Questions for Laurie Hill

1.You talk about bringing the science closer to nature – can you elaborate on this?

Genentech has always been a pioneer, leading the way in revolutionary medical breakthroughs. We pride ourselves on following the science toward innovative medical advancement and treatment.

Disease arises when the body deviates from the healthy state. We are working to create treatments that replicate the body's own natural processes to return patients to a healthy state. Some of the most important developments in medicine have and will come from developing products that more closely resemble natural compounds than traditional synthetic drugs. Such developments harness natural processes, such as the body's own immune system or microbiome, or use a patient's individual characteristics to create personalized medical treatments to create treatments that are deliberately closer to nature. For example, Genentech has been a leader in the use of therapeutic monoclonal antibodies to fight a variety of conditions, including various types of cancer. These antibodies are created in a lab, but are generally humanized or fully human, which helps reduce negative immune response from the patient by making the antibodies more closely resemble the kinds found naturally in a patient's body.

In another approach, our scientists are developing cutting-edge cancer therapies, such as our TECENTRIQ® (atezolizumab) medicine, that harness a patient's immune system to attack a tumor. Unlike earlier conventional cancer therapeutics that often involve introduction of harsh substances that affect every part of the body, these new immunotherapies replicate the body's normal immune process by stimulating the body to attack the cancer. 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.

However, the current Section 101 regime calls into question the patent eligibility of medicines that are deliberately closer to nature and replicate the body's own processes. This is gravely concerning to the future of medicine. 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—the kind that Genentech and other biotechnology companies are engaged in. It is absolutely essential that Congress return Section 101 to its proper role: one that incentivizes investments in innovation, especially for companies investing in breakthrough medicines that are deliberately closer to nature.

2.Can you talk more about what AI means for your company and how use of AI for you may be different than for others on the panel?

Genentech firmly believes that the possibilities of Artificial Intelligence (AI) combined with biotechnology are endless. One important transformation on the horizon is the rise of

bioinformatics, which bring together biotechnology and AI to inform all stages of personalized medicine. This includes medicine development, diagnostic development, and patient treatment. As an example, AI is used in personalized cancer treatments to decode information necessary to develop the medicine. Such treatments use nucleic acid sequences to encode a portion of a patient's own tumor so we can then create a personalized medicine to stimulate the patient's immune system to fight the tumor. AI is critical to the development of such treatments, which often 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. In short, personalized cancer treatments are more targeted, sophisticated, and effective because of the infusion of AI in the process. Yet under the current Section 101 law, bioinformatics and AI face patent eligibility challenges due to the judge-made exceptions that often characterize such inventions as unpatentable abstract ideas or mental processes.

Thanks to AI and data science, we are able to harness and aggregate real-world data as a powerful complement to traditional clinical trials. Data acquired in everyday clinical practice can provide valuable insights drawn from information about a patient's lifestyle, disease biology, and treatment outcomes. When combined with AI, such data can inform and reform personalized healthcare in ways we have never seen before. 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. Also, liquid (or non-blood fluid) biopsies may allow scientists to non-invasively track how cancer evolves over time and adjust treatments accordingly. Such innovation holds great promise for the future of medicine, and bioinformatics will be an integral, cost-effective tool in making this process possible. Our goal is to ensure that the screening, diagnosis, treatment, and prevention of diseases will enable the right treatment for the right patient at the right time.

Unlike use of AI in some other industries, AI used in medicine must be extremely precise and of superior quality at the point of launch. In other words, unlike other software that can be unveiled to the public at an early stage and then corrected over time through patches and updates, use of bioinformatics to inform serious patient treatments or to design personalized medicines requires extreme precision on the very first try to ensure that patients are not harmed or given incorrect treatments. We are up to the challenge to present bioinformatics that perform with stability, accuracy, and predictability at the time of launch. But in order to secure the investment needed to do so, there must be no question that innovations in bioinformatics are patent-eligible. Any alternative regime may force companies seeking to advance this field to protect their intellectual property through trade secrets, which do not result in the same public disclosure and enrichment of the sciences as patents.

3.Are you seeing first-hand innovation being invested in the EU or China instead of the US because of the current patent subject matter eligibility laws? What happens to the biotechnology industry in particular if the innovation is moved to China, for example?

It is particularly troubling that the patent laws in the European Union (EU) and China are currently more advanced than U.S. laws. This is the result of uncertainty in the patent eligibility laws in the U.S. In the EU, for example, natural products, diagnostics, and bioinformatics are all patent-eligible. In China, natural products and bioinformatics are also generally patent-eligible.

And this is no accident. In 2016, China committed to making "precision medicine" part of its five-year plan with an expected investment of over $9 billion for research – the largest investment in precision medicine of any country in the world. For context, the according to the World Economic Forum, the U.S. Precision Medicine initiative also began in 2016 with a financial commitment of $215 million, meaning that for every $1 spent in the U.S. on its precision medicine initiative, China is spending $43.[1] China also has committed to leading the way in AI and precision medicine above all other countries and is making significant investments now in order to do so.

The unfortunate reality is that because of the uncertainty with Section 101 in the U.S. patent laws, companies like ours have often had to make business decisions about where to pursue patents based on these facts. And sometimes that means pursuing patent protection in countries other than the U.S. due to uncertainty surrounding U.S. patent eligibility laws.

4.We've heard some testimony here that the suggested changes to 101 we are proposing will lead to genes being taken out of the public domain if a new utility is identified. Do you believe that this will happen?

No, this legislation does not change the fundamental principle that genes should never be granted to anyone as intellectual property. This legislation will not impede anyone's access to their genetic information. As was discussed in the hearings, the human genome has already been sequenced and is in the public domain and thus human genes are not patentable due to this prior art. Moreover, additional genetic sequence information is made public every day through commercial genetic testing and other efforts. The proposed changes to Section 101 would not change that.

We do, however, believe that the proposed legislation clarifies that practical applications of genetic material, for example, as used to create personalized cancer medicines, would be rightly patent-eligible under the coarse filter of Section 101. The analysis would then proceed to the other sections of the Patent Act for more detailed scrutiny.

5.How would you respond to the statement that patents get in the way of innovation, that we will have more drugs, more diagnostic tests, without patents?

Without patents, innovation in the field of medicine is simply not feasible and would lead to a dearth of medicines and diagnostic tests. In other words, without patents, society would be stuck in a time warp, having to use only the medicines available today, as no one could afford to invest in innovation for the future.

None of the work that Genentech has done and continues to do would be possible without strong patent protection. We believe this to also be true for the biotechnology industry as a whole. Patents are designed to be an exchange with society – in exchange for disclosing the science to the public, inventors are granted a limited term of patent exclusivity to commercialize

[1] *See "3 ways China is leading the way in precision medicine,"* World Economic Forum, Nov. 2, 2017, available at https://www.weforum.org/agenda/2017/11/3-ways-china-is-leading-the-way-in-precision-medicine/.

their inventions. And because of that exchange, scientists can stand on the shoulders of others to create breakthrough medicines.

In the field of biotechnology, researching and developing a new medicine can cost billions of dollars and often results in several failures before reaching one success. 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).[2] The estimated time it takes a medicine to travel from R&D to market is approximately 12 years.[3] Companies often invest substantial sums of private capital to make their innovations possible and in exchange, companies need to know that patent protection is available to recoup their investments. A stable patent system is critical to developing breakthrough medicines. The alternative will inevitably steer investment away from ground-breaking and novel medicines and potentially slow the progress of science, as companies will either 1) not innovate in the field at all, or 2) keep their work as a trade secret which is never made public and thus does not advance the science as a whole.

6. What is the public policy value in encouraging investment, research, development and innovation in life sciences and precision medicine? In other words, can you explain in layman's terms why precision medicine is the future?

Precision medicine is an unprecedented convergence of medical knowledge, technology and data science that is revolutionizing patient care. Precision medicine brings together a unique understanding of human biology with new ways to analyze health data. Our vision is to ensure that the screening, diagnosis, treatment and even prevention of diseases will more quickly and effectively transform the lives of people everywhere – ensuring the right treatment for the right patient at the right time.

Every person is unique and in many ways, so are diseases. Yet the precision medicine revolution in healthcare provides new ways to both collect high-quality data from each patient and connect it to data from large pools of other patients for analysis with AI-based algorithms. This enables us to arrive at a deeper understanding of how to treat an individual. Only then can we see what distinguishes each of us as individuals, and translate that into personalized, and thus improved, care for every person.

Sometimes this means using technologies like next-generation sequencing to map out an individual's full genetic makeup, tumor mutations, and other defining molecular features to generate diagnostics to find the most appropriate treatment for the individual. Sometimes this means using diagnostic testing of liquid biopsies to non-invasively track how a disease evolves over time and adjust treatment accordingly. Sometimes this means using sophisticated bioinformatics to design a medicine that is personalized to the individual's own cancer.

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[2] *See* https://www.igeahub.com/2018/08/28/evaluation-of-clinical-trial-costs-and-barriers-to-drug-development/.
[3] *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.

The public policy value in incentivizing precision medicine is to avoid the "one size fits all" medicine of the past and instead focus on innovative, new, tailored medicines for all patients. However, without amendments to Section 101, the future of precision medicine is uncertain. Current case law has largely foreclosed patenting advances in diagnostics testing. And the sophisticated bioinformatics and AI algorithms used for precision medicine analysis and to design personalized medicines are frequently found patent-ineligible under current law.

Despite the layman's description of precision medicine above, this area of biotechnology is extremely difficult to achieve. It has taken teams of scientists years to get to where we are today – and this is just the tip of the iceberg. We are at a pivotal juncture in personalized medicine, much of which depends on whether such innovation is considered patent-eligible in the U.S. Genentech strives to push the bounds of medical innovation in pursuit of better medication and treatments. But we need to know that when we develop precision medicine 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.

7. Some have claimed we want to allow the patenting of human genes as they exist in the body. That's false. However, I do think there's value in promoting researchers and innovators to isolate human genes and apply that isolation to personalized treatment. Can you explain for us why that's valuable? In other words, what advancements in treatment occur because of such innovation?

We agree that the draft legislation will not allow for the patenting of human genes as they exist in the human body. We also agree that there is value in the practical application of genetic material in the development of medicines and treatments and in incentivizing research and development to that end.

Some of the most critical developments in medicine have and will come from practical applications of genetic material in medicines and treatments. Genentech was a pioneer in the use of recombinant DNA technology to create synthetic versions of human proteins, including 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 valuable to patients through its ability to mimic naturally occurring human growth hormone.

Today, as noted above, Genentech is expounding on the uses of therapeutic monoclonal antibodies to treat many conditions, including various types of cancer. Even though such antibodies are created in a lab, they are generally humanized or fully human, which is why they are more effective and have fewer side effects. Our TECENTRIQ antibody medicine harnesses the body's immune system to attack the tumor and is just one example of promise that the future of medicine holds.

The microbiome is another emerging area in biology and medicine, and it is faced with similar patent eligibility challenges. 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 patients' physical health and their 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, to treat inflammatory bowel disease.

Due to of the Supreme Court's expansion of the current Section 101 regime, the patent eligibility of such medicines is at risk simply *because* they utilize genetic material or bacteria to create a medicine or treatments. Genentech is not in the business of patenting a person's genes. But we think that medicinal compositions that are based on genetic material merit protection. An example of this is in personalized cancer regimens that use nucleic acid sequences encoding a portion of a patient's own tumor to stimulate the immune system to fight the tumor. Section 101 must incentivize such innovation accordingly so that companies have certainty to invest in personalized treatments for the benefit of patients.

8. Looking forward ten to fifteen years, if we don't correct the current state of patent eligibility what is the negative impact that American patients will experience?

Simply said, if the U.S. does not correct the current state of patent eligibility laws, it will be making the choice to forgo the next generation of innovation and to let other countries surpass the U.S., particularly in areas of technology using AI and in the biotechnology field.

The present certainty 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 patent law, 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. And a stable patent system is critical to developing such medicines.

Section 101 was never designed to be anything more than a coarse filter. Congress must return Section 101 to its coarse filter function. It acts like the 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. The type of investment that Genentech is making depends on that coarse filter of Section 101: a system that rewards innovation and risk-taking. Biotechnology companies pursing innovative medicines are willing to make such investments, but they need to be assured that the patent system will offer protections for their innovations. Ambiguous or shifting rules on patent protection can be nearly as damaging as providing no protection at all.

The time for Congress to fix Section 101 is now. We have already seen other jurisdictions such as the European Union and China allowing patents for natural products including gene sequences, and bioinformatics. By not returning Section 101 to its proper role as

a coarse filter, the U.S. risks losing innovation to other countries who do incentivize these types of inventions.

Throughout history, America has had a reputation as a global leader in innovation and scientific progress. U.S. companies like Genentech are already pushing the bounds of medical innovation in pursuit of better solutions for our patients. But we need to know that the U.S. patent system will protect such true innovation. We strongly urge Congress to act now to clarify the law of patent eligibility and reward true innovation through the patent system as our forefathers intended.

Questions for the Record for Laurie Hill
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?

   We absolutely agree with Judges Lourie and Newman that Section 101 needs clarification by Congress, and we strongly believe that the time for that reform is now.

   From our perspective at Genentech, the current judicial exceptions to Section 101 are barriers that prevent the protection of the next generation of life-changing medicines and diagnostics. 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 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 process they describe to qualify as patent-eligible processes that apply natural laws?"[1] Such a "precise" test has proven to be anything but precise and has created tremendous uncertainty in the patent eligibility laws and regulations that only Congress can remedy.

   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 on Section 101 grounds, even when our inventions pass all other sections of the Patent Act and clearly merit protection. This includes personalized medicine methods of treatment, diagnostics inventions and antibody-related inventions.

   We believe the U.S. patent system needs to provide stability and predictability, protect innovations, and incentivize American investment in revolutionary treatments. The mantle

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

now rests with Congress to clarify Section 101 so that companies like Genentech can invest in the future of medicine with confidence. We believe that legislation along the lines of that proposed by Senators Tillis and Coons would promote the stability necessary for our company and incentivize inventors to create the next generation of therapies and cures.

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"?

   We think that "field of technology" provides sufficient legislative guidance for the courts to draw sensible lines. Use of the word "any" will emphasize to courts that the term should be interpreted broadly, and the reference to technology follows logically from the Constitution's reference to the useful arts. Appropriate legislative history could also be used to provide courts with a sense of what the term means without having to provide a comprehensive list of fields.

   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?

   The result of the European Union (EU) and China's "technology" requirements in their patent eligibility statutes is that the patent laws in both the EU and China are currently more advanced than U.S. laws. In the EU, for example, natural products, diagnostics, and bioinformatics are all patent-eligible. In China, natural products and bioinformatics are also generally patent-eligible. And this is no accident. In 2016, China committed to making "precision medicine" part of its five-year plan with an expected investment of over $9 billion for research – the largest investment in precision medicine of any country in the world. For context, according to the World Economic Forum, the U.S. Precision Medicine initiative also began in 2016 with a financial commitment of $215 million, meaning that for every $1 invested in the United States on its precision medicine initiative, China is investing $43.[2] China also has committed to leading the way in artificial intelligence (AI) and precision medicine above all other countries and is making significant investments now in order to do so.

   The way to learn from the experiences of the EU and China is to amend the U.S. patent eligibility laws to incentivize such critical technology, which includes pursuing solutions to the persistent medical challenges of the 21st Century. If the United States does not correct the current state of patent eligibility laws, it will be making the choice to forgo the next generation of innovation and to let other countries surpass it, particularly in areas of technology using AI and in the biotechnology field.

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[2] *See "3 ways China is leading the way in precision medicine,"* World Economic Forum, Nov. 2, 2017, available at https://www.weforum.org/agenda/2017/11/3-ways-china-is-leading-the-way-in-precision-medicine/.

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?

We do not believe that a method for hedging against the financial risk of price fluctuations like the one at issue in the *Bilski* case would be patent-eligible under the current "field of technology" test in the Section 101 draft legislation.

We believe the Congress should thoroughly build out the legislative history with several examples in all areas of technology that would serve as important guidance for the courts as to what does and does not fall into the "field of technology" requirement. For example, "field of technology" should include a composition with biological activity, such that it might be used in the field of medicine. It should also include methods of treatment, methods of diagnosis, methods of manufacturing, and use of bioinformatics or artificial intelligence in diagnosis, treatment, and medicine design. "Field of technology" should not include an intangible idea, an aesthetic creation, a work of literature, or a mere "do it on a computer" claim. We would be glad to provide you with additional specific examples as needed to create clarity in the legislative history.

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

Again, we think that "field of technology" provides sufficient legislative guidance for the courts to draw sensible lines. We also think that "useful arts" would be an acceptable term, but we have a slight preference for "field of technology" since "useful arts" is an older term and could confuse some courts as they confront new technologies. We think the greatest changes needed are to clarify "field of technology" in the legislative history through explicit examples, which should inform the courts as to what does and does not meet the "field of technology" requirement.

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?

We agree that no one should be able to patent gravity, a mathematical equation, or a purely mental process. We also agree that no one should be able to patent an intangible idea, an aesthetic creation, or a work of literature. Genentech is also not in the business of patenting a person's genes, and we agree with Senators Tillis and Coons that genes as they exist in the human body would not be patent-eligible under their proposal.

However, we do think that the legislation should make it abundantly clear that practical applications of genetic material, such as medicinal compositions that consist of fragments of genetic material, merit protection. An example of this is personalized cancer regimens that use nucleic acid sequences encoding a portion of a patient's own tumor to stimulate the

immune system to fight the tumor. Section 101 must incentivize such innovation accordingly so that companies have certainty to invest in personalized treatments for the benefit of patients.

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?

It is true that many of the complaints relating to claims in the high tech space are primarily complaints about overbroad claims that sweep far beyond the subject matter disclosed in the patent. Addressing this problem does not necessarily require legislative change to Section 112, however. Cases interpreting Section 112 already require the full scope of the claimed invention to be enabled and described in a patent's specification[3]. These tools would likely be used more often by courts if Section 101 returned to being a coarse filter rather than an all-purpose tool for challenging patent claims.

The biotechnology industry has experienced extremely robust enforcement of Section 112. For instance, the biotech industry is already subject to vigorous enforcement of the written description requirement in Section 112(a). The requirement applies across all industries, but in practice, it is enforced most strictly in biotech. This already prevents abusive use of functional claiming, since if a biotech claim contains functional language at the point of novelty, there is already a substantial likelihood that the scope of the claim will be challenged on written description and enablement grounds. *See, e.g*., *AbbVie Deutschland GmbH &. Co., KG v. Janssen Biotech, Inc*., 759 F.3d 1285, 1301 (Fed. Cir. 2014) ("Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus.").

Accordingly, while we are continuing to work through how the proposed changes to Section 112(f) would work in practice for the biotechnology industry, we have some concerns that the new language would unduly restrict the scope of claims and create loopholes that potential infringers could exploit.

For example, consider a classic method of treatment claim in the following form:

"A method of treating a patient in need of treatment for condition X comprising administering a therapeutically effective amount of compound Y."

[3] *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (It is already established that the "full scope of the claimed invention" must be enabled and described in a patent's specification. This ensures that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.") (internal quotation marks omitted); *see also MagSil Corp. v. Hitachi Global Storage Technologies, Inc*., 687 F.3d 1377, 1381 (Fed. Cir. 2012) ("a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage").

Under current law, the word ″administering″ would be given a broad scope because a person of ordinary skill would understand that there are numerous well-known ways to administer a drug. Under the new language, however, ″administering″ could be interpreted as a functional limitation restricted to the particular acts disclosed in the specification. Moreover, the knowledge of a skilled artisan could not be used to supply corresponding acts that were not in the specification. *See Atmel Corp. v. Information Storage Devices, Inc*., 198 F.3d 1374, 1382 (Fed. Cir. 1999).

That means a small omission in the specification could be devastating. For instance, imagine the specification says that administration can be oral, rectal, topical, transdermal, subcutaneous, intramedullary, intraarticular, intramuscular, or intraperitoneal. In that long list, the drafter accidentally left off the word "intravenous." So suddenly a claim to a new method of treatment that is clearly worthy of patent protection and would have been readily understood to cover intravenous administration would not gain such protection, illustrating a giant loophole that never would have occurred before.

As a second example, consider the following purification claim:

A method for purifying compound X from a composition comprising the compound X and one or more contaminants selected from the group consisting of Chinese Hamster Ovary Proteins leached protein A, DNA, and aggregated compound X, which method comprises the sequential steps of:

(a) loading the composition onto a cation exchange material wherein the composition is at a pH from about 4.0 to about 6.0;

(b) washing the cation exchange material with a wash buffer at a pH from about 5.0 to about 6.0 and a conductivity of 0.1 to 3 mS/cm; and

(c) eluting the compound X from the cation exchange material using an elution buffer with a pH from about 5.0 to about 6.0 and a conductivity from about 10 mS/cm to about 20 mS/cm.

Under current law, a skilled artisan would immediately understand what "loading" and "washing" mean and the various techniques that could be used within the specified parameters. But under the new proposal, all of that detail may have to be spelled out in the specification even though the claims provide ample detail such that the particular washing technique used is not the point of novelty. This will incentivize the creation of lengthy specifications, which will increase prosecution expense and complexity of examination.

Encouraging bloated specifications that repeat large amounts of information already known in the art does not benefit anyone. It makes the examination process more

difficult and time-consuming, and it will increase the expense of obtaining and enforcing patents.

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

The main effect of the new Section 112(f) provision on the biotechnology industry will be to limit the scope of functional terms that are not used at the point of novelty—as in the "administering," "loading," and "washing" examples above—in a way that could create unintended gaps in claims, which are likely to lead to extremely lengthy and repetitive specifications.

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

This is definitely a concern. Designing around the patent will be easier under 112(f), which will increase pressure on the drafter to include all known embodiments. As noted in our example above, if one word in the specification is inadvertently omitted, it could remove a very important aspect of the invention, even if it is an element that is very well-known in the art (and not at the point of novelty for the invention).

Predictability is also of great concern to us. It would be unfair to apply the new version of Section 112(f) to existing patents, because the specifications of those patents were not drafted with the new requirement in mind.

Another source of uncertainty comes from the difficulty of deciding what language should be considered functional. Under current law, the patent drafter can provide a signal by using the term "means," knowing that the use or omission of that term will create a presumption regarding whether the claim is limited to the corresponding structure or acts identified in the specification. The proposed changes would apply to all functional elements, which could create definitional problems. For example, it is common for biotech claims to use language that sounds functional but refers to a specific composition or step (e.g., "promoter"). We anticipate significant additional attention will be devoted in the U.S. Patent and Trademark Office and in litigation to debating whether a term is functional or not functional.

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?

The doctrine of obviousness-type double patenting should not be codified, and certainly should not be expanded.

The judicially created doctrine of obviousness-type double patenting provides that if the inventions claimed in two different patents are sufficiently close that one can be considered an obvious variant of the other, the claim in the longer-lasting patent will be invalidated, unless the patent owner disclaims the extra patent term.

This rule might have made sense in the era when a patent lasted 17 years from issuance. In that situation, if multiple patents were issued on obvious variants of an invention over time, an inventor could get new 17-year term for each additional patent and effectively extend the total period of patent protection. But 20 years ago, Congress changed the way that patent terms are calculated. Rather than running 17 years from the date they are *issued*, patents now run 20 years from the date they are *filed*. That means the successive patents issuing at different times from the same priority application will generally expire on the same day—20 years from the original *filing* date. There are only a few ways similar patents could end up with different expiration dates today, and none warrants invalidating the patent.

A patent is granted only if the patent is new (Section 102), non-obvious (Section 103) and well described and enabled (Section 112). Section 103 plays an important role in ensuring that non-inventive *later-filed* inventions are not patentable. Section 103 is working as intended, and therefore should not be brought into legislation focused on a separate section altogether – Section 101.

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?

While we do think there would be significant concerns with making changes to Section 112(f) retroactive, applying the changes to Section 101 retroactively is less problematic. Retroactive application of Section 112(f) would restrict the scope of patents that have already been granted, and thus cut back on existing property rights based on drafting decisions made years before the new rules took effect. In contrast, application of the new Section 101 standard would not take existing property or deprive anyone of property without due process. Instead, the changes are primarily directed at restoring property rights by rolling back recent judicial decisions that substantially changed the law.

Article I Section 8 Clause 8 of the U.S. Constitution grants Congress the power "[t]o promote the progress of science and useful arts…" We have already seen other jurisdictions such as the European Union and China allowing patents for natural products and bioinformatics. By not returning Section 101 to its proper role as a coarse filter, the U.S. risks losing innovation to other countries that do incentivize these types of

inventions. Throughout history, America has had a reputation as a global leader in innovation and scientific progress. U.S. companies like Genentech are already pushing the bounds of medical innovation in pursuit of better solutions for our patients. But we need to know that the U.S. patent system will protect such true innovation. We strongly urge Congress to act now to clarify the law of patent eligibility and reward true innovation through the patent system as our forefathers intended.