NOVARTIS

Responses to Questions for the Record

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United States Senate Committee on the Judiciary
Subcommittee on Intellectual Property

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

I. Introduction

My name is Corey Salsberg, and I am Vice President, Global Head of IP Affairs for Novartis. On June 11, 2019, I testified before the Subcommittee on behalf of our company, sharing some of the ways that today's patent eligibility laws have impacted our current and past innovation efforts, and relaying our concerns over how we believe they will negatively impact the future of medicine absent significant reforms. In my testimony, I also expressed our support for the draft Section 101 reform legislation in concept, while proposing some ways that the legislation may still be further improved.

Following the hearing, on June 18, I received questions for the record from Chairman Tills and Senator Hirono. My responses to these questions are set forth below.

I. QUESTIONS FROM CHAIRMAN TILLS

1. How has the current state of patent eligibility impacted research and development by your company?

As set forth in my principal testimony, the current state of eligibility law has impacted our innovative research and development (R&D) efforts in three major ways. First, the expansion of the judicially-created exceptions ("laws of nature," "natural phenomena" and "abstract ideas") into areas of technology that have always historically been patent-eligible has resulted in the loss of patent claims in several areas of our innovative business. As detailed in my testimony, these include patent claims to a digital microscope, a laser device system, and modified proteins that do not exist in nature. The ability to secure patents on our inventions is one of the critical factors that enables us to sustainably invest in research in a given field. While we rarely make investment decisions on the basis of a single patent, the accumulated loss of patents in a field or project over time significantly undermines our ability to continue to devote substantial resources to that field or project.

Second, the current eligibility framework is so vague and uncertain that it has become exceedingly difficult for us to predict whether inventions of certain types are eligible or not. One important example described in my testimony is the area of "method of treatment" claims, which pertain to the treatment of a patient with a manmade medicine. As I explained, despite clear direction from the Supreme Court and Federal Circuit that these types of claims are eligible and distinguishable from diagnostic methods,[i] we have lost cancer-related "method of treatment" claims that, as part of treatment, involve first checking to ensure that the patient has the specific genetic mutation that the novel drug targets. The implication of these rejections is that "method of treatment" claims are eligible when you administer a drug to all patients, but somehow become ineligible if you selectively administer the same drug to only those patients who are likely to benefit from it. Decisions like these make little sense from a legal or policy perspective. They also create uncertainty and *dis*incentives for companies like ours to invest in diagnostics, personalized medicine, and related fields of technology that have the potential to both improve patient outcomes and lower healthcare costs.

Third, the rapid expansion of the judicial exceptions since *Mayo*, *Myriad* and *Alice Corp.* raises serious concerns with respect to the emerging technologies that we are investing in today to enable the future of medicine. To reiterate what I said on this point in my testimony, we are today in the

earliest stages of a true revolution in medicine, marked by technologies that are increasingly based on biology, genes, the manipulation of our own immune systems, and a wide array of software and digital tools. I provide a more detailed description of our work in these areas in my responses to Questions 2 and 3. For purposes of this question, suffice it to say that the current eligibility framework, which has already denied patent protection to an expanding array of gene and protein-based technologies, diagnostics, cloned animals, other "nature-based" technologies, and software, does not inspire confidence that America's patent system will continue to be able to reliably provide the incentives we need to enable and deliver these nascent technologies.

2. Can you give an example of the types of research into next generation medicines your company is abandoning as a result of the current uncertainty?

Research and development (R&D) investment decisions are complex decisions that involve a variety of different considerations. These include the scientific feasibility and medical promise of the work; the resources, skills and infrastructure needed to conduct it; the nature of preliminary or interim results; the geographies in which the R&D is feasible; the nature of the regulatory system and market environment; and the availability of patents and other forms of intellectual property to enable a sufficient return on investment to move forward. As such, at the present time, we are not able to point to fields of medicine or other technologies that we have specifically decided to abandon as a result of Section 101 uncertainty in the United States.

That said, the certainty and strength of a country's eligibility laws and its broader patent system are critically important factors in our decisions regarding where to conduct our R&D, where to invest in building innovation infrastructure, and where to prioritize launches of our newest medicines. The systemic uncertainty surrounding patent-eligibility in the United States is therefore one of our top concerns, as we increasingly invest in transformational medical technologies that are based on biological principles and materials, that harness the power of our own bodies to fight and potentially cure diseases, and that modify the genetic and other biological roots of some of humanity's most devastating ailments. These nascent technologies are uncertain enough from a scientific, regulatory, and logistical perspective, even assuming that we can rely on the patent system to help offset some of their costs and risks in the small percentage of projects that succeed.

Unfortunately, our ability to continue to rely on the system is quickly being called into question, not only on account of the current trajectory of Section 101 in the United States, but around the world, as the IP system struggles to apply conventional laws and policies to unconventional new technologies, and as those who wish to see the system fail argue for its abandonment. As an example, a narrative is emerging in Geneva that cutting-edge cell and gene therapies should be completely exempted from World Trade Organization requirements that all member nations offer and respect patent rights in all fields of technology.[ii] Likewise, in parts of Europe, some argue that hospitals and pharmacies should be permitted to broadly disregard patent rights in cutting-edge cell and gene therapies and appropriate these innovative therapies for their own administration to patients, undermining the incentive to invest in their creation and development. Meanwhile, on the digital medicine front, legal and philosophical questions about the patent-eligibility and patentability of many software and artificial intelligence (AI)-based technologies abound, as patent offices around the globe scramble to adapt to a digital and data-driven world. Developments like these have prompted us to create an entire digital legal-IP practice team within our company that,

among other things, regularly questions if and how we will be able to use the IP system to enable the future of digital medicine.

Until recently, the United States was a relative safe harbor from the types of systemic IP pressures just described. We and our peers across the world's innovative industries have long relied on America's leadership in innovation policy to fuel the work that we do, one of the primary reasons why we have made the United States home to our global R&D headquarters (the Novartis Institutes for BioMedical Research (NIBR)), and some of our most cutting-edge sites. As some further examples, the United States hosts our first manufacturing facility for Kymriah®, the world's first chimeric antigen receptor T-cell (CAR-T) therapy, and our manufacturing sites for Zolgensma,® our newest gene replacement therapy, both of which were invented and developed here in America. We have also just recently launched in California what we call the "Novartis Biome," a digital innovation lab, incubator, and series of open innovation initiatives powered by our company that aims to empower and support health-tech innovators passionate about disrupting healthcare through data and digital technologies.[iii]

The strength and predictability of the United States patent system is a significant factor in making these types of investment decisions, as it must be if we are to continue to invest in the types of high-risk R&D that lead to tomorrow's treatments and cures. For this reason, we are counting on Congress to address the deep uncertainty that surrounds patent eligibility law, which will help to create the conditions necessary for companies like ours to make confident decisions to invest in the future of medicine.

3. Please explain exactly why Congress should encourage the type of work and innovation your company performs? In other words, what are the real-world, life-saving impacts of your work?

Novartis is a recognized leader in developing and delivering many of the technologies that are transforming medicine, including some of the world's first cell and gene therapies, nuclear medicines, cutting-edge digital medical tools, and a wide array of biologic and small molecule medicines that extend and improve people's lives. Our CAR-T therapy, Kymriah®, for example, is a personalized one-time treatment for certain forms of leukemia and lymphoma that uses a patient's own T-cells to fight cancer. The world's first treatment of its kind, the FDA called its approval in 2017 an "historic action," marking the beginning of "a new frontier in medical innovation" that "hold[s] out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses."[iv] In terms of real-world impact, in our global clinical trial of pediatric patients with relapsed or refractory B-Cell Acute Lymphoblastic Leukemia (ALL), 83% of children and young adults treated with Kymriah® had their cancer go into remission, 100% of those in remission had undetectable levels of cancer left in their bone marrow, and 88% of those in remission did not need an allogeneic transplant.[v] As another example, in May of this year, we secured approval of Zolgensma®, the world's first gene therapy to treat children with spinal muscular atrophy (SMA), a rare and devastating disease that is a leading genetic cause of infant mortality. The FDA called the approval of this one-time gene replacement treatment "another milestone in the transformational power of gene and cell therapies to treat a wide range of diseases," noting their potential to "change the lives of those patients who may have faced a terminal condition, or worse, death" and to "provide[] hope for the future."[vi] Other cutting edge technologies in our portfolio and pipeline include nuclear medicines such as

radioligand therapies (RLT) that precisely deliver radiation to tumors, and a variety of digital medicine innovations, including some of the world's first "prescription digital therapeutics," which are software apps that act as "virtual medicine" for substance abuse and behavioral disorders.

Congress should strongly encourage investment in technologies like these, as well as in more traditional medicines (both small molecules and biologics), because, as the above examples demonstrate, they directly save and improve patient's lives, and have a strong potential to lead to future advances with similar or greater impact. In the case of CAR-T, for example, we and several other companies are already conducting clinical trials on other forms of cancer. Likewise, the technology behind Zolgensma® is a platform technology, whose approach we are already testing in genetic forms of ALS (a.k.a. Lou Gehrig's disease) and an autism-like disease called Rett syndrome that primarily impacts infant girls.

In addition to the demonstrated impact on patients, technologies such as the ones I have described have the potential to lower healthcare costs in a variety of ways. Targeted cell and gene therapies like Kymriah® and Zolgensma® are one-time treatments that, if successful, obviate the need for chronic treatment, and restore the potential for patients to live normal lives. More broadly, personalized treatments and diagnostics help to match patients to the right medicine, improving patient outcomes while reducing costs. And a growing variety of digital tools are helping to make all aspects of drug discovery and R&D more efficient, while bringing "virtual" clinical trials into the home, and improving patient experiences and compliance.

For all of these reasons, Congress should ensure that the United States has the right set of incentives in place to encourage the development of technologies like these. As set forth in my principal testimony, fixing Section 101 to remove the uncertainty that currently surrounds patent eligibility in these nascent fields is critical to achieving this goal.

4. **Do you have any comments on our draft proposal? Are there any changes you believe we should make?**

We continue to believe that the draft legislation reflects a thoughtful and balanced solution to the current eligibility crisis, and reaffirm our support for the proposal in concept.

At this stage, our primary concern relates to whether and to what extent the draft legislation allows for the patenting of critical life sciences inventions such as modified, purified, and isolated genes, practical applications of genes, and other gene-based technologies. While we fully agree with the Chairman's and Senator Tillis' statements that genes *as they exist in the human body* will and should remain ineligible under the draft legislation, conflicting statements by others during the hearings raise renewed questions about the eligibility of gene-based technologies. As I stated in my testimony, gene-based technologies created through acts such as isolation, purification, modification and application are important tools in biotechnology, and provide a critical foundation for the future of medicine. The same is true for similar technologies based on proteins, antibodies, and other biology-based products that do not occur in, but are created from, nature. Of particular concern is whether or not the legislation intends to overrule *Myriad*, a question which currently appears to be unsettled. In our view, it is imperative that the legislation overrule the case at least in part, both because its holding expressly pertains to *isolated* human genes (not genes as they exist in nature), and because the lower courts have since applied its rationale to everything from primers and vectors, to proteins and cloned animals. We do not share the view that overruling

Myriad would enable the patenting of genes in the body. That outcome is not possible, both because *Myriad* did not concern patents on genes in the body (only patents on isolated genes), and because the draft legislation's definition of "useful," in any event, firmly precludes that result. To the extent concerns remain about overruling the case in full, we would urge Congress to consider alternative ways to clarify the eligibility of gene-based and other nature-based products and processes, lest the legislation fail to achieve one of its primary goals of restoring eligibility to life sciences technologies.[vii]

As a separate comment, while we appreciate that the primary intent of proposed Section 112(f) is to address concerns over potentially overbroad patent claims in the high-tech space, we renew our concern that broadly applicable changes to Section 112 could have unintended consequences in other fields. While we continue to assess the potential implications for life sciences inventions such as novel antibodies, we, in addition and in the meantime, urge Congress to continue to seek input on this issue from a wide variety of stakeholders in the life sciences and beyond.

II. QUESTIONS FROM SENATOR MAZIE K. HIRONO

1. Last year, Judge Alan Lourie and Judge Pauline Newman of the Federal Circuit issued a concurring opinion to the court's denial of en banc rehearing in Berkheimer v. HP Inc., in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems." Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?

We agree that Congressional action is needed at this stage to address the current state of patent eligibility law and to restore it to the broad scope that Congress has intended for over 225 years.

As a foundational matter, as the "gateway" to the patent system, we believe that Section 101 is the purest embodiment of Congress's Constitutional authority 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," U.S. Const. art. I, § 8, and that Congress alone has the power and responsibility to set the scope of subject matter eligibility. In our view, this includes the power and responsibility to step in today to reaffirm the proper scope of the patent system, and to take control of America's innovation policy as the Founders intended.

While we respect and appreciate the courts' efforts over the years to apply the law to new technologies, we believe that the very concept of *judicially* created or implied exceptions (i.e. "laws of nature," "natural phenomena," and "abstract ideas," which appear nowhere in the statute and never have) oversteps the proper bounds of judicial authority and warrants Congressional action.[viii] The Supreme Court itself has all-but acknowledged this overstep, noting with frequency in its own case law that Congress, since 1793, has purposefully cast the eligibility statute "in broad terms" with "no ambiguity" to invite judicial interpretation.[ix] As the Court has explained, "in choosing such ***expansive terms***" as "*any* new and useful process, machine, manufacture, or composition of matter, or *any* new or useful improvement thereof," "modified by the comprehensive 'any,' ***Congress plainly contemplated that the patent laws would be given wide scope,"*** [x] a mandate underscored by the preservation of this language through *six* patent acts over

225 years,[xi] and by the Committee Reports of the 1952 Patent Act, which "reflect [that] ***Congress intended statutory subject matter to 'include anything under the sun that is made by man.***'"[xii] While we believe this history reflects a clear and consistent Congressional mandate to construe Section 101 to the limits of human ingenuity, the courts in recent years—however well intentioned—have clearly had their doubts, expanding a set of exceptions that were always questionable to an ever-expanding array of technologies at a critical time of global technological transformation. In our view, the status quo and the harms that it has caused and is poised to cause to innovation (as detailed in my primary testimony) demand prompt Congressional action to clarify, and if necessary, recast the scope of eligibility law to align it with Congress's goals for American innovation policy.

Even if Congress would prefer to allow the Courts to continue to shape the law, we believe the status quo demonstrates that they are not in a position to fix it. Judge Lourie's and Judge Newman's calls for Congressional intervention, detailed in the Senator's question, are far from the only signs that judicial confusion and frustration have reached their limits. In *Ariosa v. Sequenom*, for example, in denying *en banc* review in a case finding "breakthrough" diagnostic claims to be ineligible, *four* Federal Circuit judges wrote to express their struggles with the current law, and their perceived inability to change it. Judges Lourie and Moore called it "unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility," yet opined that "under Supreme Court precedent [they] had no option other than to affirm."[xiii] Judge Dyk likewise wrote that while the Supreme Court decision in *Mayo* "may not be entirely consistent with the Supreme Court's decision in *Myriad*," and "some further illumination as to the scope of *Mayo* would be beneficial," "any further guidance must come from the Supreme Court."[xiv] Judge Newman, meanwhile, did not even agree "that this incorrect decision is required by Supreme Court precedent."[xv] The Supreme Court, for its part, promptly declined to grant *certiorari* in the case—despite these pleas from the Federal Circuit and extensive amicus briefs, including our own—and has since declined review in every other Section 101 case to date. In the meantime, lacking guidance from either Congress or the Court, the Federal Circuit and district courts continue to struggle with the Section 101 framework, issuing inconsistent decisions, often with dissents, all while other innovation-leading jurisdictions like the European Union, Japan, and even China, continue to incentivize and make patents available for most of the subject matter that has been excluded by our eligibility laws.

Under these circumstances, and for all the reasons stated, we believe Congressional intervention is imperative.

2. The Federal Circuit rejected a "technological arts test" in its *en banc* Bilski opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and ever-changing." The draft legislation includes the requirement that an invention be in a "field of technology."

a. Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?

In our experience as a global company, we believe that the term "technology," while not without some ambiguity, reflects a generally well-understood concept that should be far more predictable and easier to apply than the current exceptions-based eligibility framework. In general, and

without supporting this or any other specific wording as a final definition at this stage, we understand "technology" to encompass either: 1) practical applications of science, math, or nature by humans or by entities directed or created by humans (e.g. machines); or 2) products or other outputs of such practical applications. We believe that these concepts largely capture the categories of eligible statutory subject matter that Congress has included in Section 101 since 1793—namely, processes, machines, manufactures, and compositions of matter[xvi] that result from human activity.

A good test of this, or any alternative definition of "technology," is to subject some hypotheticals to the framework to assess the result. For example, it is widely accepted that humanity's earliest technologies were tools made from stone, wood, antlers, and bones.[xvii] Under our understanding and statement of "technology," we would consider the practical *use* of these tools to perform a task (e.g. the use of a rock to cut a mammoth steak) to be a form of patent-eligible technology, because it meets the first criterion. We would also consider the tool itself to be a form of patent-eligible technology *if*, under the second criterion, it resulted from human activity, such as a rock or a stick that was carved, shaped or otherwise modified by humans. In contrast, an unmodified stick or rock found in nature is not itself a form of technology, because it is not a product of human application or intervention in nature. The *use* of such an unmodified object to perform a practical task, however, would again be a form of technology, because it meets the first criterion. For each of these examples, it is important to remember that we are only discussing a standard for *eligibility*. In modern times, while they would remain patent-*eligible*, none of these technologies would be *patentable*, because millions of years of prior art would render them no longer novel and obvious.

In our view, this last point is a critical one, because the threshold for *eligibility*, in contrast to those for novelty and non-obviousness, should not change with the state of the art. We believe strongly that a workable eligibility standard—including any definition of "technology" or similar terms—must be broad and adaptable enough to encompass new, even unimaginable forms of technology, just as Jefferson's 1793 statutory standard has withstood the test of time.[xviii]

b. The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?

"Technology"-based eligibility standards are not only common in other jurisdictions, they form the basis for the international agreements that set minimum intellectual property standards around the world. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), for example, one of the agreements that binds all member nations of the World Trade Organization, provides that "patents shall be available for any inventions, whether products or processes, ***in all fields of technology***, provided that they are new, involve an inventive step and are capable of industrial application."[xix]

The European Union (EU) more or less adopts this standard in Article 52 of the European Patent Convention (EPC), which provides that "patents shall be granted for any inventions, ***in all fields of technology,*** provided that they are new, involve an inventive step and are susceptible of industrial application."[xx] Article 52 then proceeds with an exceptions-based eligibility standard, providing a list of subject matter that the EU has determined should not be eligible for patenting. These include "discoveries, scientific theories and mathematical methods," "aesthetic creations," "mental acts," business methods and "programs for computers" among others, but "***only*** to the

extent to which a European patent application or European patent relates to such subject-matter or activities ***as such.***"[xxi]

In our view, two aspects of the EU approach are worthy of note. First, the *exceptions*-based approach indicates that a "technology"-based eligibility framework is generally workable, even if it initially encompasses certain subject matter that is deemed inappropriate for patenting. Second, the "***as such***" approach to the exceptions acts as an express limitation on the exceptions, ensuring that the identified categories remain narrow and are not expanded to encompass more than the Legislature intended. In practice, the EU approach has successfully worked to draw what we view as appropriate lines between patent-eligible technology and ineligible subject matter. We note, for example, that under Europe's standards, isolated human genes of the type that our Supreme Court found ineligible in *Myriad* ***remain eligible for patenting***, while human genes as they exist in the body do not. Likewise, computer programs having a "technical character" and "computer-implemented inventions" remain eligible in Europe, while non-technical "programs for computers" *as such* do not.[xxii]

Notwithstanding the relative clarity and success of the EPC approach for Europe, we believe the *definitional* approach of the draft Section 101 legislation is a better choice for the United States due to fundamental differences in our legal systems. Compared to Europe's civil law system, in which case law is secondary and generally subordinate to statutory law, our common law system, by its nature, empowers our courts to continually question and interpret our statutes. In practice, this means that the more terms that Congress includes in a statute, the more likely it is over time that the courts will ascribe meaning to those terms, which may lead to implications that Congress did not intend. In our view, the current state of eligibility law based on judicially created exceptions is a prime example of this phenomenon. Thus, while a European-style exceptions-based approach may be possible if the exceptions were drafted narrowly and with an "as such" limitation, we believe the proposed definitional approach is better suited to the US legal system. In our view, the proposed legislation achieves a similar result to the EPC by defining "useful" (and, if necessary, "technology") in such a way that delineates human ingenuity from raw ideas and the natural universe, while minimizing the use of new terms that may be subject to judicial misinterpretation.

c. Is a claim that describes a method for hedging against the financial risk of price fluctuations—like the one at issue in the *Bilski* case—in a "field of technology"? What if the claim requires performing the method on a computer?

We believe that general business method patent claims like the ones at issue in *Bilski* are not forms of technology, because, among other things, they are not "practical" applications of math, science or nature. While definitions vary, the term "practical" is generally understood to involve the actual doing or use of something, rather than merely encompassing theory or ideas. *See, e.g.,* Oxford English Dictionary ("of or concerned with the actual doing or use of something rather than with theory and ideas");[xxiii] Merriam-Webster Dictionary ("manifested in practice or action: not theoretical or ideal").[xxiv] Moreover, general business methods such as those at issue in *Bilski* often do not involve applications of science or math. In contrast, if a claim requires performing a business method on a computer or other machine, we believe that this would and should constitute a form of technology and satisfy the threshold for eligibility. This is *not* to say, however, that such claims would meet the criteria for patentability under Sections 102, 103 and 112. We believe these

other sections of the patent law are best equipped to address concerns over generalized or overly broad computer-implemented methods.

d. What changes to the draft, if any, do you recommend to make the "field of technology" requirement more clear?

Because the proposed definition of "useful" already contains requirements that further refine the meaning of "technology"—namely, that any invention must also "provide specific and practical utility" and involve "human intervention"—we believe that further definition of the term "technology" may be unnecessary. To the extent that refinements or explanations of this term are deemed necessary, we suggest a definition that incorporates the concepts set forth in my response to Question 2a.

Separate from the general "field of technology" requirement, further clarity may be needed for certain forms of technology, such as diagnostic methods and substances that have been isolated, purified or modified by humans, including DNA. As previously noted, these types of inventions remain patent-eligible as forms of "technology" under European law, and we believe they would (and should) be similarly eligible under the proposed Section 101 legislation, particularly given Guiding Principle 3 that led to the draft, which provides that "diagnostic and life science technologies should be eligible for patent protection per se, subject to meeting the other existing statutory requirements, and should not be considered a law of nature, natural phenomena, or otherwise patent ineligible subject matter."[xxv] That said, testimony from some witnesses at the Subcommittee Hearings suggested ambiguity in some of these areas. While some ambiguity may be inevitable, we believe that be successful, Section 101 reforms must result in a fair degree of certainty and predictability for life sciences technologies. With that in mind, as we have previously proposed, providing some examples or other guidance in the legislative history to better document the bill's intent with respect to eligibility for these technologies may be helpful.

3. Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal. Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?

We appreciate the Senators' clarifications that genes as they exist in the human body are not, and would not be, patent-eligible under the proposed legislation. As I stated in my testimony, we agree with this reading of the proposed statute, and in any event, do not support the patenting of genes as they exist in the body or nature. In contrast, as noted in previous answers, we believe it is critical that the statute provides for eligibility for useful *applications* of genes and gene-based *technologies* that result from isolating, purifying, modifying, replicating, or enhancing genes and other natural products compared to their natural state. These technologies provide the foundation of the future of medicine, and require incentives to enable that future.

With regard to specific subject matter that should be excluded from eligibility, while we agree that the proposed statute would not allow for the patenting of genes in the body, we do not read it as a specific exclusion of this or any other particular subject matter. Rather, the exclusion of genes in the body and anything else that exists in nature absent human intervention is a broad result of a

definitional framework that elegantly distinguishes the essence of invention from the workings and phenomena of the natural universe. In this respect, we believe it is important to reiterate our view that the strength of the proposal lies in its *avoidance* of identifying specific ineligible subject matter. In general, we do not believe that Congress should seek to identify subject matter to *exclude* from the patent system, as the nature of innovation is such that disincentivizing investment in any area of technology often leads to unintended consequences. The current state of eligibility law is a salient reminder that exclusions that were once as seemingly clear and uncontroversial as "laws of nature," "natural phenomena," and "abstract ideas" have now led to the dramatic decline of the diagnostic industry in the United States, and to the invalidity of everything from modified proteins to microscopes.[xxvi]

While there are indeed a small number of specific statutory restrictions on patenting for certain subject matter, these restrictions are not part of the general eligibility framework of Section 101, and generally arise from moral and national security concerns rather than Congressional decisions over innovation policy. The "human organism" patent ban of the America Invents Act, for example, was aimed at addressing moral and ethical concerns over the implications of patenting human beings, human fetuses, human embryos, and human-animal chimeras.[xxvii] Likewise, the United States bans patents on atomic weapons out of concerns over national security.[xxviii] While we support the right of all governments to regulate and restrict behavior on moral, national security and similar grounds—a right recognized in international legal instruments[xxix]—we believe it is important to distinguish and separate these types of specific patenting exclusions from the general patent eligibility discussion, so as not to conflate their very different purposes.

4. I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.

a. Are these valid complaints?

As a science-based healthcare company, our primary area of innovation is in the life sciences. As such, we do not have sufficient experience with the enforcement of Section 112 in the high tech space to comment on this question.

b. Do the proposed changes to Section 112 adequately address those complaints and limit the scope of claims to what was actually invented?

As above, we do not have sufficient experience in the high tech space to comment on the likely efficacy of newly proposed Section 112(f) in addressing the complaints identified in the question. However, as a general matter, and based on our experience in the life sciences, we believe that current Section 112 already serves to limit patent claims to what was invented. As the Federal Circuit has explained, "the purpose of [Section 112] is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification."[xxx] At least in the life sciences space, Section 112 has been found to lead to either a narrower claim scope than the wording of the claims might otherwise suggest, or to invalidation of claims that are found to be broader than what the inventor possessed.[xxxi]

While, again, we do not have sufficient experience to comment on the potential impact of new Section 112(f) on patent claims in the high tech space, we do believe it is important to proceed cautiously when making general changes to a statute that will apply to all fields of technology. In the case of Section 112(f), the new scope limitations on functional elements will undoubtedly impact life sciences technologies such as newly created antibodies, which are often claimed functionally due to their nature. Before enacting broad changes to address what appears to be a problem primarily in the high tech field, we urge Congress to solicit input from the life sciences sector and other fields to ensure that the new provisions do not have unintended consequences.

c. Are you concerned that the proposed changes will make it too easy for competitors to design around patent claims that use functional language?

Viewing proposed Section 112(f) through a life sciences lens, we do have some concerns that the scope limitations on functional claim elements could lead to unduly narrow claims for inventions such as antibodies. We are still assessing the potential impact of this section on our fields of innovation. In the meantime, we would again urge Congress to invite and consider expanded stakeholder input on this topic as this or any other proposal to amend Section 112 proceeds.

5. There is an intense debate going on right now about what to do about the high cost of prescription drugs. One concern is that pharmaceutical companies are gaming the patent system by extending their patent terms through additional patents on minor changes to their drugs. My understanding is that the doctrine of obviousness-type double patenting is designed to prevent this very thing. The Federal Circuit has explained that obviousness-type double patenting "is grounded in the text of the Patent Act" and specifically cited Section 101 for support. Would the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 do away with the doctrine of obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?

While we recognize the need to address the rising costs of healthcare in America, we respectfully disagree that systemic "gaming" of the patent system is to blame for high drug costs, or that securing patents on improvements to existing medicines constitutes "gaming." Allegations to this effect are unfortunately common in the media and in reports from stakeholders with certain interests, but these are largely based on erroneous facts, and on fundamental misunderstandings about patent law and the biopharmaceutical R&D process. For example, contrary to widespread claims that medicines routinely enjoy terms of market exclusivity that exceed the 20-year patent term, fact-based studies conducted as recently as 2017 confirm that the average time on market before loss-of-exclusivity is just 13.5 years, a figure that has steadily declined since 1998.[xxxii]

With regard to allegations that securing patents on improvements constitutes "gaming," we disagree for a variety of reasons. First, we believe that the nature of improvements in the field of medicine is poorly understood, and should be clarified before passing judgment as to their value. When companies like ours improve existing medicines, it typically means that we are investing substantially in new research, including new clinical trials, to adapt a medicine to a new use to treat a different disease; create new formulas, dosages or routes of administration to improve safety, efficacy or patient compliance; or develop a medicine in other ways to create other new

patient benefits. Recent examples from our own portfolio include repurposing a cancer drug for novel use in multiple sclerosis; redeveloping an Alzheimer's medicine from an oral form to a "patch" worn on the skin, which helps improve patient compliance while reducing a gastric side effect; and reformulating a treatment used for gastrointestinal complications of certain types of tumors so that it can be injected once every four weeks instead of every day. As these examples demonstrate, innovations like these deliver significant new benefits for patients, which should not in our view be dismissed as "minor" or "trivial" changes.

Additionally, as a matter of patent law, it is important to understand that new patents on improved versions of medicines do *not* extend patents on the original medicine. New patents on an improvement only cover the improvement, meaning that a generic or other competitor can practice the original invention once the original patent expires. As a further clarification, far from constituting "abuse" of the system, improvements are a statutory category of patent-eligible subject matter that are expressly authorized in Section 101, and have been since 1793. *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, *or any new and useful improvement thereof,* may obtain a patent therefor, subject to the conditions and requirements of this title.") (emphasis added).[xxxiii]

With these important background clarifications, we do not view the doctrine of obviousness-type double patenting as a tool designed for curtailing, or that is necessary to curtail, the patenting of important innovations like the ones described above that we strive to deliver to patients. In fact, as the Federal Circuit has explained, at least in recent times, obviousness-type double patenting has been most significant as a tool to address a problem of older patents in all fields of technology, filed before 1995, when patent term was measured from the time of patent grant.[xxxiv] Under the pre-1995 patent system, delays in patent prosecution could lead to situations where patents filed years before would suddenly issue and begin a new 17-year patent term measured from the time of grant (so-called "submarine patents"). In 1995, the Uruguay Round Agreement Act (URAA) changed the way that patent term is measured to the current term of 20 years from filing.[xxxv] While it is true that the Federal Circuit still applies obviousness-type double patenting in a small number of other situations, the Court itself has recognized that the doctrine is "less significant in post-URAA patent disputes" and "may have 'limited force in . . . many double patenting rejections today."[xxxvi]

In any event, the proposed Section 101 reforms will not, in our view, impact obviousness-type double patenting. While the Federal Circuit has occasionally tied this doctrine to Section 101's provision than an inventor "may obtain *a* patent"[xxxvii] for a single invention and not more, it remains primarily a court-made doctrine, separate from the "same invention"-type double patenting rooted in the statute. Moreover, even if the statute played a larger role in obviousness-type double patenting, the draft legislation does not modify the "may obtain a patent" aspect of Section 101, and the additional provision abrogating Section 101 case law is limited to cases establishing or interpreting the judicially created eligibility exceptions. We therefore see no possibility that Section 101 reforms will reduce or eliminate obviousness-type double patenting as an available defense or tool in cases that warrant its application.

6. In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is property for purposes of the Due Process Clause or the Takings Clause. What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?

As a clarifying point, we do not read the Supreme Court's *Oil States* decision as avoiding answering the question of whether patents are property for purposes of Due Process and the Takings Clause. What the Court said is that its decision "should not be *mis*construed as suggesting that patents are *not* property for purposes of the Due Process Clause or the Takings Clause."[xxxviii] We read this statement as an explicit affirmation that patents *are,* in fact, property for purposes of the Due Process and Takings Clauses, a reading underscored by the Court's direct citation to its earlier precedents that held precisely that. *See, e.g., Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank*, 527 U. S. 627, 642 (1999) (Patents "are surely included within the 'property' of which no person may be deprived by a State without due process of law"); *James v. Campbell,* 104 U.S. 356, 358 (1882) (A "patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt."); *see also Horne v. Dep't of Agric.,* 135 S. Ct. 2419, 2427 (2015) (A patent "confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation.") (quoting *James*, 104 U.S. at 358).

With that clarification, in our view, the Due Process and Takings implications of retroactively applying Section 101 revisions to already-issued patents largely depend on whether such revisions would narrow or broaden the scope of eligibility. If changes to Section 101 would broaden the scope of eligibility from the status quo—or more accurately, *restore* it to the "wide scope" that the statute has reflected since 1793,[xxxix] as we believe the draft legislation would—we anticipate few if any Due Process or Takings implications, because such changes would not appear to result in the rescission or invalidation of issued patents. Of course, if the draft bill were to be revised in a way that *narrows* the current scope of eligibility, this would raise Due Process and Takings concerns (in addition to making little policy sense, given the restorative purpose of the present reform efforts).

In contrast to the draft Section 101 reforms, we do have concerns that the proposed Section 112 revisions could raise Due Process and Takings concerns if they were applied retroactively to already-issued patents. Newly proposed Section 112(f) would impose a new "written description" standard, limiting the scope of functional patent claim elements to the specific structure, material or acts disclosed in the patent specification, or their equivalents. If applied to already-issued patents, this new provision would, in many cases, have the effect of narrowing the scope of issued patent claims. In practical terms, given that patents and the inventions they cover are property, and that the claims define the bounds of that property, applying new Section 112(f) retroactively to patents in those cases would, in our view, amount to an unconstitutional taking. Moreover, because owners of existing patents will have relied on the present Section 112 when drafting their claims and specification with no pre-issuance notice of the changes or ability to adapt, we believe that retroactive application of new Section 112(f) would also likely violate due process. These constitutional concerns are another reason for Congress to invite and consider expanded stakeholder input on this, or any other, proposal to amend Section 112.

One further relevant consideration is whether retroactivity would (and should) apply to patents that have already been invalidated under current eligibility law at the time that any reforms are enacted. We believe that it should not. *Stare decisis* should apply to any final unappealable decision that has found a patent to be ineligible under existing case law, and the public should be able to rely on these decisions. We believe this should not raise Takings or Due Process concerns. As a precedent for this, we note that patents invalidated in litigation for failure to disclose their "best mode" were not resurrected with enactment of the America Invents Act, despite that Act's abolishment of the best mode requirement as a defense to patent infringement.

Applying the above considerations to the proposed legislation (and assuming that any revisions maintain the effect of restoring a broader scope of eligibility to the patent laws), we believe the following approach to retroactivity reflects the correct legal and policy balance while minimizing Constitutional concerns:

1. The proposed Section 101 reforms should apply retroactively to all patents still in force at the time of enactment, including those expired patents still within their 6-year statutory period of enforcement for past damages.

2. The proposed Section 101 reforms should not apply retroactively to any patent that has been invalidated under current eligibility law in any final non-appealable decision.

3. The proposed Section 112 reforms should not apply retroactively, as these will likely raise Due Process and Takings concerns.

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[i] *See Mayo v.Prometheus*, 132 S. Ct. 1289, 1302 (2012), ("Unlike, say, 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).

[ii] *See* World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Art. 27.1 ("patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.")

[iii] *See* https://www.novartis.com/our-science/novartis-biome.

[iv] US Food & Drug Administration, *FDA approval brings first gene therapy to the United States,* August 30, 2017, https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states

[v] https://www.hcp.novartis.com/globalassets/products21162/kymriah---full-site/ped-all/patient-resources/kymriah-digital-core-patient-brochure.pdf

[vi] US Food & Drug Administration, *FDA approves innovative gene therapy to treat pediatric patients with spinal muscular atrophy, a rare disease and leading genetic cause of infant mortality*, May 24, 2019, https://www.fda.gov/news-events/press-announcements/fda-approves-innovative-gene-therapy-treat-pediatric-patients-spinal-muscular-atrophy-rare-disease

[vii] 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 . . . .")

[viii] While we believe that judicial exceptions are constitutionally improper, and do not agree with the expansive scope that the courts have given them in recent years, we do not believe that "laws of nature," "natural phenomena" or "abstract ideas" *as such* currently are or should be patentable. It is, rather, our view that the patent system already contains other mechanisms to exclude patents on these categories, and that to the extent it does not, Congress, not the Courts, should set America's innovation policy.

[ix] *Diamond v. Chakrabarty,* 447 U.S. 303, 315 (1980).

[x] *Id.* at 308 (emphasis added).

[xi] These include the Patent Acts of 1793, 1836, 1870, 1874, 1952, and 2011 (the America Invents Act), the only change being a non-substantive exchange of the term "process" for the outdated term "art" in the 1952 Patent Act. *See id.* at 309.

[xii] *Id.* (quoting S Rep. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952))

[xiii] *Ariosa Diagnostics v. Sequenom,* 809 F.3d 1282, 1287 (Fed. Cir. 2015) (Lourie, J., and Moore, J., concurring). Their comments echo Judge Linn's concurrence below that "[b]ut for the sweeping language in the Supreme Court's Mayo opinion, I see no reason, in policy or statute, why this this breakthrough invention should be deemed patent ineligible." *Ariosa Diagnostics v. Sequenom,* 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring).
[xiv] *Id.* at 1287, 1289-90 (Dyk, J., concurring).
[xv] *Id.* at 1293.
[xvi] *See Chakrabarty,* 447 U.S. at 309.
[xvii] *See, e.g.,* Smithsonian Museum of Natural History, *What does it mean to be human?: Stone Tools* (http://humanorigins.si.edu/evidence/behavior/stone-tools); Panger, M. A.; Brooks, A. S.; Richmond, B. G.; Wood, B. (2002). *Older than the Oldowan? Rethinking the emergence of hominin tool use*. Evolutionary Anthropology: Issues, News, and Reviews. 11 (6): 235–245.
[xviii] *See* Act of Feb. 21, 1793, § 1, 1 Stat. 319.
[xix] TRIPS Art. 27.1.
[xx] European Patent Convention, Art. 52, Patentable Inventions.
[xxi] *Id.* (emphasis added)
[xxii] *See* EPC Examination Guidelines 3.6, Programs for computers.
[xxiii] Oxford English Dictionary (https://en.oxforddictionaries.com/definition/practical)
[xxiv] Merriam-Webster Dictionary (https://www.merriam-webster.com/dictionary/practical)
[xxv] March 26, 2019 Guiding Principles for Section 101 Reform
[xxvi] *See* my written testimony, *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*," at 3.
[xxvii] *See* AIA Section 33 ("Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."); 57 CONG.REC.E1178(daily ed. June 23, 2011) (statement of Rep. David Weldon).
[xxviii] *See* 42 U.S.C. § 2181 ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.")
[xxix] *See* TRIPS Art. 27.2 ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality . . . .")
[xxx] *Reiffin v. Microsoft Corp.,* 214 F.3d 1342, 1345-46 (Fed.Cir. 2000); *accord Ariad Pharmaceuticals et al. v. Eli Lilly and Company,* 598 F.3d 1336 (Fed. Cir. 2010) (en banc).
[xxxi] *See, e.g., Amgen v Sanofi*, 872 F.3d 1367 (2018)*; Ariad,* 598 F.3d 1336; *Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916 (Fed.Cir. 2004); *Fiers v. Revel*, 984 F.2d 1164, 1170-71 (Fed.Cir.1993).
[xxxii] Quintiles IMS, *Lifetime Trends in Biopharmaceutical Innovation: Recent Evidence and Implications*, January 2017 (https://www.iqvia.com/institute/reports/lifetime-trends-in-biopharmaceutical-innovation-recent-evidence-and-implications).
[xxxiii] As Thomas Jefferson, author of the 1793 Act, later explained "In the arts . . . many ingenious improvements are made in consequence of the patent-right giving exclusive use of them for fourteen [now 20] years." Letter of T. Jefferson to M. Pictet, 1803. ME 10:356.
[xxxiv] *Abbvie Inc. v. Mathilda & Terrence Kennedy Inst. of Rheumatology Tr.,* 764 F.3d 1366 (Fed. Cir. 2014).
[xxxv] Uruguay Round Agreement Act (URAA), Pub. L. 103-465, 108 Stat. 4809, effective June 8, 1995.
[xxxvi] *Mathilda*, 764 F.3d 1366, quoting *In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009).
[xxxvii] 35 U.S.C. § 101 (emphasis added)
[xxxviii] *Oil States Energy Svcs v. Greene's Energy Group,* 584 U.S. ___, ___ (2018) (emphasis added).
[xxxix] *Chakrabarty*, 447 U.S. at 308 (emphasis added).