

July 25, 2018

Hon. Andrei Iancu  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
600 Dulany St.  
Alexandria, VA 22314  
Via e-mail: Eligibility2018@uspto.gov

Re: Response to Request for Comments on Determining Whether a Claim Element is Well-Understood, Routine, Conventional for Purposes of Subject Matter Eligibility (Docket No. PTO-P-2018-0033)

Dear Director Iancu,

Thank you for the opportunity to provide comments on the subject matter eligibility guidance in the *Berkheimer* memorandum to the Patent Examining Corps (“the Guidance”). The comments below are made on behalf of Regeneron Pharmaceuticals, Inc. of Tarrytown, NY (“Regeneron”).

We believe the law of subject matter eligibility may have considerable impact on the ability to protect inventions in emerging technological areas, such as precision medicine and genetics, which we believe are vital to the continued development of the biotechnology industry in the United States. Accordingly, Regeneron commends the United States Patent and Trademark Office (“the Office”) on its continuing efforts to improve examination in an uncertain and continually evolving area of patent law, and to provide a more structured approach for determining subject matter eligibility. Further, Regeneron appreciates the proactive approach taken by the Office in providing new memoranda as soon as feasible after the Federal Circuit issues a significant subject matter eligibility decision.

Regeneron supports the Guidance. Regeneron believes that the Guidance will help avoid high-level and conclusory analyses surrounding the determination of whether additional claim elements sufficiently embody a transformative inventive concept. Further, the Guidance should help restore the appropriate burden on examiners in this area, and thereby afford applicants an opportunity to fully understand an examiner’s rationale and rebut an examiner’s findings with contradictory facts tailored to this rationale. Additionally, a more developed and structured prosecution record will likely benefit the PTAB and the courts in assessing subject matter eligibility in later proceedings.

Nevertheless, Regeneron believes that certain aspects of the Guidance may benefit from additional details that provide even more structure, which, in turn, may help mitigate against a formalistic approach to examination under the Guidance that focuses the analysis solely on specific elements

without further evaluating the elements in view of claims on the whole. In particular, with respect to formulating a rejection by “citation to a publication” (Section III.A.3), the Guidance should more clearly (a) delineate the difference between being “simply known in the prior art” and being “well-understood, routine, and conventional,” (b) specify how an examiner should particularize and support a finding that an element is “well-understood, routine, and conventional,” and (c) specify how applicants can rebut an examiner’s findings. In addition, the Guidance should clearly articulate that an examiner should not end an eligibility determination with a determination that a particular element is “well-understood, routine, and conventional” but, consistent with Supreme Court precedent, must still consider the claims on the whole.

First, the Guidance distinguishes between demonstrating that an element is “well-understood, routine, and conventional” (sufficient to fulfill the examination burden) and demonstrating that an element is “simply known” in the art/disclosed in a publication (insufficient to fulfill the burden). The Guidance does not, however, explain the difference between these two categories. Both examiners and applicants may gain further perspective if the Office were to provide at least a basic explanation of the difference.

For example, the Guidance could specify that for an element to be “well-understood, routine, and conventional,” such an element would (1) typically be part of the base knowledge and basic skill set or training of the skilled artisan. Accordingly, such elements (2) would be expected to be widely disseminated and have a broader, less specialized recognition within the art, (3) would tend to be in practice for longer, and (4) tend not to be controversial. The Guidance could also specify that, in contrast, for an element to be “simply known,” that element (1) would typically be more of a specialized knowledge or skill set, (2) would not be widely disseminated or recognized, (3) may require new training, (4) would tend to be newer or considered cutting edge, and (5) may be the subject of dispute or debate. In any case, if the Office were to provide a minimal set of boundaries, such boundaries should reduce subjective interpretations of these terms and provide for more uniformity in the implementation of the Guidance.

Second, the Guidance does not provide an analytical framework for how examiners can properly fulfill their burden (*e.g.*, make a *prima facie* showing) for demonstrating that an element is “well-understood, routine, and conventional.” Instead, the Guidance refers to the standard for assessing specification sufficiency under 35 U.S.C. § 112(a) and suggests using “a book, manual, review article, or other source.” But the standard for assessing sufficiency under § 112(a) circularly centers around what is “well-known to those of skill in the art and already available to the public.” MPEP § 2164.05(a). And as far as Regeneron is aware, neither the MPEP nor the case law clearly articulates factors or considerations for establishing an element as well-known or for distinguishing between “simply known” and “well-understood, routine, and conventional.”

Regeneron recommends establishing an analytical framework to assist examiners in fulfilling the burden of the Office, which will further assist applicants in rebutting the examiner’s findings, as appropriate. Ideally, the analytical framework should include objective moorings.

By way of example (not intending to be an exhaustive framework or list of considerations), as the first step of the analysis, examiners should identify the proper field (*e.g.*, bioinformatics machine learning algorithms) and sub-field (*e.g.*, neural network training) of the element in question. Then, examiners should make particularized findings sufficient to make a *prima facie* showing that the element is “widely prevalent” or “in common use.” For example, examiners could (i) provide literature showing the maturity of the field or particular technology, (ii) demonstrate whether the element has been described in textbooks, manuals, review articles, etc., (iii) show the extent to which the element is published (*e.g.*, how many publications make reference to the element in the correct context), (iv) identify applicable attributions or accolades, (v) establish how recently the references relied upon were published relative to the priority date, (vi) point out whether and to what extent the publications expressly characterize the element as well-known, prevalent, in common use, etc., and/or (vii) indicate whether other publications contradict the characterization of the element as well-known within the proper field and sub-field.

Third, the Guidance does not specify the type of information or evidence appropriate to rebut an examiner’s findings concerning whether an element is “well-understood, routine, and conventional.” In the spirit of the burden-shifting nature of examination, providing basic categories of applicable rebuttal arguments (*e.g.*, akin to MPEP § 2145) should assist both examiners and applicants in allocating and fulfilling their respective burden. Certainly, a more structured analytical framework, such as the framework outlined above, should afford applicants an opportunity to understand the examiner’s position and consider appropriate contrary arguments. However, applicants should also understand how to support those arguments and how the examiner will weigh the arguments and attendant support against the particularized findings that the element is “well-understood, routine, and conventional.”

For example, the Guidance could specify that once the examiner has made a *prima facie* showing sufficient to establish that an element is “well-understood, routine, and conventional,” the burden shifts to the applicants to rebut this showing with information and evidence sufficient to demonstrate that the element is not, in fact, “widely prevalent” or “in common use,” or that the element is “simply known.” The Guidance could further specify that, commensurate with this burden, the applicants may submit technical literature or expert testimony (*e.g.*, Rule 132 Declarations) that corrects the field and/or sub-field identified by the examiner, and that controverts the examiner’s particularized findings concerning the prevalence or common use of the element. The Guidance should also indicate that examiners must weigh the arguments and evidence and, in the next Office Action or in the Reasons for Allowance, detail the reasons why the arguments and evidence were or were not sufficient to rebut the *prima facie* showing (*e.g.*, update MPEP § 2106.07(b)(2) accordingly).

Finally, factual findings according to the *Berkheimer* opinion should not substitute for or alter the overarching requirement from *Diamond v. Diehr*, 450 U.S. 175 (1981) that in determining eligibility, the “claims must be considered as a whole.” *Diamond* cautioned against the “fallacy” that if all other steps are determined to be old in the art, the claim cannot recite statutory subject matter. *Id.* at 189, fn. 12. *Diamond* also explained that “a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made,” *Id.* at 188, and further explained that the ineligible concept (*e.g.*, the mathematical algorithm or law of nature) should still be considered when making the eligibility determination. *Id.* at 189, fn. 12. Accordingly, over-emphasizing evaluation of particular elements<sup>1</sup> may risk a failure to consider the claims as a whole, or result in a faulty conclusion of ineligibility on the basis that the additional elements of the claim are determined to be “well-understood, routine, and conventional” without due consideration of their interrelationship to each other or the ineligible concept (the “fallacy”).

The Guidance should make clear that a determination that an element is “well-understood, routine, and conventional” is, by itself, insufficient to satisfy the requirement that the claim be considered on the whole. The Guidance should require examiners to make additional and separate particularized findings demonstrating consideration of elements and combinations of elements found to be “well-understood, routine, and conventional” as interrelated to each other and to the ineligible concept in order to demonstrate assessment of the claims on the whole.

In summary, the Guidance stands as a good platform that will improve examination by restoring burden allocation to the evaluation of whether an element is “well-understood, routine, and conventional.” Additional structure around supporting a rejection by “citation to a publication” along the lines of the suggestions offered in the foregoing comments should help to refine this burden allocation by providing examiners and applicants alike with a framework for supporting and rebutting factual determinations about the state of knowledge in the art at the time of an invention. Such structure could include a recitation of the differences between being “simply known” and “well-understood, routine, and conventional,” as well as a list of factors that examiners and applicants can consider in building their case for the character of the element in question, a summary of the categories of appropriate rebuttal evidence, and a more firm requirement to consider whether

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<sup>1</sup> The Guidance refers to the combination of elements by way of a parenthetical, *e.g.*, “element (or combination of elements).” The parentheses should be removed; their use here is not trivial. Case law and proper examination procedure require that the combination of steps/elements be considered. *Diamond* at 188; MPEP § 2106.07(a)(II). Placing this critical analytical step in parentheses gives the impression that the step is optional, secondary, or unimportant, or makes it easy to overlook. Instead, the Guidance should make clear that elements in combination must be considered, particularly in view of the requirement that claims be considered on the whole.

elements found to be “well-understood, routine, and conventional” nevertheless are sufficiently transformative when considered on the whole.

Thank you for the opportunity to provide constructive feedback on the Guidance and offer suggestions for further improvements to examination in this challenging area of patent law.

Respectfully submitted,

Brian Cocca  
Gonzalo Merino  
On behalf of Regeneron Pharmaceuticals, Inc.