June 26, 2019

**Responses by Natalie M. Derzko to Questions for the Record**
**Senate Committee on the Judiciary**
**Subcommittee on Intellectual Property**
**Hearing on "The State of Patent Eligibility in America: Part II"**
**June 5, 2019**

The answers provided below are being submitted on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which represents the country's leading innovative biopharmaceutical research companies. These companies are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

PhRMA is committed to ensuring the continued health and competitive strength of a biomedical research and development ("R&D") ecosystem that fosters innovation, incentivizes competition, and benefits U.S. consumers. Strong and predictable intellectual property ("IP") protections are essential to the United States' economic well-being, and signal to other jurisdictions the critically important economic benefits of IP. The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. The IP-intensive biopharmaceutical industry supports a total of more than 4.7 million jobs across the U.S. economy and contributes $1.3 trillion in economic output when direct and indirect effects are considered.[1]

PhRMA appreciates the Subcommittee's leadership in exploring how best to reform patent subject matter eligibility to ensure that the patent system encourages and stimulates continued innovation, including medical innovation. PhRMA also appreciates the opportunity to address written questions posed by Senators Blumenthal, Hirono, and Tillis following the Subcommittee's hearing on June 5, 2019.

Given PhRMA's area of expertise, the answers provided below focus on the biopharmaceutical industry. However, to best stimulate and support innovation in the United States, PhRMA believes that Section 101 should continue to be drafted in a technology-neutral manner, in accordance with current U.S. practice and international obligations.

[1] *See* TEConomy Partners, *The Economic Impact of the US Biopharmaceutical Industry: 2015 National and State Estimates*, at 7–8 (Oct. 2017).

## Questions From Senator Blumenthal

**1. Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system.**

**a. What impact will broadening the subject matter that can be patented have on industry?**

**Answer:** Likelihood of patent protection is a key factor considered by biopharmaceutical companies when making research and development (R&D) investments. The Section 101 reform proposal would provide the biopharmaceutical industry and other industries involved in medical innovation with greater certainty about the types of inventions that are eligible for patenting. Importantly, although the proposal may impact what subject matter *can* be patented, it would not necessarily impact what subject matter *will* be patented. Before a patent can issue, patent claims would still need to meet the stringent requirements of Sections 102, 103, and 112 of the Patent Act.

By providing additional clarity and certainty, the proposal would likely incentivize companies to develop new therapeutics and methods in areas such as personalized medicine and nature-based products. Recently, the Federal Circuit in *Athena Diagnostics, Inc. v. Mayo Collaborative Services LLC* expressly recognized that "the public interest is poorly served by adding disincentive[s] to the development of new diagnostic methods," and that "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts."[2] But current Section 101 jurisprudence has thrown patent eligibility of diagnostic methods and nature-based products into question. The proposal's framework provides a solution for this problem.

**b. What impact will broadening the subject matter that can be patented have on consumers?**

**Answer:** Patients would benefit from innovation and research into new types of treatments that would be patent eligible under the proposal—including treatments such as personalized medicine and nature-based products. In particular, patients could benefit from new personalized medicine treatments that utilize methods not yet studied or developed due to uncertainty as to their patent eligibility under current Section 101 law. Patients would also benefit from innovations resulting from the increased clarity that the proposal would provide regarding patent eligibility of vaccines, antibiotics, and other nature-based products.

**c. Could these reforms increase consumer prices? If so, in what industries or on what products?**

**Answer:** The proposal would not in and of itself raise consumer pricing for biopharmaceuticals. In the biopharmaceutical space, the proposal would incentivize

[2] 915 F.3d 743, 753 n.4 (Fed. Cir. 2019).

companies to develop important treatment options for many diseases—for example, diagnostic tests and nature-based products. In many cases, these types of innovations provide important tools that enable physicians to reduce unnecessary and expensive treatments for patients. For example, new methods to identify patients most likely to benefit from a particular treatment could actually decrease costs. As noted in my previous written testimony submitted for the Subcommittee's June 5, 2019 hearing, personalized medicine methods such as biomarker identification and genomic testing for various mutations have been shown to increase survival time and decrease costs for treating multiple types of cancer.

**Questions for the Record for Natalie M. Derzko**
**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?**

   **Answer**: As noted in PhRMA's previous written and oral testimony to the Subcommittee, PhRMA believes that reform of Section 101 is appropriate at this time. The Supreme Court and Federal Circuit's jurisprudence regarding application of the judicial exceptions to Section 101—particularly the jurisprudence following the *Alice* and *Mayo* decisions—has created significant uncertainties in the biopharmaceutical patent landscape. Groundbreaking inventions related to diagnostic methods, as well as inventions based on the application of human ingenuity to natural products, are being challenged in the courts and declared ineligible under current Section 101 jurisprudence.

   For example, in the recent *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*[3] and *Athena Diagnostics, Inc. v. Mayo Collaborative Services LLC*[4] cases, the Federal Circuit held major advances in diagnostic methods ineligible under the current *Alice/Mayo* framework—even though judges on both panels indicated that the inventions were meritorious. In *Ariosa*, Judge Linn recognized that the claimed diagnostic method—a method for analyzing cell-free fetal DNA in maternal blood samples to determine fetal characteristics—represented a "breakthrough invention," as "no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers" and "the maternal plasma used to be routinely discarded."[5] Yet Judge Linn concluded that he was bound to find this invention ineligible by "the sweeping language in the Supreme Court's *Mayo* opinion."[6] The majority in *Athena* expressed similar concerns about the overbreadth of *Mayo*.[7] When considering a method for diagnosing myasthenia gravis using

[3] 788 F.3d 1371 (Fed. Cir. 2015).

[4] 915 F.3d 743 (Fed. Cir. 2019).

[5] *Ariosa*, 788 F.3d at 1381 (internal quotations and citation omitted).

[6] *Id.*

[7] *Athena*, 915 F.3d at 753 n.4 ("Whether or not we as individual judges might agree or not that these claims only recite a natural law . . . the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature . . . and [p]urely conventional or obvious [pre]-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.").

new man-made reagents and targeting a subset of these patients that were not identifiable using previous diagnostic methods, the judges ultimately concluded that *Mayo* compelled their finding of ineligibility despite expressly recognizing that "the public interest is poorly served by adding disincentive[s] to the development of new diagnostic methods" and that "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts."[8]

The uncertainties created by current Section 101 jurisprudence discourage investors and inventors from pursuing research in critical areas of medicine. PhRMA believes that returning Section 101 to its threshold gatekeeping function (as a coarse filter that identifies eligible categories of subject matter) has the potential to significantly aid biomedical innovation in the United States by providing consistency and clarity to this important area of patent law—thereby promoting innovation of important medical technologies that can enhance patients' lives.

**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"?**

**Answer:** PhRMA believes that the term "field of technology" would encompass inventions and discoveries broadly in the biopharmaceutical space, and would include diagnostic methods and nature-based products, such as vaccines and antibiotics, and other types of medical advances. A similar term, "in all fields of technology," is used in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to describe patentable subject matter.[9] However, in another patent context, the term "technological" is used in U.S. patent law to specify that a "covered business method patent" for the transitional post-grant proceeding relating to covered business method patents "does not include patents for technological inventions."[10] These examples present varied uses of the term "technology" or "technological," and some stakeholders have suggested that the term is not clear. If the term "field of technology" is removed from Section 100 in the legislative proposal, it is nonetheless important for Section 101 to maintain a technology-neutral stance so as to comply with the United States' international obligations and to allow U.S. patent law to adapt more easily to new technology not yet invented.

**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**

[8] *Id.*

[9] *See* TRIPS Agreement, Article 27.1.

[10] Leahy-Smith America Invents Act, H.R. 1249 § 18(d)(1).

**their experiences?**

**Answer:** PhRMA expresses no views on this question at this time.

**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?**

**Answer:** PhRMA represents the country's leading innovative biopharmaceutical research companies. As such, PhRMA has no expertise in this area and takes no position on whether such a claim would fall within a "field of technology."

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

**Answer:** PhRMA does not have a recommendation at this time.

**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?**

**Answer:** PhRMA does not propose any categories at this time.

**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?**

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

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

**Answer:** PhRMA represents the country's leading innovative biopharmaceutical research companies and thus takes no positions on complaints generated in the high tech space.

**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?**

**Answer:** Double patenting doctrine exists in U.S. patent law "to prevent the unjustified extension of patent exclusivity beyond the term of a patent."[11] Statutory double patenting, which prohibits an inventor from obtaining more than one patent for a single invention, "finds its support in the language of 35 U.S.C. § 101, which states that 'Whoever invents or discovers any new and useful process . . . may obtain *a* patent therefor . . . .'"[12] Obviousness-type double patenting, on the other hand, is a "judicially created doctrine grounded in public policy," that "prevent[s] the extension of the term of a patent, even where an express statutory basis for the rejection is missing, by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent."[13] The proposed revisions to Section 101 do not alter the language prescribing that an inventor "may obtain *a* patent" for a single invention. Moreover, obviousness-type double patenting is an established doctrine, and it will not be disrupted by any changes in the proposal.

PhRMA does have concerns regarding the mischaracterization of post-approval innovations in the debate. Patents can be granted for a range of new innovations post-FDA approval that reflect substantial R&D investments, which may include clinical trials and other clinical studies required by the FDA. Post-approval clinical trials are used to assess a medicine in additional patient populations (e.g., in children or at different stages of disease), in new delivery modes (e.g., as a timed-release capsule), or for new uses or indications (i.e., for the treatment of a different medical condition). When these clinical trials are intended to support FDA approval of the new innovation (e.g., new use of the drug), the trials are subject to the same standards as those used to support initial approval of the drug, thus representing similarly significant investment.

**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?**

**Answer:** From PhRMA's perspective, the proposal does not appear to implicate rights under the Due Process or Takings Clauses because the proposal does not narrow the scope

[11] M.P.E.P. ¶ 804.

[12] *E.g.*, *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985) (quoting 35 U.S.C. § 101) (emphasis in original).

[13] *Id.*

of eligible subject matter. Therefore, the proposal would not take away any issued patent rights if applied retroactively. Rather, the proposal returns the Section 101 inquiry to a coarse-filter approach that broadly permits patenting of subject matter within its enumerated categories. This approach would provide much-needed clarity to present and future innovators seeking patent protection for their inventions and discoveries, which can lead to increased R&D investment.

**Senator Thom Tillis**
**Questions for Natalie Derzko**

1. **Some of the hyperbole I've heard from anti-reform advocates is that somehow doing something on patent eligibility is going to lead to an increase in drug prices or the patenting of "frivolous" or "useless" drug patents. I understand why anti-reform advocates are trying to make that argument, it's politically charged and is a good way to try and de-rail this project. However, as both of you know, that argument is totally inaccurate. Those arguments ignore the fact that patent eligibility is just the first of many steps in order to secure a valid patent. A patent still has to be novel, nonobvious, and meet numerous other requirements in order to issue. In addition, drug pricing is determined by a number of factors that have to deal with things beyond the actual patent. Can you briefly describe the minimal role patent eligibility plays in overall "drug pricing" and explain very clearly to this Committee how broadening the eligibility standard *isn't* going to lead to "bad patents" being issued?**

   **Answer:** The proposal will not lead to "bad," "frivolous," or "useless" drug patents because the patentability doctrines, including double patenting and further patentability requirements of the Patent Act under Sections 102, 103, and 112 prevent issuance of such patents. The proposal also does not impact the pricing of products that result from a patented invention. Rather, the proposal merely broadens the gateway through which meritorious inventions initially pass in order to be considered further for patent protection. Section 101 as proposed would function as a coarse filter that identifies what types of inventions and discoveries are eligible for patenting in the first place. It would realign our Patent Act with the United States Constitution to incentivize development of groundbreaking products. Clear incentives encourage development of innovative products, which ultimately benefits consumers. As the Chairman correctly observed during the Subcommittee's June 5, 2019 hearing: a drug, treatment, or diagnostic that never gets created "costs nothing because it doesn't exist."[14]

   A large body of literature demonstrates that the innovation triggered by patents spurs rather than chills competition, as detailed below:

   - A greater number of options increases competition on price and clinical effects. Since payers have strong tools to drive high generic use rates, new products will succeed in the marketplace only if they can demonstrate added value for patients. Medicines in the same class compete through quality and price for preferred placement on drug formularies and physicians' choices for patient treatment.

   - While patents might prevent a competitor from bringing an exact duplicate of a medicine to market during the term of the patent, they do not act as an absolute bar against bringing similar, but non-infringing, products to market. This happens

[14] *The State of Patent Eligibility in America: Part II: Hr'g Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 116th Cong. (2019) (statement of Chairman Thom Tillis, starting at 3:27:36).

regularly.

- For example, less than a year after market entry of the first in a new class of hepatitis C treatments, multiple competitors entered the market—resulting in lower prices and improved clinical effectiveness. The competition was so fierce that Express Scripts, the largest U.S. pharmacy benefit manager, now touts hepatitis C treatment as less expensive in the U.S. as compared to other Western countries thanks to its aggressive negotiation.

- Innovations that reduce the number of times a patient will have to take a given medicine, reduce the number of different medicines a patient must take, and provide new methods of delivery can make a big difference in terms of patient convenience, compliance, and outcomes—as well as provide cost savings in other parts of the health care system.

**2. One of the reasons I'm concerned by the current legal landscape is that I've heard from numerous companies that they are abandoning research into life-saving treatments and medications. You both probably heard Sherry Knowles testimony a bit earlier on this exact subject. It's easy to paint "pharma" companies as big bad boogeyman, but that ignores the point Sherry made so eloquently: if people don't develop new drugs to treat disease and improve currently existing treatments, people will die.**

**That concerns me. I want America to remain the world's leader in innovative health care and precision medicine. Can you describe briefly the impact the current legal framework is having on the willingness of your member companies to invest in the research and development needed to bring new medicines and treatment methods to market?**

**Answer:** Patent protection is central to providing the incentives needed for overcoming the staggering costs and risks of developing new products and therapies. The current legal framework has created substantial uncertainty for biopharmaceutical companies seeking to invest in areas with significant scientific risk. The uncertainties created by current Section 101 jurisprudence make it hard for an inventor to know which inventions will be patentable and which will not. As such, the current framework does not provide effective protection for advancements that our society should incentivize—making it more challenging for companies to invest in those inventions. Section 101 reform would help realize the promise of diagnostics and personalized medicines for developing new targeted therapies that address unmet patient needs.

**a. Looking out ten to fifteen years from now, if we don't address the current patent eligibility mess, what impact will that have on the delivery of healthcare for Americans? In other words, will America continue to be the go-to-country for groundbreaking medical research and innovation?**

**Answer**: When a company cannot rely on the patent system to protect the innovation resulting from its R&D investments, that company is disincentivized to invest the

substantial amount of time and resources necessary for innovating in a given area. Lack of investment and inventive human capital could slow the pace of advancement in medical diagnostics and other areas, allowing other countries to become the new hub of global innovation and groundbreaking medical research.

IP protections are designed to incentivize the substantial R&D efforts required for discovering and developing new and improved products, including medicines. Patents confer the right to exclude competitors from practicing the invention for a limited time within a given scope, as defined by patent claims. Once a new medicine's patent term (as well as any statutory exclusivity protections) expire, generic equivalents and biosimilars—which require substantially lower capital investments—can enter the market. In fact, 90% of all medicines dispensed in the United States are generic copies of an innovator medicine.[15] In the absence of IP protections, biopharmaceutical companies would be unlikely to invest in developing innovative therapies.

New medicines play a central role in transforming the trajectory of many debilitating diseases, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Researchers are pursuing cutting-edge research and novel scientific strategies to continue driving therapeutic advances for patients. There are currently about 8,000 medicines in clinical development globally with the potential to impact U.S. patients.[16] And, across all medicines in the pipeline, 74% have the potential to be first-in-class treatments.[17]

The U.S. is the global leader of biopharmaceutical innovation. That global leadership is built upon a robust R&D ecosystem. Further, the economic impact of the biopharmaceutical industry and its closely-integrated supply chain translate into high-wage jobs, substantial tax revenue, and growing economic output in local communities. In 2017, the combined effects of biopharmaceutical direct jobs, supply chain, wages, and benefits resulted in more than $1.3 trillion in economic output and more than 4.7 million jobs.[18] Indeed, every job in the biopharmaceutical industry supported a total of five jobs across the economy due to the broader impacts of its supply chain and the personal spending of its workforce.

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[15] *See* IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2022* (Apr. 18, 2019), https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[16] *See* Adis R&D Insight Database (accessed June 2018).

[17] *See* Analysis Group, Inc., *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development* (July 2017).

[18] *See supra* note 1, at 7–8.

But continued global leadership is not guaranteed. While the U.S. currently leads the world in biopharmaceutical innovation, the industry faces mounting competition from emerging nations as well as developed countries.[19] As the Information Technology and Innovation Foundation observed, "The United States' lead in the life sciences is being challenged. Other countries have aggressively courted life-sciences companies with lower tax rates . . . improved intellectual protections and streamlined approval processes."[20] Continued U.S. global leadership depends on public policies that support biopharmaceutical R&D and manufacturing. The proposal would provide clarity needed for incentivizing R&D in critical areas such as vaccines, antibiotics, and personalized medicines.

**a. If not, what is the practical consequence going to be for millions of Americans who depend on these types of innovative medicines and treatment mechanisms?**

**Answer**: Reducing incentives to invest in R&D could threaten the development of promising drug candidates and chill the discovery of other promising therapeutic targets, diagnostic methods, and a host of innovative solutions to some of the world's costliest and most devastating diseases. Failure to address concerns regarding unpredictability generated by Section 101 could result in less R&D investments and, consequently, less innovation in the areas of vaccines, antibiotics, and personalized medicines. Over the longer term, this outcome could have the unintended consequence of driving up health care spending. As discussed in my written testimony, reforming Section 101 to incentivize R&D investment in personalized medicines could transform treatment for many diseases. These medicines shift the treatment paradigm for patients by enabling increasingly precise assessment of which medical treatments and procedures will best serve each patient. By targeting treatments most likely to benefit a given patient, personalized medicines serve as an important tool to reduce the use of unnecessary and often costly treatments or procedures—guiding health care decisions toward "the most effective treatment for a given patient and, thus, improve the quality of care while reducing the need for unnecessary diagnostic testing and therapies."[21]

**3. Perhaps the most disingenuous arguments I've heard from anti-reform advocates is that our proposal will somehow allow the patenting of "human genes." That's not true. Neither the intent or effect of our proposal will be to allow the patenting of human genes. Period. Anyone who says differently is simply engaging in hyperbole and trying to fatten their own pockets through fundraising efforts.**

**I want to dispel this notion that somehow we're going to allow the patenting of "Human**

[19] *See* TEConomy Partners, *Closing the Gap: Increasing Global Competition To Attract And Grow The Biopharmaceutical Sector*, at 1 (June 2017).

[20] ITIF, *How to Ensure that America's Life-Sciences Sector Remains Globally Competitive*, at 4–5 (Mar. 2018).

[21] Geoffrey S. Ginsburg & Kathryn A. Phillips, *Precision Medicine: From Science to Value*, Health Affairs 694, 694–701 (May 2018).

**genes." So, let me ask you a series of questions:**

**a. It's my understanding that the *Myriad* case already held that a particular gene form, cDNA, for example remains patent eligible. Is that correct?**

**Answer**: Yes. The Court in *Myriad* explained that "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring," and concluded that, "[a]s a result, cDNA is not a 'product of nature' and is patent eligible under § 101."[22]

**b. With respect to the argument that reform would change anything related to human genes, wouldn't it be accurate to say that argument is arguably specious?**

**Answer:** The proposal's definition of "useful" requires human intervention. As such, genes as they exist in the human body would remain ineligible for patenting. cDNA, by contrast, would remain patentable under the proposal because creation of an exons-only cDNA sequence incorporates human intervention and has a specific and practical utility. Further, even if patent claims involve human intervention and thus would satisfy Section 101, such as claims directed to cDNA sequences, these claims would need to be evaluated under Sections 102 or 103 based on the prior publication of the human genome.

**c. Second, and importantly, isn't it true that genomic DNA forms of human genes are not patentable under 102 and 103 because they have been in the public domain for about 20 years? In other words, even if Congress abrogates Supreme Court precedent, human genes, outside the cDNA form, would not be subject to patent protection. Correct?**

**Answer:** Yes. Genomic DNA forms of human genes that have been in the public domain for 20 years are not patentable under Sections 102 or 103. Even if Congress abrogates judicial precedents interpreting Section 101, the published human genome remains in the public domain, and therefore remains available as prior art under Sections 102 and 103 against patents claiming human genes.

**d. Finally, can you talk about the merits of providing patent protection for the isolation of certain genes and the use of the isolated genes in personalized medicine? No one is advocating for patent protection for genes in their pure form. No one. But, what is the value to the patient in encouraging companies and researchers to isolate genes and use that isolation to provide new and innovative treatments? How does that type of incentive ultimately benefit patients?**

**Answer:** The exclusivity conveyed in a patent grant provides a needed incentive for investing in the research and development of genetic diagnostic tests and personalized medicines. Any available patent protection would be based on the scope of the claims that encompass inventive aspects of these technologies. Without patent protection, the

[22] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013).

companies with the expertise necessary for developing these technologies could have insufficient incentives to make the enormous time and resource investments—particularly given the high level of scientific and regulatory uncertainty associated with that development.

Personalized medicines allow the tailoring of medical treatments to the individual characteristics of patients. This tailoring allows physicians to target specific treatments to patient subpopulations who will benefit, sparing expense and side effects for broader patient populations who would not benefit.

Encouraging and incentivizing the use of isolated genes in new diagnostics and treatments can benefit patients by:

- Improving the ability to detect and prevent disease, allowing for earlier determination of whether treatment is needed, and preventing use of unneeded treatments;
- Identifying more quickly the most optimal therapy for a patient;
- Helping to avoid adverse drug reactions and reducing side effects;
- Improving quality of life and treatment options for patients; and
- Providing improved methods of administration.

It is important to recognize that patents drive biopharmaceutical companies to innovate by providing a degree of assurance that companies can obtain a return on an otherwise risky and costly R&D investment. As a result, multiple biopharmaceutical companies often simultaneously research and develop potential new medicines in order to be the first to launch in a new therapeutic class—all the while recognizing that they might be second or third (or fail altogether). This race to market fuels competition among pharmaceutical products—not only to differentiate based on price, but also to address remaining unmet need—which increases treatment options for patients. Moreover, patent protections do not prevent competition from non-identical drugs, but rather encourage it while also fueling innovation to address unmet patient needs.