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Novartis Comments on "Well-Understood, Routine, Conventional" Test for Subject Matter Eligibility (Fed. Reg. 83(77); p. 17536-538, April 20, 2018)

Novartis is a global healthcare company whose mission is to discover new ways to extend and improve patients' lives. In pursuit of that mission, we use science-based innovation and employ the latest technologies to invent and develop new medicines and other therapies aimed at delivering better patient outcomes in growing areas of healthcare. As with others in our field, we rely heavily on the patent system to enable our work and to sustain the extraordinary investments, commitments, and efforts required to fuel our R&D and to continue to create the types of cutting-edge innovation that advances patient health. For this reason, we have long been an active voice in policy discussions concerning the system's operation, efficacy and direction.

Subject matter eligibility is an area of particular focus and importance for us, as we continue to develop innovative therapies that harness the power of biology, immunology, and other aspects of the human body to treat and move closer to curing diseases, and as we increasingly employ an array of digital technologies to optimize research and drug discovery, collect and put real-world data use, and enhance the experience and impact of our medicines. To that end, over the last several years, we have actively engaged with the Office, submitted public comments, participated in round tables, panels, and other public fora, and submitted amicus briefs at critical junctures in the development of subject matter eligibility law.

The recent Federal Circuit decisions in *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018) and *Vanda v. West-Ward*, 887 F.3d 1117 (Fed. Cir. 2018) represent two additional critical developments in this area, the first providing important guidance on how to apply the "well understood, routine and conventional" factor of Step 2 of the test set forth in *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012), and the second again validating the important distinction that the Supreme Court itself made between the diagnostic claims at issue in *Mayo* and method-of-treatment of claims, the latter of which by definition reflect a practical application of human technology. In that context, we were pleased to see the Office's quick recognition of the significance of these decisions, its prompt issuance of internal guidance to operationalize them (the

"*Berkheimer* memorandum" and "*Vanda* memorandum"), and its invitation for public comment. We are likewise pleased to now provide our comments, which we hope will prove useful in helping examiners to properly apply these latest case developments.

1. The Office should consider further revisions to MPEP 2106.05(d)(I) to ensure consistency between *Berkheimer* and Office practice

Novartis believes that the *Berkheimer* and *Vanda* memoranda, like the underlying cases that they implement, will each help bring further consistency and clarity to the Office's analysis of claims under 35 U.S.C. §101. In *Berkheimer*, the Federal Circuit clarified that "whether a claim recites patent eligible subject matter is a question of law which may contain underlying facts." *Berkheimer*, 881 F.3d at 1368. In conjunction, the Court held that "[w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination." *Id.* at 1369. With this clarification that the inquiry is factual, we concur with the revised MPEP 2106.07(a) procedure set forth in the *Berkheimer* memorandum, which now appropriately instructs examiners to presume that an additional element (or combination of elements) "is not well understood, routine and conventional unless the examiner finds, and expressly supports a rejection in writing with," one or more types of evidence. *Berkheimer* memorandum at 3. For additional clarity and certainty, however, we would ask the Office to consider further revising MPEP 2106.05(d)(I) to delete the statement that "courts have not required evidence to support a finding that additional elements were well-understood, routine, conventional activities, but instead have treated the issue as a matter appropriate for judicial notice." We find this statement to be inconsistent with the new guidance and at odds with *Berkheimer*, and believe its deletion will help to keep Office practice in line with the new case law.

2. The Office should consider providing additional guidance and training for examiners on the proper application of case law under MPEP 2106.05(d)(II)

To help further ensure consistency, we recommend that the Office consider providing additional training to examiners on some of the ways of factually establishing that an additional element is "well understood, routine or conventional." Specifically, the second of the four ways set forth in the memorandum is "citation to one or more of the court decisions discussed in MPEP 2106.05(d)(II) as noting the well understood, routine, conventional nature of the additional element(s)." While we agree that this can be a basis for concluding that an element is well understood, routine and conventional in appropriate cases, we believe it is equally important for examiners to recognize that the particular invention at issue in these court decisions may be factually distinct from the invention set forth in a claim under examination. In some cases, what at first may appear superficially comparable may ultimately be sufficiently distinct that such court decisions are no longer fairly applicable. For this reason, we believe it may be helpful for the Office to provide further training on the holdings and underlying facts of these decisions, as well as some additional guidance on how to properly apply them to new claims under examination to avoid overgeneralizations and improve consistency.

3. The Office should clarify the role of "additional elements" in its eligibility framework to ensure consistency with the precedent of *Diamond v. Diehr*

Similarly, while we again agree with and support the general approach set forth in the *Berkheimer* memorandum, we believe that both the *Berkheimer* and *Vanda* decisions present an important opportunity for the Office to clarify the meaning and role of "additional elements" in its subject matter eligibility framework. Specifically, though the Office refers frequently to a standard based on the nature of "additional elements," we wish to underscore the critical importance of determining eligibility not just based on "additional elements," but based on the "claims as a whole," as the Supreme Court emphasized in *Diamond v. Diehr*, 450 U.S. 175 (1981). In *Diehr*—which the Supreme Court in *Mayo* reaffirmed as "controlling precedent," *Mayo*, 132 S. Ct. at 1298—the Court indeed made clear that it is *not* sufficient to merely consider whether "additional elements" standing alone establish an inventive concept. The claim must *also* be "considered as a whole," *Diehr*, 450 U.S. at 188, meaning the ineligible subject matter *along with* the additional elements, to determine if *together* they recite statutory subject matter.[1] In the context of *Berkheimer*, *Diehr* has at least two important implications. First, because an inventive concept can be present in a new *application* of known elements (as well as through new elements), a factual inquiry under Step 2B of the Office's framework should be required regardless of how an examiner decides to separate a claim into a judicial exception and its "additional elements" in Step 2A. In other words, a broad framing of a judicial exception should not dispense with the need to support a finding of ineligibility with evidence. Second, affirmative statements in the specification, or other factual evidence, demonstrating that the invention reflects a new *application* of known elements should be highly relevant to the eligibility inquiry and, barring contrary evidence, sufficient to overcome a rejection.

4. The Office should consider broadening its guidance to apply a factual inquiry to nature-based product claims under Step 2A of its eligibility framework

We also suggest that the Office consider broadening its new guidance to apply not only to the "well understood, routine, and conventional" test applicable to method claims, but also to the "markedly different characteristics" test applicable to nature-based product claims under the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). Under the Office's current eligibility framework, it approaches nature-based product claims differently from other claims, instructing examiners to apply *Myriad*'s "markedly different characteristics" analysis to such claims as part of Step 2A, which examines whether a patent claim is

[1] *See id.* at 189, n12 ("[It is argued that] if everything other than the [patent-ineligible concept] is determined to be old in the art, then the claim cannot recite statutory subject matter. The fallacy in this argument is that we did not hold in *Flook* that the [patent-ineligible concept] could not be considered at all when making the §101 determination. To accept [that] analysis . . . would, if carried to its extreme, make all inventions unpatentable …")

directed to a judicial exception. Under this current approach, a nature-based product claim is patent-eligible and is not subjected to Step 2B's "inventive concept" inquiry if the claim exhibits a difference in "structure, function and/or other properties." Only if the claim fails to exhibit this difference does the inquiry proceed to Step 2B and its associated search for aspects that are not "well understood, routine, and conventional."

While the *Berkheimer* decision focused on the "well understood, routine and conventional" test, and did not specifically address the "markedly different characteristics" test, we note its more general holding that "whether a claim recites patent eligible subject matter is a question of law which may contain underlying facts." *Berkheimer*, 881 F.3d at 1368 (emphasis added). *Berkheimer* therefore makes clear that the underlying factual nature of the eligibility inquiry is not dependent on which test applies. Moreover, whether a claimed invention differs from a naturally occurring product and by how much—the questions at the core of the "markedly different characteristics" test—are plainly factual in nature. Accordingly, consistent with its guidance regarding the "well understood, routine, and conventional" test of Step 2B, the Office should consider broadening its guidance to clarify that Step 2A's "markedly different characteristics" test is also factual in nature. This addition seems particularly appropriate given that a nature-based product claim that fails Step 2A of the Office's framework will indeed now be subject to the factual inquiry of Step 2B.

5. The Office's *Vanda* memorandum properly instructs examiners how to resolve eligibility of method-of-treatment claims under Step 2A of its framework

Novartis last wishes to express its agreement with and support for the Office's *Vanda* memorandum, which, consistent with the Federal Circuit decision in the case, the Supreme Court's decision in *Mayo*, and the Office's current practice, properly characterizes method-of-treatment claims as patent-eligible *applications* of natural relationships that are distinguishable from the types of claims at issue in *Mayo* and are not "directed to" ineligible subject matter. We agree with the Office's conclusions that, under *Vanda* and *Mayo*, method-of-treatment claims should generally be considered patent-eligible *per se* under Step 2A of the Office's framework, without any need to include or demonstrate non-routine or unconventional steps.

We again thank the Office for its prompt guidance on these important case developments, and its efforts to bring further clarity and consistency to this critical area of patent law. We hope that the above comments prove useful, and look forward to continuing dialogue on these and other matters of patent policy.

Respectfully submitted,

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