

Question for the Record from Rep. Issa for Ms. Claire Laporte
“Artificial Intelligence and Intellectual Property: Part III – IP Protection for AI-Assisted
Inventions and Creative Works”
April 10, 2024

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1. In some industries more than others, significant investment is needed to develop a product following an initial discovery or innovation, even when AI is used to assist in those initial stages. Do you agree that restricting patent protection, such as for AI use, harms those industries because they rely on patents to recoup their investments?

I agree that restricting patent protection for AI use can harm industries that rely heavily on patents to recoup their investments.

Most biotechnology products require significant investment following an initial innovation. In the development of biologic therapeutics, the bulk of the expense – which can be enormous – is consumed in the clinical trial and FDA regulatory processes. These expenditures of money and time follow the initial innovation. Similarly, in the agricultural area, lengthy regulatory processes are required before a biological product can be marketed.

The biotechnology industry relies on patents to protect its investments as products go through the gauntlet of clinical trials or regulatory approvals. Patent protection is particularly important for smaller companies that are not yet profitable, because the capital markets use those companies’ patents as a proxy for the value they expect the company to achieve when its products finally come to market. But even for larger, more established companies, patent protection is important in recouping the large initial investments that must be made, particularly because only a subset of products will succeed in making it all the way to market.

Requiring AI Disclosures Could Harm Innovation

Requiring new disclosures in response to the use of AI could harm industries that would benefit from the use of AI. At the hearing, I discussed the extent to which a patent’s specification should be required to disclose details of an AI system along with the prompts given to that AI system. I emphasize that, *unless a patent is directed to an AI system itself*, when AI is used to develop a new innovation, *neither* the specific design of the AI system used in making the invention *nor* the prompts given to the system need to be disclosed under our current law. Such disclosures would not be helpful to subsequent researchers and would burden the patent applicant to the point where it might decide not to use AI at all – thus inhibiting the progress of science and the useful arts.

I will use as an example the design of a new enzyme that can be used in a pharmaceutical manufacturing process. If a scientist designs and patents a new enzyme, the patent specification must explain how to make and use that enzyme. In particular, *the specification must disclose the enzyme’s amino acid sequence, which is the information both necessary and sufficient to enable*

a skilled person to re-make the enzyme after patent expiration. The patent must also explain the best mode of implementing the invention.

In contrast, the inventor's tools and thought processes that *led* to the new enzyme are rarely going to be relevant. Other scientists don't need to (nor do they typically want to) retrace the thought process (as embodied in an AI system) that led the inventor to the new enzyme design in the first place. As long as the enzyme can be made and used in accordance with the patent's specification, it doesn't matter whether it was originally discovered with the help of AI, or through tedious trial-and-error, or sheer serendipity, or in any other way. Disclosing the details of an AI model that was used to design the patented enzyme would not be helpful to subsequent researchers who just want to make and use, not reinvent, the enzyme.

Further, disclosure of the details of AI tools would not be practicable, because AI systems are, to a fundamental extent, shaped by the data used to train them. The data used to train current AI systems will be radically sparse and deficient compared to the data available to train AI systems twenty years from now. Describing or disclosing the dataset used to train an AI system would be burdensome and impracticable, because even the small datasets we currently have in the field of biology would be vast if enumerated or specifically listed in a patent specification. Moreover, it would not be helpful to subsequent researchers to disclose the specific prompts used with the AI system, because those same prompts would be likely to yield different results with a system trained using a different (and presumably more updated) dataset twenty years hence, at the time of patent expiration – rendering such disclosures unhelpful for those seeking to reproduce the invention.

AI is Very Unlikely to “Flood” the Patent Office

During the hearing, I discussed the concern expressed by some that researchers using AI might flood the Patent Office with inventions that are obvious to anyone using AI. As set forth in my earlier written and oral testimony, I believe that this concern is not well-founded.

The obviousness of an invention is assessed against the prior art. AI tools may enable researchers to combine and recombine information in novel ways to create new and useful genetic constructs that do not currently exist. But if the product of an AI-assisted process is not inventive relative to the closest prior art, it will be rejected as obvious, just as with any other invention.

There is nothing inherent in the use of AI that makes the resulting inventions more likely to be anticipated or obvious, nor does an applicant's use of AI make it harder for patent examiners to identify relevant prior art over which to issue rejections. Nothing in the current debate over AI tools should change this aspect of the examination process.

Indeed, AI-enabled search tools may assist examiners in more quickly locating the closest prior art – potentially improving patent quality and resulting in fewer patents issued for mere incremental advances.

The US's Focus on Inventorship Could Put Us at a Competitive Disadvantage Globally

During the hearing, I mentioned that other countries are less concerned with inventorship than the United States is. I write to elaborate on this point, which I touched on only briefly in oral testimony.

The United States has historically been more concerned with inventorship than other countries (and is applying that intense scrutiny now in the AI context). This is because, until the passage of the America Invents Act, we had a first-to-invent system, not a first-to-file system. Thus, in some situations where rival groups were working to achieve a scientific breakthrough in parallel, the Patent Office and courts would be called upon to adjudicate, through the [interference process](#), which person or persons were first to invent a particular innovation. The interference process, in turn, closely scrutinized when and how invention actually occurred, with the combatants often arguing that their opponents had not actually made a complete invention as of the asserted date of priority of that party. Essentially, these disputes over inventorship were a proxy for disputes about which of several competing inventors (and their respective employers) was first in time and should therefore actually own and control patent rights in a particular invention. The stakes are also high in inventorship disputes because errors or omissions of inventors can result in the invalidation of a patent.

An example of how our first-to-invent system led to a focus on inventorship can be found in the case *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), which related to the invention of recombinant beta-interferon, a product that, at least at times in the past, has been manufactured in Representative Ross's district. This was a three-way interference between inventors from Yeda Research and Dev. Co., Biogen, and a Japanese foundation devoted to cancer research. Ownership of this valuable invention turned on which purported inventor had actually completed the inventive process first. Ownership and control over CRISPR technology similarly turns on questions of the timing of inventorship; because the CRISPR patent estates predate the America Invents Act and its establishment of our current first-to-file system, multiple interference proceedings on this issue are still pending between The Broad Institute, the University of California, and other parties.

In most other countries, the patent systems have long been based on a first-to-file system. Under a first-to-file system, it is immaterial if someone other than the named inventor on a patent invented the patented subject matter before the patentee did. If the alleged prior inventor failed to file first, their alleged priority of invention has no legal effect. Thus, the systems in these other countries place far less emphasis on inventorship. Since we also now have a first-to-file system, we should also reduce our focus on inventorship.

While many other countries that have considered the “inventions” purportedly made by Steven Thaler’s DABUS artificial intelligence system¹ have ruled that an invention is not patentable unless the patent application names a natural person as the inventor, those countries have not attempted to parse the extent of an inventive contribution by AI in the way that the current USPTO [guidance](#) does. For example, courts in [Germany](#) and the [UK](#) have indicated that a patent *can* be issued even on an extensively AI-supported invention so long as the patent applicant names a human as the inventor instead of insisting on naming only an AI system as Thaler did. The USPTO guidance, on the other hand, sets forth a path where there might be no patent at all if “too much” AI support was used in making the invention. As I testified in person, the imposition of

¹ Thaler’s global effort to obtain patents solely in the name of his AI system DABUS was the catalyst for the USPTO’s current concern with inventorship. The Federal Circuit ruled, as have courts worldwide, that patents should not be issued from applications listing no human inventor. See *Thaler v. Vidal*, 43 F.4th 1207, 1210 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 1783 (2023). While the Federal Circuit’s ruling was consistent with the approaches of other courts globally, the USPTO’s subsequent focus on parsing inventorship between humans and their AI tools is not consistent with approaches in other major jurisdictions.

a requirement to conduct a determination of the supposed contribution of AI imposes burdens on the patent process that are not imposed in other countries that are less preoccupied with inventorship. 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 burdening it with new legal complications. Adding yet more complexity will not encourage the progress of science and the useful arts.