Answers to Questions for the Record for Robert Deberardine

From Chairman Tillis

Thank you for the opportunity to answer the following Questions for the Record. I have answered the questions in my capacity as Chief Intellectual Property Counsel for Johnson & Johnson.

1. How has the current state of patent eligibility impacted research and development by your company?

Answer: Patent eligibility is an important consideration when a pharmaceutical company considers embarking on the long, uncertain, and costly task of developing a new drug.[1] A predictable patent system encourages pharmaceutical companies to take on the significant risks associated with solving the world's greatest healthcare challenges.[2] Unfortunately, the current state of patent eligibility law is anything but predictable.

We believe that the pharmaceutical industry is on the cusp of a healthcare revolution - personalized medicine that allows for the development of highly specific and individually tailored medicines based upon patient data, diagnostic techniques that detect a disease at an early stage or before disease onset, new treatments that activate and amplify the natural immune responses of the body, safe and effective new formulations derived from natural resources, and the use of digital technologies and "big data" all hold great promise. Advances in these emerging technologies could profoundly change patients' lives and realize significant cost savings for the healthcare system. However, substantial investment by pharmaceutical companies will be required to realize the full potential that these technologies hold. Unfortunately, as confirmed by the testimony of many witnesses that have appeared before this Subcommittee, the current state of patent eligibility law discourages investment in these very same technologies because they all, to some extent, relate to or rely upon "abstract ideas", "laws of nature", or "natural phenomenon." Without restoring clarity and predictability to § 101, we

[1] It is estimated that it takes, on average, 10-15 years and 2.6 billion dollars to develop one single new medicine. PhRMA 2016 Biopharmaceutical Research Industry Profile. The Pharmaceutical Research and Manufacturers of America (PhRMA). Available at: http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdfhttps://www.letstalkaboutcost.org/ and DiMasi JA, Grabowski HG, Hansenc, RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. 2016; 47(05):20-33.

[2] The Janssen Pharmaceutical Companies of Johnson & Johnson have invested roughly $40 billion on R&D over the last five years (2014-2018). .

are concerned that research in these areas may be under funded in the years to come and the full potential of these technologies may not be realized.

Failure to fix § 101 could also influence biopharmaceutical company research decisions in ways that may produce unintended consequences in the pharmaceutical marketplace. For example, in the absence of reliable patent protection, innovative companies may be incentivized to develop products that are more difficult to copy and benefit from other forms of protection – such as trade secrets and regulatory exclusivity. This might suggest that a larger proportion of research dollars should be allocated to biologic pharmaceuticals (which are more susceptible to trade secret protection and are provided a longer period of data exclusivity in the United States) as compared to small molecules. This could result in fewer new small molecule drugs being brought to market, which in turn would result in fewer low cost generic alternatives. Although the benefits of biological pharmaceuticals are well established, we believe a mix of both biologic and small molecule development would best serve patients and the health care system.

Governmental leaders should, in our opinion, pursue technology neutral policies that encourage biopharmaceutical companies to pursue innovation that delivers on unmet patient needs and provides the greatest benefit to society. Companies should be incentivized to seek out the very best solutions for patients wherever they might find them, including those solutions that relate to or rely upon "abstract ideas", "laws of nature", or "natural phenomenon." The current proposal represents an important first step towards achieving that goal.

2. Can you give us an example of the types of research into next generation medicines your company is abandoning as a result of the current uncertainty?

Answer: As discussed above in our answer to Question 1, the current state of patent eligibility law discourages research and development in some of the very same technologies that hold the greatest promise for healthcare advancements. Research and development is discouraged because it is impossible under the current state of the law to predict, with any degree of certainty, whether the inventions resulting from this research will be deemed patent eligible. As a result, business leaders currently face the following, very real, question:

> ***Do you want to invest hundreds of millions of dollars, and a decade or more, into a technology that you may never be able to protect?***

Any prudent business leader presented with the above question will be reluctant to invest in a high-risk, high-cost, technology. We believe the dilemma presented by the above question also

has a profound impact on the research decisions of universities, smaller technology companies, and individual inventors with whom we partner. In most cases the primary business asset held by these entities that protects their basic research is a patent. In addition, the patent is the legal instrument that enables larger companies, such as J&J, to partner with these entities and develop their technology into a safe and effective treatment for patients. Considering the limited financial resources of many smaller companies, and/or their need to secure venture capital, investing in a technology that they may never be able to protect is a challenging if not wholly untenable business proposition.

In view of the above, we are concerned that without restoring clarity and predictability to § 101 the technologies referenced in our answer to Question 1 may be under researched by large and small companies, start-ups, universities, and individual inventors alike in the years to come.

3. Please explain for us exactly why Congress should encourage the type of work and innovation your company performs? In other words, what are the real-world, life-saving impacts of your work?

Over the last few decades, the pharmaceutical industry has developed new medicines that have profoundly transformed and saved patient's lives. HIV/AIDS, once considered a deadly disease is now a manageable condition. Until recently the treatments available for hepatitis C cured only half of the patients and produced significant side effects in some patients. Today, the available treatments for hepatitis C have cure rates nearing 100 percent. Even with these advances, and many others, some of our greatest healthcare challenges remain unsolved. Alzheimer's disease is one such challenge and provides an instructive example of why § 101 reform is desperately needed.

Alzheimer's disease is a debilitating illness that slowly impairs patient brain function resulting in loss of memories, diminished cognitive function, speech loss, and eventual death. In addition to the effects on the patient, Alzheimer's disease takes a profound emotional and financial toll on families as they care for a loved one that is slowly progressing through the disease state.[3] According to the Alzheimer's Association about 5.7 million American's are currently affected by Alzheimer's dementia, the symptomatic phase of the disease.[4] This number is expected to grow as the population in the United States ages. Experts predict that 13.8 million patients in the United States could have Alzheimer's by 2050, with the direct costs associated with the disease

[3] Often family and friends act as caregivers for patients with Alzheimer's. The unaccounted for cost of this care is massive. It is estimated that caregivers provided 18.4 billion hours of care in 2017, valued at approximately 232.1 billion. Alzheimer's Association, "2018 Alzheimer's Disease Facts and Figures" (2018). https://www.alz.org/media/HomeOffice/Facts%20and%20Figures/facts-and-figures.pdf

[4] *Id*.

reaching 1.1 trillion.[5] Today, Alzheimer's disease is the sixth leading cause of death in the United States.[6] Alzheimer's disease also places a significant burden on our health care system accounting for $277 billion each year in direct medical costs.[7] In 2018 alone, Medicare is projected to spend $140 billon treating patients with Alzheimer's and other dementias.[8]

To date, the development of new medicines to treat Alzheimer's has been a slow and complex process. According to one recent analysis, between 1998 and 2017, there have been 146 unsuccessful attempts (representing billions of dollars in R&D and clinical trial costs) to develop new medicines to treat Alzheimer's.[9] However, despite these challenges, each setback provides insights into the disease and learnings that will eventually form the basis of a breakthrough. A single new treatment could produce profound effects. According to one estimate, the discovery of a medicine that would delay onset of Alzheimer's disease by five years would mean 1.6 million fewer Americans would have Alzheimer's by 2030, in turn saving $100 billion in annual medical costs.[10] We believe governmental leaders must enact patent policies that encourage companies to continue to make the R&D investments, and pursue the technological solutions, required to find better Alzheimer's treatments and a cure. Unfortunately, as explained below, development of important technologies that may hold the key for an Alzheimer's breakthrough is discouraged under current patent eligibility law.

Considering the complex nature of the neurological diseases it is likely that multiple research paths will need to be explored to advance our understanding of Alzheimer's. For example, research is needed to better understand genetic factors that correlate to disease development, to better identify individuals at most risk. New diagnostic tests, that measure biomarkers, must be developed to identify patients in the early stage of the disease. These tests will be critically important in our opinion because they will eventually allow for proactive disease management at a very early stage. Research indicates that the disease process starts 10 to 20 years prior to actual symptoms so these tests may ultimately enable the prevention of symptom development with early treatment. These tests also will allow us to better assess the effects of new drug candidates and more accurately monitor the progression of the disease over time. Additional research also is needed to understand the body's immune response to the disease and whether the immune system response can be controlled in a way that treats the disease. This could lead to therapies that modify the body's natural response to the disease either slowing disease progression or even preventing the onset of symptoms. Digital technologies may also play a critical role in

[5] *Id*.
[6] *Id*.
[7] *Id.*
[8] *Id*.
[9] Researching Alzheimer's Medicines, Setbacks and Stepping Stones. The Pharmaceutical Research and Manufacturers of America (PhRMA). Available at https://www.phrma.org/alzheimer-s-medicines-setbacks-and-stepping-stones.
[10] Alzheimer's Association. "Changing the Trajectory of Alzheimer's Disease: A National Imperative," May 2010.

diagnosing and monitoring the disease. Development of wearable sensors that provide real-time patient data could prove pivotal.

Unfortunately, all of the potential breakthroughs described above, could be deemed patent ineligible under current law as relying upon "natural phenomena" or "abstract ideas." In view of the very real patient need for new technologies and treatments, Congress must act to fix § 101 and resolve the ambiguity surrounding patent eligibility.

4. Do you have any comments on our draft proposal? Are there any changes you believe we should make?

Answer: We strongly support the draft bill language as announced on May 22, 2019. However, we do not believe that a solution to the current § 101 problem requires any change to § 112. We are concerned that changes to § 112 could produce unintended consequences. We believe that any contemplated changes to § 112, including those set forth in the draft proposal, should be carefully considered and discussed separately from § 101. Therefore, we recommend removing the § 112 language from the draft proposal.

Answers to the Questions for the Record for Robert Deberardine

From Senator Mazie K. Hirono

Thank you for the opportunity to answer the following Questions for the Record. I have answered the questions in my capacity as Chief Intellectual Property Counsel for Johnson & Johnson.

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 *Berkheimber v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems."

Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?

Answer: Yes, we agree with Judges Laurie and Newman that §101 requires a congressional fix. Due to the tangled Supreme Court precedent surrounding § 101, the Federal Circuit has been reluctant, or unable, to fix the multiple inconsistent District Court decisions addressing patent eligibility under § 101. As Judge Lourie acknowledged "individual cases ... are imperfect vehicles for enunciating broad principles because they are limited to the facts presented." The focus of courts should be the fair application of well settled law based upon the facts, not the development of patent law *ab initio*. As has been articulated by the many experts that have testified before the Committee, the current state of § 101 jurisprudence is anything but settled. As I noted in my oral testimony, Congress excels at understanding the needs of society and legislating practical legal solutions for those needs and that is why Congress is the right place to fix §101.

2. The Federal Circuit rejected a "technological arts test" in its *en banc Bilski* opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and ever changing." The draft legislation includes the requirement that an invention be in a "field of technology."

a. Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?

Answer: The phrase "field of technology" can be ambiguous because the terms "technology" and "technological" have not been assigned a consistent meaning in the patent field, but rather have had different meanings depending upon the context in which the terms have been used. Having said that, given the use of the phrase "any field of technology" and the role of § 101 as a *course* filter, we do not have great concerns with that language. The language distinguishes the "useful arts" discoveries referenced in the constitution from the "fine arts" concepts supported by copyright law and the commercial branding concepts embodied in trademark law

b. The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?

Answer: The meanings ascribed to "technology" and "technological" in the European and Chinese patent systems differ from one another and must be viewed within broader context of the patent systems in which they exist. Since the patent systems in China and Europe differ from one another, and both differ from the patent system in the United States, we believe any attempt to import a definition of "technology" or "technological" from Europe or China would create confusion.

c. Is a claim that describes a method for hedging against a financial risk of price fluctuations – like the one at issue in the *Bilski* case – in a "field of technology"? What if the claim requires performing the method on a computer?

Answer: In our opinion a method for hedging against a financial risk would be unpatenable as lacking novelty under § 102 and being obvious under § 103. With regard to performing a "method on a computer" we do not believe that merely performing a known method on a computer is sufficient to transform an otherwise unpatentable method into a patentable one.

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

Answer: If it is determined that any change to the "field of technology" langue is needed, the langue "in the useful arts" might be substituted. This language has its origins in the U.S. Constitution at Article I, Section 8, Clause 8 which reads as set forth below.

"The Congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

3. Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal.

Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?

Answer: The current proposal sets forth a well-reasoned, technology neutral, approach to restoring § 101 to its role as a course filter for determining patent eligible subject matter. Thus, we do not believe a specific listing of excluded subject matter is required.

4. I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.

a. Are these valid complaints?

Answer: Although any individual § 112 analysis is case dependent based upon the specific facts including the nature of relevant technology, what is considered "ordinary skill" in the applicable field of art, and the patent specification in question, there is well developed case law that sets forth what is required to satisfy the "enablement" and "written description" requirements of § 112. In our opinion, courts do a very good job of applying this case law. Perceived errors of law in applying § 112 standards are appealable and considered by the Federal Circuit *de novo*. In addition, we believe that restoring § 101 to its appropriate role as a course filter for determining subject matter eligibility will have positive impacts on the development of § 112 case law. In particular, we believe that some courts have recently misapplied § 101 to address issues that are better served through appropriate application of § 112 standards. As such, restoring clarity to § 101 will encourage courts to appropriately apply § 112 standards.

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

Answer: We do not believe that a solution to the current § 101 problem requires any change to § 112. We are concerned that changes to § 112 could produce unintended consequences. Accordingly, we believe that any contemplated changes to § 112, including those set forth in the current proposal, should be carefully considered and discussed separately from the § 101 proposal.

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

Answer: We believe there is a valid concern that if the current § 112 proposal were to be implemented some parties may seek to avoid infringement based upon a hyper-technical interpretation of the patent specification, seeking out variants of claim elements that are not explicitly identified in the specification but would be understood by one of ordinary skill in the art to be a clear equivalent. In addition, we are concerned that the current § 112 proposal could cause patent practitioners to draft exhaustive disclosures of old information that could add cost and complexity to the patent process. Under current law inventors are not required to provide an exhaustive list of every conceivable equivalent for each claim element. Rather, the specification is drafted to inform one of ordinary skill in the art how the invention differs from the "prior art." This allows the inventor to highlight to others skilled in the art, and the Examiner at the USPTO, the distinguishing features of the claimed invention relative to what is already known in the relevant art. This approach is efficient and practical for the inventor, patent agents and attorneys, the USPTO, and the public alike. The current § 112 proposal could encourage patent practitioners to draft exhaustive specifications which would diminish or eliminate these practical efficiencies.

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 patents 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 to 101 do away with the doctrine of obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?

Answer: As a general point we do not believe that patent law determines the price of any individual product but rather functions to incentivize innovation. In addition, since the proposal is technology neutral we do not see how it would impact the pricing of products in any individual field of technology.

There are two types of "double patenting", neither of which would be impacted by the current proposal. The first type of "double patenting", known as "same invention" double patenting, has its basis in § 101 which states in relevant part "whoever invents or discovers any new and useful process ... may obtain ***a*** patent therefor ..." (emphasis added). "Same invention" double patenting prevents an inventor from claiming identical subject matter in two different patents. The current proposal would not impact the current "same invention" analysis. "Obviousness-type" double patenting prevents obtaining a patent claim in a subsequently filed application that is "obvious" in view of a granted claim in an earlier patent. A "terminal disclaimer" may be filed to overcome an "obviousness-type" double patenting rejection and functions to "disclaim" or "give up" the term of the subsequent patent that would extend beyond the term of the earlier patent. The current proposal would have no impact on the current "obviousness-type" double patenting analysis.

6. In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is a property for purposes of the Due Process Clause or the Takings Clause.

What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?

Answer: We have not identified any potential Due Process or Takings implications that would result from the current proposal. The proposal will provide clarity and predictability to the patent eligibility analysis and will restore § 101 to its tradition role as a course filter.