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The Denial of Certiorari in 'American Axle': What It Means for Patent Law and What (If Anything) It Says About the Supreme Court's Case-Selection Criteria

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The Denial of Certiorari in *American Axle*: What It Means for Patent Law and What (If Anything) It Says About the Supreme Court's Case-Selection Criteria

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Presenters

Laura W. Smalley is a partner at Harris Beach and practices in the Intellectual Property Group. She is co-leader of the Pharmaceuticals, Medical Devices and Life Sciences Intellectual Property Team. Selected as one of the Best Lawyers in America, she focuses her legal practice on technology development and exploitation, including the enforcement of intellectual property rights. Ms. Smalley has litigated several patent infringement suits involving medical devices, electrical components and imaging technology. She also prosecutes patents in the chemical and biotechnology fields.

Brian D. Ginsberg is a partner at Harris Beach and practices primarily in the firm's Appellate Practice Group, leading high-stakes appeals in federal and state courts across the country. He has substantial experience litigating appeals in numerous different areas of law, including patent appeals in the U.S. Court of Appeals for the Federal Circuit. Before joining Harris Beach, Brian served in the Office of the New York State Solicitor General, representing New York's many agencies and officials in some of their most significant appeals, including matters in the U.S. Supreme Court.

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Subject-Matter Eligibility

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101

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Subject-Matter Eligibility

"This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms."

Judicially-created exceptions:

1. Laws of nature (gravity).
2. Natural phenomenon (new mineral or new plant).
3. Abstract ideas: "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Le Roy v. Tatham*, 14 How. 156, 175 (1853).

Diamond v. Diehr, 450 U.S. 175, 185 (1981)

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Subject-Matter Eligibility

Not patentable based on subject-matter eligibility or other grounds?

1. Improved method of making wrought pipe by extruding metal through a die. *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).
2. Electromagnetism. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 77-78 (1854).
3. Paper pulp produced from wood. *Am. Wood-Paper Co. v. The Fibre Disintegrating Co.*, 90 U.S. (Wall.) 566 (1874).
4. Fiber consisting of the cellular tissues of pine needles. *Ex Parte Latimer*, 1889 Dec. Comm'r Pat. 123 (1889).

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Subject-Matter Eligibility

Subject Matter Eligibility Jurisprudence Starting to Ramp Up Again:

1. Method of converting binary-coded decimal numerals into pure binary numerals is an unpatentable abstract idea. *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).
2. Method for updating alarm limits with post-solution activity is an unpatentable abstract idea. *Parker v. Flook,* 437 U.S. 584 (1978).
3. BUT Process for curing synthetic rubber using mathematical equation subject-matter eligible. *Diamond v. Diehr*, 450 U.S. 175 (1981).
4. BUT Genetically-engineered bacterium subject-matter eligible. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

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Mayo Collaborative Services v. Prometheus Labs., 566 U.S. 66 (2012)

- The claims recited methods for calibrating the proper dosage of thiopurine drugs.
- The disclosed correlation between 6–TG blood levels and over/under thiopurine dosage is an unpatentable law of nature because the relation is a consequence of the ways in which thiopurine compounds are metabolized by the body.
- Noted the difference between claims to laws of nature themselves (not patent eligible) and claims to specific applications of such laws (patent eligible).

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Mayo Collaborative Services v. Prometheus Labs., 566 U.S. 66, 68 (2012)

- Application of a law of nature is patentable, but "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." Concluded that the instructions in the claim add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field; and
- The steps of the method, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

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Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 212-214 (2014)

- The patents at issue disclosed schemes to manage certain forms of financial risk.
- The challenged claims related to a computerized scheme for mitigating "settlement risk"—*i.e.*, the risk that only one party to an agreed-upon financial exchange will satisfy its obligation—and were designed to "facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary."
- The patents-in-suit claimed (1) a method for exchanging obligations, (2) a computer system configured to carry out the method for exchanging obligations, and (3) a computer-readable medium containing program code for performing the method of exchanging obligations.

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Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 218-219 (2014)

- These claims were drawn to the abstract idea of intermediated settlement.
- "It follows from our prior cases, and *Bilski* in particular, that the claims at issue here are directed to an abstract idea. Petitioner's claims involve a method of exchanging financial obligations between two parties using a third-party intermediary to mitigate settlement risk. The intermediary creates and updates 'shadow' records to reflect the value of each party's actual accounts held at 'exchange institutions,' thereby permitting only those transactions for which the parties have sufficient resources. At the end of each day, the intermediary issues irrevocable instructions to the exchange institutions to carry out the permitted transactions."

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Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 221-222 (2014)

- The method claims, which required merely generic computer implementation, failed "to transform that abstract idea into a patent-eligible invention."
- "'Simply appending conventional steps, specified at a high level of generality,' was not 'enough' to supply an 'inventive concept'" in *Mayo*.
- Use of a computer does not change the analysis—"the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention" nor does limiting the use of an abstract idea "to a particular technological environment" render a claim eligible.
- Using the same rationale, the claims to a computer system and a computer-readable medium were also not patent-eligible subject matter.

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Subject-Matter Eligibility

Mayo/Alice Test for Subject Matter Eligibility:

- Step 1: Are claims "directed to" a law of nature, natural phenomenon or abstract idea?
- Step 2: If yes, then do the claims embody an "inventive concept" sufficient to ensure that the patent claims amount to "significantly more" than a patent on the natural law, natural phenomenon, or abstract idea itself?

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)(correlation between metabolite concentration and likely harm of drug treatment), and *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014)(process for mitigating settlement risk).

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Subject-Matter Eligibility

Difficulties in applying test:

- USPTO Guidance (2014, 2015, 2016, Berkheimer memo, 2019, 2019 update). Current guidance is in Manual of Patent Examining Procedure and at https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility.
- USPTO June 2022 Report to Congress: *Patent eligible subject matter: Public views on the current jurisprudence in the United States* https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf
- Over 200 Federal Circuit decisions applying test since *Mayo* and *Alice* decided.

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American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1290 (Fed. Cir. 2019)

- Patent infringement complaint filed in 2015, claiming infringement of U.S. Pat. No. 7,774,991, directed to a method of manufacturing a quieter automobile driveshaft.
- Parties filed cross-motions for summary judgment as to the eligibility of the asserted claims of the patent-in-suit under 35 U.S.C. § 101.
- The patent identified “a need in the art for an improved method for damping various types of vibrations in a hollow shaft” that “facilitates the damping of shell mode vibration as well as the damping of bending mode vibration” simultaneously.

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American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1290 (Fed. Cir. 2019)

22. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:

providing a hollow shaft member;

tuning a mass and a stiffness of at least one liner, and

inserting the at least one liner into the shaft member;

wherein the at least one liner is a tuned resistive absorber for attenuating shell mode vibrations and wherein the at least one liner is a tuned reactive absorber for attenuating bending mode vibrations.

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American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1290 (Fed. Cir. 2019)

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wherein the at least one liner is a tuned resistive absorber for attenuating shell mode vibrations and wherein the at least one liner is a tuned reactive absorber for attenuating bending mode vibrations.

Application of Hooke's Law—an equation which describes the relationship among an object's mass, its stiffness and the frequency at which it vibrates

Friction dampening—natural phenomenon

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American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1291, 1295 (Fed. Cir. 2019)

Panel decision:

- Determined as a matter of law that the claimed method of manufacturing a drive shaft assembly for a car was not patent-eligible subject matter under 35 U.S.C. § 101 because it was directed to the use of a natural law.
- Concluded that the claims simply applied Hooke's law, "an equation that describes the relationship between an object's mass, its stiffness, and the frequency at which the object vibrates," to tune a propshaft liner to dampen vibrations.
- Although neither the specification nor the prosecution history mentioned Hooke's law or provided the formula, the challenged claim was **directed to** a natural law because it disclosed "a result that involves application of a natural law without limiting the claim to particular methods of achieving the result."

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American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1308, 1319 (Fed. Cir. 2019)

Dissent:

- The majority decision presents an unwarranted expansion of 35 U.S.C. § 101 to claims whose performance would require the application of a natural law.
- Stated that the majority opinion in effect held that "use of an unclaimed natural law in the performance of an industrial process is sufficient to hold the claims directed to that natural law."
- The majority's holding to the contrary "leaves patentees awash in a sea of uncertainty . . . Every mechanical invention must apply the laws of physics—that does not render them all ineligible, or maybe it does now."

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American Axle & Manuafacturing, Inc. v. Neapco Holdings LLC, 966 F.3d 1347, 1364 (Fed. Cir. 2020).

American Axle petitioned for *en banc* review:

- The Federal Circuit split 6-to-6 and the petition was therefore denied.
- Judge Kara F. Stoll's dissent: "one can still reasonably ponder whether foundational inventions like the telegraph, telephone, light bulb, and airplane—all of which employ laws of nature—would have been ineligible for patenting under the majority's revised approach."
- Advocates for grant of *en banc* review criticized state of confusion in section 101 jurisprudence.

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American Axle's Petition for Writ of Certiorari

- *Amici curiae* included former decision makers from the USPTO, former Federal Circuit Chief Judge, law professors, industry organizations and bar associations.
- Briefs requested clarification of when a claim is "directed to" a natural law.
- *Amici curiae* noted urgent need for guidance and reform:
  - Courts need consistency in precedent to provide reliable judgments, as unpredictability in the patent system is harmful to the economy, the patent system as a whole, and to inventors, business entities, investors, innovators attempting design around solutions, and other interested parties who need to understand what is, and is not, patentable.

Brief of New York Intellectual Property Law Association as *Amicus Curiae* in Support of Petitioner (Jan. 25, 2021)

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American Axle's Petition for Writ of Certiorari

- "[T]he Federal Circuit's *American Axle* decision revised the [Mayo/Alice] test, transforming it from an already-difficult-to-apply two-step analysis into a subjective one-step determination dependent on the intuition of judges."
- "And, as noted by Judge Moore's dissent, the Federal Circuit's panel majority did so through a series of compounding errors.

  First, at step one, the court improperly reduced the substance of the claim, i.e., what the claim is 'directed to,' to its simplest and most basic form, which it found to be Hooke's law.

  Second, by defining the scope of the invention as a natural law and nothing more at step one, the court collapsed Mayo's two steps into a single inquiry that could, without this Court's intervention, be used to characterize any invention an ineligible law of nature, natural phenomenon, or abstract idea, including as happened here, methods of manufacturing that have been considered patent eligible since the beginning of the U.S. patent system."

Brief of Biotechnology Innovation Organization and AUTM as *Amicus Curiae* in Support of Petitioner (March 1, 2021)

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Aftermath of *American Axle*

- Represents expansion of section to traditionally “safe” mechanical/industrial processes.
- Uncertainty in section 101 jurisprudence will remain—each new patent that gets litigated represents a potential change/expansion of section 101.
- The biggest impact of the uncertainty of section 101 jurisprudence is on the “new frontier” – personalized medicine, cutting-edge diagnostics and “natural” therapeutics.
- Focus of protecting innovation may change more to either trade secret protection (if possible) or to other jurisdictions more conducive to protecting these types of innovations.

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Aftermath of *American Axle*

Investment and research in impacted areas will decrease—Judge Michel's recent IPWatchDog article series makes a compelling case that the decrease in investment and patent filings is already happening.

- Studies show significant impact on innovation, including decreased willingness to invest.
- US failure to protect its position in Artificial Intelligence and bio-tech related inventions.
- Examples of abandoned diagnostics and improved software inventions.
- R&D and commercialization moving to other jurisdictions (China) with stronger/increasing IP protection.

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Aftermath of *American Axle*

- https://ipwatchdog.com/2022/10/06/presenting-evidence-patent-eligibility-reform-part-consensus-patent-law-experts/id=151886/
- https://ipwatchdog.com/2022/10/11/presenting-evidence-patent-eligibility-reform-part-ii-harm-rd-investment-innovation-u-s-interests/id=151960/
- https://ipwatchdog.com/2022/10/18/presenting-evidence-patent-eligibility-reform-part-iii-case-studies-litigation-data-highlight-additional-evidence-harm/id=152193/
- https://ipwatchdog.com/2022/10/26/presenting-evidence-patent-eligibility-reform-part-iv-uncertainty-burdening-litigants-courts-threatening-u-s-competitiveness-national-security/id=152341/

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Aftermath of *American Axle*

Examples of abandoned inventions include:

(1) *Abandoned Lupus Diagnostic*: Researchers at a prominent Midwest university developed a diagnostic test that helped physicians proactively treat Systemic Lupus Erythematosus (SLE). Licensees terminated licenses intended to develop and commercialize the diagnostic "based on the new vulnerability of the issued patents and the inability to obtain the full scope of patent protection with additional patents."

(2) *Abandoned Rare Disease Diagnostic*: Researcher studied the genetic origins and pathogenesis of Noonan syndrome and developed a diagnostic test for early detection of the disease to enable early intervention. One patent was obtained—an additional application was rejected under section 101 and abandoned. After *Mayo* and *Myriad*, the licensee refused to pay royalties and no further commercialization efforts were undertaken.

https://ipwatchdog.com/2022/10/18/presenting-evidence-patent-eligibility-reform-part-iii-case-studies-litigation-data-highlight-additional-evidence-harm/id=152193/

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Patent Eligibility Restoration Act of 2022 (Senate Bill 4734)

- Proposed by Sen. Thom Tillis (R-NC)
- Act purports to restore "patent eligibility to important inventions across many fields, while also resolving legitimate concerns over patenting of mere ideas, the mere discovery of what already exists in nature, and social and cultural content that everyone agrees is beyond the scope of the patent system, which is a system aimed at promoting technology-based innovation."
- The Act would overrule *Mayo* and impact other section 101 decisions, such as *Alice*

Patent Eligibility Restoration Act of 2022, Senator Thom Tillis (R-NC), One Pager

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Patent Eligibility Restoration Act of 2022 (Senate Bill 4734)

The Bill proposes amendments to 35 U.S.C. 101 to read:

“§ 101. Patent eligibility

“(a) IN GENERAL.—Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject only to the exclusions in subsection (b) and to the further conditions and requirements of this title. ‘

“(b) ELIGIBILITY EXCLUSIONS.—

“‘(1) IN GENERAL.—Subject to paragraph (2), a person may not obtain a patent for any of the following, if claimed as such:

“‘(A) A mathematical formula, apart from useful invention or discovery.

“‘(B) A process that—

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Patent Eligibility Restoration Act of 2022 (Senate Bill 4734)

"(i) is a non-technological economic, financial, business, social, cultural, or artistic process;

"(ii) is a mental process performed solely in the human mind; or

"(iii) occurs in nature wholly independent of, and prior to, any human activity.

"(C) An unmodified human gene, as that gene exists in the human body.

"(D) An unmodified natural material, as that material exists in nature.

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Patent Eligibility Restoration Act of 2022 (Senate Bill 4734)

"(2) CONDITIONS.— "

"(A) CERTAIN PROCESSES.—Notwithstanding paragraph (1)(B)(i), a person may obtain a patent for a claimed invention that is a process described in such provision if that process is embodied in a machine or manufacture, unless that machine or manufacture is recited in a patent claim without integrating, beyond merely storing and executing, the steps of the process that the machine or manufacture perform.

"(B) HUMAN GENES AND NATURAL MATERIALS.—For the purposes of subparagraphs (C) and (D) of paragraph (1), a human gene or natural material that is isolated, purified, enriched, or otherwise altered by human activity, or that is otherwise employed in a useful invention or discovery, shall not be considered to be unmodified.

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"(c) ELIGIBILITY.—

"(1) IN GENERAL.—In determining whether, under this section, a claimed invention is eligible for a patent, eligibility shall be determined—

"(A) by considering the claimed invention as a whole and without discounting or disregarding any claim element; and

"(B) without regard to—

"(i) the manner in which the claimed invention was made;

"(ii) whether a claim element is known, conventional, routine, or naturally occurring;

"(iii) the state of the applicable art, as of the date on which the claimed invention is invented; or

"(iv) any other consideration in section 102, 103, or 112.

https://www.tillis.senate.gov/services/files/AC4F15C8-8652-4760-8EB9-8D064616DB3B

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Role of the Solicitor General in Patent Cases

- *American Axle*: cert. denial ***itself*** was significant
- ***Especially*** significant: cert. denied ***despite recommendation of U.S. Solicitor General that cert. be granted***

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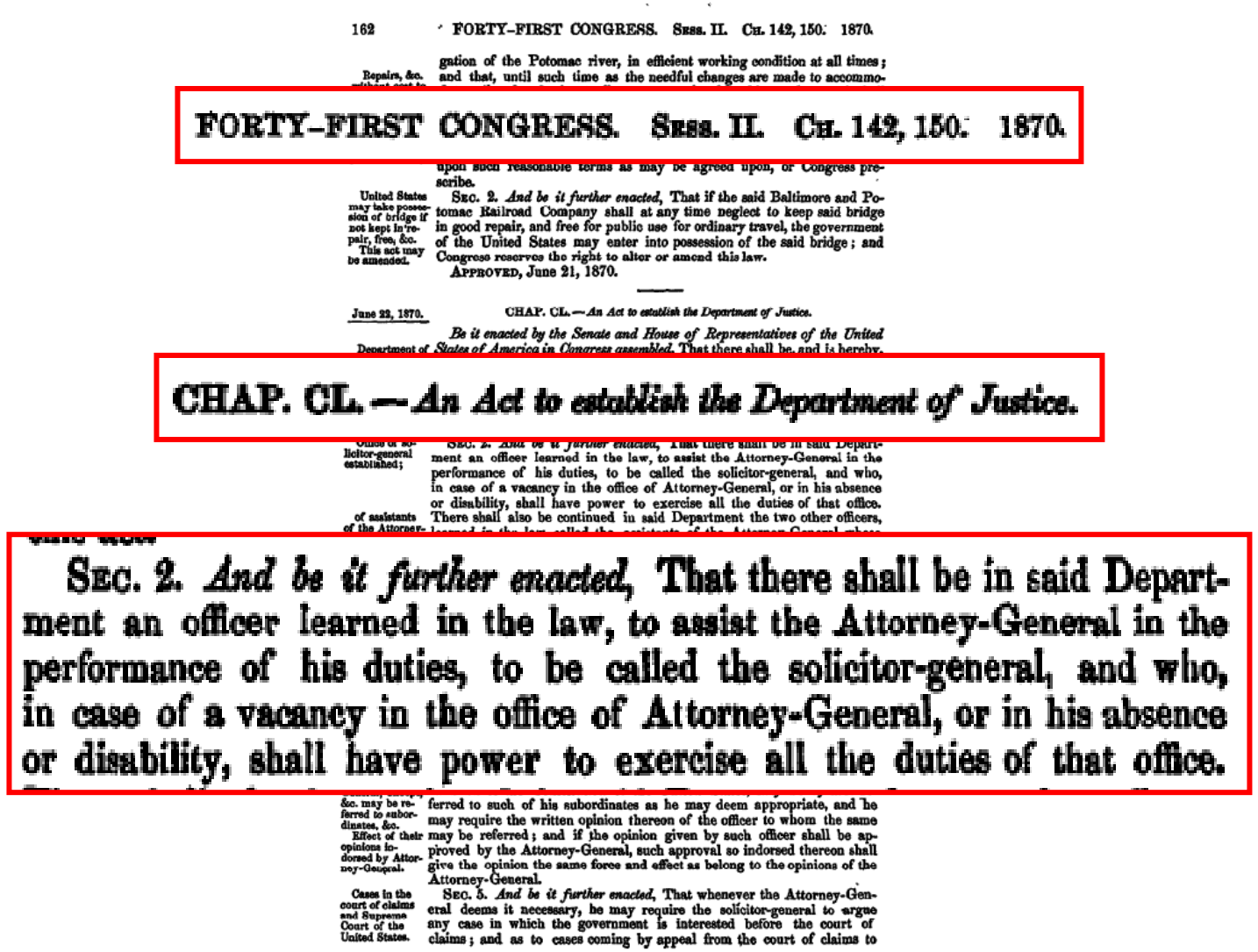
The Solicitor General: Historical Roots



162 FORTY-FIRST CONGRESS. Sess. II. Ch. 142, 150. 1870.

gation of the Potomac river, in efficient working condition at all times; and that, until such time as the needful changes are made to accommo-

Repairs, &c.

FORTY-FIRST CONGRESS. Sess. II. Ch. 142, 150. 1870.

upon such reasonable terms as may be agreed upon, or Congress prescribe.

United States may take possession of bridge if not kept in repair, free, &c.

Sec. 2. *And be it further enacted*, That if the said Baltimore and Potomac Railroad Company shall at any time neglect to keep said bridge in good repair, and free for public use for ordinary travel, the government of the United States may enter into possession of the said bridge; and Congress reserves the right to alter or amend this law.

This act may be amended.

Approved, June 21, 1870.

June 22, 1870.

Chap. CL.—*An Act to establish the Department of Justice.*

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That there shall be, and is hereby,

Department of Justice established;

CHAP. CL.—*An Act to establish the Department of Justice.*

Office of solicitor-general established;

Sec. 2. *And be it further enacted*, That there shall be in said Department an officer learned in the law, to assist the Attorney-General in the performance of his duties, to be called the solicitor-general, and who, in case of a vacancy in the office of Attorney-General, or in his absence or disability, shall have power to exercise all the duties of that office. There shall also be continued in said Department the two other officers,

of assistants of the Attorney-

Sec. 2. *And be it further enacted*, That there shall be in said Department an officer learned in the law, to assist the Attorney-General in the performance of his duties, to be called the solicitor-general, and who, in case of a vacancy in the office of Attorney-General, or in his absence or disability, shall have power to exercise all the duties of that office.

&c. may be referred to subordinates, &c.

Effect of their opinions indorsed by Attorney-General.

ferred to such of his subordinates as he may deem appropriate, and he may require the written opinion thereon of the officer to whom the same may be referred; and if the opinion given by such officer shall be approved by the Attorney-General, such approval so indorsed thereon shall give the opinion the same force and effect as belong to the opinions of the Attorney-General.

Cases in the court of claims and Supreme Court of the United States.

Sec. 5. *And be it further enacted*, That whenever the Attorney-General deems it necessary, he may require the solicitor-general to argue any case in which the government is interested before the court of claims; and as to cases coming by appeal from the court of claims to

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How Does the SG "Assist the Attorney General"?

- Most visibly: arguing on behalf of the federal gov't in cases heard on the merits by the U.S. Supreme Court

- But argument in the U.S. Supreme Court is only a small part of the SG's job duties . . . .

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How Does the SG "Assist the Attorney General"?

- Another Supreme Court responsibility: participating in cases at the certiorari stage
- Includes seeking/opposing review in which U.S. is a party
- Also: providing *amicus* recommendations on review in certain private-party cases

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SG's *Amicus* Participation at Cert. Stage

- SG, on behalf of federal gov't, can proactively participate as *amicus*
- Usual route to SG *amicus* involvement: "CVSG"
  - Supreme Court, after receiving cert. petition in private-party cases, may **c**all for the **v**iews of the **SG** (on behalf of the federal gov't)
  - CVSG is framed as "invitation," but in practice SG always complies

ORDERS IN PENDING CASES

22M22 LABRANCHE, AMOS V. SCHUMACHER/FFVA MUTUAL INSURANCE

22M23 KOMATSU, TOWAKI V. CUBESMART, ET AL.

The motions to direct the Clerk to file petitions for writs of certiorari out of time are denied.

22-22 TROPP, DAVID A. V. TRAVEL SENTRY, INC., ET AL.

The Solicitor General is invited to file a brief in this case expressing the views of the United States.

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Responses to CVSG Orders

- CVSG orders generally do not prescribe hard deadlines
- SG endeavors to file responsive *amicus* brief within 4-6 months of order
- CVSG briefs will always contains “grant”/“deny” recommendation – but can be highly nuanced
  - Explains the “interest of the United States” in detail
  - May contend that legal issue is certworthy but particular case is not best vehicle for Supreme Court’s consideration

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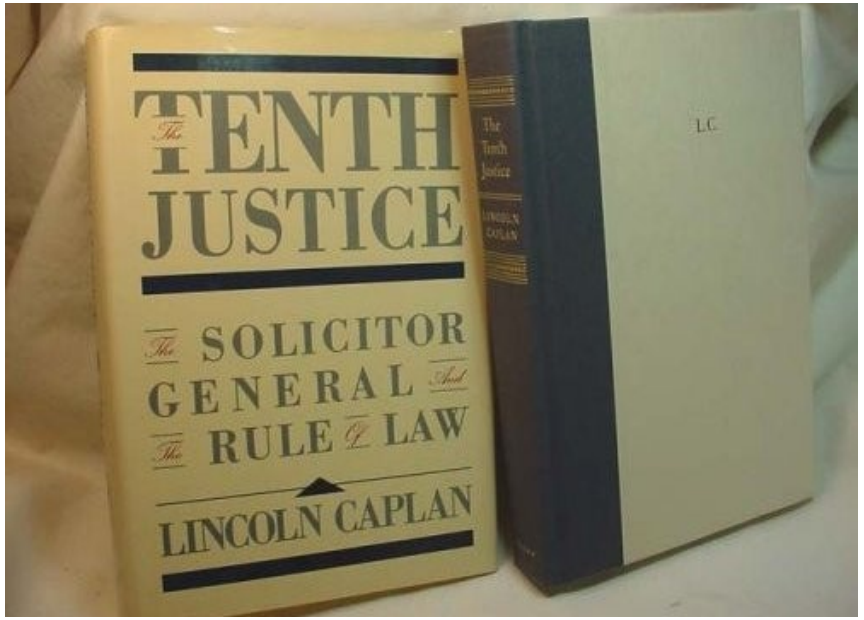
SG's Cert.-Stage Influence: Generally and in Patent Cases



- In general: Supreme Court ***agrees 75%*** with CVSG grant/deny recommendation
- ***Even higher*** in patent cases: ***90%***

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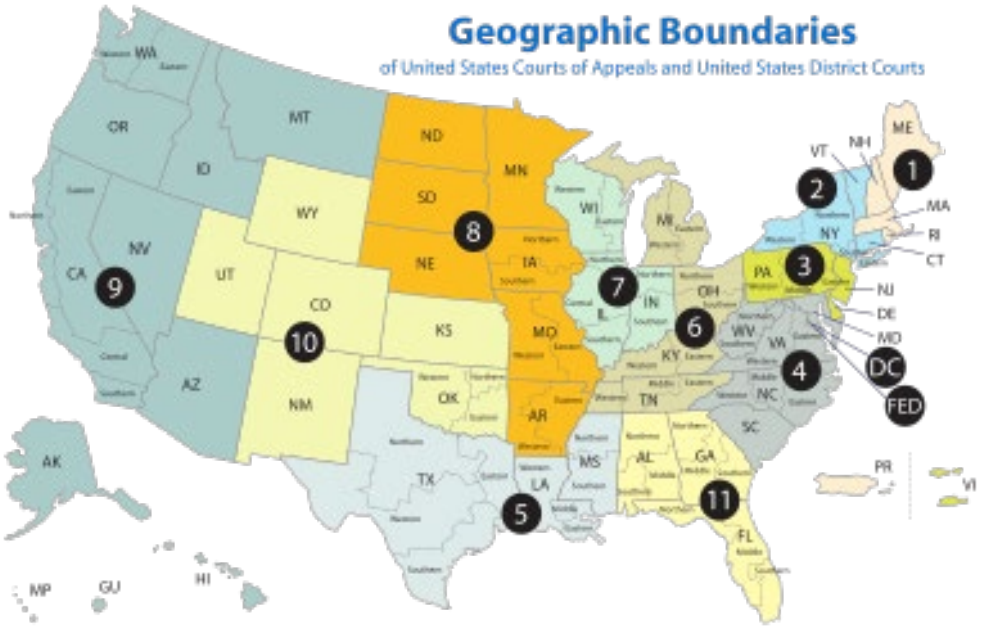
Why Is SG So Unusually Influential In Patent Cases?

- One theory: **almost* no circuit splits in patent cases**
  - Generally: Presence/absence of circuit split is most important criterion for cert. analysis
  - ***Usually* N/A for patent cases***: Patent cases come almost exclusively from Federal Circuit



*Fed. Cir. Decisions may implicate circuit splits on *non-patent issues*, e.g. applicability of laches

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Cert. Denial in *American Axle* Not Unprecedented: *Athena Diagnostics v. Mayo Collaborative Servs.* (Fed. Cir. 2019)

- Athena had patent on method of diagnosing neurological diseases
- Fed. Cir.: method not eligible for patent protection under § 101 – directed to natural correlation between affliction with disease and subsequent presence of antibodies

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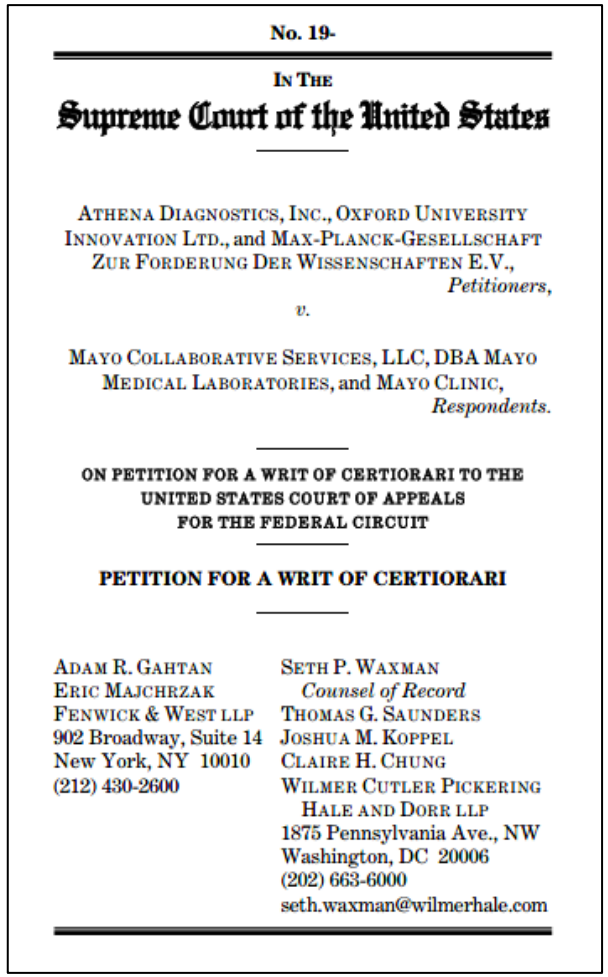
Athena Diagnostics

- Athena Diagnostics filed cert. petition challenging Fed. Cir. decision
- Supreme Court did not issue CVSG order, but . . .



No. 19-

IN THE

Supreme Court of the United States

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., and MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Petitioners,

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, and MAYO CLINIC,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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Athena Diagnostics

- Supreme Court ***did*** CVSG in related patent case (*Hikma Pharms.*) presenting same legal issue as *Athena Diagnostics*

18-817 HIKMA PHARMACEUTICALS, ET AL. V. VANDA PHARMACEUTICALS

The Solicitor General is invited to file briefs in these cases expressing the views of the United States.

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Brian Ginsberg

Athena Diagnostics

- SG recommended denying cert. in *Hikma Pharms.* . . .
- But SG recommended ***granting cert. in*** **Athena Diagnostics**

The Court instead should provide additional guidance in a case where the current confusion has a material effect on the outcome of the Section 101 analysis. For example, *Mayo* has had particularly significant practical effects with respect to medical-diagnostic methods. See *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352-1353 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible."), petition for cert. pending, No. 19-430 (filed Oct. 1, 2019). In contrast to

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Athena Diagnostics

- Supreme Court ***denied cert.*** in *Athena Diagnostics*
- Supreme Court did not grant cert. in ***any*** of the 40 patent cases it considered during the 2021-2022 court term

Laura Smalley
Brian Ginsberg

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Another Supreme Setback for the SG: *Amgen v. Sanofi* (Fed. Cir. 2021)

- Amgen held patents on monoclonal antibodies that dramatically reduce levels of “bad” cholesterol
- Fed. Cir.: patents were invalid for failure to satisfy § 112 “enablement”:
  - Patents must “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 ... to make and use the same.

Laura Smalley
Brian Ginsberg

Amgen: Federal Circuit's Decision

- Amgen's relevant patent claims were "genus" claims: claims that cover a group of potential products that incorporate the basic advance of the patented invention.
- Fed. Cir. precedent: enablement is ***not satisfied*** if it would take skilled artisan "substantial time and effort" to make ***all*** claimed embodiments of the invention – even if individual embodiments consistently can be made with ease
- HELD: Relevant patent claims did ***not*** "enable" skilled artisans in the manner that prior precedent required: full scope of embodiments could not be made without "undue experimentation"

Laura Smalley
Brian Ginsberg

Amgen: The Case Reaches the Supreme Court

- Amgen petitioned for cert. in U.S. Supreme Court
- Supreme Court issued CVSG order
- Solicitor General filed brief recommending that cert. be ***denied***
  - Cert. denial (as opposed to grant) is ***always*** the more likely outcome
  - Should be ***even more likely*** with SG support
- But . . . cert. was granted (11/4/22)!

CERTIORARI GRANTED

21-757 AMGEN INC., ET AL. V. SANOFI, ET AL.

The petition for a writ of certiorari is granted limited to Question 2 presented by the petition.

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Brian Ginsberg

Wither the Trend of Deference to the SG?

- Three recent setbacks for the SG
  - *Athena Diagnostics* (cert. denial despite SG's recommendation to grant) (Jan. 2020)
  - *American Axle* (cert. denial despite SG's recommendation to grant) (June 2022)
  - *Amgen* (cert. grant despite SG's recommendation to deny) (Nov. 2022)

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Brian Ginsberg

What Explains The SG's Recent Patent Law Setbacks?

- One theory: Supreme Court is less interested in patent cases that present unique patent law issues than patent cases that present issues cutting across legal domains, e.g. procedural issues like applicability of laches

  -- Prof. Tejas Narechania (Univ. of Cal. at Berkeley Law)

- Explains cert. denials in *Athena Diagnostics* and *American Axle*
- But ***does not explain*** cert. ***grant*** in *Amgen*
  - Enablement is a unique patent issue

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Brian Ginsberg

So What Explains The Cert. Grant In *Amgen*?

- Impossible to know definitively: Supreme Court doesn't explain its cert. grants
- SG's brief may have been viewed as less persuasive because brief was not joined by USPTO
- SG's brief ***was successful to some extent***
  - Amgen petitioned for cert. on two questions: (1) whether enablement was a factual determination or a legal one, and (2) whether Fed. Cir.'s test for enablement of "genus" claims was correct
  - Supreme Court ***denied*** cert. on first question presented

Laura Smalley
Brian Ginsberg

What's Next?

- CVSG order recently issued in *Interactive Wearables* (Fed. Cir.) – another § 101 eligibility case (10/3/22)
- SG's brief likely will be filed in Spring 2023
- Possible that cert. could be decided before 2023 summer recess

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