Hearing on

“The State of Patent Eligibility in America: Part III”

U.S. Senate Committee on the Judiciary,
Subcommittee on Intellectual Property

June 11, 2019

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Good morning Chairman Tillis, Ranking Member Coons, and Members of the Subcommittee. Thank you for inviting me to testify today on the critical need to reform Section 101 of the patent law.

My name is Laurie Hill and I am the Vice President for Intellectual Property at Genentech, Inc., a member of the Roche Group, a U.S. company that has been investing in American innovation and delivering on the promise of biotechnology for over 40 years. At Genentech, we make medicines to treat people living with serious and life-threatening diseases. We are transforming the treatment of serious medical conditions, including cancer, auto-immune conditions, and infectious diseases. Last year alone, 127 million patients worldwide benefited from our medicines.

I. Introduction to Genentech

Genentech, the first biotechnology company, developed the first recombinant therapeutic human proteins approved by the U.S. Food and Drug Administration (FDA) starting in the 1980s, such as recombinant human growth hormone. Genentech also pioneered the use of revolutionary antibodies to treat various types of cancer, such as HERCEPTIN® for HER2-positive breast cancer, RITUXAN® for Chronic Lymphocytic Leukemia, Rheumatoid Arthritis, among other indications, and AVASTIN® for certain cancers, including colorectal, glioblastoma, and ovarian cancer. More recently, Genentech received approval for the first

antibody treatment for Hemophilia A.[1] Today, Genentech has 40 medicines on the market and a promising development pipeline.[2]

These medicines represent just the beginning of our journey in finding breakthrough therapies—and indeed, cures—through serial innovations that build on what we know to push the boundaries of scientific advancement and treatment.

We are also a science company dedicated to pursuing revolutionary medical breakthroughs for the 21st Century. As of January 2019, we have 67 new investigational medicines and 74 additional indications for existing medicines in clinical development. Our development pipeline covers a broad range of diseases and highly innovative technologies, including Alzheimer's, Parkinson's, and autism. As of March 2019, Genentech has received 26 Breakthrough Therapy Designations from the FDA. Our commitment to robust R&D investment is unparalleled: we invest approximately $11 billion per year in R&D, more than any other healthcare company in the world.

Genentech, Inc., a member of the Roche Group, is an American company headquartered in South San Francisco and has 15,000 employees in the U.S. dedicated to making life-saving medicine a reality. We have approximately 2,200 research employees, including approximately 1,800 scientists and 110 post-doctoral researchers. Several of our scientists are members of the National Academy of Sciences.[3] Last year, our scientists published more than 350 papers in

[1] *See* Alex Keown, *Genentech's Hemlibra Approved for Hemophilia A Patients Without Factor VIII Inhibitors*, BioSpace (Oct. 5, 2018), *available at* https://www.biospace.com/article/genentech-s-hemlibra-approved-for-hemophilia-a-patients-without-factor-viii-inhibitors/.
[2] *See* Genentech, *Our Medicines*, https://www.gene.com/patients/medicines (last visited June 10, 2019).
[3] *See GRED: A World of Discovery*, Genentech, https://www.gene.com/careers/professional-areas/research-early-development (last visited June 10, 2019).

leading peer-reviewed scientific journals, including *Nature, Science,* and *Cell*. We have been awarded more breakthrough therapy designations by the FDA than any other company.[4]

Every day, our teams work to solve some of the hardest biomedical problems in the history of humankind, always with the goal of putting patients first. However, the life-changing work of our scientists depends on a stable and predictable patent system that rewards innovation. In short, it depends on amendments to Section 101 of the patent law along the lines of the legislation drafted by Senators Tillis and Coons that is before this Subcommittee.

II. Section 101 and the Importance of Patent Protection

None of the work that Genentech has done and continues to do would be possible without strong patent protection. The present uncertainty surrounding Section 101 threatens to disrupt development of a wide range of important medicines, diagnostics, treatments, and other innovations that benefit society. As biotechnology pushes the bounds of medical innovation in pursuit of better treatments, companies need to know that when they develop a method of treatment that meets the other requirements of the patent law—novelty, non-obviousness, and enablement—it will not be disqualified from patent protection because Section 101 has been conscripted to a bounded view of innovation.

The persistent medical challenges of the 21st Century require a modernized U.S. patent system: a system that fosters American innovation, encourages the development of products that are closer to nature, and enables individual-based treatments for optimal care and outcomes. Yet, researching and developing a new medicine can cost billions of dollars and biotechnology companies invest substantial sums of private capital to make their innovations possible.

[4] Breakthrough Therapy designation is a process administered by the U.S. Food and Drug Administration designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing available therapies. *See Breakthrough Therapy*, FDA, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (updated Jan. 4, 2018).

According to a 2018 report from the Tufts Center for the Study of Drug Development, the estimated cost of bringing a medicine to market at present is $2.6 billion (compared with $802 million in 2003).[5] The estimated time it takes a medicine to travel from R&D to market is approximately 12 years.[6] For every success, there are thousands of failures. With the significant investment required to bring new medicines or treatments to the market, companies need to know that patent protection is available to recoup their investments. But recouping investment goes beyond a single product. We have also had some high-profile failures, which is part of the process. Nonetheless, we are always willing to invest in new breakthroughs, even if they end up being unsuccessful.

A stable patent system is critical to developing breakthrough medicines. The alternative will inevitably steer investment away from ground-breaking and novel medicines and therapies as well as potentially slow the progress of science as companies will start to keep more and more of their work a trade secret. Unlike patents, trade secrets are only valuable if the innovation is not disclosed to the public, which is detrimental to society as a whole because the work is not available for others to learn from and improve upon.

The type of investment like the kind Genentech is making depends on a stable U.S. patent system that rewards innovation and risk-taking. Biotechnology companies pursuing innovative medicines are willing to make the significant dedication of resources necessary to develop new products, but given the considerable investments of time, resources, and human power to develop a potential therapy, they need to be assured that the patent system will offer protections for their

[5] *See* https://www.igeahub.com/2018/08/28/evaluation-of-clinical-trial-costs-and-barriers-to-drug-development/.

[6] *See* Ingrid Torjesen, *Drug development: the journey of a medicine from lab to shelf*, The Pharmaceutical Journal (May 12, 2015), *available at* https://www.pharmaceutical-journal.com/test-tomorrows-pharmacist/tomorrows-pharmacist/drug-development-the-journey-of-a-medicine-from-lab-to-shelf/20068196.article.

innovations. Ambiguous or shifting rules on patent protection can be nearly as damaging as providing no protection at all.

III. Opportunities for Reforming Section 101

Today's Section 101 is a barrier that prevents the protection of the next generation of life-changing medicines and diagnostics. It is a problem that needs to be solved now.

In their original form, the judicially created exceptions to Section 101—abstract ideas, laws of nature, and natural phenomenon—were relatively unobjectionable, concerning basic scientific principles like gravity, a mathematic equation or a purely mental process. We agree that no one should be able to patent gravity, a mathematical equation, or a purely mental process.

However, the heart of the current patent eligibility issues stems from a trio of cases beginning in 2012 in which the Supreme Court created tremendous uncertainty in the way that the judicially created exceptions are applied. In these cases, the Supreme Court expanded the judicial exceptions in a manner that lacks clarity and consistency. For instance, in the so-called *Alice-Mayo* two step test, after saying that a claim must "do significantly more than simply describe" natural correlations, the Supreme Court "test" then said: "To put the matter *more precisely*, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?"[7] Such a "precise" test has proven to be anything but precise and has created tremendous uncertainty in the patent eligibility laws and regulations, calling into question whether medicines that are deliberately close to nature or whether medical therapies using AI might be excluded from patent eligibility.

[7] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77 (2012).

As drafted, Section 101 was never designed to be anything more than a coarse filter. It acts like the open top of a funnel, which channels the patent system in certain directions but leaves it to the other requirements of the Patent Act to substantially narrow the scope of what can be patented. However, since 2012, we have experienced regular rejections from the U.S. Patent and Trademark Office (USPTO) on Section 101 grounds, even when our inventions pass all other sections of the Patent Act and clearly merit protection. This includes cancer medicine using proteins from the patient's body and curated bacteria isolated from the patient's microbiome for treatment of Irritable Bowel Syndrome. As the Vice President of Intellectual Property, I have had to advise our company that there are innovations that are not patentable in the United States, while they remain patentable outside the United States.

As we previously stated, we believe the U.S. patent system needs to provide stability and predictability, protect innovations, and incentivize American investment in revolutionary treatments. The mantle now rests with Congress to clarify Section 101 so that companies like Genentech can invest in the future of medicine with confidence. To that end, we appreciate the diligent work by Members of this Subcommittee and their staffs, in particular, Senators Tillis and Coons, for their recognition of the Section 101 problem and their dedication to providing a solution. We believe that legislation along these lines is essential to promote stability and allow inventors to reap the fruits of their labor through patent protection, as the founding fathers envisioned.

Strengths of the New Proposal

Now is the time for Congress to correct Section 101. The USPTO is doing all it can through examiner guidance to bring some clarity to Section 101, but, like the lower courts, it is

still constrained by judicially created standards. It is up to Congress to create certainty in the patent eligibility standards and such action must be taken without delay.

While we understand that this is just the first draft and is subject to additional revision, we believe the draft is a strong step in the right direction. We look forward to working with the Senators, their staff, and Members of this Subcommittee on further discussing and refining the proposal. Genentech supports several key elements of the Senators' draft proposal:

Patent-Eligible Subject Matter: This proposal maintains the existing statutory categories of patent-eligible subject matter: "process, machine, manufacture, or composition of matter." These are critical tenants of the Patent Act that must be preserved. They have known definitions among patent practitioners and USPTO examiners. Thus, maintaining the existing statutory categories creates much-needed stability.

Common-Sense Eligibility Test: The legislation eliminates existing judicial precedent and establishes a single, common-sense test of eligibility: whether the invention provides "specific and practical utility in any field of technology through human intervention." Although we are continuing to analyze this language, we believe it is an improvement upon prior iterations.

Patent Claims as a Whole: The draft requires the courts and the USPTO to consider patent claims as a whole, without discounting or disregarding claim limitations. This ensures that the standards will remain consistent, avoiding the potential that courts effectively reintroduce the prior Supreme Court *Alice-Mayo* two-step test that created the existing patent eligibility uncertainty.

Patent Act Outside of Section 101: The draft would construe the provisions of Section 101 in favor of eligibility, thereby maintaining Section 101 as a coarse filter and correctly

leaving the majority of the patentability analysis to the other sections of the Patent Act, which play the predominant role in "weeding out bad patents."

Section 112: the draft would amend Section 112, the written description section of the Patent Act. We are continuing to review this section, and we appreciate the open invitation by the Senators and their staff to continue to discuss it and other aspects of the legislation.

IV. Proposed Reforms advance science and are for the benefit of patients

We would like to emphasize that Genentech does not and is not interested in patenting an individual's genes. In fact, the human genome has already been sequenced and is in the public domain. It is no longer eligible for patent. We want medical breakthroughs that simulate processes found in nature so that we can have treatments that are tailored for each individual, not a blunt instrument for all. Personalized medicine relies on the ability to identify the right medicine for the right patient, and current patent system caselaw frustrates this research by foreclosing the patentability of advances in diagnostic testing. This decreases the likelihood of research that will lead to earlier detection, personalized treatment, and better health outcomes.

There are aspects of learning and advancing the science of medical breakthroughs that can only occur when a medicine is on the market. For example, HERCEPTIN represents a revolutionary shift in the treatment of breast cancer over the last 20 years, providing not only a potential cure for some populations for one of the deadliest forms of breast cancer, but also forming the foundation for a series of follow-on advancements that have allowed us to develop new breakthrough therapies.[8] HERCEPTIN was the first treatment for HER2-positive metastatic breast cancer, an extremely aggressive form of cancer with high recurrence and low survival

[8] Herceptinl® (transtuzumab). Additional information available at: www.herceptin.com

rates. Before, 50% of all patients diagnosed with this disease died within two years. HERCEPTIN has changed the natural progression of that disease. With the combination of a second Genentech-developed medicine, PERJETA, 80% of patients are alive after two years.[9] But the story does not end there: after thousands and thousands of patient trials, costing hundreds of millions of dollars, we learned that HERCEPTIN can have curative benefits for women with early-stage breast cancer, helping them to defeat this disease once and for all. We further iterated on these breakthroughs to develop KADCYLA, which uses the antibody component of HERCEPTIN but adds on a potent chemical toxin delivered directly to the tumor.[10] KADCYLA reduces the risk of cancer recurrence in a particular high-risk group by half compared to HERCEPTIN and was granted a Breakthrough Therapy Designation by the FDA during its development.

The Future of Medicine Brings the Science Closer to Nature

Some of the most important developments in medicine have and will come from attempts to create treatments that are deliberately closer to nature or that harness natural processes such as the body's own immune response to treat or prevent disease.

Genentech was a pioneer in the use of recombinant DNA technology to create synthetic versions of human proteins, including a human growth hormone product to treat children with growth hormone deficiency. This replaced the process of extracting growth hormone from human cadavers and was highly beneficial to patients precisely because the goal was to mimic naturally-occurring human growth hormone.

[9] Perjeta® (pertuzumab) + Herceptin® (transtuzumab). Additional information available at: www.perjeta.com
[10] Kadcyla® (ado-transtuzumab emtansine). Additioal information available at: www.kadcyla.com

Another example is our work involving Factor VIII, a protein that plays an essential role in blood clotting. In the human body, Factor VIII is secreted into the bloodstream by certain cells found in the liver, kidneys, spleen, and lymph nodes. The protein is missing or inactive in patients with Hemophilia A, a condition that can be marked by spontaneous and uncontrolled internal bleeding. If proper measures are not taken promptly, the bleeding can cause crippling deformities or even death. Through extensive research and development, HEMLIBRA was developed to mimic the missing or faulty Factor VIII in Hemophilia A patients by bridging pieces of the blood clotting pathway, imitating the natural process.[11] HEMLIBRA received Breakthrough Therapy designation from the FDA in 2018. For patients, HEMLIBRA meant replacing daily infusion treatments and hospitalizations with one medicine administered subcutaneously weekly at home. And for kids struggling with Hemophilia A, HEMLIBRA also meant the opportunity to be more normal—to walk and play with the other kids—instead of the risk of being confined to a wheelchair. This is real-life evidence that bringing medicine closer to nature can have a positive and life-changing impact on our patients.

Genentech has also been a leader in the use of therapeutic monoclonal antibodies to treat a variety of conditions, including various types of cancer. Although created in a lab, these antibodies are generally humanized or fully human, which helps reduce any negative immune response by making the antibodies more closely resemble the types of antibodies found naturally in the body.

In contrast with conventional cancer therapeutics that often involve introduction of harsh substances that affect every part of the body, Genentech has developed cutting-edge cancer therapies designed to harness the body's own immune system. Our TECENTRIQ antibody

[11] Hemlibra® (emicizumab-kxwh). Additional information available at: www.hemlibra.com

medicine harnesses the body's immune system to attack the tumor.[12] The medicine of the future is a totally personalized medicine, tailored to each patient's cancer. Our personalized cancer therapeutics that are currently in development are a promising form of treatment that use nucleic acid sequences encoding a portion of a patient's own tumor to stimulate the patient's immune system to fight the tumor. These more natural treatments have the potential to be far more effective and far less harmful—leading to more positive, long-lasting health outcomes for patients. Unfortunately, under the current Section 101 regime, such medicines may not be patent-eligible subject matter.

The microbiome is another emerging area in biology and medicine. Only in the last several years has it become clear that the complex collections of bacteria found on our skin, in our gut, and elsewhere can play a vital role in our physical health and our reaction to certain medicines. Our scientists are researching medicines based on gut microbiome bacteria taken from patients which can then be carefully selected, and used to create medicines for patients—for example, for the treatment of inflammatory bowel disease. And again, because of the Supreme Court's expansion of the current Section 101 regime, the patent eligibility of such medicines is at risk because they are closer to nature. Section 101 was never intended as a means to foreclose patentability and limit protections to develop these types of promising new medicines. Instead, it was designed to encourage breakthrough science just as Genentech is doing, often in partnership with other cutting-edge life sciences companies.

A robust patent system incentivizes the investment in risky innovation—including that in medicine and healthcare. In other words, the patent system—and an amended Section 101—

[12] Tecentriq® (atezolizumab). Additional information available at: www.tecentriq.com

needs to work not only for today's treatments, but for future innovations that have the potential to save lives and improve patient outcomes.

The Future of Medicine Utilizes Artificial Intelligence

Genentech firmly believes that the possibilities of Artificial Intelligence (AI) combined with biotechnology are endless. Thus, it is important to ensure a stable and certain environment for investment in the future of innovation, which is likely to include more and more innovation involving AI.

One important transformation on the horizon is the rise of bioinformatics, in which biotechnology and AI are brought together to inform all stages of personalized medicine, including medicine development, diagnostic development, and patient treatment.[13] For example, the personalized cancer treatment regimens discussed above use AI to decode information necessary to develop the medicine. As mentioned, this promising form of treatment uses nucleic acid sequences to encode a portion of a patient's own tumor to create a personalized medicine to stimulate the immune system to fight the tumor. The development of such treatment methods can involve sophisticated algorithms that are used to carefully select portions of a patient's tumor protein. Nucleic acid sequences encoding those fragments are then administered to the patient. Put simply, these treatments are more targeted, sophisticated, and effective—and they are the future of innovative breakthrough medicine. Under the current Section 101 law, bioinformatics

[13] See *Artificial Intelligence: Will It Change the Way Drugs are Discovered?,* The Pharmaceutical Journal, 7 December 2017, available at www.pharmaceutical-journal.com/news-and-analysis/features/artificial-intelligence-will-it-change-the-way-drugs-arediscovered/20204085.article; Bertalan Mesko (2017) The role of artificial intelligence in precision medicine, Expert Review of Precision Medicine and Drug Development, 2:5, 239-241, Available at https://doi.org/10.1080/23808993.2017.1380516; *Artificial Intelligence In Clinical Development and Regulatory Affairs*; The Regulatory Rapporteur – Vol 15, No 10, October 2018; Available at www.topra.org

and AI face patent eligibility challenges under the judge-made exceptions, which often characterize these inventions as unpatentable abstract ideas or mental processes. That is why it is absolutely critical that Section 101 be clarified to incentivize investment in this area.

In another area, AI technology is used to inform clinical trial design, leading to innovative trial designs and analyses that promise to reduce the cost of clinical trials and to expedite product approvals.[14]

Data acquired in everyday clinical practice can also provide valuable insights drawn from information about a patient's lifestyle, disease biology, and treatment outcomes. Thanks to AI and data science, we are able to harness and aggregate real-world data as a powerful complement to traditional clinical trials. Genentech believes that data representative of real-world patient populations is required to improve clinical outcomes for patients. We aspire to create a path for more representative patient populations in clinical research, using the data capabilities we are only starting to develop. Such tools and research methods are only the beginning of our journey toward the future of personalized healthcare. Technologies like next-generation sequencing can map out an individual's full genetic makeup, tumor mutations, and other defining molecular features to find the most appropriate treatment. In addition, liquid (or non-blood fluid) biopsies

[14] Roche, *Medical software and the value of digital health*, https://www.roche.com/about/business/diagnostics/value-of-digital-health.htm (last visited June 10, 2019); Lee & Park, *Personalizing the Future of Healthcare* (May 31, 2018), https://www.gene.com/stories/personalizing-the-future-of-healthcare; Arnaub Chatterjee et al., McKinsey & Co., *Real-world evidence: Driving a new drug-development paradigm in oncology* (July 2018), https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/real-world-evidence-driving-a-new-drug-development-paradigm-in-oncology; Elia Stupke, Health Catalyst White Paper, *Extended Real-World Data: The Life Science Industry's Number One Asset* (2019), https://www.healthcatalyst.com/insights/real-world-data-chief-driver-drug-development; Jackie Hunter, Drug Target Review, *How artificial intelligence is the future of pharma* (Dec. 5, 2016), https://www.drugtargetreview.com/article/15400/artificial-intelligence-drug-discovery/.

may allow us to non-invasively track how a cancer evolves over time and adjust treatment accordingly.

Such innovation holds great promise for the future of medicine and the future of American innovation. Our goal is to ensure that the screening, diagnosis, treatment, and prevention of diseases will more quickly and effectively transform the lives of all people—enabling the right treatment for the right patient at the right time. Bioinformatics will be an integral, cost-effective tool in making this process possible.

However, to achieve the level of quality and precision necessary to make bioinformatics commonplace technology available for patients, we must make significant investment at the outset. Unlike other software that can be launched at an early stage and developed, corrected, and extended to an appropriate performance level while in the marketplace through a sometimes endless series of updates, use of bioinformatics to inform serious patient treatment decisions or to design personalized medicines requires extreme precision and more upfront investment from the beginning of the process so that it can perform with stability, accuracy, and predictability at the time of launch.

In order to secure such investment, there must be no question that such innovations are patent eligible. As noted above, any alternative regime may force companies seeking to advance this field to protect their intellectual property through trade secrets, which will inevitably stymie the growth of scientific and medical knowledge because it does not result in the same public disclosure and enrichment of the sciences as patents.

V. This Legislation is a Step Forward for the Advancement of Medical Innovation

In, sum, while we recognize there are many issues and stakeholders to consider in enacting legislation on Section 101, such action is absolutely vital to the future of medicine.

Given the great cost to develop a medicine, and the clear public health need of patients being addressed, clarity over what is patent eligible at the outset is essential. The present uncertainty surrounding Section 101 threatens to disrupt the development of a wide range of important medicines, diagnostics, treatments, and other innovations that benefit society.

Genentech strives to push the bounds of medical innovation in pursuit of better treatments that bring the science closer to nature and use AI to develop personalized treatments. But we need to know that when we develop a method of treatment that is novel, non-obvious, and enabled, that it will not be disqualified from patent protection based on an overly exclusionary and misguided judicial interpretation of Section 101 that undermines America's reputation as the global leader in innovation and scientific progress. We strongly urge you to act now to clarify the law of patent eligibility and reward true innovation through the patent system as our forefathers intended.