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

CORRECTED *AMICUS CURIAE* BRIEF OF MERCK SHARP & DOHME, LLC, ASTRAZENECA PHARMACEUTICALS LP, AMGEN INC., ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, INC. ("AUTM"), JOHNSON & JOHNSON, AND NOVO NORDISK INC. SUPPORTING REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CORRECTED CERTIFICATE OF INTEREST

Case Number 2022-1293, -1294, -1295, -1296

Short Case Caption In re: Cellect LLC

Filing Party/Entity Merck, Sharp & Dohme, LLC

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 11/28/2023

Signature: /s/ Howard W. Levine

Name: Howard W. Levine

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. ☑ None/Not Applicable	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
Merck, Sharp & Dohme, LLC		Merck & Co., Inc.
AstraZeneca Pharmaceuticals LP		AstraZeneca PLC
Amgen Inc.		None
Novo Nordisk, Inc.		Novo Nordisk A/S
Johnson & Johnson		None
The Association of University Technology Managers, Inc.		None

☐ Additional pages attached

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).

☑ None/Not Applicable ☐ Additional pages attached

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)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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TABLE OF ABBREVIATIONS

ODP	Obvious-type double patenting
PTA	Patent term adjustment
USPTO	United States Patent and Trademark Office
Patent Reform Hearing (statement of Hon. Dana Rohrabacher), at ___	Patent Reform and the Patent and Trademark Office Reauthorization for Fiscal Year 2000: Hearing on Serial No. 51 Before the Subcomm. on Courts and Intell. Prop. of the Comm. on the Judiciary House of Representatives, 106th Cong. (1999) (statement of Hon. Dana Rohrabacher, a Representative in the Congress from the State of California).
Italicized text	All emphases in this brief have been added unless otherwise noted.

I. STATEMENT OF INTEREST OF *AMICUS CURIAE*

Amici Merck Sharp & Dohme, LLC, AstraZeneca Pharmaceuticals LP, Amgen Inc., Johnson & Johnson, and Novo Nordisk Inc., are global leaders in developing pioneering medicines and are committed to improving the health and well-being of patients. As leading innovators, Amici have portfolios of patents protecting inventions arising from the discovery of new medicines and associated methods of treatment.

Amicus The Association of University Technology Managers, Inc. ("AUTM") is a non-profit leader that supports the development of academic research that drives innovation and focuses on advancing early-stage inventions. AUTM members manage technologies in research intensive industries, including computer hardware and software, novel materials and chemical products, and healthcare innovations, including pharmaceuticals and medical devices.

Amici collectively submit this brief supporting the request for en banc review of the Panel's decision in *In re Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023), which raises an issue of exceptional importance.[1] The Panel's decision involves ODP, which is a judge-made equitable doctrine. This Court has

[1] This brief was not authored in whole or in part by any party's counsel; no person or entity other than Amici or their counsel contributed financially to its preparation or submission; and Amici have no stake in the parties or case outcome.

unpredictably expanded ODP over the years, much to the consternation of the inventive community. The problems with ODP have culminated in the Panel's decision where the Panel has now expanded ODP to such an extent that it directly conflicts with the Patent Statute and this Court's precedent. The Panel's decision uses PTA—a statutory right—as a basis for ODP and consequently holds an otherwise valid patent invalid. Judge-made law, however, cannot be used to negate a statutory right, especially when that involves fundamentally misconstruing the PTA statute to support that unwarranted result. The Panel's decision hinders the ability of Amici to protect the full patent term for their innovations, and review is needed now to prevent the harm caused by the Panel's decision.

II. ARGUMENT

A. PTA Exists to Make Patentees Whole Due to USPTO Delay

Congress enacted PTA "[t]o account for any undue delays in patent examination caused by the [USPTO]" and "to compensate inventors for lost time on their patent term resulting from such delays." *Pfizer, Inc. v. Lee*, 811 F.3d 466, 468 (Fed. Cir. 2016). Congress enacted The Patent Guarantee Act when the U.S. patent system transitioned from a 17-year term from issuance (where USPTO delays did not impact the patent's term) to a 20-year term from the non-provisional effective filing date (where such delays did). The Patent Guarantee Act "essentially gives back to the non-dilatory patent holder . . . a guaranteed 17 year

patent term," such that the patent holder maintains the right to exclude the public from his invention for a limited time—a time that is guaranteed and clearly defined." Patent Reform Hearing (statement of Hon. Dana Rohrabacher) at 8. Thus, upon a showing of undue delay caused by the USPTO, a patent is statutorily entitled to PTA to restore its full term.

B. The Panel Misconstrued the PTA Statute

The Panel's decision, however, contravenes the statutory grant of PTA based on judicially-created ODP. The Panel has now held that when considering ODP in the context of PTA, one must consider the expiration date of the extended patent *after* the PTA has been added. *In re Cellect*, 81 F.4th at 1226. Applying the Panel's reasoning condones invalidation of patents whose terms differ only due to a statutory award of PTA. The Panel's decision may mean that because a parent patent is adjusted for USPTO delay, as awarded by statute, the expiration of child continuation applications can be used as an ODP reference against the originally-filed parent, resulting in holding the parent invalid over its later-filed child. The Panel's decision may also result in a child continuation with PTA being invalid over the earlier expiring parent. Judge-made law, however, cannot override statutory rights enacted by Congress. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1370 (Fed. Cir. 2018).

In *Novartis*, the issue was the application of ODP in the context of the patent term extension (PTE) statute (provides extension due to delays by the FDA), as opposed to PTA (provides extension due to delays by the PTO). *Id.* There, this Court reached the *opposite* conclusion of the Panel, refusing to allow an earlier expiring patent to render an earlier filed, earlier issued patent invalid based on patent term obtained by statutory extension (PTE). *Id.* The Court was right to reach this holding, as shown by decisions in other contexts that declined to use a judge-made doctrine to nullify statutory rights. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001) (in exercising equitable powers, a district court "cannot . . . override Congress' policy choice, articulated in a statute"); *United States v. Noland*, 517 U.S. 535, 543 (1996) (equitable subordination doctrine cannot contradict congressional choice); *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981) ("[F]ederal common law is 'subject to the paramount authority of Congress.'") (citation omitted); *Moragne v. States Marine Lines, Inc.*, 398 U.S. 375, 390-93 (1970) (federal common law must accord with statutory choices).

As its basis for distinguishing *Novartis*, the Panel interpreted the PTA statute to allow ODP to apply to patents whose terms differ solely due to PTA, but the Panel's statutory construction contradicts the plain words of the statute. The

statutory framework for PTA recognizes that patent term subject to a *pre-existing* disclaimer cannot be modified:

> 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). The statute only refers to disclaimers that have *previously* been filed, meaning that PTA cannot be awarded *after* the patent term has been disclaimed. The statute says nothing more, and it certainly does not require that a disclaimer *must* be filed when a patent term is appropriately extended by PTA where *no* disclaimer previously existed. And more so, it does *not* demand that PTA be retroactively disclaimed if later filed patents of differing scope or obvious variants issue within the same patent family.[2]

Logically, the purpose of Section 154(b)(2)(B) must be to prevent PTA beyond the date of a terminal disclaimer, where an applicant has intentionally pursued claims in an application that are not patentably distinct to get a longer term based purely on the different filing dates of the applications. Under circumstances where a terminal disclaimer already "has been" filed, whether during prosecution

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[2] In fact, PTA is calculated at a time different from when patentees elect terminal disclaimers and thus the ability to file a terminal disclaimer is not an adequate solution to the alleged problem.

or after, the statute states that a terminal disclaimer should operate to disclaim any PTA during the period of the term that has been disclaimed associated with the later-filed, later-expiring patent. This language could never have meant to apply to continuation applications because, absent a statutory extension like PTA, patents issuing from those applications always have the same term and that term should never be considered unjust. The Panel's construction is incorrect and warrants en banc review.

C. ODP is an Equitable Doctrine

ODP is rooted in equity, created to prevent patentees from obtaining a so-called "unjustified" extension of patent term based on a particular set of facts that seemed inequitable to courts. *See Immunex Corp. v. Sandoz, Inc*., 964 F.3d 1049, 1059 (Fed. Cir. 2020); *Novartis*, 909 F.3d at 1375. ODP evolved at a time when a patent's term was defined by its issuance date, i.e., 17 years from issuance. Under the current system, however, patent term is now defined by the effective filing date, i.e., 20 years from the filing of a non-provisional U.S. or PCT application. This change has mooted an applicant's ability to manipulate the expiration date of related patents by purposely delaying patent issuance.

Although patent term calculations changed under the new law, the equitable nature of ODP did not. In assessing whether ODP applies, the analysis should turn on the facts and equities of each case, including an assessment of the patent

applicant's conduct. The Panel's decision, however, seemingly dismisses such equitable considerations in using ODP to cut-off PTA due to an earlier expiring patent. *In re Cellect*, 81 F.4th at 1230. At least one district court has interpreted the Panel's decision to create a bright-line rule where the equitable considerations are "immaterial" to the ODP analysis. *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd*., No. CV 19-1727, 2023 WL 6295496, at *21 (D. Del. Sept. 27, 2023). There, the district court held a parent patent on the compound, which had been extended due to PTA, *invalid* in view of the prior expiration of a child continuation application reciting methods of administering that compound. *Id.* at *22. The district court stated it was foreclosed from considering any equitable considerations due to the Panel's decision. *Id.* This would be a significant change in the law that is contrary to precedent.

D. Amici Depend Upon Continuation Practice and Should Receive Statutory PTA Without the Risk of Invalidating Their Patents

One of the goals of the pharmaceutical and healthcare innovation industries is to discover new classes of potentially life-saving compounds and treatments. Because the patent system rewards the first-to-file and encourages the early disclosure of new inventions to the public,[3] an early patent application typically

[3] *See* The Patent Reform Act of 2007, S. Rep. 110-259 at 7 (2008) ("a first-to-file system encourages the prompt filing of patent applications").

covers the class of compounds and particular compounds of interest. Due to the rigorous written description and enablement requirements of 35 U.S.C. § 112, particularly in the case of pioneering patents claiming a genus or class, inventors are required to disclose their inventions in sufficient detail to show that they actually invented the full scope of the claimed genus. *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The U.S. Supreme Court recently confirmed in *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023), that the scope of the claims *must* be commensurate with the scope of enablement, i.e., the more one claims, the more the specification must teach.

Pharmaceutical companies are further forced to disclose the details of clinical work to the public very early on in the development process due to the early disclosure requirements imposed by the FDA. *See* 42 U.S.C. § 282(j). This in turn also forces companies to file patents capturing those innovations very early in the process—often before details of the particular embodiment that is ultimately commercially developed are known and years before FDA approval.

For example, a patent specification may disclose a new class of life-saving drugs, specific members of the class, their uses, delivery methods, manufacturing methods, dose ranges, and information about formulations for their delivery. The first prosecuted application in a family may claim the compound that is the focus of early pre-clinical and clinical development activities, or that is the most

commercially-viable embodiment at the time prosecution begins, leaving it to subsequent continuation applications to prosecute claims to later-developed compounds, indications, or methods of administration.

Further, continuation practice allows an applicant to agree to one set of claims and then continue to pursue claims of different wording, scope, and variation that were either not presented or were not agreed upon in the initial examination. Continuation practice thus promotes efficiency because it allows agreed upon claims to issue as patents, while areas that are not yet agreed upon become the subject of continuation practice. As a result, patents issue sooner, thereby providing the public with clarity on the protected subject matter.

Continuations can also be used to "refile an application containing rejected claims in order to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection." *Symbol Techs, Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir.), *amended on reh'g in part*, 429 F.3d 1051 (Fed. Cir. 2005). And unexpected results need not be available as of the original filing. *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011).

Continuations thus provide a critically important means for inventors to prosecute claims covering embodiments that appear commercially important at the time of filing while still preserving the possibility to later file continuation

applications as the technology develops. And the filing of continuation applications, claiming priority to an earlier application, is expressly allowed by statute. 35 U.S.C. § 120. Provided that the statutory requirements are met, continuation applications "shall have the same effect, as to such invention, as though filed on the date of the prior application." *Id.*

Nevertheless, the Panel's decision eliminates PTA whenever a child continuation application (e.g., claiming a species) expires before a parent application (e.g., claiming the genus) that has had its term extended due to PTA. There is no dispute that if an inventor files only a single patent application, he or she would be entitled to the full term of the resulting patent, including any PTA. Under the Panel's decision, however, the filing of subsequent continuation applications could retroactively—and unjustly—curtail the full term of an earlier-issued patent with PTA when subsequent applications in the same family expire earlier, which is what happened in *Allergan.*

The Panel's decision may also bar subsequent applications within the same family from obtaining PTA. A subsequent application that includes narrower claims, which suffers USPTO delay (and thus entitled to PTA), may similarly be invalid just because it extends beyond the expiration of any earlier-issued patents. The Panel's decision in effect treats continuation applications as second class by

denying the full benefits of their parent applications with the same priority date, a result that is contrary to statute. This cannot be what Congress intended.

E. The Panel's Decision Upsets Expectations

Pharmaceutical development requires the expenditure of significant resources and years of research and development. Accordingly, the retroactive application of new law-changing rules years after investment decisions have been made does significant damage. By eliminating PTA for commonly-owned patents that have different expiration dates and unmooring ODP from its equitable underpinnings, the Panel's decision constitutes a significant change in law.

The U.S. Supreme Court has warned that courts "must be cautious before adopting changes that disrupt the settled expectations of the inventing community . . . . The responsibility for changing them rests with Congress . . . . Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980); *Diamond v. Diehr*, 450 U.S. 175, 182 (1981).

The text of the applicable statutes, this Court's *Novartis* decision, and prior decisions, such as *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc*., 533 F. Supp. 3d 170, 215 (D.N.J. 2021) (following *Novartis*), and *Amgen Inc. v. Sandoz Inc*, No. CV 18-11026, 2021 WL 5366800 (D.N.J. Sept. 20, 2021) (following

Mitsubishi and *Novartis*), demonstrate that Amici reasonably expected that they were entitled to PTA, even in the face of earlier expiring continuation applications. The Panel's decision upsets such settled expectations and warrants en banc review.

III. CONCLUSION

For all the above reasons, Cellect's petition for en banc review should be granted.

Dated: November 28, 2023

Respectfully submitted,

/s/ Howard W. Levine
Howard W. Levine

Counsel for Amici Curiae, Merck Sharp & Dohme, LLC, AstraZeneca Pharmaceuticals LP, Amgen Inc., AUTM, Johnson & Johnson, and Novo Nordisk Inc.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation set forth in Federal Circuit Rule 35(g)(3). The relevant portions of the brief, including all footnotes, contain 2,580 words as determined by Microsoft Word.

This brief complies with the typeface requirements set forth in Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief was prepared in Microsoft Word using a proportionally spaced 14 point Times New Roman font.

Dated: November 28, 2023

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