Post-*Amgen* § 112

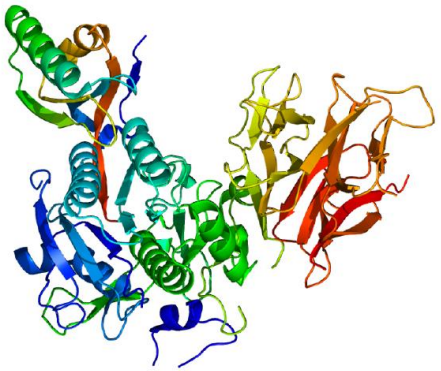
November 7, 2024

Larry Coury

Amgen v. Sanofi

Amgen v. Sanofi

- Innovator v. Innovator (antibody litigation)
- Sanofi patented Praluent® and Amgen patented Repatha®; both drugs inhibit PCSK9 to reduce LDL
- Amgen claimed a genus of antibodies that bind to particular residues of PCSK9 and block PCSK9 from binding to LDL receptor (i.e., recited two functions)
- Amgen sued Sanofi in 2014, alleging Praluent® infringed its patents



PCSK9

Amgen v. Sanofi (S.Ct. 2023)

"Amgen has failed to enable all that it has claimed.'"

Amgen's "roadmap" and "conservative substitution" approaches "amount to little more than ***two research assignments***" that leave scientists "forced to engage in 'painstaking experimentation' ***to see what works***. That is not enablement… it is a 'hunting license.'"

"Amgen offers persons skilled in the art little more than advice to engage in 'trial and error.'"

Amgen v. Sanofi (S.Ct. 2023)

"That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class."

"[D]isclosing [a] general quality may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset."

"Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing."

USPTO Guidelines (January 2024)

"In *Amgen*, the Supreme Court, in a unanimous decision, affirmed *Sanofi-Aventisub*."

"[C]onsistent with the Federal Circuit in *Sanofi-Aventisub* and in post-*Amgen* enablement decisions, ***the Wands factors***, which were used by the USPTO prior to *Amgen*, ***will continue to be used*** to assess whether the experimentation required by the specification to make and use the entire scope of the claimed invention is reasonable."

"Federal Circuit precedent applying the *Wands* factors prior to *Amgen* is still informative as to how the *Wands* factors should be analyzed in different situations."

Post-*Amgen* § 112

Baxalta v. Genentech (Fed. Cir. 2023)

- Innovator v. Innovator (antibody litigation)
- Representative claim:

> An isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa.

- Relying on *Amgen*, the Federal Circuit affirmed summary judgment of nonenablement for ***functional genus claims***

https://www.hemlibra.com/about/how-it-works.html

Baxalta v. Genentech (Fed. Cir. 2023)

"The only guidance the patent provides is 'to create a wide range of candidate antibodies and then screen each to see which happen to bind' to Factor IX/IXa and increase procoagulant activity. ***Amgen makes clear that such an instruction, without more, is not enough to enable the broad functional genus claims at issue here***."

"The facts of this case are materially indistinguishable from those in *Amgen*."

"The Supreme Court held these methods 'amount to little more than two ***research assignments***' and fail to enable the full scope of the claims."

Teva v. Eli Lilly (D. Mass. 2023)

- Innovator v. Innovator (antibody litigation)
- Representative claim:

> 17. A method of reducing incidence of or treating headache in a human, comprising administering to the human an effective amount of an anti-CGRP antagonist antibody, wherein said anti-CGRP antagonist antibody is a human monoclonal antibody or a humanized monoclonal antibody.

- Court granted JMOL of invalidity for lack of enablement and WD after jury awarded $175M for infringement
- Teva appealed to the Federal Circuit (fully briefed, no oral argument yet)

Teva v. Eli Lilly (D. Mass. 2023)

"***[T]he Asserted Claims cover the entire functionally defined genus*** of humanized anti-CGRP antagonistic antibodies; the ***specification disclosed only one covered antibody***; there are a large number of antibodies that could potentially antagonize CGRP, and the actual number is unknowable; the claims did not identify any amino acid sequence or unique structure for a covered antibody; and a POSA could not predict whether an antibody would satisfy the claims based on its amino acid sequence or structure, and thus ***antibodies would have to be made and individually tested to determine whether they were viable candidates for antagonizing CGRP***."

Daiichi v. Seagen (PTAB 2024)

- Claims to broad genus of antibody-drug conjugates
- In a PGR FWD, the PTAB found the claims lacked enablement and WD

  "***[T]he claims are extremely broad, encompassing*** an antibody-drug conjugate composed of ***any antibody and any drug moiety***."

  "The facts here are consistent with the situation in *Amgen*… [***the patent***] describes two drug classes" and "***leaves the readers to 'random trial-and-error discovery***.'"

- Seagen appealed the decision to the Federal Circuit

USA v. Gilead (D. Del. 2024)

- Claim to a process for preventing HIV infection by giving patients emtricitabine and tenofovir prodrugs
- Jury verdict of non-enablement; JMOL denied
- The court found that the jury was entitled to credit the testimony of Gilead's expert re the *Wands* factors
  - "***Tenofovir prodrugs***" is "incredibly broad" and ***applies to "thousands or possibly tens of thousands of prodrug candidates***"
  - An "enormous amount of experimentation" would be required to determine which tenofovir prodrugs work in the claimed process with "essentially no guidance or direction" from the patent on how to make that determination (only 1 example)
- The US appealed to the Federal Circuit

Regeneron v. Mylan (NDWV 2023)

- Claims to formulations of aflibercept
- The court distinguished *Amgen* and found that the *Wands* factors favored enablement (also satisfied WD)

"***Here, in contrast [to Amgen], the claims are directed to formulations of a specific protein at a specific concentration—not 'an entire kingdom' or proteins*** … [t]he excipients recited in the claims are also structures … [b]ecause the claims in *Amgen* were not limited to any particular structure, the POSA was left with 'painstaking experimentation to see what works,' since 'changing even one amino acid in the sequence can alter an antibody's structure and function."

"***The claims recite specific structures, and the specification provides significant guidance to practice the claims***, with examples and lists of excipients and amounts to use."

Supernus v. Torrent (D.N.J. 2024)

- Claims to sustained release formulations that have an extended release topiramate-containing component and achieve a specific plasma concentration
- The court went through *Wands* factors and distinguished *Amgen* to find the claims enabled (and also satisfied WD)

  "***[U]nlike Amgen's claim, the Asserted Claims do not claim an 'entire genus' of release-controlling coatings*** … [t]hey claim sustained release formulations of topiramate comprising an XR component with cellulosic or acrylic polymers."

  "The Court finds that the ***Patents-in-Suit require some trial and error but not the type of '<u>random</u> trial-and-error discovery' that gave the Supreme Court pause***."

- Torrent appealed to the Federal Circuit (fully briefed, no argument yet)

Wyeth v. AstraZeneca (D. Del. 2024)

- Claims to method for treating certain lung cancer patients with daily administration of a composition comprising a unit dosage of an irreversible EGFR inhibitor
- After jury verdict awarded Wyeth $107.5M in damages, the Court granted AZ's motion for JMOL for lack of enablement and written description
- Exemplary claim:

> 1. A method for treating gefitinib and/or erlotinib resistant non-small cell lung cancer in a patient in need thereof, comprising administering daily to the patient having gefitinib and/or erlotinib resistant non-small cell lung cancer a pharmaceutical composition comprising a ***unit dosage*** of ***an irreversible epidermal growth factor receptor (EGFR) inhibitor*** that covalently binds to cysteine 773 residue in the ligand-binding pocket of EGFR or cysteine 805 residue in the ligand-binding pocket of erb-B2.

Wyeth v. AstraZeneca (D. Del. 2024)

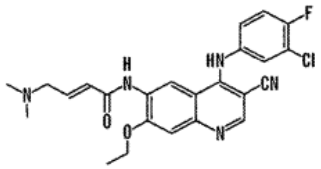
- On JMOL, the court held that no reasonable jury could find that the patents enabled a POSA to administer a "unit dosage" of any irreversible EGFR inhibitor covered by the claims to a patient without undue experimentation
- No working examples of unit dosages administered to patients
- While the patent disclosed general dosage ranges of 1-1000 mg and 2-500 mg, the court found that AZ presented unrebutted evidence that some dosages of irreversible EGFR inhibitors that fall within the claims could be toxic

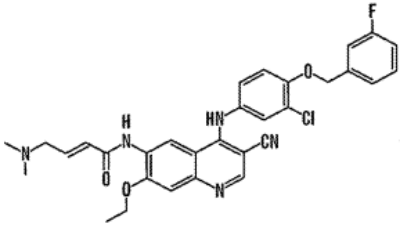
Wyeth v. AstraZeneca (D. Del. 2024)

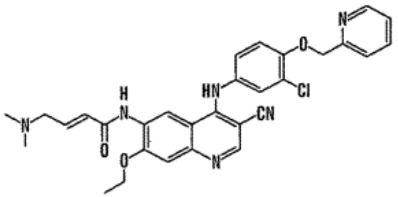
"Here, the patents-in-suit do not teach which unit dosages of compounds covered by the claims could be administered daily to a patient and which could not … ***[and] provide no guidance that would help a POSA reliably screen between compounds that would have the desired therapeutic effect at toxic versus non-toxic dosage ranges***… Instead, a POSA would have to conduct further experimentation unassisted by the patents-in-suit. This renders the claims insufficient to meet the enablement requirement."

Wyeth v. AstraZeneca (D. Del. 2024)

- AZ also argued that the patents did not describe or enable the full scope of claimed irreversible EGFR inhibitors
  - The specification had 3 examples:


EKB-569


HKI-357


HKI-272

- Wyeth's expert stated that claimed inhibitors were not in the "billions" (as argued by AZ), but a far smaller genus due to restrictions for irreversible binding to cysteine 773
- The Court denied JMOL on this ground and held that the jury was entitled to credit the testimony of Wyeth's expert
- The decision is on appeal to the Federal Circuit

In re Cellect and Allergan

The Rerouting ~~Intersection~~ of Obviousness-type Double Patenting and Patent Term Adjustment

Paul Coletti
Johnson & Johnson
November 7, 2024

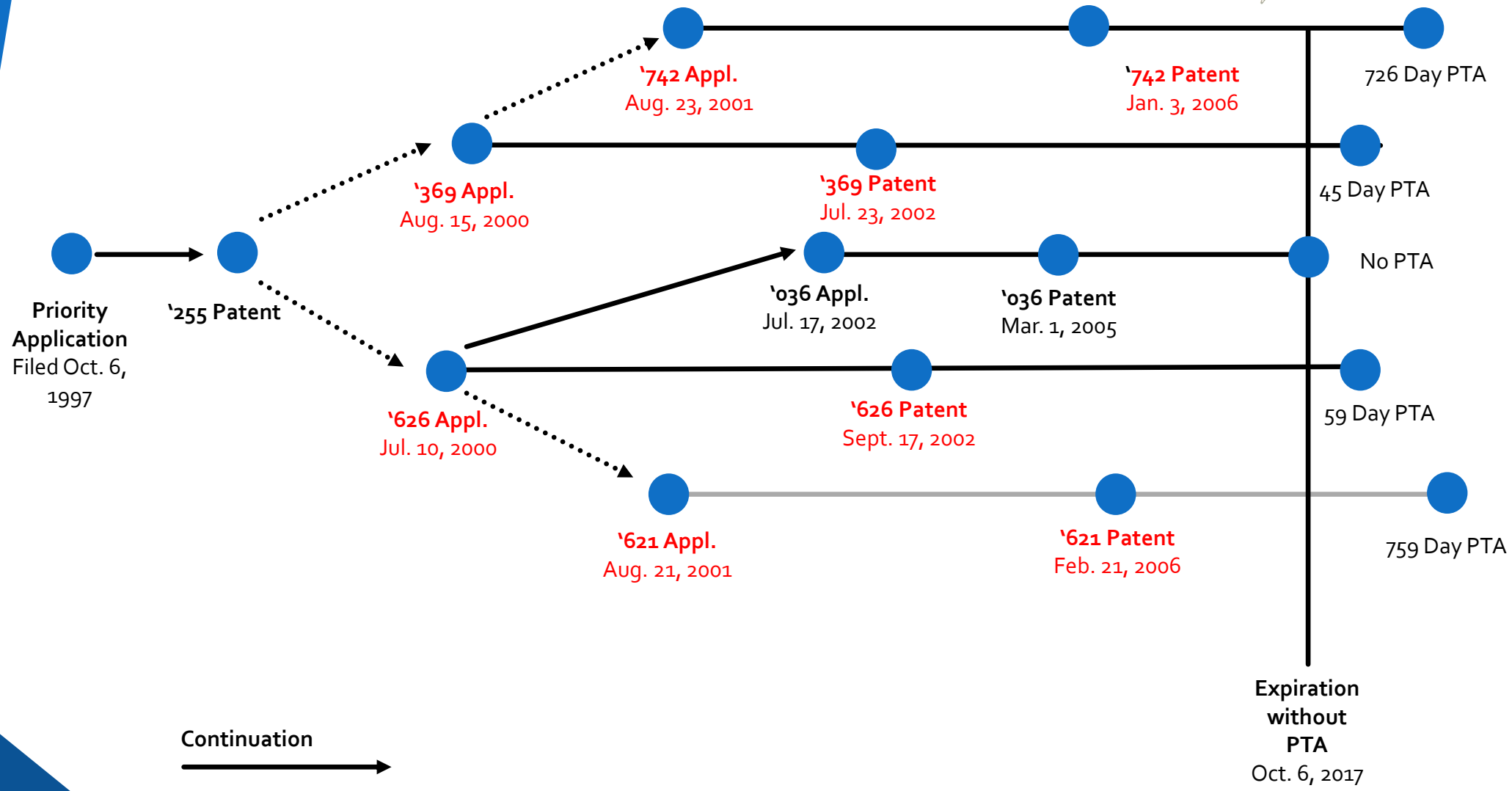
The issue

How does Patent Term Adjustment (PTA) - added to the term of a patent due to USPTO delays - affect application of the doctrine of Obviousness-type Double Patenting (ODP) over a patent in the same family?

Procedural History

- Cellect owns a family of patents - all but one patent have varying amounts of PTA
- Cellect sued Samsung for infringement of 4 of the patents and Samsung filed an ex parte reexam, alleging the patents are invalid for ODP
- The reexam examiner rejected the claims for ODP **even though the original examiner had not raised this rejection**
- Cellect appealed to the PTAB, which affirmed the examiner
- Cellect then appealed to the Federal Circuit, which affirmed the PTAB

Cellect Patent Family



At the USPTO

Patent	Claims	ODP Ref 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

- All of the challenged patents and reference patents were expired, so no Terminal Disclaimer could have been filed
- Cellect did concede claims of the various patents were patentably indistinct
- The '255 patent was never asserted against the challenged patents

USPTO's Position

- Cellect does not dispute that the challenged and reference patents are commonly owned and that the challenged claims were patentably indistinct over claims in the reference patents
- **The statutory language and precedent indicates that PTA and PTE should be treated differently when determining whether or not claims are unpatentable under ODP**
- Novartis' statement that judge-made doctrine, such as ODP, cannot be used to cut off statutorily granted term extension is limited to PTE determinations
- **The statutory language is clear that TDs cut short PTA but not PTE**

The Court's Findings

The Court held that Section 154 expressly limits the grant of PTA by any disclaimer of patent term (i.e., in a TD), therefore the proper calculation is

- First calculate the expiration date of each challenged and reference patent including any PTA
- Then consider ODP and any TDs with all patentably indistinct patents expiring on the earliest expiration date

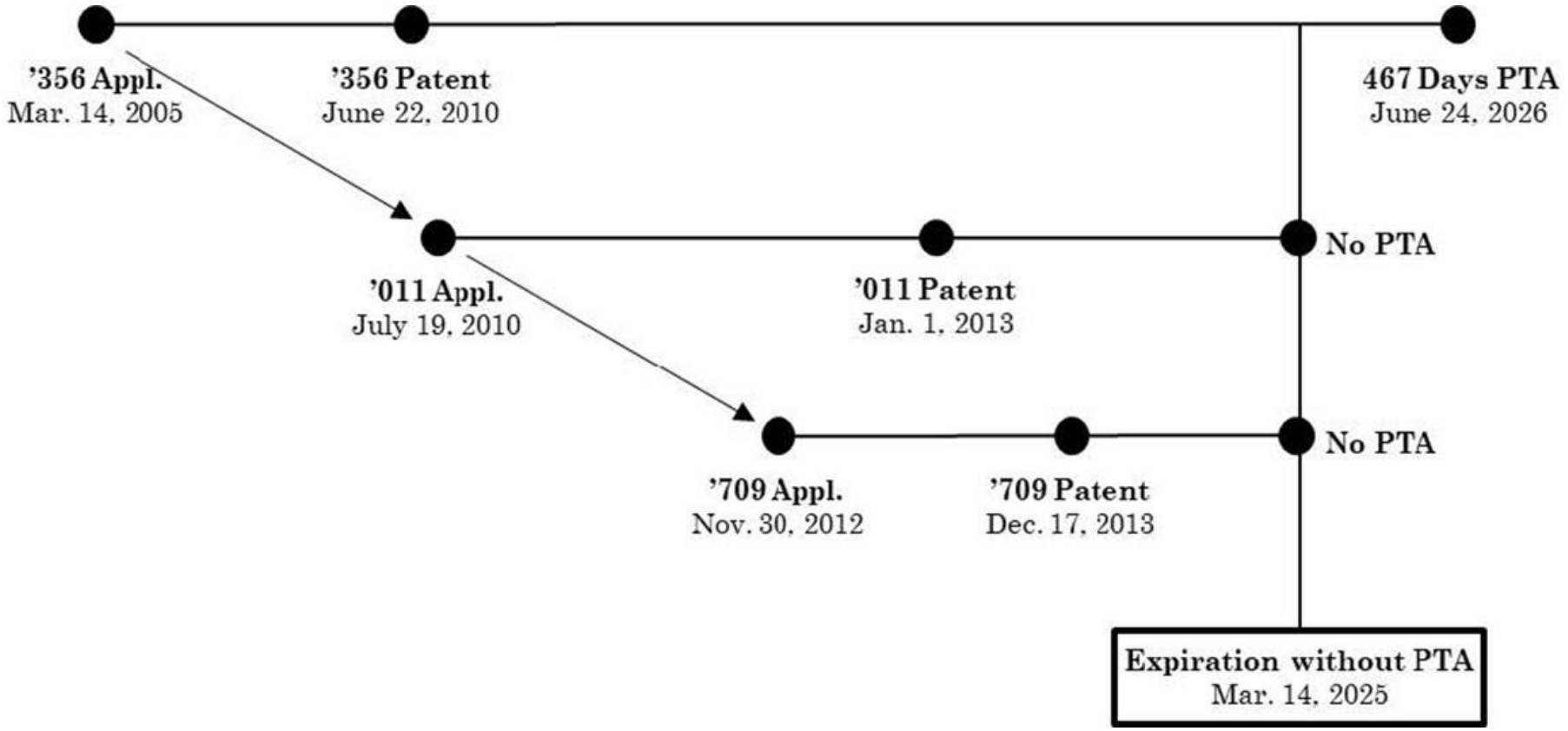
- The Court also consider that there may be situations, as in the present case, where no TD was filed. It determined that TDs are generally filed in response to ODP and so its holding applies to such situations

- Before Lourie, Dyk, Reyna, opinion by Lourie

Cellect is already having an impact

Allergan v. MSN (D.DE. 19-1727)

- Unlike Cellect, the challenged patent was first filed and first to issue relative to the ODP reference patents
- To address common ownership, Allergan filed a TD in the non-expired ODP reference patent (already expired before the challenged patent because the challenged patent obtained PTA) – No term given up
- Claim 40 of the challenged patent was found invalid for ODP in view of the two referenced patents
- Court said that the fact that the challenged patent was first filed and first issued was immaterial. One should look at the expiration dates of the respective patents and whether the claims are patentably distinct from one another.
- Allergan appealed


'356 Appl.
Mar. 14, 2005
'356 Patent
June 22, 2010
467 Days PTA
June 24, 2026
'011 Appl.
July 19, 2010
'011 Patent
Jan. 1, 2013
No PTA
'709 Appl.
Nov. 30, 2012
'709 Patent
Dec. 17, 2013
No PTA
Expiration without PTA
Mar. 14, 2025

Federal Circuit Reverses

- Although *Cellect* requires courts to assess ODP based on expiration dates after PTA has been added, it "does not follow … that the [challenged patent] must be invalidated by the [child reference patents] simply because it expires later."
- Because both child reference patents were filed after, issued after and claimed priority to the challenged patent, neither could serve as an ODP reference to the challenged patent.
- "[t]o prevent patentees from obtaining a second patent on a patentably indistinct invention to effectively extend the life of a first patent to that subject matter."
- Notably, same panel as *Cellect* (Lourie, Dyk, Reyna), opinion by Lourie. Dyk dissents in part on other grounds.

The Court's Findings

- The Federal Circuit agreed with the USPTO that these types of term adjustments should be treated differently
- 35 U.S.C. § 154 (PTA):

  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. § 156 (PTE):

  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)

Practice Considerations

- Consider listing co-pending applications
  - List applications and status
  - Include statement such as:
    - "The foregoing statuses were pulled from the USPTO's Patent Center on _____ [date when data is pulled, not when amendment filed]. The Examiner is encouraged to review and monitor each of these file wrappers, including the issued and pending claims, all art of record, and any rejections. Details of these cases are available through the Office's records. No representation is made or intended that the foregoing cases are material to patentability of the present claims, or that the foregoing is a comprehensive list of copending applications."
- Evaluate patent strategy for new portfolios early and often:
  - Consider possible claim categories to be pursued and whether to attempt to trigger restriction
- Evaluate potential intra-family ODP concerns
  - Cases do not need to be part of the same family to raise ODP

Practice Considerations

- **Note: each application is different. The following considerations are not to be construed as legal advice.**
- Review pending portfolios to determine if any ODP rejections are outstanding:
  - Traverse ODP rejections on the merits, when possible
  - Traverse on procedural grounds, when possible
    - *"Applicant traverses this rejection and requests reconsideration. A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Applicant submits that the cited combination fails to establish a prima facie case of obviousness, and therefore the obviousness-type double patenting rejection is improper."*

Practice Considerations

- Review pending portfolios to determine if any ODP rejections are outstanding (con't):
  - Withhold agreement until claims are otherwise found allowable
- Consider abandoning earlier expiring case
  - Closely review applications to determine most valuable claims as part of analysis

*Rubric for Determining Validity**

Challenged Patent / Patent Relationship	"First" Not Invalid for ODP		"Second" Invalid for ODP	
Different Priority Dates	First-filed (first-issued) *Ezra*		Second-filed (First-issued) *Gilead*	Second-filed (second-issued) *AbbVie* *Sun*
Shared Priority Dates	First-issued (first-filed) *Allergan* *Breckenridge*	First-issued (second-filed)	Second-issued (second-filed) *In re Cellect*	

*See, https://www.mintz.com/insights-center/viewpoints/2231/2024-10-21-new-rubric-obviousness-type-double-patenting

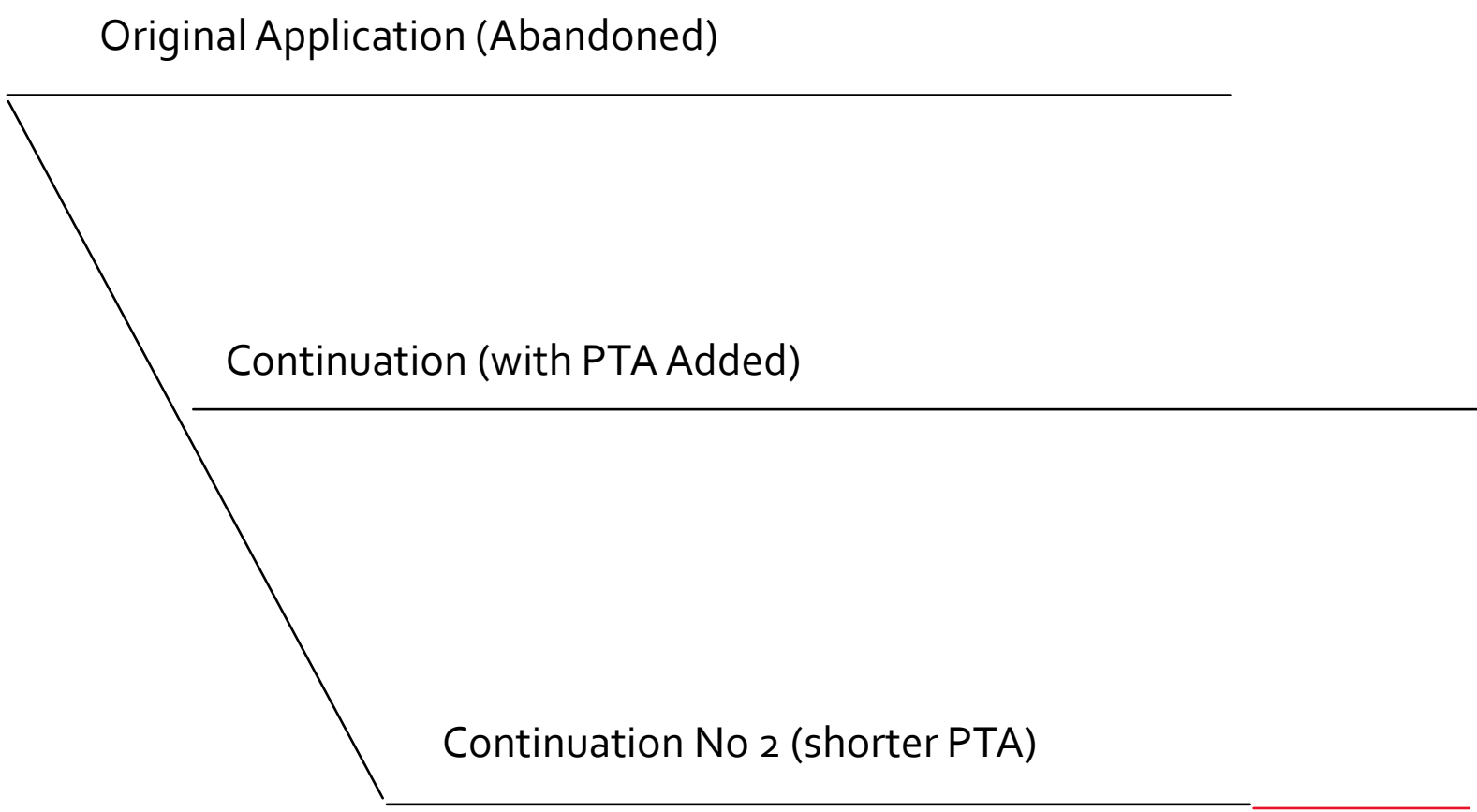
Hypothetical Prosecution No. 1

Original Application (Abandoned)

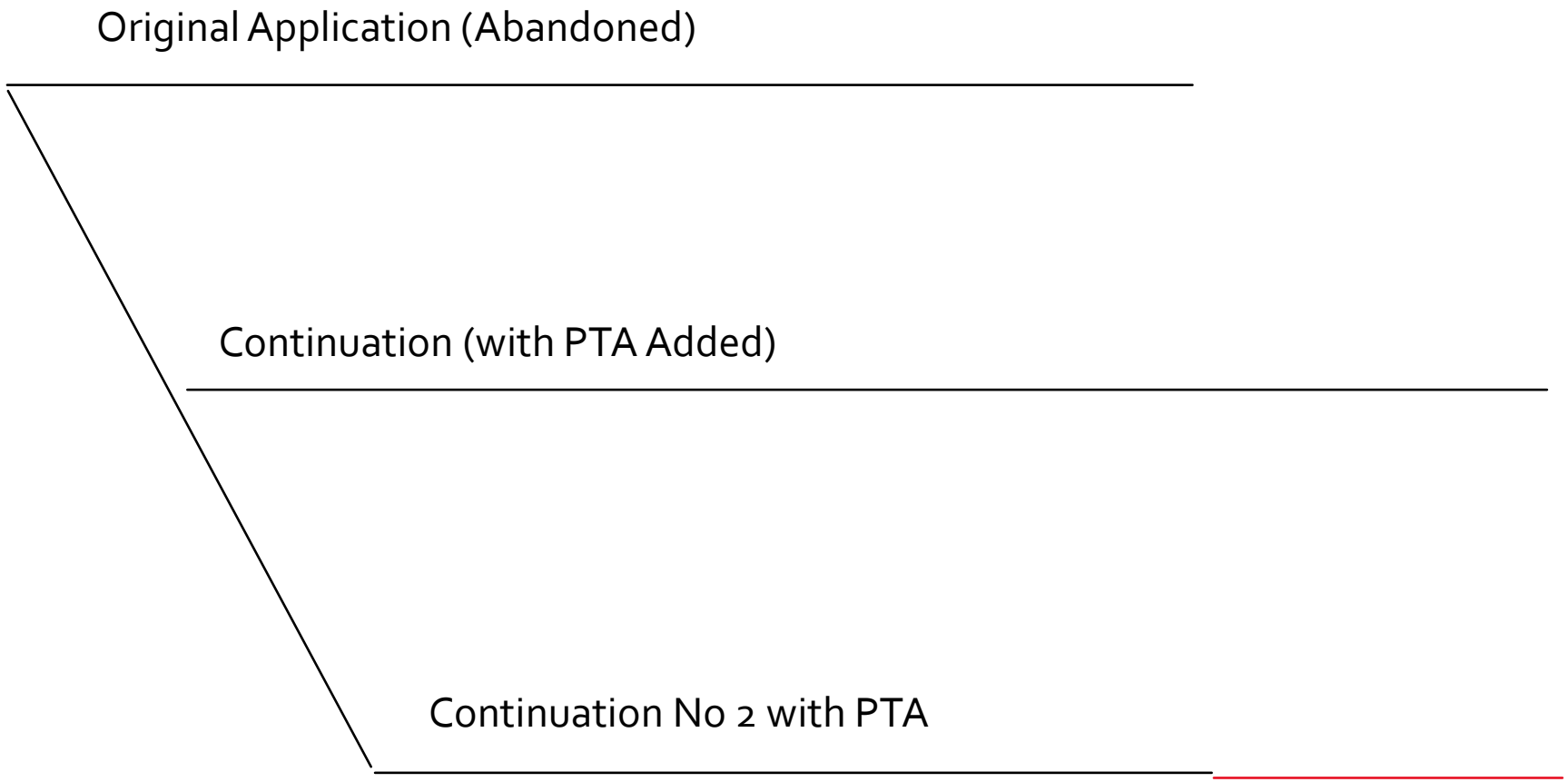
Continuation (with PTA Added)

Continuation No 2 (no PTA)

Hypothetical Prosecution No. 2



Hypothetical Prosecution No. 3 and Beyond



Thank you!

Backup

Cellect's Position

Cellect raised 3 arguments on appeal:

- **The Board erred by not considering whether a patent is unpatentable for ODP based on expiration without reference to duly granted PTA**
- The Board erred in failing to consider equitable concerns underlying the finding of ODP during the reexamination procedure
- The Board erred in finding a substantial new question of patentability in the underlying reexaminations

PTE CASES

Merck & Co. v. Hi-Tech Pharamcal Co., 482 F.3d 1317 (Fed. Cir. 2007)

- ODP rejection made during prosecution and TD filed
- ***Patent later awarded 1233 days of PTE***
- Court: "patent term extension under § 156 is not foreclosed by a terminal disclaimer," and "Hatch-Waxman 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"

Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367 (Fed. Cir. 2018)

- Patent contained claims challenged as patentably indistinct from those of a reference patent and expired after the reference patent solely because of statutorily-mandated PTE awarded to the challenged patent (no TD filed)
- Court: "as a logical extension of our holding in *Merck & Co. v. Hi-Tech*' that double patenting also should be considered **before a PTE**"
- Thus, the ODP analysis is conducted before PTE is applied

Cellect's Position

- In these cases, the Federal Court indicated that the correct analysis is: first determine the expiration date of the patent, including any ODP/TD consideration; and only then add PTE to that expiration date
- Cellect urged the court to similarly find that patents subjected to ODP are still entitled to PTA and that the PTA should be calculated in a similar manner – first consider when the patent would expire based on ODP/TD and then add any statutorily granted PTA to that date

A Little History of ODP

- In 1995, the US harmonized patent term with the rest of the world and all applications filed on or after June 8, 1995 had a patent term of 20 years from date of filing
  - Submarine patents were sunk
  - ODP remained viable because, at least, of the safe-harbor provision of Section 103 (*but for the fact that the reference is not available prior art, this would otherwise be double-patenting*)
    - Can occur in unrelated cases having different expirations
  - Opponents argued that judicially-created doctrine cannot overrule statutory prohibition on double patenting
    - Proponents respond that a variation on an invention is not the same invention, therefore not prohibited by statute
      - Cannot legally assert obviousness if reference is not available as prior art due to 103 safe harbor

Legal Posture/Next Steps

- Note that decision was unanimous and there were no concurring opinions
  - Original case heavily briefed by industry
    - BIO, PhRMA, IPO, the Association for Accessible Medicine, Samsung, and Alvogen submitted amicus briefs
    - BIO, PhRMA, IPO argued to overturn PTAB
- *En banc* rehearing has not been granted
  - Petitions for rehearing were due on November 13, 2023
  - Amicus briefs are due on November 27, 2023
- Assuming it stands, it affects everyone
  - Re-evaluate competitive patents for advantage where possible
  - Adopt best practices to minimize *Cellect* considerations going forward

No. 2024-1408

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

REGENXBIO INC. and THE TRUSTEES OF
THE UNIVERSITY OF PENNSYLVANIA,
Appellants,

v.

SAREPTA THERAPEUTICS, INC. and
SAREPTA THERAPEUTICS THREE, LLC,
Appellees.

On Appeal from the United States District Court for the District of Delaware,
No. 1:20-cv-01226-RGA, Hon. Richard G. Andrews

CORRECTED BRIEF OF *AMICUS CURIAE* THE HONORABLE PAUL R. MICHEL (RET.) IN SUPPORT OF APPELLANTS

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1408

Short Case Caption Regenxbio Inc. v. Sarepta Therapeutics, Inc.

Filing Party/Entity The Honorable Paul R. Michel (Ret.)

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.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

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

Date: 05/17/2024

Signature: /s/ Matthew J. Dowd

Name: Matthew J. Dowd

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
The Honorable Paul R. Michel (Ret.)		

☐ 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

Matthew J. Dowd Dowd Scheffel PLLC	Robert J. Scheffel Dowd Scheffel PLLC	

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 AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae Paul R. Michel is a former judge of the U.S. Court of Appeals for the Federal Circuit, appointed in 1988 and serving until 2010, when he retired from the bench as Chief Judge. Since his retirement, *Amicus* has remained active in patent policy discussions, working to help ensure that U.S. patent laws and policy are geared to achieving the proper balance between incentivizing innovation and allowing free-market competition.

The present case is of concern to *Amicus* because the district court's ruling continues a troubling trend of misapplying 35 U.S.C. § 101.

Patent-eligibility law is now denying even the possibility of patent protection for lifesaving medical diagnostic inventions. Patent protection is critical to incentivizing innovation in the field of medical diagnostics, and life-saving diagnostics are precisely the type of innovation that the U.S. patent system should be encouraging. The outcome in this case wrongfully shut the door on patent protection before any evaluation of the claimed invention's merits ever occurred.

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[1] No party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person contributed money to fund the preparation or submission of this brief. All parties consent to the brief's filing.

SUMMARY OF THE ARGUMENT

This is an easy case.

That is a phrase that should not be used lightly. Too many appellants have come to this Court asserting that their cases are "easy" ones that should be reversed. Of course, most patent appeals are not easy, and district courts generally reach the correct conclusion. But the present appeal is a clear exception to that general rule.

Quite simply, the district court misapplied the statute and misapplied precedent when it held that the claimed genetically engineered cells are not patent eligible under § 101. The court's decision overlooks the plain language of the statute, which allows patents on any "new" "composition of matter." Beyond the statute, the district court's ruling misunderstands controlling precedent of the Supreme Court and this Court. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), itself confirms that Appellants' genetically engineered cells are patent eligible. And later cases, such as *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), only strengthen that conclusion.

ARGUMENT

I. Patent Protection Drives Innovation And Encourages Investments In Lifesaving Technologies

The innovation ecosystem needs robust patent protection for novel technologies that lead to lifesaving medicines and treatments. Robust patent protection encourages the necessary investment so that inventors invent, firms commercialize the inventions, and society benefits.

A. The Importance of Rewarding Inventors and Innovators for their Investment of Time and Money

Study after study confirms that robust and reliable patent protective is a key driver of innovation in the biotechnology and healthcare industries. *See, e.g.*, U.S. Patent and Trademark Office, *Request for Comments: Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace*, 89 Fed. Reg. 18,907, 18,907 (Mar. 15, 2024) ("Intellectual property (IP) forms the bridge that moves innovation to impact for the benefit of society."); David O. Taylor, *Patent Eligibility and Investment*, 41 Cardozo L. Rev. 2019, 2094 (2020) (presenting data confirming the "negative effects of the [Supreme] Court's heightened eligibility standard on investment in technological development in the United States").

B. The Current Innovation Ecosystem is Under Assault

Unfortunately, the U.S. innovation ecosystem is under assault. Over the past fifteen years or so, a series of decisions have decimated the U.S. patent system, which has led to increased certainty and decreased investments.

The decline of the U.S. patent system has been well documented elsewhere and need not be repeated here. *See, e.g.*, Adam Mossoff, *The U.S. Must Fix Its Innovation Engine: The Patent System*, STAT (Mar. 8, 2022) ("American innovators are no longer promised reliable and effective rights for the fruits of their labors.")[2]; Paul R. Michel & Matthew J. Dowd, *From a Strong Property Right to a Fickle Government Franchise: The Transformation of the U.S. Patent System in 15 Years*, 69 Drake L. Rev. 1 (2021).

One particularly insidious trend is the declining availability of injunctive relief. *See, e.g.*, Julie Carlson, *New Data Show There Is a Problem with the U.S. Patent System—But It's Not Patent Trolls*, IP Watchdog.com (May 6, 2024) ("The report shows that injunction grants

[2] https://www.statnews.com/2022/03/08/the-u-s-must-fix-its-innovation-engine-the-patent-system/.

(excluding default judgments) have fallen from a peak of 80 in the period 2008 to 2012 to just 36 in the period 2018 to 2022.")[3]; *see also* Paul R. Michel & John T. Battaglia, *eBay, the Right to Exclude, and the Two Classes of Patent Owners*, 2020 Patently-O Patent L. J. 11, 18 (2020) (explaining how "courts over the last decade-plus have instead created the very thing that *eBay* condemned; *viz.*, a 'categorical rule' (or something close to it) that bars NPEs from obtaining injunctions").[4] Indeed, injunctions—particularly preliminary injunctions—have become extraordinarily rare.

Beyond the legal decisions over the past years, dangerous policy proposals have contributed to the weakened status of U.S. patents and the U.S. innovation ecosystem. A steady drumbeat from academics has argued for waiving intellectual property rights for inventions related to treating COVID-19. But there has never been any evidence that any waiver was needed, and eviscerating patent rights would have set a dan-

[3] https://ipwatchdog.com/2024/05/06/new-data-show-problem-us-patent-system-not-patent-trolls/id=176149/.

[4] https://patentlyo.com/media/2020/11/Michel.2020.RightToExclude.pdf.

gerous precedent. *See, e.g.*, Paul Michel, *Waiving COVID-19 IP Protections Would Harm US Industry*, Law360 (Jan. 4, 2024).[5] The irony of the COVID-waiver debate is that almost all the technologies that enabled the rapid development of COVID treatments existed because earlier innovators were rewarded with robust patent rights.

Other dangerous policy arguments have been advanced that will further harm the innovation ecosystem. The current Biden administration has suggested using the Bayh-Dole Act to trample the patent rights of innovators simply for the short-sighted and politically motived objective of lowering drug prices. Paul Michel & Kathleen O'Malley, *White House's Drug Patent Plan Undercuts Research and Innovation*, Bloomberg Law (Jan. 9, 2024) ("[A]llowing the government to void exclusive patent licensing agreements would prove economically devastating.")[6]; *see also* Paul Michel & Kathleen O'Malley, *Biden's Bayh-Dole Act Proposal Misuses "March-In Rights*", The Tribune-Democrat (Apr. 25,

[5] https://www.law360.com/ip/articles/1779536.

[6] https://news.bloomberglaw.com/us-law-week/white-houses-drug-patent-plan-undercuts-research-and-innovation.

2024)[7]; Andrei Iancu & Cooper Godfrey, *The Bayh-Dole Act and the Debate Over "Reasonable Price" March-In Rights*, FedSoc Blog (Apr. 18, 2024) ("Because the Bayh-Dole Act does not clearly authorize the use of march-in rights to control prices, courts will likely conclude that the administration is essentially claiming unbounded power to set prices and relicense patents without any meaningful guidance from Congress.")[8]. The mere threat of misusing the Bayh-Dole Act further weakens the U.S. innovation ecosystem by devaluing patents by placing them under a cloud of uncertainty.

II. The District Court's Decision Is Plainly Wrong Under Settled Precedent

Despite the ongoing damage to the U.S. patent system, the Court need not delve deeply into policy considerations to reach the correct outcome in this appeal. The correct outcome flows from a straightforward application of the statute and precedent.

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[7] https://www.tribdem.com/news/editorials/columns/paul-michel-and-kathleen-omalley-bidens-bayh-dole-act-proposal-misuses-march-in-rights/article_2d9b0cfa-0233-11ef-a25b-03ff478ee734.html.

[8] https://fedsoc.org/commentary/fedsoc-blog/the-bayh-dole-act-and-the-debate-over-reasonable-price-march-in-rights.

A. The Claimed Invention is a "New" "Composition of Matter"

The invention at issue is a novel genetically modified cell. It is not a product of nature. It exists only as the fruits of human innovation. It is precisely the type of invention contemplated by the 1952 Patent Act when "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Chakrabarty*, 447 U.S. at 309 (quoting S. Rep. No. 82-1979, at 5 (1952), and H.R. Rep. No. 82-1923, at 6 (1952)).

The plain language of § 101 authorizes patents for a "new" "composition of matter." Here, there appears to be no reasonable dispute that the genetically engineered host cell is both "new" and a "composition of matter." Of course, over the years, courts have created judicial exceptions, but none of the judicial exceptions ever contemplated a recombinant cell made in a laboratory using revolutionary technology discovered in the 1970s and barely contemplated, if at all, by Congress in 1952. Appellants' opening brief shows that there is no dispute about the claimed bacterial host cell being a human-made construct, as it is engineered to contain a non-naturally occurring recombinant nucleic acid molecule that

contains the two specific DNA sequences, *i.e.*, an AAV sequence and a heterologous non-AAV sequence.

B. The District Court's Decision Flies in the Face of *Chakrabarty* and Decades of Precedent

Beyond the statute, it is not possible to reconcile the district court's holding with the Supreme Court's ruling in *Chakrabarty*. This again is another independent basis for reversing and holding that summary judgment should have been granted in favor of Appellants.

In *Chakrabarty*, the invention was a genetically engineered bacterium that was created—through human intervention—to degrade crude oil. 447 U.S. at 305. To make the engineered bacterium, the scientists transferred naturally occurring DNA plasmids, which encoded for proteins that could degrade hydrocarbons, the *Pseudomonas* bacterium. *Id.* By doing so, the scientists created a new bacterium which, absent human intervention, could not express the proteins that degrade crude oil. *Id.* at 305 n.1. The novel, genetically engineered bacterium was made of biological components that separately existed in nature but were combined in a way that created a "new" "composition of matter" and having characteristics that were "possessed by no naturally occurring bacteria." *Id.* at 305.

As should be evident, the invention at issue in this case is conceptually no different than what the Supreme Court held as patent eligible in *Chakrabarty*. Both inventions were directed to genetically engineered organisms, made possible only through human innovation and intervention. Both inventions do not exist in nature. Both inventions create engineered cells that have physical characteristics that are different than the naturally occurring cells.

Moreover, subsequent cases have not changed the impact of *Chakrabarty*. Start with *Myriad*. While the Supreme Court reiterated the "markedly different" analysis, the key was that the claimed BRCA genes in that case occurred in nature. 569 U.S. at 590–91. The Court was emphatic: "Myriad did not create anything." *Id.* at 591.

But here, the inventors did create something—and it was something that never existed before their creative efforts. They engineered a novel host cell with a unique plasmid DNA that expresses specific proteins. That distinction alone shows how the Supreme Court's concern about monopolizing "the information-transmitting quality of the DNA" is not applicable here and does not alter how *Chakrabarty* controls the outcome.

Importantly, the Supreme Court in *Myriad* stated that it was "important to note what is *not* implicated" by the decision there. 569 U.S. at 595 (emphasis in original). The Court recognized that it was not "consider[ing] the patentability of DNA in which the order of the naturally occurring nucleotides has been altered." *Id.* at 596. That issue is implicated here, however, as it was in *Chakrabarty*. The genetically engineered organisms exist only because there is a novel combination of DNA sequences that does not exist in nature. Indeed, as the Court recognized, "[s]cientific alteration of the genetic code presents a different inquiry." *Id.* Scientific alteration of the genetic code is at the root of genetic engineering. While that same phrasing was not used in *Chakrabarty*, that case necessarily understood that genetically engineered organisms—created by the manipulation and scientific alteration of the genetic code—are patent-eligible inventions under 35 U.S.C. § 101. The same sound reasoning should be applied in the present case to reach the only rational outcome.

III. The District Court's Confusion Highlights The Need For Patent Reform

In one sense, the district court's decision is utterly shocking. Who would have imagined, just a handful of years ago, that federal courts

would use § 101 to regularly invalidate patents for groundbreaking, gene-based technologies? Indeed, the type of innovation here was not even remotely possible when Congress passed the 1952 Patent Act, and only through human innovation have we reached the stage where scientists can create extremely useful genetically modified organisms.

The district court's erroneous decision appears to be a manifestation of the confusion that imbues current patent-eligibility jurisprudence. The continuing confusion is all the more reason why Congress must act to improve the law by passing the Patent Eligibility Restoration Act ("PERA"), S. 2140, 118th Cong. (2023).[9] While new legislation is unnecessary to correct the error in this appeal, legislation to improve § 101 will lessen the likelihood of additional aberrant decisions such as the one at issue here.

[9] https://www.congress.gov/bill/118th-congress/senate-bill/2140.

A. Patent-Eligibility Law Remains a Mess

"The law of patentable subject matter is a mess."[10] That assessment was widely circulated after it was made to Congress almost five years ago. Unfortunately, the assessment remains true today.

Members of this Court have highlighted the confusion in patent-eligibility law. Chief Judge Moore, for instance, observed that the "blended 101/112 analysis" applied in one case "expands § 101, converts factual issues into legal ones and is certain to cause confusion for future cases." *Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC*, 967 F.3d 1285, 1305 (Fed. Cir. 2020) (Moore, J., dissenting); *see also Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring) ("I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents.").

Despite this Court's efforts to apply Supreme Court precedent, innovators are left with seemingly inconsistent outcomes, with some patents covering innovative diagnostic methods upheld while other very similar inventions are deemed patent ineligible. *See, e.g.*, *Illumina, Inc.*

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[10] Mark A. Lemley, *Patentable Subject Matter* Reform Hearings Before the Senate Judiciary Committee, at 1 (June 4, 2019), https://www.judiciary.senate.gov/imo/media/doc/Lemley%20Testimony.pdf.

v. Ariosa Diagnostics, Inc., 952 F.3d 1367, *opinion modified by* 967 F.3d 1319 (Fed. Cir. 2020); *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1319–20 (Fed. Cir. 2019) (invalidating claims for detecting hereditary nasal parakeratosis in Labrador retrievers); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1381 (Fed. Cir. 2018) (invalidating a patent directed to novel methods for detecting the pathogenic bacterium *Mycobacterium tuberculosis*); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1052 (Fed. Cir. 2016) (holding, as patent eligible, a method of producing a preparation of multi-cryo-preserved hepatocytes).

B. Congress Should Fix the Law by Passing the Patent Eligibility Restoration Act ("PERA")

Here, the district court's erroneous outcome appears to be a product of existing confusion in patent-eligibility law. As noted above, this Court can and should rectify that error by correctly applying precedent. It need do no more.

At this time, it is worth acknowledging that much of the responsibility for fixing the confusion in patent-eligibility law lies not with this Court but with Congress. It has been fourteen years since the Supreme Court started its campaign to rework patent-eligibility law. *See Bilski v.*

Kappos, 561 U.S. 593 (2010). It has been far from successful with its follow-on decisions in *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208 (2014), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). Due to the lack of clear guidance from the Supreme Court, this Court has had to wrestle with the reimagined confines of patent-eligible subject matter. Despite pleas from this Court, the Supreme Court has declined numerous opportunities to make the necessary corrections.

If patent-eligibility law is not rationalized, the consequences will continue to worsen for the U.S. innovation community. While patents for lifesaving technologies are struck down in the United States under vague "judicial exceptions," the same or very similar inventions are deemed worthy of patent protection in Europe and Asia. Moreover, the United States needs to take concrete steps to improve its leadership on the global innovation stage, lest the nation fall far behind advancing competitors.

That leaves Congress to improve the situation. Current pending legislation, specifically the PERA, is the best current solution for improving the law and providing clearer boundaries for this Court to apply. Introduced by Senators Tillis and Coons, the proposed legislation would

simplify the patent-eligibility analysis by codifying specific, defined exceptions to patent-eligible subject matter and would thus minimize aberrant decisions, such as the one at issue in this case.

The courts cannot, of course, enact legislation. Even so, a court is free to express its view that legislation is needed to improve the quality of its judicial decisionmaking. The Supreme Court has done so on several occasions. *E.g.*, *Sinclair Refining Co. v. Atkinson*, 370 U.S. 195, 214 (1962) ("The question of what change, if any, should be made in the existing law is one of legislative policy properly within the exclusive domain of Congress—it is a question for lawmakers, not law interpreters."). Here, the Supreme Court's repeated cert-petition declinations are, in effect, an invitation to this Court to emphasize the need for legislative action to improve the law. *See, e.g.*, *In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985) ("It is the province of Congress to make changes in law based on public policy.").

IV. Conclusion

For the foregoing reasons, *Amicus* respectfully submits that the Court should reverse the grant of summary judgment that held the claims to be patent ineligible. The Court should rule that, as a matter of

law, the claimed genetically modified cells are patent eligible. The suggested outcome will then allow the parties to litigate whether the claimed invention satisfies the statutory requirements of patentability under 35 U.S.C. §§ 102, 103, and 112.

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Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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