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

To the United States Senate, Committee on the Judiciary
Subcommittee on Intellectual Property

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

June 11, 2019, 2:30 PM, Dirksen Senate Office Building, Room 226

Good Afternoon, Chairman Tillis and Ranking Member Coons, and Members of the Subcommittee. On behalf of Regeneron Pharmaceuticals, thank you for the opportunity to testify.

At Regeneron, I serve as Vice President and Chief Intellectual Property Counsel. In this capacity, I lead a team of 33 experienced patent attorneys and support staff.

Regeneron's focus is simple: it's about the science and the patients. We were founded by a two physician scientists. We have been routinely selected as one of the most innovative companies in the world by Forbes and six out of the last eight years, as the top employer in the biotech by Science Magazine.

We have seven FDA-approved therapeutics, three of which have received breakthrough designation. We also have used our rapid response technologies for global good, partnering with the U.S. government to develop treatments for emerging infectious diseases including Ebola, Influenza, and MERS.

Significantly, since 2011 we have never raised the price on any drug for which we control pricing.

The Dilemma

The current dilemma we face, and the reason we are here today, is that the current law on patent eligible subject matter is having a real-world effect on our ability to address the needs of patients.

Although we have made tremendous strides in treating patients with serious diseases, there remain many under-served medical conditions, such as Alzheimer's and rare diseases. Further, as anyone who has had a family member with such an illness knows, we need treatments *as quickly as possible*.

To address these concerns, in 2014, Regeneron launched the Regeneron Genetics Center.

The Genetics Center is carrying out one of, if not the, largest genetics sequencing efforts in the world. We have already sequenced over half a million consented individuals.

Our expertise in genetics allows us to make tremendous advances in identifying new therapeutic indications, build better-informed clinical trials, shorten developmental timelines and advance precision medicine efforts.

For example, we have already identified genetic signatures that can predict the response of patients to certain drugs. If we invest the substantial human and financial capital necessary to understand, validate and obtain clinical approval for these important discoveries, we could deliver treatment in a safer and more effective manner, and likely decrease drug spending. This can make all the difference to patients and to the public.

Point 1

Unfortunately, these innovations are being attacked under section 101. The inability to obtain patent protection will disincentivize investment and collaboration, and limit the sharing of scientific information to the detriment of patients and the scientific community.

To be clear, we are *not* talking about patenting genes. We are talking about the ground-breaking discoveries from our analysis of genetic data and the application of such for the benefit of patients.

We have filed 36 patent applications on our genetic innovations. Some have already been rejected and we anticipate that *nearly all* of our applications will be rejected under section 101. This mirrors what we see in general involving applications in these areas- we refer to the supplemental materials detailing our analysis submitted with this testimony.

Even if we are successful in overcoming these rejections, we would still face absolute uncertainty as the courts have flatly rejected the Patent Office guidelines on patent eligible subject matter.

Point 2

The time to correct the problems with subject matter eligibility is right now if the United States is to maintain its position as the global leader in biotech innovation.

The disparity in subject matter eligibility requirements between the US and other countries is stunning. Indeed, our applications that were rejected in the US have not been rejected elsewhere, including Europe and China.

Further, we strongly believe that the time is now to make a substantial investment in genetics- that the era of genetics playing a critical role in serving the needs of patients has arrived.

If the United States is to maintain its leadership position, the government also needs to act now. Science is exploding with possibilities and section 101 should not get in the way.

Point 3

As a final point, advances in genetics are as reliant on innovation in biotech as in hi-tech. Indeed, the biggest bottleneck in genetics is storing, accessing and analyzing the massive amounts of data.

Accordingly, although there may be disparity on section 101 reform between bio-tech and hi-tech, an amicable fix is critical to advancement in this area.

We believe the current legislation addresses the concerns of biotech by amending section 101. We also believe, and sincerely hope, that it addresses the concerns of hi-tech relating to frivolous lawsuits by amending sections 100 and 112.

In closing, we believe your legislation will have a profound impact on innovation and ensuring the United States' leadership in science, medicine and technology. We understand that there is a need to balance patents and the free exchange of information

We also are eager to continue discussion and engage stakeholders who have expressed concerns about this legislation. On behalf of Regeneron and especially those patients depending on us, thank you for your leadership and we look forward to our continued dialogue.