Testimony of Corey Salsberg,
Vice President and Global Head Intellectual Property Affairs for Novartis

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

Subcommittee Hearing on "The State of Patent Eligibility in America, Part III"

June 11, 2019, 2:30 p.m., Dirksen Senate Office Building, Room 226

I. Introduction

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

My name is Corey Salsberg, and I am Vice President, Global Head of IP Affairs for Novartis. On behalf of our company, thank you for the opportunity to testify at today's hearing, and to share our experiences and perspectives on the state of patent eligibility in America. We appreciate the leadership that you and your staffs have demonstrated on this crucial issue of innovation law and policy, and are grateful for the opportunity that you, as well as Representatives Collins, Johnson, and Stivers and their staffs, have provided through the roundtables to share our input as a stakeholder. We believe that, overall, the draft Section 101 reform bill reflects a thoughtful, balanced and elegant solution to a highly complex problem, and goes a long way to restoring the predictability that we need from America's patent laws to make sound and confident investment decisions that enable and advance the development of new medicines and potential cures. While there are some aspects of the bill that may need further refinement, and we are still assessing the proposed amendments to Section 112(f), we support the draft legislation in concept and look forward to continuing to work with the Subcommittee as the process proceeds.

II. Background

By way of personal background, I am an attorney with over 18 years of experience practicing law in the areas of intellectual property (IP) law and policy, and related areas of innovation, access, and trade. I have a JD from Stanford Law School, where I wrote one of the frequently cited works on the law and ethics of cloning endangered and extinct species, and a B.A. in American Studies from Yale University. Prior to joining Novartis in 2010, I was a litigator in private practice with the law firms of McDermott, Will & Emery and Morrison & Foerster, among others. In addition to my role at Novartis, I currently serve on the Board of Directors of the not-for-profit legal aid society California Lawyers for the Arts. I am also one of the developers of the Patent Information Initiative for Medicines (Pat-INFORMED), a voluntary global online database of patent information now co-sponsored and hosted by the World Intellectual Property Organization (WIPO) and the International Federation of Pharmaceutical Manufacturers (IFPMA), and am a founder and member of the Steering Committee of the international Inventors Assistance Program (IAP), a joint initiative of WIPO and the World Economic Forum that provides pro bono legal services to under-resourced inventors in developing countries.

Today, as noted, I am here to speak on behalf of Novartis. Novartis is a science-based healthcare company whose mission is to reimagine medicine to improve and extend people's lives. Our products, which include innovative medicines, cell and gene therapies, radiopharmaceuticals, as well as high-quality generics and biosimilars, reach over 800 million patients around the world every year, treating diseases that range from cancer, to heart failure, to multiple sclerosis and psoriasis, to retinal disorders, rare genetic diseases, malaria and many more.[i] We operate in over 140 countries, and our medicines are available in 155, but the United States plays an outsized role in our work. America is home to the global headquarters of our Novartis Institutes for BioMedical Research (NIBR), what we call our "innovation engine." Between NIBR's drug discovery efforts, and the other research and development (R&D) that we do at our other major sites across the

country, we invest nearly 40% of our annual $9 billion global R&D spend here in America, employing roughly 14,000 American workers, including at our newest facilities for developing and manufacturing our cutting-edge cell and gene therapies.

Speaking of cutting-edge, as a research-driven organization with a focus on patients, we continuously push the boundaries of modern medicine, using the latest science and advanced technologies to invent and develop new therapies that are transforming the practice of medicine. Some of our recent milestones include the approval in 2017 of the world's first chimeric antigen receptor T-cell (CAR-T) therapy,[ii] [iii] a personalized one-time treatment for certain forms of leukemia and lymphoma that uses a patient's own T-cells to fight cancer, as well as the approval last month of the world's first gene therapy to treat children with spinal muscular atrophy (SMA), a leading genetic cause of infant mortality.[iv] We are also at the forefront of the fast-emerging field of digital medicine, working both in-house and with a variety of cross-sector partners to put the power of software and artificial intelligence to use to facilitate drug discovery, improve the efficiency of clinical trials, bring clinical trials into the home, and enhance patient treatment in various ways. This includes another "world's first," our launch last year through our Sandoz division of the first FDA-authorized "prescription digital therapeutics," software applications that act as virtual "medicine" for use in treating substance abuse disorder. With *fifteen* novel molecules approved in 2015-2018, *ten* FDA breakthrough therapy designations in the last two years alone, over 200 projects in clinical development, and the types of transformational therapies that I've just described, our record speaks to the real-world impact that innovative biopharmaceutical R&D is having on patients, medicine, and human progress.

This record, however, is built on more than just science, hard work, and a focus on patients. The true story of biopharmaceutical innovation is the story of risk-taking, investment, a willingness to fail, and a practical means to keep it all going at a scope and scale that can keep yielding results. The patent system has successfully provided that means since the earliest days of modern medicine, and continues to do so today. With an average development timeline of 10-15 years per medicine, and a success rate of less than 12% even *years* into the process when clinical trials begin, [v] patents, simply put, are what enable us to finance our failures with our few successes, and to convert the daunting scientific odds we face into a viable and sustainable business model. On account of the patent system, last year alone, we invested $9.1 billion dollars—17% of our global net sales—in R&D, a figure which places us among the top 15 R&D investors in any industry.[vi]

III. The troubling state of patent eligibility in America

Section 101 is the gateway to the patent system. In practical terms, it serves as a guide as to which technologies can support sustained investment, and which likely cannot. That is why we have such deep concerns about the current state of eligibility law. In the aftermath of *Mayo v. Prometheus,* 132 S. Ct. 1289 (2012), *Ass'n for Molecular Pathology v. Myriad Genetics,* 133 S. Ct. 2107 (2013), and *Alice v. CLS Bank,* 134 S. Ct. 2347 (2014), the narrowing of Section 101 in the United States has put the system that drives our innovation engine in substantial jeopardy, a threat that now continues to expand. This is particularly true for the emerging and converging technological areas that hold the greatest promise for the future of medicine. Other witnesses in these hearings have described the patent eligibility status quo as "uncertain," "unpredictable," and

"a mess." We agree with each of these descriptions, but would like to provide the Subcommittee with a sense of what it is really like to navigate this landscape, and what it means in terms of real-world impact on innovation and R&D investment.

In our experience as an innovative biopharmaceutical company, we see three major problems with the current law. First, "laws of nature," "natural phenomena" and "abstract ideas"—once constrained to the types of universal constants that almost everyone agrees should not be patent-eligible (e.g. "a new mineral discovered in the earth," "a new plant found in the wild," "E=mc2," and "the law of gravity"[vii])—have become so untethered from their sensible origins that we no longer know what they mean. To provide some recent examples from our portfolio:

- Our patent claims to a new *digital microscope* for use in ophthalmic surgery were found ineligible for patenting on the basis that a physical "primary lens" coupled with "an image sensor" is an "abstract idea."

- Our patent claims to a specific "laser device" system "applied to" a human "tissue region" in surgery, coupled with a "control computer" to calculate tissue gas levels and adjust the lasers as needed, were rejected as an "abstract idea."

- Our patent claims to a novel "pharmaceutical composition" to treat osteoarthritis, made up of a modified protein that does *not* exist in nature, was found to be an ineligible "natural phenomenon," despite the fact that the sequence was different from that of any natural protein, and that the desired medical effect was present only in our modified product.

While, to secure a patent, inventions like these are rightly subject to meeting the requirements of Sections 102, 103 and 112, it is hard to fathom how they can fail to constitute the types of "process[es], machine[s], manufacture[s]," and "composition[s] of matter" that our system has incentivized since 1790.

Second, the vagueness of the Supreme Court's eligibility framework, and its lack of guidance as to how to apply it, has made it exceedingly difficult for us to predict whether even today's innovations are patent-eligible. While we have certain guideposts—such as *Mayo*'s holding that most diagnostics are out, while claims to "methods of treatment" are in,[viii] and *Myriad*'s holding that genes are out, while cDNAs are in—there are wide gaps between these holdings, and little guidance as to where the line between them lies. As a poignant example, under Section 101 we have lost several cancer-related "method of treatment" claims that involve first checking to ensure that the patient has a specific genetic mutation before administering the novel drug that targets that mutation. These types of claims reflect important innovations that in practice help to **improve health outcomes *and* save healthcare costs** by ensuring that patients get the right drug tailored to their disease. Yet, they are the very types of inventions that the current law threatens, and will continue to disincentivize without reforms.

The third and perhaps most concerning problem is what we call "ineligibility creep," brought about, in addition to all of the above, by an eligibility standard that is inextricably linked to the "inventiveness" of the claim compared to the prior art. Exacerbated by a lower court approach to

eligibility that refuses to consider a claim "as a whole" (as even the Supreme Court instructs a court to do),[ix] and that instead looks only at elements that are "new," the current law virtually ensures that the scope of the "judicial exceptions" will continue to expand as the state of the art develops. As an example, the Supreme Court was careful in *Myriad* to state that "we merely hold that genes and the information they encode are not patent eligible under §101 . . . ."[x] Yet, six years on, we face regular rejections on everything from medically promising isolated and purified proteins, to important biomarkers, primers, and vectors.

IV. The state of eligibility law and the future

The potential consequences of this trajectory are alarming. Returning to the future that we are already building, four major trends define our approach to innovation:

- First, as our ability to work with biology develops, we are moving away from traditional "small molecule" medicines and further into replicating, improving and modifying biology-based materials (e.g. biologics).

- Second, medicine is becoming increasingly "personalized," as we continue to discover the genetic basis for disease and how it varies from individual to individual.

- Third, we are moving away from "pills" altogether, and into complex therapeutic processes that harness the power of our own bodies to target and fix the basis for disease. Examples include CAR-T therapies that re-engineer the body's own immune system to fight cancer, gene therapies that replace and restore normal gene function, and gene editing to repair genes through "molecular scissors" like CRISPR.

- Fourth, we are increasingly relying on software, digital tools, artificial intelligence (AI), and AI-trained models, not just to make all aspects of our R&D process more efficient, but also as complements to our medicines and therapies, and sometimes even as the "medicine" itself, as with our previously mentioned work in "digital prescription therapeutics."

Considering where the stresses on the system are today—laws of nature, nature-based products, and "abstract ideas" like algorithms and software—and the way that these exceptions are evolving, we are deeply concerned that eligibility law is on a collision course with the future of medicine.

As we charge ahead with our mission and work in these earliest days of these nascent technologies, we need to make investment decisions today for medicines and therapies that may not be developed and launched for perhaps another ten or more years. We are making those investments, as our record shows, and we know we have the expertise and science to get us there. We are not certain, however, that we will have a patent system that is fit for purpose.

V. The draft legislation

As I said at the start of my testimony, while some additional refinement may be needed, we believe that, on the whole, the draft legislation represents a thoughtful, balanced and elegant solution to the current eligibility crisis. In particular, we applaud the bill's overall approach of defining

eligible subject matter with sufficient scope to encompass a broad array of present and future innovations, while preserving the existing statutory categories that have been in place since 1790. This approach avoids the pitfalls of enumerating new exceptions that, in our common law system, would be subject to future judicial interpretation and potential expansion.

We also support the bill's deletion of the "new" requirement in Section 101, which has no place in a general eligibility standard that is intended to define *categories* of eligible inventions. Under today's patent laws, novelty and non-obviousness are more appropriately addressed at the level of the individual invention in Sections 102 and 103.

We also support the maintenance of the "useful" requirement, as well as the general approach of new Section 100(k), which endeavors to define "useful" in a logical, balanced, and technology-neutral way that separates the fruits of human ingenuity from what exists independently in nature or the universe. While we share the view of others that the terms "specific and practical utility," "technology," and "human intervention" may need some additional work to ensure that they clearly reflect the boundaries that we believe the bill intends, we believe this can be worked out through additional engagement with stakeholders. As one suggestion, it may be useful for Congress to seek and ultimately provide some examples in the legislative history to better document the bill's intent. Relevant to this, we note that one of the Guiding Principles of the roundtable was to ensure that diagnostics and life sciences inventions be made eligible *per se*.[xi]

We further support the new statutory requirement (proposed Section 101(b)) that eligibility be determined "only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation." This simple and logical requirement, which codifies the proper reading of *Diamond v. Diehr,* 450 U.S. 175 (1981), will go a long way to addressing the current crisis by restoring the ability to secure patents on novel *applications* of known techniques to new discoveries, which is the hallmark of many forms of innovation.[xii]

With regard to new Section 112(f), we understand that this provision is primarily intended as a mechanism to address concerns over vague and broad patent claims, such as those that merely seek to implement abstract ideas on a computer. We are still evaluating the potential implications of this new section for life sciences inventions, such as novel antibodies, and look forward to providing additional input as we complete our analysis.

We also support each of the "additional legislative provisions." Construing Section 101 in favor of eligibility advances certainty and predictability, while still subjecting all inventions to the further patentability requirements of Sections 102, 103 and 112. Abrogating the existing judicial exceptions and the prior case law interpreting them ensures that the uncertainty created by the current jurisprudence is resolved, while rightly restoring the Constitutional power to determine innovation policy to Congress. Last, excising considerations of novelty, inventiveness and the "state of the art" from eligibility law further addresses the "ineligibility creep" that underlies much of today's unpredictability, a goal which we fully support.

VI. Patents on genes in the body

Finally, with respect to the concerns raised by some that the draft bill would enable the patenting of genes in the body, other laws and products of nature, basic mental processes, or "the facts of life," we respectfully disagree. The "technology," "utility," and "human intervention" requirements of new Section 100(k) would, as we read the provision, firmly foreclose this possibility. Furthermore, where gene sequences are already known, as is the case for the human genome (which was fully sequenced by 2003), [xiii] Sections 102 and 103 would also preclude any such claims.

Novartis, in any event, does not and has never supported the patenting of genes as they exist in the body or in nature. In contrast, useful *applications* of genes and gene-based *technologies* that result from isolating, modifying, replicating, or enhancing genes and other natural products compared to their natural state are the foundation of the future of medicine, and require incentives to enable that future.

With regard to concerns over the potential impact of patents on genes on non-commercial research, we would welcome a discussion around the development of a balanced "research use exemption."

VII. Conclusion

Once again, we thank the Chairman, the Ranking Member, the Subcommittee, Representatives Collins, Johnson, Stivers and all of your staffs for your collective leadership on this important issue. We welcome any questions and look forward to continuing to work with the Subcommittee on this matter as the process moves forward.

---

[i] Our complete list of focus areas and medicines is available at https://www.novartis.com/our-focus.
[ii] *See* https://www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriahtm-ctl019
[iii] https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states
[iv] https://www.fda.gov/news-events/press-announcements/fda-approves-innovative-gene-therapy-treat-pediatric-patients-spinal-muscular-atrophy-rare-disease
[v] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016;47:20-33
[vi] *See* 2018 Industrial R&D Investment Scoreboard (http://iri.jrc.ec.europa.eu/scoreboard18.html).
[vii] *Diamond v. Chakrabarty*, 447 U.S. 303 at 309 (1980).
[viii] See *Mayo*, 132 S. Ct. at 1302 ("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."); *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018) (confirming that methods of treatment are eligible).
[ix] *Diamond v. Diehr,* 450 U.S. 175, 188 (1981). For an in-depth discussion of our views on this issue, please see our amicus curiae brief to the United States Supreme Court in *Sequenom v. Ariosa*, attached as Appendix 1.
[x] *Myriad,* 133 S. Ct at 2119-2120.
[xi] See March 26, 2019 Guiding Principles for Section 101 Reform ("3. Diagnostic and life science technologies should be eligible for patent protection *per se*, subject to meeting the other existing statutory requirements . . . .")
[xii] See *Ariosa Diagnostics v. Sequenom,* 788 F.3d 1371 (Fed. Cir. 2015), for example, where the Court's failure to properly apply *Diehr* led to the invalidation of patents on an invention that the Court acknowledged was "a significant human contribution . . .[that] combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care."
[xiii] National Human Genome Institute (https://www.genome.gov/human-genome-project/What)

Appendix 1

No. 15-1182

IN THE

Supreme Court of the United States

SEQUENOM, INC,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF NOVARTIS AG AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

COREY A. SALSBERG*
Counsel of Record
NOVARTIS INTERNATIONAL AG
Novartis Campus
CH-4002 Basel
Switzerland
+41 61 324-4320
corey.salsberg@novartis.com

Counsel for Amicus Curiae

**Admitted in California, Massachusetts and to this Court*

April 20, 2016

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page(s)

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

IN THE

Supreme Court of the United States

No. 15-1182

SEQUENOM, INC,
Petitioner,
v.
ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF NOVARTIS AG AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*[1]

Novartis is a science-based global healthcare company whose mission is to discover new ways to extend and improve patients' lives. Our products, which include innovative medicines, eye-care, high-quality generic medicines and biosimilars, reach almost a billion patients around the world each year,

[1] This brief is filed with the written consent of all parties through letters of consent on file with the Clerk. No counsel for any party authored this brief in whole or in part, and no person or entity other than *amicus curiae* or its counsel made a monetary contribution intended to fund its preparation or submission.

treating diseases that range from cancer, to heart failure, to diabetes, psoriasis, macular degeneration, malaria, and many more. Many of our products embody cutting edge breakthroughs in medical innovation that have literally transformed the treatment of disease. *See, e.g.*, Leslie A. Pray*, Gleevec: The Breakthrough in Cancer Treatment,* Nature Education 1(1):37 (2008); Ariana Cha, *New 'Once-in-a-Decade' Novartis Drug for Heart Failure Approved by FDA***,** Washington Post (July 8, 2015). With 6 "novel compound" approvals in 2015, 5 FDA breakthrough therapy designations over the last few years, and over 80% of our current compounds in development discovered internally, our record is a testament to the real-world impact that innovative research and development (R&D) can have on patients and "the Progress of Science and the useful Arts," U.S. Const. art. I, § 8.

This record, however, is built upon more than just hard work, science, and a focus on patients. It owes its existence as well to the massive investments that we make each year in cutting edge R&D. We are in fact one of the world's top investors in innovation, committing more of our resources to R&D than any other healthcare company—$8.9 billion in 2015 alone—a figure which places us 5th in the world across all companies in all industries. *See* European Commission, *2015 EU Industrial R&D Investment Scoreboard* at 43-44, http://iri.jrc.ec.europa.eu/scoreboard15.html.

We choose to invest so heavily in R&D because the future of medicine depends on it. It is indeed no exaggeration to say that none of our medicines would exist today without the investments that enabled their invention and development, investments which in

turn are only made possible by the incentives of the intellectual property system. That is because the costs of the work that we do are so vast, and the risks and failure rates are so high,[2] that the innovation cycle simply could not run without the fuel that patents provide.

As a global company with operations in over 140 countries, we of course approach the patent system with a global mindset. The United States, however, is crucial to our business. This is so not only because it represents one of our largest markets, but because we maintain major research sites in strategic locations across the country. This includes Cambridge, Massachusetts, where our Novartis Institutes for Biomedical Research (NIBR) are headquartered; East Hanover, New Jersey, where pharmaceutical development takes place; Fort Worth, Texas, where we invent and develop innovative eye care treatments; and La Jolla, California, where our Genomics Institute of the Novartis Research Foundation (GNF) develops novel technologies to drive cutting-edge drug discovery research, identify new biological pathways and discover the mechanisms underlying human disease. Without question, the strength of the United States patent system is one of the key factors that drives our strategic decisions to conduct these important activities here.

With the future of our business and the health of billions dependent on the continued strength of that system, we have a profound interest in preserving its

---

[2] For instance, only 12 percent of drugs entering clinical trials ever become a marketed medicine, and thousands of compounds never progress beyond the early discovery and pre-clinical testing stages. *See* PhRMA, Medicines: Cost in Context (http://www.phrma.org/cost#innovation).

integrity and in ensuring that the direction it takes continues to enable the work that we do. Concomitant with this comes a deep responsibility to intervene when we see things moving in the wrong direction. We have done this before through amicus briefing, extensive public comment, and regular participation in public dialogues around subject matter eligibility issues like (and including) the ones in this case. But when the Judges of the Federal Circuit themselves sound the alarm, declaring, as Judge Lourie did here, "a crisis of patent law and medical innovation," *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 809 F.3d 1282, 1285 (Fed. Cir. 2015) ("*Ariosa II*") (Lourie, J., concurring), our responsibility to act takes on new urgency. With that background, we add our voice here to the chorus of others in urging this Court to review this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

Mark Twain described "a country without . . . good patent laws" as "just a crab" that "c[annot] travel any way but sideways or backwards." Mark Twain, *A Connecticut Yankee in King Arthur's Court,* 107 (Charles L. Webster & Co., 1889). But a country without patent laws whose scope is understood, or whose *future* scope can be reasonably predicted, is every bit as crippled. That, unfortunately, is the situation in the United States today after the Federal Circuit's decision below—and that, in turn, is why this Court should take this case.

In the aftermath of this Court's recent patent-eligibility trilogy—*Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics,* 133 S. Ct. 2107 (2013); and *Alice v. CLS Bank Int'l*, 134 S. Ct.

2347 (2014)—the United States has a Patent Office that, after at least four attempts to guide examiners and applicants, still finds the administration of a uniform *Mayo* framework "difficult to reconcile with the judicial precedent" that sets forth a variety of other tests that do not fit neatly into it. USPTO, *July 2015 Update: Subject Matter Eligibility* at 2 (July 1, 2015) (http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf). It has a specialized appellate Court—arguably the most experienced and respected in the world—that, despite a trail of breadcrumbs from this Court (e.g. *Diamond v. Diehr*, 450 U.S. 175 (1981), *Mayo*'s cautions, and *Myriad*'s "important" caveats, 133 S. Ct. at 2119-2120), plainly feels it lacks the tools, direction, or authority to trailblaze through this Court's admittedly nuanced precedents in a way that soundly reconciles patent law and policy. *See e.g. Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371, 1381 (Fed. Cir. 2015) ("*Ariosa I*") (Linn, J., concurring); *Ariosa II,* 809 F.3d at 1288 (Dyk, J., concurring) ("[A]ny further guidance must come from the Supreme Court, not this court."). And now, added to the underlying struggles of these institutions, the country has a reluctant, but sweeping, new precedent that—accompanied by a set of concurrences and dissents that simply oozes with frustration—definitively extends *Mayo* well beyond the "particular claims" that drove its holding, into new areas of traditionally eligible subject matter whose boundaries are now anyone's guess. *Mayo,* 132 S. Ct at 1289.

But it gets worse. The interpretation of *Mayo* that the Federal Circuit felt compelled to cement in this case *cannot* really ever know any bounds, because it gives rise to a new eligibility standard that ensures that the judicial exceptions expand, and that the scope of eligible subject matter shrinks, as the field of art

progresses. That is indeed the alarming consequence of a test that removes all natural phenomena from a patent claim and searches only among the remaining pieces for the presence of an "inventive concept." Such a test, which ignores this Court's guidance to consider "claims . . . as a whole," *Diehr,* 450 U.S. at 188—and which is *not* what this Court prescribed in *Mayo* step 2—leads to more than the troubling result that we see below. To be sure, one consequence of tying eligibility to only "what is left" in an altered claim is that applications of existing knowledge become foreclosed as a matter of law, no matter how inventive they may be in fact. But another consequence, far more unsettling, is that the exclusions now become inextricably linked only to the state of the art, changing and growing *ad infinitum* with it until they threaten to "swallow all of patent law." *Alice*, 134 S. Ct. at 2354.

This is not a state of affairs that inspires confidence in a country's patent laws. Nor, we suspect, is it the result that this Court intended when it set out in its decisions to create a framework that clarifies the boundaries of patent-eligible subject matter. But, intentional or not, the damage that the *Mayo* framework has already inflicted—rendering everything from biomarkers and their uses, to DNA primers, to cloned animals, to methods of genetic analysis ineligible—is alarmingly real, as is the profound sense of uncertainty that led to the decision in this case, and that now will proliferate with the Federal Circuit's creation of a standard that evolves as quickly as technology progresses.

This case presents the right opportunity for this Court to retake the reins of subject matter eligibility law, to avert the "crisis of patent law and medical

innovation" that Judge Lourie lamented is upon is, *Ariosa II,* 809 F.3d at 1285, and to restore the confidence that so many have now lost in the system of incentives that controls the fate of so many critical areas of medicine.

To that end, we begin below by further illuminating some of the lingering uncertainties and incongruous results that this Court's *Mayo* framework has injected into the patent system, which in large part we believe are responsible for the Federal Circuit's frustrated and highly unsettling decision below. We then voice and further explain our serious concerns about the way that the Federal Circuit's interpretation of the "inventive concept" test has created a new standard of eligibility that is sure to lead to more uncertainty, likely in perpetuity. Last, we explain the impact that this uncertainty is already having on innovators like us, and the likely implications that it will have for the future, if allowed to progress along its current trajectory. That future is indeed a dark one for many different fields of cutting edge innovation. But it is a future that need not be, if this Court takes this case and puts the system back on track.

ARGUMENT

I. CLARIFYING THE SCOPE OF PATENT-ELIGIBLE SUBJECT MATTER, THE ISSUE AT THE HEART OF THIS CASE, IS AN ISSUE OF EXCEPTIONAL IMPORTANCE

A. This Court's Subject Matter Eligibility Framework Has Created Profound Uncertainty in the Patent System Which Only This Court Can Resolve

As the field of biopharmaceuticals continues to evolve from chemically-based treatments designed for all, to biologically-based treatments personalized to the patient, few things are more critical to the future of medicine than the innovation that occurs at the intersection of natural phenomena and human ingenuity. Undoubtedly aware of these implications, this Court opted to review a trilogy of cases in recent years (*Mayo*, *Myriad* and *Alice*) to clarify the bounds of what is patent-eligible, and what is not, in this critically important area of patent law and policy.[3] This pursuit of clarity is plain from the Court's selection of cases that, in its view, reflect subject matter that approaches those bounds. It is plain as well from the Court's careful efforts to limit its holdings to "the particular claims before us," *Mayo*, 132 S. Ct. at 1294, to emphasize the dangers inherent in "too broad an interpretation," *id.* at 1293, and to provide extensive, and at times quite specific,

[3] While *Alice* concerned software and abstract ideas, its pronouncement that the *Mayo* framework apparently applies to all of the judicial exceptions has obvious implications for natural phenomena.

guidance as to the types of subject matter for which the doors to the patent system *must* remain open. *See id.* at 1302 ("a new way of using an existing drug" is patent-eligible); *Myriad,* 133 S. Ct at 2119-2120 (Emphasizing that "we merely hold that [isolated] genes and the information they encode are not patent eligible under §101" and addressing the "important" topic of "what is not implicated by this decision.").

Unfortunately, despite these attempts at guidance, the Court's decisions in these cases have had the opposite effect. Far from clarifying the bounds of what is patent-eligible from what is not, or setting forth a workable "framework for distinguishing" the same, *Alice,* 134 S. Ct. at 2355, the Court's decisions have sent a shockwave of uncertainty through the patent system that has left its principal stewards (the Patent Office and the lower courts) unable to reconcile one decision with the next, and paralyzed to exercise the critical restraint that this Court was so careful in each case to prescribe. Meanwhile, as we discuss further below, users of the system like us are left scratching our heads as to what remains patent-eligible today, let alone what will *still* be eligible by the time today's investments in R&D translate into tomorrow's medicines and other healthcare innovations.

This uncertainty comes from a variety of sources, but can be traced at least in part to a palpable disconnect between this Court's apparent pronouncement of a universal framework in *Alice*, and the analysis undertaken in *Myriad* and earlier decisions, which did not apply the tests included in that framework (e.g. searching for an "inventive concept" as set out in *Mayo* step two), but instead recognized a variety of different tests that do not appear to neatly fit anywhere into it (e.g.

Chakrabarty's "markedly different characteristics" analysis, which this Court in *Myriad* deemed "central", *Myriad*, 133 S. Ct at 2116, and the "enlarged range of utility" and "distinctive name, character or use" tests set forth in earlier decisions. *See, e.g., Diamond v. Chakrabarty,* 447 U.S. 303, 309-310 (1980); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) *Hartranft v. Wiegmann,* 121 U.S. 609, 615 (1887).) The uncertainty appears to come too from a perceived lack of clarity in this Court's decisions as to how to reconcile what some see as "the sweeping language" of *Mayo, Ariosa I,* 788 F.3d at 1380, with the Court's caveats and cautions to interpret these decisions narrowly. *See e.g. Mayo* 132 S. Ct. at 1293-94; *Myriad,* 133 S. Ct at 2119-2120.

The struggles of the Patent Office are illustrative here. Since the Court's decision in *Mayo*, the Patent Office has engaged in at least four attempts to craft practical guidance in this area to help its examiners navigate this Court's decisions. But uncertainty has plagued this process from the start. With the *Myriad* decision, the Office initially followed this Court's guidance and advised its examiners to apply the case narrowly and to deny eligibility only to patents claiming isolated DNA. USPTO, *Memo to Patent Examining Corps Re: Supreme Court Decision in Myriad,* June 13, 2013 (http://www.uspto.gov/sites/default/files/patents/law/exam/myriad_20130613.pdf). Notably, although *Mayo* had issued over a year earlier, the Office at that point (correctly, in our view) did not read *Myriad* as containing any guidance or instruction to apply the *Mayo* framework to product claims or to those involving natural phenomena.

Nine months later, the Office changed course in an apparent effort to reconcile *Mayo* with *Myriad*. Lacking any guidance from this Court as to how to achieve this, the Office initially merged the "significantly more"/"inventive concept" test (step two of *Mayo*) into the "markedly different characteristics" approach of *Myriad*, creating its own new hybrid framework that hinged eligibility on the presence of something "significantly different" from judicially excepted subject matter. USPTO, *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* (March 4, 2014) (http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf). After a wave of controversy and concern from a variety of stakeholders (including us), the Patent Office acknowledged the flaws in this approach and sought the help of the public in fashioning a usable framework that more faithfully reflected the various holdings of this Court's patent eligibility decisions.

This, however, was easier said than done; for after the issuance of the Office's hybrid guidance, this Court issued its decision in *Alice*, which for the first time suggested (in dicta) that the *Mayo*-based framework may in fact govern natural phenomena, but again without explaining how or where in the framework tests like *Myriad's* "markedly different characteristics" might fit. *See Alice*, 134 S. Ct. at 2355. Faced with this continuing uncertainty, the Patent Office did what is perhaps the best it can do to give effect to this Court's cases, issuing revised guidance that attempts to fit the "markedly different characteristics" analysis into the *first* step of the *Mayo* test (whether the claim is directed to a judicial exception) as a "way out" of step two for nature-based

products, coupled with a "streamlined" side approach that remains largely a mystery (but that in theory may enable some of this Court's other eligibility tests). *See* USPTO, *2014 Interim Guidance on Patent Subject Matter Eligibility,* 79 Fed. Reg. 74618, 74621-22, 74625 (December 16, 2014) (https://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf). Defending this complex "workaround" model in its most recent guidance, the Office explained that it must leave the "markedly different characteristics" test where it is in *Mayo* step one, because placing it in step two as an expression of *Mayo*'s "inventive concept"/"something more" test would be "difficult to reconcile with the judicial precedent." USPTO, *July 2015 Update* at 2. Here, the Office may well be correct. But like the complex pre-Copernican geocentric models of the universe, all of which turned out to be wrong, we suspect that a simpler reality exists that, unfortunately at this stage, is only known to this Court.

The lower courts have meanwhile equally struggled to piece together the many mysteries of this Court's decisions. Just last week (April 11, 2016), Judge Gilstrap of the Eastern District of Texas remarked of this Court's *Alice* decision that "it's a challenge to interpret the [C]ourt's analysis and apply it faithfully." *See* Ryan Davis, "Gilstrap, Stark Say Alice, AIA 'Sea Change' Means More Work," Law360, April 11 2016 (http://www.law360.com/articles/783102/gilstrap-stark-say-alice-aia-sea-change-means-more-work). For its part, even before the unsettling decision in this case, the Federal Circuit, like the Patent Office, has struggled to reconcile *Mayo* and *Alice* with the different approach and implications of *Myriad*. In *Roslin Institute*, for example, the Federal Circuit applied a straight *Myriad* analysis to patents

claiming live-born clones. *In re Roslin Inst.,* 750 F.3d 1333, 1337 (Fed. Cir. 2014). The Court made no mention of *Mayo's* two-step framework, indicating that it sees a clear distinction between method claims and product claims and the respective tests that apply, a distinction in tension with the Patent Office's universal approach, and with this Court's allusion to a single framework in *Alice*.

If the Federal Circuit is correct about this distinction (which it may well be, *Alice* notwithstanding), a profound disconnect still exists between what this Court suggests should be eligible in *Myriad*, and the interpretation of *Mayo* that the Federal Circuit felt compelled to apply to the method claims in this case. Judge Dyk in fact discussed this frustrating result in his concurring opinion denying en banc review, observing that "*Mayo* may not be entirely consistent with the Supreme Court's decision in *Myriad*." *Ariosa II,* 809 F.3d at 1289-1290. Judge Dyk was referring to *Myriad*'s guidance that, for example, "new applications of knowledge about [naturally occurring] genes" are patent-eligible under a *Myriad* framework, but now appear not to be under the reading of *Mayo* now enshrined in the decision in this case. *Id.* (quoting *Myriad*, 133 S. Ct. at 2112-13).

And indeed, with this decision, the Federal Circuit now also injects a panoply of other inconsistencies and uncertainties into patent-eligibility law, many of which the Judges acknowledge, but apparently feel compelled to ordain stuck amidst conflicting signals from this Court. Judge Linn, for example, suggests that the "sweeping" and "unnecessary" breadth that most of the Federal Circuit perceives in *Mayo* now makes it "unclear how a claim to new uses for existing drugs would survive," despite *Mayo*'s express

suggestion to the contrary. *Ariosa I*, 788 F.3d at 1380-81 (Linn, J. concurring) (citing Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343–44 (2013)); *cf. Mayo,* 132 S. Ct. at 1302 ("a new way of using an existing drug" is patent-eligible). He further sees a clear inconsistency between *Mayo*'s supposedly "sweeping language" and "policy [and] statute," both of which in his view should have enabled the eligibility of the "breakthrough invention" in this case. *Ariosa I,* 788 F.3d at 1381. Judge Dyk, for his part, shared these sentiments when denying en banc review, lamenting that "[w]e cannot confine *Mayo* to its facts," *Ariosa II,* 809 F.3d at 1288, despite this Court's indication in *Mayo* that "our conclusion rests upon an examination of the particular claims before us… ." *Mayo*, 132 S. Ct. at 1294; *see also Myriad,* 133 S. Ct at 2119-2120. Concerned, however, for what this breadth may mean for the future of "new diagnostic and therapeutic methods in the life sciences," he suggested that "some further illumination as to the scope of *Mayo* would be beneficial," but that it "must come from the Supreme Court." *Ariosa II,* 809 F.3d at 1288.

Underscoring this need for illumination, Judge Newman, meanwhile, saw *Mayo* quite differently, dissenting on the grounds that since "[t]he facts of this case diverge significantly" from *Mayo* and *Myriad*, she could "not share [the] . . . view that this incorrect decision is required by Supreme Court precedent." *Ariosa II,* 809 F.3d at 1293-94 (Newman, J., dissenting). She invoked the above-mentioned caveats, observing that "[p]recedent does not require that all discoveries of natural phenomena or their application

in new ways or for new uses are ineligible for patenting; the Court has cautioned against such generalizations." *Id.* at 1294.

Taken together, what the above indicates is a state of lingering uncertainty that neither the Patent Office nor the lower courts are able to resolve. The Office's guidance remains frustratingly unclear, *Mayo* and *Myriad* continue in conflict, and the Federal Circuit, by its own admission, cannot really reconcile its decision in this case with the caveats and examples in this Court's precedents that suggest that this Court must have meant something different. Meanwhile, innovators like us can only continue to guess what falls in and outside the scope of the patent system. Such a poor understanding of what is eligible for the incentive designed to "promote the Progress of Science and the useful Arts," U.S. Const. art. I, § 8, cannot be what this Court intended. As Judge Dyk suggested, this poor understanding in such a critical area is reason enough for this Court's review.

B. The Federal Circuit's Interpretation of the "Inventive Concept" Test is Inherently Unpredictable and Could Eviscerate Patent Law

The Federal Circuit's interpretation of *Mayo*'s "inventive concept" test (step two) in this case creates an independent need for this Court's urgent review. For, if the decision below represents the "perhaps unintended" consequence of a precedent already taken too far, *Ariosa I,* 788 F.3d at 1380 (Linn, J. concurring), the Federal Circuit's interpretation threatens to take it much further, at rates and in directions that cannot be predicted. That, unfortunately, is a logical consequence of an eligibility

test that, according to the Federal Circuit, defines natural phenomena not as the constants that they are in nature—the subject matter that the judicial exceptions were designed to address—but as an ever-advancing set of variables that continuously evolves with the state of the art. If this interpretation, which is contrary to this Court's decision in *Diehr*, is permitted to stand, it means that the scope of the judicial exceptions will continue to grow, and the scope of patent-eligible subject matter will continue to shrink, until perhaps nothing remains of the patent system.

This expanding nature of the judicial exceptions originates with the Federal Circuit's rejection in this case of the "claims as a whole" analysis set forth in *Diehr*. In *Diehr*, this Court made clear that in assessing whether patent claims contain enough to distinguish themselves from what exists in nature (what *Mayo* calls an "inventive concept"), they must not only be mechanically analyzed for "additional elements" beyond the natural phenomenon, but "must [also] be considered as a whole," with the natural phenomen left intact. *Diehr*, 450 U.S. at 188:

> [It is argued that] if everything other than the [patent-ineligible concept] is determined to be old in the art, then the claim cannot recite statutory subject matter. The fallacy in this argument is that we did not hold in *Flook* that the [patent-ineligible concept] could not be considered at all when making the §101 determination. To accept [that] analysis . . . would, if carried to its extreme, make all inventions unpatentable … .

Id. at 189, n12. In *Mayo*, this Court reaffirmed *Diehr*, calling it a "controlling precedent" and a case "most

directly on point." *Mayo,* 132 S. Ct. at 1298. Despite this, in searching for an "inventive concept" in this case, the Federal Circuit completely excised the natural phenomenon (cffDNA and its presence in maternal blood) from the claims at issue, determining eligibility only on the basis of the novelty of what remained when it was taken out. Oddly, the panel majority did not mention *Diehr*, let alone apply it, a decision that, we agree with Petitioners, was a fundamental error.

But the Federal Circuit's misstep here amounts to far more than a mere misapplication of precedent. In failing to recognize *Diehr*'s continuing pertinence, the Federal Circuit effectively abrogated the decision, creating its own precedent under which patent-eligibility will now be determined only by tearing the claims apart, removing all natural phenomena, and assessing what is left. That, of course, means that the application of known techniques to new scientific discoveries can never be patent-eligible, no matter how novel, inventive or even "revolution[ary]" they may be—a result made clear in the decision below. *Ariosa I*, 788 F.3d at 1379. But it also means that the eligibility bar—which is now based *only* on what is novel to the field, divorced from any inventive context that the natural phenomenon provides—will continue to move higher and higher with every advance in the art.

In effect, what the Federal Circuit has done in this case is unleashed a parasite that will feed on the field of art, adding every technological advance to itself as it slowly consumes the scope of eligible subject matter. Left unchecked, this noxious standard will continue to grow until the exclusions far outweigh the host, achieving the very "eviscerat[ion] [of] patent law" that

this Court has repeatedly feared. *Mayo,* 132 S. Ct. at 1293. This Court itself concluded as much when considering a similar approach under Sections 102 and 103. *See id.* at 1304 ("[S]tudiously ignoring all laws of nature when evaluating a patent application under §§ 102 and 103 would 'make all inventions unpatentable … .'") (quoting *Diehr*, 450 U.S. at 189, n. 12). In the meantime, the path that this destructive agent takes through the patent system can never be predicted with any certainty, leaving the scope of eligible subject matter forever in doubt.

Such a standard is not only legally wrong and toxic to the patent system—it is also wholly unnecessary to serve the purpose for which the judicial exceptions were designed. For, while there may be disagreement as to whether 35 U.S.C. § 101 or the judicial exceptions are necessary at all, *see e.g., Mayo,* 132 S. Ct at 1303-4, certainly these vehicles at best are meant to guard against the patenting of what exists in nature. It is only those things, after all, that arguably are not within the reach of subsequent provisions of the patent laws, and therefore only those things that Section 101 should address. *See id.* ("§§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections.") To be clear, this is not to say that claims directed to natural phenomena should escape the reach of Section 101 whenever they are written to appear to contain more. But if the eligibility approach involves reading the natural phenomenon entirely *out of the claim*, as the Federal Circuit has held here, Section 101 and the judicial exceptions are plainly *not* necessary to assess what is left. That, after all, can be done handily under Sections 102 and 103.

C. Certainty is Critical to Biopharmaceutical Innovation and to the Progress of Science and the Useful Arts

For the reasons discussed, this case has implications that extend far beyond the field of cffDNA testing, and far beyond the field of medical diagnostics. As Judge Lourie expressed in his concurring opinion, "It is . . . said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern." *Ariosa II*, 809 F.3d at 1285. There is indeed more than some truth in that concern, in part because of the damage that the *Mayo* framework as interpreted has already done—leading to the ineligibility of everything from biomarkers and their uses, to DNA primers, to cloned animals, to methods of genetic analysis[4]—but more so due to the profound uncertainty that this decision now cements and creates in the law (described in Sections A and B above).

In our field, the uncertainty and risks of biopharmaceutical innovation are high enough without having to worry about whether the incentives that we rely upon to offset those risks will still be there when our efforts yield the next life-saving medicines. Some amount of risk is of course inherent in a system which rightly rewards only inventors that conceive of what has not been done before—an important principle for which Sections 102 and 103 of the Patent Act serve as arbiter. But because that risk impacts incentives only

---

[4] *See,* e.g., *Myriad,* 133 S. Ct. 2107 (2013); *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 774 F.3d 755, 758 (Fed. Cir. 2014); *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333; *Genetic Techs. Ltd. v. Merial L.L.C.,* 2016 U.S. App. LEXIS 6407 (Fed. Cir. Apr. 8, 2016).

on the level of the particular invention, it is one that innovators can usually bear. This case, in contrast, concerns the very entrance to the patent system (section 101), and turns that entrance into a virtual funhouse door, whose size and shape can no longer be predicted with the certainty needed to make the broad investment decisions that determine our future directions of research. Indeed, after the decision below, we can no longer proceed on the assumption that the United States patent system—once the gold standard—will reliably continue to play its Constitutionally-directed incentivizing role.

If things continue on their current trajectory, we see three possibilities for the future of our business and, given the importance of what we and our peer companies do, for the future of medicine. First, companies like ours may be forced to take at least parts of our business elsewhere to jurisdictions with friendlier patent laws. That apparently is the advice already being given by no less than the former Director of the United States Patent Office. *See, e.g.* Ryan Davis, *Kappos Calls For Abolition Of Section 101 Of Patent Act,* Law360 (April 12, 2016) (Reporting that former Director Kappos "said he has begun telling clients that . . . they are better off seeking patents in [e.g. Europe and China], because of the way U.S. courts have interpreted Section 101."). Second, in order to protect our investments in innovation, we may be forced to rely on trade secret protection in areas where patents are, and continue to become, less predictable. That, of course, frustrates the patent system's important public aim of ensuring that the scientific and innovative communities can learn from and build upon the scientific and technical knowledge of others—one of the principle ways of achieving "the Progress of Science and the useful Arts." U.S. Const.

art. I, § 8. Third, and most depressing, we and our peers may be forced to abandon our R&D efforts in certain areas, not because we want to, but because the costs and risks would just become too high without an incentive that enables us to recoup our investment.

Tragically, we fear that the third possibility may eventually become the most probable. This is so because much of the rest of the world still looks to and admires the United States for its guidance in matters of patent policy. Already, we see other developed markets like Australia following and expanding this Court's holdings, at least in areas like isolated genes and cDNA. *See D'Arcy v Myriad Genetics Inc. [2015] HCA 35, S28/2015* (holding ineligible claims to isolated nucleic acids, including cDNA). Given the mounting pressures on biopharmaceutical patents across the world, it may only be a matter of time before courts and legislatures in other jurisdictions follow this Court's lead, or take it further in directions unknown. If that happens, there may eventually be nowhere left for innovation to go.

Trade secrets, too, have severe limitations. In addition to frustrating the sound public policy enshrined in Article I, Section 8, they only work where secrecy is effective to limit competition. As we know from the robust generic pharmaceutical industry and the burgeoning field of biosimilars—businesses for which we ourselves are world leaders in addition to our innovative pharmaceutical division—few if any medicines, whether small or large molecule-based, are beyond the reach of reverse engineering. And we need not speculate as to what happens to investment and R&D when secrecy does not offer adequate protection. As we know from history, inventors and investors will put their limited efforts and resources only into those

limited areas where it does. *See, e.g.,* Petra Moser, *How do Patent Laws Influence Innovation?: Evidence From Nineteenth-Century World's Fairs*, American Economic Review, vol. 95(4), 1214-1236 (September 2005) (https://ideas.repec.org/a/aea/aecrev/v95y2005i4p1214-1236.html and http://www.nber.org/papers w9909) (Analyzing close to 15,000 innovations at the 1851 and 1876 World's Fairs and concluding that inventors in countries without patent laws focused on a small set of industries where secrecy worked, while innovation in countries with patent laws was much more diversified.)

The upshot of it all is that, without some substantial clarification of the scope of eligible subject matter, in a way that makes the *future* scope of eligibility predictable, innovation is highly likely to suffer. And given the breadth that the judicial exceptions have assumed over the last few years—encompassing not only diagnostics, genetics, and personalized medicine, but also software and high-tech applications—and the increasing convergence of these once disparate technologies in the nascent fields of wearable devices and digital medicine, the consequences of inaction will be far-reaching indeed.

II. THE UNCERTAINTY CANNOT BE RESOLVED WITHOUT THIS COURT'S INTERVENTION

The uncertainty described above cannot be addressed by a further evolution of case law in the lower courts, or by the Patent Office, which of course is bound by the decisions of those and this Court. That ship has sailed, and is lost at sea, as Judge Dyk candidly acknowledged below. *See Ariosa II,* 809 F.3d at 1288 ("[A]ny further guidance must come from the Supreme Court, not this court.") While Congress may

perhaps also act by amending or rescinding Section 101 (as some have suggested), since the uncertainty that plagues the scope of subject matter eligibility originates with the *judicial* exceptions, this Court is in the prime position to provide the guidance needed to put the country's patent laws back on track. If it opts to do so here—as we join the Petitioner and other amici in urging it to do—we further urge it to do so guided by Jefferson's philosophy that "ingenuity should receive a liberal encouragement" in order to fulfill the Constitutional directive of "promot[ing] the Progress of Science and the useful Arts." 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871); U.S. Const. art. I, § 8.

CONCLUSION

For the foregoing reasons, the Court should grant the Petition.

Respectfully submitted,

COREY A. SALSBERG*
Counsel of Record
NOVARTIS INTERNATIONAL AG
Novartis Campus
CH-4002 Basel
Switzerland
+41 61 324-4320
corey.salsberg@novartis.com

Counsel for Amicus Curiae

**Admitted in California, Massachusetts and to this Court*

April 20, 2016