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Artificial Intelligence and Intellectual Property: Part III – IP Protection for AI-Assisted Inventions and Creative Works

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Chairman Issa, Ranking Member Johnson, members of the Subcommittee, I am honored by your invitation to speak today.

My name is Claire Laporte. I am testifying today as a Fellow at Ginkgo Bioworks, having recently stepped down from my role as Head of Intellectual Property. I served in that role for over five years. In my current capacity, I work on strategic and policy issues relating to intellectual property. Before that, I was a partner in a law firm for almost thirty years, engaging in patent and trade secret litigation, much of it in biotechnology.

Ginkgo Bioworks is a fifteen-year-old biotechnology company. We're publicly traded, and we have over 1,200 employees. Ginkgo is headquartered in Boston. We also operate sites in California and Europe.

This Subcommittee is wise to consider applications in biotechnology as it evaluates Intellectual Property (IP) law and policy in the context of advancements in Artificial Intelligence (AI). AI has the potential to revolutionize biotechnology. Taking a smart approach to IP is essential to ensuring the health of the U.S. biotechnology ecosystem, maintaining the many diverse jobs created by that system, and strengthening the global competitiveness of the United States.

In this testimony, I will briefly introduce the emergence of biotechnology as a technology of geopolitical importance. I will discuss the ways in which AI is accelerating R&D and unlocking new applications of biotechnology. Lastly, I will recommend that we not burden our patent law with unnecessary new rules and processes like inventorship determinations between human beings and AI. Our patent law should support, not hinder, the responsible use of AI to achieve transformative results for the economy and human health.

Biotechnology is among the key technologies shaping national security and economic competition.

The U.S. government expects biotechnology to have "outsized importance over the coming decade" in the context of geopolitical competition. Across the Atlantic, the European Commission has declared that "advances in life sciences, supported by digitalization and artificial intelligence (AI), and the potential of solutions based on biology to solve societal issues, make biotechnology and biomanufacturing one of the most promising technological areas of this century."

Biotech is featured prominently in China's 14th Five-Year Plan, and China aims to be at the forefront globally in the comprehensive strength of its bioeconomy. Japan, Germany, the United Kingdom, Singapore, and Saudi Arabia, for example, are similarly looking to biotechnology to meet major environmental, economic, and security challenges.

This intense prioritization of biotech is motivated by advancements in the ability to "read, write, and edit genetic code, which has rendered biology programmable." At a basic level, DNA runs on code – DNA – just as computers run on binary code. Depending on the sequence of its DNA, a cell can be programmed to produce, for example, an antibody, a food protein, a gene therapy, a natural fertilizer, or a specialty chemical. Analysts at McKinsey Global Institute have estimated that programmed cells can be used to make up to 60 percent of the physical inputs to the global economy.

In other words, a large number of things that are traditionally manufactured using industrial processes - such as plastics, fuels, foods, materials, and medicines - could be (and sometimes already are) produced using biotechnology. And given this potential, governments looking to maintain resilient supply chains, ensure food security, and meet emissions reduction targets are devoting resources to develop and support biotechnology. Experts anticipate that by the end of the decade, biotechnology could be used extensively in manufacturing industries that account for more than a third of global output—a shade under $30 trillion in value.

In large part, these expanding applications of biotechnology are made possible by dramatic improvements in the tools of biotechnology, combined with changes in the way biotechnology R&D is conducted. Traditionally, biological research was done "by hand": scientists would laboriously manipulate biological materials in what was an expensive and cumbersome process. Consequently, the history of biotech has been marked by a relatively languid pace of discovery and a high barrier to entry.

Today, however, the approach to biological research is changing rapidly. The field is transitioning from a fragmented landscape of expensive, commercially risky experimentation that has served primarily the pharmaceutical sector to a more integrated and standardized platform-based approach that can meet the needs of all of the many industries that can benefit from biological research. Ginkgo is among the companies leading this charge; in our highly automated laboratories, biological materials can be manipulated at high throughput, yielding a step-change in the power of experimental techniques.

The transition from by-hand to automated engineering in biology holds the promise of bending the R&D cost curve down and improving the speed and probability of success. This is important

not only for biopharma, but across the broader economy. Biotech applications in chemicals, materials, foods, and agriculture offer great promise and are more practicable when each small developer does not have to invest in costly lab infrastructure. The shift resembles the emergence of cloud computing. We all probably recall the acceleration in the digital economy that occurred in shifting away from expensive, fixed-cost on-site servers to flexible, powerful cloud computing. Arguably, we are on the threshold of a similar moment for biotech innovators, if we resist the urge to respond to it by adding unnecessary complications to the patent system.

The expansion of biotechnology applications across the economy, along with their growing geopolitical and societal implications, is widely referred to as the "bio revolution." Today, the bio revolution is being accelerated by another revolutionary technology: AI.

AI can accelerate biotechnology R&D. The U.S. should prioritize leading the development of AI for biology. Patent law and policy must support the development and use of AI in biological innovation.

AI has the potential to further accelerate biotechnology's transition from low-capacity, by-hand laboratory work to large automated platforms that can generate biological data more quickly and accurately. We believe that AI models can be trained to greatly reduce the scale and time currently required to solve biological engineering challenges.

Before we began to develop and use LLMs (large language models) and other deep-learning methods, the process of optimizing a biological construct to perform a new task might take many iterative rounds of engineering, each requiring the investment of significant time and resources. And this was the case even in Ginkgo's large, automation-enabled laboratories (which we refer to as the Foundry) and even supported with the best pre-LLM computational tools available. The latest AI technologies hold out the promise of being able to achieve the same or better results with fewer, smaller iterations, because they can analyze and make sense of orders of magnitude more data than our previous tools could.

Indeed, the United States will need to make significant investments in generating new data to train AI models. Ginkgo's Foundry, a 300,000+ square-foot automated laboratory space is, as far as we know, unique in its ability to generate these data assets, although we understand that China is investing to compete. While the creation and acquisition of data assets is beyond the scope of today's topic, it is an important issue to consider in the future; it would be unwise for the United States or its partners to outsource data acquisition to other countries or rely on them to provide fundamental R&D services and capabilities. We believe that it would be wise for the United States to direct the development of AI from a position of leadership.

Today, most clinical trials fail, and there are many other difficult biological problems we urgently need to solve. The biological challenges ahead are hard, but we believe that the AI we and others are developing will be essential to making biology easier to engineer, with implications for economic growth, human health, and national security. Patent law and policy must encourage, not hinder, the development and use of AI in biotechnology R&D. The United States cannot afford to

lag behind in our development of AI for biological research while other economies benefit. As discussed further below, the current concern that AI tools might actually be patent inventors is an example of how our patent law is developing in a direction that is needlessly complicated and may disincentivize AI research, putting the United States at a competitive disadvantage.

AI is an increasingly important tool, but it is just an extension of prior computational tools.

Ginkgo's new biology-based LLMs have evolved from earlier tools for conducting complex statistical analysis. In our AI research, we use a variety of deep learning tools, including neural network-based models trained using methods like large-scale self-supervision, supervised training, and fine-tuning. These tools can be used for a variety of engineering tasks, including classifying biological components, predicting assay values, and designing new biological constructs. For the foreseeable future, we cannot design a useful biological system simply by prompting one of these models. They assist in individual steps of this scientific process.

Biologists have been using computation to conduct science for a long time. For decades now, an entire field, called computational biology, has been devoted to developing and deploying algorithmic biology tools. Ginkgo uses these existing tools extensively. For example, we search databases using BLAST, an algorithmic tool dating back to the early 90's. We use Clustal algorithms to align and make judgments about non-identical sequences. We use MEME to discover motifs across disparate sequences that may indicate functional similarity. We use hidden Markov models (HMMs) for a variety of prediction tasks. The list goes on and on.

In other words, developments in the machine learning world have been central to computational biology for decades, and the newest generation of deep-learning-based tools is simply the newest incarnation of a tight interplay between computer science and biology. Many of these tools can and have been powered either by special-purpose algorithms or by the neural network-powered deep learning that underlies AI. The deep learning systems we are using to construct our LLMs are an extension of these previous tools.

AI must be guided and prompted by humans to create useful results. Humans are the sole inventors of AI-assisted biological inventions and will be for the foreseeable future.

Under current U.S. inventorship law, "formation [of an invention] in the mind of the inventor" is necessary to form a "definite and permanent idea of the complete and operative invention, as it is [t]hereafter to be applied in practice," and such a process can only take place in the human mind. The use of AI tools may facilitate a human's conception of an invention, but the AI cannot itself "conceive" anything and thus cannot participate in the activity that is the "touchstone of inventorship." As the Federal Circuit has explained, conception of an invention is a "mental act."

An AI system like ChatGPT can sometimes seem like a magical black box that autonomously produces creative ideas upon request. While I would disagree that these systems exhibit creativity in any sphere, biological research is constrained by physics. ChatGPT can write a serviceable kids' bedtime story with elves and flying purple cows, or create deepfakes. But

biology operates in the real physical world, so the results from using AI will either work for their intended purpose, or they won't. In the realm of text creation, or image creation, the output of the system is the end of the process, but in biology, the output will be used to make a physical thing. The biological equivalent of the flying purple cow – something fanciful and unreal – is not going to work when it is tested in a living organism.

In biology, AI is a tool to help solve engineering problems. Like any sophisticated tool, it will produce useful results only when wielded with skill, purpose, and experience. It is not, alone, a creative force; it is merely an enabler of human creativity. Humans must drive the exploration. If a Ginkgo scientist uses AI to assist in devising a DNA sequence for a particular task, the sequences that the AI suggests in response to our scientist's prompts will only matter if converted into actual biological materials that successfully perform the assigned task. The sequences still need to be tested in the lab. The use of AI to develop designs is an iterative process where the scientist must coordinate between the computational world of AI and the realities of laboratory science. Thus, while AI has the potential to be transformative for biotechnology R&D by making it faster, cheaper, and more predictable, AI is not autonomous. Using AI to solve biological problems requires extensive human engagement and physical testing.

In fact, the skills required to interact usefully with AI are so sophisticated that companies and universities are starting to offer educational materials about "prompt engineering" – the science of crafting a prompt (or series of prompts) to steer AI toward a useful result. While "prompt engineering" is a limited discipline – currently only offered to help with non-biological fields of endeavor such as software development and limited to manipulation of words to achieve a desired result – our experience at Ginkgo suggests that the guidance of AI models through the iterative refinement of prompts in the biology space will require considerable creativity, as will testing the results to determine whether they in fact achieve the solutions we are seeking. Among other issues with the notion that AI could act autonomously or creatively to make biotechnology inventions is the fact that our AI tools do not know what problems we need to solve. This Subcommittee and the PTO should not credit the idea that AI is now, or will foreseeably be, autonomously generating such inventions.

The Patent Act expressly provides that "patentability shall not be negated by the manner in which the invention was made." Yet the Guidance recently issued by the PTO may put us on a path where the exact same invention may be patentable or not patentable depending on the tools that were used to make the invention. Imagine, for example, a new, useful, and unobvious industrial enzyme that was derived through traditional, iterative by-hand biological engineering. There is no particular reason why such an enzyme shouldn't be patentable just because it was made in a wet laboratory using conventional, non-computational techniques. Why should the result be different if that same enzyme was instead derived through the use of machine learning and generative AI tools? The incentives provided by the patent system should still be there to sustain the patent owner through the investment required to further develop and commercialize the enzyme.

Novel antibodies can be generated by immunizing a mouse or other animal with a target antigen and then screening the antibodies that the mouse produces to find those that match desired criteria. Nobody would argue that the mouse should be named as an inventor on the subsequent patent, or that the mouse and the human scientist each made separate contributions to the invention that should be apportioned between the two. Nor would it be argued that a human scientist cannot be named on the patent unless their contribution is sufficient to qualify as a co-inventor with the mouse (which is the approach taken by the newly-issued PTO inventorship Guidance for AI). There is really no difference between deployment of a biological tool, such as a mouse, to solve a complex immunology problem, and deployment of a computational tool like AI. The results, in either case, were prompted by a human's selection of a target and a tool, and the results must be appreciated, screened and characterized before any of them can meet statutory criteria for patentability.

To name just a few of these statutory criteria, an invention must be novel, useful, enabled, and adequately described. These criteria will suffice to weed out AI-assisted ideas that should not be patented. In biology and many other fields, describing how an invention is made and used, as is required by the Patent Act, typically requires screening and characterizing of the invention. Without confirmatory data, a biological invention cannot realistically be patented. Valid inventions will be supported by data and, if they meet all other statutory requisites, should be patentable. This should suffice to address concerns that the use of AI could make it "too easy" to make inventions, thereby flooding patent offices with computer-generated meritless patent applications.

Adding yet another hurdle to the patent process by subjecting patent applications to new analytical and disclosure requirements depending on which tools were used in making the invention can only hurt our global competitiveness in the long run. If AI fulfills its promise to unleash human creativity in science – and provides tools that allow humans to be creative in quicker and more efficient ways – we should be celebrating that possibility, not setting policy to curtail those benefits.

Thus, we think that it is a serious mistake to burden the patent system with the unnecessary additional complexity of a determination of inventorship between humans and their AI tools. Doing so – as the PTO has already begun to do – means that every time a patent application is filed, there must be not only an inquiry into who the human inventors were, but also what computational tools they used. And critically, as I discussed earlier, computational tools have been central to biological research for decades, including AI tools. Large-scale generative AI is merely the newest and most powerful incarnation of these tools. Burdening the system with inventorship-related inquiries will add cost, delay, and complexity without improving the quality of the patent system.

Added complexity and difficulties will be magnified during the patent litigation process, making an already cumbersome and expensive process yet more unwieldy.

The negative consequences of establishing a new inventorship determination that must occur when an inventor uses AI tools will be magnified in the patent litigation process. Because the PTO's recently issued Guidance leaves open the possibility that an otherwise perfectly valid patent could be struck down because the claimed invention was made without a human conceiving of it, it dangles irresistible bait before anyone challenging a patent in litigation. Now patent litigators will seek discovery about the role of AI in making inventions. Allegations of inequitable conduct will be brought based on alleged failures to acknowledge the role of AI during patent examination. A sideshow into the role of AI in the inventive process will become yet another expensive step in litigation, burdening every case with additional document requests, interrogatories, depositions, and motion practice concerning whether there was sufficient human involvement for the invention to be patentable. As a long-time patent litigator, I can attest that this will surely add another layer of cost and complexity to a system that is already so costly and unpredictable that it is justly referred to among IP lawyers as the "sport of kings."

These problems will not be confined to inventions made using the most recently developed AI tools. The PTO's new Guidance on this subject does not define AI. Presumably its drafters made this strategic choice because they recognize that there is no way to draw a bright line between AI and preexisting computational biology tools. Because there is no certainty about what "AI" means in the Guidance, the scenario I discussed just above is already certain to occur in biotechnology patent litigation unless the PTO revises the Guidance or, at a minimum, makes clear what it means by the term "AI."

Conclusion

Our patent system is already groaning under the weight of complexity, and adding yet more will not improve our international competitiveness or encourage the progress of science and the useful arts. A patent system that requires extra steps and imposes extra burdens when applicants use AI will discourage the use of AI, especially if innovators are afraid that their use of it will jeopardize the patentability of their inventions. The last thing we should do is discourage scientists from using the best tools available to them. We cannot cede our competitive edge in biotechnology to countries that appreciate the value of AI to create novel biological products.