No. 22-1293

In the
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 and 90/014,457.

AMICI CURIAE BRIEF OF BIOTECHNOLOGY INNOVATION ORGANIZATION AND BIOCOM CALIFORNIA IN SUPPORT OF PETITION FOR REHEARING *EN BANC*

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1293

Short Case Caption In Re: Cellect, LLC

Filing Party/Entity Biotechnology Innovation Organization

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Date: 05/23/2022

Signature: /s/ Kevin E. Noonan

Name: Kevin E. Noonan

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.
☐ None/Not Applicable	☑ None/Not Applicable	☑ None/Not Applicable
Biotechnology Innovation Organization		

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4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1293

Short Case Caption In Re: Cellect, LLC

Filing Party/Entity Biocom California

Instructions:

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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 11/27/2023

Signature: /s/ Kevin E. Noonan

Name: Kevin E. Noonan

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Biocom California		

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☑ No ☐ N/A (amicus/movant)

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☑ None/Not Applicable ☐ Additional pages attached

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INTEREST OF *AMICI CURIAE*[1]

The Biotechnology Innovation Organization ("BIO") is the world's largest biotechnology trade association, providing advocacy, development, and communications services for over 1,200 members worldwide. BIO members—most of whom are small, emerging companies—are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

Biocom California ("Biocom") is the advocate for California's life science sector. With more than 1,700 members, including biotechnology, pharmaceutical, medical device, genomics, and diagnostics companies, as well as research universities and institutes, Biocom drives policy initiatives to positively influence the state's life science community.

Amici express no opinion on the ultimate validity of the patents at issue in this appeal but submit this brief in the hope that it will assist the Court in the orderly development of the law of obviousness-type double patenting. This brief reflects the

[1] No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than *amici*, their members, or counsel contributed money intended to fund preparing or submitting the brief. Consent has been sought from each party, none of whom opposed the filing of this brief. Fed. R. App. P. 29(a)(4)(E).

prevailing views of *amici*'s members[2], but not necessarily the individual views of any particular member.

REASONS FOR GRANTING REHEARING *EN BANC*

This case presents a question of exceptional importance that merits *en banc* reconsideration (Fed. Cir. R. IOP 13): whether the judicially created doctrine of obviousness-type double patenting ("ODP") should be applied after application of patent term adjustment ("PTA"), thereby raising questions about the equitable underpinnings of the doctrine and introducing unpredictability for patent applicants, patentees, patent office personnel, and the public.

I. The Equitable Underpinnings of Obviousness-type Double Patenting Weigh Against an Inflexible Application of the Doctrine

ODP is a judicially created equitable doctrine, intended to keep patentees from obtaining *unjust* time-wise extensions of patent term by manipulating (or "gaming") the patent system. *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013); *see also Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014). The doctrine arose when patents had a term of 17 years from issuance. 35 U.S.C. § 154(c)(1). Since the adoption of the Uruguay Round Agreements Act, patent terms are 20 years from their effective filing date. 35 U.S.C. § 154. This change substantially eliminated manipulation of term by the patentee for patents in the same

[2] https://www.bio.org/bio-member-directory; https://www.biocom.org/members/.

family (*i.e.*, that have the same effective filing date) having claims that are patentably indistinct. Statutorily mandated PTA, based on United States Patent and Trademark Office ("USPTO") delays in reviewing patent applications, patent applications, was introduced by the American Inventors Protection Act. Congress expressed its intent that PTA would give patentees a patent term substantially equivalent to prior law (*i.e.*, 17 years). H.R. Rep. 106-287(I) (1999) at *51. The panel's evaluation of the interplay between ODP and PTA in the present case is inconsistent with the purpose of both.

The panel decision in this case wrongly concludes that any time-wise extension of term for one patent over another in the same patent family solely as a result of PTA is "unjustified." But Congress said the opposite in mandating that patent applications, without exceptions, that are delayed in examination by the USPTO's actions have their terms adjusted upon issuance to account for the delay and loss of effective patent term. PTA is based on the timing of actions or inactions by the USPTO and can only be decreased—and not increased—by the actions or inactions of the patent applicant. Indeed it is hard to imagine, absent error in the PTA calculation, how a grant of PTA can ever be "unjustified."

The panel's ODP analysis fails to correctly address the question of whether the "time-wise extension of the patent term" is "unjustified." *See In re Hubbell*, 709 F.3d at 1145. The "unjustified" element of the ODP analysis is key, as it highlights

the doctrine's equitable nature. The panel's opinion gives short shrift to the equities here, basing its analysis entirely on two issues: the scope of the claims (*i.e.*, whether they are patentably distinct) and the expiration date, *even though* that date only varies because of the grant of a statutory PTA. The equitable nature of the ODP doctrine and its application requires attention to the facts and circumstances of each case thereby leaving more room to craft remedies that are fair and "just" under the circumstances. Yet the panel decision, at least on its face, equally impacts applicants that engaged in very different conduct – those with many overlapping continuing applications as well as those with potentially just one; the diligent as well as the careless ones; the well-intentioned as well as the irresponsible ones. And at least one district court interpreting *Cellect* found that the facts (*i.e.*, the filing and issuance dates) are now "immaterial" in assessing ODP. *See Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd*., No. CV 19-1727, 2023 WL 6295496, at *21 (D. Del. Sept. 27, 2023) (stating that "*In re Cellect* recognizes no exception to the rule it announced, whether first-filed, first-issued claims or otherwise").

The *en banc* Court can now address this important question and clarify application of the ODP doctrine when the expiration dates of two patents differ *only* due to PTA, specifically, whether a first-to-expire patent with the same effective filing date can be a reference for determining ODP, regardless of the equities associated therewith. The panel's opinion constitutes a significant departure from

the prior case law and the importance of the equitable considerations to the application of ODP. *See, e.g.*, *In re Schneller*, 397 F.2d 350, 355 (CCPA 1968).

This court should not foreclose the possibility that differently situated and differently acting applicants may fairly need to be treated differently under a judicial ODP analysis. *C.f.* M.P.E.P. § 804(II)(B)(6) (stating that "[e]ach double patenting situation must be decided on its own facts."). For example, prosecuting claims in a continuation application that are of broader scope than those allowed in an initial patent issued from the same patent family presents a common practice in patent prosecution and exhibits no indication of gamesmanship. On the other hand, there might be instances where an applicant strategically seeks to exploit inefficiencies in the USPTO for no apparent purpose other than to secure a longer PTA. An equities analysis that accounts for specific applicant conduct should be part of any ODP determination because the equities are part and parcel of determining the justification, or lack thereof, of any time-wise extension of patent term. The USPTO's grant of a statutorily mandated PTA that creates a variance in expiration dates of related patents, without more, should neither be deemed unjust nor be a basis for invalidating patent claims.

II. The Panel's Decision Introduces Significant New Uncertainties into Patent Terms and Prosecution

The changes that the panel's decision creates will be dramatic and will reverberate to multiple areas of patent practice. It will impact continuation practice

– filings that are authorized by statute – and require much more frequent use of terminal disclaimers. And perhaps most significantly, the panel decision puts in jeopardy patents with terms adjusted as required by Congress if one or more continuation applications issue with no or different amounts of PTA. This uncertainty impacts many issued patents, the owners of which have made investment decisions based on PTA-adjusted patent terms, and as discussed below, applications to be examined in the future.

a. As a Result of the Panel's Decision, How and When an Examiner Assesses a Patent Application for Potential Obviousness-type Double Patenting Becomes Unmanageable

Prior to *Cellect,* examiners considered a patent application for possible ODP in view of previously filed applications. Under M.P.E.P. § 804(a), examiners based ODP determinations on the "patent term filing date" for patent applications. The "patent term filing date" is either the actual filing date of the application in question or the filing date of the earliest application for which the application claims the benefit of an earlier filing date.[3] M.P.E.P. § 804(I)(B)(1)(a) and M.P.E.P. § 804(I)(B)(1)(b). Crucially, the "patent term filing dates" of patent applications do not change during prosecution. Thus, prior to *Cellect,* it had been sufficient for an

[3] M.P.E.P. § 804(I)(B)(1)(a) lays out how to determine the "patent term filing date" of each application in question (in a provisional nonstatutory double patenting rejection) and M.P.E.P. § 804(I)(B)(1)(b) provides direction regarding how to handle the various combinations of dates. *Id.*

examiner to analyze a patent application for ODP *once* during an application's prosecution based on its patent term filing date.

The panel's decision shifts this paradigm because the amount of PTA impacts the relevant date for ODP analysis. *In re Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023). The "patent term filing date" is no longer a sufficient proxy when considering ODP. Instead, the patent expiration date must be considered in the ODP analysis. However, the patent expiration date is frequently a moving target during patent prosecution because accrued PTA is not fixed until a patent issues. *See* 35 U.S.C. § 154(b) and 37 C.F.R. § 1.703(a)(6). Post-*Cellect*, the status of whether an issued patent becomes subject to an ODP rejection can change during prosecution, leading to the absurd result that an examiner or the Patent Trial and Appeal Board would periodically have to reassess whether ODP should apply as additional PTA accrues (or dissipates, in the case of applicant delay). While the panel indicated that the examiner had "perhaps the obligation" to reject Cellect's claims for ODP during prosecution, *In re Cellect, LLC*, 81 F.4th at 1228, an examiner cannot issue a reliable rejection based on a yet-to-be-determined, still-shifting amount of PTA. The deserved amount of PTA can be indeterminate until a patent issues and, therefore, cannot be known by an examiner even when exercising perfect diligence. *See, e.g.*, 35 U.S.C. §§ 154 (b)(1)(A)(iv) and 154(b)(1)(B).

The burden this puts on patent prosecution becomes even more apparent when there are two (*or more*) co-pending applications. Co-pending applications having the same effective filing date can accrue PTA at different rates.[4] Consequently, at any given time, one of the applications may have more PTA, while thereafter the other application may have more PTA. Examiners would need to issue and then withdraw the same provisional ODP rejections multiple times in both applications (based on whichever application has more accrued PTA when that application was examined).

Thus, an applicant may file a terminal disclaimer during prosecution to obviate an ODP rejection which thereafter becomes unnecessary (*e.g.*, if the application ultimately has an earlier expiration date due to less PTA than a co-pending application). While such a situation might not shorten the term of the resulting patent, it would certainly inhibit a patentee's rights to otherwise separately alienate the patents in question based on the common ownership requirement of terminal disclaimers.[5] *See* 37 C.F.R. § 1.321(c).

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[4] As an example, Cellect's '742 Patent, '369 Patent, '036 Patent, '626 Patent, and '621 Patent were all, at one point in time, co-pending with one another, yet the accrued PTA for each of these patents varied wildly from 0 days to 759 days. *In re Cellect, LLC,* 81 F.4th at 1220.

[5] In light of the equitable underpinnings of ODP, see Section I above, it can at any rate be asked whether disclaimers of term and common ownership must always go hand in hand. It is, for example, not inconceivable that there might be instances where it would be fair to commit patentees to maintaining common ownership of related patents without necessarily wiping out patent term that was promised by statute and that accrued through no fault of the patentee.

While the panel decision suggested that terminal disclaimers are a readily available solution, *In re Cellect, LLC*, 81 F.4th at 1228, the consequences of that decision will invite additional unnecessary complications and often will not be a practicable approach. For one, under the panel's decision, the need for a terminal disclaimer and its scope will frequently become apparent only after prosecution is closed—an undesirable outcome given the USPTO's goal of issuing patent rights that are "robust and reliable" at the time of issuance. Instead of addressing ODP during prosecution, applicants may need to file terminal disclaimers in previously issued patents each time additional patents issue with differing amounts of PTA. This situation requires a patentee to promptly review its existing patents to identify any arguably related patent claims, compare the expiration dates (including PTA) in those related patents to the expiration date of the newly issued patent (including PTA), and then file terminal disclaimers in those that have a later expiration date—an unwieldy and inherently speculative exercise.

b. The *Cellect* Decision Dramatically Impacts a Wide Swath of Current and Future Patent Applications

The problems highlighted above are neither speculative nor duplicative of issues already present in the patenting process. With respect to all published U.S. applications filed in 2022 (138,873 applications), 32.7% were continuing applications, where shifting PTA can be particularly problematic for the reasons discussed above. Additionally, 8.2% of rejections issued by the USPTO in 2022

were ODP rejections, which are likely to increase under the panel's decision. Further, while cases like *Gilead* have held that later-issued, earlier-expiring patents can be used to invalidate earlier-issued, later-expiring patents, the panel's decision here goes further, because, among other issues, the *Gilead* court did not consider PTA or patents in the same family with the same effective filing date. *Gilead Scis., Inc.*, 753 F.3d at 1208. Hence, *Gilead* did not address how an ODP analysis could be impacted by a metric—PTA—that, by its very nature, is constantly in flux during prosecution. Instead, potential ODP of the patents in *Gilead* could still have been properly considered *only once* (had the respective examiners been timely notified of the existence of the other applications). *Id.* at 1210.

The ability of the public to make determinations about patent validity and term, meanwhile, would often be made far more difficult by the panel decision. Prior to *Cellect*, the public could analyze an issued patent to determine its validity and term (*e.g.*, by reviewing the prior art, specification, claims, and prosecution history). Now, however, such efforts are fraught with increased risk of error because a later-filed, later-issued patent having less PTA would invalidate the issued patent for ODP.

It will also become increasingly difficult to interpret and process terminal disclaimers associated with issued patents if, as is likely, the panel decision creates pressure to craft terminal disclaimers conditioned on future events. 37 C.F.R. §

1.321(b)(2) requires that a terminal disclaimer "specify the portion of the term of the patent being disclaimed." 37 C.F.R. § 1.321(b)(2). However, in order to protect validity, terminal disclaimers filed by patentees under the panel's decision may take the form of a tangle of hypothetical statements about what term is being disclaimed in the eventuality of potential future PTA determinations for yet-to-be-filed and/or issued patents. Even though the public might have access to the terminal disclaimers filed by patentees, they will have no assurance of the exact expiration dates of the associated patents.

Given the challenges above, it is unrealistic to expect the USPTO, applicants, and patentees to comprehensively and consistently address ODP based on constantly shifting PTA during prosecution, and ODP may simply become an increasingly popular way to invalidate patents *post hoc*, an outcome contrary to the equitable underpinnings of the ODP doctrine. H.R. Rep. 106-287(I) (1999) at *49.

CONCLUSION

For the above reasons, *amici* respectfully request that this Court grant Appellant's petition for rehearing *en banc*.

Respectfully Submitted,

November 27, 2023 /s/ Kevin Edward Noonan

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UNITED STATES COURT OF APPEALS
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