"IN RE CELLECT POSES AN OBVIOUS DILEMMA"

By Sommer Zimmerman, Ph.D[1]

Background

In August 2023, the Federal Circuit in *In re Cellect* held that in evaluating unpatentability for obviousness-type double patenting (ODP) of a patent that has received patent term adjustment (PTA), the relevant date is the reference patent's expiration date after PTA is added.[2] Cellect promptly filed a petition for rehearing *en banc*. A flood of amicus briefs in support of a rehearing ensued, filed by key players in the pharmaceutical industry including AbbVie, Merck, Novartis, AstraZeneca, and Johnson & Johnson, among others. Although the petition was ultimately denied, this case has ongoing implications. These implications, together with additional cases that may yet be impactful, are summarized here.

ODP always trumps PTA

35 U.S.C. § 154(b) provides three bases by which patent term can be adjusted due to various delays in prosecution. Specifically, these bases include (1) if the USPTO fails to take certain actions within certain time periods ("A" delay); (2) if the USPTO fails to conclude prosecution within three years of the actual filing date ("B" delay); and (3) if issuance is delayed due to secrecy orders, derivation proceedings, or successful appellate review ("C" delay). The statute further clarifies 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" (emphasis added). Thus, the statute clearly imposes a limitation by which the presence of a terminal disclaimer voids any additional term that may be granted by PTA.

In *Cellect*, however, a terminal disclaimer was not present in any of the patents at issue. Yet, the Federal Circuit deemed this essentially irrelevant. According to the *Cellect* panel, "ODP for a patent that has received PTA, *regardless [sic] 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" (emphasis added).[3]

The *amici curiae* briefs were adamant that the position of the panel is a clear misinterpretation of Congressional intent, noting that the "reference to terminal disclaimers [in Section 154(b)]

---

[1]Sommer Zimmerman, Ph.D., is an associate of Ballard Sparhr and works in the office located in Atlanta, Georgia, U.S.A. (https://www.ballardspahr.com/People/Attorneys/Z/Zimmerman-Sommer; https://www.ballardspahr.com/).

[2] See also *Gilead Sciences, Inc. v. Natco Pharma Limited*, 753 F.3d 1208 (Fed. Cir. 2014), which held that a later-granted patent can render an earlier-granted patent invalid for ODP. Neither of the patents at issue in *Gilead* received PTA.

[3] *In re Cellect*, 81 F.4th 1216, 1229 (Fed. Cir. 2023).

made clear that Congress specifically considered ODP in establishing PTA."[4, 5] Under the panel's interpretation, however, the presence of ODP in and of itself is sufficient to null any additional term awarded by PTA. The presence – or absence – of a terminal disclaimer is inconsequential.

Patents expiring later due to PTA are always susceptible to challenge in view of earlier-expiring obvious variant patents

It is well established that the judicially created doctrine of ODP is firmly rooted in equitable considerations, focusing on preventing patentees from obtaining an unjustified extension of patent term.[6] In this way, the doctrine secures against improper extensions of term due to "gamesmanship" of the patentee.[7]

The decision in *Cellect* makes clear that although ODP outweighs PTA, and although equity is yet a component of ODP, it is not a component of PTA. Simply stated, an equitable analysis is not sufficient to evaluate a patentee's entitlement to their PTA award. "[T]he risk remains for multiple assignees to seek past damages."[8] Moreover, "good faith during prosecution does not entitle [Cellect] to a patent term to which it otherwise is not entitled."[9] Rather, additional concerns such as patent expiration dates must be contemplated.[10] What is not clear, however, is whether good faith remains a part of the analysis at all.[11]

Moreover, it does not matter if the reference patents are in the same patent family and, therefore, subject to examination by the same patent Examiner, nor does it matter if the Examiner raises a rejection based on ODP or not.[12] There is no presumption that the reference patent was considered. Indeed, the *Cellect* panel suggests quite the opposite, noting

[4] Brief of *Amici Curiae* Abbvie Inc. and Innovation Alliance in Support of Appellant on Rehearing (November 27, 2023).

[5] See also Brief of *Amicus Curiae* American Intellectual Property Law Association in Support of Appellant's Petition for Rehearing En Banc (November 22, 2023) (stating that the statute "provides only that *if* a terminal disclaimer has been filed, PTA cannot extend a patent's expiration beyond the date specified in the disclaimer").

[6] See, *e.g.*, *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985) and *In re Schneller*, 397 F.2d 530 (CCPA 1968).

[7] See, *e.g.*, *Abbott Labs v. Lupin Ltd.*, 2011 U.S. Dist. LEXIS 53846 (D. Del. 2011) and *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355 (Fed. Cir. 2018).

[8] *Cellect* at 1230.

[9] Id.

[10] See also *Gilead*.

[11] See, *e.g.*, *Cellect* Rehearing Petition at page 14 ("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").

[12] *Cellect* at 1228 (irrespective of whether the examiner "had the opportunity, and perhaps the obligation, to reject certain of the pending claims" for ODP, so, too, Cellect had the opportunity to file a terminal disclaimer).

that 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" (emphasis added).[13]

Thus, in families for which multiple patents exist, if any one of those patents receives PTA, the PTA itself is sufficient to put that patent at risk for challenge due to ODP.

The risk imposed by an award of PTA is invalidation of the patent in its entirety

Upon affirming the decision of the USPTO Patent Trial and Appeal Board that the claims at issue are unpatentable for ODP, the *Cellect* panel further affirmed that the Cellect patents themselves were invalid because of ODP and not only in respect of the additional PTA term. Specifically, the panel stated, "invalidation of only the adjustment would be tantamount to granting a retroactive terminal disclaimer" and "would in effect give Cellect the opportunity to benefit from terminal disclaimers that it never filed."[14]

This ruling makes evident that an award of PTA to one patent amongst a family of others brings with it not only a risk that the additional term (*i.e.*, the PTA award) can be lost but a risk that the patent itself may be invalidated – a result that could have devastating consequences to a damages award. If a disclaimer is filed in the challenged patent before the reference patent expires, a patentee may yet be entitled to truncated damages (*i.e.*, damages for the original patent term minus the PTA award).[15] If, however, the reference patent has expired such that the patentee no longer has the option to file a terminal disclaimer, the challenged patent may be subject to invalidation, in which case the entire damages award would be forfeit. As Intellectual Property Owners Association (IPO) puts it, "the Congressionally-authorized grant of patent term adjustment is a poison pill that invalidates the patent in its entirety."[16, 17]

Additional recent ODP cases worth noting

Allergan v. MSN

Allergan holds a New Drug Application for Viberzi® (eluxadoline), which is approved for the treatment of irritable bowel syndrome with diarrhea. Both Sun and MSN submitted Abbreviated New Drug Applications to market and sell generic versions of Viberzi® and also filed Paragraph IV certifications for certain patents owned by Allergan, including the '356

---

[13] *Cellect* at 1231.

[14] Id.

[15] Under 35 U.S.C. § 286, a patentee cannot recover damages for infringement committed more than six years before the infringement complaint was filed.

[16] Brief for *Amicus Curiae* Intellectual Property Owners Association in Support of Appellant (November 27, 2023).

[17] But see *Boehringer Ingelheim International GmbH v. Barr Laboratories, Inc.*, 592 F.3d 1340 (Fed. Cir. 2010), noting that a retroactive terminal disclaimer can yet be filed after patent grant to overcome an ODP rejection *so long as* the reference patent is still pending ("a patentee may file a disclaimer after issuance of the challenged patent or during litigation, even after a finding that the challenged patent is invalid for obviousness-type double patenting"). See also *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).

patent.[18] Allergan filed suit against Sun and MSN alleging infringement. In response, Sun argued, *inter alia*, that the asserted claim of the '356 patent is invalid for ODP.

The '356 is one of three patents from the same family. Although the '356 patent issued before the other two patents, it expired after them due to PTA. In analyzing the facts of the case, the district court purports to "apply the rule dictated in *In re Cellect*," stating that "ODP depends solely on patent expiration dates and should not be influenced by equitable concerns."[19] "The 'first-filed, first-issued' distinction is immaterial."[20]

Acadia Pharm. v. Aurobindo Pharma

Acadia Pharmaceuticals, Inc. owns several patents directed to pimavanserin, which is the active ingredient in Nuplazid®. Nuplazid® is approved for the treatment of hallucinations and delusions associated with Parkinson's disease. MSN filed an Abbreviated New Drug Application for a generic version of Nuplazid® that was since approved by the FDA. Acadia filed suit against MSN.

Both parties filed cross-motions for summary judgment regarding the validity of the '740 patent[21] for ODP over the '271 patent.[22] The '740 patent issued on October 13, 2009 and received grants of both PTA and PTE. The '271 patent was filed after the '740 patent issued, and claims priority to a series of continuation applications reaching back to a divisional of the '740 patent.

The key issue was whether the '740 patent is entitled to the benefit of the safe harbor provision of 35 U.S.C. § 121[23] even though the '271 patent was not filed before the '740 patent issued. The district court found that the requirement that the application be "filed before the issuance of the patent" does not apply whereas here, the challenged patent issued from the original application. Thus, the '740 patent is protected by the safe harbor provision.

The court also addressed the question of whether the '271 patent was a proper ODP reference against the '740 patent. Although noting that the *Allergan* court interpreted *Cellect* as cutting off ODP even when the patent is the first-filed and first-issued patent in its family, the *Acadia* court disagreed, noting that "[i]f a later-filed patent is used as a reference, the logic and purpose of

[18] US 7,741,356

[19] *Allergan USA, Inc. v. MSN Labs Priv. Ltd.*, 2023 U.S. Dist. LEXIS 172641, at *60.

[20] Id.

[21] US 7,601,740

[22] US 9,566,271

[23] The § 121 safe harbor provision states: "A patent issuing on an application with respect to which a requirement for restriction … has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application."

ODP is flipped on its head."[24] Pointing to statements by the Federal Circuit in *Cellect* that ODP only applies to "later-filed obvious variations of earlier-filed, commonly owned claims," the *Acadia* court noted that *Cellect* did not challenge the availability of the reference patents for an ODP challenge, but instead focused on the impact of ODP on a PTA award. Thus, the availability of the reference patents was not considered in *Cellect*. As such, the court concluded that the '740 patent claims, which were filed before the '271 patent claims, were entitled to their full term.

Key Takeaways

The effects of the *Cellect* decision need not have significant impacts on day-to-day patent filing strategies. To the extent available, divisional filing practice should be leveraged, but continuation filings should still be utilized as well. Terminal disclaimers need not be proactively filed, and PTA should still be accepted. Indeed, if a patentee has no plans to enforce their patent, no further action or consideration in this regard need be taken. If, however, a patentee *does* plan to enforce their patent, this is where the crucial distinction lies.

For high value patents (*i.e.*, patents that are likely to be enforced), US family members should be monitored, and, as a family member nears expiration, the remaining family members should be proactively evaluated for ODP issues. If one is found, the patentee is advised to file a terminal disclaimer to moot the issue before that family member expires to ensure that the entire patent term is not in jeopardy.

[24] *ACADIA Pharm. v. Aurobindo Pharma.*, C. A. 20-985-GBW (D. Del. Dec. 13, 2023)