Johnson & Johnson

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Andrew Hirshfeld
Commission for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313

Re: Patent Eligibility Jurisprudence Study Request for Information: Docket Number PTO-P-2021-0032

Johnson & Johnson ("J&J") submits the following comments in response to the United States Patent and Trademark Offices (USPTO's) *Request for Information for its Patent Eligibility Jurisprudence Study*, 86 Fed. Reg. 36257-36260 (July 9, 2021) (Federal Register Notice).

J&J is the world's most comprehensive and broadly-based manufacturer of health care products for consumer, pharmaceutical, and medical device markets. For nearly 130 years, we have led the way in innovation supplying a broad range of health care products, beginning with the first antiseptic bandages and sutures. Continuing this heritage of innovation today, we are bringing important new pharmaceutical products to market in a range of therapeutic areas, as well as, developing important advancements in medical devices and new consumer products.

J&J is thankful for the USPTO's ongoing outreach to stakeholders regarding patent subject matter eligibility and appreciates the opportunity to comment on this important topic.

Comments

For over a century, J&J has developed groundbreaking medical treatments that have transformed, and saved, people's lives. It is only because of the United States patent system, and the predictability 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 it is only with the support of a predictable patent system that we will be able to solve today's most challenging healthcare problems and develop the groundbreaking treatments of tomorrow.

Although patent protections are important to all three of J&J's business segments (consumer, medical device, and pharmaceutical), the challenges, uncertainty, and risks

inherent in biopharmaceutical drug development perhaps best illustrate the need for a predictable patent system. Every day, employees at our Janssen business (the "Janssen Pharmaceutical Companies of Johnson & Johnson") 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 these 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, it is estimated that just 9.6% of these candidates ultimately receive regulatory approval.[1] In addition, it is estimated that it takes, on average, 10-15 years and $2.6 billion to develop one new medicine.[2] In 2020 alone, Janssen invested $9.6 billion in discovering and developing new medicines and vaccines making Janssen one of the world's top R&D investors, in any industry, anywhere in the world.[3]

Patent eligibility is an important consideration when a pharmaceutical company considers embarking on the long, uncertain, and costly process of developing a new drug. A predictable patent system encourages pharmaceutical companies to take on the significant risks associated with solving the world's greatest healthcare challenges. Unfortunately, the current state of patent eligibility law in the United States is anything but predictable. Respected thought leaders in patent law and policy have described the current state of patent eligibility law as follows:

Hon. Andrei Iancu (former USPTO Director): "Our 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 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

[1] 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

[2] 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.pdf, 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.

[3] https://transparencyreport.janssen.com/_document/the-2020-janssen-us-transparency-report?id=00000178-b8c7-d811-a5fd-bac73ba50000

addressing this challenging issue. The current standards are difficult for all: stakeholders, courts, examiners, practitioners, and investors alike."[4]

Hon. David Kappos (former USPTO Director): "Our current patent eligibility law truly is a mess. The Supreme Court, Federal Circuit, district courts, and USPTO are all spinning their wheels on decisions that are irreconcilable, incoherent, and against our national interest."[5]

Hon. Paul R. Michel (Chief Judge, ret'd. CAFC): "If I, as a judge with 22 years of experience deciding patent cases on the Federal Circuit's bench, cannot predict outcomes based upon case law, how can we expect patent examiners, trial judges, inventors and investors to do so?"[6]

Sen. Thom Tillis (R-NC): "Why would anyone in their right mind risk millions if not billions of dollars to develop a product when they have no idea if they're eligible for protection?"[7]

Sen. Chris Coons (D-DE): "Today, U.S. patent law discourages innovation in some of the most critical areas of technology, including artificial intelligence, medical diagnostics, and personalized medicine."[8]

The courts have likewise recognized the untenable state of patent eligibility law in the United States. In *Ariosa Diagnostics, Inc. v. Seqenom, Inc.* the United States Court of Appeals for the Federal Circuit stated 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."[9] In a concurring opinion, Judge

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[4] Hon. Andrei Iancu, "Role of U.S. 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.

[5] Hon. David Kappos, Oral Testimony Before the U.S. Senate Sub-Committee on Intellectual Property, 116th Cong. (2019), https://www.judiciary.senate.gov/imo/media/doc/Kappos%20Testimony.pdf.

[6] Hon. Paul R. Michel, Testimony Before the Subcommittee on Intellectual Property U.S. Senate Committee on the Judiciary, 116th Cong. (2019), https://www.judiciary.senate.gov/imo/media/doc/Michel%20Testimony.pdf.

[7] Liz Hollis, *Experts Tackle the Current State of Patentability,* BioWorld, (Oct. 25, 2019), https://www.bioworld.com/articles/430661-experts-tackle-the-current-state-of-patentability.

[8] Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework, (Apr. 17, 2019), https://www.coons.senate.gov/news/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework.

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

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."[10]

We believe the pharmaceutical industry is on the cusp of a healthcare revolution. Numerous advances including: the emergence of 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 even before disease onset; new treatments that activate and amplify the natural immune response of the body; safe and effective new formulations derived from natural resources; and the use of artificial intelligence and "big data", all hold great promise to 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, the current state of patent eligibility law discourages investment in these technologies because they all, to some extent, relate to or rely upon "abstract ideas", "laws of nature", or "natural phenomenon." The current state of patent eligibility law discourages investment and research and development in these areas because it is impossible to predict, with any degree of certainty, whether the inventions resulting from this research will be deemed patent eligible. As a result, business leaders face the following, very real, question:

> ***Do you want to invest hundreds of millions of dollars, and a decade or more of time, 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. Without restoring clarity and predictability to Section 101, we 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.

In addition to the challenges that patent eligibility law presents busines leaders making innovation investment decisions, it has also introduced considerable complexity and cost into patent prosecution process. In some technology areas, we readily face Section 101 rejections during prosecution which necessitate the preparation and filing of additional office action responses. Often, these very same inventions do not face subject matter eligibility hurdles in other jurisdictions - including Europe and China.

To enable companies like Johnson & Johnson to continue to invest in the patient-focused innovations of tomorrow, it is important that predictability and reliability be restored to the U.S. patent system. Section 101 reform would represent an important step towards achieving this goal.

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

J&J, together with our many research partners, look forward to bringing life-transforming and lifesaving products to healthcare consumers for the next 130 years. We support Section 101 reform that will help us realize this mission and will ensure that the United States retains its position as the world's healthcare innovation leader. Johnson & Johnson thanks the USPTO for the opportunity to submit comments on the current state patent eligibility law and welcomes further dialogue with the USPTO on this important issue.

Respectfully,

Robert Deberardine
Chief Intellectual Property Counsel, Johnson & Johnson