Testimony before the U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

Hearing on

"Artificial Intelligence and Intellectual Property – Part I:
Patents, Innovation, and Competition"

June 7, 2023

John Villasenor
Professor of Law and Electrical Engineering
Faculty Co-Director, UCLA Institute for Technology, Law, and Policy
University of California, Los Angeles

Chair Coons, Ranking Member Tillis, Members of the Subcommittee: Thank you for the opportunity to testify at today's hearing.

I am on the faculty of the UCLA schools of law and engineering. I also founded and am faculty co-director of the UCLA Institute for Technology, Law, and Policy. In testifying today, I am providing my own views, not the views of any institution I am affiliated with.

Key points in my testimony include the following:

- To ensure American economic competitiveness over the coming decades, our innovation ecosystem—including our patent system—should provide an environment in which the promise of AI can be fully realized.
- Inventions made using AI should be patentable, with inventorship attributed to persons, not AI systems.
- More specifically, persons who use tools, including AI, as extensions of their mind, should be deemed to have conceived inventions generated through the use of those tools. I believe that this approach is consistent with current U.S. patent law.
- I do not support changing U.S. patent law to permit AI systems to be named as inventors.
- I do not believe that a computer-written online preemptive prior art disclosure with no substantive nexus to human understanding of its contents should count as a "printed publication" under 35 U.S.C § 102(a).

To explore these issues in more depth, I will first provide some brief comments regarding the role of AI in American economic competitiveness. I will then address the intersection of AI and patents. My testimony today is focused on utility patents, and not on design or plant patents.

AI and American Economic Competitiveness

A few weeks ago, a team of researchers from universities in the United States and Canada published a peer-reviewed paper describing how they used Artificial Intelligence (AI) to find a new antibiotic that can be effective against drug-resistant infections.[1] This discovery is important not only in relation to future medical treatments, but also symbolically: It underscores how AI can enhance the ability of scientists to advance human well-being and the frontiers of knowledge.

AI has the potential to bring benefits not only to drug development, but also to education, motor vehicle safety, medical diagnostics, agriculture, cyberdefense, weather forecasting, logistics, and a long list of other areas. To ensure American economic competitiveness over the coming decades, our innovation ecosystem—including our patent system—should provide an environment in which the promise of AI can be fully realized.

The goal of promoting AI innovation is closely linked to broader questions of American AI policy. Subjecting AI to overly burdensome regulation would favor large, well-funded incumbents that can easily bear the compliance costs, while disfavoring the newer, smaller companies that have historically been the source of so much of American innovation.

This does not mean that we should avert our eyes from the reality that AI, like most other technologies, can be used for both beneficial and problematic purposes. But in contemplating new AI regulation it is important to consider not only how effectively it would mitigate the targeted harms, but also the unintended consequences, including in relation to innovation.[2] This includes considering the geopolitical implications of regulation, so as not to push AI innovation and investment—and the associated job creation—to non-U.S. jurisdictions.

In discussing AI governance, it is also important to recognize that many non-AI-specific frameworks will apply to AI. For instance, it would violate Title VII of the Civil Rights Act of 1964 for a company to use AI to make hiring decisions in a manner that discriminates based on a protected characteristic such as race or gender. If the AI system in a driverless car causes an accident, products liability provides a way to seek legal recourse.

AI and Patents: Three Categories

When discussing the intersection of AI and patents, it is helpful to identify three categories. First, there can be patents *about* AI. Second, there can be patents describing inventions created *using* AI. Third, AI can be used to *write* patent applications or public disclosures intended to serve as prior art. I discuss each of these categories below.[3]

---

[1] Anne Trafton, *Using AI, scientists find a drug that could combat drug-resistant infections*, MIT NEWS (May 25, 2023), https://news.mit.edu/2023/using-ai-scientists-combat-drug-resistant-infections-0525.
[2] *See also* John Villasenor, *Four Key Questions to Ask*, THE CONVERSATION (Apr. 3, 2023), https://theconversation.com/regulating-ai-3-experts-explain-why-its-difficult-to-do-and-important-to-get-right-198868.
[3] There can be overlaps between two or even all three of these categories.

Patents *About* AI

The U.S. Patent and Trademark Office (PTO) is well-equipped to handle patent applications for inventions *about* AI, and has been doing so for years. A search on Google Patents shows that the PTO granted thousands of patents in the decade from 2013 to 2022 with claims containing one or more of the phrases "artificial intelligence," "machine learning," or "deep learning." Unsurprisingly, there were many more such patents issued in 2018-2022 than in 2013-2107.

Since U.S. patent applications are typically not published until 18 months after filing,[4] it is difficult to get public visibility into the number of patent applications about AI filed in 2022 and year-to-date in 2023. But that number is sure to be high given the level of recent attention to AI in the technology community and beyond. While there are operational responses within the PTO that might be expected in light of growing inventor interest in AI (e.g., hiring more examiners with expertise in AI), the PTO is in a good position to effectively examine patent applications regarding inventions about AI, just as it has over the decades for so many other rapidly changing technologies.

Patents on Inventions Made *Using* AI

Inventions made *using* AI pose a complex set of policy questions.[5]

The PTO has helped lead the policy dialog on these questions. The PTO announced the launch of the AI and Emerging Technologies Partnership in June 2022,[6] issued a "Request for Comments Regarding Artificial Intelligence and Inventorship"[7] in February 2023 for which responses were due in May, and held two "listening sessions", one on the East Coast in April and the second on the West Coast in May.[8]

I will refer to inventions made using AI as "AI inventions", and will use the following definition: "inventions for which an AI system has contributed to the conception in a manner that, if the AI system were a person, would lead to that person being named as an inventor."[9]

---

[4] If an application claims the benefit of an earlier filing, then the 18-month publication clock starts with that earlier filing. *See* 35 U.S.C. §122(b)(1)(A). Another factor impacting publication is that an application can be accompanied by a non-publication request in accordance with 35 U.S.C. § 122(b)(2)(B)(i).

[5] For a summary of some of the points made in this section, see John Villasenor, *AI Inventions: Policy Options and a Path Forward*, BROOKINGS INST. (Mar. 6, 2023), https://www.brookings.edu/blog/techtank/2023/03/06/ai-inventions-policy-options-and-a-path-forward/.

[6] 87 Fed. Reg. 34,669 (June 7, 2022). *See also* https://www.uspto.gov/initiatives/artificial-intelligence/ai-and-emerging-technology-partnership-engagement-and-events (last visited May 28, 2023).

[7] 88 Fed. Reg. 9,492 (Feb. 14, 2023).

[8] *AI Inventorship Listening Session - East Coast*, USPTO, https://www.uspto.gov/about-us/events/ai-inventorship-listening-session-east-coast (last visited May 30, 2023); *AI Inventorship Listening Session - West Coast*, USPTO, https://www.uspto.gov/about-us/events/ai-inventorship-listening-session-west-coast (last visited May 30, 2023).

[9] John Villasenor, *Reconceptualizing Conception: Making Room for Artificial Intelligence Inventions*, 39 SANTA CLARA HIGH TECH. L. J. 197, 199 (2023).

Two key questions raised by AI inventions are: First, should they be patentable? Second, how should inventorship be handled?

I believe that AI inventions *should* be patentable, and that inventorship should be attributed to the *natural persons* who use AI as a tool to enhance their ability to innovate. More specifically, as I explained in a recent law review publication in the *Santa Clara High Technology Law Journal*,

> conception should encompass ideas formed through collaboration between a person and tools that act as extensions of their mind. The "formation" of those ideas should be attributed to the person, including when the ideas underlying the invention were first expressed by a tool used to enhance their creative capacity and subsequently conveyed to them.
>
> Reconceptualizing conception in this manner would not require any change to the text of the Patent Act, and would promote investment in AI as a means to complement and enhance human creativity. and would avoid the many problems that would be associated with permitting non-human inventors.[10]

To operationalize this approach, no statutory changes are needed. The view of conception described above is fully consistent with current U.S. patent law.

The Patent Act, which is codified at Title 35 of the United States Code, does not define conception. As the Federal Circuit wrote in 2013, "[t]he definition of conception in patent law has remained essentially unchanged for more than a century."[11] Conception is defined as "the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."[12] This definition was published by Robinson in an 1890 treatise,[13] and has been cited in many cases over the years by both the Court of Customs and Patent Appeals (the precursor to the Federal Circuit) and by the Federal Circuit, including as recently as 2021.[14]

There is no need to change the text of Robinson's definition. It is sufficient to view it through a broader lens. As I wrote in the *Santa Clara High Technology Law Journal* article cited above, "[p]ersons who use tools, including AI, as extensions of their mind, should be deemed to have conceived inventions generated through the use of those tools."[15]

---

[10] *Id.*
[11] Dawson v. Dawson, 710 F.3d 1347, 1352 (Fed. Cir. 2013).
[12] WILLIAM C. ROBINSON, 1 THE LAW OF PATENTS FOR USEFUL INVENTIONS § 376 (1890), https://babel.hathitrust.org/cgi/pt?id=uc1.b3124815&view=1up&seq=698. The quoted text is part of a paragraph that also includes "[t]he conception of the invention consists in the complete performance of the mental part of the inventive act."
[13] *Id.*
[14] Bio-Rad Labs., Inc. v. ITC, 996 F.3d 1302, 1318 (Fed. Cir. 2021).
[15] Villasenor, *supra* n.9 at 230.

The Problems with Naming AI Systems as Inventors

I do not believe that AI systems should be inventors.

As an initial matter, as the Federal Circuit made clear in 2022 in *Thaler v. Vidal*,[16] current U.S. patent law does not permit naming a non-human inventor. Therefore, to make it permissible to name an AI system as an inventor, Congress would have to change the law. Many Members of Congress would rightly be quite hesitant to support a change of this magnitude, especially given the uncertainty about the downstream implications.

Legislative challenges aside, there are multiple additional concerns with changing U.S. patent law to allow AI systems to be inventors:

- An AI system cannot provide the required inventor's oath/declaration that must accompany a utility patent application.[17]
- An AI system is not equipped to engage in legal transactions associated with inventorship (e.g., assigning the invention).
- An AI system cannot get deposed in litigation regarding an invention.[18]

The Problems with Deeming AI Inventions Unpatentable

Another approach that has been proposed in the academic community is to deem AI inventions unpatentable. I do not support this approach, which has at least the following drawbacks:

- It would disincentivize investment in the use of AI in areas where it has high potential. For instance, a pharmaceutical company would be unlikely to make significant investments in AI-assisted drug development if it expected that any resulting drugs would be deemed unpatentable.
- It would lead to uncertainty and disputes regarding how to determine which inventions fall into the category of AI inventions, thereby rendering them unpatentable.
- It would create a new category of patent ineligibility based on having used too much AI when making an invention.[19] The resulting "how much is too much?" question would generate years of confusion.
- These new patent ineligibility issues would arise in litigation involving patents where a question might be raised regarding whether and to what extent AI was used to make the invention.
- These risks would also reduce patent value in licensing and acquisitions.

[16] 43 F.4th 1207 (Fed. Cir. 2022), *cert. denied*, 91 U.S.L.W. 3268 (U.S. Apr. 24, 2023) (No. 22-919).
[17] 35 U.S.C § 115(b)(2).
[18] The fact that an AI system may be able to answer questions is not sufficient. A deposition is sworn testimony, and there is no meaningful way for an AI system to be sworn in.
[19] It is relevant to note here that 35 U.S.C. § 103 states that "[p]atentability shall not be negated by the manner in which the invention was made."

Preemptive Prior Art and Patent Applications *Written* by AI

The use of AI writing tools to help create explanatory text (or figures) regarding inventions is not inherently problematic. It is reasonable for an inventor, or an attorney or patent agent working on behalf of an inventor, to use AI as a time-saving tool for describing an invention.[20] However, a problem arises when AI is used to describe alleged "inventions" for which there is no conception by a human.

Algorithmically-Generated Preemptive Prior Art

Computer algorithms (whether or not AI-enabled) can be used to write disclosures intended to foreclose patentability. This idea is not new. The creators of the website allpriorart.com, which the Wayback Machine indicates has been online since at least as early as 2016,[21] explain that

> [t]he system works by pulling text from the entire database of US issued and published (un-approved) patents and creating prior art from the patent language. While most inventions generated will be nonsensical, the cost to computationally create and publish millions of ideas is nearly zero – which allows for a higher probability of possible valid prior art.[22]

As everyone with an interest in AI knows, ChatGPT was publicly released in late 2022. ChatGPT is an example of "generative AI," a term that, as a recent post from IBM Research explains, "refers to deep-learning models that can generate high-quality text, images, and other content based on the data they were trained on."[23] ChatGPT and the much more capable tools that will certainly follow it will make it far easier to create and publish massive online databases intended to foreclose patentability over broad areas of subject matter.

To the extent that such publications occur without any substantive nexus to human understanding of their contents, there is a good argument that they should not count as "printed publication[s]" under 35 § U.S.C. 102(a).[24] The entire concept of prior art is tied to what a *person* of ordinary skill in the art (POSA) would know.

---

[20] Of course, in doing so the writer would need to devote proper attention to accuracy, avoiding plagiarism, compliance with the written description requirement of 35 § U.S.C. 112, etc.

[21] *See* ALL PRIOR ART, https://web.archive.org/web/20160409211309/http:/allpriorart.com/ (Apr. 9, 2016).

[22] *About*, ALL PRIOR ART, https://allpriorart.com/about/ (last visited May 30, 2023) (parentheses in original). *See also About*, ALL PRIOR ART, https://web.archive.org/web/20160410071034/http://allpriorart.com/about/ (Apr. 10, 2016) (parentheses in original). The current and April 2016 "About" pages state that the published content is "algorithmically" generated but do not specify whether or not the algorithms used involve AI.

[23] Kim Martineau, *What is Generative AI?*, IBM RESEARCH (Apr. 20, 2023), https://research.ibm.com/blog/what-is-generative-AI.

[24] 35 U.S.C § 102(a) provides in relevant part that "[a] person shall be entitled to a patent unless— (1) the claimed invention was patented, *described in a printed publication*, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." (emphasis added) (I am considering here the version of the statute after the revisions introduced by the America Invents Act).

The POSA is a hypothetical construct who is presumed to know of all prior art in the relevant field at the relevant time. But I do not believe that a POSA's knowledge should be so broad as to include purported "art" embodied in computer-generated text for which there is no evidence that any human has ever understood the significance. A POSA should not be presumed to know the entire contents of massive algorithmically-generated online preemptive disclosure databases filled with mostly—though not entirely—nonsensical content. I believe that this view is consistent with Federal Circuit case law on the interpretation of "printed publication."[25]

AI-Written Patent Applications

AI writing tools can be used to draft provisional and utility patent applications. As noted above, the fact of using AI to help speed the process of drafting a patent filing is not inherently problematic. Rather, concerns arise if an individual or group were to use AI to flood the PTO with auto-generated (or largely auto-generated) patent applications where there is no substantive nexus to human conception. There are several factors that will impose friction on this scenario.

First, provisional and utility patent filings (and the subsequent prosecution process initiated by the filing of a utility application) cost money. Thus, there is an economic disincentive against filing very large numbers of AI-written patent applications.[26] That said, for some entities, these costs may not be viewed as significant in light of the anticipated payoffs.

Second, both provisional and utility patent applications need to satisfy the written description requirement.[27] This requires that the specification describe the invention in "full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use" the invention.[28] There is plenty of evidence indicating that today's generative AI technology still falls far short of being able to generate the quality of writing that a patent attorney or patent agent can produce.[29] It would be a highly risky enterprise to file a patent application written

[25] *See, e.g.*, Blue Calypso, LLC v. Groupon, Inc 815 F.3d (Fed. Cir. 2016). The *Blue Calypso* court explained that the fact that something was available online (or in the pre-World Wide Web days, in physical form in a library) does not necessarily mean it is a printed publication under § 102. Rather, the court wrote, "[t]o qualify as a printed publication, a reference 'must have been sufficiently accessible to the public interested in the art.'" *Id.* at 1348 (quoting In re Cronyn, 890 F.2d 1158, 1160 (Fed. Cir. 1989)). While *Blue Calypso* addressed a set of patents subject to pre-America Invents Act (AIA) § 102, it is reasonable to assume that "printed publication" has the same meaning in both pre- and post-AIA § 102. *See also* Voter Verified, Inc. v. Premier Election Sols., Inc., 698 F.3d 1374 (Fed.Cir.2012).

[26] If the goal is to simultaneously get thousands of pages of disclosure on file, filing a smaller number of longer applications would generally be even more expensive, due to the size fees that apply to provisional and utility filings exceeding 100 sheets. *See* 37 C.F.R. § 1.16(s).

[27] *See* 35 U.S.C § 112(a). *See also* 35 U.S.C. § 111(b)(1), which provides that a provisional application "shall include— (A) a specification as prescribed by section 112(a) . . ." Of course, a provisional application is not examined by the PTO. But to the extent that a provisional application fails to satisfy § 112(a), the patent owner could lose a priority date challenge arising in future litigation involving a utility patent issued from an application claiming priority to the provisional. Losing that priority date would expand the universe of prior art that could be asserted against the patent claims in a validity challenge.

[28] 35 U.S.C § 112(a).

[29] *See, e.g.*, Benjamin Weiser, *Here's What Happens When Your Lawyer Uses ChatGPT*, N.Y. TIMES (May 27, 2023), https://www.nytimes.com/2023/05/27/nyregion/avianca-airline-lawsuit-chatgpt.html.

entirely by today's AI tools, with no human supervision. But generative AI will improve with time, and the writing it will output will require correspondingly less human editing to render it as good as what an attorney or patent agent would write.

Third, a utility application must be accompanied by an oath or declaration stating that "such individual believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application."[30] Invention requires conception, and as discussed earlier, conception must occur in the human mind. It would strain credulity to assert that a single person or small group of persons, including under the broadened view of conception I have advocated for in the section on AI inventions, could credibly claim to have simultaneously or nearly simultaneously conceived of hundreds or thousands of inventions.

It is possible to predict some but certainly not all of the scenarios under which generative AI might be used in the future to write patent applications in ways that undermine the goals of the U.S. patent system.[31] That means that it will be important not only to identify the predictable scenarios but also to be agile in identifying emerging, unforeseen scenarios and formulating policy responses. It will also be important to ensure that these policy responses do not cause collateral damage by impeding inventors who are using AI for productive purposes.

I will also mention that I am currently finishing up the process of writing a new law review publication on the issues raised by the use of generative AI in writing patent applications and preemptive prior art. I would be happy to share the article with interested Members of the Subcommittee once it is published.

In closing, I would like to thank the Members of the Senate Judiciary Committee's Subcommittee on Intellectual Property for the opportunity to participate in today's hearing. I look forward to the discussion today and beyond on ways to ensure that the United States remains a global innovation leader.

In the era of AI, I am confident that with engagement from Members of Congress, the PTO, civil society, businesses, and academia, the U.S. patent system will retain its vital role in promoting American innovation, technology leadership, and economic competitiveness.

[30] 35 U.S.C § 115(b)(2).

[31] Here is an example scenario: Once generative AI becomes sufficiently capable, an entity could use it to autogenerate and file on the same day hundreds of provisional applications in a particular field of art. The entity could then use the subsequent 11 months to study those filings and harvest patentable ideas. Then, in the subsequent month, and before the expiration of the one-year period following the provisional filing date, the entity could file a set of utility applications, each claiming the benefit of a carefully selected subset of the provisional filings. Of course, this sort of invention-by-hindsight approach would mean that conception had not in fact occurred as of the date the provisional applications were filed. But it would nonetheless be challenging to address.

UNIVERSITY OF SURREY

Faculty of Arts and Social Sciences
Guildford, Surrey GU2 7XH UK

Professor Ryan Abbott, MD, JD, PhD
Professor of Law & Health Sciences

School of Law

T: +44 (0)1483 682851
E: r.abbott@surrey.ac.uk

www.surrey.ac.uk/law/people/ryan_abbott

June 1, 2023

The Honorable Chris Coons, Chair
The Honorable Thom Tillis, Ranking Member
Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate United States Senate
Washington, DC 20510

Dear Chairman Coons and Ranking Member Tillis:

My name is Ryan Abbott, I am Professor of Law and Health Sciences at the University of Surrey School of Law, Adjunct Assistant Professor of Medicine at the David Geffen School of Medicine at University of California, Los Angeles (UCLA), partner at Brown, Neri, Smith & Khan, LLP, and a mediator and arbitrator with JAMS, Inc. I submit these written comments for the record in conjunction with my oral testimony for the June 7th, 2023 hearing entitled "Artificial Intelligence and Intellectual Property – Part I: Patents, Innovation, and Competition."

My research has focused on the intersection of AI and the law, and on what legal rules will best help the United States and other jurisdictions maximize the social benefits of AI while minimizing its risks. Among other publications, I am the author of *The Reasonable Robot: Artificial Intelligence and the Law*, Cambridge University Press (2020). I have also written specifically on issues related to AI and IP and patent law, including as the editor of the *Research Handbook on Intellectual Property and Artificial Intelligence*, Edward Elgar (2022), and the author of Everything is Obvious, UCLA Law Review (2019) and *I Think, Therefore I Invent: Creative Computers and the Future of Patent Law*, Boston College Law Review (2016). I am a licensed physician and patent attorney in the United States, and a solicitor advocate in England and Wales.[1]

I also lead the Artificial Inventor Project, which includes a series of pro bono legal test cases seeking intellectual property rights for AI-generated output in the absence of a traditional human inventor or author. This includes acting as lead counsel for *Thaler v.*

[1] www.ryanabbott.com.

Vidal, 43 F.4th 1207 (Fed. Cir. 2022) (cert denied), which regards the patentability of AI-Generated Inventions, and *Thaler v. Perlmutter*, 1:22-cv-01564 (D.D.C.), which regards the copyrightability of AI-generated works. I directly lead or manage the foreign analogs of these cases in 17 foreign jurisdictions worldwide. This project is intended to, among other things, promote dialogue about the social, economic, and legal impact of frontier technologies such as AI and to generate stakeholder guidance on the protectability of AI-generated output.[2]

Interest in AI and patent law has blossomed in recent years, due to advances in AI functionality and the increased adoption of AI across a range of industries. These issues have become a focus of industry, policy makers, and even the public.[3] Artificial intelligence (AI) is expected to drive substantial economic growth, with one report estimating that AI could contribute up to $15.7 trillion to the global economy by 2030, with approximately $3.7 trillion of that growth in North America.[4] The National Security Commission on Artificial Intelligence has noted that, "[t]he United States must recognize IP policy as a national security priority critical for preserving America's leadership in AI and emerging technologies."[5]

To summarize my comments below, I make three sets of recommendations. First, that AI should be defined functionally for purposes of regulatory efforts and regulated in a technologically neutral manner. Second, that the Patent Act should be amended so that AI-Generated Inventions are patentable, and so that patentability shall not be denied based on how an invention is discovered. Third, that in the case of an AI-Generated Inventions lacking a traditional human inventor, the AI system that has functionally invented should be listed as the inventor and the AI's owner should be the owner of any intellectual property generated by their system. This would facilitate the incentive structure of the patent system, promote integrity and transparency, and protect the moral rights of human inventors.

I. Regulating Artificial Intelligence

It is important to regulate using standardized definitions. In the almost 70 years since the term "artificial intelligence" was introduced, it still lacks a generally accepted definition. While this ambiguity has not negatively impacted the work of computer scientists, it is necessary to have clarity in laws to ensure that statutory text achieves its purpose.

I recommend the Subcommittee adopt the following definition of AI: "Artificial intelligence" means an algorithm or machine capable of completing tasks that would otherwise require cognition.[6]

---

[2] http://artificialinventor.com/.
[3] Alexandra George & Toby Walsh. Artificial intelligence is breaking patent law. Nature. 24 May 2022.
[4] "Sizing the prize: What's the real value of AI for your business and how can you capitalize?," PwC, https://www.pwc.com/gx/en/issues/data-and-analytics/publications/artificial-intelligence-study.html.
[5] https://www.nscai.gov/wp-content/uploads/2021/03/Full-Report-Digital-1.pdf.
[6] Ryan Abbott, The Reasonable Robot: Artificial Intelligence and the Law (2020), at 22.

A functional definition of AI is preferrable to one that attempts to distinguish between AI and other sorts of software or computer systems based on specific programming techniques. That is because policy makers should be concerned with the capabilities and behavior of AI, rather than the specific way an AI is programmed or designed. It should make no difference whether an autonomous vehicle operates according to a machine-learning based algorithm or good-old-fashioned AI, just whether the car negligently strikes a pedestrian.

For example, the evolving draft EU AI Act takes a non-neutral approach to AI regulation by prohibiting the use of AI for social scoring.[7] This approach is misguided, because the underlying mischief to be solved is the use of social scoring generally rather than AI-enabled social scoring specifically. A jurisdiction could have a human-centric government agency devoted to social scoring each citizen by paper and pencil, and that would be equally offensive to European values as having that work automated. EU law should thus prohibit social scoring without regard to the use of particular technology to better improve social outcomes.

II. Artificial Intelligence and Patent Law

AI raises important challenges in the context of patent law. My comments will focus on those related to the patentability of AI-Generated Inventions, related ownership and inventorship issues, and the test for non-obviousness including the standard of the person having ordinary skill in the art (PHOSITA or the "skilled person").

I recommend the Subcommittee adopt the following definitions:

- "AI Inventions" means an invention functionally conceived or reduced to practice using AI.
- "AI-Generated Invention" means an invention functionally conceived of by an AI under circumstances in which no person traditionally qualifies as an inventor.
- "AI/Human-Generated Invention" means an invention functionally co-invented by an AI and a human being.
- "AI-Assisted Invention" means an invention is which an AI functionally assists with reduction to practice.

"Conception," as distinguished from "reduction to practice," is the test for inventorship under US law.[8] AI Inventions also raise a different group of issues from other inventions related to AI, such as patents claiming, in some fashion, algorithms or computers ("software patents" or "computer-implemented inventions").

---

[7] https://www.europarl.europa.eu/resources/library/media/20230516RES90302/20230516RES90302.pdf.

[8] Conception is "the complete performance of the mental part of the inventive act". It is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice…." *Townsend v. Smith,* 36 F.2d 292, 295 (CCPA 1929). "[C]onception is established when the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill." *Hiatt v. Ziegler,* 179 USPQ 757, 763 (Bd. Pat. Inter. 1973). See also *Coleman v. Dines,* 754 F.2d 353 (Fed. Cir. 1985) (to establish conception, a party must show possession of every recited feature and that every limitation was known to the inventor at the time of conception).

As a matter of patent policy, the use of AI should not render an invention unpatentable. Patentability should be based on whether an invention objectively meets substantive requirements rather than how the invention is created. The purpose of patent law is to provide an incentive for innovation, disclosure of confidential information, and the commercialization of inventions. Denying patent protection for inventions based on the use of AI would run counter to the purpose of the patent system.

Whether and to what extent AI is automating the inventive process remains controversial.[9] In some ways, this mirrors historic debates over whether and to what extent AI is automating the creative process. AI has been creative for decades, but recent advancements in AI over the past year or two have largely put this debate to rest. There are now dozens of publicly accessible large language models and generative AI systems that are occupying the role of a traditional human author on a widespread scale.

Similarly, there have been credible claims of AI inventing for decades made by entities ranging from academics to large enterprises.[10] Yet in discussions about inventive AI, AI is sometimes referred to as "just a tool" like a pencil or a microscope to suggest that it is not capable of invention. This can be misleading. In some sense, any AI is a tool. It is made by human beings (perhaps a step(s) removed if another AI is generating code), and it completes tasks as directed by human beings. To use an autonomous vehicle again as an example, the AI that drives the vehicle was programmed by people, and it only drives (hopefully) to where a person directs. On the other hand, the AI automates a task that was once something only people could do, namely driving a vehicle from one place to another. The AI is thus stepping into the shoes of a person and performing an activity that historically was exclusively human. In that sense, it is autonomous.

In the inventive context, the use of an AI system can differ significantly from something like a pencil or a microscope. That is because, certain AI systems, in certain contexts, can automate aspects of the inventive process—whether that is identifying: 1) a problem to be solved, 2) a technical solution to a technical problem, or 3) the utility of a particular solution. These are activities that if performed by a human being (depending on specific facts) make that person an inventor. In essence then, some systems are stepping into the shoes of traditional human inventors and automating some or all of the inventive process.

Most of the time, of course, humans are still very much involved in AI Inventions and can directly qualify as inventors. In some instances, a person may qualify as an inventor

[9] See response to the USPTO Request for Comments on AI and Inventorship, https://www.regulations.gov/docket/PTO-P-2022-0045.

[10] See, e.g., Ryan Abbott, The Reasonable Robot: Artificial Intelligence and the Law (2020), Ch 4 & 5, (describing claims of AI-Generated Inventions from the 1980s and 1990s); https://c.connectedviews.com/05/SitePlayer/wipo?session=31245, Beat Weibel, AI Created Inventions – Digital Inventor Computer-Implemented Simulations – Digital Twin, WIPO CONVERSATION ON INTELLECTUAL PROPERTY (IP) AND ARTIFICIAL INTELLIGENCE (AI), Sept. 30, 2019 (describing Siemen's inability to file for patents on AI-Generated Inventions in the 2010s); https://www.supremecourt.gov/DocketPDF/22/22-919/263320/20230412115821327_No.%2022-919_Brief.pdf (describing more recent possible AI-Generated Inventions).

by identifying a problem to be solved, programing/training an AI to solve a particular problem, interpreting/iterating AI output, or recognizing the utility of AI output.

Some of the time however, such individuals will not qualify as inventors. A programmer/developer/trainer who merely develops to an AI with problem-solving capabilities without specifically conceiving of a particular output should not qualify as an inventor under US law. Treating a programmer as an inventor is particularly problematic in cases where the programmer creates an AI without expectation or knowledge of the specific problems the AI will go on to solve. It is also more problematic in cases where an AI has been developed by a large and distributed group of programmers over a significant time frame. Further challenging programmer-based inventorship, some AI systems such as neural networks can behave unpredictably, such that their programmers may not understand precisely how they generate specific and unexpected output. By analogy to human inventorship, a human inventor's teachers, mentors and even parents do not qualify as inventors on their patents—at least, not without directly contributing to the conception of a specific invention.

Attributing inventorship to an AI user, rather than a programmer, may also be problematic. It may sometimes be the case that a user makes an inventive contribution through the way that instructions or prompts are provided to an AI, or that a user otherwise makes a significant contribution to an AI's output. However, it may also be the case that a user simply asks an AI to solve a problem, and the AI proceeds to independently generate an answer. Again, by analogy to human inventorship, simply instructing another person to solve a problem does not usually qualify for inventorship.

Finally, it may be the case that an individual conceives of an invention by recognizing the utility of an AI's output. That may be appropriate where an AI generates numerous outputs and human judgment is needed to select a particular solution from a group of outputs. It may also be appropriate where inventive skill is needed to understand the importance of specific AI output. However, it may also be the case that the value of AI output is obvious, identified directly by the AI, and does not require inventive skill for a person to recognize. In these cases, it would be inappropriate to make a user an inventor.

Thus, in at least some instances, AIs are generating output traditionally entitled to patent protection under circumstances in which no natural person qualifies as an inventor according to traditional criteria. Or, an AI is acting as a co-inventor together with a person.[11] In practice, it may be difficult to determine when a person or an AI, or both, have invented. However, this is not unlike making sense of human inventorship for joint inventions where individuals make diverse contributions.

[11] https://www.federalregister.gov/documents/2023/02/14/2023-03066/request-for-comments-regarding-artificial-intelligence-and-inventorship. As the United States Patent and Copyright Office (USPTO) is exploring under its recent Request For Comments, if an AI system is not eligible to be an inventor under US patent law, this presumably includes a joint inventor. As a result, there will be circumstances in which an AI contributing as a joint inventor renders an invention unpatentable, or at least certain claims unpatentable. That may occur where natural person inventors only conceive of part of an invention, and conception of the complete invention requires, at least functionally, partial conception by an AI. This may also occur where an AI entirely generates the content of certain claims.

Inventorship is a very fact specific inquiry and frankly a muddled one in US law even without AI in the picture. Plus, even without an AI acting as an inventor, inventorship determinations involving the very large number of people who may be involved in building and using modern AI systems, spread over time and space, may be a complex exercise.

III. Patentability of AI-Generated Inventions

The most serious, and fixable, current problem with AI and patent law is the Federal Circuit's recent decision in *Thaler v. Vidal* to prohibit patents on AI-Generated Inventions. This puts the United States at a major disadvantage in terms of industrial strategy and international competition compared to jurisdictions that currently allow such patents or that will allow them in the future, and it sends a signal that the US does not respect intellectual property rights.

Congress should amend the Patent Act so that patentability cannot be denied based on how an invention is made. In fact, in 1952, Congress did change patent law so that, "[p]atentability shall not be negated by the manner in which the invention was made." 35 U.S.C. § 103. As the Supreme Court recognized long ago in Graham v. John Deere Co., 383 U.S. 1 (1966), this was intended to abolish the so-called "flash of genius" test for patentability, instead making it possible to achieve patent protection for an invention resulting from the mechanical process of investigating possibilities until hitting upon a new and workable invention (the second sentence of § 103 makes it "immaterial whether [the invention] resulted from long toil and experimentation or from a flash of genius"). The text of § 103, though falling within a section pertaining to whether an invention is obvious in light of existing knowledge, is not expressly limited by its language to the nonobviousness requirement. However, the Federal Circuit has now held for the first time that this statutory provision only applies to nonobviousness. The Federal Circuit's decision has effectively resurrected the flash of genius test by categorically denying patentability to inventions conceived by an AI system rather than a human being.[12]

Allowing patents on AI-Generated Inventions will incentivize innovation by making AI output more valuable, thus encouraging people to use and develop inventive AI to generate inventions. These patents have value independently of patents directly on AI systems or computer-implemented inventions. In addition, patents on AI-Generated Inventions will incentivize the disclosure of confidential information and trade secrets. If AI-Generated Inventions cannot be patented, this may force AI owners to keep their inventions confidential thus limiting beneficial public disclosures. Finally, patents on AI-Generated Inventions will encourage the commercialization of inventions. It is often the case, particularly in the life sciences, that the cost of developing a commercial product is incurred primarily after the initial act of invention. For example, patents play a critical role in encouraging pharmaceutical companies to invest in clinical trials to obtain marketing approvals for new drugs.

[12] https://www.supremecourt.gov/DocketPDF/22/22-919/259306/20230317125139087_Thaler%20Cert%20Petition.pdf.

It is particularly important for the US to protect AI-Generated Inventions because the US is likely to be a net exporter of AI-Generated Inventions given its current status as a leader in AI use and development. By failing to protect these inventions domestically, the US will not only be freeriding on AI-Generated Inventions made in other jurisdictions such as the European Union, but the US will not be able to require that foreign jurisdictions respect the property rights of US enterprises abroad.

Finally, it is not only vital to ensure the protection of AI-Generated Inventions based on the current state of AI, but to encourage today's investment in the AI of tomorrow. AI is only going to continue to improve in terms of its capabilities, and having appropriate rules in place will accelerate the use and development of AI to generate tremendous social value—ranging from the development of new life-saving drugs to new forms of clean energy. All of this is threatened by a regime that denies patent protection for AI-Generated Inventions in violation of the purpose of the Patent Act.

IV. Inventorship and Ownership of AI-Generated Inventions

US law requires an invention to have an inventor, so in cases without a human inventor, or if joint inventorship presents a problem for patentability, a person could be a deemed inventor and proxy for AI activity. In other words, the law could treat, for example, an AI's user as responsible for any inventive work done by the AI, even if the user has not directly exhibited any inventive skill. This has so far been the approach suggested by the European Patent Office (EPO) Legal Board of Appeal in the European analog of *Thaler v. Vidal*. J 0008/20 (Designation of inventor/DABUS) of 21.12.2021. It has also been the approach adopted by the intermediate federal German court, the Bundespatentgerict, in the German analog of *Thaler v. Vidal*. 11 W (pat) 5/21 (currently under appeal by the German Patent Office (DPMA) to the German Supreme Court). Alternately, no inventor could be listed in cases lacking a traditional human inventor, as has been advocated to the United Kingdom Supreme Court in the United Kingdom analog of *Thaler v. Vidal* (pending judgment). Case ID: 2021/0201. Different jurisdictions have significantly different rules regarding patent inventorship. For instance, Israel and Austria do not require an inventor to be listed in a patent application, and Cypress and Monaco, both EPO Member States, have reported they do not require inventors to be natural persons. The net of this is that major foreign markets will likely allow patents on AI-Generated Inventions, but not the United States.

While any of the above approaches would be preferrable to being unable to patent an invention based on how it was created, it would be optimal to list an AI as an inventor or joint inventor where the AI is factually responsible for conception or partial conception. This would promote transparency and the integrity of the patent system, and it would facilitate the incentive function of patents by allowing rewards to flow directly to the owners of inventive AI systems. This has been the approach of South Africa which has issued the patents in the South African analog of *Thaler v. Vidal* naming an AI system as an inventor and granting the patents to the AI's owner. Similarly, the

Saudi Arabian patent office has accepted the designation of an AI inventor in the Saudi analog of *Thaler v. Vidal* with the AI system's owner as the patent applicant.[13]

Although AI can factually invent and could be a legal inventor if the Patent Act is amended, AI is not a legal person and cannot own property. It would also be undesirable for an AI to be a legal person or own property as a matter of policy. This means that property generated by AI needs to be owned by someone, and there are several obvious candidates for ownership including the AI system's owner, programmer, or user.

So long as there is a clear property right in an AI-Generated Invention and an initial allocation of that right, then in cases in which the owner/programmer/user of an AI are different parties, they can contract among themselves to an optimal ownership solution. However, as a default, the system's owner should be the owner of intellectual property it generates. This is consistent with bedrock rules of property ownership, namely that a person owns property made by their property. As far back as Roman law this principle has applied so that a person owns fruit from their tree, or a calf from their cow. Modernly, the rule generally applies to tangible property produced by machines such that, for example, the owner of a 3D printer owns physical property created by their printer. There is no reason why the owner of an inventive or creative AI should be any less entitled to intangible property made by their machine. This is a common law principle that exists in numerous jurisdictions including the United States, and an appropriate basis for statutory ownership.[14]

Listing an AI as an inventor is not a matter of crediting an AI but rather of appropriate attribution of patent ownership, informing the public of how an invention was generated, and preventing a person from taking undeserved credit. Taking credit for work done by an AI would not be unfair to the AI, which has no self-interests, but it would dilute the meaning and significance of inventorship, equating the work of a person who has exhibited genuine ingenuity with someone who has simply asked a machine to solve a problem.

The consequence of changing patent law to protect AI-Generated Inventions would be that businesses and inventors would not have to be concerned that their use of AI would jeopardize obtaining intellectual property rights.

---

[13] The patents at issue in *Thaler v. Vidal* were filed in 18 jurisdictions. They have been granted in South Africa and allowed in Saudi Arabia, and rejected on a final, non-appealable basis in the United States, Australia, and Taiwan. Initially, Justice Beach in the Federal Court of Australia (FCA) held that under the Australian Patent Act an AI could be an inventor, and that the AI's owner had the best claim of entitlement. *Thaler v Commissioner of Patents* [2021] FCA 879. This decision was reversed in an *en banc* appeal to the FCA and the High Court subsequently declined to hear the case. *Commissioner of Patents v Thaler* [2022] FCAFC 62 (cert denied). In the remaining jurisdictions, the patent applications are either pending examination by patent offices or under appeal from patent office denials. See www.artificialinventor.com (for an updated status of foreign cases).

[14] Alternately, the United Kingdom's Copyright Act explicitly protects AI-generated works which are owned by the person by whom the arrangement necessary for the creation of the work are undertaken. Copyright, Designs and Patents Act 1988, §9 (3). These works are defined as those "generated by a computer in circumstances such that there is no human author of the work[s]." *Id*.

V. Artificial Intelligence and Obviousness

To obtain a patent, an invention needs to be, among other requirements, novel, nonobvious, and useful. Nonobviousness requires that an invention should not have been obvious to a hypothetical person having ordinary skill in the art (PHOSITA or the "skilled person"). The skilled person essentially represents an average worker in the field of an invention, and specifically does not represent what an inventor would find obvious (this would be too high a bar). This test is the designed to ensure that only meaningful technological advances are protected, rather than trivial ones that do not require patent incentives to come about. It is, however, a challenging test to administer because it requires subjective reasoning about what a hypothetical person would find obvious, and this reasoning takes place in hindsight with the benefit of a patent application that has already solved a technical problem.

Because the skilled person essentially represents the average worker in the field of an invention, the standard should evolve as the characteristics of average workers change over time. In particular, as AI comes to commonly augment the average researcher, the skilled person should be conceptualized as an average worker using AI. AI can make a person more knowledgeable and sophisticated, which in turn should raise the obviousness bar. With respect to making a person more knowledgeable, the skilled person is deemed to have knowledge of certain information in their field (analogous art) for purposes of nonobviousness, but some AI can usefully access a superhuman amount of information across fields. With respect to making a person more sophisticated, certain activities that once required inventive skill may become routine with the use of AI, such as modeling protein folding.[15]

Given continued advancements in AI it is likely that, at some point in the medium to long term future, AI will transition from routinely augmenting human researchers to automating R&D—at least in some fields. This may happen, initially, in areas where AI has a comparative advantage such as discovering new uses of existing drugs from pattern recognition in large data sets. If the skilled person standard fails to reflect the capability possessed by AI, then once the average worker routinely uses inventive AI, or inventive AI replaces the average worker, then inventive activity will be normal instead of exceptional. This will result in too lenient a standard for patentability. Allowing the average worker to routinely patent their outputs would cause social harm. As the U.S. Supreme Court has articulated, "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may . . . deprive prior inventions of their value or utility." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 402 (2007).

Once inventive AI becomes the standard means of research in a field, considering the skilled person as a skilled person using AI would also encompass the routine use of inventive AI by average workers. Taken a step further, once inventive AI becomes the standard means of research in a field, the skilled person should be an inventive AI. Specifically, the skilled person should be an inventive AI when the standard approach to

[15] See, e.g., https://www.nature.com/articles/d41586-021-03499-y.

research in a field or with respect to a particular problem is to use an inventive AI (the "Inventive AI Standard"). Conceptualizing the skilled person as using a skilled person using AI might be administratively simpler but replacing the skilled person with the inventive AI would be preferable because it emphasizes that the AI is engaging in inventive activity, rather than a natural person directly.

To obtain the necessary information to implement this test, the USPTO should establish a new requirement for applicants to disclose when an AI contributes to the conception of an invention, which is the standard for qualifying as an inventor. Applicants are already required to disclose all human inventors. Similarly, applicants should need to disclose whether an AI has done the work of a human inventor. This information could be aggregated to determine whether most invention in a field is performed by people or AI. This information would also be useful for determining appropriate inventorship, and more broadly for formulating innovation policies.

Yet simply substituting an inventive AI for a skilled person might exacerbate existing problems with the inventive step inquiry. With the current skilled person standard, decisionmakers, in hindsight, need to reason about what another person would have found obvious. This results in inconsistent and unpredictable nonobviousness determinations. In practice, the skilled person standard bears unfortunate similarities to the "Elephant Test"—I know it when I see it. This may be even more problematic in the case of inventive AI, as it is likely to be difficult for human decisionmakers to theoretically reason about what an AI would find obvious.

An existing vein of critical scholarship has already advocated for nonobviousness inquiries to focus more on economic factors or objective "secondary" criteria, such as long-felt but unsolved needs, the failure of others, and real-world evidence of how an invention was received in the marketplace. Inventive AI may provide the impetus for such a shift. Nonobvious inquiries utilizing the Inventive AI Standard might also focus on reproducibility, specifically whether standard AI could reproduce the subject matter of a patent application with sufficient ease. This could be a more objective and determinate test that would allow the Patent Office to apply a single standard consistently, and it would result in fewer judicially invalidated patents. A nonobviousness inquiry focused on either secondary factors or reproducibility may avoid some of the difficulties inherent in applying a "cognitive" Inventive AI Standard.

However the test is applied, an Inventive AI Standard will raise the current benchmark for patentability. Inventive AI will be significantly more capable than skilled persons and able to productively engage with a broader range of prior art. An Inventive AI Standard would thus make obtaining patents more difficult: A person or AI might need to have an unusual insight that other inventive AI could not easily recreate, developers might need to create increasingly capable AI that could outperform other models, or, perhaps most likely, invention will be dependent on leveraging specialized, non-public sources of data. The nonobviousness bar will continue to rise as AI inevitably becomes increasingly sophisticated.

Taken to its logical extreme, and given there may be no limit to how intelligent AI will become, it may be that every invention will one day be obvious to commonly used AI. That would mean no more patents should be issued without some radical change to current patentability criteria. But in a (likely distant) future world where superintelligent AI can automate the solving of technical problems with ease, there would be less need for incentives to innovate and to disclose confidential information (as inventions could be more easily independently discovered or reverse engineered). There may still be similar needs for encouraging the commercialization of new inventions. For example, even if an AI could easily develop a new cancer treatment, costly clinical trials may still be needed to have the Food and Drug Agency (FDA) allow that treatment to be provided to patients. Long term, this may require a shift from patents to other sorts of incentives such as market/data exclusivity based on FDA approvals of pharmaceutical and biological drugs.

VI. Closing

Thank you for the opportunity to provide these comments. I support the Subcommittee's efforts to improve the patent system, welcome the opportunity to answer any questions these comments may raise, and look forward to a continuing dialogue on this very important subject.

Respectfully Submitted,

SPECIAL COMPETITIVE STUDIES PROJECT

Written Testimony of Rama G. Elluru

U.S. Senate Judiciary Subcommittee on Intellectual Property

"Artificial Intelligence and Intellectual Property –
Part I: Patents, Innovation, and Competition"

Wednesday, June 7, 2023 | 3:00 PM EST | Dirksen Senate Office Building Room 226

Chairman Coons, Ranking Member Tillis, and Members of the Committee, thank you for the honor of being invited to provide testimony on this important topic.

I am here to discuss the implications of artificial intelligence (AI) on our intellectual property (IP) regime.

I am testifying in my capacity as Senior Director for Society and Intellectual Property at the Special Competitive Studies Project (SCSP), a nonpartisan, nonprofit organization dedicated to strengthening America's long-term competitiveness as AI and other emerging technologies shape our national security, economy, and society. My views have been informed by my time as a patent attorney in the private practice, as an Administrative Patent Judge at the United States Patent and Trademark Office (USPTO), and as staff for the National Security Commission on AI (NSCAI), which issued its Final Report in March 2021 that included a chapter dedicated to Intellectual Property (IP) recommendations. I would like to share those recommendations with you today, and to emphasize that a robust IP ecosystem is critically important to ensure United States technology competitiveness..

To start, I want to set the context. **We are in a global technology competition.** The People's Republic of China (PRC) is the United States' chief ideological opponent. It is our largest economic competitor, technology peer, and the most capable military challenger for the foreseeable future. And AI and other emerging technologies are at the center of this competition. The Chinese Communist Party (CCP) leadership understands that the way to achieve their objective of global dominance is through technological supremacy in emerging technologies — with AI at the forefront. The CCP wants to dominate AI and the emerging technologies that are fueling the industries of the future. They have made this clear in their public messaging. The CCP seeks to apply emerging technologies to set the rules of the road in its vision — a vision that is very different from the rules-based International order we have become accustomed to since World War II.

AI and other emerging technologies are the epicenters of this technology competition. The PRC has taken the lead over the United States in several critical technology areas, including 5G network components, advanced batteries, financial technology, and commercial

drones. Global leadership in AI, semiconductors, advanced manufacturing, and next-generation networking remain highly contested fields.

The emerging AI revolution will lead to the most rapid transformation of humanity in our history. AI is a foundational technology, like electricity, upon which other technologies are built and accelerated. AI analyzes and makes assessments from vast amounts of data quickly. Like past technological leaps, AI will increase productivity and spur economic growth. These systems will result in widespread human progress, increased efficiency, profound improvements in human health, advances in basic science, advanced solutions to climate change, and better education. AI and other emerging technologies like faster semiconductors and biotechnology will only accelerate our discoveries.

Today, AI-enabled Large Language Models (LLMs) can generate language that is indistinguishable from that generated by humans. Tomorrow, we can only make informed guesses at what LLMs might be able to achieve. In a striking departure from millennia of human history, we are on the cusp of a world in which humans will await to see what LLMs have discovered for us instead of us telling AI what to discover. AI has been part of discovering new drug candidates and just recently was part of the process of discovering a superbug-killing antibiotic. AI was also used to discover more precisely controlled nuclear fusion reactions, surpass human decision-making in intensive care units, and conduct up to 10,000 autonomous experiments daily for scientific microbiology discovery. AI has the potential to serve as personalized tutors for students and teachers. Machine learning models can improve CO_2 storage, which can help combat climate change.

We are in a race with China to develop the AI future. This innovation competition will shape the world's future. The nations that hold the market share in the combination of these emerging technologies will be able to reinforce their economies and societies and, importantly, assert geopolitical influence. Which nations and how those nations shape the development and adoption of these technologies will determine geopolitical order. We want these technologies to be developed according to our norms and ethics, which is the antithesis of how China uses this innovation on its citizens for undemocratic purposes, including surveillance and oppression of minority groups.

We cannot do it alone. The United States, along with our many close allies and partners, must maintain our technological lead over China. So how does the United States retain its global technology leadership? We leverage the strength that has allowed the United States to outpace and outmatch every technology challenger we have faced over the past century. That strength is American innovation.

We must harness our innovation power. Our capability to invent new technologies is fundamental to our economic and military power, allowing us to lead in global standards. Importantly, our technology leadership means we will be able to embed democratic values in technology design, development, and use.

The Importance of Protecting Intellectual Property

Intellectual property rights have historically been a critical lever in ensuring America's innovation power. America's traditional IP regime – patents, trademarks, copyrights, and trade secrets – has spurred American ingenuity since the 18th century with the 1790 Patent Act. The last major overhaul of the patent system was in the early 1950s, right before the field of AI emerged in 1956. The United States has long been the world leader in securing property rights in technological innovation, granting patents for the next wave of discoveries when the rest of the world hesitates. Patents are property rights that incentivize new ideas and inventions. They reward inventors for sharing valuable information with the public domain as our founding fathers envisioned. Patents are often the only currency a company has in transactions, especially for smaller entities that need to attract capital.

Unlike the United States, the CCP has recognized the importance of IP policies as a critical tool within its national strategies for emerging technologies. China publishes five-year IP plans expressly stating its IP goals and objectives for that period. They have implemented IP policies to strengthen their national technology competitiveness. For example, the PRC has developed a leading-edge national system of IP tribunals and courts, not surprisingly, one that resembles ours. The CCP has also recently elevated the role of its patent and trademark office, the China National IP Administration (CNIPA), to a State Council-level agency. This is roughly equivalent to CNIPA becoming a cabinet-level agency in contrast to the U.S. fractured agency approach with USPTO within the Department of Commerce, the Office of the Intellectual Property Enforcement Coordinator within the Executive of the President, and the U.S. Copyright Office within the Library of Congress. The CCP has made significant revisions to its IP legislation to ensure that they support economic and national industry policy goals. IP is used in setting metrics and expectations in federal and local industrial policies. Also, China's patent office is implementing pilot projects across China's innovation hubs to explore the potential for data IP rights. Lastly, China has also generally favored more liberal granting of patent rights and more deterrent remedies over the last several years. We need an effective response to China's domestic and geopolitical strategies centered on its IP institutions.

This brings me to Chapter 12 of the NSCAI's Final Report. I have two core messages. First, the United States must recognize IP policy as a national security priority critical for strengthening and preserving America's innovation power. Second, our patent policies must be modernized

to further national security, economic, and technology competitiveness strategies for the emerging technology era. Given the transformative nature of AI and other technologies, we must reimagine our patent system to ensure it still serves the purpose our founding fathers envisioned – securing for a limited time to inventors the exclusive right to their discoveries.

Currently, the U.S. Government has no comprehensive IP strategies and policies, nor does it have an efficient mechanism for integrating critical IP strategies into national security, economic, and tech competitiveness strategies. Meanwhile, the CCP is both leveraging and exploiting IP policies as a tool within its national strategies for emerging technologies. To compete, the U.S. Government must address these vulnerabilities. Part of the challenge is that U.S. Government IP equities span all three branches with no single entity unifying these disparate equities. The result from this policy void is that the United States could lose its IP global leadership position, including its influence over other countries adopting its technologies. The domestic harm is that the United States lacks sufficient IP incentives for fueling innovation power. The international harm is that the U.S. loses its IP leadership position, allowing China to attract innovation to its borders.

America's IP laws and institutions must be considered critical components for safeguarding U.S. national security interests, including advancing economic prosperity and technology competitiveness. The United States must articulate and develop national IP reforms and policies to incentivize, expand, and protect AI and emerging technologies at home and abroad. Such policies should be developed and proposed via the Executive Branch with a process that integrates the disparate departments and agencies that promote U.S. innovation. These proposals must then be integrated into our broader national competitiveness strategies.

How can this be implemented in practical terms?

Recognize IP as a National Priority: The President should issue an executive order to recognize IP as a national priority and require developing a comprehensive plan to reform and create IP policies and regimes that further national security, economic interests, and technology competitiveness strategies.

Propose Executive and Legislative actions for reforming IP policies and regimes: We need an entity with IP expertise that can coordinate IP equities across our government to continuously develop and propose IP policies. At NSCAI, we recommended that the Secretary of Commerce, in coordination with the Under Secretary of Commerce for Intellectual Property and Director of the USPTO and other relevant Executive Branch agencies, should lead the development of proposals, for both Executive and Legislative Branch actions, to reform and establish new IP policies and regimes to incentivize, expand, and protect AI and emerging

technologies. Similarly, Chair Coons and Ranking Member Tillis, in an October 2002 letter to USPTO and the U.S. Copyright Office, called for the creation of a national AI commission to address IP reform. With either approach, these efforts should include: (1) establishing a committee of multidisciplinary experts, from inside and outside the U.S. Government, to provide technical and IP-related expertise and advice and (2) convening public deliberations to include, at a minimum, academia and industry, in executing these Executive Order responsibilities. The outcome of these deliberations should inform proposed IP policies and regimes.

The Secretary of Commerce and the USPTO Director need the requisite directives to carry out these efforts to develop and implement IP proposals.

Executive Branch departments and agencies must also establish resources and support the Secretary of Commerce in executing these efforts, including providing metrics and trends to inform IP policy proposals. Due to the breadth of the IP considerations that must be assessed and the far-reaching impact of IP upon many segments of the U.S. economy and innovation ecosystem, many U.S. Government entities may already track relevant metrics or can expand their analyses to address the necessary prioritization of IP for AI and emerging technologies. For example, innovation and investment trends based on patent filings and, where possible, licensing data—in various technology sectors, including by foreign countries, mainly China—should be analyzed (e.g., to assess quality and research trends), with care not to rely solely on patent counting. Other potential metrics include but are not limited to, tracking of patents self-declared as standard essential in comparison to patents licensed; licensing to unrelated parties; the impact of prior art on the U.S. patent and trademark examination systems; international filings for IP protections on U.S.-funded research, particularly without U.S. funders' or inventors' awareness; the ratio of U.S. companies filing for IP protections, as well as pursuing IP-related litigation, in the United States versus abroad; and patent assignment data.

Integration into National Strategies: The United States must elevate and coordinate technology policy in the White House by empowering a single entity to implement a comprehensive technology strategy that integrates IP proposals.

A key recommendation of the NSCAI and SCSP is to create a Technology Competitiveness Council (TCC). The TCC would include Cabinet secretaries and leaders of other key White House offices and be chaired by the Vice President, with a newly appointed Assistant to the President for Technology Competitiveness as the day-to-day leader. To coordinate the Council's work, the Assistant to the President for Technology Competitiveness would ensure policies pertaining to emerging technologies receive sufficient Presidential-level attention.

The TCC would ensure that the gaps between NEC, OSTP, and NSC responsibilities are filled and linked to OMB. It would provide a forum for reconciling competing security, economic, and scientific priorities and elevate technology policy and concerns from a technical to a strategic level. This Office would be responsible for assessing IP proposals that should be integrated into broader national strategies.

Priority IP Considerations: The United States must prioritize the IP considerations that need addressing now and continuously. Many questions must be addressed to ensure our patent system is efficiently working to strengthen our innovation power. The **NSCAI proposed a non-exhaustive list of 10 "IP-considerations"** that should be assessed. The USPTO is grappling with some of these issues by establishing an AI and emerging technology partnership with stakeholders that include academia, independent inventors, small businesses, industry, other government agencies, nonprofits, and civil society and seeking the public's views on various IP policy issues that uniquely affect the AI and emerging technology community.

The 10 National Security Commission on AI considerations include:

1. **Patent eligibility:** Assess and articulate the impact of the current United States patent eligibility doctrine on innovation in AI and other emerging technology from an economic, trade, and national security policy perspective. While China is making acquiring patent rights to inventions easier, U.S. Courts have severely restricted patent protection for computer-implemented and biotech-related inventions.

2. **Counter China's narrative on "winning" the innovation competition:** China-connected entities have filed a massive number of patent applications domestically and internationally. China also ensures its presence in standard-setting organizations and aggressively asserts its patents as "standard essential." Assess how the United States might best counter China's efforts to shape the narrative that it is winning the innovation competition based partly on its patent filings.

3. **Impact of China's filings on USPTO resources and U.S. inventors:** Assess whether the USPTO requires additional resources to ensure high-quality patent examination, including assessing the effects of increased filings from China and AI-generated prior art.

4. **Impediments to AI public-private partnerships and international collaboration:** Assess impediments to the IP contractual ecosystem and propose mechanisms to strengthen AI PPP and international collaboration.

5. **IP protections for data:** Assess the need for additional protections for data, including legislation, if IP-type protections are deemed necessary and ways to encourage sharing of datasets.

6. **Combat IP theft:** Assess additional Executive Branch efforts to counter IP theft threats, including actions in collaboration with allies and partners; articulate U.S. counter-IP theft strategy with criminal and civil economic dimensions.

7. **Inventorship by AI:** Assess the need for policies relating to AI-generated inventions.

8. **Global IP Alignment:** Work with allies and partners on global AI-related IP alignment, including disincentives for IP theft, alleviating inconsistencies in patent regimes, and assessing current forums for AI-related IP alignment.

9. **Democratize innovation and IP ecosystems:** Expand the innovation base and democratize access to innovation and the IP ecosystem through streamlining guidance for startups and small/medium-sized enterprises seeking IP protections.

10. **"Standard-essential" patents process:** Assess policies to protect the integrity of processes by which "standard essential" patents are claimed, asserted, and litigated, and ensure adequate US representation in such processes. Monitor legal decisions to ensure US sovereignty isn't degraded.

Lastly, at SCSP, we are exploring several of these considerations in partnership with the Renewing American Innovation Project at the Center for Strategic and International Studies, headed by former Under Secretary of Commerce for IP and USPTO Director Andrei Iancu. This collaboration aims to provide assessments of the current state of the U.S. IP regime and considerations for the U.S. Executive & Legislative Branches to modernize the regime for AI and other emerging technologies.

Thank you again for this opportunity to appear before you, and I look forward to our discussion.

Testimony of Corey Salsberg,

Vice President, Global Head IP Affairs, Novartis

Before the United States Senate Committee on the Judiciary

Subcommittee on Intellectual Property

Subcommittee Hearing on "Artificial Intelligence and Intellectual Property – Part I: Patents, Innovation, and Competition"

June 7, 2023

Dirksen Senate Office Building, Room 226

I. Introduction

Chairman Coons, Ranking Member Tillis, and Distinguished Members of the Subcommittee:

My name is Corey Salsberg, and I am Vice President, Global Head of IP Affairs for Novartis. On behalf of our company, thank you for the opportunity to testify at today's hearing, and to share our experiences and perspectives on the intersection of artificial intelligence (AI), intellectual property, and innovation law and policy.

Today's hearing is timely and extremely important, because as every witness today will attest, and as everyone else in the room knows, AI is already here, in wide use across industries and society, and it is fast shaping our future. In the life sciences, AI tools are driving operational efficiencies, facilitating new discoveries, and adding value across the biopharmaceutical R&D process—value that will ultimately benefit patients and society. As an early adopter of AI in our field, Novartis is using today's AI tools to help us accelerate certain aspects of drug discovery, identify new patterns and leads in data, to make our clinical trials more efficient, and in certain early applications, to even help us design new molecules. As some examples, machine-learning tools are helping us speed the early sorting, identification and selection of drug candidates with desirable properties, such as the ability to bind to a disease-implicated target in the body. Our AI-enabled platform, "Nerve Live," uses AI tools to help us anticipate, identify and resolve issues that might slow or compromise our clinical trials. And our scientists have trained, guided and used our proprietary AI-enabled "generative chemistry" research platform, called JAEGER, to assist in generating new virtual molecules for potential use in treating malaria. Tomorrow's AI tools promise to expand on these activities, and enable many more, helping us unlock the secrets of the human genome; discover new scientific and medical insights which might otherwise remain hidden forever; and to ultimately help us develop new medicines that are more effective, personalized, safe, and efficient than may ever be possible using traditional tools. What this means is that the time is right to ensure that the right laws and policies are in place to enable that future, which is well within reach.

But the right policies depend on the right information being shared, the right contexts being considered, and the right questions being asked, which makes this hearing especially timely. While everybody knows that AI is here, not everyone understands or agrees what that means. It is easy, and perhaps tempting, to equate the outputs of a generative AI chatbot, or the familiar sounds of an AI-generated pop song, with human-level thoughts and creativity, and equally easy to assume that the role that AI plays in one field or circumstance is the same as in all others. But when it comes to AI, ubiquity does not mean uniformity. Last month, with reference to our JAEGER platform, a headline in *Politico* posed the question "Can JARVIS hold a patent?," apparently referring to the fictional artificial superintelligence entity "JARVIS" in the Marvel movie franchise.[i] While this may make an intriguing headline, JAEGER is not JARVIS. And whether AI can or should itself be awarded a patent is not, in our view, the right question at this point in time.

As a foundational matter, before addressing whether AI can earn or own a patent, the right question is whether the tasks that AI is performing today can even be considered "inventing." In our experience, as a matter of fact, the answer is no. At least in our field, AI tools today are still just that—tools that are helping to facilitate, optimize and enhance *human* activity and ingenuity, and to advance human-defined goals.

But that does not resolve the matter. A second important question, which is top-of-mind for innovators like us who are increasingly integrating AI into our R&D processes, is whether using such technologies to assist with innovation compromises the ability of our *human* researchers to obtain otherwise duly earned patents. Here, as a matter of law, we believe the answer is ultimately no, but there are certain clarifications that the Patent Office, the Courts, and if necessary, Congress, should make, if our goal is to encourage the continued development, uptake and use of AI tools. In particular, because certain AI tools, namely generative AI tools, *do* in some cases perform tasks and enhance human intelligence in ways that traditional tools do not—and in ways that our lawmakers and judges of the past could not possibly have contemplated—America's innovators could be put at a disadvantage, and the nation's innovation, economic and strategic leadership could be undermined, if the United States' unique laws concerning how inventions are "conceived" are too rigidly applied.

A third question worthy of this Subcommittee's attention is whether we will even need patents if and as AI advances to the point where it is able to fully invent on its own. As a matter of policy, we believe the answer to this question is resoundingly yes, because the real genius of the patent system is not merely its ability to encourage invention, but to encourage publication and/or development, without which the system's constitutional goals of scientific, technological and societal progress cannot be realized. In this regard, it is important to remember that in fields like ours, the invention of new molecules, proteins, and other substances is only the start of the long, complex, and risky process of creating and developing new medicines. Without patents or comparable incentives to enable that work, and from which to learn and expand, we would not have new treatments and cures, no matter how many new leads appear on computer screens.

Today, I would like to further describe some of the ways that we are actually using AI tools across our organization, to help provide this Subcommittee with a realistic understanding of the role that AI plays and the promise it holds for the future of medicine—which, in our view, is a critical foundation for any policymaking in this area. With that grounding, I would like to provide further perspective on some of the information and questions that we believe the Subcommittee should consider, as well as views on some other topics at the intersection of AI and IP.

II. Background

As a personal introduction, I am an attorney with over two decades of experience in the areas of IP law, innovation policy, and the intersection of these areas with technology, access and trade law and policy. I earned my JD from Stanford Law School in 2001, where I wrote one of the frequently cited works on the law and ethics of cloning endangered and extinct species, and I earned my undergraduate degree in American Studies from Yale University in 1997. Prior to joining Novartis in 2010, I was a litigator in private practice with the law firms of McDermott, Will & Emery and Morrison & Foerster, among others. In addition to my current role as Global Head of IP Affairs for Novartis, I currently serve as Secretary of the Board of Directors of the Federal Circuit Bar Association, and as a Board Member of the Intellectual Property Owners Association (IPO), and of California Lawyers for the Arts, an arts-related legal aid society which also administers the west coast arm of the USPTO's patent pro bono program. I am also a member of the Steering Committee of the international Inventors Assistance Program (IAP), a joint initiative of the World Intellectual Property Organization (WIPO) and the World Economic Forum that I helped found, which provides pro bono legal services to under-resourced inventors in developing countries; and

I have helped to establish, build and launch two groundbreaking IP-related biopharmaceutical industry initiatives: *Pat-INFORMED*, a voluntary global database for medicine-related patent information now co-sponsored and hosted by WIPO and the International Federation of Pharmaceutical Manufacturers (IFPMA), and the *IP PACT*, a set of principles that sets forth a patient-centric approach to IP shared by its signatories, which include Novartis.

Today, I am here to testify on behalf of Novartis. Novartis is a science-based healthcare company whose purpose is to reimagine medicine to improve and extend people's lives. Our products, which include innovative small and large molecule medicines, cell and gene therapies, and radiopharmaceuticals, reached over a quarter billion patients around the world in 2022 alone, and are available in over 130 countries, treating diseases in the fields of cardiology, hematology, oncology, immunology, neuroscience, ophthalmology, respiratory illness, and rare genetic disorders.

While we are global in our mission, scope and reach, the United States plays an outsized role in our work. With its robust innovation ecosystem—including what is still the world's leading patent system, and inspired complementary policies under laws like the Bayh-Dole Act—America is home to the global headquarters of our Novartis Institutes for BioMedical Research (NIBR), what we call our "innovation engine." It is also where some of our newest technologies, such as our cell and gene therapies, were developed and continue to be manufactured. All told, in 2022, we invested $10 billion, or around 20% of our global net sales,[ii] in R&D, a major portion of which was invested in the United States, where we employ about 14,000 people, providing high-quality American jobs that benefit patients and the public good.

The patent system is a critical enabler of innovation in our field, where it takes 10-15 years on average to discover and develop a single medicine, at an average cost of over $2.5 billion, and with a success rate of only around 12% even years into the process when clinical trials begin.[iii] Simply put, as an economic tool that enables us to manage the challenges and risks inherent in our work, the patent system converts what would otherwise be an impractical and unworkable set of dynamics into a viable and sustainable business model that benefits patients and society. But in a field as complex and unpredictable as ours, the breadth and flexibility of the patent system is often as important as its strength. In recent years, that breadth and flexibility has enabled us to invest in and experiment with new technologies that go well beyond traditional chemistry, giving rise to the many "firsts" that now characterize our company, including the world's first chimeric antigen receptor T-Cell (CAR-T) therapy, Kymriah®, a personalized one-time treatment for certain forms of leukemia and lymphoma that uses a patient's own T-cells to fight cancer;[iv] the world's first gene therapy to treat children with spinal muscular atrophy (SMA), Zolgensma®[v]; and two of the world's first Peptide Receptor Radionuclide Therapies (PRRTs), Lutathera®[vi] and Pluvicto,™[vii] which precisely deliver radiation to treat neuroendocrine tumors and prostate cancer.

This same breadth and flexibility has given rise to powerful new technologies outside of our field, including digital and AI-enabled tools, that are opening up new opportunities to improve and enhance how we innovate, and new possibilities for the future of medicine. With our purpose of "reimagining medicine" and our pioneering mindset, we are one of the early adopters of AI in our field. Through our own in-house community of digital experts, and in collaboration with our external technology partners, we have enthusiastically integrated AI and other computer-based tools across our organization, aiming to make our work as effective and efficient as the state-of-

the-art allows, from certain back-office operations, to drug discovery, clinical trials, and post-launch patient monitoring in conjunction with healthcare professionals. As I will explain, these tools are already improving efficiencies, and adding significant value to a field of innovation that, by its nature, is rife with opportunities for these powerful assets. In the coming years, as these tools advance, those opportunities will only increase, opening new avenues for scientific exploration, new approaches for innovation, and new hope for patients waiting for new treatments and cures for their diseases and still-unmet medical needs.

With the promise that AI holds for the future of medicine and so many other fields, we believe it is critical that the United States—the cradle of so many of the world's modern technologies and the home to so many innovators—continues to ensure that the right laws, conditions and incentives are in place to encourage both the development of value-adding AI tools, and their adoption and use to progress the state of the art across all technological fields. Those efforts should be built upon a realistic understanding of how AI technology works, and how it is actually being used today. And they should ultimately be guided by the IP system's constitutional goals of advancing scientific, technological and societal progress.

III. Biopharmaceutical Innovation, AI and IP in Context

To understand the role of AI in the biopharmaceutical field, and its potential for the future, it is helpful to have a basic understanding of our general R&D process, of the challenges and hurdles that we face, and of the new opportunities that recent advances in science present.

The biopharmaceutical innovation process generally begins with drug discovery, which entails analyzing millions of compounds or more for properties that may be medically useful, such as a shape or structure that is likely to bind with a particular target cell or protein that is implicated in a particular disease. Through this process, candidates are eventually narrowed to the most promising ones, which then proceed to pre-clinical laboratory testing for further assessment. From there, the field is further narrowed to one or more lead candidates that are promising enough to begin human clinical studies. These in turn proceed through three clinical phases (I, II and III), first to test their safety in humans, and then to assess their efficacy. During each of these clinical phases, innovation continues through drug development, which entails inventing, designing and testing the safest, most effective and most stable forms, formulations, dosages, and methods of treatment, among other things. As I explained earlier in my testimony, on average, it takes 10-15 years and costs over $2.5 billion to discover and develop a single new medicine through this process, with only one out of every 10,000 initial compounds, and only around 12% of those beginning clinical studies, ultimately succeeding.[viii] But these same figures, challenges and risks present prime opportunities to put the processing power of AI to work to help streamline various steps in the process.

At the same time, several major trends and developments are shaping the future of science, medicine, and our industry, which also open up exciting opportunities for AI. Scientifically, revolutions in fields like genomics, proteomics and structural biology now enable us to see what is happening in the body at a molecular level, helping us better understand the root causes of many diseases and paving the way for highly complex, targeted, and effective personalized cures. These revolutions in science have helped to reveal massive amounts of new information with potential medical value, such as the three billion base pairs of DNA in the human genome

that may hold the secrets to what causes many illnesses, or why some patients respond better to certain treatments than others. Other troves of potentially useful information are hidden in the data collected and generated by and through technologies like digital medical tools and wearable devices. As with the millions of compounds that must be analyzed and tested in early drug discovery, AI tools are well-suited to automate and accelerate analysis of these vast data pools, and to identify new patterns and correlations in that data that human minds alone cannot, and they are already beginning to help us do so.

In the next section of my testimony, I will provide specific examples of how we are currently using AI in our field to address the challenges and embrace the opportunities that I have just described. But before I do so, with so many legal and policy discussions around AI occurring in the abstract or around hypothetical examples, we also believe it is important to take a moment to further focus the conversation on those issues that present actual near-term questions and challenges, based on the current state of the art and on how the technology is actually being used.

As an innovative medicines company, our primary interest in the intersection of AI and IP at this stage relates to AI's role in biopharmaceutical innovation, and how, if at all, the use of AI in that process impacts our ability to continue to secure the patents we need—and for the foreseeable future will continue to need—on the resulting inventions, in order to continue to enable and sustain our work developing lifesaving medicines. In particular, the questions of inventorship and ownership are top-of-mind, as this is where most public policy discussions, including current discussions at the USPTO and WIPO, have focused to date, and where debates about the current state of AI's intellectual abilities are most immediately relevant.

To summarize our position on this core set of issues, while we cannot speak to uses of AI in other fields, it is our strong view based on our experience in the life sciences that

1) As a matter of fact, current AI technologies are not yet "inventing;"

2) As a matter of law, using such technologies in the innovation process should not affect the inventorship status of humans who do so—though, clarifying "conception" law would be helpful to increase certainty in this area, and to ensure robust development, adoption and use of AI in innovation in the United States; and

3) As a matter of policy, as AI technology continues to advance and play increasing roles in innovation, our patent laws must keep pace and continue to ensure that patents remain available for useful inventions that promote human progress and advance the state of the art.

IV. AI is Not Currently Inventing: The State of AI in the Life Sciences

With its prevalence in science fiction, humanlike interfaces in our smartphones, cars, and home devices, and the recent dispersion of "generative" AI technologies in the creative fields and in our daily lives, it is easy to make unrealistic assumptions about the "intelligence" of AI, and generalizations about the state of the art across different applications and industries. But at least in the life sciences, based on our experience using AI in all stages of our R&D process and in many other aspects of our business, AI at this time is still functioning as a tool that human beings

are using to advance, enhance and optimize their work, and to achieve human-directed outcomes and goals. That said, for purposes of assessing current US law and policy, including AI's implications for inventorship and other areas of patent law when it is used in the innovation process, we believe it is useful to distinguish between "non-generative" AI tools and "generative" AI tools.

A. Non-Generative AI in Biopharmaceutical R&D

Generally speaking, we categorize as "non-generative" those AI tools that are used to automate, simplify, or accelerate processes or tasks that would otherwise be done less accurately or efficiently by humans, as well as those AI tools used to help reveal more information about the world that we would not be able to observe on our own. In our view, these technologies are not qualitatively different from traditional tools, such as machines that automate manufacturing, calculators that make complex math instantaneous, or microscopes that let us see what human eyes cannot. At present, most of the AI tools that we use in biopharmaceutical innovation are non-generative, and are being used to increase efficiencies across all the stages of the R&D process that I described earlier.

Beginning with the drug discovery phase, we are now using machine and deep-learning AI technologies to automate and accelerate certain aspects of the screening, testing and analysis of the compounds in our library to help us more quickly and accurately identify promising candidates. In these applications, software-based algorithms are "trained" on large sets of data, such as molecular structures or protein sequences with known traits and properties, results and insights from past experiments,[ix] or digital images of cells that have been impacted in various ways after treatment with different experimental compounds.[x] Once this data is integrated, these trained models can then be applied to new untested data sets; for instance, to quickly find, sort and classify compounds with similar properties in our broader library, or predict how they will fare in future experiments, leading us in minutes or days to insights and results that might otherwise take months or years to reach using traditional experiments and visual inspection. The same technologies are now also being applied in some instances without being taught specifically what to look for, finding new patterns and trends that we may have missed, and even those that we might never discern, due to subtleties in the patterns and the vast sizes of the data.

Further along in the process, we are using similar non-generative AI tools to help make our clinical trials more efficient, and to help reveal new leads that may accelerate or eventually even obviate the need for certain trials. For instance, our proprietary AI-enabled platform, "Nerve Live," uses machine learning and advanced data analytics to monitor our hundreds of ongoing worldwide clinical trials across thousands of sites in real time—much like an air traffic control tower monitors flights—which is helping us anticipate, identify and resolve issues that slow or compromise our clinical testing.[xi] Through another proprietary platform, data42, we have pooled and standardized what amounts to over 2 million patient years of anonymized clinical data from our decades of past clinical trials into a "data lake," which is now able to be mined by our human scientists and AI alike to help advance drug development.[xii] Some of these activities, which may be AI-assisted, include optimizing future clinical trials by learning from past data; replacing certain real control trials with simulated ones based on statistical modeling from data; conducting virtual proof of concept studies by identifying the potential for existing drugs to treat other diseases through analysis of past trial data; and using AI to identify previously unknown

underlying genetic characteristics associated with disease or treatment response, which can be used to select the right patients for clinical trials, and to develop more tailored treatments.[xiii]

While not directly related to our R&D, we also regularly develop or co-develop AI tools that can be used by healthcare providers to bring important benefits to patients and healthcare systems by helping with disease diagnosis, patient monitoring and patient care. One example is a joint program that we have launched with Microsoft called "AI4Leprosy." One of the oldest diseases known to humanity, leprosy is curable with today's medicines, but over 200,000 people are still diagnosed each year, largely in developing countries; and earlier diagnosis generally leads to better clinical outcomes. AI4Leprosy is a machine-learning based AI tool that has been trained with anonymous images of leprosy from patients with confirmed diagnoses, and can now be used to diagnose new patients. A 2022 study confirmed that it is over 90% accurate in detecting leprosy on new patients,[xiv] and our aim is now to roll it out on smartphones to help support early leprosy diagnosis for patients in remote areas without the patient having to travel a clinic.

As these examples demonstrate, non-generative AI tools are in wide use in our company, functioning analogously to conventional tools by automating and accelerating tasks and analysis that humans would otherwise do, either alone or with other tools. As such, we do not believe that these tools by themselves are engaged in anything that resembles inventive activity, and human uses of these tools in the innovation process should not raise any genuine issues of inventorship or patentability.

B. Generative AI in Biopharmaceutical R&D

"Generative AI" differs from non-generative AI because, as its name implies, rather than merely helping to make human activity more efficient or accurate, it is used to generate new material or information that does not, and in many cases likely would not, otherwise exist. As I will explain, while this does not mean that generative AI is presently inventing in the human or legal sense, this "generative" feature arguably makes it less analogous to conventional tools than non-generative AI, which in turn raises some unique policy considerations that we believe are worthy of the Subcommittee's attention.

Generative AI is not new, but recent advances in the technology, high-profile examples of AI-generated art and music, and its broad dissemination into daily life through popular chatbots and similar applications, has launched it into the public spotlight. Particularly in light of these recent developments, we believe it is important to consider the use of generative AI tools in fields like biopharmaceutical innovation in their proper context, and to avoid assumptions and conclusions drawn from headlines and hype.

At this stage, our primary use of generative AI in the innovation process is in a field called generative chemistry. In generative chemistry, we use an approach similar to non-generative machine-learning tools, training an AI platform with data on existing molecules with known properties of interest so it can later apply that information to other tasks. The main difference is that, in generative chemistry, rather than directing the trained AI to search for and identify useful assets or information in existing sources, we direct the AI to profile and propose new virtual molecules *in silico* that do not already exist.

One example of a generative chemistry tool is our proprietary deep-learning neural network-based AI platform called JAEGER, which I mentioned earlier in my testimony. JAEGER was a purpose-built tool, created to assist our scientists in designing potential new anti-malarial drugs. The platform was initially trained on a dataset of over 21,000 proprietary molecules from our compound library that had been previously tested for anti-malarial properties.[xv] Once trained, our scientists fed JAEGER three existing proprietary malaria inhibitors as "seed molecules." Using those as a starting point, JAEGER then proceeded to generate 282 novel virtual molecules, different from any that previously existed, but with realistic properties comparable to those in the training set.[xvi] Using other AI-assisted tools and their own intuition, our scientists then selected, synthesized and tested two of the most promising from the set of 282, and confirmed that they have strong anti-malarial activity and low cytotoxicity on par with approved anti-malarial medicines. [xvii]

While it may be tempting to call JAEGER an inventor of the 282 novel candidate molecules it generated, we do not believe that this an accurate portrayal, either factually or legally. Factually, JAEGER neither identified a problem, nor considered how to address it without prompting from human scientists and modeling from human-made precedents. Nor did it appreciate the properties or utility of its outputs, which had to be further analyzed, synthesized, developed and tested by humans before the results were realized. Legally, while statute does not define what it means to "invent,"[xviii] courts have defined "conception" as the hallmark of inventorship, and in turn have held that "conception" is "the complete performance of the mental part of the inventive act" and "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention."[xix] Conception also requires recognition and appreciation of the invention.[xx] Applying these principles, we believe it is clear that, at least presently, AI systems like JAEGER are wholly incapable of "recognizing" or "appreciating" anything, or of otherwise engaging in the type of "mental" activities required for inventorship. In other words, while JAEGER may have *generated* what did not exist before, there was no thought process equivalent to conception. Instead, JAEGER is effectively operating as an advanced tool used by humans in a human-directed innovation process aimed at achieving a human-defined goal.

V. The Impact of AI on Human Inventorship: Conception Law in Proper Context

While it is clear in our view that, at least as presently used in biopharmaceutical R&D, AI is not itself inventing, that alone does not resolve the AI-inventorship quandary. In fact, the more pertinent question at this point in time is whether and how a human's use of AI to assist in processes like biopharmaceutical innovation impacts a *human's* status as an inventor under current law. This issue is ripe because, as I have explained, generative AI, unlike non-generative AI, plays a qualitatively different role than most traditional tools, and is already changing the way that humans innovate. The issue, in our view, is also one that the Subcommittee should watch, because, with respect to certain uses of generative AI in innovation, current US "conception" law could, if too narrowly construed, be misapplied to deprive human inventors of legitimate patent rights in their inventions, putting the United States at a distinct disadvantage compared to the rest of the world, which has no comparable law.

For context, conception law was primarily developed to help determine inventorship contests between competing inventors in interference practice under the "first to invent" system that existed in the United States prior to the enactment of the America Invents Act. Under that

historical regime, in order to assess which of several different competing inventors was truly the first to invent the subject matter of the patent, and thus entitled to the patent, courts focused on who was first to "conceive" of the invention. Describing "conception" explicitly as "an issue of priority of invention," the Court of Customs and Patent Appeals in one of the seminal cases in this area of law explained that conception is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. . . ."[xxi] That standard, devised for the purpose of determining *when* an invention occurred, rather than *if* it did—and, needless to say, long before technologies like generative AI could possibly have been envisioned—has now become a standard statement of conception law.

We do not believe that this "mind of the inventor" standard is problematic *per se* for inventions created with generative AI, but if it is applied without context and without considering other important principles of conception law that have been developed over many years, it could lead to patent examiners or courts improperly denying patents to human inventors who use these tools in their work. We recently raised this concern with the USPTO,[xxii] because current Patent Office guidance on conception in the Manual for Patent Examining Procedure (MPEP) appears to focus too narrowly and rigidly on whether the full conceptive act literally occurred inside the human "mind of the inventor," [xxiii] and it indeed omits other pertinent principles that in reality make the law much more flexible than would appear from that standard alone. For instance, *Morse v. Porter*, 155 USPQ 280, 283 (Bd. Pat. Inter. 1965), which is no longer included in the MPEP, provides that so long as a person "maintains intellectual domination" of the invention through the steps of "successful[ly] testing, selecting or rejecting" the final product, that person qualifies as an inventor, even if he or she considers and adopts ideas, materials, information or suggestions from others.[xxiv] *Morse* and other cases have held that those ideas, suggestions and materials can even be "the key that unlocks [the] problem," and they can come from any number of sources, including employees, consultants, friends, or other external sources.[xxv] Other cases set forth the principle that a person can also be an inventor in some circumstances by virtue of being a necessary actor to actually make the invention, for instance where a first inventor is incapable of completing the operative invention him or herself.[xxvi] And, because conception requires recognition and appreciation of the invention, courts have long held that one can be first to conceive of an invention, and thus an inventor, even if someone else "obtained the novel subject matter at a date earlier" but failed to recognize it.[xxvii]

We believe these additional principles make clear that a human who guides and uses generative AI as a tool to generate novel inventions or elements of inventions *in silico*, rather than literally in the mind, does not thereby lose the right to the resulting inventions, particularly in cases like JAEGER where the inputs were carefully selected and controlled by humans and the outputs cannot be made or appreciated without significant further human skill and ingenuity. Rigid application of a "mind of the inventor" standard in disregard of these other principles does not make sense in a world where technological advances now allow some aspects of inventive activity to occur *in silico*, particularly in a post-AIA "first-to-file" system, where the whole body of conception law is of limited utility. For these reasons, we have requested that the USPTO reinstate these other missing principles to the MPEP, and have further requested that it consider expressly adding AI to the list of sources under the *Morse* line of cases that can permissibly supply "ideas and materials" to the human inventor without compromising inventorship.[xxviii] We believe these clarifications are consistent with existing law, and can go a long way to increasing

certainty for innovators who use AI in their inventive processes, which in turn will encourage further development, adoption and use of these value-adding tools across the US economy.

Because no changes to existing law would appear to be necessary to address this issue at this time, we raise it with the Subcommittee today primarily for awareness, and as an area to monitor as the USPTO and courts begin to evaluate and potentially act on an increasing number of patent applications and granted patents for inventions made with the assistance of AI.[xxix] Ultimately, given that no other country maintains a conception requirement at all, we believe this is a critical issue for the United States to get right. If the United States were to deny patents to those who use AI to assist their innovative efforts, it would put our nation's innovators at a distinct disadvantage, and threaten America's innovation, economic and strategic leadership.

VI. AI Inventorship Policy and the Constitution

For the reasons I have discussed, we do not believe that we are yet at a point in the life sciences field where United States patent law needs to change to accommodate either AI inventorship or AI-assisted human inventorship. But that does not mean we will never reach that point. We also cannot fairly speak to the state of AI in other industries, and we acknowledge the existence of examples from some—including the DABUS example from my fellow witness at today's hearing—that have described and characterized certain simple inventions as having been fully invented by AI.[xxx]

Whether it takes many more years, or whether we are already there in some fields, whenever we reach the point where an otherwise patent-eligible and patentable invention cannot issue under United States patent law due only to the question of inventorship, we believe the response from Congress should be guided by the patent system's policy goals of promoting scientific, technological, and societal progress, as enshrined in the Constitution. Importantly, those goals are not achieved simply by encouraging *invention*. They also require encouraging the publication and/or development and commercialization of inventions, which is the true genius of the patent system compared to other forms of IP such as trade secret protection.

As I discussed in my introductory comments, in the biopharmaceutical field, AI tools are already helping to make innovation more efficient, and they ultimately hold the promise of leading to more effective, tailored, safer, and more cost-efficient medicines—in other words, innovations that advance the state of science and technology, and ultimately benefit patients and society. From a constitutional and broader policy perspective, this, in our view, clearly means that Congress should encourage and incentivize the continued development, adoption and use of AI tools in fields of innovation like ours; and it can do so by continuing to ensure that patents remain available for the downstream inventions that are created in that process, regardless of who or what made the invention. Ensuring that patents continue to be available for downstream inventions made with, or even by, AI is especially important in our field, where even the full invention of a compound is only the first step in the long innovative process of developing new medicines. Without patents or comparable incentives to enable and encourage the years of investment, hard work, and problem solving that must be done after drug discovery, including the long process of clinical trials where many additional innovations are made, we simply would not have new medicines.

To be clear, we do not at this stage advocate for any particular solution to an issue which, as I have said, at least for our industry is not ripe at this time. We are aware of many different proposals, from changing the law to allow AI to be an inventor, to eliminating the conception requirement, to dispensing with inventorship altogether. Each of these proposals carries risks and benefits, which, in our view, should be considered and vetted in due course, and with ample opportunity for stakeholder input, and always with the constitutional goals of the patent system as a guide.

VII. Perspectives on Select Other Issues at the Intersection of AI and IP

A. Ownership of Patents on AI Inventions and AI-assisted Inventions

AI inventorship considerations also raise corollary questions concerning who should own any patents that issue on inventions made by, or with the assistance of, AI. Because AI is not, in our view, presently inventing in our field, we believe the question concerning AI-*assisted* inventions—those generated by humans using AI—is the more pertinent one at this time. In our view, patents on AI-assisted inventions raise no special ownership issues, because the inventor in such cases is the natural person who uses the AI, and, as in the case with any patent, ownership vests in the inventor, absent an assignment to the contrary.[xxxi] If, at some point in the future, AI were to advance to a stage where it can be deemed an inventor, and the law were to be changed to recognize it as such or to eliminate the inventorship requirement, our preliminary view is that ownership should generally vest in the natural person or entity that owns (or "employs") the AI at the time that the invention occurs, unless by contractual arrangement, ownership is assigned to another person or entity. Given that this scenario does not presently exist, however, we believe the question should be reserved for future consideration.

B. AI, Section 101 and Patent Eligibility Reform

As I have discussed today, AI tools have a strong potential to help us further optimize and accelerate biopharmaceutical R&D, and to advance the future of medical innovation for patients and society. As such, we believe it is extremely important that Congress ensure that the right conditions and incentives are in place to continue to incentivize the development of these tools. Whether done in-house, externally by our technology-sector partners, or jointly, the creation and development of the next generation of AI tools requires investment and R&D, just as our biopharmaceutical inventions do. The strength of the United States patent system and its broader innovation ecosystem are, therefore, critical factors in whether and *where* these tools are ultimately developed.

With this in mind, we believe there is an important link between the issues raised in today's hearing, and this Subcommittee's ongoing efforts to institute patent-eligibility reforms to restore eligibility for patents on certain types of software, diagnostic methods, and other important technologies which may encompass or involve AI. Novartis has long supported those reforms through public comment, amicus briefs, and work with the USPTO and both chambers of Congress. In 2019, I had the honor of testifying before this Subcommittee on behalf of Novartis as one of the invited witnesses in favor of patent-eligibility reform,[xxxii] and we look forward to continuing our support as that work continues.

C. Obviousness

Some commentators have raised concerns that as AI advances, it will change the definition of a "person of ordinary skill the art" and ultimately render every invention obvious. On this issue, we believe it is important to again distinguish AI itself from a natural person using AI as a tool in research and innovation. Because AI is not presently treated as a person under the law, we do not believe that the abilities of an AI alone—such as its ability to search and analyze much larger scopes of information than a human—should impact how a person of ordinary skill in the art is defined, or what a human's level of ability is. As for a human inventor using AI, AI should be treated like any other tool, particularly since the operable standard is a person of "ordinary" skill in the art, and not a genius or thought leader with access to the most powerful or proprietary AI-driven tools. For now, we believe that current laws defining the person of ordinary skill in the art are adequate to determine the impact of AI-based tools in a given field, and to fairly apply that standard according to the facts presented by the applicant or parties in proceedings. Before any changes are contemplated, Congress should also see how the Patent Office and the courts are able to manage this issue over time.

D. New forms of IP Rights for Data

With the central role that data plays and will continue to play in creating, training and applying many AI tools, some have posed the question whether new IP rights are needed to strike the right balance between data ownership and access to data, in order to enable broad innovation and competition while also ensuring that resulting AI tools perform their tasks ethically, responsibly and in an unbiased manner. We are still developing our views on these complex issues, but one key principle to bear in mind as law and policy in this area is developed is that not all data is the same. Some data is collected legitimately from existing public sources like the daily weather or public records and databases, while other data may exist only in private sources, such as our proprietary compound libraries, or the customer traffic on a private website. Still other types of data must be affirmatively generated through activities that require significant investment and effort, such as the safety, efficacy and quality data generated through our clinical trial process. As a result, the right models and policies to incentivize the use of data to train and create AI tools, while also incentivizing the sharing of that data for development of other AI tools by third parties, as well as for assessment of its quality, balance and neutrality, may differ depending on the type of data involved, and these differences should be accounted for. For instance, existing IP rights in certain data, such as trade secrets, regulatory data protection, and copyrights should be respected. We believe the right answers can be reached by starting with the goals—incentivizing the broad creation of high quality, responsible and unbiased AI tools—and working backwards to reach those results.

VIII. Conclusion

Once again, we thank the Chairman, the Ranking Member, the Subcommittee and each of your staffs for your collective leadership on this important issue. We welcome any questions and look forward to continuing to work with the Subcommittee on these important topics at the intersection of AI, IP and innovation.

[i] M. Chatterjee, *Can JARVIS hold a patent? - POLITICO*, April 25, 2023; *see* J.A.R.V.I.S. - Wikipedia (J.A.R.V.I.S. is a fictional character, and an acronym for Just A Rather Very Intelligent System).
[ii] Novartis in Society Integrated Report 2022 at 4.
[iii] DiMasi JA, Grabowski HG, Hansen RW., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, J Health Econ. 2016;47:20-33; *see also* Novartis Annual Report 2022 at 31 ("The discovery and development of a new drug usually requires approximately 10 to 15 years from the initial research to bringing a drug to market."); Congressional Budget Office, Research and Development in the Pharmaceutical Industry | Congressional Budget Office (cbo.gov), April 2021 ("Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.").
[iv] USFDA, FDA approval brings first gene therapy to the United States, August 30, 2017.
[v] USFDA, FDA approves innovative gene therapy to treat pediatric patients with spinal muscular atrophy, a rare disease and leading genetic cause of infant mortality, May 24, 2019,
[vi] USFDA, FDA approves new treatment for certain digestive tract cancer, Jan. 26, 2018.
[vii] USFDA, FDA approves Pluvicto for metastatic castration-resistant prostate cancer, March 23, 2022.
[viii] *See* note iii, *supra*.
[ix] The art of drug design in a technological age | Novartis, November 18, 2021.
[x] Machine learning poised to accelerate drug discovery | Novartis, May 7, 2018.
[xi] Drug development gets big data analytics boost | Novartis, July 2, 2018.
[xii] Digital clear glass for the future of medicine - Novartis Live. Magazine, September 26, 2021.
[xiii] A single source of Healthcare R&D data - data42 | Medium, June 10, 2021.
[xiv] Artificial intelligence proves successful in accelerating leprosy detection | Novartis Foundation, February 16, 2022.
[xv] Godinez et al., *Design of potent antimalarials with generative chemistry*, 4(2) NATURE MACHINE INTELLIGENCE 180 (Feb. 23, 2022); A smart ally in the fight against malaria - Novartis Live. Magazine, March 16, 2022.
[xvi] *Id.*
[xvii] *Id.*
[xviii] Section 100(f) defines an inventor only as someone who "invents or discovers" the subject matter, without further defining the act of invention. *See* 35 U.S.C. § 100(f) ("The term 'inventor' means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.").
[xix] *Townsend v. Smith*, 36 F.2d 292, 295 (CCPA 1929).
[xx] *Silvestri v. Grant*, 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974); *Invitrogen, Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1064, 77 USPQ2d 1161, 1169 (Fed. Cir. 2005).
[xxi] *Townsend v. Smith*, 36 F.2d at 295.
[xxii] Novartis Comments on Artificial Intelligence and Inventorship, filed May 15, 2023.
[xxiii] *See, e.g.*, Manual of Patent Examining Procedure (MPEP) § 2138.04, Latest Revision February 2023 [R-07.2022] (Instructing applicants and examiners in the very first subheading that "Conception must be done in the mind of the inventor," and further stressing that "the inventor must form a definite and permanent idea of the complete and operable invention to establish conception") (emphasis in original); *see also* MPEP § 2109, Latest Revision February 2023 [R-07.2022], quoting *Board of Education ex rel. Board of Trustees of Florida State Univ. v. American Bioscience Inc.*, 333 F.3d 1330, 1340, 67 USPQ2d 1252, 1259 (Fed. Cir. 2003) (stating that "with regard to the inventorship of chemical compounds, an inventor must have a conception of the specific compounds being claimed" and that "'general knowledge regarding the anticipated biological properties of groups of complex chemical compounds is insufficient to confer inventorship status with respect to specifically claimed compounds.'").
[xxiv] *See, e.g., Morse v. Porter*, 155 USPQ 280, 283 (Bd. Pat. Inter. 1965) ("[I]n arriving at a conception [the inventor] may consider and adopt ideas and materials derived from many sources," so long as the inventor "maintains intellectual domination of the work of making the invention down to the successful testing, selecting or rejecting….").
[xxv] *Id.; In re Hardee*, 223 USPQ 1122, 1123 (Comm'r Pat.1984) ("Nor would the defendants necessarily be disqualified as 'inventors' under patent law if their work depended in part—even in large part— on information obtained from another."); MPEP § 2138.04, [R-08.2017], Subsection II (Ideas, suggestions and materials can come from "an employee, a hired consultant or a friend even if the adopted material proves to be the key that unlocks the problem.").
[xxvi] *See, e.g., Bd. of Ed. ex rel. Bd. of Trustees of Florida State Univ. v. American Bioscience Inc.*, 333 F.3d 1342 (Fed. Cir. 2003) (if the named inventors "had conceived the structures of the claimed compounds, but were then unable to make them without [another person's] help, [that other person] might have been a coinventor."); *see also*

Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998) ("All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.").

[xxvii] *Silvestri v. Grant*, 496 F.2d 593 at 597; *Invitrogen*, 429 F.3d at 1064.

[xxviii] While the Federal Circuit has noted that, as a Board decision, "*[Morse v.] Porter* is not binding on this court," *In re Verhoef*, 888 F.3d 1362, 1367 (Fed. Cir. 2018), we believe the case and its principles remain good law, particularly when viewed together with the other principles mentioned.

[xxix] We note that in *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022), the Federal Circuit, while holding that an AI cannot itself be an inventor, also made clear that "we are not confronted today with the question of whether inventions made by human beings with the assistance of AI are eligible for patent protection."

[xxx] See, e.g., *Thaler v. Vidal*, 43 F.4th 1207.

[xxxi] See 35 U.S. Code § 261.

[xxxii] Testimony of Corey Salsberg before the United States Senate Judiciary Subcommittee on Intellectual Property, Hearing on "The State of Patent Eligibility in America, Part III," June 11, 2019; Responses to Questions for the Record of Corey Salsberg, "The State of Patent Eligibility in America, Part III," July 2, 2019.

U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property
June 7, 2023

Artificial Intelligence and Intellectual Property – Part I: Patents, Innovation, and Competition

Written Testimony of
Ms. Laura Sheridan
Head of Patent Policy
Google

Chairman Coons, Ranking Member Tillis and Members of the Committee:

Thank you for the opportunity to appear before you today. My name is Laura Sheridan, and I am the head of patent policy at Google. I look forward to answering the Committee's questions on artificial intelligence and patenting.

Google's approach to artificial intelligence (AI) is both bold and responsible. We believe we must develop AI in a way that maximizes the positive benefits to society while addressing the challenges. As we innovate, we are guided by our AI Principles, first introduced in 2018. The only way to be truly bold in the long-term is to be responsible from the start.

Google is utilizing AI in our groundbreaking products used by people everywhere, in our contributions to scientific advances that benefit people, and in helping to address societal challenges. The potential of AI to solve big problems is rapidly increasing and we are proud of efforts to partner in the use of this technology to help address problems and improve the lives of people around the world.

AI has played an important role as a powerful tool for enabling more rapid innovation than was previously possible. Among other things, we are deploying AI to help forecast floods, monitor prenatal health, and detect genetic variations linked to disease. We are also using AI to help expedite chip floorplanning, identify optimal neural network architectures, and improve upon the drug design process, which are described in greater detail below.

Google's patent portfolio counts more than 62,000 patents worldwide, with more than 27,000 patents in the U.S. alone. As part of this portfolio, we pursue patent protection for many AI innovations. According to a report by the U.S. Patent and Trademark Office (USPTO) on AI patenting activity, Google has one of the largest patent portfolios in AI technology.

I. GOOGLE'S DEVELOPMENT OF ARTIFICIAL INTELLIGENCE TECHNOLOGY

AI provides tremendous potential across numerous fields, including scientific exploration such as prediction modeling. For example, in 2018, Google began our flood forecasting initiative to help combat the catastrophic damage from floods each year by equipping those in harm's way with accurate and detailed reports. With the power of AI, we expanded our reach to send out over 115 million potentially life-saving alerts. Our flood alerts display inundation maps, which show the extent and depth of flooding on top of Google Maps, so people can visualize this critical information more easily. And we developed a new manifold inundation model relying on AI that enables us to scale these efforts significantly.

AI technology has already created scientific advances yielding real-world benefits. One significant achievement includes advances in understanding protein folding. Proteins are complex molecules essential to life. Each has its own unique 3D shape that determines how it works and what it does. Knowing how proteins fold has the potential to help scientists make enormous progress in every field of biology. Google created AlphaFold, an AI-powered system which accurately predicts the shape of proteins, and released the AlphaFold Protein Structure Database containing more than 200 million protein structures, covering nearly all cataloged proteins known to science.

Google also uses AI technology to power WaveNet, which creates more natural-sounding speech for products used by millions of people around the world. WaveNet emerged from our team's research in generative models, a type of AI system that is trained on speech samples. It creates the waveforms of speech patterns by predicting which sounds likely follow each other. By including intonation, accents, emotions, and other vital layers of communication overlooked by earlier systems, WaveNet delivers a richness and depth to computer-generated voices.

II. RECENT ENGAGEMENTS WITH THE U.S. PATENT AND TRADEMARK OFFICE

A. Listening Session on Artificial Intelligence Inventorship

Google participated in the USPTO AI Listening Session on May 8, 2023. At the event, the USPTO shared that there is a spectrum of inventive behavior, with an invention resulting from a human inventor without the use of an AI tool at one end, and a purely AI-generated invention at the other end. The inventorship question is clear at both ends of the spectrum (yes for the human, no for the AI), but it becomes less clear as you have a human inventing with AI assisting in the process. In our view, current industry uses of AI are well within the zone where humans are properly named as the inventors and where AI is leveraged as a tool in the invention process. We expect to remain in this zone for some time.

Google appreciates USPTO's exploration of the end of the spectrum where AI has a more prominent role that could impact the inventorship calculus. As we shared at the Listening Session, we have time to consider this in depth and ensure we are avoiding unintended consequences with any proposed adjustments, as this is an area where "fixing" one thing may break another. In the meantime, the current law supports inventorship for technology created with the assistance of AI.

B. Comment on Artificial Intelligence and Inventorship

Google submitted a comment to the USPTO regarding AI and inventorship on May 15, 2023. In this comment, we explained that although Google is confident that inventorship for innovations brought about by using AI tools is properly held by the technologists – just as it always has been for inventions brought about through the usage of tools – we encouraged the USPTO to shed light on inventorship. Inventorship can be a challenging area for patent applicants as it is highly fact dependent and often complicated. We explained that guidance from the Office would allow for a clearer conversation between patent applicants and their counsel. This is the case whether or not AI is involved in the innovation process. This could include guidance on the usage of tools, giving patent applicants a better understanding of the role tools play in the inventing process.

We also respectfully suggested that the USPTO should encourage patent applicants to formally document inventor contributions. Having inventor contribution information memorialized would be beneficial in the patent prosecution record itself, providing transparency into the inventorship calculus and demonstrating the good faith effort made by the patent applicant to get it right. This can also be beneficial to any downstream litigation. And it is consistent with similar activity in the research community, where the contributions of individual authors on technical papers are getting more clearly identified.

To support this and other conversations about AI-related activity, we have also encouraged the USPTO to adopt standardized definitions for the different categories of AI-related inventions so that it is always clear what is, and is not, being discussed. This will provide a helpful framework as these issues grow in complexity and importance. We explained that we believe the definitions jointly proposed by the Intellectual Property Owners Association and the American Intellectual Property Law Association are a good solution. They speak to three categories of inventions: inventions on core AI technology, inventions on specific applications of core AI technology, and inventions generated by or using AI.

Finally, in its continued engagement with stakeholders at the intersection of AI and intellectual property, we have encouraged the USPTO to implement robust technical training for any patent examiner who is examining AI-related innovations, whether those are inventions on core AI technology or inventions on specific applications of core AI technology. As the USPTO's recent AI report demonstrates, the number of patent examiners who are now examining these AI-related inventions makes up a substantial portion of the examining corps, and that number is only going to increase. We urged that a comprehensive technical training program be put in place so that patent examiners are well-situated to assess whether or not to grant a patent. In addition to these generalized comments, we also provided responses to specific questions asked in the Request for Comment.

C. Testimony for Fee Hearing

While not specific to AI, Google also provided testimony in conjunction with the USPTO's recent hearing on its proposed fee structure. As we emphasized in our remarks, we believe that the USPTO will be in the best position to grant robust and reliable patent rights when the fees before grant of a patent more closely match the costs, instead of relying upon the maintenance of a patent for that recovery. This allows for more resources to be available for the challenging tasks associated with patent examination, including prior art searching, understanding what the patent claim terms mean, applying the prior art to the claims, and ensuring the statutory requirements are met. This must be accomplished in a way that does not hinder the ability of our small and micro entities to pursue patent protection for their innovations. Large companies can and should support the overall health of the patent system.

For complex technologies like AI, which 50 percent of the patents granted in 2020 related to in some way, having adequate resources up front is critical to ensuring that deserving patents are granted, while those that do not satisfy the statutory requirements are not. We thanked the USPTO for moving in this direction, and encouraged it to work toward full cost recovery.

III. AI IS A TOOL, NOT AN INVENTOR

As with other technical tools, AI has contributed to the inventive process for decades. What is different today is how AI has improved in terms of its capabilities, making it possible to carry our research much faster than ever before. As a result, AI is increasingly being leveraged by technology companies, the pharmaceutical industry, manufacturing businesses, and others. Along with AI systems, there are numerous other computational tools used in the invention process, including computational chemistry, integrated circuit design algorithms, and other computer simulations. AI and non-AI tools can similarly enable the invention process, depending on how they are leveraged by the technologist.

We have seen that when using AI as a tool for innovation, humans are involved in a way that makes them inventors for the resulting innovations. This involvement includes designing the AI system to achieve a specific purpose, analyzing the output of the AI system and appreciating it as inventive, or forming an invention based on the output. The invention being claimed in a patent application will reflect the involvement of the technologist, and their usage of the AI as a tool to enable the invention process.

Google has extensive experience leveraging AI in the innovation process across our wide range of products, services, and R&D efforts. We support AI-assisted innovation across a wide swath of industries through our cloud services like Vertex AI and our open source software like TensorFlow. Some notable examples include using it to help expedite chip floorplanning, identify optimal neural network architectures, and improve upon the drug design process. In each of these examples, AI has played an important role as a powerful tool for enabling more rapid innovation than was previously possible.

- **Chip Floorplanning:** Chip floorplanning is a step in the chip design process where engineers attempt to optimally place components on a chip. An optimal design may account for parameters like wire length, power, and timing. Chip floorplanning is frequently done with the help of computer algorithms and simulation, using as inputs a "netlist" and a canvas that provides the chip dimension and pin locations. The result of this is a floorplan, with the components placed on the chip canvas in some optimal arrangement. Google has invented novel machine learning models for chip floorplanning, and has used these models as tools in the chip design process.

  In using these models to develop chip floorplans, our technologists are involved in designing the underlying model to generate optimized floorplans, analyzing and modifying the outputted chip floorplan, and deriving concepts for optimal arrangements based on observation of several floorplans generated by the model. Patents on inventions appreciated and derived from the generated floorplan outputs could be pursued with the technologists as the proper inventors, and the AI system as the tool that helped enable the process.

- **Optimal Neural Network Architecture Search:** Neural architecture search (NAS) is a machine learning approach for identifying optimal neural architectures for training a model for a given task (e.g., image recognition). NAS is intended to replace or supplement the time-intensive manual neural architecture design process. Depending on the NAS approach, the identified neural architectures may be existing neural architectures, or may be entirely new. Google has invented an automated NAS approach called MnasNet, which is used to identify neural architectures appropriate for training models used on mobile devices.

We have used MnasNet to enable the identification of an improved model architecture for image recognition running on mobile devices. We then trained the identified neural architecture and experienced a significant improvement on what was the state of the art for mobile image recognition. The identified architecture included both 3x3 and 5x5 convolutions, which is different from previous mobile device models that only used 3x3 convolutions. Patents on the architecture for mobile image recognition that was appreciated and derived from the generated output could be pursued with the technologists as the proper inventors, and MnasNet as the tool that helped enable the process.

- **Drug Design:** An early step in drug discovery is often attempting to find small molecules that will bind to a given protein. This process is called hit-finding and was historically very expensive to scale. One current approach to make hit-finding more scalable is to use DNA-encoded small molecule libraries (DELs). A DEL is composed of many compounds, each of which is tagged with a DNA sequence to identify it. To screen a DEL against a target, the DEL is mixed with the target and the compounds in the DEL that do not bind are washed away. The remaining compound/target mixture is then DNA sequenced to identify the subset of binding compounds in the DEL.

  Google and its partners recently applied machine learning to make DELs more effective in hit-finding by predicting additional hits outside a given DEL. The data from a DEL screening was used to train an AI model to predict which compounds would be hits. The resulting model was then applied to a large library of additional compounds to predict additional hits. The resulting predicted hits were then filtered automatically and manually to account for diversity, stability, and reactivity. The filtered predicted hits were validated experimentally in a lab. Patents on the validated compounds, if novel and nonobvious, could be pursued with the technologists as the proper inventors, and the AI system as the tool that helped enable the process.

IV. CLOSING

Thank you for the opportunity to appear before you today. We appreciate this important discussion on the current state of AI and patenting. Google continues to engage with government officials and the public to further discussions on AI and responsible development principles. We will continue to provide education and resources for our researchers, engage with governments and external organizations to develop standards and best practices, and work with communities and experts to make AI safer and more useful. Google will also continue to provide our feedback on the intersection of AI and patents in order to ensure that we continue to strike the right balance for our patent system to incentivize AI innovation.