Jeffrey Coleman is an associate in the intellectual property group at Kramer Levin Naftalis & Frankel LLP, and co-chair of the NYIPLA's Amicus Briefs Committee. Jeffrey litigates complex patent and intellectual property matters in various life sciences fields, including small and large molecule pharmaceuticals, diagnostics, robotics, medical devices, vaccines, and therapeutics. Jeffrey holds a B.S. in chemistry and a Ph.D. in molecular toxicology, and his doctoral research focused on the prevention of pancreatic cancer growth and invasion at the molecular level. Prior to joining Kramer Levin, Jeffrey was an associate in the intellectual property litigation groups at WilmerHale LLP and Kirkland & Ellis LLP.

Serena Farquharson-Torres is a highly experienced and accomplished leader in the intellectual property field and in the pharmaceutical industry. Serena is Executive Director & Assistant General Counsel at Bristol Myers Squibb where she has held various roles of increasing responsibility in the Intellectual Property/ Innovation Law group since joining the company in 2016. Prior to joining Bristol Myers Squibb, she started in private practice and moved on to Merck and then Sanofi. Serena has significant experience in all aspects of patent practice. Serena received her J.D. from the University of North Carolina, her Ph.D. in Biological Chemistry from University of Minnesota, and her B.S. in Chemistry from Howard University.

Chad Peterman is a partner in the Intellectual Property practice at Paul Hastings and based in the firm's New York office. Mr. Peterman is a skilled trial attorney with a practice that focuses on patent and antitrust litigation with an emphasis on the electrical engineering and pharmaceutical arts. He has been involved in all phases of litigation from pre-suit investigation/strategy through appeal. Mr. Peterman has represented major software, telecommunications, semiconductor, and medical equipment companies in patent litigations. He has also represented major pharmaceutical companies in complex ANDA litigations, antitrust litigations, arbitrations, and mediations. In addition to litigation, Mr. Peterman also represents companies in intellectual property transactional matters, including rendering patent opinions and negotiating a variety of intellectual property agreements.

Jonathan Barbee is an accomplished trial lawyer with a focus on intellectual property and technology-related litigation. He represents inventors, innovators, startups, and research institutions, both as plaintiffs and defendants. With a degree in electrical engineering, Mr. Barbee litigates complex patent, trade secrets, and copyright matters across an array of technologies and industries, including the high tech, medical devices, and pharmaceutical industries. Mr. Barbee has extensive experience in all phases of litigation, including commencing suit, discovery, motion practice, expert witnesses, depositions, oral argument, IPRs, and trial.

Prior to joining MoloLamken, Mr. Barbee was counsel at WilmerHale LLP. He also clerked for the Honorable Barbara S. Jones of the United States District Court for the Southern District of New York and the Honorable Joseph A. Greenaway, Jr. of the United States Court of Appeals for the Third Circuit.

Dorothy R. Auth Ph.D.

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Dr. Dorothy Auth has 30 years of experience in complex patent litigation, as well as intellectual property licensing, patent procurement, and intellectual property counseling in the United States and abroad. Her experience spans diverse industries, including biotechnology, FinTech, and medical devices, as well as consumer products, computers, and other mechanical devices.

Dorothy litigates in U.S. Federal Courts, the International Trade Commission and in international arbitrations conducted under the AAA and WIPO rules.

Dorothy coordinates global intellectual property procurement and enforcement strategies for her clients to maximize their protected field. Dorothy's practice includes U.S. and international client counseling. Her international experience includes coordinating patent infringement trials and hearings between the U.S. and different European jurisdictions, including trials seeking preliminary relief and cross-border injunctions, as well as CBMs, IPRs, nullity, cancellation and oppositions proceedings on patent rights.

Dorothy also addresses intellectual property diligence issues, advising clients on the validity of target patents and performing clearance analysis on the patents and trademarks of competitors to render freedom-to-operate opinions.

Dorothy is a past President of the New York Intellectual Property Law Association. Dorothy has recently been named to the annual list of Intellectual Property Trailblazers published by *The National Law Journal*. In 2022 and multiple prior-year editions, Dorothy was recognized as an "IP Star" of *Managing Intellectual Property*, the guide to the world's leading IP law firms and practitioners. She has also been recognized in Euromoney Legal Media Group's *Guide to the World's Leading Women in Business Law and by Crain's New York Business as part of its 2022 "Notable Women in Law" list*. Dorothy has also been recognized among *The Best Lawyers in America* for "Patent Law".

At the firm, Dorothy chaired the Technology Committee and served as the Partner Chair of the Women's Leadership Initiative in each case for over five years.

Dorothy holds a Ph.D. in Biochemistry from Tufts Medical School and a law degree from St. Johns School of Law.

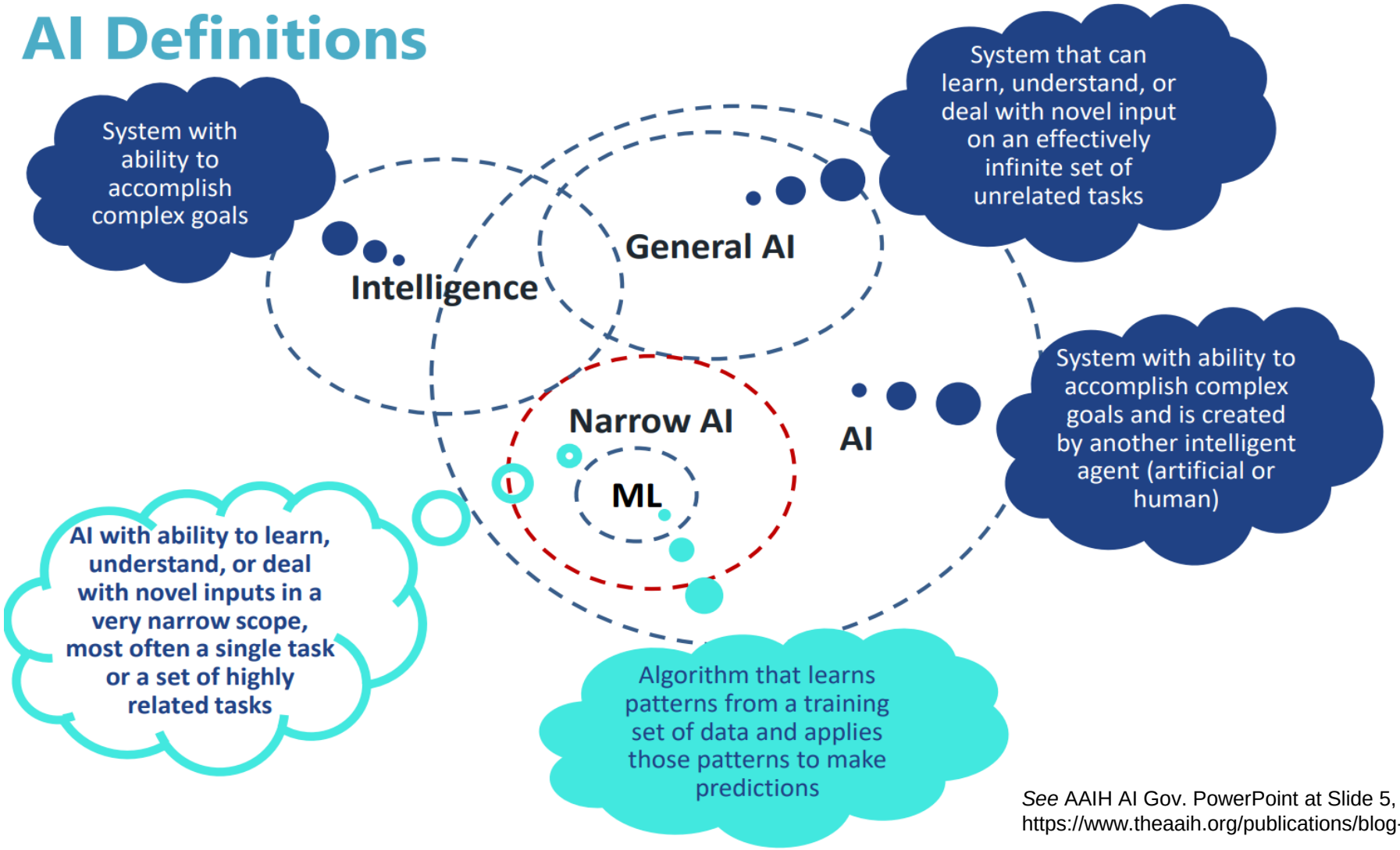
Emerging Patent Law Issues in Artificial Intelligence

November 9, 2022

Chad J. Peterman, Partner
Paul Hastings LLP
NYIPLA One-Day Patent Seminar

PAUL HASTINGS

WHAT IS AI?



See AAIH AI Gov. PowerPoint at Slide 5, *available at* https://www.theaaih.org/publications/blog-post-title-two-xx527-fhceb

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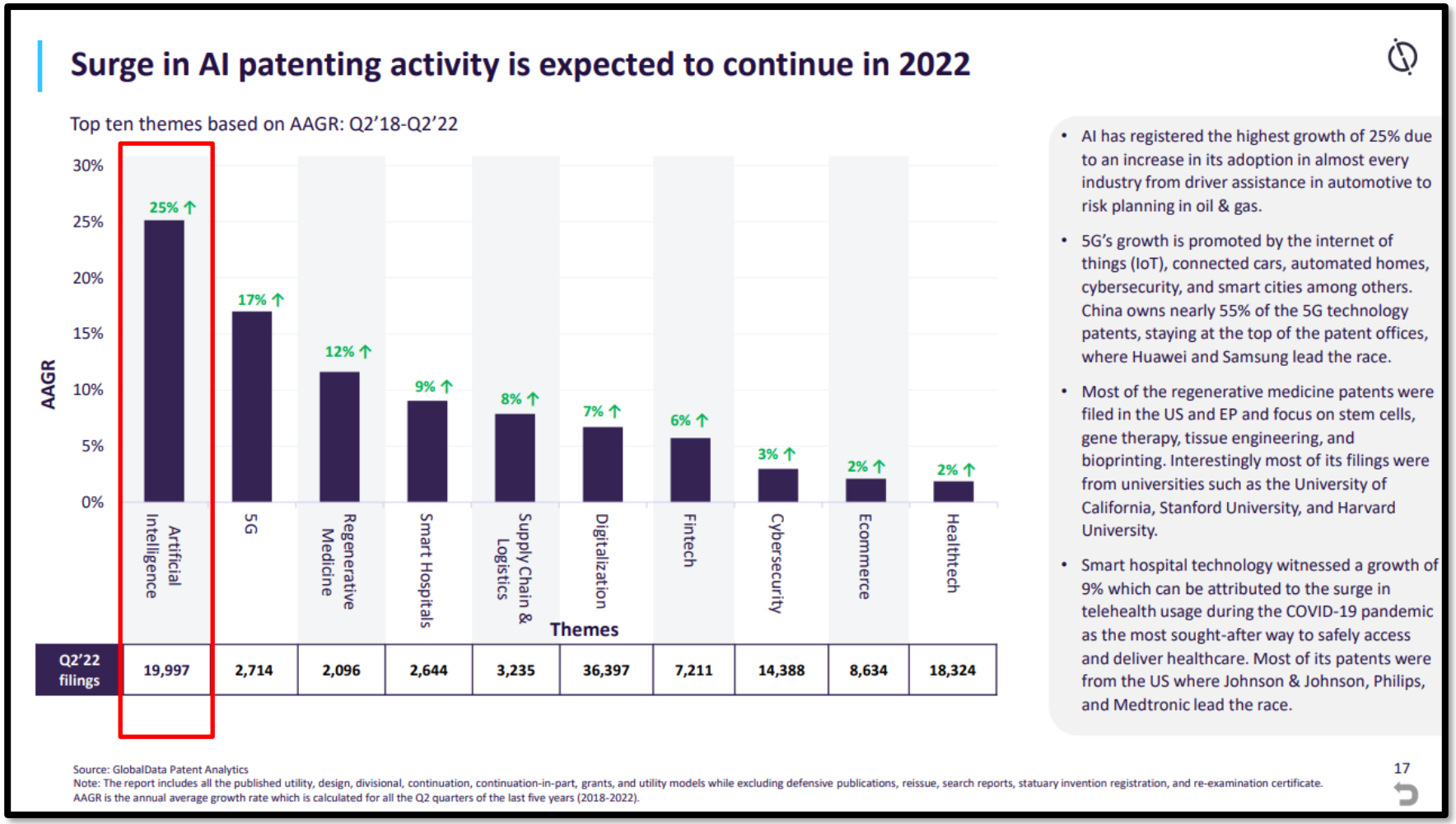
Proliferation of "AI" Patenting



See GlobalData, Patent Statistics and Analysis Q2 2022 (July 2022), *available at* https://www.law360.com/articles/1518325?utm_source=ios&utm_medium=ios&utm_campaign=ios-shared

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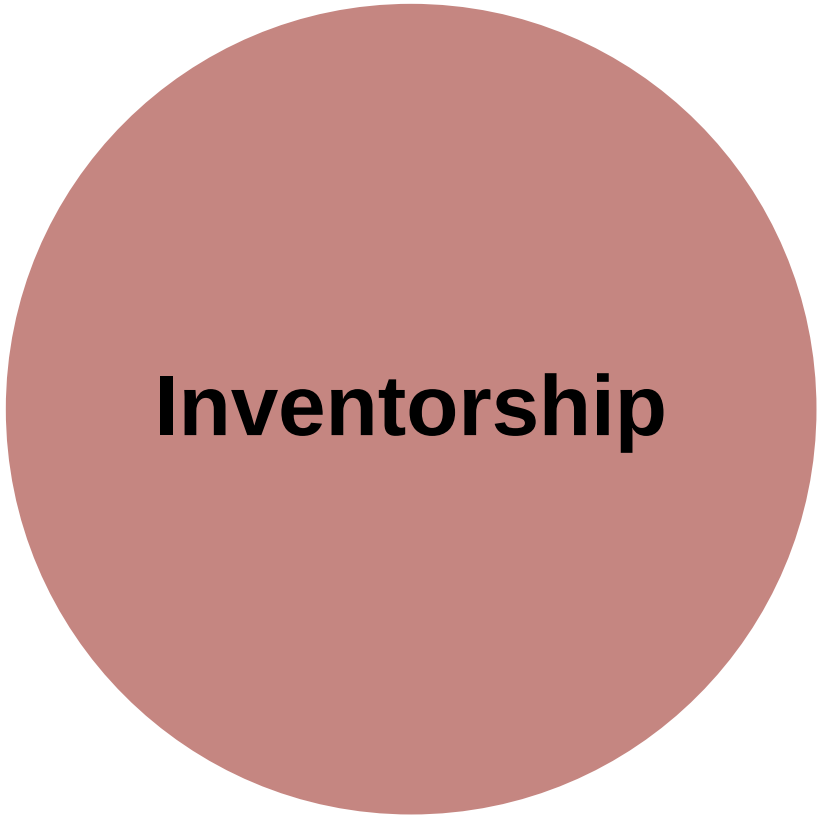
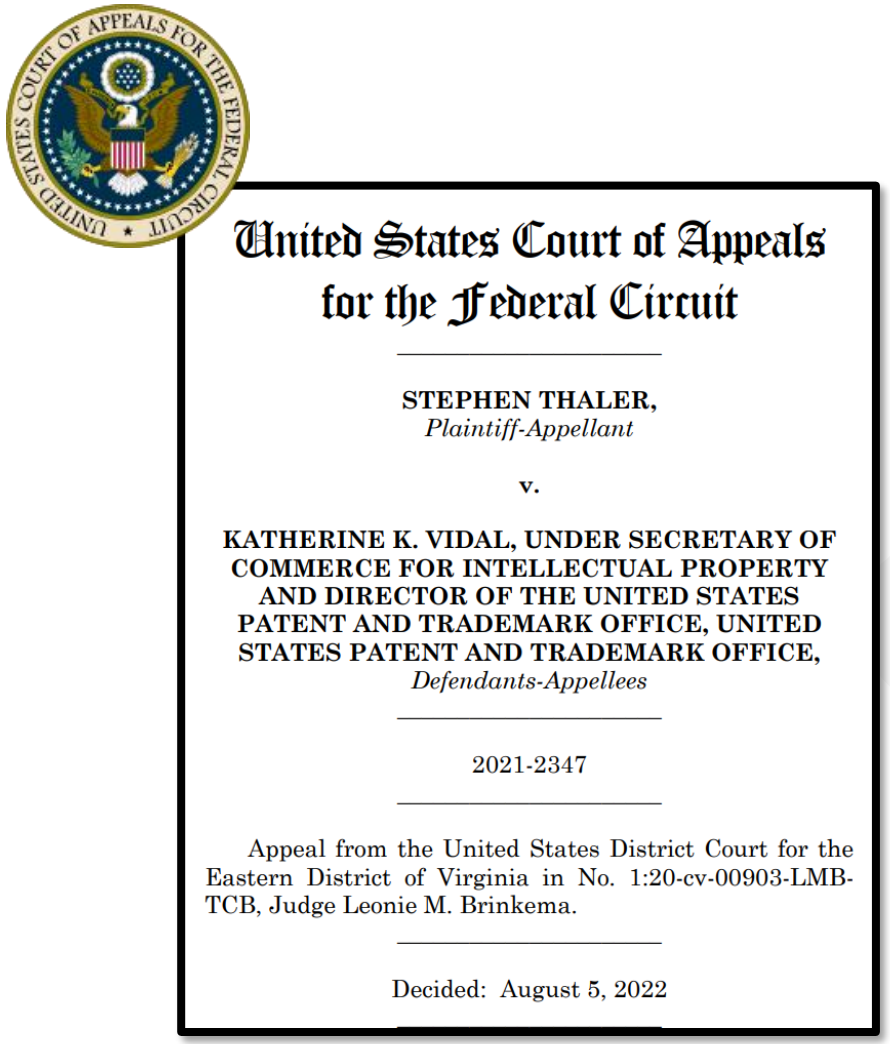
Emerging AI/ML + Patent Issues to Consider



- Federal Circuit confirmed that “inventor” is limited to natural persons
- While inventorship for narrow AI seems settled for now, may need to revisit for general AI
- Prosecution logistics (*e.g.*, declarations and oaths, duty of candor)
- Litigation logistics (*e.g.*, inventor depositions)

Thaler v. Vidal Rejects Judicial Expansion of "Inventor"



United States Court of Appeals
for the Federal Circuit

STEPHEN THALER,
Plaintiff-Appellant

v.

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendants-Appellees

2021-2347

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:20-cv-00903-LMB-TCB, Judge Leonie M. Brinkema.

Decided: August 5, 2022

This case presents the question of who, or what, can be an inventor. Specifically, we are asked to decide if an artificial intelligence (AI) software system can be listed as the inventor on a patent application. At first, it might seem that resolving this issue would involve an abstract inquiry into the nature of invention or the rights, if any, of AI systems. In fact, however, we do not need to ponder these metaphysical matters. Instead, our task begins – and ends – with consideration of the applicable definition in the relevant statute.

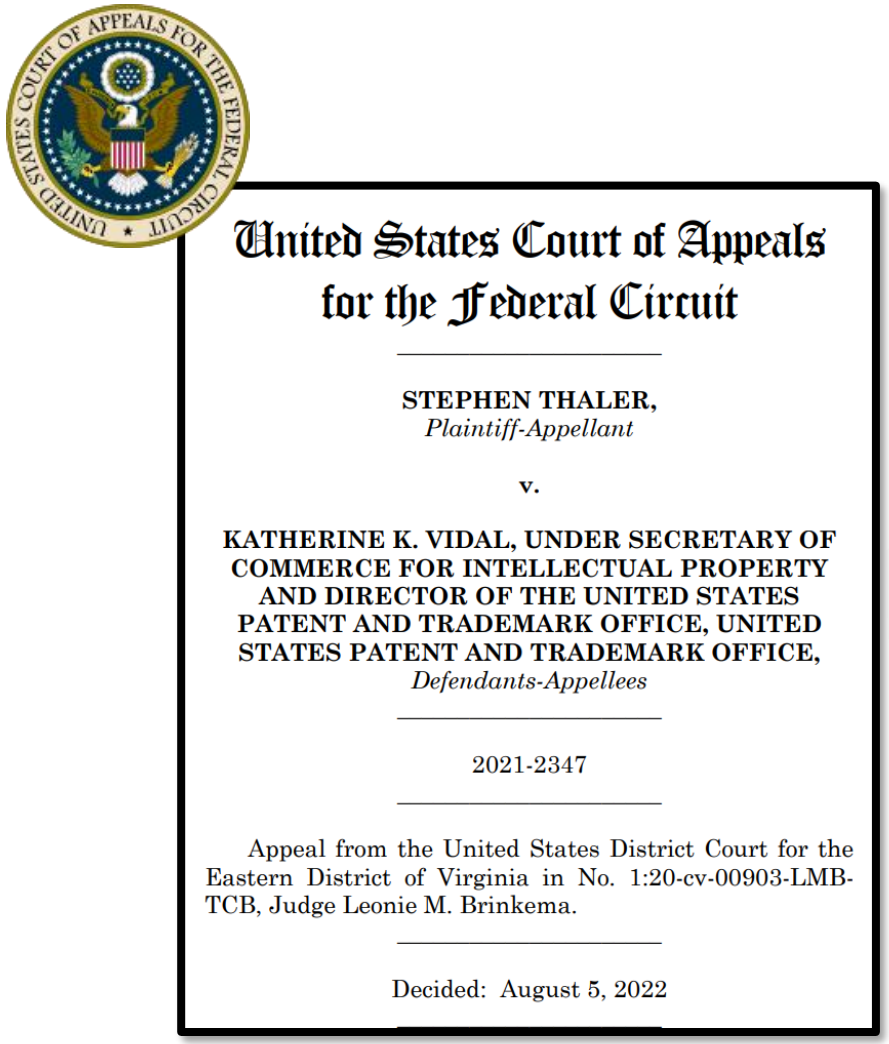
* * *

When a statute unambiguously and directly answers the question before us, our analysis does not stray beyond the plain text. Here, Congress has determined that only a natural person can be an inventor, so AI cannot be. Accordingly, the decision of the district court is affirmed.

See Thaler v. Vidal, 43 F. 4th 1207, 1209, 1213 (Fed. Cir. 2022)

PAUL HASTINGS

Thaler v. Vidal Leaves Open Implications of AI "Assistance"



United States Court of Appeals
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STEPHEN THALER,
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KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, UNITED STATES PATENT AND TRADEMARK OFFICE,
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Decided: August 5, 2022

Thaler argues that inventions generated by AI should be patentable in order to encourage innovation and public disclosure. Thaler's policy arguments are speculative and lack a basis in the text of the Patent Act and in the record. In any event, the text before us is unambiguous, and we may not "elevate vague invocations of statutory purpose over the words Congress chose." *Sw. Airlines Co. v. Saxon*, 142 S. Ct. 1783, 1792-93 (2022). Moreover, we are not confronted today with the question of whether inventions made by human beings with the *assistance* of AI are eligible for patent protection.

See Thaler v. Vidal, 43 F. 4th 1207, 1213 (Fed. Cir. 2022)

PAUL HASTINGS

DABUS Inventorship Disputes Around the World

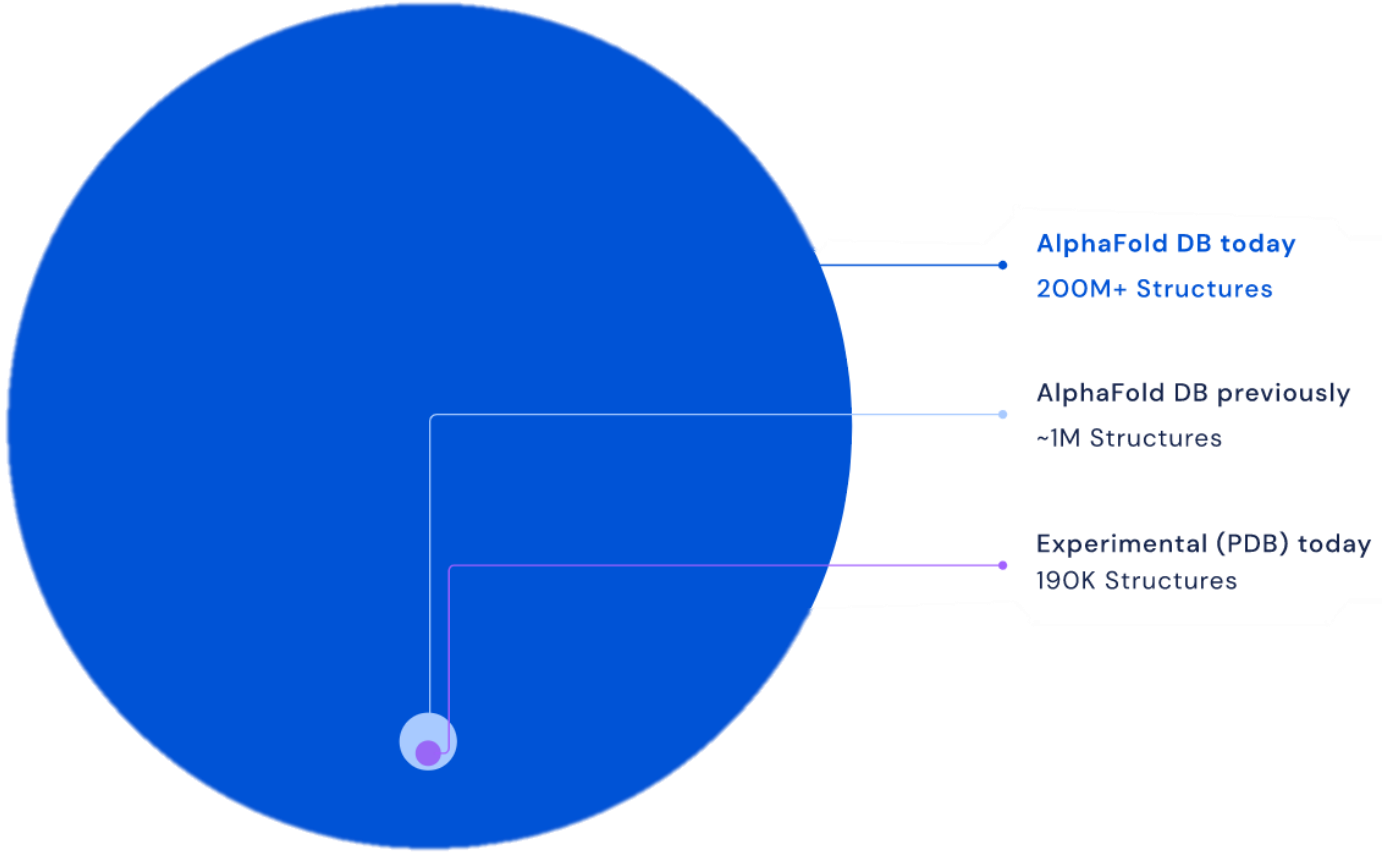
- Inventorship ***denied***
  - **Australia** → Statutes interpreted to limit inventors to natural persons
    - Appellate court in April 2022 reversed lower decision that held AI system could be named as inventor
  - **United States** → Statutes interpreted to limit inventors to natural persons
  - **United Kingdom** → Statutes interpreted to limit inventors to natural persons
  - **EPO** → Statutes interpreted to limit inventors to natural persons
- Inventorship ***middle ground***
  - **Germany** → AI system may be referenced in inventor designation
    - "Stephen L. Thaler, PhD who prompted the artificial intelligence DABUS to create the invention"
- Inventorship ***allowed***
  - **South Africa** → Examination generally permits naming any entity to start process

Emerging AI/ML and Patent Issues to Consider

- AI tools may impact reasonable expectation of success analysis
- AI may alter the skill of level of a POSA, and thus affect the bar for nonobviousness
- Proliferation of AI-generated prior art may impact duty of candor

AI-Assisted Proliferation of Protein Structure Knowledge

AlphaFold is an AI system developed by DeepMind that predicts a protein's 3D structure from its amino acid sequence.



See AlphaFold Protein Structure Database, https://alphafold.ebi.ac.uk/

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Potential § 103 Implications of AlphaFold-Type Technology

In re Diane M. DILLON.

No. 88–1245.

United States Court of Appeals, Federal Circuit.

Nov. 9, 1990.

"Structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case."

In re Dillon, 919 F.2d 688, 692-93 (Fed. Cir. 1990)

GENETICS INSTITUTE, LLC, Plaintiff–Appellant,

v.

NOVARTIS VACCINES AND DIAGNOSTICS, INC., Defendant–Appellee.

No. 2010–1264.

United States Court of Appeals, Federal Circuit.

Aug. 23, 2011.

"Yet Genetics concedes that it was not known prior to the filing of the '620 patent that amino acids 1649-89 [of the claimed truncated Factor VIII protein] were critical to maintain vWF binding."

Genetics Inst., LLC v. Novartis Vaccines and Diag., Inc., 655 F.3d 1291, 1303-04 (Fed. Cir. 1993)

PAUL HASTINGS

Potential § 103 Implications of AlphaFold-Type Technology

In re Marek Z. KUBIN and Raymond G. Goodwin.

No. 2008–1184.

United States Court of Appeals, Federal Circuit.

April 3, 2009.

This court also declines to cabin *KSR* to the "predictable arts" (as opposed to the "unpredictable art" of biotechnology). In fact, this record shows that one of skill in this advanced art would find these claimed "results" profoundly "predictable." The record shows the well-known and reliable nature of the cloning and sequencing techniques in the prior art, not to mention the readily knowable and obtainable structure of an identified protein. Therefore this court cannot deem irrelevant the ease and predictability of cloning the gene that codes for that protein. This court cannot,

In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009)

PAUL HASTINGS

MOLOLAMKEN

NYIPLA One-Day Patent Seminar

IPR Estoppel After *Caltech*

Jonathan E. Barbee
MoloLamken LLP, Counsel

November 9, 2022

Agenda

- **IPR Estoppel Before *Caltech***
- **IPR Estoppel After *Caltech***
- **Open Questions After *Caltech***
- **Key Takeaways**

IPR Estoppel Before *Caltech*

- **Estoppel bars an invalidity argument that was "raised or reasonably could have been raised" during an IPR. 35 U.S.C. § 315(e)(2).**
- **Broad Interpretation v. Narrow Interpretation**
  - » Narrow Interpretation: Only instituted grounds are estopped.
  - » Broad Interpretation: All grounds that could have been raised are estopped.
- **The Impact of *SAS***
  - » The PTAB was no longer able to pick and choose claims and grounds for institution.
  - » After *SAS*, district courts overwhelmingly adopted the broad interpretation of IPR estoppel.

Caltech Case Summary

Cal. Inst. of Tech. v. Broadcom Ltd., 25 F.4th 976 (Fed. Cir. 2022)

- The Federal Circuit held that estoppel includes claims and grounds not only raised in an IPR but that could have been reasonably raised.

- Partly due to *SAS*, the Federal Circuit adopted the broad interpretation of IPR estoppel.

- The Federal Circuit overruled *Shaw Industries Group, Inc. v. Automated Creel Systems*, 817 F.3d 1293 (Fed. Cir. 2016).

Caltech Case Summary

- On February 22, 2022, the Federal Circuit issued errata that clarified that IPR estoppel only applies to the petitioned claims.
  - » *"all claims and grounds not in the IPR but which reasonably could have been included" was changed to "all grounds not stated in the petition but which reasonably could have been asserted against the claims included"*
  - » *"grounds asserted" was changed to "challenged claims"*

Open Questions After *Caltech*

- *What does "reasonably could have been raised" mean?*
- *What does it mean to be "aware of" a prior art reference?*
- *Does IPR estoppel include all possible prior art and obviousness combinations related to petitioned claims?*
- *How should district courts deal with nearly identical claims where only one claim is petitioned?*
- *How does IPR estoppel affect defendants in related cases where the same claims are asserted?*

Key Takeaways

- **IPRs are riskier for petitioners than they used to be.**
- **The strategy behind filing an IPR needs to consider all potential grounds and prior art for petitioned claims.**
- **Plaintiffs may consider raising IPR estoppel more often on summary judgment.**
- **An unsuccessful IPR can severely limit a defendant's invalidity case at trial.**
- **The law surrounding IPRs continues to evolve.**

Questions?

Who invented CRISPR-Cas9?

UC Berkeley, University of Vienna and Emmanuelle Charpentier ("CVC") v. The Broad Institute, MIT and Harvard University ("Broad")

NYIPLA Fall One-Day Patent Seminar - November 9, 2022

CADWALADER

Dorothy R. Auth
Cadwalader, Wickersham & Taft, LLP
Dorothy.auth@cwt.com

What Constitutes a "Definite & Permanent Idea", *i.e.*, Conception?

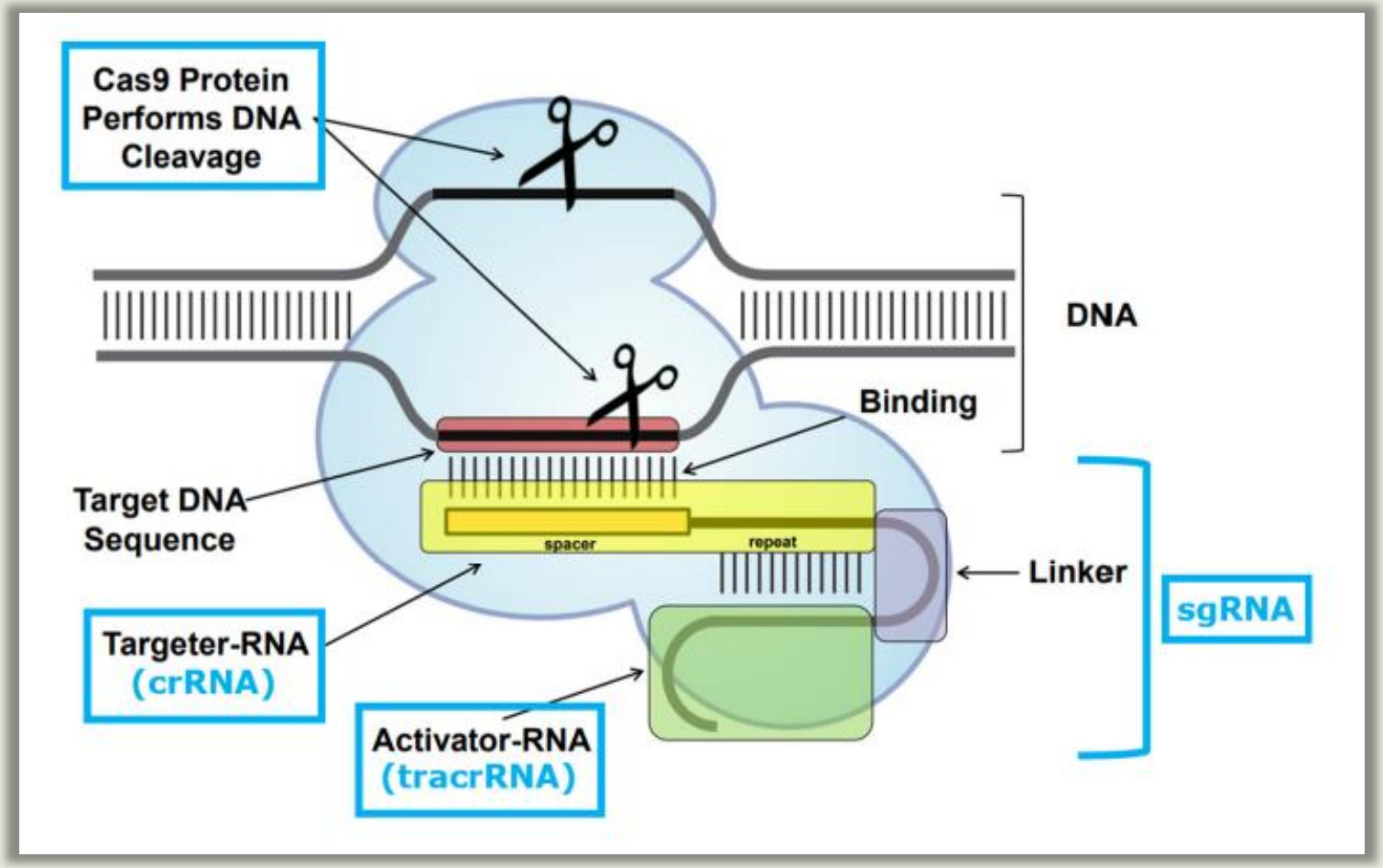
Conception Scrutinized experiments, expressed uncertainty **Reduction to Practice**

"Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."

Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

Conception is the touchstone of inventorship.

CRISPR-Cas9 Gene-editing Technology



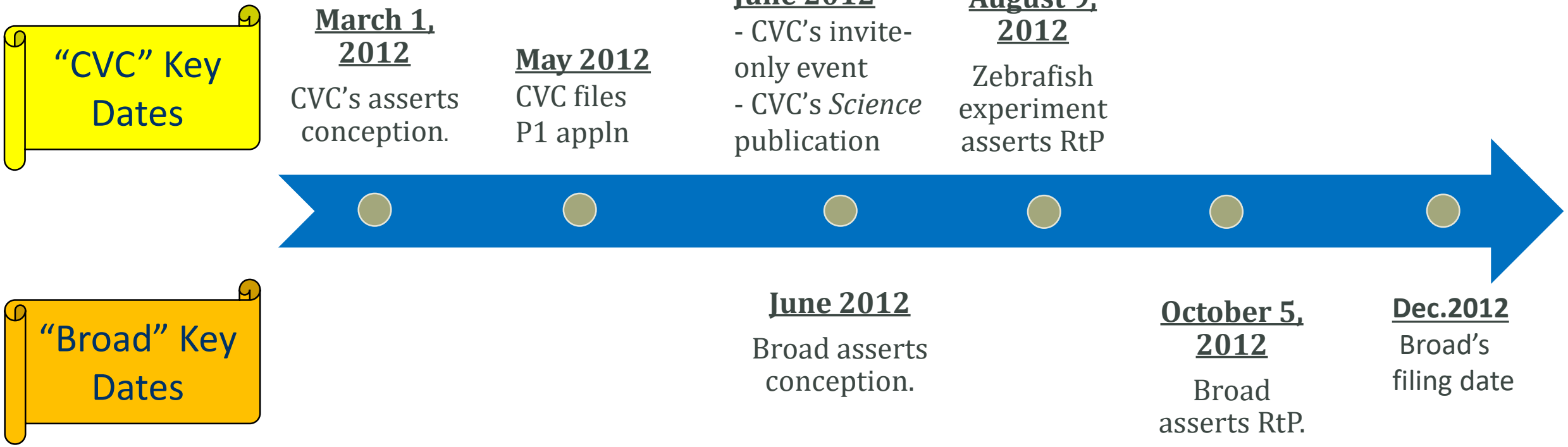
crRNA – in CRISPR systems, an RNA sequence can guide at least one DNA-cleaving protein to a complementary target DNA sequence.

tracrRNA – another RNA sequence that can convert precursor crRNA strands into their active, mature form.

sgRNA – tracrRNA and crRNA can be linked to form a single-molecule "chimeric" RNA or sgRNA.

Case No. 22-1594, Doc. 17-1 at 20.

Inventorship Timeline (2012)



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March 1, 2012 - Conceptual Drawing Dr. Jinek Notebook

"CVC" Key Dates

March 1, 2012

CVC's conception.

August 9, 2012

Zebrafish experiment is successful.

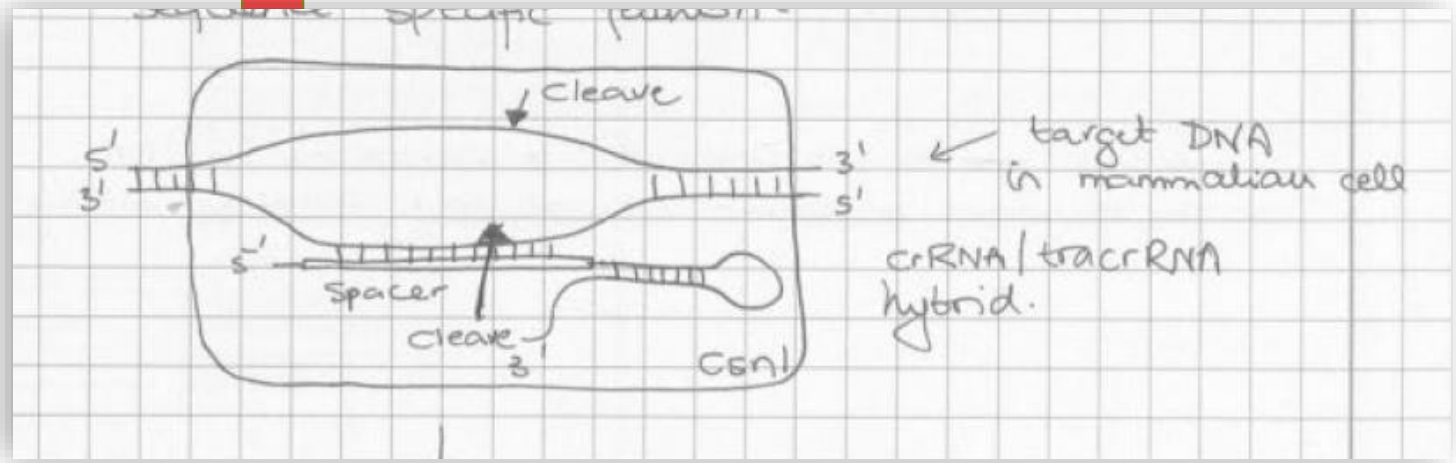
"Broad" Key Dates

June 2012

- Broad's asserted conception.

October 5, 2012

Broad reduces invention to practice.



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June 26, 2012

"CVC" Key Dates

March 1, 2012
CVC's asserted conception.

June 2012
- CVC invite event
- CVC's *Science* pub.

August 9, 2012
Zebrafish experiment is successful.

"Broad" Key Dates

June 2012
- Broad's asserted conception.
- Broad attends CVC presentation and receives email from CVC reviewer.

October 5, 2012
Broad reduces invention to practice.

CADWALADER

August 9, 2012

"CVC" Key Dates

March 1, 2012

CVC's asserted conception.

August 9, 2012

Zebrafish experiment is successful.

"Broad" Key Dates

June 2012

- Broad's asserted conception.
- Broad receives email from CVC reviewer.

October 5, 2012

Broad reduces invention to practice.

Zebrafish embryo mutation experiment

Email to inventor reporting results:

> Potentially good news about fish. We tested the NLS-tagged Cas9 that we just got from Martin as the normal protein was not giving anything conclusive…. *there are still problems with toxicity and… it will require some more optimization… Anyway, there is a hint it might work but we shouldn't be overexcited now.*

CADWALADER

October 5, 2012

- Zhang published results of successful DNA modification in mouse cells, of experiments carried out in July & August 2012
- Emails characterized the July and August experiments as "very promising"

PTAB Consideration of Emails

Neither the email reporting the results nor Dr. Charpentier's response "demonstrates that either recognized and appreciated Dr. Raible's 9 August 2012 experiment was an actual reduction to practice of an embodiment of Count 1."

Interference No. 106,115, at 14

PTAB Decision

"Although the CVC inventors developed a system on 1 March 2012 that they hoped would work in eukaryotic cells, the preponderance of the evidence demonstrates that they did not have a definite and permanent idea of how to achieve that result as of that date or by the later dates CVC asserts support that date because of their perception of these multiple failures."

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Issues for Appeal to the Federal Circuit

1. Whether the PTAB legally erred by failing to apply an objective standard for conception, instead requiring that CVC knew their invention would work
2. Whether the PTAB impermissibly awarded priority without identifying any inventive contribution by the purported inventor

Amicus Brief from Regeneron Pharmaceuticals, Inc.

Regeneron position:

- The PTAB conflated the requirements of conception and reduction to practice
  - Conception does not require an inventor to know the invention will work
  - Reduction to practice does

"The board conflated conception — a mental act that the patent system promotes and protects — with actual reduction to practice — a physical step…"

- Erroneously held that post-conception experimental failures preclude conception

REGENERON
science to medicine®

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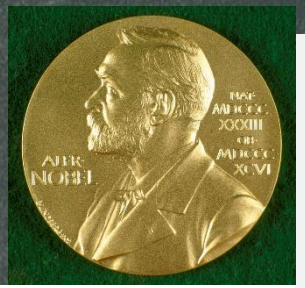
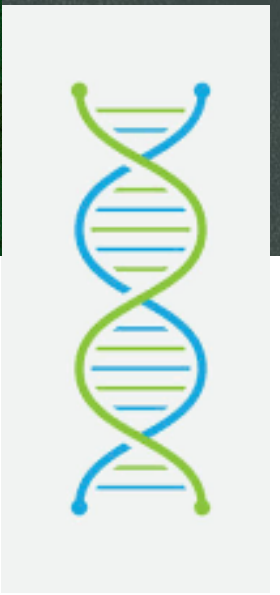
Amicus Brief World Renown Scientists in CRISPR Field





PTAB misunderstood basic principles of how skepticism and failure operate within the scientific method.

PTAB misunderstood CVC's ordinary skepticism for fundamental doubt about the specificity of their ideas.

"Without skepticism –including a willingness to recognize, even welcome, failure –scientists risk falling prey : *confirmation bias*." to one of the most pernicious problems in science

"Science is a conversation: an iterative process that allows for one idea to build and shape the next through refinement of the last."

The PTAB's decision… will discourage collaboration, slow scientific progress, and reward confirmation bias.

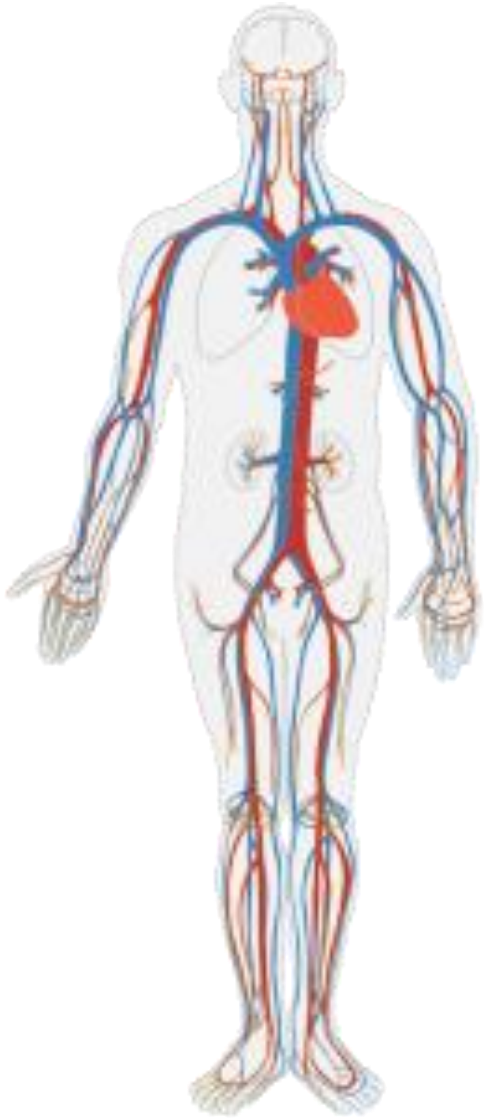
GlaxoSmithKline v. Teva
Carve Outs/ Skinny Labels & Inducement of Infringement

SERENA FARQUHARSON-TORRES PH.D.

ASSISTANT GENERAL COUNSEL, INNOVATION LAW

BRISTOL MYERS SQUIBB

NYIPLA MEETING NOVEMBER 9.2022



Background (GSK v. Teva)

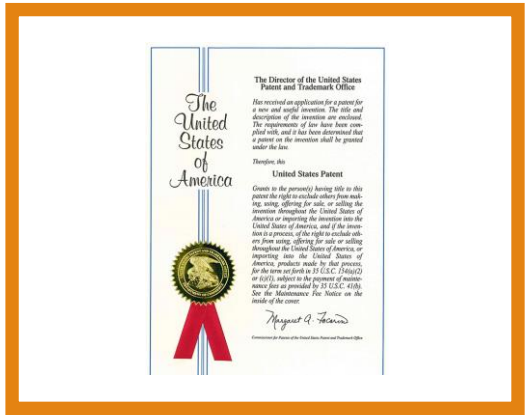
In 1997 the FDA approved GSK's branded heart failure drug Coreg (carvedilol) for three indications:

- Hypertension
- Congestive heart failure (CHF)
- Left ventricular dysfunction (LVD)

In 2007 Teva received FDA approval to market a generic version of carvedilol for only the non-patented indications:

- hypertension
- ~~mild-to-severe congestive heart failure (CHF)~~
- and left ventricular dysfunction (LVD)

More Background



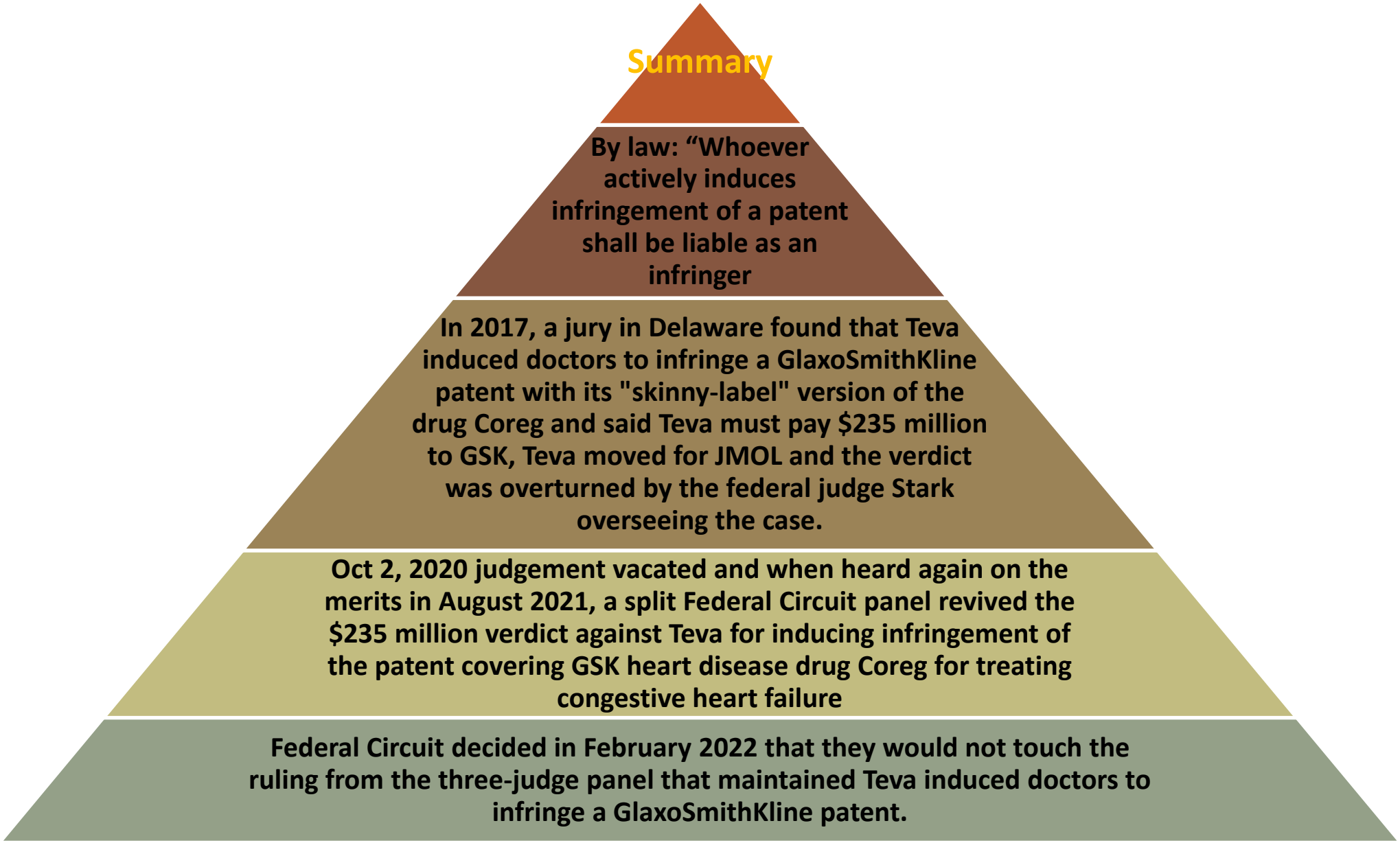
Hatch-Waxman Act allows generics to seek approval of FDA approved & non-patented uses via skinny label.

GSK U.S. Patent No. RE40,000 (reissue of US. Pat. No. 5,760,069, expired (2015)): Method patent with claims drawn to methods of decreasing mortality caused by congestive heart failure by administering to a patient Coreg ….

In press releases and marketing materials, Teva stated that its generic version of Coreg was "an AB Rated generic of Coreg tablets." An AB rating indicates Teva's generic version of Coreg is considered bioequivalent to branded Coreg.

In 2011, the FDA required Teva to amend its label to be identical in labeling to the branded drug. Teva amended its label to include the indication for treatment of congestive heart failure.

Summary


By law: “Whoever actively induces infringement of a patent shall be liable as an infringer
In 2017, a jury in Delaware found that Teva induced doctors to infringe a GlaxoSmithKline patent with its "skinny-label" version of the drug Coreg and said Teva must pay $235 million to GSK, Teva moved for JMOL and the verdict was overturned by the federal judge Stark overseeing the case.
Oct 2, 2020 judgement vacated and when heard again on the merits in August 2021, a split Federal Circuit panel revived the $235 million verdict against Teva for inducing infringement of the patent covering GSK heart disease drug Coreg for treating congestive heart failure
Federal Circuit decided in February 2022 that they would not touch the ruling from the three-judge panel that maintained Teva induced doctors to infringe a GlaxoSmithKline patent.

Federal Circuit Judges

- **Teva's promotional materials, press releases, product catalogs, U.S. Food and Drug Administration labels, and testimony from witnesses on both sides supports that Teva was inducing the doctors to prescribe Coreg for infringing uses.**
- **In reversing, the majority made no legal pronouncements that will bind any panel of this court from concluding, in a different case, on different facts, that a properly executed skinny label strategy and marketing campaign does not create inducement liability.**
- Dissent (Prost) : judgement nullified the practice of skinny label launches, a practice that has Congressional approval. She added that Teva was being punished for following the regulatory pathway set out in the Hatch-Waxman Act.

Practice Tips for Generics

- Include carve out of patented indications in the generic label; make sure that all press releases, marketing materials and catalogs are consistent with the carved-out label.
- Keep an eye out on pending applications in the branded portfolio and monitor the prosecution and types of claims that need to be part of the carve out.
- Patent lawyers need to insist on being involved in regulatory and commercial plans whenever strategy includes carve outs & skinny labels.

Questions?