



March 8, 2019

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22314

Via Electronic Mail to Eligibility2019@uspto.gov (Docket PTO-P-2018-0053)

Dear Director Iancu:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments in response to the United States Patent and Trademark Office's 2019 Revised Patent Subject Matter Eligibility Guidance (Revised 101 Guidance) as set forth in 84 Fed. Reg. 50, published on January 7, 2019. BIO commends the USPTO's continued engagement of the patent user community in improving and updating patent examination practice with respect to subject matter eligibility. As set forth in more detail below, the Revised 101 Guidance will improve examination consistency and predictability for the Office and patent applicants alike.

BIO is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues of under \$25 million and who count their patents among their most valuable business assets.

BIO believes that the procedures within the Revised 101 Guidance will result in more uniform application of patent eligibility standards across USPTO art units. While previous guidance appropriately reflected the state of patent eligibility jurisprudence, it has been reported that some art units applied more rigorous standards in rejecting claims under 35 U.S.C. § 101 than others. Although the source of the disparate treatment is unknown, it may have resulted at least in part from a perception within various art units that they should analogize to a particular subset of cases in which claims were found ineligible. A more appropriate path is to apply the principles developed by the courts rather than merely comparing to case specific fact patterns. BIO believes that the synthesized concepts outlined in the Revised 101 Guidance – namely, the inquiry into whether a claim integrates a judicial exception into a practical application – provide an approach that examiners can apply uniformly.

Implementation of the Revised 101 Guidance will also improve prosecution efficiency because examiners and applicants will be able to identify specific areas of subject matter eligibility concern and address them with particularity. For example, the Revised 101 Guidance requires examiners to “[i]dentify the specific limitation(s) in the claim under examination (individually or in combination) that the examiner believes recites an abstract idea.” 84 Fed. Reg. at 54. It is BIO’s understanding that prior to the Revised 101 Guidance, some but not all examiners followed this practice. By requiring examiners to set forth the particular claim language believed to recite an abstract idea, the examiner will necessarily outline what he or she sees as the eligibility problem. This will allow the applicant to respond directly to the examiner’s concerns. The Revised 101 Guidance is, however, less clear on whether the requirement to identify the specific limitation(s) of subject matter eligibility concern applies to claims believed to recite a law of nature or natural phenomenon. BIO urges the USPTO to make clear that this practice should apply to abstract ideas, laws of nature, and natural phenomena alike.

Finally, BIO would like to draw attention to the fact that the Revised 101 Guidance specifically emphasizes concerns regarding difficulty in determining whether a claim is directed to an abstract idea. 84 Fed. Reg. at 50 (“In particular, stakeholders have expressed concern with the proper scope and application of the ‘abstract idea’ exception.”). To the extent it is implied that determining whether a claim is directed to a law of nature or natural phenomenon is straight forward or uncomplicated, BIO urges caution. Many opinions reflect difficulty in deciding this very issue in life sciences cases. For example, in the recent *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.* decision, the majority and dissent sharply disagreed in their step 1 analyses. 887 F.3d 1117 (Fed. Cir. Apr. 13, 2018). While the majority properly concluded that the claimed method for treating patients with iloperidone with differential dosages based on patient genotype was not “directed to patent-ineligible subject matter” (*id.* at 1134), the dissent disagreed and concluded – albeit incorrectly – that the claims are directed to a law of nature (*id.* at 1140). See also *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) (finding that the claims at issue were not “‘directed to’ a patent-ineligible building block of human ingenuity” and that the district court erred in concluding otherwise). Accordingly, BIO recommends that the USPTO emphasize that examiners should treat the “directed to” inquiry with an equal level of attention and diligence across technology areas. BIO likewise urges the USPTO to update its life sciences examples to demonstrate how examiners should implement the Revised 101 Guidance. This could take a form similar to Examples 37-42, issued January 7, 2019, which apply the Revised 101 Guidance in the context of software and computer technologies.



BIO looks forward to participating in further public discourse on this and other important USPTO initiatives. BIO remains committed as a partner to the USPTO in its ongoing efforts to improve the consistency and predictability of patent examination, particularly with respect to the issue of subject matter eligibility.

Respectfully submitted,

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