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BEFORE THE SENATE COMMITTEE ON THE JUDICIARY

SUBCOMMITEE ON INTELLECTUAL PROPERTY

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Mr. Chairman and distinguished members of the Subcommittee:

Thank you for providing me this opportunity to testify on "The State of Patent Eligibility in America." I appear here today in my capacity as the Chief Intellectual Property Counsel of Johnson & Johnson. We believe that a predictable patent system is essential to the future of American innovation and Section 101 reform is necessary if the United States is to retain its position as the world's innovation leader. It is for this reason that we strongly support the Tillis-Coons proposal to reform Sections 100 and 101 of the Patent Act ("Proposal").[1] We appreciate the leadership that Senators Thom Tillis (R-NC) and Chris Coons (D-DE) and Representatives Doug Collins (R-GA-9), Hank Johnson (D-GA-4) and Steve Stivers (R-OH-15) have exhibited in facilitating this legislative initiative.

For over a century Johnson & Johnson has developed groundbreaking medical treatments that have transformed, and saved, peoples' lives. It is only because of the United States patent system, and the predictability that it has historically provided, that we have been able to make the investments, conduct the research, and take the risks required to develop these treatments. And only with predictability will we be able solve today's most challenging healthcare problems and develop the groundbreaking treatments of tomorrow. Unfortunately, the patent system in the United States today is anything but predictable. We agree with United States Patent Office Director Iancu that the current state of the law surrounding Section 101 creates confusion that is antithetical to the very nature of intellectual property rights. As articulated by Director Iancu:

> [O]ur current law surrounding patentable subject matter has created a more unpredictable patent landscape that is hurting innovation and, consequently, investment and job creation. Recent cases from the Supreme Court – Mayo, Myriad, and Alice – have inserted standards into our interpretation of the statute that are difficult to follow. Lower courts applying these cases are struggling to issue consistent results. Patent lawyers

[1] We do not believe that changes to Section 112(f) are necessary to address the current patent eligibility problem. We suggest that any contemplated changes to Section 112 be separately studied and discussed utilizing a process similar to the one used by the Subcommittee for Section 101.

> trying to advise their clients are, in turn, struggling to predict the outcome with respect to certain patents. And examiners at the USPTO must spend increased amounts of time addressing this challenging issue. The current standards are difficult for all: stakeholders, courts, examiners, practitioners, and investors alike.[2]

The courts have also recognized the challenges presented by the unpredictable state of the law and have asked for congressional intervention. As Judge Lourie stated in his concurring opinion in *Aatrix Software, Inc. v. Green Shades Software, Inc.*:

> I believe the law needs clarification by a higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are §101 problems. Individual cases, whether heard by this court or the Supreme Court, are imperfect vehicles for enunciating broad principles because they are limited to the facts presented. Section 101 issues certainly require attention beyond the power of this court.[3]

The untenable state of law is made clear in *Ariosa Diagnostics, Inc. v. Seqenom, Inc.* In *Ariosa* the United States Court of Appeals for the Federal Circuit acknowledged that the claimed invention "reflects a significant human contribution" but felt bound by the Supreme Court decision in *Myriad* noting that under current law "groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[4] In a concurring opinion Judge Linn concluded "it is hard to deny that [the] invention is truly meritorious" and "but for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this *breakthrough invention* should be deemed patent ineligible."[5] If courts feel compelled under current case law to find that "groundbreaking" and "breakthrough" inventions are patent ineligible, then the time for legislative intervention is clearly at hand.

Today, instead of discussing the legal precedents that have created patent eligibility confusion in the United States (which others have already done so eloquently)[6], I would like to explain why predictability is a fundamental requirement of any patent system and how patents benefit both the individual and society. I will also explain how Johnson & Johnson and its partners rely upon a predictable patent system. In this way, I hope to illuminate why Section 101 reform is so desperately needed.

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[2] Director Iancu, "Role of U.S. Patent Policy in Domestic Innovation and Potential Impacts on Investment," Keynote Address, April 11, 2018, www.uspto.gov/about-us/news-updates/remarks-director-andrei-iancu-us-chamber-commerce-patent-policy-conference.

[3] 890 F.3d 1354, 1360 (Fed. Cir. 2018) (Lourie, J., joined by Newman, J., concurring in denial for rehearing en banc).

[4] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371, 1381 (Fed. Cir. 2015).

[5] *Id.* at 1381, Emphasis Added.

[6] Johnson & Johnson is a member of The Coalition for 21st Century Patent Reform ("21C"). To better understand our legal reasoning as it relates to Section 101 reform we direct you the written testimony submitted by Phil Johnson, Chair of the 21C Steering Committee.

Patents Benefit the Individual and Society

Our nation is founded on the premise that the individual, unbound the by restrictions of a rigid hierarchical society, can through their hard work, intellect, and individual talents, find success – and be rewarded for their efforts. Our founding fathers validated this principle, as it relates to inventions, in the Constitution of the United States at Article I, Section 8, clause 8:

"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 …"

Patents exist to encourage individuals to take on the world's greatest technological challenges. Patents do not provide a guarantee of success but rather some degree of predictability that *if* the individual succeeds they will be rewarded for their efforts. The patent system provides an individual the freedom to try, knowing that if they succeed, they will be provided a limited term of exclusivity during which they can realize a reasonable return for the value that their invention provides society. Patents function not only to compensate the inventor for the value of their "successes" but also for the cost of their "failures".[7] Absent such a mechanism research would only be conducted in technologies where success is a near certainty thereby depriving society access to the most groundbreaking innovations.

Patents give inventors confidence to publicly disclose their invention, knowing that they have a property right upon which they can rely. This allows the inventor to raise capital, find partners necessary to bring their product to market, and ultimately offer their product for sale. Society benefits from the commercial product that embodies the invention but also benefits from the learnings and teachings disclosed in the published patent application. With the confidence a patent provides, inventors also often voluntarily publish research papers and other materials which contribute to public technological discourse and debate and furthers society's collective intellectual capital. Absent a predictable patent system, inventors would be incentivized to keep their inventions secret. This would potentially deprive society the benefit of the invention altogether (if the inventor chooses not to bring a product to market) and would do little to further society's shared knowledge.

The benefits that patents promise to the individual and society can only be realized when the patent system is predictable. Only then can an individual engage in the mental calculus required to determine whether the risk and uncertainty that accompanies technological innovation is

[7] Thomas Edison, one of the most prolific inventors in American history clearly recognized this benefit when he stated "I haven't failed, I've just found 10,000 ways that won't work."

"worth it." Unfortunately, in the United States, we have arrived at a point in our history where this calculus has become impossible. As noted by Director Iancu and the Federal Circuit in *Ariosa* the current state of the law regarding Section 101 is hurting investment and job creation and is rendering "groundbreaking" and "breakthrough" innovation unpatentable. And that is why we need change.

Johnson & Johnson – A 133-Year-Old Start Up

Although you may think of Johnson & Johnson today as a large multinational corporation, we were once a small family start-up company, founded by three brothers in New Brunswick, New Jersey. Today, Johnson & Johnson is the world's largest and most broadly-based healthcare company with more than 130,000 employees worldwide - but we still think of ourselves as a start-up. We continue to challenge ourselves every day to seek out cutting-edge innovation for the betterment of the human condition. And we continue to rely on the United States patent system to provide the predictability needed to allow us to invest in new technologies and develop the next generation of medical breakthroughs.

Although patent protections are important to all three of our business segments (consumer, medical device, and pharmaceutical) I will be focusing my comments on our Janssen pharmaceutical business (the "Janssen Pharmaceutical Companies of Johnson & Johnson") because I believe the challenges, uncertainty, and risks inherent in biopharmaceutical drug development best illustrate the need for a predictable patent system. Every day employees at Janssen are conducting groundbreaking research, both independently and with our many research partners, to address the world's most challenging healthcare problems including cancer, mental health conditions, and immunology disorders. But finding solutions to the world's most intractable healthcare problems requires tremendous investments of time and money. Millions of compounds may be screened, developed or tested for each one that meets safety and efficacy standards for use in patients. Even for the very few compounds that are subject to clinical testing, its estimated that just 9.6% of these candidates ultimately receive regulatory approval.[8] It is estimated that it takes, on average, 10-15 years and $2.6 billion to develop one new medicine.[9] In 2018 alone, Janssen invested $8.4 billion in research and development making

[8] David W. Thomas, Justin Burns, John Audette , Adam Carroll , Corey Dow-Hygelund , Michael Hay. Informa, Amplion, Biotechnology Innovation Organization (BIO). Clinical Development Success Rates 2006-2015. Available at: https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

[9] 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.

Janssen one of the world's top R&D investors, in any industry, anywhere in the world.[10] Patent protections allow innovative drug companies to take on this level of uncertainty and financial risk. Without a predictable patent system, new discoveries would be immediately copied, and investors would pursue far less risky endeavors. Ultimately new research would be limited, and many new medicines would go undiscovered.

In the biopharmaceutical space the patent system has other competitive, transparency, and innovation benefits that often go overlooked. While a drug is covered by patent protection, other companies must compete by developing non-infringing technologies. This encourages the development of alternative treatments that ultimately benefit patients. Transparency and public disclosure of information is encouraged and promoted in the biopharmaceutical research space to facilitate robust academic discourse between universities, other research entities, start-ups, and the pharmaceutical industry. Patents further this objective and free up parties to publish research related materials, present and discuss their ideas at conferences, and engage in public debate. This allows other researchers, universities, and innovative drug companies to use these learnings to develop the next generation of drugs. As discussed above, absent a patent system, inventors would be incentivized to keep their inventions secret so as to avoid copying. This could have particularly profound implications on biopharmaceutical drug development where disclosure of confidential information (including clinical data) is required for regulatory approval purposes. Finally, upon expiration of the patent term, today's innovative drugs become the generic drugs of tomorrow. In this way, innovative drugs are the basis of the generic drug pipeline. This dynamic has a compounding benefit to society over time. Specifically, while the number of innovative products in the marketplace remains relatively constant (fluctuating somewhat year to year depending upon the number of FDA approvals), the pool of generic products continues to grow. This ever-growing inventory of generic options increases patient choice and treatment alternatives.

At Janssen, we recognize that solving the world's greatest healthcare problems is tremendously challenging and we are not always going to be the first to come up with a new idea or a new way of approaching a problem. So, we must tap into the best science in the world, wherever that science originates. The patent system allows us to do that. We partner with doctors, nurses, hospitals, start-ups, entrepreneurs, and others, all of whom have their own patented ideas that we help develop into safe and effective treatments.[11] Although many types of researchers are involved in the early phases of research, larger pharmaceutical and biotechnology companies typically conduct the complex drug development process and pay for the costly clinical trials in

[10] https://jnj-janssen.brightspotcdn.com/30/0e/a365aea641e28a57573355358e01/2018-janssen-us-transparency-report.pdf.

[11] These parties also rely upon a predictable patent system. For some small companies and start-ups with whom we partner their patents are their primary (in some cases only) business asset.

humans required for drug approval.[12] In 2015, pharmaceutical companies spent over 2.5 times more on R&D than the U.S. governments world-leading investment in basic research through the National Institutes of Health.[13] Without the investment of larger pharmaceutical and biotechnology companies basic research could not be transformed into safe and effective treatments that benefit patients. In addition to the benefits patients derive from our treatments, our partners financially benefit from our investment, many receiving royalty payments for licensed research. This practice is consistent with the broader pharmaceutical industry – 90% of royalty payments to the top 10 research universities comes from the life sciences industry.[14] The patent system allows us to partner with this diverse group of stakeholders, which contributes to economic growth, new jobs, and most importantly the development of much needed new treatments.

I hope that I have clearly articulated the vital importance that the United States patent system plays in allowing us to deliver on our mission of solving today's most challenging healthcare problems. We strongly support the approach taken in the Proposal to fix our current patent eligibility problem. Thank you for the opportunity to testify before you today and I look forward to continuing to work with you on this much needed and important reform.

[12] The Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA Chart Packs: Biopharmaceuticals in Perspective. Report. Summer 2018. https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018.

[13] The Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA Chart Packs: Biopharmaceuticals in Perspective. Report. Summer 2018. https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018.

[14] Reslinski MA The Value of Royalty, Nat Biotechnol. 2014.