COMMENTS OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) TO THE USPTO FEBRUARY 13, 2024 INVENTORSHIP GUIDANCE FOR AI-ASSISTED INVENTIONS, 89 FR 10043

On behalf of its member organizations, Biotechnology Innovation Organization ("BIO") respectfully submits this Comment in response to the United States Patent and Trademark Office's (the "Patent Office" or "PTO") February 13, 2024 Request for Comments. *See* 89 FR 10043 (the "Guidance").

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members include startup companies developing their first commercial products to multi-national Fortune 500 pharmaceutical corporations.

The use of artificial intelligence and machine learning (together: "AI") tools is becoming increasingly common, though not ubiquitous, among BIO's member companies, who deploy this technology to assist in drug discovery, clinical trial design, manufacturing process improvements, and a range of other applications. While BIO's member companies have not yet developed a uniform view on the Office's Inventorship Guidance, we would like to offer a few high-level comments that we believe reflect prevalent attitudes among BIO's membership:

First, BIO members have commented that they believe the Guidance will probably produce generally the right outcomes for now. This is not because the PTO's legal framework is uniformly viewed as the best or legally most sound – in fact, BIO members hold a variety of perspectives on the matter. Rather, the extent of human involvement, at least in the biotech space, is such that the Guidance's standard of "significant human contribution" will likely usually be met at the current stage of technology implementation, regardless of whether it is the right or best standard the PTO could have articulated.

Second, while the Guidance seems to offer a workable framework for now, it is important to acknowledge that it applies the law of "conception" and joint inventorship in new and unfamiliar ways. This body of law developed to determine the rights of putative human inventors relative to each other – to decide, for example, which of several collaborators should share patent rights in a resulting invention; or which of several competing investigators was first in time to conceive an invention relative to the others. The Guidance now applies the law of joint inventorship to situations where there is no one else to join, and the law of first mental conception when there is no priority contest. Or to put it differently, this body of law was designed to *allocate* rights between individuals, while the Guidance applies it to potentially decide whether any rights can be granted at all. It will be important to carefully monitor how well these historic tests will work to account for the impact of AI and other computational tools on the patentability of resulting inventions.

Third, it will be important to monitor whether the U.S. may be deviating in important and unnecessary ways from how foreign patent systems address similar questions about the use of AI and other computational tools in the invention process. The USPTO Guidance implicitly but

clearly casts doubt upon the substantive patentability of inventions that result from the use of AI. It suggests that even where there has been some human involvement, there may be no patentable invention because no natural person contributed "enough" -- and the specter of unpatentability is there even if the invention is otherwise perfectly novel, unobvious, and properly described. Other jurisdictions, in contrast, don't seem to view the involvement of computational tools as a potentially patentability-destroying event in the way the Guidance implies.

It is true that courts in other countries have ruled that an invention is not patentable unless the patent application names a natural person as the inventor, but those foreign courts have not attempted to define, as a requirement of patentability, a requisite quantum of human contribution to an otherwise AI-supported invention in the way the 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 her- or himself as the inventor instead of insisting on naming only an AI system.[1]

To illustrate, the German Federal Patent Court has stated that:

> "it is - for purposes of assessing whether an invention exists and is based on an inventive step […] - irrelevant how that invention came to be, or whether designated persons are properly to be regarded as inventors. An invention is judged according to objective criteria, so that it is not relevant whether it is based on conscious thought, systematic work with planned experiments or merely on the exploitation of coincidentally discovered relationships governed by the laws of nature *or - as here - on the use of AI.*"[2] (emphasis added).

It is apparent that, so far, foreign patent systems have viewed AI-related inventorship questions predominantly as questions of ownership and derivation of rights, while on the other hand the USPTO Guidance, written on a background of peculiarly American inventorship law, views these same questions as important for patentability. The ultimate effect could be that the same AI-supported invention may be patentable in foreign countries (provided that a human inventor is named), but unpatentable in the United States where no human is deemed to have made a sufficiently significant mental contribution. In this way, by erecting obstacles to patentability that don't exist in other countries, the Guidance could create a disincentive to using AI and other computational tools to their fullest potential in the United States. American litigiousness and a judicial receptivity to novel theories of patent invalidation could then lead to further instability in the law and unpredictable outcomes. To be clear, BIO does not believe that US-based inventors are currently shying away from using AI and other computational tools - only

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[1] See e.g. Thaler v Comptroller-General of Patents, Designs and Trade Marks [2023] UKSC 49 (UK Supreme Court), at para. 52: ("[It] is not and has never been Dr Thaler's case that he was the inventor and used DABUS as a highly sophisticated tool. *Had he done so, the outcome of these proceedings might well have been different*.") available at https://caselaw.nationalarchives.gov.uk/uksc/2023/49 (emphasis added).

See also: German Federal Patent Court 11 W(pat) 5/21 (Fractal Container)(affirming the rejection of patent application where only AI system is listed as inventor, but granting auxiliary request where Dr. Thaler instead named *himself* as the inventor). Opinion and English translation available at: https://artificialinventor.com/wp-content/uploads/2022/12/DABUS-decision-BPatG-English-translation.pdf

[2] See Id., German Federal Patent Court 11 W(pat) 5/21 (Fractal Container) at p. 12 (translated from German original); available at: https://www.ipwatchdog.com/wp-content/uploads/2022/04/DABUS-BPatG-11-W-pat-5-21.pdf . Notably, US patent law takes a similar objective stance, codified in the 1952 Patent Act (in reference to 35 USC 103). The "Historical and Revision Notes" to 35 USC 103 clarify that "it is immaterial whether it [the invention] resulted from long toil and experimentation or from a flash of genius." (see, https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35.htm).

time will tell. But it must be acknowledged that, while the use of such productivity- enhancing tools should be encouraged and facilitated, under the Guidance their use is clearly also fraught with perils that could jeopardize the patentability of resulting inventions, and that over time could cause innovative businesses to become more circumspect and conservative in the way they adopt and use AI and other computational tools.

Fourth, BIO members have noted approvingly that the Guidance does not seem to systematically seek new or additional disclosure requirements during patent examination for inventions that were facilitated by AI or other computational tools. Information should, of course, be disclosed to the extent it is material to patentability, but BIO's members do not believe that blanket disclosures of the details of the AI system, the data that were used to train it, and the prompts that were used to elicit its outputs would be helpful to examiners or be material to patentability in the majority of cases. AI systems and other computational tools are fundamentally shaped by the data used to train them. Data used to train AI systems today are likely to be sparse, constrained, even outdated in comparison to the training data that will be available even just 3-5 years from now. Similarly, there would be little rationale to disclose the specific prompts used with the AI system, because those same prompts would be likely to yield different results if used with a system that is configured differently or trained using a different dataset. Even with the same AI system, posing the same inquiry repeatedly may lead to different outputs due to degrees of randomness or stochasticity that are configured into such systems. And finally, in most instances it will be possible to describe how to make and use an invention – such as a new drug molecule or a new synthetic enzyme – by providing adequate technical instructions in the patent specification. After all, others reading the patent only need to be able to make and use the invention itself in conformity with the patent's written description – there is no need to retrace the steps, tools, and prompts that led the inventor to the invention in the first place.

Finally, BIO cautions the USPTO and public policymakers against premature and reflexive actions in response to the increasing adoption of AI and other computational tools among US innovators. There is nothing inherently harmful or problematic about novel and unobvious inventions just because they were generated with the help of AI tools. In fact, public discourse should celebrate the emergence of efficiency-enhancing tools that allow more US innovators to make more inventions more quickly, cheaply, and efficiently. Seen this way, it is hard to understand the impetus for emerging debates over whether US inventors are using "too much AI" and whether something must be done to prevent or make the issuance of resulting patents more difficult. BIO hopes that the USPTO will play a moderating role in addressing such inchoate concerns in the public sphere.

To reiterate, many BIO members view the Guidance as a currently-workable framework that is likely to produce adequate outcomes at the present stage of technology implementation. In the not too-distant future, however, the increasing power and sophistication of AI- and other computational tools is likely to present additional, thorny questions that the current Guidance conservatively avoids, and that may eventually necessitate revisiting the USPTO's joint-inventorship approach to AI-facilitated inventions. BIO looks forward to continued dialogue with the USPTO about this important topic.

Respectfully submitted,

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