Genentech
A Member of the Roche Group

LEGAL DEPARTMENT

October 15, 2021
The Honorable Drew Hirshfeld
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

*Via www.regulations.gov*

RE: Docket No. PTO-P-2021-0032, Request for Comments Regarding the U.S. Patent and Trademark Office's Patent Eligibility Jurisprudence Study

Dear Mr. Hirshfeld:

Genentech, Inc., a member of the Roche group of companies, is a U.S. company that has been investing in American innovation and delivering on the promise of biotechnology for 45 years. As the first biotechnology company, with a long history of solving the toughest medical problems,[1] Genentech is uniquely poised to tackle the hardest medical challenges of the future. We are dedicated to following the science, and in doing so, creating medicines and treatments for people living with serious and life-threatening diseases. We are transforming the treatment of serious medical conditions, including cancer, autoimmune conditions, and infectious diseases.

Today, Genentech has over 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 innovations that build on what we know to push the boundaries of scientific advancement and treatment. Every day, our teams work to solve some of the hardest biomedical problems, always with the goal of putting patients first. The life-changing work of our scientists, depends on a stable and predictable intellectual property system that protects innovation and thereby fosters the next generation of medicines.

Genentech has been an active participant, supporter, and stakeholder of the U.S. Patent and Trademark Office's ("USPTO") as patent owners throughout Genentech's 45-year history. We have witnessed firsthand the concerning impacts of the current patent eligibility (or "Section

[1] Genentech 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. *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] Genentech, Inc., Company Information, http://www.gene.com/media/company-information.

101") jurisprudence especially for the biotechnology industry.[3] Therefore, we are grateful for the opportunity to provide our thoughts and perspectives to the USPTO on an issue of such importance to Genentech and the future of medicine.

## Section I —Observations and Experiences

**The following response is to questions 1, 2, and 3.**

We appreciate the USPTO's continued dedication to studying patent eligibility jurisprudence, both now and through the USPTO's past initiatives to clarify patent eligibility guidance for examiners and the public. We believe the USPTO's recent patent eligibility guidance is a step in the right direction, but unfortunately it is still constrained by existing case law that lacks clarity and predictability and unduly restricts U.S. patent eligibility jurisprudence overall and in the life sciences area in particular. Since 2012, we have experienced impacts resulting from ambiguity in the state of patent eligibility jurisprudence, including regular rejections from the USPTO on Section 101 grounds, even when our inventions pass all other sections of the Patent Act and clearly merit protection. Section 101 jurisprudence impacts all aspects of our patent-related activities, including patentability evaluations, patent filing decisions and strategy, patent prosecution and counseling, portfolio evaluation, transactions, litigation assessment, and support of our research and development organizations. And the current trajectory of Section 101 case law has only served to expand the confusion of what is patent eligible subject matter.[4] Our attorneys have had to advise our scientists and business colleagues that there are some innovations that are simply not patentable in the United States, while they remain patentable outside the United States.

The cost of researching and developing a new medicine is quite substantial. At Genentech and Roche, our commitment to robust R&D investment is unparalleled: last year alone, we invested approximately $12 billion in R&D, more than any other healthcare company in the world. However, the estimated cost of bringing just one medicine to market is significant and the time is lengthy: according to a 2018 report from the Tufts Center for the Study of Drug Development it costs approximately $2.6 billion (compared with $802 million in 2003) to bring one medicine to market.[5] The estimated time it takes a medicine to move from R&D to market is approximately 12 years, including several years of research and clinical studies involving hundreds or thousands

[3] As noted in the Federal Register Notice per the Government's briefs in *HP Inc. v. Berkheimer and Hikma Pharms. USA Inc. v. Vanda Pharms. Inc.*: "the [Supreme] Court's recent decisions have strayed from earlier precedent and have fostered uncertainty regarding the patent eligibility standards."

[4] *See ChargePoint v. SemaConnect,* 920 F.3d 759 (Fed. Cir. 2019) (deeming an electric car charger a patent ineligible abstract idea; *see Chamberlain Group v. Techtronic Industries,* No. 18-2103 (Fed. Cir. 2019) (deeming a garage door opener a patent-ineligible abstract idea); *see Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC,* 1347 (Fed. Cir. 2020) (holding that a method for turning driveshaft liners that improved damping capabilities was directed to a law of nature and therefore patent ineligible).

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

of patients.[6] And for every success, there are thousands of failures.[7] Fewer than 12% of medicines make it from the start of human clinical trials to FDA approval.[8]

Genentech is willing to invest in new breakthroughs, even if they end up being unsuccessful since we recognize that failures are part of the process. However, with the high rate of failure and 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 and further future research and development. Ambiguous or shifting rules on patent protection can be nearly as damaging as providing no protection at all. 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 as trade secrets. 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.

As detailed in the sections below, we believe that the greatest impacts of the current state of patent eligibility will be to the future of medicine, particularly: medicine that is closer to nature; personalized medicine and diagnostics; and bioinformatics inventions that exist at the interface of biomedicine and artificial intelligence.

***Future of medicine: therapeutics that are closer to nature***

Some of the most important developments in medicine have and will come from attempts to create biopharmaceutical 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. For example, 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. Another example is our work involving Factor VIII, a protein that plays an essential role in blood clotting. The protein is missing or inactive in patients with Hemophilia A, a condition that can be marked by spontaneous and uncontrolled internal bleeding. 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.[9] 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 to fight the cancer. Genentech has also been a leader in the use of therapeutic

[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.
[7] *See* DiMasi JA, Grabowski HG Hansen RA, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,* Journal of Health Economics 47:20-33 (2016).
[8] PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicine, available at* http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.
[9] Hemlibra® (emicizumab-kxwh). Additional information available at: www.hemlibra.com.

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 the likelihood of negative immune response by making the antibodies more closely resemble the types of antibodies found naturally in the body.

However, the rapid expansion of the judicial exceptions since *Mayo*, *Myriad* and *Alice* raises serious concerns with respect to the emerging technologies-including those deliberately engineered to be closer to nature- that are the future of medicine. For example, 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. Because they are tailored to a specific patient, these more natural treatments have the potential to be more effective and less harmful than conventional therapeutics, leading to more positive, long-lasting health outcomes for patients. Yet under the current patent eligibility jurisprudence, these revolutionary therapeutics may not be patent eligible.

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. "Obtaining patent protection is essential for the development of [microbiome] therapeutics," yet the ability to do so has been affected profoundly by the state of patent eligibility jurisprudence simply because these medicines are derived from natural products.[10]

The U.S. patent system has historically been a robust patent system, designed to incentivize the investment in risky innovation. In other words, the patent system—and Section 101—needs to work not only for today's treatments, but for future innovations that have the potential to save lives and improve patient outcomes. But at present, the state of the patent eligibility law threatens to foreclose whole areas of promising therapies, including those deliberately engineered to be closer to nature.

We appreciate the efforts of the USPTO in promulgating the 2019 Revised Patent Subject Matter Eligibility Guidance, but the USPTO has little latitude to change the landscape regarding certain life sciences therapeutics inventions, limited by existing Supreme Court precedent that has effectively rendered certain types of life sciences invention ineligible.

***Future of medicine: personalized medicine (also known as precision medicine)***

Personalized medicine holds great promise for the future of medicine and the future of American innovation. When we discuss personalized medicine here, we refer to at least two concepts:

[10] Mark J. FitzGerald and Erik J. Spek, *Microbiome therapeutics and patent protection,* Nature Biotechnology, Vol. 38 at 808 (Jul. 2020), *available at* https://doi.org/10.1038/s41587-020-0579-z ( "After the *Mayo* and *Myriad* decisions, patent prosecution of composition claims of natural products came to a halt…".).

medicine that relies on genetic or other diagnostic testing and/or other patient health information to optimize treatment for a particular patient, and medicines where the medicine itself is personalized for each patient (as with the personalized cancer therapeutics discussed above). Our goal is to ensure that the screening, diagnosis, treatment, disease management 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. Such personalized treatments guide health care decisions toward "the most effective treatment for a given patient and, thus, improve care quality while reducing the need for unnecessary diagnostic testing and therapies."[11]

Physicians, clinicians, and researchers have long recognized that people with the same disease often respond very differently to the same treatment. Yet, historically, patients who suffered from a broad category of disease were all treated with the same, "one-size-fits-all," medicines in a trial-and-error type of approach. Unsurprisingly, the same medicine did not work or did not work in the same way for each individual patient. This single, imprecise approach left doctors struggling to predict when and how a particular patient would benefit from a particular medicine.

Now, scientists have begun to understand, target and diagnose illnesses on a molecular level and our approach to treatment has fundamentally changed. However, our understanding of medicine continues to grow every day.

Personalized medicine research includes research in discovering and developing diagnostics and medicines, as well as in genomic profiling, imaging analytics, real-world data and bioinformatics software tools and other areas. We are now on the path to be able to leverage the vast amounts of data that we can access to help patients receive the right treatment at the right time. For example, data acquired in everyday clinical practice can provide valuable insights drawn from information about a patient's lifestyle, disease biology, and treatment outcomes. Thanks to artificial intelligence ("AI") and data science (discussed further below), 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 biopsies (a test done on a sample of blood or non-blood fluid, e.g., to look for cancer cells from a tumor that are circulating in the blood or for pieces of DNA from tumor cells that are in the blood) may allow us to non-invasively track how a cancer evolves over time and adjust treatment accordingly.

Personalized medicine relies on the ability to identify the right medicine for the right patient, and current patent eligibility case law frustrates this research by foreclosing the patentability of advances in diagnostic testing and by the impact on technology that lies at the intersection of

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

biology and AI (discussed further below). This decreases the likelihood of research that will lead to earlier detection, personalized treatment, and better health outcomes.

We would like to emphasize that Genentech does not patent 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 protection. 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.

***The future of medicine: Artificial Intelligence***

Genentech firmly believes that the possibilities of 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 medicine, including medicine development, diagnostic development, and patient treatment.[12] For example, the personalized cancer medicine discussed above uses 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 and AI inventions face patent eligibility challenges under the judge-made exceptions, which often characterize these inventions as unpatentable abstract ideas or mental processes. In addition, bioinformatics and AI inventions at the intersection of biology and AI also face rejections under the life sciences patent eligibility law. That is why it is critical that Section 101 be clarified to incentivize investment in this area.

AI technology is also 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.[13]

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[12] 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.

[13] Roche, *Medical software and the value of digital health*, https://www.roche.com/about/business/diagnostics/value-of-digital-health.htm (last visited Sept. 13, 2021); 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-

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.

Ophthalmology is another area where we are seeing great potential for improved patient outcomes through personalized health care. When we apply artificial intelligence and deep learning approaches to images of the eye, we are gaining insights into whether a given patient with a retinal disease, such as that resulting from diabetes, will progress. For two patients who look similar to the conventional assessment by the ophthalmologist, we are finding that the AI-based algorithms can pick up additional information that tells us a different story: We are learning how to tell if one patient is going to lose their vision in the next two years and the other will not, or if one patient will require intensive treatment for a whole year while another may only need a few doses. This potentially allows us to tailor therapeutic strategies—intensifying treatment for the more aggressive disease and maybe taking a less aggressive approach for the other.[14]

However, to achieve the level of quality and precision necessary to make bioinformatics commonplace technology available for patients, biotechnology companies 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 this type of investment, there must be no question that such innovations are patent eligible.

Genentech strives to push the bounds of medical innovation in pursuit of better, more targeted treatments for patients. We believe that AI/bioinformatics hold great promise for the future of medicine and the future of American innovation. They are integral, cost-effective tools for the future personalized medicine, to enable the right treatment for the right patient at the right time. They are also integral tools for the creation of truly personalized medicines-- medicines personalized for each and every patient. Unfortunately, our current patent system is unable to keep pace with such groundbreaking medical innovation because of an overly exclusionary and misguided judicial interpretation of Section 101. We believe that for America to continue to lead the innovation race in the future of medicine, particularly personalized medicine, it must clarify and prioritize advancements in bioinformatics, AI, and diagnostics.

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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/.

[14] https://www.gene.com/stories/seeing-the-unseen-with-artificial-intelligence.

**Response to question 4:**
There are many cutting-edge inventions that are not patent eligible in the United States, while they remain patentable outside the United States. Compared to the United States, naturally occurring material is patent eligible subject matter in China, Japan, Korea and Europe. And unlike in the United States where diagnostic method patents have routinely been found to be not patent eligible, China, Japan, Korea, and Europe view diagnostic methods as being patent eligible under certain circumstances.

Europe, for example, "permits a broader range of subject matter to be patented than US law...includ[ing] a wider variety of products derived from nature, such as isolated DNA, and methods of in vitro detection and diagnosis based on natural laws and phenomena."[15] In addition, diagnostic methods can be patent eligible in Europe so long as the technical steps of the claimed diagnostic method can be carried out separately from the body. An example of this is a diagnostic method that is carried out on an *in vitro* tissue sample which, because it is not carried out on the human or animal body, can therefore be patented.[16]

In China, claims directed to a gene or a DNA fragment are considered to be per se eligible, and the process to obtain it may be patented provided certain criteria are met.[17] Claims directed to diagnostic methods are patent eligible so long as the method does not lead to a diagnosis or health assessment, regardless if it is carried out separately from the body or performed on the body.[18]

In Japan, claims directed to medicines, vectors, medical materials, and methods of manufacturing the same are considered to be patent eligible by the Japanese Patent Office. A method of diagnosis may be patent eligible in Japan if the method is performed outside the human body, does not include the steps of medical doctors judging the physical condition of a human body for medical purposes, or is used to collect information from a human body.

In Korea, isolated biological materials, cells, higher life forms, genetic sequences, and proteins are patent eligible. In addition, methods of diagnosis are also patentable in some forms, namely where the claims do not require the human body to carry out the invention.

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[15] Jonathan Liddicoat, Kathleen Liddell, Mateo Aboy, *The Effects of Myriad and Mayo on Molecular-Test Development in the United States and Europe: Interviews from the Frontline,* Vand. J. Ent. & Tech. L. (Vol. 22, Issue 4 -2020), *available at* https://scholarship.law.vanderbilt.edu/jetlaw?utm_source=scholarship.law.vanderbilt.edu%2Fjetlaw%2Fvol22%2Fiss4%2F5&utm_medium=PDF&utm_campaign=PDFCoverPages; Guidelines for Examination in the European Patent Office, Part G, Chpt. 2, §3.1, https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm.

[16] *See* European Patent Convention, Art. 53(c).

[17] Yu Guo, *China v US: what can be patented in the life sciences field?* Life Sci. Intell. Prop. Rev., (9/8/2016), *available at* https://www.lifesciencesipreview.com/article/china-v-us-what-can-be-patented-in-the-life-sciences-field.

[18] Article 25 of Patent Law of the People's Republic of China; CNIPA Guidelines for Patent Examination, Part II, Chapter 1, § 4.3.1.2.

Eligibility assessments pertaining to the bioinformatics intersection of software and pharmaceuticals appear to be much more consistent in Europe and China as compared to the United States[19].

For example, the European Patent Office (EPO) only considers claim features that are of a concrete and technical character to differentiate an invention from prior art. The agency has specified that computational models and algorithms (e.g., neural networks and genetic algorithms) are per se of an abstract mathematical nature and do not, themselves, contribute to an invention's technical character.[20] However, if such a model is used for a technical purpose (e.g., to identify irregular heartbeats[21]), steps pertaining to training and/or using the model can "contribute to the technical character of the invention" (and thus can be relied upon to demonstrate novelty and/or inventive step).[22] Consequently, for those patent claims involving the application of AI to a technical problem in the drug discovery,[23] diagnostics,[24] bioinformatics,[25] or similar spaces are eligible for patenting in Europe.

In China, abstract algorithms and pure business rules and methods are ineligible for patent protection. However, in February 2020, China's Guidelines for Patent Examination were amended to include new rules for examining patent applications "containing algorithms or business rules and methods" (Part II, Chapter 9, Section 6), which include applications relating to artificial intelligence (as well as applications relating to "Internet +", "Big Data", or blockchain) frequently include algorithms or business rules and methods. In short, if a claim includes only algorithm, business-rules, or business-method features, the claim is patent ineligible. However, if the claim as a whole includes a technical feature (e.g., beyond an algorithm, business-rules, or business-method features), the claim is patent eligible. These new rules add clarity as to how examination is to be conducted with respect to AI claims, and reinforce a long-standing eligibility requirement in China: patent inventions are to include a technical solution with technical features.[26] This framing is similar to the European framing, and thus at this early stage it appears that China may be shifting its eligibility rules to align closer to the European viewpoint

[19] Innovations at the intersection of AI and biotechnology may face a unique patenting challenge in the US. *See* Hayim, Samuel and Kate Gaudry, "Eligibility Rejections are Appearing in Greater Frequency across all Computer Related Technology Centers." *IPWatchDog*, 24 May 2018, https://www.ipwatchdog.com/2018/05/24/eligibility-rejections-greater-frequency-uspto/id=97615/.

[20] European Patent Office. *Guidelines for Examination,* 2020, https://www.epo.org/law-practice/legal-texts/html/guidelines2018/e/g_ii_3_3_1.htm.

[21] Board of Appeal of the European Patent Office 3.4.01, *Decision No. T 0598/07*, 19 May 2010, https://www.epo.org/law-practice/case-law-appeals/pdf/t070598eu1.pdf.

[22] European Patent Office. *Guidelines for Examination,* 2020, https://www.epo.org/law-practice/legal-texts/html/guidelines2018/e/g_ii_3_3_1.htm.

[23] *See*, *e.g.*, Smith, Christopher, "Artificial Intelligence and Antibiotics: Overcoming Excluded Subject-Matter Hurdles." *Reddie & Grose*, 27 Feb. 2020, https://www.reddie.co.uk/2020/02/27/artificial-intelligence-and-antibiotics-overcoming-excluded-subject-matter-hurdles/.

[24] *See*, *e.g.*, Ford, Hazel, "Patentability of Diagnostic Methods in Europe." *Finnegan*, 4 Jan. 2018, https://www.finnegan.com/en/insights/blogs/european-ip-blog/patentability-of-medical-methods-in-Europe-copy.html.

[25] "A Guide to Patenting Bioinformatics Inventions at the EPO." *Mewburn Ellis*, https://www.mewburn.com/a-guide-to-patenting-bioinformatics-inventions-at-the-epo-sign-up.

[26] People's Republic of China, Standing Committee of the National People's Congress of China, Article 2.2, Patent Law of the People's Republic of China.

than that of the United States. Further, the China National Intellectual Property Administration further published draft examination-guidance amendments in December 2020, which specify that a claim that uses computer-implemented technical means is eligible if it provides a technical solution and achieves technical effects (which may even further align China's eligibility rules with Europe's).[27]

**Question 7:**
Please refer to our responses to questions 2, 3, and 4.

**Question 8:**
Please refer to our response to question 2.

## Section II—Impact of Subject Matter Eligibility on the General Marketplace

**The following is in response to Questions 10 and 11:**

We believe the U.S. patent system needs to provide stability and predictability, protect innovations, and incentivize American investment in revolutionary treatments. With the high rate of failure and 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 and further future R&D. Ambiguous or shifting rules on patent protection can be nearly as damaging as providing no protection at all. The systemic uncertainty surrounding patent eligibility in the United States[28] is therefore one of our top concerns, as we increasingly invest in transformational medical technologies that are closer to nature, 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 emerging technologies are uncertain enough from a scientific and regulatory perspective, even assuming that we can rely on the patent system to help protect our investment given costs, high risks and the small percentage of projects that succeed.

**Question 12:**

Please refer to our response to questions 10 and 11.

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[27] Yue, Weining and Jun Wang, "Draft Amendments to Patent Examination guidelines." *China Law Insight*, 2 Dec. 2020, https://www.chinalawinsight.com/2020/12/articles/intellectual-property/draft-amendments-to-patent-examination-guidelines/.

[28] U.S. Chamber of Commerce, Global Intellectual Property Center, *International IP Index: Recovery through Ingenuity* 9 (2021), https://www.theglobalipcenter.com/wp-content/uploads/2021/03/GIPC_IPIndex2021_FullReport_v3.pdf (observing that "[T]he patenting environment in the United States continues to be held back by uncertainty over what constitutes patentable subject matter," and explaining that "[s]ince the Supreme Court decisions in the Bilski, Myriad, Mayo, and Alice cases, there has been a high and sustained level of uncertainty as to which inventions are patentable in the United States.").

**Question 13:**

Lack of investment is likely to slow meaningful innovation in areas of the biopharmaceutical sector where patent protection is unavailable. This could lead to lost opportunities to improve healthcare outcomes for affected patient populations. We know that a stable patent system is absolutely essential to incentivize the countless hours and investment of time and resources that could result in breakthrough medicines for patients. But the cost to society of not having such medicines – treatments and cures for cancers, multiple sclerosis, and other devastating diseases – cannot be quantified. The current Section 101 jurisprudence threatens development of such promising medicines and therapies that can be life-changing for patients.

Second, the state of patent eligibility jurisprudence may encourage more inventors to utilize trade secrets instead of the patent system. Patent protection is important not only to foster innovation, but as a way to meaningfully further scientific and medical knowledge overall. If patent protection is unavailable, it may force companies seeking to advance this field to protect their intellectual property through trade secrets. While trade secrets are important forms of intellectual property, their value lies in their secrecy. Accordingly, only patents, through their public disclosure requirement, enhance scientific and medical knowledge, to allow other inventors to build on the work of those who have gone before them. Doing so can serve as a foundation on which others build as well as a catalyst for developing new ways of achieving the same result.

Lastly, advances in personalized medicine will result in improved efficiency in the health care system, by avoiding unneeded treatments, ensuring patients get the right treatments, and preventing disease and side effects. Personalized medicine also serves to advance health equity and inclusion in medicine. For example, enriching the quality and breadth of clinical information available allows for greater development of personalized healthcare resources for all patients.[29] To realize the promise of personalized medicine, companies like ours and others in the industry need to be assured that the patent system will offer protections for their inventions. The patent eligibility law needs to work not only for today's treatments, but for future innovations that have the potential to save lives and improve patient outcomes.

Respectfully submitted,

/Cara M. Coburn/

Cara M. Coburn
Associate General Counsel
Genentech, Inc.

[29] *See* Nicole Richie, Ph.D., *More Inclusive Data, Better Health Equity,* Genentech (Sept. 23, 2019), *available at* https://www.gene.com/stories/more-inclusive-data-better-health-equity.