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.