



Statement of
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Before the
SENATE JUDICIARY COMMITTEE'S
SUBCOMMITTEE ON INTELLECTUAL PROPERTY

on
SECTION 101 LEGISLATION

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2:30 p.m.

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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to appear on this panel and discuss the State of Patent Eligibility in America. By way of introduction, I am Senior Vice President & Deputy General Counsel at Bristol-Myers Squibb (BMS), where I have served as Chief Intellectual Property Counsel since 2011. I am a registered patent attorney and have practiced IP law and litigation since 1991, initially in private practice and then in-house for the past twenty years, including prior employment as Chief IP Counsel of Schering-Plough Corporation. Although BMS and I are members of various stakeholder groups that are testifying during these hearings, I am today testifying in my capacity as the President of Intellectual Property Owners Association (IPO). The views that I share today reflect IPO's position on patent eligibility and should not be taken as the views of BMS or any other organization.

INTRODUCTION

IPO is a trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. We are a diverse organization, representing members that include about 200 companies in industries ranging from pharmaceuticals and biotechnology to electronics and information technology. IPO believes IP rights drive innovation, which creates economic prosperity. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative issues and disseminating information to the public on the importance of IP rights.

My comments are based on positions adopted by the IPO Board of Directors in 2017 and 2018 recommending legislation to amend section 101 of the U.S. Patent Act in

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response to several Supreme Court decisions that significantly changed the law on patent eligibility and compromised the ability to patent important innovations in the United States. The IPO position was merged with efforts by AIPLA, and our joint proposal was adopted by many other significant bar associations in recognition of the great uncertainty and confusion regarding patent eligibility faced by inventors, businesses, the USPTO, and the federal courts. Important technological advances are being denied patent protection despite efforts by the USPTO and the lower courts to rationally apply the current law. Congressional action is needed.

We applaud the Subcommittee's leadership on addressing this issue and thank Chairman Tillis and Ranking Member Coons for hosting roundtables to receive input from stakeholders and engage in a thoughtful, constructive dialogue about the extent of the problem and to identify possible balanced solutions. IPO supports this bipartisan, bicameral effort to develop a pro-innovation bill to clarify section 101. While IPO has not taken an official position yet on the proposed legislative text released on May 22, the draft language relating to section 101 is consistent with the approach taken in our earlier legislative proposal. IPO notes that certain aspects of the May 22 legislative proposal, such as the suggested changes to section 112(f), have not been addressed by the IPO Board and may require further study to understand how they would interplay with the existing requirements of section 112, which already serve as an effective check on patent claim breadth.

IPO will continue during this process to provide input about reforms that will increase certainty, consistency, and predictability for patent owners and promote innovation, investment and job creation. We look forward to working with this

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Subcommittee, and the corresponding Subcommittee in the House, to find a balanced solution that addresses the varying interests of IPO's members.

I. Problems with the Current State of the Law

The U.S. Constitution provides Congress with the 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.”¹

The current language of 35 U.S.C. § 101 was enacted in 1952, establishing that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” Section 101 is directed to the classes of inventions or discoveries that are the proper subject matter of patents versus other types of IP protection. Other sections of the Patent Act govern patentability, which is a qualitative analysis of whether an invention is novel and non-obvious to a skilled artisan and whether the formal requirements of properly disclosing and claiming the invention are satisfied.

Since 2006, the U.S. Supreme Court has been significantly active in patent law, issuing several cases on average per year that have largely either diminished patent

¹ U.S. CONST. art. I, § 8.

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protection or made it more uncertain.² Four of these opinions—*Bilski v. Kappos*,³ *Mayo Collaborative Servs. v. Prometheus Labs.*,⁴ *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*,⁵ and *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*⁶—have drastically limited and confused the scope of what is patent-eligible by creating a vague and subjective test for eligibility that lacks basis in the Constitution or statute. The test conflates the requirement that subject matter must be eligible for a patent with the other statutory requirements that must be satisfied to obtain a patent. As a result of the Supreme Court’s jurisprudence, section 101 has become a blunt instrument for invalidating patents without reaching these other statutory requirements.

Under the Supreme Court’s test, determining whether an invention is patent-eligible requires (1) determining whether the patent claim is directed to an abstract idea, natural phenomena or product of nature, and if so, (2) whether the claim contains an “inventive concept,” i.e., elements that are not routine or conventional that “transform the nature of the claim’ into a patent-eligible application.”⁷ There are numerous problems with this framework. First, the test requires an inquiry as to whether claim

² See, e.g., *Ebay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (holding that injunctive relief is not a remedy available as a matter of right for patent infringement); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (rejecting the Federal Circuit’s “teaching-suggestion-motivation” test for obviousness in favor of a more flexible standard); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915 (2014) (holding that induced infringement under 35 U.S.C. § 271(b) requires a single direct infringer); *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 581 U.S. ___, 137 S. Ct. 1523 (2017) (holding that the foreign sale of a U.S.-patented article, when by or with the approval of the U.S. patentee, does not exhaust the patentee’s U.S. patent rights); *TC Heartland L.L.C. v. Kraft Foods Group Brands L.L.C.*, 581 U.S. ___, 137 S. Ct. 1514 (2017) (holding that domestic defendants “reside” only where incorporated for venue purposes); *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 584 U.S. ___, 138 S. Ct. 1365 (2018) (holding that a U.S. patent is a “public right” rather than private property).

³ 561 U.S. 593 (2010).

⁴ 566 U.S. 66 (2012).

⁵ 569 U.S. 576 (2013).

⁶ 573 U.S. 208 (2014).

⁷ *Alice Corp. v. CLS Bank Int’l*, 572 U.S. 208, 217 (2014) (quoting *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. 66, 78 (2012)).

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elements are “routine or conventional,” which are questions properly evaluated under section 102’s novelty requirement. Second, the Patent Act of 1952 codified the requirement of non-obviousness in section 103 in part to preclude an analysis of an invention’s inventive concept. Section 103 provides a better filter because it bases non-obviousness on the objective standard of a person of ordinary skill in the art. Finally, recent lower court opinions have invalidated patents as ineligible under section 101 by explaining that the claims are too broad, an issue that is properly evaluated under section 112.⁸ Rigorous application of section 112’s current requirements of written description, enablement, and definiteness in claiming could address many concerns that courts are currently addressing through section 101.

The Supreme Court’s test has caused confusion and uncertainty for applicants seeking to obtain patents from the U.S. Patent and Trademark Office. Speaking at the IPO Annual Meeting in September 2018, USPTO Director Andrei Iancu acknowledged this uncertainty when he announced that the USPTO was working on revised guidance for examiners that he said was urgently needed given their daily struggles to apply the Supreme Court’s test. The USPTO issued that guidance in January 2019, and we applaud Director Iancu’s leadership in trying to provide more consistency and predictability across the USPTO. However, the guidance is constrained by the Supreme Court’s jurisprudence, and uncertainty still exists about whether certain important inventions are eligible for protection. Even after issuing the new guidance, in April of this year Director

⁸ See, e.g., *ChargePoint, Inc. v. SemaConnect, Inc.*, No. 2018-1739, slip op at 15, (Fed. Cir. Mar. 28, 2019); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015).

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Iancu called patent eligibility “the most important issue of substantive patent law” that “must be addressed now” because of the remaining “significant confusion” in the law.⁹

The Supreme Court’s jurisprudence has also caused uncertainty and confusion as patent owners seek to enforce their rights in court. Judges at the U.S. Court of Appeals for the Federal Circuit have authored numerous opinions critical of the U.S. Supreme Court’s test, which has required the Federal Circuit to find important inventions ineligible for patent protection. In the diagnostics area, for example, in 2015’s *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,¹⁰ the Federal Circuit held that Sequenom’s groundbreaking claims for a method for detecting fetal DNA in maternal blood were patent-ineligible because they were directed to a natural phenomenon and the steps of amplifying and detecting the fetal DNA were “well-understood, routine, or conventional activity.”¹¹ In a concurring opinion, Judge Linn agreed that the “sweeping language” of the Supreme Court’s test necessitated the result in this case, but he said that there was otherwise “no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.”¹²

More recently, the Federal Circuit found claims for methods for diagnosing neurological disorders by detecting antibodies to a protein ineligible because they recited “only a natural law together with conventional steps to detect that law.”¹³ In a footnote, however, Judge Lourie agreed with the sentiment expressed by Judge Newman in a

⁹ Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office Andrei Iancu, USPTO Updates: New Section 101 Guidance & Other Hot Topics, Remarks at 27th Annual Intellectual Property Law & Policy Conference at Fordham Law School (April 25, 2019), *quoted in* James Nurton, *Iancu Calls on Federal Circuit to Fix Section 101 Problem*, IP WATCHDOG (May 2, 2019), <https://www.ipwatchdog.com/2019/05/02/iancu-calls-federal-circuit-fix-section-101-problem/id=108813/>.

¹⁰ 788 F.3d 1371 (Fed. Cir. 2015).

¹¹ *Id.* at 1377.

¹² *Id.* at 1381 (Linn, J., concurring).

¹³ *Athena Diagnostics v. Mayo Collaborative Servs.*, 915 F.3d 743, 757 (Fed. Cir. 2019).

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dissenting opinion that “the public interest is poorly served by adding disincentive to the development of new diagnostic methods,”¹⁴ saying that “providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts.”¹⁵ However, “whether or not we as individual judges might agree or not that these claims only recite a natural law,” Judge Lourie explained, “precedent leaves no room for a different outcome here.”¹⁶

In other opinions, Federal Circuit judges have recognized that the Supreme Court’s test has created an “incoherent body of doctrine”¹⁷ that makes it “near impossible to know with any certainty whether the invention is or is not patent eligible.”¹⁸ This concern was demonstrated in *Thales Visionix Inc. v. United States*,¹⁹ involving an invention that used software. The Court of Federal Claims had ruled that Thales’s claims for a helmet-mounted system used for navigating fighter jets was ineligible for patent protection. This decision was reversed when the Federal Circuit determined that the patent claims were “directed to a new and useful technique for using sensors to more efficiently track an object on a moving platform,” and the use of a mathematical equation did not “doom the claims to abstraction.”²⁰ The case demonstrates, however, how unsettled this area of law is, putting at risk the significant investment companies make in developing and commercializing advanced technologies.

In *Chargepoint, Inc. v. Semaconnect, Inc.*, another software-related case, the Federal Circuit found method and apparatus claims for electronic charging stations for

¹⁴ *Id.* at 762 (Newman, J., dissenting).

¹⁵ *Id.* at 753, n.4 (majority opinion).

¹⁶ *Id.*

¹⁷ *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J. concurring).

¹⁸ *Id.*

¹⁹ 850 F.3d 1343 (Fed. Cir. 2017).

²⁰ *Id.* at 1349.

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electric vehicles patent-ineligible because they were directed to an “abstract idea.”²¹

While it is possible that this invention might not have satisfied the criteria necessary to merit issuance of a patent, such as novelty or non-obviousness, software inventions are important technologies that should be eligible for patent-protection. Software is deployed in additional areas of technology with each passing day. Disincentivizing invention or failing to realize the value of commercializing technology that results from this interplay, as well as important emerging technologies such as artificial intelligence, will handicap the U.S. against our global competitors.

The Supreme Court seems unlikely to reconsider this issue anytime soon. Two Federal Circuit judges stated in an opinion last year that “the law needs clarification by higher authority, perhaps by Congress.”²² IPO agrees. The current patent eligibility jurisprudence is unjustified as a matter of legal principle and sound domestic policy. Moreover, confusion about what is patent-eligible discourages inventors from pursuing work in certain technology areas, including discovering new genetic biomarkers and developing diagnostic and artificial intelligence technologies. For businesses, uncertainty disincentivizes the enormous investment in research and development that is necessary to fuel the innovation cycle. This is detrimental to America’s competitiveness in the global economy as other large patent systems such as China and the European Union take a more expansive view of what is patent-eligible.²³ This creates the risk that investment

²¹ *ChargePoint, Inc. v. SemaConnect, Inc.*, No. 2018-1739 (Fed. Cir. Mar. 28, 2019).

²² *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., joined by Newman, J., concurring in denial of rehearing en banc).

²³ In recent years, China has formulated policies and invested in strengthening its IP system, with a stated objective of becoming a global innovation leader; to that end, in 2017 it provided updated examiner guidance that relaxed previous restrictions on issuing software and business method patents. Likewise, in 2018 the European Patent Office issued updated guidance for examiners lowering the bar for what should be considered “technical,” i.e., eligible, with regards to computer-implemented inventions, mathematical methods, and artificial intelligence/machine learning.

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dollars will be spent overseas rather than in the U.S., for which there is evidence to suggest is already happening,²⁴ or on non-R&D intensive industries.²⁵ Perhaps most importantly, disincentivizing innovation is bad for the American public, which will suffer from the lack of valuable new products, services and jobs.

II. Supporting Legislation to Amend 35 U.S.C. § 101

In 2017, IPO adopted the first proposed statutory amendment of section 101. Our goal was to clarify the scope of subject matter eligibility in a technology-neutral manner, require evaluation of the invention as a whole rather than parsing a patent's claims into individual elements, and clearly state that no consideration of an "inventive concept," or the statutory requirements of sections 102, 103, and 112, should factor into determining whether an invention is patent-eligible.

Shortly thereafter, we joined forces with the American Intellectual Property Law Association (AIPLA) and synthesized our work into a joint legislative proposal that both associations adopted in 2018. The IPO-AIPLA proposal (attached as appendix) has received wide support from organizations including the New York IP Law Association, New Jersey IP Law Association, Boston Patent Law Association, Philadelphia IP Law Association, the Intellectual Property Law Association of Chicago, and the National Association of Patent Practitioners.

²⁴ See Lance Ng, *China Could Dominate Venture Capital in 2019*, MEDIUM (Jan. 11, 2019), <https://medium.com/behind-the-great-wall/chinas-venture-capital-market-could-dominate-the-world-in-2019-5bc56e7d4edd>.

²⁵ See *U.S. Startup Company Formation and Venture Capital Funding Trends 2004 to 2017*, USIJ ALLIANCE FOR U.S. STARTUPS & INVENTORS FOR JOBS, <https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/5c40b4d3c2241b6146c26cc9/1547744468287/USIJ%2BU.S.%2BStartup%2BFormation%2BTrends%2B--%2B2004-2017%2B--%2BFinal.pdf>. (last visited June 3, 2019).

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We applaud the Subcommittee's leadership on addressing this issue and, in particular, thank Chairman Tillis and Ranking Member Coons for hosting roundtables to receive input from stakeholders and engage in a thoughtful, constructive dialogue about the extent of the problem and possible balanced solutions. IPO has participated in this process enthusiastically and has provided comments consistent with the substance of our proposal. We are committed to working with the Subcommittee to address this problem through legislation.

IPO supports this bipartisan, bicameral effort to develop a pro-innovation bill to clarify section 101. IPO has not taken an official position yet on the proposed legislative text released on May 22, but the draft legislative text modifying section 101 is consistent with the spirit of our earlier legislative proposal. Much of the draft legislative text is the same in substance as the IPO/AIPLA proposal.

We support eliminating judicial interpretations that prohibit patents that build on “abstract ideas,” “laws of nature,” or “natural phenomena” so long as the claimed invention is useful and is the result of human intervention. We agree that the word “new” should be omitted from section 101, leaving the well-defined novelty requirement in section 102 to determine whether an invention is new. We also support requiring that eligibility be determined based on an analysis of the claim as a whole, rather than dissecting an invention into its component parts. We are in agreement that eligibility should be determined “without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.”

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Finally, we agree with the use of restraint when it comes to stating exceptions to patent eligibility. Our joint proposal emphasizes the principle that human activity to “make” something should be the touchstone of eligibility, reflecting the Framers’ intent in 1790 and Congressional intent when passing the 1952 Patent Act that “anything under the sun that is made by man” should be eligible. The four existing categories of inventions—process, machine, manufacture, and composition of matter—do most of this work. The two narrow, precisely defined exceptions in the IPO-AIPLA proposal were intended to further distinguish subject matter that is made by humans from that which is not and to preserve a broad scope of subject matter eligibility.

We are studying the elements of the May 22 draft that differ from our legislative proposal with respect to the changes proposed to sections 100 and 112. We will want to avoid any interpretation that the amended statute intends to create a heightened utility requirement rather than merely codifying existing law including the Supreme Court opinion in *Brenner v. Manson*²⁶ and Federal Circuit decisions such as *In Re Brana*.²⁷ We will also study whether the phrase “field of technology” could be interpreted to foreclose eligibility of some of our members’ inventive contributions.

Turning to the proposed changes to section 112(f), we will need to understand the possible effects of the proposed amendment on the full range of technologies on which our member companies seek patents, and the potential interplay between the new proposed provision and various existing provisions in section 112, which presently have the ability to address the patentability of overly broad functional claim elements. We will

²⁶ 383 U.S. 519 (1966).

²⁷ 51 F.3d 1560 (Fed. Cir. 1995).

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continue to provide input about reforms we believe will increase certainty, consistency, and predictability for patent owners and will thus promote innovation.

The time has come for Congress to take control of innovation policy in the U.S. We must not allow the “incoherent body of doctrine” of subject matter eligibility to continue undermining innovation. We look forward to working with this conscientious Subcommittee that understands that imperative and seeks to find a balanced solution that addresses the varying interests of IPO’s members.

I am pleased to answer any questions or supply any additional information.

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APPENDIX



Joint IPO-AIPLA Proposal Concerning Legislative Amendment of 35 U.S.C. § 101

Eligible Subject Matter

a) Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.

Sole Exceptions to Subject Matter Eligibility

b) A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole (i) exists in nature independently of and prior to any human activity or (ii) is performed solely in the human mind.

Sole Eligibility Standard

c) The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to:

- (i) the requirements or conditions of sections 102, 103, and 112 of this title;
 - (ii) the manner in which the claimed invention was made or discovered;
- or
- (iii) whether the claimed invention includes an inventive concept.