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RESPONSES TO QUESTIONS FOR THE RECORD

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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"

I. Introduction

My name is Corey Salsberg, and I am Vice President, Global Head of IP Affairs for Novartis. On June 7, 2023, I testified before the Subcommittee on behalf of our company, sharing our experiences and perspectives on the intersection of artificial intelligence (AI), intellectual property, and innovation law and policy.

Following the hearing, on June 14, 2023, I received questions for the record from Ranking Member Tillis. My responses to these questions are set forth below.

II. Responses to Questions for the Record

1. Under current U.S. patent law AI cannot be named as an inventor.

a. What is the motivation and benefit of attempting to change patent law to allow an AI to be named as an inventor?

As I explained in my testimony, at the present time, we do not believe there is a need to change patent law to allow an AI to be named as an inventor, because in our experience, AI is not currently engaging in, or capable of engaging in, the type of activity that can be considered "inventing."[1] Rather, at least in the life sciences field, 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. As a result, we believe that humans who use such tools in the process of innovating should continue to be recognized as the inventors of patentable subject matter that results from those efforts. Likewise, clarifications and any necessary changes to patent law should, in our view, aim to achieve that outcome, rather than naming an AI as an inventor.

Those who advocate for changing patent law to allow AI to be named as an inventor appear to believe that AI is currently capable of inventing patentable subject matter on its own, or that it will soon reach that point. While that does not reflect our experience, it is our understanding that proponents of such changes are motivated by concerns that patents will otherwise become unavailable for inventions made by AI, and that this will 1) discourage the use of AI in innovation, 2) discourage the disclosure of uses of AI in innovation, and/or 3) discourage the publication, development and commercialization of AI-made inventions, ultimately undermining the patent system's constitutional goals of promoting scientific and technological progress.

As I explained in my testimony, we agree that it is extremely important to avoid all three of these harmful outcomes, and that patents must continue to be available for otherwise patentable inventions, regardless of the role that AI plays in innovation. However, we do not believe that naming AI as an inventor is the only way to achieve these goals, or necessarily the most optimal way, given the many legal and practical complications that would likely result. Rather, as I further explained, we believe that these issues should be approached in stages. For now, we believe longstanding principles of existing "conception" law are adequate to attribute inventorship to

[1] For instance, as I explained in my written and oral testimony, even advanced generative AI platforms are essentially applying patterns based on algorithms, and are not capable of recognizing or appreciating what they are doing or why. For a further explanation of why we do not believe AI is inventing, see Testimony of Corey Salsberg, Subcommittee Hearing on "Artificial Intelligence and Intellectual Property – Part I: Patents, Innovation, and Competition" ("Salsberg Testimony") at 5-8.

humans who use today's AI technologies in the innovation process, provided that patent examiners and courts properly and consistently apply them.[2] While we support guidance and clarification of these principles for patent examiners to help ensure that result, we do not believe that any legislative changes are needed in regard to AI-assisted innovation at the present time. Congress should instead monitor USPTO policies, guidance and outcomes in this area, as well as Court decisions, and only consider statutory changes if USPTO and Courts misapply principles of conception law to deny patents to otherwise patentable AI-assisted inventions.

With regard to the future, if and as AI technologies advance to the point where human contributions are no longer sufficient to confer inventorship status on those human contributors under current law, we believe that there are multiple potential ways to address the situation. One approach would be to eliminate the common law "conception" doctrine, and to broaden the definition of "inventor" by statute in such a way that allows humans to continue to be recognized as inventors by virtue of the new activities that humans perform in connection with AI, however those activities evolve with the state of the technology. Another could be to eliminate a formal inventorship requirement as a part of patentability, and to relegate it to the limited context of human-to-human inventorship disputes, which is effectively the approach that Germany, China, and several other countries take. While changing the law to allow AI to be named as an inventor may also be a viable option, each of these approaches has its benefits and risks, including potential legal and constitutional considerations that should be vetted and explored with stakeholder input, before concluding which presents the best way forward. As we do not believe that any statutory changes are currently urgent, we think it is important that Congress take the time to explore each of these options more fully, and perhaps a variety of others, before advancing any particular solution.

b. What impact, if any, would this have on innovation – in other words, do you foresee some detriment to innovation due to AI not being able to be named an inventor?

As explained in my response to the previous question, if otherwise patentable AI-assisted or AI-made inventions were ultimately to become unpatentable as a result of our current laws, we believe the consequences would be highly detrimental to innovators, society, and America's economic and strategic leadership. Specifically, as mentioned, an inability to secure patents on such inventions would likely 1) discourage innovators from using AI in the innovation process, which would, in turn, likely deprive them and society of the efficiencies and other benefits of AI technologies, while also discouraging the development of such technologies; 2) disincentivize the disclosure of the uses of such technologies in innovation; and/or 3) discourage the publication, and/or development and commercialization of inventions made with the assistance of or by AI. As I further explained in my testimony, the third consequence is particularly acute in the innovative biopharmaceutical industry, where the invention of substances like molecules and proteins—tasks which are increasingly involving AI technologies—is only the start of the long, complex, and risky process of creating and developing new medicines. The ability to patent such substances in cases where AI was used to invent or to assist in inventing them is, and will continue to be, a critical incentive to enable innovators to invest in the clinical trials and further innovation needed to develop them into treatments, cures and other useful medical innovations.

[2] See Salsberg Testimony at 8-10 and Response to Question 10, *infra*.

As previously explained, however, we believe these detrimental outcomes can likely be addressed in a variety of ways that do not necessarily involve naming AI as an inventor. Again, we believe Congress should evaluate those options in due course, and compare their pros and cons, before deciding on the most appropriate solution.

c. If an AI alone cannot be named inventor, what are your thoughts regarding allowing an AI to be named as a co-inventor if named alongside that which we currently consider an inventor (i.e., a "natural person")?

We do not currently see a legal, practical or policy basis for changing the law to allow an AI to be named as a co-inventor on a patent. At the present time, we do not believe such changes are necessary, because we do not believe that AI is currently capable of engaging in the types of activities that qualify as "inventing," whether alone or as a co-inventor. In the future, if AI advances to the point where it becomes capable of activity that would qualify as inventing if a human performed the activity, we still see no reason to recognize the AI as a co-inventor on a resulting patent, so long as a natural person can be properly named as an inventor. In such a situation, under current law, the natural person would be recognized as both an inventor and owner of the patent based on his or her own inventive contributions. Moreover, because a non-natural person cannot be an inventor under current law,[3] omitting the AI from such a patent should not impact the validity of the patent. Specifically, such a patent would satisfy 35 U.S.C. §101's requirement that a patent be obtained by "whoever invents" the invention, and 35 U.S.C. §115's requirements that a patent application include "the name of the inventor for any invention claimed in the application" and that "each individual who is the inventor or a joint inventor . . . execute an oath or declaration in connection with the application," because only natural persons are subject to those requirements.

While there may be situations in the future where joint contributions to an invention by separate entities—some through natural persons acting alone, and some through contributions made or assisted by AI—raise inventorship or ownership questions, we believe those situations would be best addressed by the same approaches to AI inventorship discussed in my responses to the previous questions. In other words, joint inventorship could likely be addressed by broadening the ways that a "human in the mix" can be recognized as an inventor for those entities employing AI, or perhaps by eliminating inventorship as a formal patentability requirement, at least in some circumstances. While naming an AI as an inventor is also an approach that could eventually be considered, we see no reason why that approach would apply any differently to joint inventorship situations than it would to sole AI inventorship situations. That is, if AI were to eventually be recognized as a valid sole inventor, it should also be recognized as one of multiple inventors on a patent, where some are natural persons and some are not.

2. The Intellectual Property Office of Singapore has promoted the patenting of AI-related inventions by offering accelerated examination. Do you think that the USPTO should be doing more to encourage and support AI-related patent applications in the U.S.?

As I explained in my testimony, today's AI tools are already providing significant value across our R&D process and beyond, and future generations of these technologies have the potential to help

[3] *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022).

us develop and deliver better, safer, more personalized and efficient medicines, which will ultimately benefit patients and society. As a matter of policy, we believe the United States government should therefore encourage robust investment in the development of such tools.

The patent system plays a central role in encouraging such investment and development, as it does with all fields of technology,[4] providing a direct incentive to developers of such tools. But, due to the novel inventorship questions raised by the use of AI tools in innovation, the patent system also plays an indirect role in encouraging (or discouraging) the development of AI tools, through its potential to impact demand. Specifically, if United States patent law were to penalize innovators who adopt and use AI tools in innovation by depriving them of patents in the resulting downstream inventions, demand for such tools would substantially decline, reducing or eliminating incentives for AI developers to continue to develop them.

With this in mind, one way that USPTO can help to further encourage and support the development of AI-related technologies is to ensure that its policies and examiner guidance on AI-assisted inventorship are clear, complete, and up to date, so that innovators have the confidence they need to continue using AI tools in innovation. As I explained in my testimony, we believe that it would be particularly helpful for USPTO to clarify its current guidance on "conception" law in the Manual of Patenting Examination Procedure (MPEP), by reinstating and strengthening certain important existing legal principles that are presently missing or unclear. I elaborate on these principles in my response to Question 10 below. For purposes of this question, the key point is that further clarity from USPTO in this area would, in our view, help to reassure innovators who use AI tools to assist with innovation that doing so will not impair their ability to properly patent resulting inventions. Those assurances will allow innovators to continue to confidently embrace and employ AI tools in their work, increasing demand, and strengthening incentives for developers of AI technologies to invest in developing those tools.

3. In February 2023 the USPTO issued a request for public comments (RFC) seeking stakeholder input on the current state of AI technologies and inventorship issues that may arise in view of the advancement of such technologies.

a. What were your key takeaways from this RFC?

Novartis was pleased with the USPTO's approach to these important issues, and very much appreciated the opportunity to share our experiences and perspectives through our written submission[5] and at the public listening session. As we explained in those fora, we especially appreciated the USPTO's effort to hear from stakeholders in different industries who are actually using AI in their innovation processes and businesses, and to ground its questions concerning AI inventorship and AI-assisted inventorship in those real-world contexts and examples. Based on the RFC itself, the questions raised by USPTO staff during the Listening Session, and follow-up discussions, the USPTO AI/ET Partnership appears to be asking the right questions and taking an informed and level-headed approach, guided by stakeholder input. We are hopeful that the USPTO will make the clarifications concerning "conception" law that we proposed in our written and oral

[4] *See, e.g.*, USPTO, Director's Blog: the latest from USPTO leadership. April 18, 2023 (Noting that "AI now appears in 18% of all utility patent applications we receive, and in more than 50% of all the technologies that we examine at the USPTO.").

[5] *See* Novartis Comments on Artificial Intelligence and Inventorship, filed May 15, 2023.

remarks, and look forward to continued dialogue and engagement with the Office on these and other AI-related patent issues.

b. Was there anything that wasn't addressed that should have been?

Given its specific focus on AI and inventorship issues, we believe the RFC was generally complete and amply addressed the topic. While there are other AI-related patent issues that would benefit from future dialogue, it is clear from the RFC that the USPTO intends to address those in future RFCs.

4. With regard to patent eligibility law, do you agree that the lack of certainty hampers innovation when it comes to the field of AI-related patent applications and patents?

As I explained in my testimony, 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 the right conditions are present and that the right incentives are in place to continue to encourage the development of these tools. We agree that strong, clear and predictable patent-eligibility laws are a core part of those conditions and incentives, and, conversely, that the lack of certainty in current United States eligibility law discourages investment and hampers innovation in areas impacted by that uncertainty, which includes AI-related technologies. Given the role that AI and other software-based tools are poised to play not only in biopharmaceutical innovation, but also in helping to diagnose disease, monitor disease progression, and manage patient care, current patent-eligibility restrictions on software, diagnostics and other methods in the United States raise particular concerns for the future of medicine. For these reasons, Novartis has long supported patent-eligibility reforms, and looks forward to continuing to do so as those efforts advance.

5. Patent Examiners at the USPTO currently use an agency search tool called Patents End to End (PE2E) to perform prior art searches. This tool leverages AI and is being developed to further support AI search capabilities.

a. What are your thoughts on this?

At the present time, we do not have sufficient familiarity with PE2E to comment specifically on this tool.

b. How else should the USPTO leverage AI to help with prior art searches?

Generally speaking, we support the USPTO's use of AI-enabled tools and other technologies that help to make prior art searching and patent examination more efficient, provided that such tools and technologies demonstrably return accurate and reliable results that lead to legally correct and unbiased patentability determinations, without creating new inefficiencies or burdens on applicants. In that regard, at least until there is extensive and robust data demonstrating these qualities, we believe it is imperative that such tools continue to serve as supplements to searching by human examiners, rather than as replacements. Even if and as AI reaches a point where it can fully replicate human searching, we believe it is crucial that human examiners continue to closely guide and review AI-based search results, and that they continue to exercise human judgment in evaluating, characterizing, and prioritizing prior art references.

6. **Do you agree that recognizing an AI as an inventor would require statutory changes to Section 103 to adapt the obviousness test to AI? If so, what would be the most appropriate and feasible way to assess whether a claimed invention would be obvious to an AI?**

We agree that if United States patent law were changed to allow an AI to be named as an inventor, this could impact the obviousness assessment under Section 103, which is based on the perspective of a "person of ordinary skill in the art" ("POSA"). The nature and extent of such impact, and of what changes were required to Section 103, would largely depend on how Congress chose to implement AI inventorship, and what policy approach it desired for assessing obviousness of AI-made inventions. For example, if Congress wished to expand the current POSA standard to include the perspective of an AI, and to apply that perspective equally to human and non-human inventors, it could define a "person" in Section 100 to include an AI, which would obviate the need to make any statutory changes to Section 103. If, on the other hand, Congress wished to maintain the current POSA standard for human inventors, and to create a new standard of obviousness that applies only to AI inventors, it could do so either by creating a new standard of AI obviousness outside of Section 103, or by amending Section 103 to include two different standards (one for humans and one for AI). In the latter cases, it could enable AI inventorship through changes only to Sections 101, 115, or through other definitions in Section 100, leaving the POSA standard intact.

Importantly, any approach to implementing AI inventorship would impact not just obviousness, but also many other areas of patent law that involve the POSA standard, such as claim construction, enablement, and written description, raising additional complex legal, policy, and practical questions that we believe would require significant thought, discussion, and potential statutory changes to resolve. For these reasons, as I explained in my testimony and in my responses to Question 1, given that AI is not currently engaged in the type of activity that can be considered "inventing," and is likely far away from reaching that point, we believe it is premature to consider changing patent law to allow AI to be named as an inventor at this time, and accordingly premature to be proposing new standards for assessing obviousness, or for addressing the other complications that would arise from such a change.

Assuming this question is forward-looking, and aimed at beginning to consider how to address AI's role in innovation in the future if and as it reaches a point where it can factually be considered an inventor, we again believe there are a variety of potential solutions that Congress should consider before changing the law to allow an AI to be an inventor. As explained in Question 1 and in my testimony, these include eliminating or changing the common law approach to "conception," adapting and broadening the ways that a human can qualify as an inventor, or eliminating inventorship as a formal patentability requirement altogether and instead taking an "inventor-agnostic" approach. As I have noted, there are pros and cons to each of these options, which should be thoroughly explored and vetted through stakeholder input before deciding which is the best approach. But given the current state of AI technology, we again believe there is ample time to reflect on these options as the technology develops.

7. There has been talk regarding whether advances in AI warrant a sui generis ("of its/their own kind") IP protection – a new form of IP protection separate from patent, copyright, trademark, and trade secret – for data rights. What are your thoughts on this?

Whether to establish a new *sui generis* IP right for data is a complex issue. We are still developing our views as to whether this is the best approach for addressing the increasing importance and evolving role of data in AI-related applications. If a new IP right in data were established, however, we believe the goal should be to strike an appropriate balance between incentivizing the generation of data and the use of data to develop valuable new AI tools on the one hand, with enabling sufficient access to data on the other, in order to allow appropriate levels of competition in the AI tool space, as well as appropriate risk-based levels of government oversight. This is a complex balance to strike, in part because, as I explained in my testimony, not all data is the same. Some data is publicly accessible by nature or design, such as that derived from nature, public sources, or public records and databases, while other data exists 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 private investment and effort, such as the safety, efficacy and quality data generated through clinical trials. Any new IP rights in data should account for these differences, while also ensuring that existing IP rights in certain data, such as trade secrets, regulatory data protection, and copyrights, continue to be respected.

8. Given where AI now stands in practice – it's a powerful tool that speeds the innovation process, but it does not itself innovate – what specific regulatory and/or legislative action should be and should not be taken this Congress?

At this point in time, we believe the only specific legislative action that Congress should take related to AI and patents is to strengthen America's patent-eligibility laws through Section 101 reform. As I discussed in response to Question 4, we believe these reforms are needed to restore the incentives and conditions necessary to enable and support the development of the next generation of AI tools, including AI-enabled tools for biopharmaceutical R&D, and AI-enabled diagnostics.

With the increasing development and use of "generative" AI tools to assist with innovation in fields like biopharmaceuticals, we also believe it is imperative that America's patent laws continue to properly recognize the humans who use these tools as the inventors of resulting patentable inventions. As I explained in my testimony, we believe existing inventorship laws, if properly applied and viewed in their full and proper context, are sufficient to ensure this result, but clarifying "conception" law in certain ways (discussed in my response to Question 10 below) would help increase certainty in this area, and help to ensure the robust development, adoption and use of AI in innovation in the United States. At the present time, as previously noted, we believe these clarifications can be made by the USPTO in the MPEP based on existing case law—an action we have specifically asked the USPTO to take in the comments we submitted through the RFC on AI and Inventorship—and by the courts, as they are presented with cases of AI-assisted inventorship.[6]

[6]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."

In the meantime, while Congress should monitor the issue to ensure that it proceeds in the right direction, and while guidance and oversight from this Subcommittee would be helpful, we do not believe legislation is currently required. If the USPTO or courts were to begin to deny or invalidate patents on otherwise patentable inventions made with the assistance of AI, Congress should at that time legislate to address the issue.

9. With jurisdictions appearing to require disclosure of AI operation, including source code, for software-based innovations is trade secret a viable option for the protection of AI code? And if not, are there steps that regulators and governments can take to help make AI code subject to trade secret protection?

We believe that trade secrets can be a viable option for protecting AI code and other information submitted to governments and regulators, but only if those governments and regulators are required by statute or rule to prevent the further disclosure of that information to the public, and to commit to maintaining its confidentiality. The FDA employs this type of model for trade secret and confidential commercial or financial information that biopharmaceutical innovators submit to the agency as a part of their regulatory submissions. Specifically, under FDA rules, "data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure," and, subject to certain exceptions, may be further designated as exempt from disclosure under the Freedom of Information Act. 21 C.F.R. § 20.61(c), (d); 5 U.S.C. § 552(b)(4). We believe a similar approach could work for AI code, algorithms, and data sets submitted to governments in confidence for regulatory purposes, but similar safeguards would have to be enacted. To the extent this question also refers to governments and regulators outside of the United Sates, the viability of such an approach would also strongly depend on the existence and strength of trade secret protection in those foreign jurisdictions, the existence and strength of enforcement mechanisms, and the general ability of those jurisdictions to robustly comply with these laws and regulations.

10. In your testimony you mention that clarifying the law surrounding "conception" would restore certainty. Specifically, you state that if too narrowly construed the law could potentially be misapplied to deprive human inventors legitimate patent rights to their inventions. Please elaborate on this statement and also explain how U.S. law surrounding "conception" compares to other countries?

We believe that the common law "conception" standard—which is one of two judicially-created components that must be present to demonstrate inventorship under United States law (the other being "reduction to practice")—is at some risk of being too narrowly construed and misapplied to situations involving AI-assisted innovation, due to its historic and common formulation as "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. . . ."[7] As I explained in my testimony, while we do not believe that this "mind of the inventor" standard is problematic *per se* for inventions created with AI tools, if the USPTO or courts were to focus too narrowly or rigidly on whether the full conceptive act literally occurred inside the "mind of the inventor," we believe this could result in the improper denial of legitimate patents to human inventors who use AI as a tool

[7] *Townsend v. Smith*, 36 F.2d 292, 295 (CCPA 1929) (emphasis added).

to generate novel inventions or elements of inventions *in silico* (i.e. on a computer), rather than literally in the human mind.

As I further explained, we do not believe that the law is, or was ever intended to be, so rigid, but current USPTO guidance in the MPEP appears to focus too narrowly on the "mind of the inventor" standard, without reference to historical context or other important principles of conception law that in reality make the standard much more flexible than would appear from that standard alone. Briefly, those other principles include the doctrines that 1) a person who "maintains intellectual domination" over the inventive process qualifies as an inventor, even if he or she considers and adopts ideas, materials, information or suggestions from others;[8] 2) a person can be an inventor by virtue of the fact that their contribution is needed to make the invention operable, e.g., where a first inventor cannot do so;[9] and 3) conception only occurs at the point that there is "recognition and appreciation" of the invention, which means that a person can be an inventor of novel subject matter even where someone else "obtained [it] earlier" but did not recognize it.[10] Other cases have further held that, at least in certain unpredictable areas of chemistry and biology, "there is no conception until a reduction to practice is attained."[11] Taken together, as I have explained, we believe these principles provide ample precedent and support for attributing inventorship to humans who use AI tools to generate leads and ideas, or to otherwise assist in innovation, but we believe it is important for the USPTO to update the MPEP with these doctrines and cases, train examiners accordingly, and to consider formal guidance that applies them to AI-assisted innovation, which would help increase certainty for innovators.[12]

In comparison with other countries, to our knowledge, the United States is the only country in the world that has a conception requirement, or any standard of invention that is tied specifically to the "mind of the inventor." In most other countries, including Europe and China, the question of inventorship only arises on rare occasion, in disputes between inventors over proper recognition or remuneration. In such cases, courts and tribunals consider the entirety of the facts, without any framework comparable to United States conception law. For this reason, as stated in my testimony, we believe this is a critical issue for the United States to get right. Simply put, denying patents in

[8] *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…."); *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.").

[9] *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.").

[10] *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)

[11] *Alpert v. Slatin,* 305 F.2d 891, 894, 896 (CCPA 1962).

[12] For further discussion of this issue, and of the steps we have asked USPTO to take to clarify the issue, see Salsberg Testimony at 8-10, and Novartis Comments on Artificial Intelligence and Inventorship, filed May 15, 2023.

America to those who use AI to assist their innovative efforts would put our nation's innovators at a distinct disadvantage, and threaten America's innovation, economic and strategic leadership.

11. Please describe the amount of human input/guidance required to use AI in the inventive process?

The amount of human input and guidance required to use AI in the inventive process varies depending on the nature and complexity of the AI and the use. In our experience at this stage, generally speaking, the more advanced the task, the more human input and guidance is required. As I explained in my testimony, some of our most advanced uses of AI in innovation today are in the field of "generative chemistry" and related applications, where we are using AI tools to help us design virtual molecules, virtual proteins, and other potential drug candidates. These advanced uses of AI require a high degree of human involvement on both the front and back ends. For example, in the case of our proprietary AI platform, JAEGER, used to help design virtual molecules as potential leads for new antimalarials, our human scientists among other things identified the problem (malaria); selected the data to train JAEGER (around 21,000 proprietary molecules from our compound library); selected and seeded JAEGER with three examples of effective anti-malarial medicines with desirable properties; evaluated the 282 virtual molecules that JAEGER proposed; narrowed and determined which of those were most likely to have the desired properties; successfully synthesized two of the virtual molecules, a complex process that is not routine and often fails; and designed the functional assays to validate those molecules in a wet lab. As this example demonstrates, at least in our field, a high degree of human input, guidance, supervision and involvement are currently required to employ AI tools in innovation, and likely will be for the foreseeable future.

12. If AI eventually reaches a point where it can invent new molecules on its own, why should the American public care whether patents are issued to biopharmaceutical companies?

As my response to the previous question demonstrates, the day when AI can actually invent new molecules on its own—particularly molecules that can be successfully synthesized and validated as having the desired properties for a medicine—is still far away. Even if and when that day arrives, however, an AI's autonomous invention of a new molecule will not yield a new treatment or therapy. Discovering new molecules is, in fact, only the first step in the long, complex and risky process of biopharmaceutical innovation, where it takes 10-15 years on average to invent 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.[13] While AI tools are helping to make many aspects of this process more efficient, and may eventually reach a point where they can execute the early stages on their own, human scientists will still be needed to conduct the many years of complex research, innovation and problem solving that must be done after drug discovery to develop a molecule into a new medicine, including the long process of clinical trials where many

[13] 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.").

additional innovations are made. Patents will continue to be needed to enable the deep investments and other conditions required for that work.