NOVARTIS

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Before the United States Senate Committee on the Judiciary
Subcommittee on Intellectual Property

Subcommittee Hearing on "*The Patent Eligibility Restoration Act* – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"

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Dirksen Senate Office Building, Room 226

I. Introduction

Chairman Tillis, Ranking Member Schiff, and Distinguished Members of the Subcommittee:

My name is Corey Salsberg, and I am Vice President, Global Head of IP Affairs for Novartis, one of the world's leading innovative medicines companies, and a pioneer in cell and gene therapy, radioligand therapy, gene-based medicine and other frontier medical technologies. We appreciate the opportunity to testify today about the need for patent eligibility reform in America and the Patent Eligibility Restoration Act (PERA)—a sensible and necessary bill that we support.

II. Background

As a personal introduction, I am an attorney with over twenty-five years of experience in the areas of IP and innovation law and policy, and the intersection of these areas with related fields such as technology and trade law and policy. I earned my Juris Doctor (JD) from Stanford Law School in 2001, and my undergraduate degree from Yale University in 1997. Prior to joining Novartis in 2010, I was a litigator in private practice with the law firms of McDermott, Will & Emery and Morrison & Foerster. In addition to my current role as Vice President, Global Head of IP Affairs for Novartis, I am the President of the Federal Circuit Bar Association, and a Board Member of the Intellectual Property Owners Association (IPO), and of California Lawyers for the Arts, an arts-related legal aid society that also administers the west coast arm of the USPTO's patent pro bono program. I am also a founder and member of the Steering Committee of the international Inventors Assistance Program (IAP), a World Intellectual Property Organization (WIPO)-sponsored program now active in 10 countries that provides pro bono legal services to under-resourced inventors, which just celebrated its 10th anniversary. Outside of the IP field, I am the author of *Resurrecting the Woolly Mammoth*, one of the first works to explore the science, law and ethics of the emerging field of "de-extinction."[i]

Today, I am here to testify on behalf of Novartis. Novartis is a science-based innovative medicines company whose purpose is to reimagine medicine to improve and extend people's lives. Our products, which include novel chemistry-based medicines, biotherapeutics (also known as biologics), cell and gene therapies, and radiopharmaceuticals, reached nearly 300 million patients in 118 countries last year alone, treating diseases in the fields of oncology, immunology and neuroscience, as well as cardiovascular, renal, metabolic and rare genetic disorders.

While our company is global, Novartis and its predecessor companies have had a major presence in America for nearly a century. Today, the United States is home to the global headquarters of our Biomedical Research organization—what we call our "innovation engine"—where our in-house scientists invented and developed many of our past and present breakthrough medicines and continue to direct our global R&D efforts. The US is also where our revolutionary cell and gene therapies were developed, including Zolgensma®, the world's first gene therapy to treat infants and young children with spinal muscular atrophy (SMA), and Kymriah®, the world's first chimeric antigen receptor T-Cell (CAR-T) therapy, a personalized one-time treatment that uses a patient's own T-cells to fight blood cancer. At our cutting-edge facilities across America, we manufacture these and other pioneering treatments, like our targeted radioligand cancer therapies, through innovative platforms that we continue to evolve to prepare for the next generation of

treatments and cures that emerge from our labs and through our work with US-based collaborators. Currently, we employ around 12,000 people from coast to coast in America, and we estimate the contribution of our local R&D activities to US GDP to be around $5.1 billion annually.[ii]

Building on our longstanding US organization, earlier this year, we announced plans to invest an additional $23 billion into our infrastructure to expand our US R&D and manufacturing footprint over the next 5 years.[iii] This includes the construction of seven brand new state-of-the-art facilities, and the expansion and enhancement of three existing sites—investments that will create thousands of new high-quality American jobs, and, notably, enable all of our key medicines for American patients to be manufactured end-to-end here.[iv] Especially relevant to the topic of today's hearing, our plans also include the establishment of a brand new Biomedical Research innovation hub in San Diego, which will be our second global R&D hub in the United States. This exciting new endeavor builds upon our 25-year legacy as a pioneering research organization in the area—a legacy that includes a wide array of drug discovery innovations, over 1,150 peer-reviewed scientific publications, and a Nobel Prize—all of which have made us a major contributor to the American-led genomics and gene-based medicine revolution.[v]

As I will explain in a moment, America's once world-leading patent-eligibility laws played a central role in enabling that revolution, and in ensuring that it happened here. But today, on account of an unclear and often confusing eligibility framework established by the Supreme Court, and a lower judiciary that has frequently misapplied that framework, those same laws are moving steadily in the opposite direction, chipping away at the next wave of progress and investment, and threatening America's leadership in these still-nascent fields—all without Congressional mandate or endorsement. As an innovator that is heavily invested in and committed to America, we count on the strength of its innovation ecosystem to enable and support our efforts to discover, develop and deliver the next generation of medicines, including gene-based therapies. We hope that the experiences and perspectives that we share with you today will assist Congress in taking steps to reverse course on the troubling state and trajectory of patent-eligibility law, and to restore America's patent system to the gold standard that it should be.

III. From bad to worse: Patent eligibility law's growing threat to American biotech leadership

Six years ago, I testified before this Subcommittee about the state of patent eligibility law in America, and agreed with the majority of the other witnesses that it was not good.[vi] While we shared the overwhelming view at that time that the Supreme Court's patent eligibility framework is unclear and unpredictable,[vii] and that it had wrongly led to many important inventions, and even entire fields of inventions, being shut out of the patent system, our main concern was for the future. The Supreme Court, we feared, had created a juridical "snowball"—a test that, by its nebulous approach and uncertain contours, would lead the lower courts and the patent office to continually expand the scope of ineligible subject matter well beyond the conventional "judicial exceptions," and well beyond even what the Supreme Court intended in *Mayo,*[viii] *Myriad,*[ix] and *Alice*,[x] into the core of the cutting-edge fields that were defining the future of medicine.

We wish our predictions had been wrong, but unfortunately, a mere six years on, the state of patent eligibility law in America has gone from bad to worse. Just yesterday, the Federal Circuit heard oral argument in a case with potentially dire consequences for the future of gene therapy and many other areas of biotechnology. The case, *Regenxbio v. Sarepta*,[xi] concerns an important component of gene therapy platforms: genetically engineered host cells that produce the type of innovative viral vectors that deliver missing or restorative genes to patients, treating and potentially curing a range of genetic and other disorders. Virus-based vectors like these are central to today's gene therapies, and with thousands of ongoing clinical trials in the field,[xii] they and similar bio-engineered components will continue to be pivotal to the technology's future. The patents at issue in the case claim "cultured" host cells that are created in a laboratory through the insertion of a "recombinant" DNA sequence made up of genes spliced together from at least two completely different species of organism. Even the accused infringer in the case agreed that neither the spliced-together gene sequence, nor the claimed resulting host cells exist or are the same as what exists in nature. Yet, the district court concluded that the claimed cells are patent-ineligible "products of nature," because they are built from components of nature.[xiii]

The decision is as much at odds with law as it is with common sense. "Compositions of matter" have been statutorily patent-eligible since 1793.[xiv] In 1980, in a landmark decision called *Chakrabarty*, the Supreme Court held that "organisms produced by genetic engineering"—and specifically those created through insertion of other species' DNA into a host cell—are a type of "non-naturally occurring . . . composition of matter" that "plainly qualifies as patentable subject matter."[xv] In the *Myriad* decision three decades later, the Supreme Court reaffirmed that precedent. While it carved out a carefully limited exception for isolated human "genes and the information they encode,"[xvi] it equally stressed that *modifications* and *applications* of genes remain patent-eligible, and held that, for example, a "lab technician unquestionably creates something new" when he or she constructs a non-naturally occurring sequence, such as cDNA, which it held "is not a 'product of nature' and is patent eligible under §101."[xvii]

As the first case to declare a genetically engineered composition of matter that everyone agrees does not occur in nature to be ineligible subject matter, *Regenxbio* now razes a foundational holding that innovators in gene-based medicine have relied upon for nearly half a century to support their groundbreaking work at the cutting-edge of science. The implications of the decision should worry everyone. The Supreme Court's confirmation in *Chakrabarty* forty-five years ago that such compositions *"*plainly qualify" as patent-eligible subject matter is widely credited with having spawned the American biotechnology industry, giving rise to everything from polymerase chain reaction (PCR)—a revolutionary sequencing technology that enabled much of today's gene-based science, medicine, and forensics—to genetically optimized crops, to breakthrough medicines like monoclonal antibodies used to treat cancer and other diseases.[xviii] As one commentator wrote even just a few years after the decision, "[w]ith *Chakrabarty* as the basis, man is finding the capability of making anything and everything," and "inventors are moving in all directions, producing an astounding number of useful products including pharmaceuticals, improved plant varieties, pesticides and chemical feedstocks."[xix] The same foundational decision later led to the sequencing and unlocking of the human genome, and to the types of scientific and

applied technological breakthroughs made in laboratories like ours that eventually became today's gene therapies and other gene-based treatments.

Regenxbio now threatens all of that, risking the progress that has been made to date, and jeopardizing investment in new fields that have only just begun to be built upon the same legal foundation, from the next generations of gene and cell therapy, to gene-editing, gene-silencing treatments and other gene-based medicines. In fact, if the decision or its flawed logic stand, countless inventions in almost every field of technology could be at risk, because, as the Supreme Court has reminded us time and again, "all inventions at some level embody, use, reflect, rest upon, or apply" laws or elements of nature.[xx]

Of course, the Federal Circuit may still reverse the lower court's decision. But it cannot reverse the new levels of uncertainty that the case has now injected into the life sciences industry. To help enable and guide our research and development decisions, innovators need laws and incentives that are clear, predictable and stable. The Supreme Court's patent eligibility framework has proven to be anything but. Viewed through that lens, *Regenxbio* is not a standalone anomaly, but the latest advance in a steady expansion of ineligible subject matter into territory once considered safe and investible. With new ground now broken in that advance, even if the Federal Circuit reverses, innovators know that it is only a matter of time before another litigant in another case challenges a similar set of patent claims and secures a different outcome. In that regard, *Regenxbio* is the proverbial fairytale egg that no appellate panel by itself can put back together again.

These concerns are not theoretical. They are a well-documented consequence of the Supreme Court's ill-defined eligibility framework, and precisely what has happened with the other types of judicial exceptions—so-called "laws of nature" and "abstract ideas." In fact, the Federal Circuit has itself lamented that it is "at a loss" as to how "to consistently apply the judicially created exceptions," and as a result, it has "slowly create[d] a panel-dependent body of law."[xxi] While, until now, expansion of the "product of nature" exception has been relatively slower than the other two in the courts—notable exceptions being newly created exclusions for cloned organisms[xxii] and synthetic DNA primers[xxiii]—the patent office has not been so restrained. We shared some examples of this in our 2019 testimony, highlighting some of our claims to pharmaceutical compositions made up of non-naturally occurring modified proteins that had been rejected on grounds that they were "products of nature." [xxiv] More recently, our claims to synthetic gene promotors, important components of gene therapy created by combining different DNA-promoting sequences in ways that do not exist in nature, were rejected on grounds similar to the court's reasoning in *Regenxbio*. And, while not a life sciences case, in another notable decision earlier this year, the Federal Circuit reversed an ITC decision that had held patent claims to a synthetic material useful as a cutting element for rotary drill bits to be patent-ineligible, even though the ITC had acknowledged in the case that the claims "obviously do recite compositions of matter that are not found in nature."[xxv]

These examples and others prove precisely what we feared in 2019—that patent-eligibility law is on a downhill trajectory that will continue to expand the scope of ineligible subject matter in the patent office and courts until Congress acts.

IV. The troubling state of method patent eligibility in America

Equally concerning—and a worrying preview of what may be near on the horizon for genetically engineered compositions of matter—is the continually devolving state of patent-eligibility for innovative biotechnological and pharmaceutical methods, important for everything from diagnosing disease, to discovering and preparing new treatments, to making sure patients get the most effective medicines for their illnesses. "Processes" (originally encompassed by the term "arts") have been statutorily patent-eligible since 1790, even longer than have compositions of matter.[xxvi] While the Supreme Court in *Mayo* found that certain diagnostic methods do not qualify, it is doubtful that the Court intended its holding—stated to be based on "the particular claims before us"[xxvii]—to foreclose patents on the *entire field* of diagnostics. Yet, that has been the result.[xxviii] Even clear boundaries established in *Mayo*, such as the Court's guidance that "unlike" the diagnostic claims at issue in the case, patents on "a new way of using an existing drug" (also known as method-of-*treatment* claims) *are* patent-eligible[xxix]—a conclusion also expressly stated in the patent statute[xxx]—have since been questioned and distorted in the lower courts, with fewer than all judges of the Federal Circuit able to agree that the sweeping eligibility framework can support that result.[xxxi]

In the last few years, boundaries between diagnostic methods and methods of treatment have only been further blurred, with often confusing and inconsistent outcomes. As we testified in 2019, for example, despite "methods of treatment" being generally eligible, the very same methods seem to become suddenly ineligible if they include any attempt to ensure that the patient actually has the target disease before administering the drug—an unfortunate disincentive to develop personalized treatments that optimize efficacy and reduce healthcare costs.[xxxii] To make matters worse, method patent eligibility often comes down not to what invention the patent actually covers, but what particular words are used to describe it and in what particular order. As things stand today under the case law, "methods of treatment" are generally in,[xxxiii] but "methods of diagnosing" are out.[xxxiv] "Methods of detecting" a biomarker or disease indicator are out,[xxxv] but "methods of preparing" samples for exactly the same purpose may be in.[xxxvi] "Methods of optimizing" health-related indicators with a drug are out,[xxxvii] but "methods of regulating" them may be in.[xxxviii] Methods of "assessing,"[xxxix] "determining,"[xl] and "genotyping"[xli] are out, but methods of "producing preparations"[xlii] or "operating" an apparatus to perform these assessments and analysis may be in.[xliii]

Patent-eligibility law should not be this complex. It is simply a matter of deciding what types of innovations we want to promote in America, and what types we do not. The Constitution entrusts those decisions exclusively to Congress.[xliv] As the Supreme Court itself has said, "[i]t is, of course, correct that Congress, not the courts, must define the limits of patentability."[xlv] And, having now denied at least 64 *certiorari* petitions seeking further clarity on the issue since *Mayo*, the Supreme Court has made clear that it does not intend to provide that guidance. With the current law continuing to drift, leading to inconsistent, irrational and plainly detrimental results, it is time for Congress to reassert its constitutional authority and restore a sensible patent-eligibility law and innovation policy in America.

V. Promoting Progress: Restoring sensible eligibility laws and securing America's future

Patent-eligibility law may seem esoteric and unimportant to the average American, and perhaps even to Congress. But it has a massive real-world impact, serving as the gateway to America's patent system and a proxy for the innovation policy aims embodied in the Constitution's "Progress clause."[xlvi] In practice, the patent eligibility statute, Section 101, plays a major role in driving the direction and location of our work—and with it the progress of medicine—because, to put it bluntly, the risky, costly and complex research and business of inventing and developing medicines needs a stable legal footing for it to occur. From the earliest days of the modern pharmaceutical industry and its roots in the chemical arts,[xlvii] to the dawn of the biotechnology age following *Chakrabarty*, the ability of innovators to patent inventions in our field has consistently provided that footing, catalyzing every chapter and verse of modern medicine. Just as *Chakrabarty* opened the gates to the era of personalized treatments and gene-based medicine, allowing those gates to now swing closed on account of a judicially-created framework that the Courts themselves have made clear was never meant to replace Congress's innovation policymaking role, risks derailing the next era of progress.

The same is true for America itself. *Chakrabarty* told biotechnology innovators that America is open for research and business, which in turn made it the epicenter of the genomics age. The current state of eligibility for biotechnological methods, and the new threats posed to genetically engineered compositions of matter, now send the opposite signals, forcing innovators to question whether cutting-edge R&D and manufacturing should be taken elsewhere. That is not the outcome we or other innovators want. As I said earlier in my testimony, with our planned $23 billion investment to expand our US R&D and manufacturing footprint, we're counting on America's innovation ecosystem to enable and support our next chapter. As America approaches its 250th birthday, and faces new challenges from competitors and adversaries abroad, it's important to reflect on the outsized role that its strong patent system has played in making it the global innovation leader up to this point. As Mark Twain put it, writing on the centennial of the Constitution's ratification, "a country without . . . good patent laws [i]s just a crab, and [cannot] travel any way but sideways or backwards."[xlviii]

The Patent Eligibility Restoration Act (PERA) is a "good patent law." For innovators like us who rely on patents to enable the decade or more of investment, experimentation and risk that it takes to convert science and bold ideas into breakthrough treatments and cures, PERA restores the predictability that cases like *Mayo* and the district court's decision in *Regenxbio* have taken away. For America, PERA solidifies the legal and policy footing needed to secure its place as the venue of choice for the future of medicine. Last, to answer its critics, PERA codifies *Myriad*, making clear that human genes, whether isolated or in their natural state, are *not* patent-eligible, while also ensuring—as the Supreme Court also held—that *modifications* and *applications* of genes, the foundations of biotechnology, remain eligible. In this regard, it is important to stress that, in so doing, PERA still sets the United States behind most other innovative economies. China, Europe, Japan, and Korea, to name a few, all continue to grant patents on useful isolated human genes, and they do so without impeding science, innovation, or access, and without any of the other ill effects

that critics of patent-eligibility reform claim would occur if the same were done here.[xlix] Despite this, we believe PERA strikes a workable balance between those who object to such policies, and the research scientists and innovators who need sensible patent laws to successfully innovate at the frontiers of medicine. It is, after all, the inventions "that push back the frontiers of chemistry, physics, and the like," that are "most benefiting mankind."[l] And, as the Supreme Court reminds us, it is "precisely because such inventions are often unforeseeable" that Congress has, for the last 235 years, cast Section 101 in broad and clear terms—[li] the same reason it should take action to do so again now.

I. Conclusion

Once again, we thank the Chairman, Ranking Member, Co-sponsors, and the members of the Subcommittee and all of your staffs for your leadership and vision on this important issue. We welcome any questions and look forward to continuing to work with you as the bill advances.

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[i] Corey Salsberg, *Resurrecting the Woolly Mammoth: Science, Law, Ethics, Politics, and Religion*, Stanford Technology Law Review, 2000 Stan. Tech. L. Rev. 1 (Spring 2000).
[ii] Novartis Pharmaceuticals in the U.S. | Novartis U.S.
[iii] Novartis plans to expand its US-based manufacturing and R&D footprint with a total investment of $23B over the next 5 years (April 10, 2025).
[iv] *Id.*
[v] Novartis San Diego: 25 Years of Biomedical Research Success (August 21, 2025).
[vi] Testimony of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis, *The State of Patent Eligibility in America: Part III:* Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property, 116th Cong. (2019).
[vii] At least 40 of the 45 witnesses, including most of those who opposed reforms, testified that the Supreme Court's framework has injected uncertainty into eligibility law. *See* Judge Paul R. Michel (ret.), David J. Kappos, Corey A. Salsberg, and Matthew J Dowd, *Presenting the Evidence for Patent Eligibility Reform: Part I, Appendix B*, IP Watchdog, October 6, 2022.
[viii] *Mayo v. Prometheus,* 566 U. S. 66 (2012).
[ix] *Assoc. for Molecular Pathology v. Myriad Genetics,* 569 U.S. 576 (2013).
[x] *Alice v. CLS Bank,* 134 S. Ct. 2347 (2014).
[xi] *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, Case No. 24-1408 (Oral Argument held Oct. 7, 2025).
[xii] *See* National Institutes of Health, ClinicalTrials.gov ("gene therapy").
[xiii] *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.,* No. 20-1226 RGA (D. Del., Jan. 5, 2024) (Holding that while the claimed host cells combined "two sequences from two different organisms" that do not occur together in nature, the claims nevertheless were patent-ineligible because the inventors did "not chang[e] any of the claimed invention's naturally occurring components.")
[xiv] *See* Patent Act of 1793 (Patents shall be available for "any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement" thereof)
[xv] *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 318 (1980)
[xvi] *Myriad,* 569 U.S. at 596 ("We merely hold that genes and the information they encode are not patent eligible under §101 . . . .").
[xvii] *Id.* at 595.
[xviii] *See, e.g.,* M. Jordan, et. al., *Forty Years Since Diamond v. Chakrabarty: Legal Underpinnings and its Impact on the Biotechnology Industry and Society*, Jan. 2021; Jane M. Marciniszyn, *What Has Happened Since Chakrabarty*, 2 J.L. & Health 141 (1987-1988).
[xix] Marciniszyn, *supra,* at 156.
[xx] *Mayo,* 566 U.S. at 71 (2012).
[xxi] *Am. Axle & Mfg., Inc. v. Neapco Holdings*, 977 F.3d 1379, 1382 (Fed. Cir. 2020) (Moore, J., concurring in denial of stay of mandate); *see also Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., concurring-in-part, dissenting-in-part) ("The law, as I shall explain, renders it near impossible to know with any

certainty whether the invention is or is not patent eligible."); *Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC*, 966 F.3d 1347, 1357 (Fed. Cir. 2020) (Newman, J., dissenting from denial of rehearing en banc) ("The court's rulings on patent eligibility have become so diverse and unpredictable as to have a serious effect on the innovation incentive in all fields of technology."); *Athena v. Mayo*, 915 F.3d 743 (Fed Cir. 2019) (Newman, J., dissenting) ("This court's decisions on the patent-ineligibility of diagnostic methods are not consistent, and my colleagues today enlarge the inconsistencies...").

[xxii] *In re Roslin Inst.,* 750 F.3d 1333, 1337 (Fed. Cir. 2014).

[xxiii] *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 774 F.3d 755, 758 (Fed. Cir. 2014); *Roche Molecular Sys., Inc. v. CEPHEID,* 905 F.3d 1363 (Fed. Cir. 2018).

[xxiv] Testimony of Corey Salsberg, *The State of Patent Eligibility in America: Part III* (2019) at 3.

[xxv] *US Synthetic Corp. v. International Trade Commission,* Case No. 2023-1217 (Fed. Cir., Feb. 13, 2025).

[xxvi] *See* Patent Act of 1790 (Authorizing patents for "any useful art [e.g. processes], manufacture, engine, machine, or device, or any improvement therein not before known or used.")

[xxvii] *Mayo,* 566 U.S. at 72 ("Our conclusion rests upon an examination of the particular claims before us . . . .").

[xxviii] See *Athena Diagnostics, Inc. v. Mayo Collab. Servs.,* 927 F.3d 1333, 1352, 1354 (Fed. Cir. 2019) (Moore, J., dissenting) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible," turning it into "a per se rule that diagnostic kits and techniques are ineligible.")

[xxix] See *Mayo*, 566 U.S. at 87 ("Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws.").

[xxx] *See* 35 U.S.C. § 100 ("The term 'process' . . . includes a new use of a known . . . composition of matter.")

[xxxi] *See Vanda Pharms. Inc. v. West-Ward Pharms.*, 887 F.3d 1117 (Fed. Cir. 2018) (Prost, CJ., dissenting, finding claims expressly directed to "a method for treating a patient" with a particular drug to have "no distinction from *Mayo*").

[xxxii] *See* Testimony of Corey Salsberg, *The State of Patent Eligibility in America: Part III* (2019) at 3; *see also INO Therapeutics LLC v. Praxair Distribution Inc.,* 782 Fed. App'x 1001 (Fed. Cir. 2019) (finding claims to methods of treatment ineligible because only patients with the confirmed profile are treated with the drug).

[xxxiii] *See, e.g., Vanda*, 887 F.3d 1117; *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, 919 F.3d 1347 (2019); *The Cleveland Clinic Foundation v. True Health Diagnostics LLC,* 859 F.3d 1352 (Fed. Cir. 2017); *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC,* 918 F.3d 1338 (2019).

[xxxiv] *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC,* 915 F.3d 743 (Fed. Cir. 2019)

[xxxv] *See,* e.g., *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371 (2015) (Claims to a "method for detecting" fetal DNA in maternal blood to diagnose fetal chromosomal abnormalities found ineligible); *Genetic Technologies Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (2016); *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371 (Fed. Cir. 2022).

[xxxvi] *See Illumina, Inc. v. Ariosa Diagnostics, Inc.,* 967 F.3d 1319 (Fed. Cir. 2020) (Claims to a "method for preparing" paternal DNA for purposes of analyzing fetal chromosomal abnormalities are eligible because this is "not a diagnostic case. And it is not a method of treatment case, it is a method of preparation case.").

[xxxvii] *Mayo,* 566 U. S. 66.

[xxxviii] *Natural Alternatives,* 918 F.3d 1338.

[xxxix] *Cleveland Clinic,* 859 F.3d 1352.

[xl] *Id.*

[xli] *Genetic Veterinary Sciences v. Laboklin GMBH & KG* , 933 F.3d 1302 (Fed. Cir. 2019).

[xlii] *Rapid Litigation Management Ltd. v. Cellzdirect, Inc.,* 827 F.3d 1042 (Fed. Cir. 2016).

[xliii] *XY, LLC v. Trans Ova Genetics, LC,* 968 F.3d 1323 (Fed. Cir. 2020).

[xliv] United States Constitution, Art. I., S. 8, Cl. 8 (giving Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.")

[xlv] *Chakrabarty*, 447 U.S. at 315; *see also United States v. Dubilier Condenser Corp.,* 289 U.S. 199 (1933) (Courts "should not read into the patent laws limitations and conditions which the legislature has not expressed.").

[xlvi] United States Constitution, Art. I., S. 8, Cl. 8.

[xlvii] *See, e.g.,* US Patent No. 579,412 (1897) (covering pyrazolon); US Patent No. 644,077 (1900) (covering acetyl salicylic acid, a.k.a. "aspirin").

[xlviii] Mark Twain, *A Connecticut Yankee in King Arthur's Court* (Charles L. Webster & Co., 1889).

[xlix] *See, e.g.,* China National Intellectual Property Administration (CNIPA), *Patent Examination Guidelines (2023)* Part II, Chapter 10, § 9.1.2.2 ("[I]f a gene or DNA fragment is first isolated or extracted from nature, its nucleotide sequence is not recorded in the prior art, can be precisely characterized, and has industrial utility, then both the gene

or DNA fragment itself and the methods used to obtain it are subject matter eligible for patent protection."); *EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions*, Article 3(1), 5(2) ("Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature," including "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene . . . even if the structure of that element is identical to that of a natural element."); *Receptor Tyrosine Kinase*, X ZR 141/13 (Bundesgerichtshof 2016) (Upholding isolated DNA claims, even where the claims do not directly specify that the genes were "isolated" or "obtained by a technical process."); Japan Patent Office, *Examination Guidelines for Patent and Utility Model in Japan*, Part III Ch. 1, Section 2.1.2 ("[I]f things in nature such as chemical substances or microorganisms have been isolated artificially from their surroundings, those are creations and considered as a statutory 'invention'.")

[l] *Chakrabarty*, 447 U.S. at 316 (internal citations omitted).

[li] *Id.*