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July 2, 2019

The Honorable Lindsey Graham
Chairman
Committee on the Judiciary
U.S. Senate
Washington, D.C. 20510

Re: Answers to Questions for the Record from Senator Hirono

Dear Chairman Graham:

I attach answers to the questions for the record from Senator Hirono with respect to the hearing held on June 11, 2019 on The State of Patent Eligibility in America: Part III.

Thank you for your attention to this important issue, which we believe will have a profound impact on innovation and ensuring the United States' leadership in science, medicine and technology, and for considering the views of stakeholders. Please let us know if we can further assist your efforts as this process moves forward.

Very truly yours,

Gonzalo Merino, Ph.D., J.D.
Vice President and Chief Intellectual Property Counsel
Regeneron Pharmaceuticals, Inc.

Encl.

**Questions for the Record for Gonzalo Merino**
**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: I agree with Judges Lourie and Newman. The courts' Section 101 decisions have created a high degree of uncertainty for Regeneron and the biotech industry as a whole. This uncertainty is negatively affecting investment in innovative technologies, particularly in the areas of diagnostics and precision medicine, and may ultimately harm patients in need of new forms of treatment. It is within Congress's purview to reform Section 101 through legislation, taking into account and balancing various policy concerns.

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: The nature of technology in the biotech industry is perpetually changing due to continued innovation. It is therefore critical that the terms "technological arts" and "technology" are construed broadly, and in favor of patent eligibility, so as to capture not just existing technologies, but also future development and innovations, including those that we cannot predict today.

   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?**

      Answer: Regeneron routinely prosecutes patent applications in jurisdictions such as the European Union and China that have "technology" requirements in their patent eligibility statutes. In Regeneron's experience, the patent eligibility statutes in these jurisdictions work. We have not experienced the same degree of uncertainty surrounding patent eligibility in these jurisdictions as we have in the United States.

**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: I understand that this question may be of great interest to those in the financial sector. As Regeneron is a biotech company and my experience is primarily in the biotech area, I leave it to others with more expertise in the relevant field to comment.

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

Answer: I do not have any specific recommended changes regarding the "field of technology" requirement in the draft, but would like to reiterate that the phrase should be construed broadly, and in favor of patent eligibility, to take into account the perpetually evolving nature of innovation.

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: None that I am aware of.

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?**

Answer: Regeneron is a biotech company. While we rely on high tech innovations, I cannot speak to the specific complaints on Section 112 that are coming from the high tech space.

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

Answer: I believe that the proposed changes to Section 112 are necessary to ensure that patents are not overly broad and that they serve their constitutional mandate to promote the progress of science. Due to the imprecise nature of functional language, claims containing such language may be interpreted so broadly so as to go well beyond what was actually invented. Such broad patents stymie entire fields of innovation rather than promote it. In the field of medical innovation, such patents might prevent the development of life-altering treatments for the benefit of patients. The proposed changes to Section 112 will help ensure that functional language is limited to what was actually invented.

I leave it to those in the high tech space to comment on whether the proposed changes adequately address complaints in that field.

**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: I do not believe the proposed changes will make it too easy for competitors to design around patent claims that use functional language.

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: No, I do not believe that the proposed changes to Section 101 were intended to do away with the doctrine of obviousness-type double patenting. Obviousness-type double patenting remains grounded in Sections 102 and 103, and those sections will continue to address any concerns related to this doctrine.

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: I do not believe Due Process or Takings implications are raised by the proposed draft reform of Section 101. The patent law is constantly evolving, both as the result of legislation (for example, the America Invents Act) and through case law. Many of these changes have been applied retroactively and have not raised Due Process Clause or Takings Clause issues. The proposed draft is intended to restore certainty to the Section 101 analysis. This certainty has been lost due to the case law of the last several years.