Chris Israel is a Senior Partner at ACG Advocacy and is also the co-lead of the firm's technology and intellectual property group.

He joined ACG in 2010, after serving in the George W. Bush Administration as Deputy Chief of Staff to the Secretary of Commerce and later becoming the first U.S. International Intellectual Property Enforcement Coordinator.

At ACG Advocacy, Chris works with a diverse range of clients including some of the largest and most innovative companies in the world to support their efforts to build a policy environment in the U.S. that promotes and protects their investments in intellectual property. He has also developed a unique focus leading a coalition of top venture capitalists and innovative startups to pursue a policy agenda that has led to improvements in tax policy, investments in R&D, and strengthening patent protection.

Chris maintains a leadership profile working on IP and innovation issues and has been a frequent public speaker and has testified before Congress multiple times both as an Administration official and since he left public service. He was previously named one of the 50 "Most Influential People on IP" by Managing Intellectual Property magazine.

His international experience in government, particularly in working with China, has enabled him to successfully engage clients on global trade and technology matters ranging from the negotiations of trade agreements, tariff policy, and engaging international organizations. His client relationships have included automakers, global manufacturing companies, shipping companies, and Chinese e-commerce and social media platforms seeking to better understand the U.S. market.

Chris' experience leading coalitions has also included serving as Executive Director of the musicFIRST Coalition during the lead-up to the passage of the landmark Music Modernization Act. During this time he was named to Medium's inaugural "Power 10" list of music policy leaders.

Within ACG Advocacy, he provides guidance on the firm's day-to-day interaction with all its clients and helps lead ACG's extensive policy research team. He has also launched the firm's podcast focused on policy trends and developments in Washington.

Earlier in his career, Chris worked on international policy issues at Time Warner where he was part of a team that supported then-CEO, Gerald Levin, to develop the Global Business Dialogue on E-Commerce a ground-breaking global organization of CEOs from the U.S., EU, and Asia that developed industry best practices on matters such as online privacy, cross border data flows, and online taxation.

Prior to Time Warner, he served on Capitol Hill as a legislative aide to U.S. Representatives Jan Meyers (R-KS) and Todd Tiahrt (R-KS).

Chris received his B.A. from the University of Kansas and an M.B.A. from The George Washington University.

Abigail Struthers is a partner in the IP litigation group at Arnold & Porter, where she focuses her practice on patent litigation in the life sciences sector. Abby combines her experience as a private practitioner with in-house know-how gained from serving as Sandoz's senior IP litigation counsel, to help clients achieve business-practical intellectual property solutions. She has represented leading pharmaceutical and life sciences clients in disputes relating to biologic drug products, small-molecule pharmaceuticals, drug delivery, and platform technology, in federal court and before the Patent Trial and Appeal Board. Abby also regularly advises on intellectual property aspects of corporate mergers and acquisitions and is experienced in conducting patent due diligence investigations.

Abby currently serves on the Board of NYIPLA, as Second Vice President.

Irena Royzman, Ph.D

Partner, Head, Life Sciences
New York

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Irena Royzman is the head of Life Sciences at Kramer Levin. She concentrates on pharmaceutical and biotech patent litigation and proceedings before the Patent Trial and Appeal Board. Irena holds a Ph.D. in biology from MIT and the Whitehead Institute, where she was a NSF fellow. She represents plaintiffs and defendants in some of the most complex pharmaceutical and biotech patent cases.

Irena has litigated a wide range of subject matters, including small molecules, biologics, recombinant DNA technology, gene therapy, gene editing, manufacturing processes, formulations and drug-eluting medical devices. Irena has significant experience in litigation under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA).

For plaintiffs, Irena has successfully defended against generic challenges to patents protecting blockbuster medical therapies, including a multi-billion dollar anti-psychotic drug and a best-selling HIV protease inhibitor. She has also represented an innovator in some of the first cases under the BPCIA, including the first involving an antibody. For defendants, she recently defeated a $530 million claim of patent infringement of a competitor's biotech patent, obtaining dismissal of all claims and discovery sanctions against the patent owner. In another high-stakes case, she obtained summary judgment of noninfringement and exclusion of plaintiff's experts under *Daubert* as well as a full award of attorneys' fees.

A registered patent attorney, Irena also handles *inter partes* review (IPR) proceedings. For patent owners, she has obtained denial of IPR for patents protecting blockbuster drugs, and has leveraged IPR for defendants to obtain freedom to operate.

Irena also coordinates US proceedings with parallel ex-US litigation and proceedings in foreign patent offices. She provides strategic counseling in the area of biologics and pharmaceuticals and advises clients on their IP portfolios and transactions. Irena also represents clients in high-stakes license disputes involving biotech patents, and, in a dispute concerning the use of a recombinant protein as an enzyme replacement therapy, obtained one of the largest settlement awards over the life of the contract.

Chambers USA has recognized Irena as a leading lawyer in intellectual property, where she is described as "knowledgeable, aggressive" and "an incredibly smart lawyer." *Benchmark Litigation* named her one of the "Top 250 Women in Litigation" for the last five years and a litigation star in intellectual property. Irena was also named to the Crain's New York Business 2021 list of Notable Women in Law.

Irena writes and lectures widely on patent issues. She has been principal counsel on amicus briefs to the United States Supreme Court in some of the most important life sciences cases. Irena also is frequently quoted on patent-related issues, including in the *Washington Post*, *Nature Biotechnology* and *Pink Sheet*.

ACG ADVOCACY

2022 Election – Leadership and IP Implications

House of Representatives- Leadership

Potential GOP-Controlled House:

Speaker of the House: Kevin McCarthy (CA-23)

Majority Leader: Steve Scalise (LA-01)

Majority Whip: Drew Ferguson (GA-03); Tom Emmer (MN-06); Jim Banks (IN-03)

Republican Conference Chairman: Elise Stefanik (NY-21); Byron Donalds (FL-19)

Republican Conference Vice Chair: Mike Johnson (LA-04)

Republican Conference Secretary: Lisa McClain (MI-10)

Republican Study Committee Chairman: Kevin Hern (OK-01)

Republican Policy Committee: Gary Palmer (AL-06)

National Republican Congressional Committee: Richard Hudson (NC-08); Darin LaHood (IL-18)

Potential Dem-Controlled House:

Speaker of the House: Nancy Pelosi (CA-12)

Majority Leader: Steny Hoyer (MD-05)

Majority Whip: James Clyburn (SC-06)

Assistant Speaker: Katherine Clark (MA-05)

Democratic Caucus Chairman: Hakeem Jeffries (NY-08)

Democratic Caucus Vice Chairman: Pete Aguilar (CA-31)

DCCC: Tony Cardenas (CA-29), Susan DelBene (WA-01)

If Dems lose the majority, a shake-up is expected. Many predict that Pelosi will retire, possibly before the end of the session. Jeffries' name has been floated as a possible Leader (and certainly a future Speaker), and Clark and Aguilar have also been mentioned as members likely to move up the leadership ladder.

House of Representatives- Committee Chairs

Potential GOP-Controlled House:

Agriculture: Glenn 'GT' Thompson (PA-15)	**Appropriations:** Kay Granger (TX-12)	**Armed Services:** Mike Rogers (AL-03)	**Budget:** Jason Smith* (MO-08)	**Education & Labor:** Virginia Foxx (NC-05)**	**Energy & Commerce:** Cathy McMorris Rodgers (WA-05)	**Veterans' Affairs:** Mike Bost (IL-12)
Ethics: Michael Guest (MS-03)	**Financial Services:** Patrick McHenry (NC-10)	**Foreign Affairs:** Michael McCaul (TX-10)	**Homeland Security:** Michael McCaul (TX-10), Clay Higgins (LA-03), or Rep. Scott Perry (PA-10)	**House Admin:** Bryan Steil (WI-01)	**Judiciary:** Jim Jordan (OH-04) **IP Sub:** Darrell Issa (CA-50)	**Ways and Means:** Vern Buchanan (FL-15), Adrian Smith (NE-03), or Jason Smith (MO-08)
Natural Resources: Bruce Westerman (AR-04)	**Oversight & Reform:** James Comer (KY-01)	**Rules:** Tom Cole (OK-04)	**Transportation & Infrastructure** Sam Graves (MO-06)	**Small Business:** Blaine Luetkemeyer (MO-03)	**Science, Space, & Technology:** Frank Lucas (OK-03)	

Potential Dem-Controlled House:

Agriculture: David Scott (GA-13)	**Appropriations:** Rosa DeLauro (CT-03)	**Armed Services:** Adam Smith (WA-09)	**Budget:** Hakeem Jeffries (NY-08) or Brian Higgins (NY-26)	**Education & Labor:** Bobby Scott (VA-03)	**Energy & Commerce:** Frank Pallone (NJ-06)	**Veterans' Affairs:** Mark Takano (CA-41)
Ethics: Susan Wild (PA-07)	**Financial Services:** Maxine Waters (CA-43)	**Foreign Affairs:** Gregory Meeks (NY-05)	**Homeland Security:** Bennie Thompson (MS-02)	**House Admin:** Zoe Lofgren (CA-19)	**Judiciary:** Jerrod Nadler (NY-10) **IP Sub:** Hank Johnson (GA-04)	**Ways and Means:** Richard Neal (MA-01)
Natural Resources: Raul Grijalva (AZ-03)	**Oversight & Reform:** Eleanor Norton (DC), Stephen Lynch (MA-08), or Gerald Connolly (VA-11)	**Rules:** Jim McGovern (MA-02)	**Transportation:** Eleanor Norton (DC-AL) or Rick Larsen (WA-02)	**Small Business:** Nydia Velazquez (NY-07)	**Science, Space, & Technology:** Suzanne Bonamici (OR-01) or Ami Bera (CA-07)	

Senate- Leadership

Potential GOP-Controlled Senate:

Majority Leader: Mitch McConnell (KY)

President Pro Tempore: Charles Grassley (IA)

Republican Whip: John Thune (SD)

Republican Conference Chairman: John Barrasso (WY)

Republican Policy Committee Chairman: Joni Ernst (IA)

Vice Chairman of the Senate Republican Conference: Shelley Moore Capito (WV)

Potential Dem-Controlled Senate:

Majority Leader: Charles Schumer (NY)

Democratic Whip: Dick Durbin (IL)

Assistant Democratic Leader: Patty Murray (WA)

Chairwoman of Policy & Communications Committee: Debbie Stabenow (MI)

Vice Chair of Conference: Mark Warner (VA)

Vice Chair of Conference: Elizabeth Warren (MA)

Chair of Steering Committee: Amy Klobuchar (MN)

DSCC: Osoff (GA), Lujan (NM), Duckworth (IL)

Senate- Committee Chairs

Potential GOP-Controlled Senate:

Agriculture: John Boozman (AR)z	Appropriations: Susan Collins (ME)	Armed Services: Roger Wicker (MS)	Banking and HUD: Tim Scott (SC) or Mike Rounds (SD)
Budget: Lindsey Graham (SC)	Commerce: Ted Cruz (TX)	Energy: John Barrasso (WY)	Environment and Public Works: Shelley Moore Capito (WV)
Finance: Mike Crapo (ID)	Foreign Relations: James Risch (ID)	HELP: Rand Paul (KY) or Bill Cassidy (LA)	Homeland Security: Ron Johnson (WI) or Rand Paul (KY)
Judiciary: Chuck Grassley (IA) IP Sub: Thom Tillis (NC)	Rules: Deb Fischer (NE)	Small Business: Marco Rubio (FL)	Veterans' Affairs: Jerry Moran (KS)

Potential Dem-Controlled Senate:

Agriculture: Debbie Stabenow (MI)	Appropriations: Patty Murray (WA)	Armed Services: Jack Reed (RI)	Banking and HUD: Sherrod Brown (OH)
Budget: Sheldon Whitehouse (RI)	Commerce: Maria Cantwell (WA)	Energy: Joe Manchin (WV)	Environment and Public Works: Thomas Carper (DE)
Finance: Ron Wyden (OR)	Foreign Relations: Robert Menendez (NJ)	HELP: Bernie Sanders (VT)	Homeland Security: Gary Peters (MI)
Judiciary: Dick Durbin (IL) IP Sub: Chris Coons (DE)	Rules: Amy Klobuchar (MN)	Small Business: Benjamin Cardin (MD)	Veterans' Affairs: Jon Tester (MT)

Potential Post-Election & 2023 IP

- The "extremely, underline extremely busy" lame duck scramble:
  - Omnibus FY23 funding
  - National Defense Authorization Act - currently contains:
    - INFORM Act
    - Daniel Anderl Judicial Security and Privacy Act
  - Possible, but unlikely IP amendments to FY23 funding or NDAA
    - Pride in Patent Ownership
    - PTAB Reform Act
    - Patent Examination and Quality Improvement Act
- Potential 2023 Congressional Priorities
  - Section 101 reform
  - Standard Essential Patent policy
  - PTAB Reform
  - China
  - PTO Oversight

Hot Topics in Pending and Proposed Legislation

Irena Royzman
Kramer Levin Naftalis & Frankel LLP
November 9, 2022

American Axle v. Neapco Holdings (No. 20-891)

- In *American Axle*, the Federal Circuit held that claims to a method of making automobile driveshafts to reduce noise and vibrations were patent ineligible under Section 101.
- The Supreme Court asked for the views of the United States.
- In May 2022, Solicitor General unequivocally argued that the Federal Circuit erred and misread the Court's precedents:
  - "***[H]olding is incorrect***. Historically, such industrial techniques have long been viewed as paradigmatic examples of the 'arts' or 'processes' that may receive patent protection…***The court of appeals erred in reading this Court's precedents to dictate a contrary conclusion***." SG Brief at 8-9.
  - "As the splintered separate opinions at the panel and rehearing stages illustrate, ***the Federal Circuit is deeply divided over the proper application of this Court's framework***, and the content of that framework is central here." *Id.* at 21.

American Axle v. Neapco Holdings

- The Solicitor General urged that *Mayo* and *Alice*, read correctly, permit a holistic approach to patent eligibility:
  - The "Court did not intend to endorse a categorial rule that conventional claim elements should be disregarded…"
  - "*Mayo* Court did not question the long-settled understanding that ***the patent-eligibility of a process claim turns on 'the process as a whole'*** and… that a 'new combination of steps in a process may be patentable even though all of the constituents of the combination were well known and in common use before the combination was made.'"
  - "*Alice* reiterated the need to '***consider the elements*** of each claim both individually and ***as an ordered combination***.'"

    See SG Brief at 18.

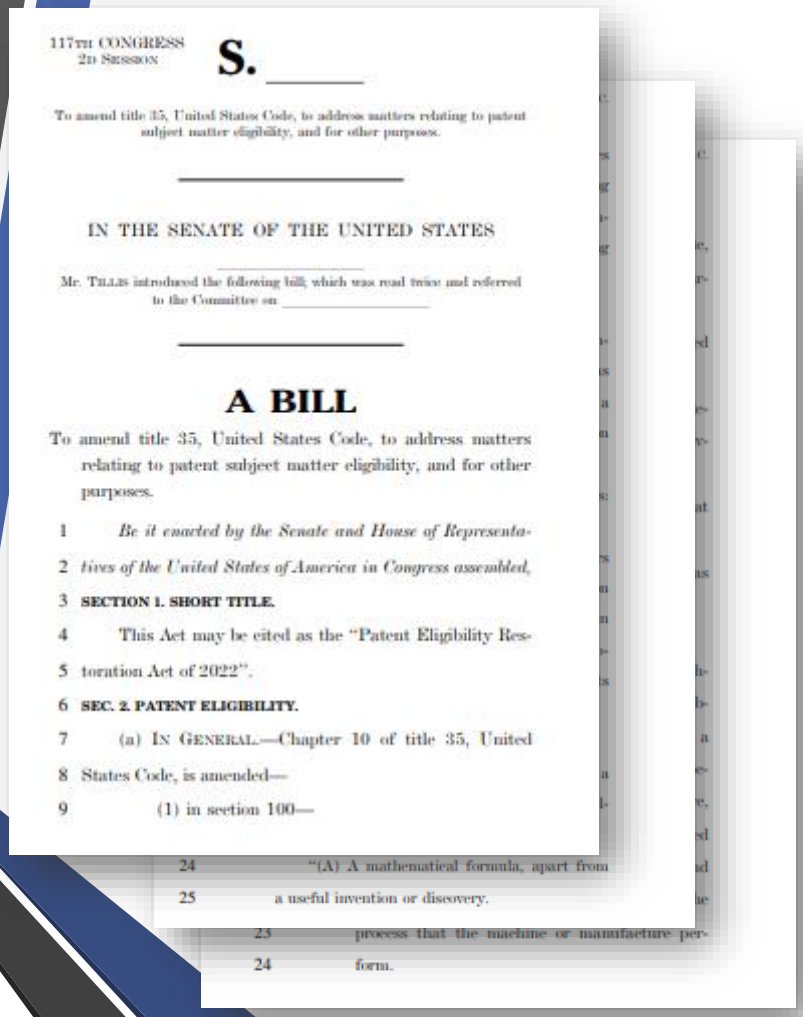
American Axle v. Neapco Holdings

- The Solicitor General concluded by urging the Court to clarify Section 101:
  - "Ongoing uncertainty has ***induced every judge on [the Federal Circuit] to request*** Supreme Court clarification."
  - "[T]he ***inconsistency and unpredictability*** of adjudication extend to all fields."

  See SG Brief at 20.

In June 2022, the Supreme Court denied *American Axle's* petition for *certiorari.*

Tillis Bill: Restoring Patent Eligibility



117TH CONGRESS
2D SESSION

S. _____

To amend title 35, United States Code, to address matters relating to patent subject matter eligibility, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. TILLIS introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 35, United States Code, to address matters relating to patent subject matter eligibility, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patent Eligibility Restoration Act of 2022".

SEC. 2. PATENT ELIGIBILITY.

(a) IN GENERAL.—Chapter 10 of title 35, United States Code, is amended—

(1) in section 100—

"(A) A mathematical formula, apart from a useful invention or discovery.

process that the machine or manufacture performs.

- "The current state of eligibility jurisprudence ***is in abysmal shambles***." – Senator Thom Tillis in written questions to Federal Circuit nominee Tiffany Cunningham
- In August 2022, Senator Thom Tillis introduced "The Patent Eligibility Restoration Act of 2022" to restore patent eligibility to important inventions across many fields.

Nineteen Hundred and Twenty-two
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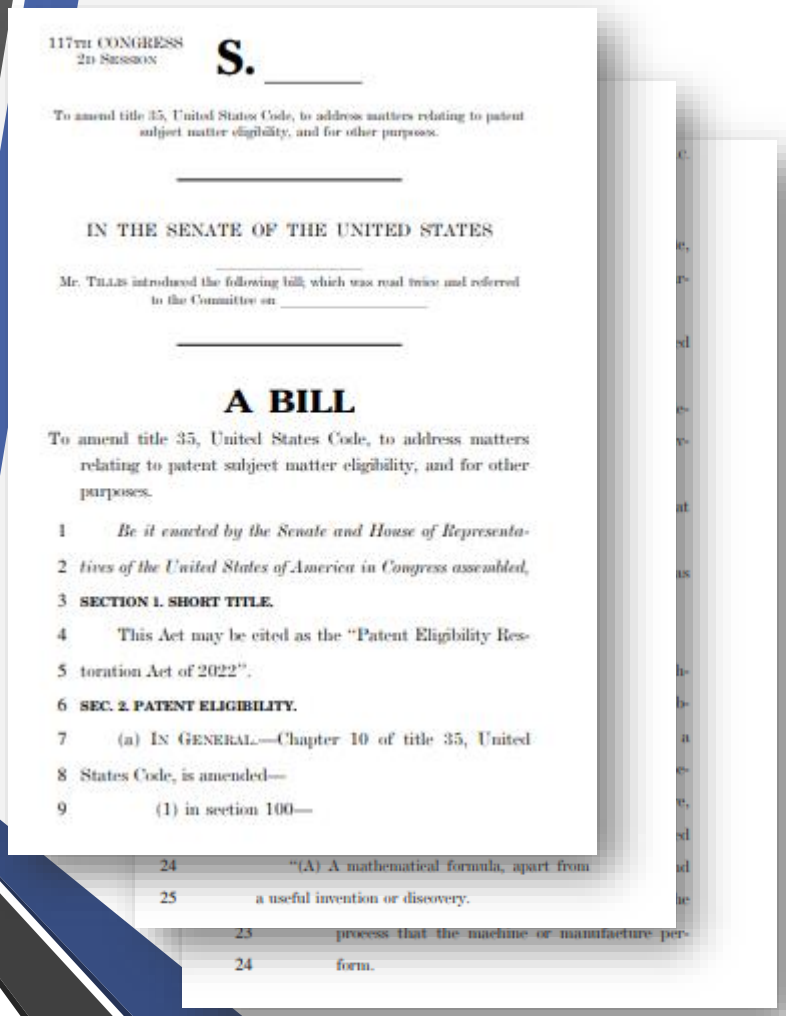
Tillis Bill: Restoring Patent Eligibility



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"(A) A mathematical formula, apart from a useful invention or discovery.

process that the machine or manufacture perform.

- "Unfortunately, due to a series of Supreme Court decisions, patent eligibility law in the United States has become confused, constricted, and unclear in recent years." – Senator Tillis.
- "As of 2021, all 12 judges of the United States Court of Appeals of the Federal Circuit have lamented the state of the law***….[R]eforms are necessary to restore the United States to a position of global strength and leadership in key areas of technology and innovation, such as medical diagnostics, biotechnology, personalized medicine***…." – Senator Tillis.

Nineteen Hundred and Twenty-two
NYIPLA®

Tillis Bill: The Four Exclusions

"(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 a useful invention or discovery.

"(B) A process that—

"(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.

- Four eligibility exclusions would be codified within a new Section 101(b):
  - ***Mathematical formulas*** (apart from a useful invention or discovery);
  - A ***process*** that is non-technological, or mental and performed "***solely in the human mind***," or one that occurs "***in nature wholly independent***" of and prior to any human activity;
  - An ***unmodified human gene***, as that gene exists in the human body; and
  - An ***unmodified natural material***, as that material exists in nature.

Nineteen Hundred and Twenty-two NYIPLA®

Tillis Bill: The Conditions

- The Bill provides conditions that ensure that the exclusions are read narrowly:
  - (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. ***Tillis Bill curtails Alice***.
  - (B) Human Genes and Natural Materials…. "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." ***Tillis Bill abrogates Myriad.***

Tillis Bill: The Eligibility Analysis

- In analyzing eligibility, the Tillis Bill requires:
  - "***considering the claimed invention as a whole*** and without discounting or disregarding any claim element; ***and***"
  - "***without*** regard to
    - the ***manner*** in which the claimed invention was made;
    - whether a claim element is ***known***, ***conventional, routine, or naturally occurring***;
    - the ***state of the applicable art,*** as of the date on which the claimed invention is invented; or
    - ***any other consideration in section 102, 103, or 112***."

Tillis Bill abrogates Alice/Mayo eligibility analysis.

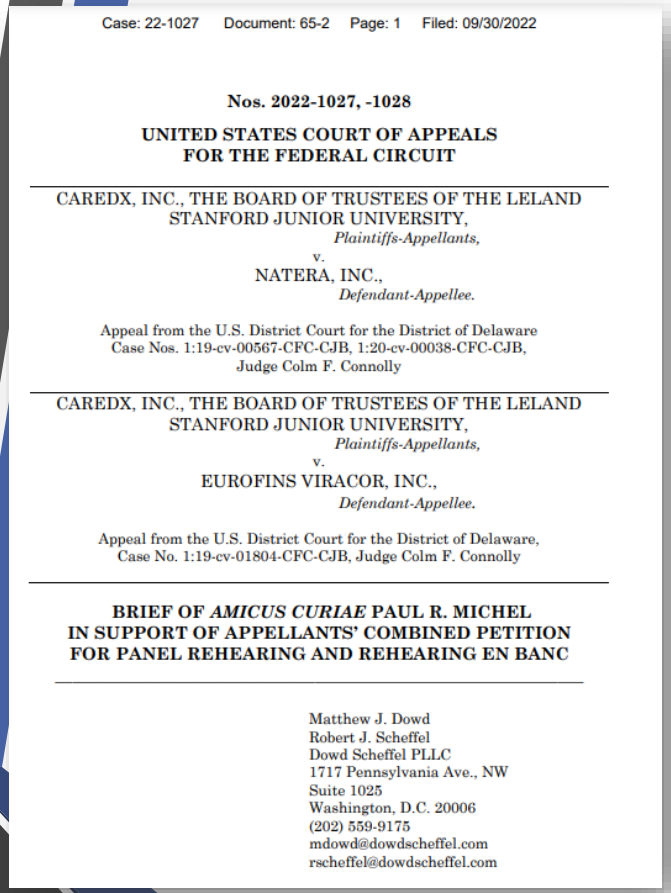
Tillis Bill: New Definitions

- (b) [Amended] "The term 'process' means process, art or method, and includes a use, ***application, or method of manufacture*** of a known ***or naturally occurring*** process, machine, manufacture, composition of matter, or material."
- (k) [New] "The term 'useful' means, with respect to an invention or discovery, that the invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains."

After Tillis Bill, SCOTUS Asks for Views of U.S. in Two Cases

- *Interactive Wearables v. Polar Electro Oy* (No. 21-1281)
  - The petition seeks guidance, for patents to an electronic hardware device, on the appropriate standard for determining whether a patent claim is "directed to" a patent-ineligible concept, whether eligibility is a question of law or fact, and whether Section 112 considerations are appropriate in a Section 101 analysis.
  - The Court called for the views of the Solicitor General on **October 3, 2022**.
- *Tropp v. Travel Sentry* (No. 22-22)
  - The petition seeks guidance on whether claims in patents for dual-access airline luggage locks that recite physical rather than computer-processing steps are patent-eligible under Section 101 as interpreted in *Alice Corp. v. CLS Bank International*.
  - The Court called for the views of the Solicitor General on **October 17, 2022**.

Judge Michel Urges En Banc Review



Case: 22-1027 Document: 65-2 Page: 1 Filed: 09/30/2022

Nos. 2022-1027, -1028

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Plaintiffs-Appellants,
v.
NATERA, INC.,
Defendant-Appellee.

Appeal from the U.S. District Court for the District of Delaware
Case Nos. 1:19-cv-00567-CFC-CJB, 1:20-cv-00038-CFC-CJB,
Judge Colm F. Connolly

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Plaintiffs-Appellants,
v.
EUROFINS VIRACOR, INC.,
Defendant-Appellee.

Appeal from the U.S. District Court for the District of Delaware,
Case No. 1:19-cv-01804-CFC-CJB, Judge Colm F. Connolly

BRIEF OF *AMICUS CURIAE* PAUL R. MICHEL IN SUPPORT OF APPELLANTS' COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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- *CareDx v. Natera*, Appeal No. 2022-1027, (Fed. Cir. July 18, 2022)
  - The Federal Circuit held that claims of patents directed to methods for detecting organ transplant rejection were invalid under Section 101.
  - On September 30, 2022, former Chief Judge Paul Michel filed an amicus brief urging the Federal Circuit to grant rehearing *en banc* and clarify Section 101.
  - "***The full Court can and should fix the current situation with § 101***." Michel Brief at 3.
  - ***"[T]he current case can be used to revisit the overly broad application of Mayo and Alice***—an application that, in this case, let to the erroneous conclusion that an entirely new method of diagnosing potential organ-donor failure is not eligible for patent protection." *Id.*

117TH CONGRESS
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SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patent Eligibility Restoration Act of 2022''.

SEC. 2. PATENT ELIGIBILITY.

(a) IN GENERAL.—Chapter 10 of title 35, United States Code, is amended—

(1) in section 100—

(A) in subsection (b), by striking ''includes a new use of a known process'' and inserting ''includes a use, application, or method of manufacture of a known or naturally-occurring process''; and

(B) by adding at the end the following:

''(k) The term 'useful' means, with respect to an invention or discovery, that the invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains.''; and

(2) by amending section 101 to read as follows:

''§ 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 a useful invention or discovery.

"(B) A process that—

"(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.

"(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.

"(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.

"(2) INFRINGEMENT ACTION.—

"(A) IN GENERAL.—In an action brought for infringement under this title, the court, at any time, may determine whether an invention or discovery that is a subject of the action is eligible for a patent under this section, including on motion of a party when there are no genuine issues of material fact.

"(B) LIMITED DISCOVERY.—With respect to a determination described in subparagraph (A), the court may consider limited discovery relevant only to the eligibility described in that subparagraph before ruling on a motion described in that subparagraph.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 10 of title 35, United States Code, is amended by striking the item relating to section 101 and inserting the following:

"101. Patent eligibility.".

No. 20-891

In the Supreme Court of the United States

AMERICAN AXLE & MANUFACTURING, INC., PETITIONER

v.

NEAPCO HOLDINGS LLC, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
JONATHAN C. BOND
Assistant to the Solicitor General
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THOMAS W. KRAUSE
Solicitor
FARHEENA Y. RASHEED
Deputy Solicitor
AMY J. NELSON
Senior Counsel for Patent Policy & Litigation
KAKOLI CAPRIHAN
ROBERT E. MCBRIDE
Associate Solicitors
United States Patent and Trademark Office
Alexandria, Va. 22314

QUESTIONS PRESENTED

Section 101 of the Patent Act of 1952, 35 U.S.C. 1 *et seq.*, provides that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," is eligible for a patent. 35 U.S.C. 101. The questions presented are as follows:

1. Whether claim 22 of petitioner's patent, which claims a process for manufacturing an automobile driveshaft that simultaneously reduces two types of driveshaft vibration, is patent-eligible under Section 101.

2. Whether patent-eligibility under Section 101 is a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of the art at the time of the patent.

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In the Supreme Court of the United States

No. 20-891

AMERICAN AXLE & MANUFACTURING, INC., PETITIONER

v.

NEAPCO HOLDINGS LLC, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be granted with respect to question 1 as framed in this brief.

STATEMENT

1. a. The Constitution authorizes Congress "[t]o promote the Progress" of "useful Arts, by securing for limited Times to * * * Inventors the exclusive Right to their * * * Discoveries." U.S. Const. Art. 1, § 8, Cl. 8. The Patent Act of 1952 (Patent Act), 35 U.S.C. 1 *et seq.*, directs that "[w]hoever 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.

By "defin[ing] the subject matter that may be patented," *Bilski* v. *Kappos*, 561 U.S. 593, 601 (2010), Section 101 confines patents to particular types of innovations. To obtain a patent, an inventor "must also satisfy" additional statutory requirements, "includ[ing] that the invention be novel, nonobvious, and fully and particularly described." *Id.* at 602 (citing 35 U.S.C. 101-103, 112 (2006)). Those requirements complement Section 101 but serve different functions. Section 102's novelty requirement, for example, ensures that an applicant cannot obtain exclusive rights for another's previous discovery. And Section 112's enablement requirement mandates that a patent's specification describe the "manner and process of making and using" the invention so "as to enable" others "skilled in the art" to do so. 35 U.S.C. 112(a).

An invention thus might satisfy the Act's other requirements but not Section 101, or vice versa. For example, a new way of structuring real-estate transactions might be novel and nonobvious, but it would not be patent-eligible under Section 101 because it would not be the *type* of innovation that has traditionally been understood to fall within the "useful Arts." Conversely, an application for a patent on Alexander Graham Bell's telephone would satisfy Section 101, but it would fail today for lack of novelty.

b. Although Section 101's coverage is "expansive," it is not limitless. *Diamond* v. *Chakrabarty*, 447 U.S. 303, 308 (1980). The Court has long recognized, for example, that "phenomena of nature" are not patent-eligible if materially unaltered by humankind. *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (citing *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1853)). Thus, although a "human-made, genetically en-

gineered bacterium" is patent-eligible, "a new mineral discovered in the earth or a new plant found in the wild is not." *Chakrabarty*, 447 U.S. at 305, 309. Similarly, the Court has long held that newly discovered "'manifestations of . . . nature'"—such as Newton's "law of gravity" or Einstein's "law that $E=mc^2$"—are not patent-eligible. *Id.* at 309 (citation omitted).

Many of the Court's decisions recognizing that such discoveries are not patent-eligible can be understood as interpreting Section 101's specific terms—"process, machine, manufacture, [and] composition of matter," 35 U.S.C. 101—based in part on history and statutory context. See, *e.g.*, *Corning* v. *Burden*, 56 U.S. (15 How.) 252, 267 (1854) ("machine"); *American Fruit Growers, Inc.* v. *Brogdex Co.*, 283 U.S. 1, 11 (1931) ("manufacture"); *Chakrabarty*, 447 U.S. at 308 ("composition of matter"); cf. *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 483 (1974) ("[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter."). For example, the Court has interpreted "process" in Section 101 based on traditional usage of that term and its patent-law precursor ("art"). *Diamond* v. *Diehr*, 450 U.S. 175, 182-184 (1981) (citation omitted).

In more recent decisions, the Court has articulated an alternative rationale for the conclusion that certain discoveries cannot be patented and has set forth a new framework for determining whether particular inventions are patent-eligible under Section 101. In *Bilski*, the Court stated that Section 101's terms should bear their general-purpose "dictionary definitions." 561 U.S. at 603. The Court further described three categories of discoveries traditionally viewed as outside Section 101's

scope—"'laws of nature, physical phenomena, and abstract ideas'"—as judicially created "exceptions" to patent-eligibility that are "not required by the statutory text." *Id.* at 601 (citation omitted). The Court then concluded that a method of hedging financial risk in energy markets was "not a patentable 'process'" because it "attempt[ed] to patent the use of [an] abstract idea." *Id.* at 611-612; see *id.* at 601-604, 606-608, 609-613; *id.* at 613-657 (Stevens, J., concurring in the judgment); *id.* at 657-660 (Breyer, J., concurring in the judgment).

In *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), the Court stated that Section 101 "contains an important implicit exception," under which "'[l]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Id.* at 70 (citation omitted). The Court held that the claims in that case—which "cover[ed] processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high"—were patent-ineligible. *Id.* at 72; see *id.* at 77-92. The Court stated that the claims "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Id.* at 77. The Court concluded that the claims had not "transformed th[o]se unpatentable natural laws into patent-eligible applications of those laws" because they did not "do significantly more than simply describe th[o]se natural relations." *Id.* at 72, 77.

The Court subsequently described *Mayo* as "set[ting] forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd.* v. *CLS*

Bank Int'l, 573 U.S. 208, 217 (2014). First, a court "determine[s] whether the claims at issue are directed to one of those patent-ineligible concepts." *Ibid.* "If so," the court "ask[s], 'what else is there in the claims'" to determine whether any "additional elements 'transform the nature of the claim' into a patent-eligible application." *Ibid.* (brackets and citation omitted); see *id.* at 212, 217-227 (applying that rubric to hold that "a computer-implemented scheme for mitigating 'settlement risk' * * * by using a third-party intermediary" was a patent-ineligible attempt to claim an abstract idea).

The Court has not invariably applied this two-step test, however. In *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576 (2013), the Court held that "a naturally occurring DNA segment" is a patent-ineligible "product of nature," but that "synthetically created DNA" (or cDNA) "is patent eligible because it is not naturally occurring" and "is distinct from the DNA from which it was derived," *id.* at 580, 595; see *id.* at 589-596. The *Myriad* Court relied in part on *Mayo* in emphasizing the need for an appropriate balance between creating adequate incentives to innovate and preserving free access to natural laws and natural phenomena. See *id.* at 589-590. The Court did not apply the two-step framework later described in *Alice*, but instead framed the question before it as "whether Myriad's patents claim any 'new and useful . . . composition of matter,' § 101, or instead claim naturally occurring phenomena." *Id.* at 590.

2. a. Petitioner is the assignee of U.S. Patent No. 7,774,911 ('911 patent), which claims a method of manufacturing automobile driveline propeller shafts (driveshafts or propshafts) to reduce multiple types of vibration. Pet. App. 2a-7a. The '911 patent's specification explains

that driveshafts are prone to three types of vibration—"bending mode, torsion mode, and shell mode"—that can produce undesirable noise. *Id.* at 3a. The specification further explains that driveshaft manufacturers previously used separate mechanisms to reduce those types of vibration individually, but that existing methods were unsuitable for reducing them simultaneously. *Id.* at 5a; see C.A. App. 30.

The '911 patent describes a method of manufacturing driveshafts that reduces both bending-mode and shell-mode vibrations. Pet. App. 4a-5a; C.A. App. 30, 34-35. Claim 22, which the courts below treated as representative, Pet. App. 5a, recites "[a] method for manufacturing a shaft assembly of a driveline system," *id.* at 6a (citation omitted). That method consists of beginning with a "hollow shaft member"; "tuning a mass and a stiffness of at least one liner" so that it is both "a tuned resistive absorber for attenuating shell mode vibrations" and "a tuned reactive absorber for attenuating bending mode vibrations"; and then "inserting the at least one liner into the shaft member." *Id.* at 6a-7a (citation omitted). The district court construed "tuning" to mean "controlling the mass and stiffness of at least one liner to configure the liner to match the relevant frequency or frequencies" of vibration of the driveshaft. *Id.* at 7a-8a (citation omitted); see *id.* at 4a; C.A. App. 32-33. The specification identifies various "characteristics of the liner"—*e.g.*, its material, thickness, and shape—that "can be controlled to tune its damping properties" to match a desired frequency, and it describes one specific embodiment in detail. C.A. App. 33.

b. Petitioner sued respondents for infringement of the '911 patent. Respondents contended that the claims are patent-ineligible under Section 101. The district

court granted summary judgment to respondents. Pet. App. 133a-145a.

3. In its initial opinion, a divided panel of the court of appeals affirmed. Pet. App. 84a-125a. Following a petition for rehearing, the panel issued a modified divided decision, again affirming in relevant part. *Id.* at 1a-70a.*

a. At step one of the *Mayo/Alice* framework, the panel majority held that claim 22 "is directed to a natural law because it clearly invokes a natural law, and nothing more, to accomplish a desired result." Pet. App. 21a. The majority explained that claim 22 calls for "controlling the mass and stiffness of" a liner to match relevant frequencies to dampen vibrations, which "requires use of a natural law relating frequency to mass and stiffness—i.e., Hooke's law," "an equation that describes the relationship between an object's mass, its stiffness, and the frequency at which the object vibrates." *Id.* at 8a, 13a (citation omitted). The majority concluded that claim 22 "simply requires the application of Hooke's law to tune a propshaft liner." *Id.* at 10a; see *id.* at 13a, 21a.

The panel majority further held that claim 22 "defines a goal"—"'tuning a liner' to achieve certain types of vibration attenuation"—without identifying specific steps or structures to achieve it. Pet. App. 13a. In the majority's view, "[t]he focus of the claimed advance here is simply the concept of achieving [the desired] result, by whatever structures or steps happen to work." *Id.* at 16a. The majority analogized claim 22 to claim 8 of Samuel Morse's telegraph patent, which claimed all potential

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* The panel's modified opinion vacated the district court's judgment holding patent-ineligible certain other claims not at issue here. Pet. App. 27a-28a.

uses of electromagnetism to print characters at a distance and was held to be unpatentable in *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62 (1854). Pet. App. 20a-21a.

At step two of the *Mayo/Alice* framework, the panel majority found no "'inventive concept'" that "transform[ed] [claim 22] into patent eligible [subject] matter." Pet. App. 23a. The panel concluded that, apart from using Hooke's law to "achieve[]" a "desired result[]," claim 22 recites only "conventional" driveshaft-manufacturing steps. *Id.* at 24a.

b. Judge Moore dissented. Pet. App. 37a-70a. In her view, petitioner's claims are patent-eligible because they "contain a specific, concrete solution (inserting a liner inside a propshaft) to a problem (vibrations in propshafts)," and a claim is not "*directed to* a natural law simply because compliance with a natural law is required." *Id.* at 37a-38a, 44a. Judge Moore also stated that the majority's conclusion that the claims merely recite a goal to be achieved had improperly introduced into Section 101 a "heightened enablement requirement." *Id.* at 66a.

4. The court of appeals denied rehearing en banc over the recorded dissent of six judges. Pet. App. 150a-152a. Ten judges joined a total of five opinions concurring in or dissenting from the denial. See *id.* at 153a-197a.

DISCUSSION

The court of appeals held that claim 22 of the '911 patent, which claims a method of manufacturing automobile driveshafts that uses specific mechanical structures and calibrates particular physical properties, is patent-ineligible under Section 101. That holding is incorrect. Historically, such industrial techniques have long been viewed as paradigmatic examples of the "arts" or "processes" that may receive patent protec-

tion if other statutory criteria are satisfied. The court of appeals erred in reading this Court's precedents to dictate a contrary conclusion. The decision below reflects substantial uncertainty about the proper application of Section 101, and this case is a suitable vehicle for providing greater clarity.

The first question presented in the petition for a writ of certiorari focuses on the first step of the *Mayo/Alice* framework, *i.e.*, "the appropriate standard for determining whether a patent claim is 'directed to' a patent-ineligible concept." Pet. i. But the second step of that framework has also produced uncertainty and confusion in the lower courts. Clarification of both steps is especially important, both because a court's step-two analysis often finally resolves the determination as to patent-eligibility, and because the nature of the initial step-one screen logically depends in part on the inquiry that courts will apply at step two. To ensure that the Court has the opportunity to consider how both steps should operate in resolving the ultimate question of patent-eligibility, the Court should grant review on question 1 as framed in this brief. See p. I, *supra*.

1. Under Section 101 as interpreted for more than 150 years, petitioner's claims recite a patent-eligible "process." 35 U.S.C. 101. In the patent context, the Court has long construed that term to include "a mode of treatment of certain materials to produce a given result," or "an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Diamond* v. *Diehr*, 450 U.S. 175, 183 (1981) (quoting *Cochrane* v. *Deener*, 94 U.S. 780, 788 (1877)); see p. 3, *supra*.

Representative claim 22 of the '911 patent recites a method of manufacturing automobile driveshafts so as

to reduce multiple types of driveshaft vibration simultaneously. Pet. App. 6a-7a. It sets forth a series of concrete steps to achieve that outcome: taking a hollow driveshaft; calibrating the mass and stiffness of a liner to match one or more vibration frequencies of that driveshaft by controlling various physical characteristics of the liner; and inserting the liner into the driveshaft. *Ibid.* "Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws." *Diehr*, 450 U.S. at 184; see *id.* at 182-184 & nn.7-8 (discussing historical understandings of the term "process" and its statutory predecessor, "art"); *id.* at 181-193 (upholding as patent-eligible claims for "an industrial process for the molding of rubber products").

2. The court of appeals held that claim 22 "is patent ineligible under section 101" based on its application of the "two-step test established in" *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*, 566 U.S. 66 (2012), and *Alice Corp. Pty. Ltd.* v. *CLS Bank International*, 573 U.S. 208 (2014). Pet. App. 10a; see *id.* at 10a-25a. Under that test, a court first "determines whether the claims at issue are directed to" a law of nature or another "patent-ineligible concept[]." *Alice*, 573 U.S. at 217. "If so," the court asks whether other "elements * * * 'transform the nature of the claim' into a patent-eligible application." *Ibid.* (citation omitted).

The *Mayo/Alice* framework has given rise to substantial uncertainty. U.S. Amicus Br. at 11-21, *Hikma Pharm. USA Inc.* v. *Vanda Pharm. Inc.*, 140 S. Ct. 911 (2020) (No. 18-817). The broader context of the Section 101 inquiry and principles this Court has emphasized, however, supply useful guideposts for applying the

framework. We highlight four relevant considerations below.

a. First, the Court has drawn a fundamental distinction "between patents that claim the 'building blocks' of human ingenuity and those that integrate the building blocks into something more, thereby 'transforming' them into a patent-eligible invention." *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 72, 89) (brackets omitted). "[L]aws of nature, natural phenomena, [and] abstract ideas" are not patent-eligible, but "'[a]pplications' of such concepts 'to a new and useful end'" are "eligible for patent protection." *Ibid.* (brackets and citation omitted); see *Mayo*, 566 U.S. at 77. A principal purpose of the *Mayo/Alice* framework is to distinguish between those two types of claimed inventions. *Mayo*, 566 U.S. at 72, 79; see *id.* at 77, 80, 87; *Alice*, 573 U.S. at 217, 221, 223.

The claims held to be patent-eligible in *Diehr* are illustrative. The *Diehr* Court upheld a patent on "a physical and chemical process for molding precision synthetic rubber products," which included "a step-by-step method for accomplishing" the stated objective. 450 U.S. at 184; see *id.* at 181-193. Although "several steps of the process" required use of a particular "mathematical equation"—the Arrhenius equation—the Court "d[id] not view [the] claims as an attempt to patent [that] mathematical formula" or the relationship it expressed. *Id.* at 185, 192. Instead, the Court held that the claims were "drawn to an industrial process" that used the Arrhenius equation "in conjunction with all of the other steps in the[] claimed process." *Id.* at 187, 192-193; see *id.* at 187 ("[T]he respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber.").

b. Second, the Court has repeatedly recognized that, "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'" *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 71); see Pet. App. 44a (Moore, J., dissenting). Courts therefore must "tread carefully in construing th[e] exclusionary principle lest it swallow all of patent law," and "an invention is not rendered ineligible for patent simply because it involves" a patent-ineligible concept. *Alice*, 573 U.S. at 217 (citing *Diehr*, 450 U.S. at 187); see, *e.g.*, *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45, 52-69 (1923) (Taft, C.J.) (upholding the patentability of a paper-making machine whose improvement over the prior art was the use of gravity to accelerate the flow of the stock used in the production process).

c. Third, the Section 101 inquiry is guided by historical practice and judicial precedent. The Court in *Bilski* v. *Kappos*, 561 U.S. 593 (2010), described the "exceptions" it recognized as rooted in decisions "going back 150 years," *id.* at 602. And the *Mayo* Court grounded its application of those exceptions in historical practice and precedent. See *Mayo* 566 U.S. at 80-85 (discussing *Diehr*, *supra*; *Parker* v. *Flook*, 437 U.S. 584 (1978); and *Neilson* v. *Harford*, Webster's Patent Cases 295, 371 (1841)); see also *Alice*, 573 U.S. at 218-219, 222-223. Courts thus should be skeptical of any assertion that a claim for the sort of process that has long been held patent-eligible, such as an industrial manufacturing process, is unpatentable under the "law of nature" exception.

d. Finally, the Court has "described the concern that drives th[e] exclusionary principle" and that "undergirds [its] § 101 jurisprudence" "as one of pre-emption":

the "'[m]onopolization'" by a patentee of one of "'the basic tools of scientific and technological work.'" *Alice*, 573 U.S. at 216, 223 (citations omitted); see *id.* at 217, 223; accord, *e.g.*, *Mayo*, 566 U.S. at 71, 86. The *Mayo* Court described its inquiry as seeking "practical assurance that the process" claimed "is more than a drafting effort designed to monopolize [a] law of nature itself." 566 U.S. at 77. And in applying Section 101, the Court has considered whether a claim would "tie up too much future use of laws of nature." *Id.* at 87. A claim that confers exclusivity only over a narrow range of activity is less likely to implicate that concern. See *Diehr*, 450 U.S. at 187 (finding that patentees "d[id] not seek to pre-empt the use of [the Arrhenius] equation" but "s[ought] only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process").

3. The court of appeals erred in applying those principles to claim 22 of the '911 patent.

a. Claim 22 does not resemble the claims that the Court held patent-ineligible in *Mayo* and *Alice*. It does not "simply describe[]" or "recite[]" any natural law. *Mayo*, 566 U.S. at 77; see *Alice*, 573 U.S. at 220. Claim 22 recites a physical process for producing a particular type of automobile component. It directs the user to begin with a hollow driveshaft; to "tun[e] [the] mass and [the] stiffness of [a] liner," *i.e.*, to "control[] [its] mass and stiffness * * * to configure the liner to match" one or more "frequencies" of the driveshaft so that the liner can dampen multiple modes of driveshaft vibration at once; and to insert the liner into the driveshaft. Pet. App. 6a-8a.

Like "[e]very mechanical invention," claim 22 "requires use and application of the laws of physics." Pet. App. 44a (Moore, J., dissenting). The panel majority

held that the "tuning" step "requires use" of Hooke's law, which relates mass and stiffness to frequency. *Id.* at 13a. But because all useful inventions that operate in the physical world depend for their efficacy on natural laws (whether known or unknown), such dependence by itself cannot render claim 22 patent-ineligible. See p. 12, *supra*. Instead, like the claims held patent-eligible in *Diehr*, claim 22 recites an "industrial process" that entails a concrete application of Hooke's law in a particular setting. 450 U.S. at 192-193.

The remaining guideposts articulated in this Court's decisions point to the same conclusion. As discussed above, claim 22 recites an "[i]ndustrial process[]" of a kind that "ha[s] historically been eligible to receive the protection of our patent laws." *Diehr*, 450 U.S. at 184; see pp. 9-10, *supra*. And it cannot accurately be described as "a drafting effort designed to monopolize" Hooke's law. *Mayo*, 566 U.S. at 77. Claim 22 "do[e]s not seek to pre-empt the use of that equation," *Diehr*, 450 U.S. at 187, in general or in the specific context of manufacturing automobile driveshafts. It instead simply "foreclose[s] from others the use of that equation in conjunction with all of the other steps in [the] process." *Ibid.*; see p. 11, *supra*.

b. At step one of the *Mayo/Alice* framework, the panel majority stated that claim 22 "is directed to a natural law because it clearly invokes a natural law, and nothing more, to accomplish a desired result." Pet. App. 21a. The majority viewed claim 22 as implicitly invoking Hooke's law to dampen multiple modes of driveshaft vibration while "provid[ing] no details" explaining how "to accomplish [that] desired result." *Ibid.*; see *id.* at 15a-23a. The majority analogized claim 22 to claim 8 of the Morse patent at issue in *O'Reilly* v.

Morse, 56 U.S. (15 How.) 62 (1854), which encompassed any "use of * * * electro-magnetism, however developed," to transmit letters or symbols "at any distances," *id.* at 112. See Pet. App. 21a. The *O'Reilly* Court found claim 8 to be invalid because, unlike the other claims in Morse's patent (which the Court upheld), claim 8 expressly disavowed *any* "limit[ation] * * * to the specific machinery or parts" disclosed in the patent. 56 U.S. (15 How.) at 112; see *id.* at 112-114. The panel majority here held that claim 22 of the '911 patent likewise is patent-ineligible because it "simply claim[s] a result" of reducing multiple modes of vibration "by whatever structures or steps happen to work." Pet. App. 16a-17a.

The panel majority was correct that "claims that state a goal without a solution are patent-ineligible." Pet. App. 17a. Although *O'Reilly* did not clearly identify the statutory source of that principle, see Lefstin & Menell Amici Br. 13-16, the rule follows from Section 101's text and is related to, but distinct from, the exception the Court has recognized for laws of nature, natural phenomena, and abstract ideas. The long-settled patent-law meaning of "process" requires not merely a "result," but also "a mode of treatment" or "series of acts" that will "produce" it. *Diehr*, 450 U.S. at 183 (citation omitted). Section 101 thus does not permit, for example, a claim for illuminating dark rooms by any efficacious means, or for doing so in any way that involves electricity. Such claims identify a goal to be achieved, but do not recite a "process" for achieving it.

Contrary to the majority's analysis, however, claim 22 goes well beyond identifying the "goal" of reducing multiple modes of vibration. Pet. App. 17a. It recites a specific sequence of steps to achieve that goal: taking a "hollow shaft"; "tuning" the "mass" and "stiffness" of a liner,

which the district court construed to mean "controlling" the liner's mass and stiffness "to match the relevant frequency or frequencies" of vibration of the shaft; and "inserting the" liner "into the shaft," whereupon the liner acts as an "absorber" of two kinds of vibrations. *Id.* at 6a-8a (citations omitted). The majority's analogy to claim 8 in *O'Reilly*, *id.* at 20a-21a, therefore is inapt.

For similar reasons, although the efficacy of the method described in claim 22 appears to depend on the operation of a law of nature (*i.e.*, Hooke's law), the claim does considerably more than "add the instruction 'apply the law.'" *Mayo*, 566 U.S. at 78. And while the panel majority acknowledged the distinction between patent-eligibility under Section 101 and enablement under Section 112, Pet. App. 30a-32a, its analysis blurs the two by demanding that the claims provide a degree of detail more appropriate to the enablement inquiry. See *id.* at 13a (explaining that claim 22 of the '911 patent does not "identify the 'particular tuned liners' or the 'improved method' of tuning the liners" (brackets and citation omitted)); *id.* at 16a, 23a (claim 22 "does not specify how target frequencies are determined"; "how, using that information, liners are tuned to attenuate" two modes of vibration; or the "physical structure" of tuned liners); *id.* at 66a (Moore, J., dissenting).

c. At the second step of the *Mayo/Alice* analysis, the panel majority concluded that "nothing in claim 22 qualifies as an 'inventive concept' to transform it into patent eligible matter." Pet. App. 23a. The majority based that conclusion in part on its perception that, "insofar as claim 22 here merely claims the achievement of results, [it is] directed to ineligible matter." *Id.* at 24a. The majority's perception that claim 22 "merely claims the achievement of results," *ibid.*, without identifying

steps to achieve them, was flawed for the reasons set forth above. See pp. 15-16, *supra*.

The panel majority also stated that "[c]laim 22 discloses no other inventive concept" because its "remaining steps * * * amount to no more than conventional pre- and post-solution activity." Pet. App. 24a. Although the dissenting judge appropriately questioned whether use of liners to reduce bending-mode vibrations in automobile driveshafts was actually "[c]onventional," *id.* at 57a; see *id.* at 56a-59a, she did not explicitly dispute the majority's apparent premise that "conventional" claim elements should be disregarded at step two of the *Mayo/Alice* framework.

The *Mayo* Court repeatedly characterized the other "steps in the claimed processes (apart from the natural laws themselves)"—which the Court held insufficient to render the claims patent-eligible—as "involv[ing] well-understood, routine, conventional activity." 566 U.S. at 73; see *id.* at 79-80, 82. The *Alice* Court characterized the steps of the claims that it held patent-ineligible in similar terms. 573 U.S. at 225. Relying on that language, the Federal Circuit has held that, to be deemed patent-eligible at the second *Mayo/Alice* step, a claim must include more than steps or elements that are "well-understood, routine, conventional activities" in the relevant field. *E.g.*, *CosmoKey Solutions GmbH & Co. KG* v. *Duo Sec. LLC*, 15 F.4th 1091, 1097 (2021) (citation omitted); see *Ultramercial, Inc.* v. *Hulu, LLC*, 772 F.3d 709, 715 (Fed. Cir. 2014), cert. denied, 576 U.S. 1057 (2015); see also United States Patent and Trademark Office (USPTO), *Manual of Patent Examining Procedure* § 2106.05(d), at 2100-72 to 2100-77 (9th ed., rev. 10.2019, June 2020) (*MPEP*).

But other statements in *Mayo* and *Alice*, and the context in which that language appeared, indicate that

the Court did not intend to endorse a categorical rule that conventional claim elements should be disregarded in determining whether particular claims reflect an "'inventive concept,'" or "add *enough*" to natural laws or phenomena, so as to warrant patent protection. *Mayo*, 566 U.S. at 72, 77 (citation omitted); see *Alice*, 573 U.S. at 217-218, 221. For example, the *Mayo* Court did not question the long-settled understanding that the patent-eligibility of a process claim turns on "the process as a whole," and that "an *application* of a law of nature or mathematical formula" may be patent-eligible even if the law or formula is applied "to a known structure or process." *Diehr*, 450 U.S. at 187. To the contrary, the Court in *Mayo* quoted with approval the *Diehr* Court's statement that a "new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Mayo*, 566 U.S. at 79 (quoting *Diehr*, 450 U.S. at 188); see *Diehr*, 450 U.S. at 188 (observing that, for that reason, a holistic approach is especially important in analyzing "a process claim").

The *Mayo* Court concluded that the various steps of the particular claimed process before it, "when viewed *as a whole*, add[ed] nothing significant beyond the sum of their parts taken separately." 566 U.S. at 80 (emphasis added). *Alice* reiterated the need to "consider the elements of each claim both individually and 'as an ordered combination'" in resolving issues of patent-eligibility at the second step of the analysis. *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 79). Holistic consideration of a claim at the second step is incompatible with an approach that ignores individual claim elements that are conventional in isolation.

Clarification of this point is especially important because the question a court addresses at step two of the *Mayo/Alice* framework—*i.e.*, whether the elements of a disputed patent claim are "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself," *Alice*, 573 U.S. at 218 (quoting *Mayo*, 566 U.S. at 72-73) (brackets omitted)—is coextensive with the ultimate question of patent-eligibility in the many cases where a court reaches that step. Given the emphasis this Court has placed on the deep historical roots of the law-of-nature inquiry, see, *e.g.*, *id.* at 216 ("We have interpreted § 101 and its predecessors in light of this exception for more than 150 years."), that step-two analysis should be performed in accordance with the longstanding principle that a *combination* of claim elements may reflect a patent-eligible invention even though each individual element was part of the prior art. See *MPEP* § 2106.05(d), at 2100-75. Under that approach to step two, the step-one determination whether a particular claim is "directed to" a natural law can simply serve as an initial screen, identifying claims that warrant further scrutiny to ascertain whether they claim patent-eligible applications of laws of nature or instead effectively claim the natural laws themselves. By contrast, if the court at step two were foreclosed from considering claim elements that have traditionally been viewed as relevant to patent-eligibility, consideration of those elements would need to be incorporated in some fashion into the step-one inquiry.

4. This is only the most recent Section 101 case that has fractured the Federal Circuit. See, *e.g.*, *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019), reh'g denied, 927 F.3d

1333 (Fed. Cir. 2019), cert. denied, 140 S. Ct. 855 (2020); *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), reh'g denied, 809 F.3d 1282 (Fed. Cir. 2015) (per curiam), cert. denied, 136 S. Ct. 2511 (2016). Ongoing uncertainty has induced "every judge on [the Federal Circuit] to request Supreme Court clarification." Pet. App. 78a (Moore, J., concurring in denial of stay). Problems arising from the application of Section 101 have attracted particular attention in certain fields, such as medical diagnostics. See, *e.g.*, *Athena Diagnostics*, 927 F.3d at 1352-1353 (Moore, J., dissenting from the denial of rehearing en banc). But the "inconsistency and unpredictability of adjudication" extend to "all fields." *Yu* v. *Apple Inc.*, 1 F.4th 1040, 1049 (Fed. Cir. 2021) (Newman, J., dissenting); see *id.* at 1042-1045 (majority opinion) (holding that claims for digital camera with designated structure to perform specified functions were directed to abstract idea); *Chamberlain Grp., Inc.* v. *Techtronic Indus. Co.*, 935 F.3d 1341, 1348 (Fed. Cir. 2019) (similar regarding garage-door opener), cert. denied, 141 S. Ct. 241 (2020).

In 2019, the USPTO provided its thousands of patent examiners and administrative patent judges with guidance designed to make application of judicial precedents more consistent. *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019). That guidance noted that applying this Court's recent Section 101 decisions "in a consistent manner has proven to be difficult"; "has caused uncertainty in this area of the law"; has made it difficult for "inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject matter is patent-eligible"; and "poses unique challenges for the USPTO" itself. *Id.* at 50, 52.

5. This case is a suitable vehicle for providing greater clarity. Respondents contend (Br. in Opp. 31) that the Court should deny review because the case was decided "after full fact and expert discovery." But to the extent any factual issues are relevant, the "developed factual record" (*ibid.*) is a virtue, not a vice. Respondents' contention (*id.* at 10-12) that the decision below is "factbound and narrow," *id.* at 10 (capitalization and emphasis omitted), is also mistaken. As the splintered separate opinions at the panel and rehearing stages illustrate, the Federal Circuit is deeply divided over the proper application of this Court's framework, and the content of that framework is central here.

Respondents suggest (Br. in Opp. 14-15) that the Court should grant review in a case involving "software [or] life sciences." *Id.* at 14 (capitalization and emphasis omitted). But in applying Section 101 to the more traditional industrial manufacturing method at issue here, the Court can more readily draw on historical practice and precedent to clarify the governing principles, which can then be translated to other contexts.

Finally, respondents assert (Br. in Opp. 15-17) that review is unwarranted because petitioner's claims are "likely invalid" under Section 112. *Id.* at 16. The government disagrees with the premise that claim 22 likely fails under that or any other Patent Act provision. In any event, the claim's potential invalidity on other grounds, which the courts below "did not reach," *id.* at 17, would not prevent this Court from determining that the claim is patent-eligible under Section 101.

6. Petitioner's second question presented urges the Court (Pet. i, 23-24, 37-39) to address whether the first and second *Mayo/Alice* steps present "questions of law for the court to decide or questions of fact for a jury to

decide," Pet. 37. The answer to that satellite procedural question depends on the substantive Section 101 standard. See, *e.g.*, *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 384-391 (1996). Answering the second question presented thus would be difficult while uncertainty about the substance of the Section 101 inquiry persists. The Court accordingly should grant review on the first question presented as framed in this brief, see p. I, *supra*. If necessary, it may then address, in this case or a future one, whether applying that standard entails a legal, factual, or hybrid analysis.

CONCLUSION

With respect to question 1 as framed in this brief, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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