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COMMENTS OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) TO THE USPTO FEBRUARY 14, 2023 REQUEST FOR COMMENTS REGARDING ARTIFICIAL INTELLIGENCE AND INVENTORSHIP, 88 FR 9492

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 14, 2023 Request for Comments. See 88 FR 9492 (the “RFC”).

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 of the questions posed in the Office’s RFC, 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, at this stage, they view AI as a tool that facilitates human invention-making. AI is not deemed to possess the agency, purpose, motivation, or the capacity for ideation that is required – at least under current law - to establish conception of an invention. Accordingly, the use of an AI tool, even one that significantly facilitated the conception of an invention, should not relegate a human inventor to the status of “part-inventor,” co-inventor or non-inventor.

Second, BIO members have commented that, at this stage, there is basically always significant human involvement in the making of AI-assisted inventions, although the precise nature of this human involvement is highly dependent on the facts and circumstances of each case. Thus, the question of AI systems autonomously making inventions without any human input or participation has not generated much commentary in BIO’s membership. Moreover, some BIO members have noted that under current law “appreciation and recognition,” as is necessary to form a “definite and permanent idea of the invention as it is thereafter to be applied in practice,” can genuinely only take place in the human mind. Thus, the use of an AI may facilitate the conception in a human inventor’s mind, but the AI cannot itself “conceive” in a legal (and probably human) sense, and therefore cannot deserve credit as a coinventor in the way a human coinventor would. Accordingly, complete “conception” under such circumstances could be deemed to occur when the human operator, having received the AI’s output, recognizes and appreciates the invention, its usefulness, and how to apply it in practice using only ordinary experimentation. To



put it differently, the use of an AI or other tool may make a difference to *how* an invention was conceived, but not *that* it was conceived.

Third, the Patent Act does not describe the act of making an invention, but it cautions that “patentability shall not be negated by the manner in which the invention was made.” This is for good reason. A novel, non-obvious, and useful pharmaceutical compound, for example, can come into existence in any number of ways – through long and goal-directed pursuit; or through sheer luck or coincidence; or through brute force using semi-random combinatorial chemistry and high-throughput assays; or with the help of any number of tools and collaborators. Regardless of how it was made, the invention is then going to require the same amount of investment, time, partnering and licensing in order to be developed for regulatory approval and market-readiness. Given this, there does not seem to be a good policy reason why patentability of a novel, useful, and nonobvious invention should be “negated” if it was conceived with the help of an AI tool, but permitted if it was conceived through a stroke of serendipity; through methodical, deep thought; or through the use of some other, conventional tool.

Fourth, to the extent there may be proposals to tally the relative “inventive contributions” of AI vs humans, it would be unproductive and cumbersome to do so. Such concepts seem based on the notion that it would be possible to reliably figure out whether the human contribution, standing alone, would be enough to render the invention patentable, or whether the human contribution was insufficient for patentability. Doing so would invite endless exercises in line-drawing and provide fodder for rich, new forms of litigation.

Fifth, BIO members have expressed that the current law on inventorship is adequate, for now. Questions of *ownership* are secondary and will be addressable after current questions about inventorship of AI-facilitated inventions are resolved. There is sufficient time for sober and thorough dialogue, and we commend the Office for its outreach to the patent user community and the broader public. We look forward to engaging further with the Office on this important initiative.

Respectfully Submitted,

/s/ Hans Sauer, Vice President, IP

Dated: May 15, 2023