Corey Salsberg
Vice President,
Global Head IP Affairs

Novartis Services Inc.
801 Pennsylvania Ave. N.W., Ste 700
Washington, DC 20004   USA
T: +1 (202) 662-4369
corey.salsberg@novartis.com

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November 8, 2019

VIA E-MAIL ONLY
AIPartnership@uspto.gov

Re: Request for Comments on Patenting Artificial Intelligence Inventions (Fed. Reg. Vol. 84, No. 166, p. 44889 (Aug. 27, 2019); Vol. 84, No. 189, p. 51522 (Sep. 30, 2019))

Novartis is a global healthcare company whose mission is to reimagine medicine to improve and extend people's lives. Using innovative science and the latest technologies, we discover and develop breakthrough medicines and other treatments, and find new ways to deliver them to as many people as possible. As is the case for many of our peers—and many other companies in nearly all industries—artificial intelligence (AI) is transforming the way that we innovate and operate. Given the impact that AI is already having across so many fields, and the promise that it holds for the future, we applaud the United States Patent and Trademark Office ("Office") for its efforts to stay in front of the technology, to anticipate in the above-referenced *Request for Comments* some of the important legal and policy questions that we agree pose challenges under current patent law, and to solicit the views of stakeholders like us in advancing the conversation. Below, we are pleased to provide our comments, beginning with our general views on the issue of patenting AI inventions, and followed by our responses to the Office's specific issues for comment.

I.   Introduction and General Comments

As a research-driven organization, we constantly operate at the cutting edge of science and technology. Among our recently approved therapies, many have been credited with transforming the practice of medicine. These include the approval in 2017 of the world's first chimeric antigen receptor T-cell (CAR-T) therapy, a personalized one-time treatment for certain forms of leukemia and lymphoma that uses a patient's own T-cells to fight cancer; the approval earlier this year of the world's first gene replacement therapy to treat children with spinal muscular atrophy (SMA), a leading genetic cause of infant mortality; and the approval in early 2018 of the first radiopharmaceutical for use in treating gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in an emerging field known as nuclear medicine. As is the case with more traditional forms of biopharmaceutical R&D, these cutting edge fields require massive investments, carry high risks of failure, and would not be possible without the robust incentives that the patent system provides.

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But even as these types of groundbreaking treatments revolutionize and disrupt traditional notions of medicine, a different kind of revolution is occurring inside our laboratories, in the clinics where we test and develop our medicines, and even in our global operations centers where we monitor the work that we do in over 140 countries around the globe. This revolution is a digital one, where new AI-driven tools are already helping to facilitate drug discovery, make R&D more efficient and effective, and enhance patient treatment in various ways. As one example, we are already using machine and deep-learning technologies in the drug discovery phase of R&D to screen and test drug candidates and analyze digitized cell images to help us more quickly and accurately identify promising leads from the millions of compounds in our in-house libraries. Further along in our R&D process, our proprietary "Nerve Live" network, a set of AI-driven platforms that incorporates machine learning and advanced data analytics, enables us 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—to help us anticipate, identify and resolve issues that slow or compromise our clinical testing. As a third example, this one aimed at clinical diagnosis, we are currently developing an AI-enabled system to perform a differential diagnosis between two similar respiratory diseases, which will allow general practitioners to diagnose a condition that can presently only be reliably diagnosed by specialists. Underscoring our commitment to these types of endeavors, and our belief in the importance of AI to our future, just last month we announced an exciting new multiyear alliance with Microsoft, which aims to comprehensively leverage AI and our proprietary data to transform how we discover, develop and commercialize our medicines.

As these examples demonstrate, whether developed in-house, or in partnership with cross-industry leaders, health-tech startups, universities, or others, AI-driven technologies are increasingly helping us improve the way we innovate and the way we conduct nearly every aspect of our work. Looking ahead, as AI grows more intelligent and autonomous, learns, and before long begins to train and improve itself based on our and others' data, it will inevitably become inseparable from many aspects of the process we today call biopharmaceutical innovation, and equally inseparable from many aspects of the practice of medicine and patient care.

With this in mind, in these early days of AI usage in our field, our principal goal in submitting these comments is to raise awareness of, and help the Office better understand, the patent-related AI issues that we believe may impact our mission and work. Our position can be boiled down to two main principles: **First**, the patent system must be ready and able to provide robust incentives for the continued development and improvement of AI-driven inventions, including the types of AI technologies that we will need to assist us in developing, delivering and optimizing tomorrow's innovative treatments and cures. **Second,** the system and its fundamental requirements must allow for the award of patents for "downstream" inventions conceived, developed, and/or implemented with the assistance of—and perhaps eventually even *by*—AI, as, at least in our resource-intensive field, patents will continue to be necessary as an economic incentive for the *humans* to invest in clinical testing, development and

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commercialization of medicines and other therapies, even as AI increasingly contributes to the inventive process.

We believe that these two basic principles—grounded in the system's unwavering Constitutional objective of promoting scientific and technological progress—should guide the Office's analysis of all legal and technical issues that AI patents may raise. In our view, returning to the fundamental purpose and goal of the patent system when questions arise should help the Office to ensure, to the extent possible within its authority, that semantic and other formalistic implications of rules written long before AI's existence do not unduly stifle innovation.

II. Responses to Issues for Comment

1. **Inventions that utilize AI, as well as inventions that are developed by AI, have commonly been referred to as ''AI inventions.'' What are elements of an AI invention? For example: The problem to be addressed (e.g., application of AI); the structure of the database on which the AI will be trained and will act; the training of the algorithm on the data; the algorithm itself; the results of the AI invention through an automated process; the policies/weights to be applied to the data that affects the outcome of the results; and/or other elements.**

We agree that inventions that constitute or incorporate AI, *and* inventions developed with the assistance of or by AI, both raise important and unsettled questions of patent law, and warrant the types of thoughtful inquiry, discussion and dialogue that the Office seeks in this Request for Comment. Beyond this, however, we would urge caution in spending too much effort defining "AI inventions" at this juncture. As set forth in our general comments above, we already operate in an environment where AI is playing a role in many aspects of our work, and that trend will only increase in our industry and most others. In our view, defining "AI inventions" as a specific field of technology, distinct from others, serves little purpose at this time, as the field promises to quickly evolve and push the boundaries of any definition, spilling into other fields and raising unnecessary uncertainty as AI becomes integrated with many other types of technology. As all fields of technology should (and must[1]) be treated equally under the patent laws, we believe a better approach to the questions raised by inventions that involve AI is to focus on the fundamentals of patent law, and to identify issues posed by AI with respect to each. While not comprehensive, we believe the areas of patent law that currently raise questions or face some uncertainty from AI include: 1) Subject matter eligibility; 2) inventorship (including conception); 3) obviousness / defining a "person of ordinary skill in the art;" 4) enablement and written description; and 5) filing and related formalities. As most of these topics are raised in the remaining questions, we address these in our answers below.

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[1] *See* Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), Art. 27.1.

2. What are the different ways that a natural person can contribute to conception of an AI invention and be eligible to be a named inventor? For example: Designing the algorithm and/ or weighting adaptations; structuring the data on which the algorithm runs; running the AI algorithm on the data and obtaining the results.

As discussed above, for purposes of these Comments, we understand the term "AI invention" to broadly encompass both inventions directed to or incorporating AI, and inventions created with the assistance or contribution of or by AI.

With respect to inventions covering AI itself, we agree that conception of these inventions (to the extent they are eligible for patenting under current US Law) may involve contributions by a natural person in the nature of the types of activities listed: e.g. designing the algorithm, defining its goals, structuring the data on which it runs, data (or feature) engineering, or running the algorithm on the data to arrive at a practical "trained model." Other types of activities that may constitute conception of an "AI invention" in a broad sense include incorporating AI or a trained model into a broader invention. In our field, this may include products such as various "smart" laboratory and research instruments, medical diagnostics, clinical instruments, wearable health devices that collect and analyze further data, or even such technologies as microchip-embedded medicines, which may eventually incorporate AI. It may also include incorporating AI into *methods,* such as using AI in a novel way to diagnose or treat a disease, or to monitor or improve a manufacturing process. Whether these activities actually amount to conception will, of course, depend on the facts of a given case and situation, but consistent with our response to Question 1, we believe it is important at this early stage for the Office to take a broad view of the types of technologies that might constitute or be impacted by AI, and therefore of the associated activities that might require more thought or legal adaptation as these technologies develop. As our further views on these issues are still evolving, we reserve further comment on this type of AI invention at this time.

With respect to "downstream" inventions conceived with the assistance of, or by AI, a natural person might contribute to the conception of such inventions in various ways and to various degrees, depending on the nature of the AI's contribution. If the AI in such circumstances were viewed similarly to a conventional tool, the contribution of the natural person would of course be the same as it is for any other field of technology (e.g. a person using a microscope, spectrometer, or conventional software program to implement his or her work). If the AI instead performs the type of activity that would traditionally be viewed as an act of human conception (e.g. making a novel, previously unknown connection between a target and a drug candidate without a natural person's guidance or direction, or designing a novel antibody or other protein structure to bind to a particular target), a natural person might either have no contribution, or still have a contribution as a joint inventor, depending on the facts and the nature of the human contribution. While we acknowledge that the ongoing debate over whether today's AI technologies can be considered "inventors"—e.g. as argued

in the pending "DABUS" ("Device for the Autonomous Bootstrapping of Unified Sentience") case—is unsettled, we believe the issue is more than philosophical, and raises significant questions of patent law that are worthy of this Office's careful attention.[2] We explain further and provide our views on this issue in the next question.

3. **Do current patent laws and regulations regarding inventorship need to be revised to take into account inventions where an entity or entities other than a natural person contributed to the conception of an invention?**

While today's AI technologies may not be capable of a level of "thinking" that one would normally associate with an act of "conception" as that term is understood colloquially, we believe that even current AI raises significant enough questions under current US inventorship law to warrant serious reflection, and possibly indeed changes to the law, or at least to the way it is currently understood and applied. The legal definition of "conception" under current US law is an area of particular concern. Under current US case law, it is well-established 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…."[3] The Federal Circuit has further held that "***every limitation*** of the count must have been ***known to the inventor*** at the time of the alleged conception."[4] In our view, these current requirements may be in tension not only with situations where an AI is alleged to have conceived of every element of a claim—as the applicants suggest is the case for the fractal-based beverage container and rescue device claimed in the DABUS applications—but also in any case where AI replaces only portions of the mental processes or contributions formerly performed by the human mind. Even where there is no possibility that AI could be deemed an inventor in such cases, in our view, current law raises equally challenging questions as to whether the natural person can still be considered to have conceived of the invention where less than all of it originated in the human mind.

The DABUS case illustrates this point. There, as we understand the facts, the applicants claim that the human inventor of DABUS had no knowledge, experience, or thought of designing the claimed beverage containers and rescue devices, but merely programmed an algorithm to identify problems and find solutions. Of course, should DABUS be found to be the *de facto* inventor of these products, questions arise under current law as to whether a software program can be a legal inventor, since, among other things, it has no true "mind," and it would be difficult to attribute "knowledge" or other mental acts to the software when there is no indication of when, how or why it did what it did. But even if DABUS is viewed only as a "tool" helping its human

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[2] AI, of course, also raises many other legal questions beyond patent law that will have to be addressed by the United States and other governments as the technology continues to evolve.

[3] *Townsend v. Smith,* 36 F.2d 292, 295 (CCPA 1929); *accord Hybritech Inc. v. Monoclonal Antibodies Inc.,* 802 F. 2d 1367, 1376 (Fed. Cir. 1986) (emphasis added).

[4] *Coleman v. Dines*, 754 F.2d 353 (Fed. Cir. 1985) (emphasis added).

inventor to solve problems, it is difficult to see how its human inventor can be found to have formed a "definite and permanent idea" of the "complete and operative invention" in his "mind," when the thought of beverage containers and rescue devices never entered his mind even generally. Just as a professor teaching his or her students the "scientific method" could hardly claim conception of specific inventions that those students later make in applying that method, we believe the DABUS case illustrates a nascent inventorship problem under current law.

As an example of how this may impact our own work, consider our use of AI in the laboratory to screen and test drug candidates and to analyze digitized cell images to assist in identifying promising compounds for further testing. While, at the present time, these programs are directed to specific tasks identified by our human scientists (e.g. searching images to identify a similar compound or cell structure, or similar impact that a substance has on a cell, compared to one that our scientists previously identified), we expect AI to eventually begin identifying promising leads of this type on its own, and likely to have the capability to design and build unique antibodies and other proteins. Notably, Google DeepMind's AI AlphaFold has already reportedly outperformed human competitors in predicting the three-dimensional structure of proteins, which is an important component of drug discovery.[5] As with DABUS, when the time comes that such activities are attributable to AI rather than humans—even if they form only a part of the overall conception of an invention of a compound, protein, or the like—it is unclear whether or how "conception" as defined by today's law can be attributed to the inventor of merely an upstream algorithm, or to a scientist who only generally directs the software to analyze a vast library of compounds or images for interesting patterns or anomalies, or to design new and useful proteins from the 20 amino acids. Other laws, such as current Section 101's requirement that patents issue only to "whoever invents or discovers" the invention[6]—and presumably only when there *is* a "whoever"—may also come into play, given that US law currently only recognizes individual humans as inventors, and not, for example, corporations.[7]

While we therefore believe that our laws may indeed need to be revised to adjust to the fast-evolving role that AI is playing in many aspects of many types of innovation, we do not suggest that the solution depends on answering philosophical questions about the nature of intelligence or whether AI can be an "inventor." In our view, returning to one of the core principles that we suggested in our general comment, the law need only adapt to ensure that a patent issues in such situations (provided, of course, that all other patentability requirements are met), without regard to whether the AI or the human is the "inventor." As discussed previously, however implemented, we believe this general "inventor-agnostic" approach to the issue would best serve the

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[5] *See* https://deepmind.com/blog/article/alphafold.

[6] 35 U.S.C. § 101.

[7] 35 U.S.C. § 100 ("The term 'inventor' means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.")

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Constitutional objective of the patent system—to promote scientific and technological progress—because the value to society of maintaining incentives to publish, and invest in the further development, commercialization and delivery of such inventions does not turn on technical questions of who or what the inventor is.

4. Should an entity or entities other than a natural person, or company to which a natural person assigns an invention, be able to own a patent on the AI invention? For example: Should a company who trains the artificial intelligence process that creates the invention be able to be an owner?

In our view, again focusing on our core suggested principles and the broader societal goals of the patent system, inventions created by or with the assistance of AI should have the same property-based attributes as any other patented invention. This can be broken down into two basic situations: original ownership and assignability. With regard to original ownership, the question of course turns in the first instance on inventorship. If a natural person is deemed to be the inventor of a downstream technology created by or with AI, ownership vests in that natural person under current law and should pose no further complications. If the AI is deemed to be the inventor, or if the law adapts to award a patent without regard to inventorship in such cases, we believe ownership should 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. In the example provided in this question, for instance, we believe the original company who trains the AI should generally be considered the default owner, provided no further transaction has occurred as of the time of invention. However, if the designer/trainer of the AI has sold the AI to another party, the new owner of the AI should generally own any downstream invention, absent terms of sale to the contrary. For other types of transactions, such as licensing of an AI system, or situations where the AI was designed or trained with or for a third party customer, ownership of downstream inventions should generally be governed by the contractual terms of the relationship. Absent such terms, other legal doctrines, such as work-made-for hire or employment laws may also provide useful guidance in some cases. Regarding assignability, we see no difference between AI inventions and any other type if invention. Once original ownership is established, any owner should be free to assign the invention to any other person or entity as is the case with all patents.

5. Are there any patent eligibility considerations unique to AI inventions?

In addition to the patent-eligibility issues that impact all software-based inventions in the US under the current state of the law—which we will not address further here, given our previous comments to the Office[8] and our testimony to the Senate Judiciary

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[8] *See Novartis Comments on "2019 Revised Patent Subject Matter Eligibility Guidance,"* (https://www.uspto.gov/sites/default/files/documents/eligibility2019comments_e_novartis_2

Subcommittee on IP on this issue earlier this year[9]—we believe there are several patent-eligibility considerations that are unique to AI inventions.

One unique question is how the "abstract idea" exception should be applied to AI inventions, which more frequently than other technologies include functions or decision making steps that may be unpredictable, poorly understood, or difficult to describe. Even where steps are concrete and understood, a related question is whether AI decision making according to an algorithm is "abstract" by analogy to the "mental steps" performed in the human mind, or whether such steps are materially different from human thought because they are ultimately the consequence of an algorithm of human design. As set forth in our general comments on eligibility,[10] we believe that current eligibility law, including the existing "abstract idea" doctrine, needs significant reforms in order to realign the system's goals with the current state of technology, including AI.

Another eligibility question unique to AI is whether, and under what circumstances, certain AI inventions may appropriately be excepted from patent eligibility on the basis of moral or national security concerns. While such eligibility restrictions may be permissible under international law,[11] and may be appropriate in limited circumstances such as the existing ban on patents for atomic weapons and "human organisms" in the United States,[12] with respect to AI technologies, we urge the Office and Congress to exercise extreme caution in using patent-eligibility as a vehicle to address these types of concerns. While there is no doubt that AI can be weaponized, and that leadership in certain AI technologies may impact national security, we believe that weakening or eliminating patent rights for AI inventions would put the United States at a distinct

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019mar07.pdf); *Novartis Comments on "Well-Understood, Routine, Conventional" Test for Subject Matter Eligibility* (https://www.uspto.gov/sites/default/files/documents/eligiblity2018comments_e_novartis_13aug2018.pdf)

[9] *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) https://www.judiciary.senate.gov/download/salsberg-testimony; *Responses to Questions for the Record of Corey Salsberg, "The State of Patent Eligibility in America, Part III,"* (July 2, 2019) https://www.judiciary.senate.gov/imo/media/doc/Salsberg%20Responses%20to%20Questions%20for%20the%20Record.pdf

[10] *See id.*

[11] See TRIPS Art. 27.2 ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality . . . .")

[12] See AIA Section 33 ("Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."); 42 U.S.C. § 2181 ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.")

disadvantage with respect to national security by sending investment in these technologies overseas. At the same time, unless narrowly tailored, such restrictions could have damaging unintended consequences on AI inventions that have nothing to do with national security. For these reasons, we believe that any national security concerns with respect to AI development and ownership should be addressed through means other than patent eligibility. Likewise, while AI technologies will at some point likely raise moral and ethical questions, such as bias in algorithmic decision-making, the elevation of statistics or logic over morality, and concerns over ownership of entities that may increasingly resemble sentient beings, we believe that these concerns are best addressed outside of patent law.

6. **Are there any disclosure-related considerations unique to AI inventions? For example, under current practice, written description support for computer-implemented inventions generally require sufficient disclosure of an algorithm to perform a claimed function, such that a person of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention. Does there need to be a change in the level of detail an applicant must provide in order to comply with the written description requirement, particularly for deep-learning systems that may have a large number of hidden layers with weights that evolve during the learning/training process without human intervention or knowledge?**

We agree that the written description requirement may pose unique challenges for AI inventions in certain cases where aspects of algorithmic decision-making may appear unpredictable, inconsistent or be poorly understood, as is often the case with machine and deep learning-related AI inventions, where, e.g., the nature or quality of training data may impact results. While our views on this issue are still evolving, for now we would note that regardless of the field of technology, written description does not generally require an inventor to disclose more information than he or she knows, or is able to discern, about how the subject invention works.[13] Consistent with this principle, in our field, for example, section 112 does not generally preclude a patent on a pharmaceutical substance simply because we do not understand the mechanism of action at the time of filing. Other technologies, such as slot machines, are also routinely issued patents, despite the fact that any particular outcome is impossible to predict. While AI may currently involve deeper levels of mystery as to why a certain algorithm reaches the result that it does, or unpredictability as to result, examples such as these from other fields may be instructive. Ultimately, we believe the written description requirement needs to be applied reasonably in view of the field of technology. As for

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[13] See *Eames v. Andrews*, 122 U.S. 40, 55–56 (1887) ("It may be that the inventor did not know what the scientific principle was....That does not vitiate the patent."); *Fromson v. AdvanceOffset Plate, Inc.,* 720 F.2d 1565, 1570 (Fed. Cir. 1983) ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.").

what the proper standard is for AI, we believe there is a need for more detailed study and continued stakeholder engagement as AI technology, Office practice, and case law develop.

7. How can patent applications for AI inventions best comply with the enablement requirement, particularly given the degree of unpredictability of certain AI systems?

We again believe that unpredictability in and of itself should not negate or weigh against a finding of enablement for any form of technology. As the examples above demonstrate, some fields of technology simply operate according to principles that are not currently well understood, or are unpredictable or variable by nature, which may well be acceptable under established principles of patent law.[14] Generally speaking, we believe that an inventor of AI, like any inventor, should be held to the usual standard of disclosing enough for one of ordinary skill in the art to practice the invention, which may, in a given case, include part or all of an algorithm, the generic type or class of the machine learning model employed, a sufficient description of the type of data used, and some showing of results achieved, to enable others to build a similar system. That standard, however, should not require an inventor to explain what he or she does not (and perhaps cannot) know, or how to necessarily achieve comparable results where variability is inherent in the nature of the technology. As before, our views on this issue are evolving, and we encourage the Office to continue stakeholder outreach as this technology and the case law develops.

8. Does AI impact the level of a person of ordinary skill in the art? If so, how? For example: Should assessment of the level of ordinary skill in the art reflect the capability possessed by AI?

Viewed as a tool to assist natural persons, we believe AI must ultimately impact the definition and skill level of a person of ordinary skill in the art, just as microscopes, calculators, and more conventional software applications have in the past. That said, at least in fields like ours, at the present time it is not clear that AI has had enough of a systemic impact to materially impact these definitions. Different biopharmaceutical companies, universities, and other research-based institutions have thus far adopted, and will continue to adopt, AI at different paces, in different areas of their work, and in most cases only with moderate impact in the near-term. Given that 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, we believe it will be some time before clear standards emerge of an average level of AI-assisted skill. That time, however, will almost certainly come. While we share some of the hypothetical concerns raised by some that eventually most inventions may become obvious on the basis that AI or artificial general intelligence (AGI) will have immediate access to all

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[14] *Id.*

public information in existence, and be capable of at least trying every possible solution to any problem in rapid time, we consider these concerns to be distant and speculative at this time. For the time being, 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.

9.   Are there any prior art considerations unique to AI inventions?

At present, the main prior art considerations unique to AI that come to mind concern the potential impact of AI on evaluation and determination of what is "public" or "available to the public"[15] at the time of patent filing. If AI is able to access sources of information that for various reasons (e.g. format, language, organization, etc.) would not be accessible, discernible, or comprehensible to a natural person, and if "the public" is further interpreted to include AI or persons with access to AI, the universe of material that is deemed to be prior art could dramatically expand. In some cases, this could potentially lead to unfair results. For example, if the definition of "prior art" expands faster than the definition of a person of ordinary skill in the art, we could be faced with situations where patents are denied for lack of novelty even where the prior art is only available to an AI system, or to a privileged segment of the public with access to that system. One way to minimize this type of consequence is to take a holistic view of the patent laws and ensure that core legal standards evolve at an even pace.

10. Are there any new forms of intellectual property protections that are needed for AI inventions, such as data protection?

At this time, we are undecided as to whether new IP rights are needed for AI inventions. For us, the key issue is whether the patent and copyright systems, as well as existing alternatives like trade secrets, are able to successfully and robustly incentivize the invention and development of the AI-driven tools that we will need to implement next-generation biopharmaceutical R&D processes, and, equally, to incentivize the use of those tools to assist in downstream invention, development, commercialization and delivery of future generations of medicines and cures. While, like many stakeholders, we believe AI inventions raise some challenging questions as to whether patents and other existing forms of IP are fit for this purpose, the answers at this stage are not clear. Should current systems prove unable to provide adequate incentives to sufficiently effectuate the promise of AI, or should important gaps arise in those systems, we believe it would be appropriate to consider new forms of IP at that time. Some possibilities include an IP right for trained models, and an IP right for non-public data where its generation required substantial effort and investment (similar to the regulatory data protection (RDP) rights available in our industry for proprietary clinical and other data submitted to FDA and other regulatory authorities).

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[15] 35 U.S.C. § 102(a).

New IP rights might also be considered as a solution to the tension that sometimes arises between data ownership, data privacy, and access to data. With RDP, for example, the *sui generis* IP right in regulatory data not only incentivizes investment in the generation of that data, but acts as compensation for disclosing that information to regulatory authorities to assess safety and efficacy, and allowing competitors to rely on that data for competing medicines after the term of protection expires. The RDP right also enables us to publish a significant portion of that data under various initiatives. While considerations, factors and circumstances will vary with other types of data, this type of approach could help to address some of the systemic challenges that big data poses.

11. Are there any other issues pertinent to patenting AI inventions that we should examine?

If AI is eventually viewed and accepted as a *de facto* sole or joint inventor, we believe that various formalities under statute and Office rules may have to be examined and adjusted to accommodate. For example, Section 115 of the Patent Act generally requires each inventor to execute an oath or declaration, including a statement that the individual "believes himself or herself" to be an inventor.[16] Under current law, it is difficult to see how an AI system could be deemed competent to execute such an oath or attest to a "belief." While Section 115 provides for exceptions to this requirement where the inventor is dead, incapacitated, hostile or cannot be found, none of these would seem to apply where the inventor is simply not a natural person. Similar complications arise on account of the inability of AI to execute a power of attorney. In practical terms, this means that an AI system cannot designate counsel to represent it before the Office, or accordingly to sign documents on its behalf under 37 CFR 1.34 without changes or exceptions to that rule.

Other problems arise if the term "inventor," as used throughout the Patent Act and Office rules, is construed to only cover natural persons. For example, if an AI is an inventor in fact, but, not being a natural person, cannot be an inventor by law, it cannot be an "applicant" on its own.[17] While, under AIA, applicants can also be assignees such as corporations or other employers, it is not clear under current law how an AI system could execute a legally recognized assignment. While applications can also be filed by "a person with a sufficient proprietary interest,"[18] the term "person" would not seem to include an AI system. Moreover, the MPEP currently accepts this alternative only where the filer is able to demonstrate that a court would award title to the filer in

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[16] 35 U.S.C §115

[17] 37 CFR 1.42

[18] 35 U.S.C §118

that situation,[19] which, in the case of AI inventions, is precedent that simply does not exist at this time. These and a variety of comparable formality-related complications will have to be addressed if at some point the Office or the Courts begin to recognize AI as an inventor.

12. Are there any relevant policies or practices from other major patent agencies that may help inform USPTO's policies and practices regarding patenting of AI inventions?

Other than sensible subject matter eligibility standards, such as those in force under the European Patent Convention[20] (and with respect to which we again direct the Office's attention to our general comments and testimony on this issue), we are not aware of any formal foreign policies or practices concerning AI inventions that would be helpful at this time. That said, as other patent agencies, including the European Patent Office (EPO), are actively considering these issues and soliciting stakeholder input, we encourage the Office to follow their progress, consult and share learnings and best practices as appropriate and consistent with the US system's Constitutional goals.

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We again thank the Office for taking the initiative to explore this important and fast evolving area of patent law, and for the opportunity to provide input into the process. We hope that our comments prove useful, and look forward to continued engagement.

Respectfully submitted,

/s/ Corey Salsberg

Corey Salsberg
Vice President, Global Head IP Affairs

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[19] *See* MPEP 409.03(f).

[20] See European Patent Convention Art. 51.