

Director Review

- *US v. Arthrex* (SCT 2021) (unconstitutionally appointed, but fixed by Supreme Court with Director Review of PTAB final decisions)
- Director review allows for political influence.



Inter Partes Review Proceedings **New Director**, New Direction

PTAB Continues to be a Very Hot venue: Most active patent court in the country.

Estoppel: California Inst. of Tech. v. Broadcom Ltd., 25 F.4th 976 (Fed. Cir. 2022) (estoppel applies to all grounds which could have reasonably been asserted against claims included in the petition; overruling Shaw Indus.)

Forum Selection Clause avoiding IPR. Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc., 25 F.4th 998 (Fed. Cir. 2022)

Enablement and Written Description

Amgen v. Sanofi (Full Scope enablement of functionally claimed antibodies)

Juno v. Kite (Full Scope written description of GM therapy)

Amgen v. Sanofi

ANTIBODY

- The Science:
 - Liver has LDL Receptors that destroy LDL ("Bad Cholesterol").
 - * BUT, naturally occurring PCSK9 binds to the LDL receptors and blocks the process.
 - Amgen's invention: a monoclonal antibody that binds PCSK9 so that it cannot interfere with the Liver's clean-up function.
- Claim directed to functional genus limitation.
 - An isolated monoclonal antibody [that] binds to [PCSK9] and ... blocks binding of PCSK9 to LDLR.



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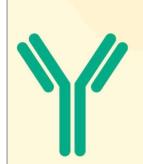
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- · Genus-Species and "Full Scope Enablement"
- Role of functional limitations.
- · Implicit question rethinking Ariad



Juno v. Kite (Cert pending)

B. WRITTEN DESCRIPTION

3. Has Kite proven by clear and convincing evidence that the following claims of the '190 Patent are invalid because the specification of the '190 Patent does not contain an adequate written description of the claims?

"Yes" means the claim does not contain adequate written description support in the specification, and "No" means the claim does contain adequate written description support in the specification.

Asserted Patent Claims	Yes (in favor of Kite)	No (in favor of Sloan Kettering and Juno)
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5, 11		V

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Juno v. Kite (Cert pending)

- 112(a): The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...
- **Science:** Juno's patent covers DNA/RNA coding for a particular "chimeric T cell receptor." CAR T-Cell therapy genetically modifies a patient's own T-Cells so that it will be able to recognize (and thus attack) specific antigens. The inventors have been awarded numerous accolades for showing that this approach works to treat some lymphomas. Kite's "YESCARTA" therapy was found to infringe.
- \$1.2 billion jury verdict, reversed on appeal by the Federal Circuit.
- Claim requires a "binding element" coding. This portion of the claim was not the key inventive feature and was an area of research in the industry with some publications already. Specification identified two binding elements by name (but without sequence or other details). Claim interpreted to cover all binding elements fitting in the category of *scFvs*.
- Petition: FedCir goes too far by requiring patentee to demonstrate the inventor's possession of 'the full scope of the claimed invention,' including all 'known and unknown.' Jan 6 Consideration.



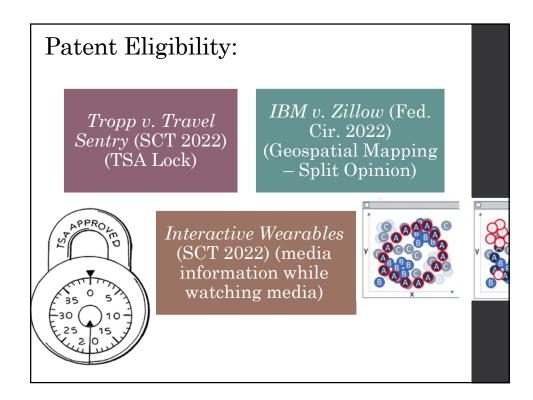
Who is the Inventor

Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022)

AI Cannot be an Inventor.

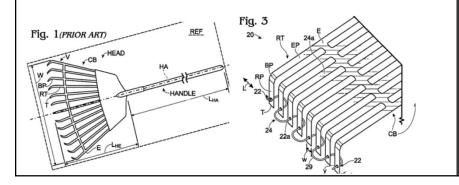
35 USC 100(f). The term "inventor" means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.

Cert petition due in January 2022



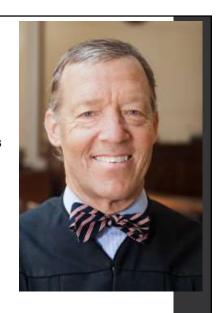
Garth Janke v. Vidal

- 1. A leaf-rake head product \dots
- 21. Installing a mathematical model of the leaf-rake head product defined in Claim 1 on a computer.
- 26. Applying the mathematical model of Claim 21 on a conventional 3D printer to result in making the leaf-rake head product defined in Claim 1.



Patent Venue

- Proper Venue 28 USC 1400(b)
- · Convenient Venue 28 USC 1404
- W.D.Tex. Case Distribution Rules





Person of Ordinary Skill in the Art

Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n, 22 F.4th 1369 (Fed. Cir. 2022) ("[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. Without that skill, the witness' opinions are neither relevant nor reliable").

Obviousness

 Auris Health, Inc. v. Intuitive Surgical Operations, Inc., 32 F.4th 1154 (Fed. Cir. 2022) (evidence of skepticism must be specific to the invention, not generic to the field).



Preliminary Injunctions

- * ABC Corp. I v. Partn. and Unincorporated Associations Identified on Sched. "A", 52 F.4th 934 (Fed. Cir. 2022); ABC Corp. I v. Partn. and Unincorporated Associations Identified on Sched. "A", 51 F.4th 1365 (Fed. Cir. 2022)
- BlephEx, LLC v. Myco Industries, Inc., 24 F.4th 1391 (Fed. Cir. 2022) (preliminary injunctions)

<u>Uniloc USA, Inc. v.</u> <u>Motorola Mobility LLC,</u> 52 F.4th 1340 (Fed. Cir. 2022)

<u>Uniloc 2017 LLC v.</u> <u>Google LLC</u>, 52 F.4th 1352 (Fed. Cir. 2022)

VLSI Tech v. Intel Corp,

• Multi Billion Dollar Drama



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