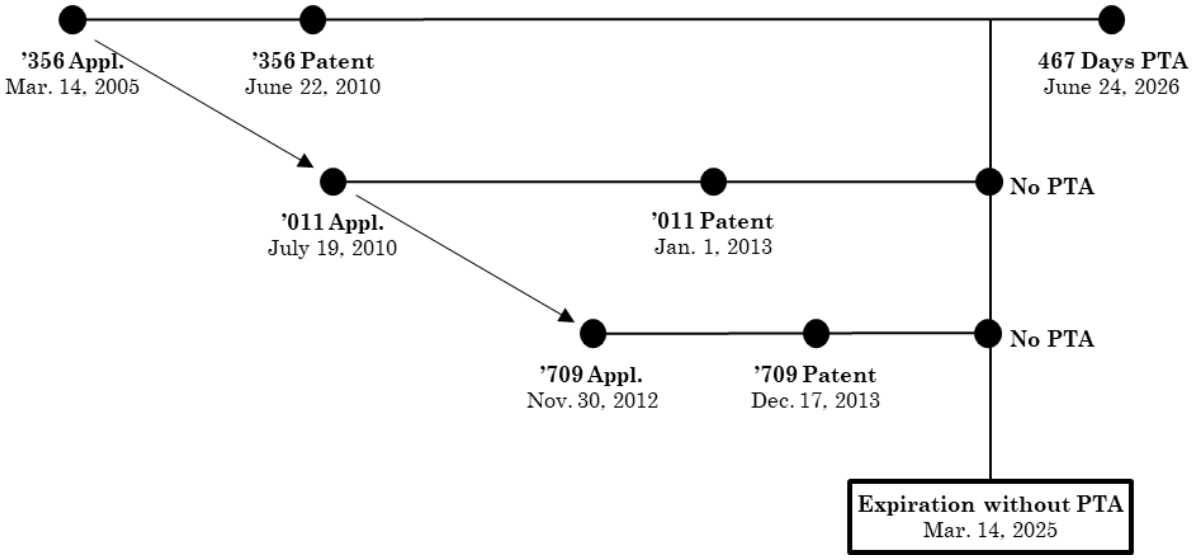
Placed in the uncertain position of not knowing the final outcome of the ODP challenge, Acadia filed a request with the USPTO seeking acceptance of a "contingent" terminal disclaimer for the '740 patent that would only become effective if it ultimately lost on the ODP issue and asked that the USPTO decide its request before the expiration of the reference patent on January 15, 2024. The USPTO denied Acadia's request, ruling that terminal disclaimers could not be made contingent on a future event. While Acadia prevailed at the district court in defeating the ODP challenge, the district court decision is currently on appeal.

The Federal Circuit's Allergan Decision Provides Some ODP Protection

On August 13, 2024, the Federal Circuit issued its decision in *Allergan USA, Inc.*, which reversed the district court's judgment that a first-filed, first issued patent receiving PTA was invalid for ODP based on later filed, later-issued continuation patents that would expire earlier because they did not receive PTA. As with *In re Cellect*, Judge Lourie authored the opinion and was joined by Judges Dyk and Renya. (*Allergan USA, Inc.*, 2024 WL 3763599, at *6; see Legal Update, First-Filed, First-Issued, Later-Expiring Claim Not Invalid Under ODP: Federal Circuit.)

At issue in *Allergan* was a family of patents directed to eluxadoline, the active compound in Allergan's Viberzi® drug product. The first filed, first issued patent in the family, US Patent No. 7,741,356 (the '356 patent) was filed March 14, 2005, and issued June 22, 2010, with 1,107 days of PTA. All but 467 days of this PTA were disclaimed. The '356 patent claimed eluxadoline in a group of eight compounds. The same patent family included (i) US Patent No. 8,344,011 (the '011 patent) which was filed July 19, 2010 claiming priority to the application for the '356 patent and issued January 1, 2013 without any PTA, and (ii) US Patent No. 8,609,709 (the '709 patent) which was filed November 30, 2012 claiming priority to the application for the '356 patent and issued December 17, 2013 without any PTA. The '011 patent claimed a method of treatment by administering eluxadoline or one of seven other compounds and the '709 patent claimed the eluxadoline compound directly. Due to the 467 days of PTA, the '356 patent is set to expire June 24, 2026 whereas the '011 and '709 patents, without any PTA, will expire March 14, 2025. Allergan conceded that the claims of the '356 patent were not patentably distinct over the reference claims of the '011 and '709 patents. (*Allergan USA, Inc.*, 2024 WL 3763599, at *1-2.)

The Federal Circuit's opinion included the following diagram:



In reversing the district court, the Federal Circuit held that "a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date." The Federal Circuit concluded that the district court failed to appreciate that "*Cellect* answered a different question than that at issue here . . . namely, under what circumstances can a claim properly serve as an ODP reference." The court stated that *Cellect* was only controlling "to the extent that it requires us to consider, in our ODP analysis, the '356 patent's June 24, 2026 expiration date (the expiration date after the addition of PTA), not the March 24, 2025 [sic, March 14, 2025] expiration date that it would have shared with the '011 and '709 patents in the absence of a PTA award." The Federal Circuit disagreed with the patent challenger's position that in *Cellect*, "an earlier-filed, earlier issued, later-expiring claim can be invalidated for ODP based on a later-filed, later-issued, earlier-expiring claim," because "*Cellect* did not involve a first-filed, first-issued patent." Seemingly more important to the Federal Circuit was that the patent owner in *Cellect* "did not challenge whether the reference claims used to invalidate the asserted claims were proper ODP reference claims" and therefore "under the principle of party presentation, the court did not consider that issue." (*Allergan USA, Inc.*, 2024 WL 3763599, at *6-7, n. 6.)

On the merits, the Federal Circuit in *Allergan* emphasized that "the fact that the '356 patent expires later is of no consequence here because it is not a '*second*, later expiring patent for the same invention.'" The court thus held that "a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date." The court additionally observed, "[t]o hold otherwise—that a first-filed, first-issued parent patent having duly received PTA can be invalidated by a later-filed, later-issued child patent with less, if any, PTA—would not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA." (*Allergan USA, Inc.*, 2024 WL 3763599, at *7-8.)

The USPTO filed its response to Cellect's certiorari petition on August, 21, 2024, after the Federal Circuit's *Allergan* decision. The USPTO's brief supported the holding and reasoning of the Federal Circuit's *Cellect* decision in all respects and asserted that the Federal Circuit's *Allergan* decision resolved the concerns regarding ODP challenges to "a first-filed, first-issued, later-expiring claim" based on "a later-filed, later-issued, earlier expiring reference claim having a common priority date" (Brief for Respondent in Opposition, *Cellect LLC,* No. 23-1231, 2024 WL 3914202, at *17-18).

Practical Considerations for Contending with *In re Cellect*

In *Allergan*, the Federal Circuit apparently dispelled the most extreme interpretation of its earlier *Cellect* decision – that a first-filed patent awarded PTA could be invalidated for ODP by a child patent that expires earlier because it received less or no PTA.

Remaining an open question on Cellect's petition for writ of certiorari to the Supreme Court is whether a child patent expiring later than a parent due to PTA should also be immune from an ODP challenge. In addition, the Federal Circuit has yet to decide the *Acadia* appeal, which will give the court another opportunity to refine its views on the impact of PTA on the ODP doctrine.

If the *Allergan* decision holds following the anticipated Federal Circuit decision on the *Acadia* appeal and the possible intervention of the Supreme Court in *In re Cellect*, there is still the ODP risk to PTA awarded to child applications which would cause the resulting patents to expire later than their parents. In such cases, the patent examiner may not issue an ODP rejection, as in *Cellect*, leaving the patentee with the uncertainty of a possible future ODP challenge.

Applicants who file continuation applications that receive PTA may feel compelled to file preemptive terminal disclaimers before the expiration of related, earlier-expiring patents, even when the USPTO did not raise ODP during examination. The *Cellect* court was unmoved by the fact that the examiner had not raised ODP during prosecution, which could have caused the filing of a terminal 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." (*In re Cellect*, 81 F.4th at 1228.) However, if the reference patent has expired, it will be too late to file a terminal disclaimer and the innovator risks losing the patent, including any PTA. Patentees need to be cautious of this result when chancing a later ODP determination.

Moreover, a recently proposed USPTO rule would tie patents connected by a terminal disclaimer together. Under the proposed rule, if one claim in one patent is found invalid as anticipated or obvious, all connected patents would be unenforceable. (See Legal Update, USPTO Proposes New Terminal Disclaimer Rules to Combat Nonstatutory Double Patenting.)

Even after *Allergan*'s clarification of *Cellect*, patent owners with later-filed child patents that expire later than their parents due to PTA face the uncertainty that ODP may be raised long after the patents have issued, including during litigation or post-grant USPTO proceedings. The risk exists even if the patent owner has a meritorious response to a potential ODP challenge and if the patent owner overcame an ODP rejection during prosecution.

Potential Patent Applicant and Owner Strategies After the Cellect Decision

Because uncertainty remains after *Allergan* on the impact of PTA on ODP, patent applicants and owners will need to address potential new ODP concerns when applications within a patent family receive different amounts of PTA, which would cause the resulting patents to have different expiration dates.

Most immediately, patent owners should conduct a detailed audit of their patent portfolios and identify patents and applications that may be subject to an ODP challenge due to different expiration dates based on PTA awards. It may be prudent for patent applicants and owners to preserve their positions and not disclaim PTA as long as the potential reference patent is not due to expire in the near term. In this way, PTA can be maintained if the Federal Circuit or the Supreme Court provides greater clarity on when an award of PTA can form a basis for ODP.

Patent owners and applicants may consider several courses of action, depending on the specific situations they face, including:

- Seeking to prosecute all important claims in a first-filed application to minimize the risk of different patent family members expiring on different dates due to PTA awards.

- In co-pending applications that may be the subject of a provisional ODP rejection, consolidating claims into one application to avoid the possibility of one of the applications receiving more PTA than the other.

- Seeking to provoke a restriction requirement to take advantage of the safe harbor provisions of 35 U.S.C. § 121 (see Practice Note, Double Patenting: Divisional Application Double Patenting Safe Harbor).

- Because terminal disclaimers cannot be withdrawn after issuance, withdrawing a terminal disclaimer before a patent issues to maintain a challenge to an ODP rejection and preserve PTA (see Practice Note, Patent Correction: Statutory and Terminal Disclaimers, Certificates of Correction, and Inventorship: Effect and Limitations of a Terminal Disclaimer).

- Filing a reissue application for a patent having PTA to add claims to additional aspects of the invention rather than pursue that claim coverage in a continuation application. However, broader claims cannot be added in a reissue application more than two years after issuance, and all claims of a reissue application are subject to examination (see Practice Note, Patent Correction: Reissue Applications).

- Appealing ill-founded ODP rejections rather than filing terminal disclaimers, although the appeal process in the USPTO is lengthy.

While the above list is non-exhaustive, it may provoke patent practitioners to develop additional strategies to preserve the important benefits of PTA in the face of the fallout from *In re Cellect*.

