

Federal Circuit 2023 Year in Review

February 14, 2024

FISH.



Meet the Speakers

Nitika Fiorella
Principal



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Senior Principal



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Life Science: Section 112 and Skinny Labels

FISH.

Genus-Species Enablement

Amgen Inc. v. Sanofi, 598 U.S. 594 (May 18, 2023)

- Covered antibodies to lower LDL cholesterol, by inhibiting the protein PCSK9, which naturally degrades the LDL receptors that extract LDL from the bloodstream
- Claims genuses that (a) “bind to specific amino acid residues on PCSK9,” and (2) “block PCSK9 from binding to [LDL receptors].” Amgen’s specification identified 26 such antibodies, though the claims covered millions.
- **Held:** If a patent claims a class, the specification must enable a skilled artisan to make the entire class. The patent here failed. Affirmed.

(Slip Opinion)

OCTOBER TERM, 2022

1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

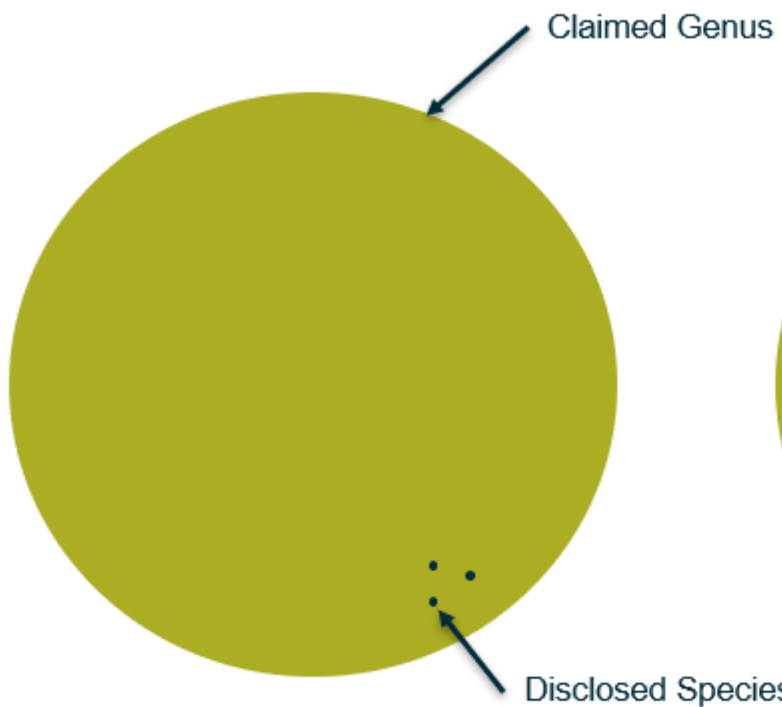
AMGEN INC. ET AL. *v.* SANOFI ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

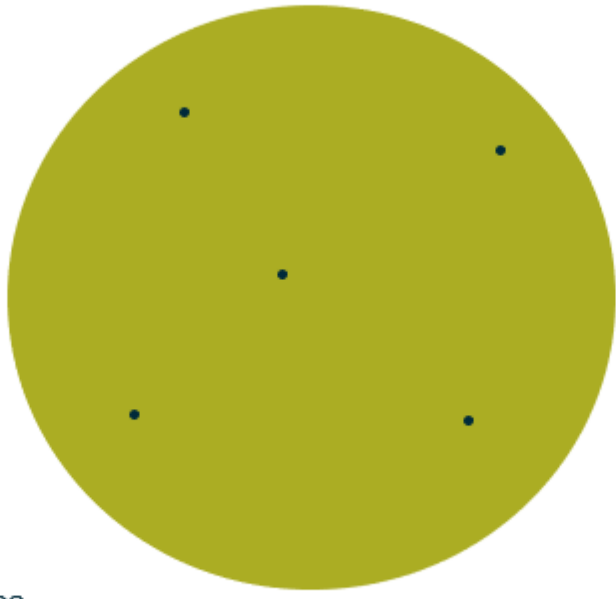
No. 21–757. Argued March 27, 2023—Decided May 18, 2023

This case concerns patents covering antibodies engineered by scientists that help reduce levels of low-density lipoprotein (LDL) cholesterol, sometimes called bad cholesterol because it can lead to cardiovascular disease, heart attacks, and strokes. To treat patients with high LDL cholesterol, scientists explored how antibodies might be used to inhibit PCSK9—a naturally occurring protein that binds to and degrades LDL receptors responsible for extracting LDL cholesterol from the bloodstream. Two pharmaceutical companies—Amgen and Sanofi—each developed a PCSK9-inhibiting drug. In 2011, Amgen obtained a patent for the antibody employed in its drug, and Sanofi received one covering the antibody used in its drug. Each patent describes the relevant antibody by its unique amino acid sequence. The dispute in this case concerns two additional patents Amgen obtained in 2014 that relate back to the company’s 2011 patent. These later-issued patents purport to claim for Amgen “the entire genus” of antibodies that (1) “bind to specific amino acid residues on PCSK9,” and (2) “block PCSK9 from binding to [LDL receptors].” 872 F. 3d 1367, 1372. As part of its submission to the patent office, Amgen identified the amino acid sequences of 26 antibodies that perform these two functions. Amgen then described two methods—one Amgen called “the roadmap” and a second it called “conservative substitution”—that scientists could use to make other antibodies that perform the binding-and-blocking functions described in the claims.

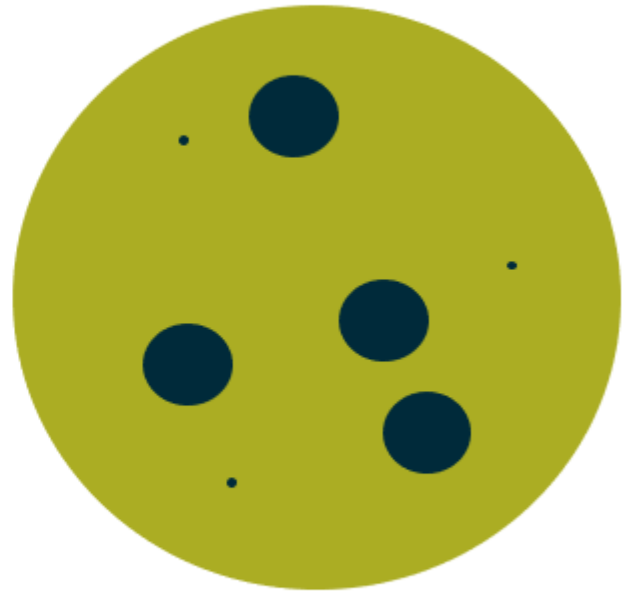
After Amgen obtained the 2014 patents, it sued Sanofi for infringement. Sanofi replied that it was not liable to Amgen for infringement because Amgen’s relevant claims were invalid under the Patent Act’s “enablement” requirement. That provision requires a patent applicant to describe the invention “in such full, clear, concise, and exact terms



Bad



Better

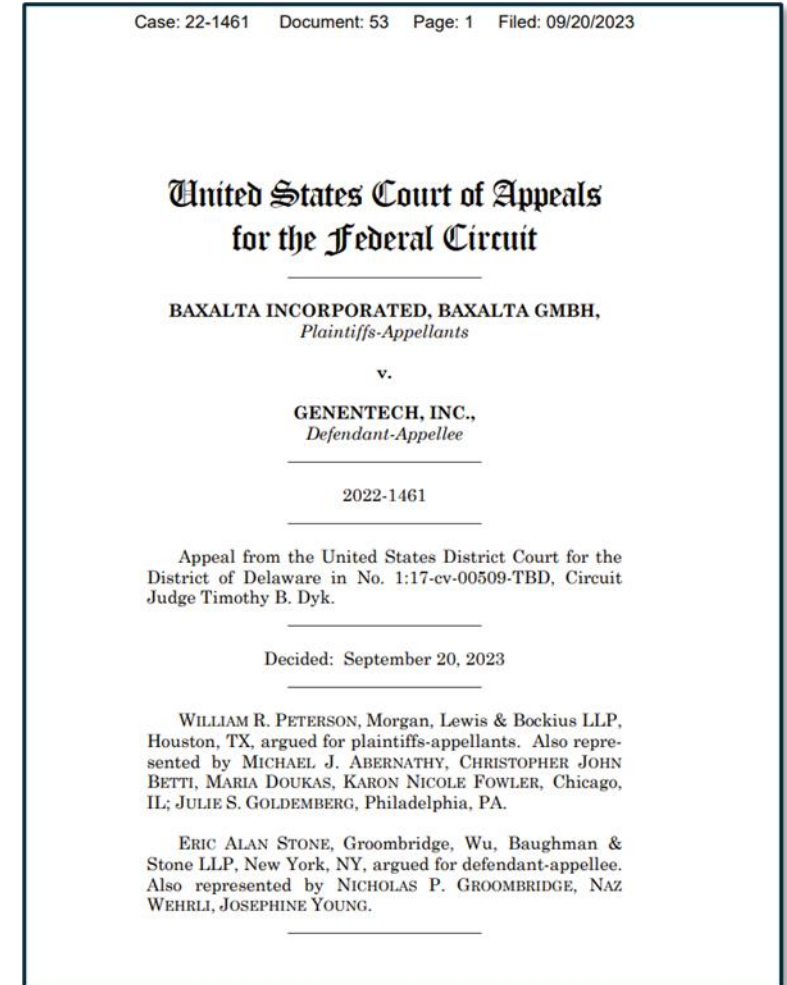


Better Yet

After Amgen

Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023)

- Affirms summary judgment of invalidity.
- Claims cover all antibodies that bind to the blood coagulating Factor IX.
- The inventors found—using a routine screening process discussed in the patent—that only 1.6% of the antibodies they screened had the desired result.
- **Held:** “The facts of this case are materially indistinguishable from those in *Amgen*. . . . There are millions of potential candidate antibodies, but the written description discloses the amino acid sequences for only eleven antibodies with the two claimed functions.” Even if one gets a result with each screening, it’s still “trial-and-error” like in *Amgen*.



Written Description: Subgenus Not Claimed

Regents of the University of Minnesota v. Gilead Sciences, Inc., 61 F.4th 1350 (Fed. Cir. 2023)

- Minnesota's patent was directed to prodrugs of nucleoside derivatives that prevent viruses from reproducing and cancers from growing
- Gilead filed IPR and challenged Minnesota's right to priority from earlier applications based on lack of written description
- The Board found no WD support and the Federal Circuit affirmed
 - Priority applications didn't provide *ipsis verbis* disclosure or sufficient blaze marks to arrive at the claimed subgenus
 - Minnesota's maze-like path, piecing together 7 claims disclosing different substituents did not provide WD support

United States Court of Appeals
for the Federal Circuit

REGENTS OF THE UNIVERSITY OF MINNESOTA,
Appellant

v.

GILEAD SCIENCES, INC.,
Appellee

2021-2168

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2017-01712.

Decided: March 6, 2023

EDGAR HAUG, Haug Partners LLP, New York, NY, argued for appellant. Also represented by MICHAEL A. ALBERT, EDWARD R. GATES, RICHARD GIUNTA, GERALD B. HRYCYSZYN, NATHAN R. SPEED, CHARLES T. STEENBURG, Wolf Greenfield & Sacks, PC, Boston, MA.

JOHN SCOTT MCBRIDE, Bartlit Beck LLP, Chicago, IL, argued for appellee. Also represented by NEVIN M. GEWERTZ, REBECCA HORWITZ, MEG E. FASULO, Denver, CO.

Before LOURIE, DYK, and STOLL, *Circuit Judges*.

Skinny Label Update

Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC, No. 22-37 (U.S. May 15, 2023)

- Cert. denied

H. Lundbeck A/S v. Lupin Ltd., 87 F.4th 1361 (Fed. Cir. 2023)

- Affirms bench trial finding of noninfringement
- Label had a carve-out for the claimed indication
- Notably, this was a Hatch-Waxman suit, and the Federal Circuit did not buy the theory that the defendants could induce infringement even with a narrow label.
- Pretty basic.

Practice Pointers

When prosecuting:

- Get as many and varied examples as possible, and identify common connections to let those examples cover more ground.
- Obtain claims of varying breadth
- Consider both the quantity and quality of your disclosure
- Identify where the invention undergoes large changes – don't bridge those with claims unless you've bridged them with disclosure

When litigating:

- Have deep discussions with experts about the how to frame the scope of the claims and the disclosed embodiments
- Consider both qualitative and quantitative issues

Section 103

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The Medtronic/Teleflex Battle

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., 70 F.4th 1331 (Fed. Cir. June 5, 2023) (Dkt. 21-2357 et al.) (MOORE Lourie Dyk)

Medtronic, Inc. v. Teleflex Innovations S.A.R.L., 69 F.4th 1341 (Fed. Cir. June 5, 2023) (Dkt. 21-2359 et al.) (MOORE Lourie Dyk)



Case 1 / Rule 1

- “Copying” (whether by the petitioner/defendant or third parties) as an objective indicium of nonobviousness, can be established circumstantially with evidence of access plus substantial similarity.
- Borrowing from copyright.
- This isn’t huge, because such copying isn’t too common, but I’m amazed it hasn’t been held before.
- Pay attention to distinction between copying invention and copying product.

Medtronic, Inc. v. Teleflex Innovations S.a.r.l., 70 F.4th 1331 (2023)

70 F.4th 1331
United States Court of Appeals, Federal Circuit.

MEDTRONIC, INC., Medtronic
Vascular, Inc., Appellants
v.
TELEFLEX INNOVATIONS
S.A.R.L., Appellee

2021-2357, 2021-2360, 2021-2364
I
Decided: June 5, 2023

Synopsis
Background: Patent challenger appealed decisions of the Patent Trial and Appeal Board (PTAB), 2021 WL 2518685, 2021 WL 2524006, 2021 WL 2524191, granting patentee’s motion to amend certain claims in two patents and finding that challenger had failed to show that certain claims in three patents directed to coaxial extension catheters insertable into standard guide catheters were unpatentable for obviousness.

Holdings: The Court of Appeals, Moore, Chief Judge, held that:

[1] the PTAB did not err in finding that challenger had failed to establish the obviousness of claims in challenged patents covering a device with a side opening in the extension catheter for receiving an interventional cardiology device;

[2] the PTAB adequately explained its determinations, as required under the Administrative Procedure Act (APA);

[3] the PTAB did not err in finding that challenger had failed to establish the obviousness of claims in challenged patents covering a device with an insertable catheter having an inner diameter not more than one French size smaller than the inner diameter of the guide catheter;

[4] the PTAB did not err in finding that challenger had failed to establish the obviousness of claims in challenged patents covering a device with multiple inclined regions separated by a non-inclined region;

[5] the PTAB did not err in finding that patentee’s proposed amendments to certain claims in two patents had sufficient written-description support to be allowed; and

[6] the PTAB did not err in finding that patentee’s proposed amendments to certain claims in two patents were not obvious and thus were allowable.

Affirmed.

See also 2023 WL 3806379.

West Headnotes (18)

[1] **Patents** — Questions of law or fact
Obviousness of a patent claim is a question of law based on underlying facts.

[2] **Patents** — Scope of Review
The Federal Circuit reviews de novo the Patent Trial and Appeal Board’s (PTAB) ultimate determination of obviousness and reviews for substantial evidence its underlying findings of fact.

[3] **Patents** — Medical devices and appliances
The Patent Trial and Appeal Board (PTAB) did not commit legal error in determining that patent challenger had failed to carry its burden to show the obviousness of certain claims in patents on coaxial extension catheters insertable into standard guide catheters, namely claims on devices with a side opening in the extension catheter for receiving an interventional cardiology device, and substantial evidence supported the PTAB’s determination; there was objective evidence of nonobviousness, such as commercial success of patented devices, that had a nexus to the claims at issue, there was evidence that challenger copied the patented device, and there was an absence of a motivation to combine the teachings in the prior-art references on which challenger’s obviousness arguments relied.

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Case 1 / Rule 2

- A prior art reference can be weaker if its relevant feature is “rare” rather than well known.
- Seems to be in tension with the whole idea of the “Winslow Tableau”—where the whole world of prior art is floating in front of the skilled artisan’s face.
- Under this holding, being prior art is not strictly binary, i.e., if a patentee can get its expert to opine that a certain feature was a one-off in the cited piece of prior art, and not something most people knew about, the patentee can use that to argue against obviousness.

Medtronic, Inc. v. Teleflex Innovations S.a.r.l., 70 F.4th 1331 (2023)

70 F.4th 1331
United States Court of Appeals, Federal Circuit.

MEDTRONIC, INC., Medtronic
Vascular, Inc., Appellants
v.
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S.A.R.L., Appellee

2021-2357, 2021-2360, 2021-2364
Decided: June 5, 2023

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Case 1 / Rule 3

- A petitioner, to counter a prima facie case of nexus for commercial success, must show that a single reference disclosed the full combination of features that are alleged to create the success—and not that the features were each individually known.
- I think the court has made this general point before, but there's lots of nice clarifying discussion in the opinion, so it should probably become your anchor opinion for this rule of law.

Medtronic, Inc. v. Teleflex Innovations S.a.r.l., 70 F.4th 1331 (2023)

70 F.4th 1331
United States Court of Appeals, Federal Circuit.

MEDTRONIC, INC., Medtronic
Vascular, Inc., Appellants
v.
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S.A.R.L., Appellee

2021-2357, 2021-2360, 2021-2364
Decided: June 5, 2023

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Case 2 / Rule 1

- Where the “entire purpose” of a prior art was to do X, and the proposed combination wipes out X, that strongly points to nonobviousness.
- The court distinguishes its other decisions where the prior art had multiple different purposes, and the combination only killed one of them.
- I don’t know if this holding is as strikingly new as the others, because it’s a lot like what the court said in Chemours 1-2 years ago, but it is notable.

Medtronic, Inc. v. Teleflex Innovations S.à.r.l., 69 F.4th 1341 (2023)

69 F.4th 1341
United States Court of Appeals, Federal Circuit.

MEDTRONIC, INC., Medtronic
Vascular, Inc., Appellants
v.
TELEFLEX INNOVATIONS
S.À.R.L., Appellee

2021-2359, 2021-2362, 2021-2366
1
Decided: June 5, 2023

See also 2023 WL 3806380.

West Headnotes (10)

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[4] Patents — Medical devices and appliances
The Patent Trial and Appeal Board (PTAB) did not commit legal error in determining that patent challenger had failed to carry its burden to show the obviousness of certain claims in patent on coaxial extension catheters insertable into standard guide catheters, namely claims covering a device with a side opening with at least two different inclined slopes; there was lack of a motivation to combine the two prior-

Synopsis
Background: Patent challenger appealed decisions of the Patent Trial and Appeal Board (PTAB), 2021 WL 2524890, granting patentee's motion to amend certain claims in one patent and finding that challenger had failed to show that certain claims in three patents directed to coaxial extension catheters insertable into standard guide catheters were unpatentable for obviousness.

Holdings: The Court of Appeals, Moore, Chief Judge, held that:

[1] the PTAB did not err in finding that challenger had failed to establish the obviousness of claims in challenged patents covering a device with an insertable catheter having an inner diameter not more than one French size smaller than the inner diameter of the guide catheter;

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Affirmed.

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Case 2 / Rule 1

More flexibility w/r/t prior art that dissuades from the invention even if it does not fully teach away:

- ***Philip Morris Products S.A. v. ITC***, 63 F.4th 1328 (Fed. Cir. 2023) (prior art that touted putting a structure in location A dissuaded a skilled artisan from putting it in location B).
- ***Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.***, 876 F.3d 1350 (Fed. Cir. 2017) (prior art pointed toward the invention but also urged caution because of safety concerns).
- ***Apple Inc. v. Samsung Elec. Co.***, 839 F.3d 1034 (Fed. Cir. 2016) (en banc)



Verdict: BRP Guilty of PWC Patent-Infringement, Owes Arctic Cat \$15.5 Million | Visit

United States Court of Appeals for the Federal Circuit

PHILIP MORRIS PRODUCTS S.A., PHILIP MORRIS USA, INC., ALTRIA CLIENT SERVICES LLC,
Appellants

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

RAI STRATEGIC HOLDINGS, INC., R.J. REYNOLDS VAPOR COMPANY, R.J. REYNOLDS TOBACCO COMPANY,
Intervenors

2022-1227

Appeal from the United States International Trade Commission in Investigation No. 337-TA-1199.

Decided: March 31, 2023

GREGORY G. GARRE, Latham & Watkins LLP, Washington, DC, argued for appellants. Also represented by GABRIEL K. BELL, MAXIMILIAN A. GRANT, BERT C. REISER, JAMIE UNDERWOOD.

LYNDE FAUN HERZBACH, Office of the General Counsel, United States International Trade Commission,

Other?

Schwendimann v. Neenah, Inc., 82 F.4th 1371 (Fed. Cir. 2023)

- Affirms PTAB rejections based on substantial evidence for “common sense” under 103.

In Re Couvaras, 70 F.4th 1374 (Fed. Cir. 2023)

- Affirms PTAB rejection on 103, because recitation of certain mechanistic limitations did not overcome prima facie obviousness.
- The mechanism of action naturally flows from administering the two chemical agents (treating essential hypertension by boosting some molecule in vessels).

Practice Pointers

- Consider obviousness flexibly, from the position of the person facing the problem.
- As a petitioner, do not make an office action-like argument.
- Be careful about how you argue things like unexpected results (part of motivation, expectation of success, or objective indicia?)
- Petitioners need to avoid falling into physical combinability, e.g., by referring to “the widget of Smith” rather than “a widget like that of Smith.”
- Start early on any objective indicia evidence.
- Develop a simple, logical story.

PTAB Procedure

FISH.

How Much Explanation Must the Board Provide?

Regents of the Univ. of Minnesota v. Gilead Sciences, Inc., 61 F.4th 1350 (Fed. Cir. 2023)

- Board not required to make explicit findings on each assertion by a party's expert.

Medtronic, Inc. v. Teleflex Innovations S.a.r.l., 70 F.4th 1331 (Fed. Cir. 2023)

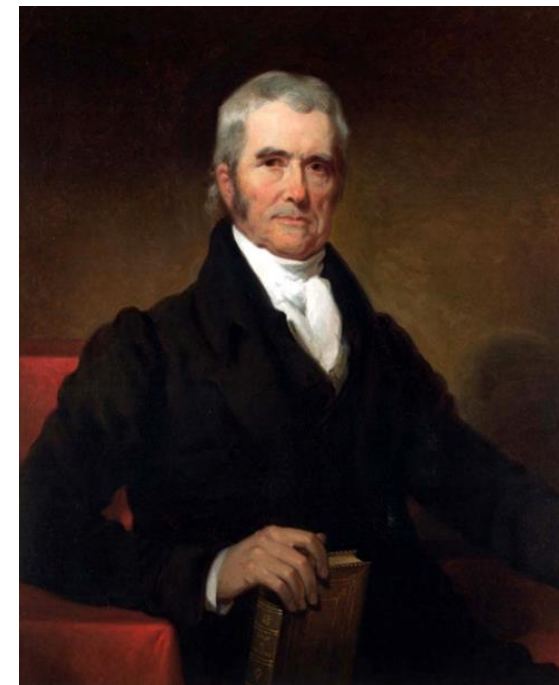
- Board not explicitly addressing all of Petitioner's reasons to combine did not mean the Board ignored them, but meant the Board found them lacking—and there was no APA violation, since the Board's path was “discernible.”

Elekta Ltd. v. Zap Surgical Sys., Inc., 82 F.4th 1368 (Fed. Cir. 2023)

- Rejects argument that Board made no findings on reasonable expectation of success, b/c that finding was implicit and “intertwined” with motivation to combine.

Incept LLC v. Palette Life Sciences, Inc., 77 F.4th 1366 (Fed. Cir. 2023)

- Affirmed 2-1 invalidation of cancer treatment claims under 102 and 103. Board did not fail to consider commercial success evidence.



How Much Explanation Must the Board Provide?

Corephotonics, Ltd. v. Apple Inc., 84 F.4th 990 (Fed. Cir. 2023)

- Vacates because unclear whether board error was typographical and harmless, or a bad error...seems to be a finding relating to analogous art.

Volvo Penta of the Ams., LLC v. Brunswick Corp., 81 F.4th 1202 (Fed. Cir. 2023)

- Vacates PTAB rejections. Analysis was “overly vague and ambiguous” – including on secondary indicia which the Board did not properly consider. Patent on a steerable tractor-type drive for a boat.

Axonics, Inc. v. Medtronic, Inc., 75 F.4th 1374 (Fed. Cir. 2023)

- Vacates because Board didn’t give petitioner a chance to reply after Patent Owner proposed a claim construction – “would create opportunities for sandbagging”



How Much APA Process is Due?

Netflix, Inc. v. DIVX, LLC, 84 F.4th 1371 (Fed. Cir. 2023)

- Rejects petitioner's argument that Board ignored some of its arguments, since the petition was "vague, generic, and/or meandering."
- Petitioner also forfeited its substantive arguments by making different arguments on appeal.

Apple Inc. v. Corephotonics, Ltd., 81 F.4th 1353 (Fed. Cir. 2023)

- Petitioner convinces Federal Circuit that PTAB cannot toss an expert report simply because of typo.
- Such is inconsistent with APA notice requirements.

After the IPR...

Ironburg Inventions Ltd. v. Valve Corp., 64 F.4th 1274 (Fed. Cir. 2023)

- A litigating patentee bears the burden of proof to establish that its opponent could have raised a particular ground in IPR and is thus estopped under 35 U.S.C. § 315(e)(2). The standard for estoppel is whether a “skilled searcher” would have found the relevant reference.

Purdue Pharma L.P. v. Collegium Pharma., Inc., 86 F.4th 1338 (Fed. Cir. 2023)

- Patent Owner complained that the Board did not issue a FWD within one year (due in part to Purdue’s bankruptcy), as commanded by Section 326(a)(11)
- The Fed Cir refused to terminate the PGR because the statute does not give consequences for missing the deadline
- Patent Owner should have filed a mandamus petition rather than waiting to see if they got an adverse decision.

Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC, 85 F.4th 1377 (Fed. Cir. 2023)

- Dismisses appeal for lacking of standing by petitioner.
- Petitioner merely provided conclusory testimony about its R&D program

Practice Pointers

As Petitioner:

- Kick the tires hard on your petition, with real skepticism.
- Consider wild claim constructions and neuter them.
- Include necessary “alternative argument” language.
- Do not make “office action” cases with your petition.
- Consider whether petitioner will have article III jurisdiction.

As Patent Owner:

- Get on top of secondary considerations immediately.
- Consider bringing in your own prior art to show that the art had all sorts of teachings.

For both:

- Consider involving experienced appellate counsel to preserve issues for appeal.
- Frame new arguments as refinements of prior arguments necessitated by opponent.

Claim Construction

FISH.

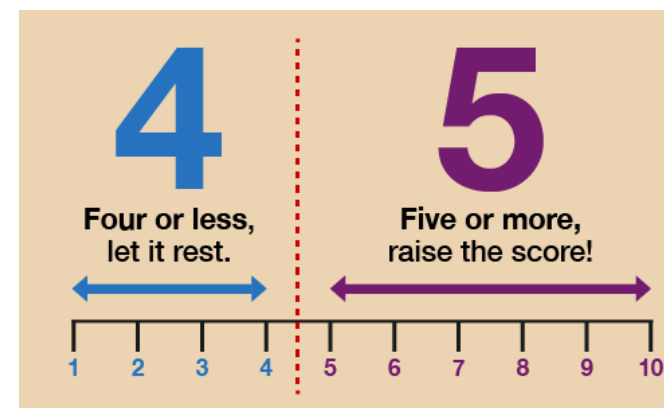
Claim Construction: Life Science

Pacific Biosciences v. Personal Genomics Taiwan, Inc., 89 F.4th 1377 (Fed. Cir. 2023)

- Affirms that “identifying a single biomolecule” requires “ascertaining the identity of one single, individual biomolecule by examining only that biomolecule.”
- Construction does not conflate *identifying* a single molecule with *detecting* a single molecule.

Actelion Pharms. Ltd. v. Mylan Pharms. Inc., 85 F.4th 1167 (Fed. Cir. 2023)

- Claim construction about “rounding” for drug pH
- Judge should have looked at textbook extrinsic evidence
- District court construed to permit “13 or higher” to include 12.x numbers that round up to 13 – that might be right or it might be wrong. So vacated.



Claim Construction: Software

ParkerVision, Inc. v. Vidal, 88 F.4th 969 (Fed. Cir. 2023)

- Board properly limited “storage element” to a structure that was part of a particular storage system.
- The Federal Circuit agreed because a paragraph that the patent incorporated by reference was definitional via “as used herein” language.

Sisvel Int’l S.A. v. Sierra Wireless, ULC, 82 F.4th 1355 (Fed. Cir. 2023)

- With a means-plus-function claim, there can be invalidity for having no structure at all or some, but insufficient, structure.
- While the former does not depend on expert testimony, the Board was required to accept testimony under the latter.

Google LLC v. EcoFactor, Inc., -- F.4th -- (Fed. Cir. 2024)

- Board’s application of claims showed an implicit construction that required inputs to thermostat to be separate from each other simply because they were separately-recited in the claims, but that construction was wrong because it excluded an embodiment.
- Becton Dickinson and Engel Industries “do not create a per se rule that separately listed claim elements are distinct components, regardless of the intrinsic record.”
- And claim differentiation is merely “a guide, not a rigid rule of claim construction.”

Practice Pointers

Prosecution:

- Draft your claims with a focus on the terms that matter, while realizing that many things are unforeseeable, especially on a tight budget
- Know what terms often cause problems (e.g., terms of relationship w/r/t how “tight” the relationship must be)
- Use claim differentiation strategically
- Check all adjectives and adverbs

Litigation:

- Don't assume that de novo review is truly de novo
- Pick a construction that pastes into the claim logically
- Don't plainly read limitations into the claim language



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Thank You!

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