



August 20, 2018

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 e-mail to Eligibility2018@uspto.gov (Docket PTO-P-2018-0033)

Re: Comments on the *Berkheimer* Memo

Dear Director Iancu:

The Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization) 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 midsize businesses that have annual revenues of under \$25 million.

BIO greatly appreciates the USPTO's outreach to the patent user community in its efforts to apply the patent eligibility requirement of 35 USC § 101, including the Federal Circuit decision in *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018). BIO commends the USPTO's high level of public engagement and transparency on the patent eligibility requirement. BIO takes this opportunity to provide its comments on the *Berkheimer* memo and other USPTO patent eligibility guidance.

I. Introduction

BIO's members are concerned that, six years after the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), increasing uncertainty exists about the patent-eligibility of biotechnological products that incorporate naturally-occurring substances, and of methods of using such products in therapeutic, diagnostic, or industrial processes. The unstable state of patent-eligibility jurisprudence affects modern biotechnologies ranging from biomarker-assisted methods of drug treatment to companion diagnostic tests, fermentation products, industrial enzyme technology, and marker-assisted methods of plant breeding. As developers of, and investors in, such advanced technologies, BIO members have a strong interest in clear and predictable rules of patent-eligibility. BIO submits these comments in the hope they will assist the USPTO in the consistent application of the law in this important area.

II. Nature-Based Products

Before addressing *Berkheimer*, BIO would like to provide comments on the patent-eligibility of what the USPTO subject matter eligibility guidance refers to as “nature-based products.”

A. The Critical Value of Nature-Based Products

Inventive preparations based on naturally-occurring substances have historically been of great importance in biotechnology, and innovation in this area has been spurred, at least in part, by the availability of patent protection. This is true for every sector of biotechnology. Examples include vaccine antigens, crop protection products, plant biotechnology and breeding, industrial enzymes, immunosuppressive drugs, anticancer compounds, and antibiotic drugs. In the continual search for new therapies, the use of patented, naturally-occurring substances is not just a historical phenomenon but continues to be important today, because preparations of novel and unobvious naturally occurring molecules continue to be an important source for drug discovery. Indeed, naturally-occurring molecules and their close derivatives have contributed an estimated 36% of all first-in-class small molecules approved by the FDA between 1999 and 2008. See Swinney DC and Anthony J, *How Were New Medicines Discovered?* Nat. Rev. Drug Discov. 10 (2011) 507-519. Antibiotics represent another area of drug development where naturally-derived products play an important role in addressing critical emerging medical needs. Among the relatively few new antibiotic drugs that were approved during the past decade, for example, are the bacterial fermentation products daptomycin and fidaxomicin, the latter having been approved as a first-in-class molecule in 2011.

Research and development within the biotechnology industry comes at a high cost, and every idea that is funded comes with a greater likelihood of failure than success. Developing a single therapy requires close to a decade of R&D, at an out of pocket cost approaching \$1.4 billion. DiMasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*. J. Health Econ. 47 (2016), 20-33. Such investments are risky. For every successful biopharmaceutical product, thousands of candidates are designed, screened, and rejected after large investments have been made. Only a small minority of drugs even advance to human clinical trials and close to 90% of those fail to obtain regulatory approval. Thomas *et al.*, *Clinical Development Success Rates 2006-2015*, BIO Industry Analysis 2016.¹

Investment is predicated on the availability of patent protection that enables biotechnology businesses to attract capital and commercial partners in order to advance basic inventions – including those based on naturally-occurring substances and processes – from the laboratory to the marketplace and ultimately to generate

¹ Available at <https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>.

an expected return on investment in the form of patent-protected products or services. In the United States alone, the biotechnology industry is responsible for more than 100 billion dollars of annual research investment and provides employment to more than one million individuals. The overwhelming majority of this investment is through private funding.

B. Supreme Court Guidance on the Eligibility of Nature-Based Products

It is highly important that investment in biotechnological innovation is not discouraged by systematically erecting special hurdles to patent protection for inventions that relate to so-called “nature-based products.” In particular, BIO urges the USPTO to be conscious of the different approaches the Supreme Court has taken when it explored the patent-eligibility of processes on the one hand, and compositions and articles on the other.

On this point, *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), provides guidance as to how to analyze process claims that implicate abstract ideas. But, *Alice* set forth only “a framework,” *id.* at 2355, not the framework, for an eligibility analysis that was particularly suited for the kind of claimed subject matter at issue in that case. There is little in the *Alice* decision to suggest that its mode of analysis necessarily applies in the same way to compositions or manufactures, which have developed their own line of case law.² For example, none of the Supreme Court cases dealing with compositions and manufactures—*Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)—have applied an “inventive concept/significantly more” analysis. The *Alice* opinion does not even mention these cases, with the exception of *Myriad*, which is only cited for the truism that “[l]aws of nature, natural phenomena, and abstract ideas are not patentable.” 134 S. Ct. at 2354. Conversely, *Myriad* not only dedicates a whole section to making clear that its analysis does not implicate method claims and “applications of knowledge” (569 U.S. at 595), it makes no mention at all of the “process” cases that feature so prominently in *Alice*: *Gottschalk v. Benson*, 409 U.S. 63 (1972), *Parker v. Flook*, 437 U.S. 584 (1978), *Diamond v. Diehr*, 450 U.S. 175 (1981), and *Bilski v. Kappos*, 561 U.S. 593 (2010). This distinction is both conspicuous and significant.

Thus, in instances where the Supreme Court encountered physical compositions and articles, it engaged in a comparative exercise that queried whether the claimed thing, viewed as a whole, has a “distinctive name, character or use” compared to the natural thing (*Chakrabarty*, 447 U.S. at 309-10), has “markedly different characteristics” (*id.* at 310), enlarges its “range of utility” (*Funk Bros.*, 333 U.S. at

² While some of the claims at issue in *Alice* were formally drawn to computer-readable media and systems, the petitioner had conceded that its media claims stand and fall with the method claims. *Alice*, 134 S. Ct. at 2360.

131), or whether the laboratory technician “created something new” (*Myriad*, 569 U.S. at 595).

Even if *Alice* could be understood to apply to compositions of matter, the Court’s use of an “inventive concept” approach in some cases but not in others underscores that there is no one-size-fits-all approach for satisfying § 101. Rather, the Court’s varied approaches in different cases demonstrates that products containing naturally-occurring elements may be patent-eligible for a variety of different reasons, depending on the claims and facts of a given case. Nothing in *Alice* suggests that important concepts such as “distinctive name, character or use,” “markedly different characteristics,” “enlarged range of utility,” or the “creation of something new” should not be a primary focus for composition and manufacture claims undergoing evaluation for patentable subject matter.

In its *Myriad* decision, the most recent decision addressing the patent-eligibility of a physical thing, the Supreme Court emphasized that it neither meant to break new ground nor to revise its prior decisions. The Court’s multiple cautionary statements about the narrowness of its holding and of all the questions it was explicitly not deciding, signal a narrow, incremental decision that should not compel broad changes in the way therapeutically and industrially useful substances and compositions are evaluated for patent-eligibility.

C. Clarification of USPTO Guidance on the Eligibility of Nature-Based Products

BIO believes the USPTO’s current patent eligibility guidance (set forth in MPEP § 2106) correctly recognizes that there is not a one-size-fits-all approach for satisfying § 101, and correctly offers different approaches for analyzing different types of claims for satisfaction of the patent eligibility requirement. With regard to “nature-based products,” BIO believes the USPTO’s current patent eligibility guidance correctly provides for determining patent eligibility at an initial step of the analytical process (at the USPTO’s “Step 2A”, which corresponds to the first step of a *Mayo/Alice* analysis). In particular, BIO agrees with the statement in MPEP § 2106.04(c) that if a claim is directed to “a nature-based product that has markedly different characteristics, then the claim does not recite a product of nature exception and is eligible.” Indeed, the Supreme Court has indicated that even when a claimed invention is derived from subject matter found in nature, a detailed *Mayo/Alice* two-step analysis may not be necessary. This makes sense. For certain claims, only minimal investigation is required to understand that the claim is directed to a “new and useful . . . composition of matter” and does not merely claim a “natural phenomenon.” See *Myriad*, 569 U.S. at 590. BIO appreciates that this Supreme Court guidance is reflected in the option for a “streamlined” patent eligibility analysis outlined in MPEP § 2116.06. As discussed below, however, BIO believes the USPTO should provide additional guidance on when a nature-based product claim is amenable to a streamlined analysis.

Additionally, BIO believes the USPTO's current patent eligibility guidance for a claim that includes a naturally occurring nature-based product requires clarification. At the outset, BIO notes that, in accordance with the usage in the USPTO's patent eligibility guidance, a claim that "includes" a nature-based product could be a claim whose subject matter as a whole is a nature-based product (*i.e.*, a claim to a nature-based chemical compound) or a claim that recites a nature-based product as one of several components (*i.e.*, a claim to pharmaceutical composition that includes a nature-based chemical compound along with one or more other components). The treatment of such claims in MPEP § 2106 is inconsistent and confusing at best.

Most troublesome is the statement in MPEP § 2106.04(c)(II) that "if the nature-based product limitation is naturally occurring, there is no need to perform the markedly different characteristics analysis because the limitation is by definition directed to a naturally occurring product and thus falls under the product of nature exception."³ That statement goes much further than the guidance in MPEP § 2106.04(c), which states that "[i]f the claim includes a nature-based product that does not exhibit markedly different characteristics from its naturally occurring counterpart in its natural state, then the claim is directed to a 'product of nature' exception." In particular, the statement in MPEP § 2106.04(c)(II) appears to preclude a "markedly different" analysis of the claimed subject matter as whole for any claim that recites a naturally occurring nature-based product as a component or ingredient, while the guidance in § 2106.04(c) appears to reflect a "markedly different" analysis of the nature-based product in the context in which it is claimed.

The preclusion of a "markedly different" analysis for naturally occurring nature-based products is not supported by any Supreme Court guidance, and conflicts with the USPTO's "Nature-Based Products" examples" and "Life Sciences" examples. Many of the USPTO's examples indicate that claims directed to a product that includes a naturally occurring product (as such) can be found eligible under a "markedly different" analysis of the claimed subject matter as a whole. Indeed, in many of the examples, a claim directed to a product that includes a naturally occurring product (as such) is found eligible because the product as a whole has "markedly different" characteristics (such as the "Pomelo Juice" example).

Because the guidance as laid out in MPEP § 2106.04(c)(II) does not indicate that a "markedly different" analysis can be applied to a claim that includes a naturally occurring nature-based product, it represents a significant, erroneous departure from the USPTO's subject matter eligibility examples that is not supported by Supreme Court guidance. Indeed, nowhere does MPEP § 2106 illustrate how a claim that recites a naturally occurring nature-based product could be found eligible. There is no discussion of nature-based product claims in MPEP § 2106.05 ("Eligibility Step 2B: Whether a Claim Amounts to Significantly More"). Yet, the

³ In that case, under MPEP § 2106.04(c), "further analysis in Step 2B [is required] to determine whether any additional elements in the claim add significantly more to the exception.

Supreme Court certainly has not held that all products that include a naturally occurring component or ingredient are outside the scope of 35 USC § 101.

BIO therefore respectfully urges the USPTO to clarify its patent eligibility guidance and revise MPEP § 2106.04(c)(II) to indicate that even if a nature-based product limitation is naturally occurring, a “markedly different” analysis should be performed to determine if the naturally occurring nature-based product as claimed, in the context of the claimed product, composition or manufacture as a whole, exhibits any markedly different characteristics from the naturally occurring product in its natural state. That is, the USPTO should clarify that products that include a naturally-occurring nature-based product are patent eligible if the claimed product as a whole is “markedly different” from the naturally-occurring product *per se* in its natural state, such as by having a “markedly different” structure, function, or utility.

D. Clarification of the Streamlined Analysis
for the “Directed To” Inquiry

Step 2A of the USPTO’s patent eligibility analysis (step 1 of the *Mayo/Alice* framework) asks whether the claim is “directed to” a judicial exception. As noted above, under the USPTO’s current patent eligibility guidance, “[w]hen a claim recites a nature-based product limitation, examiners should use the markedly different characteristics analysis discussed in MPEP § 2106.04(c) to evaluate the nature-based product limitation and determine the answer to Step 2A.” MPEP § 2106.03(b)(II). However, MPEP § 2106.03(b)(II) also provides that when such claims “are directed to inventions that clearly do not seek to tie up any judicial exception, examiners should consider whether the streamlined eligibility analysis discussed in MPEP § 2106.06 is appropriate,” in which case “it would not be necessary to conduct a markedly different characteristics analysis.” BIO suggests the USPTO provide additional guidance on when the streamlined eligibility analysis is appropriate.

For example, the USPTO should emphasize that not every claim that recites within its limitations a compound that can occur in nature is necessarily “directed to” a judicial exception to patent-eligibility. That would be in tension with the direction provided by both the Supreme Court and the Federal Circuit. *See Rapid Litig. Management v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) (“Under the Supreme Court’s test, some claims will be ‘directed to’ a patent-ineligible concept and some, necessarily, will not.”). In particular, the USPTO should advise that whether a claim is “directed to” a nature-based product depends on the subject matter of the claim as a whole. For example, a useful inquiry could be whether the focus of the claim as whole is directed to a judicial exception—or not.

BIO appreciates that MPEP 2106.06 includes examples of claims that recite a nature-based product that can be found eligible under a streamlined analysis, but notes that in each example the nature-based product is a relatively minor component of the claimed subject matter. The USPTO should revise this guidance to

provide for the possibility of a streamlined analysis even if the nature-based product is a relatively major component of the claimed subject matter, as long as the claim “clearly does not attempt to tie up the nature-based product” *per se*, such as for a claim directed to a pharmaceutical composition comprising a nature-based drug as the primary component. Such guidance would promote efficiency and consistency in patent eligibility determinations.

E. Expansion of USPTO Guidance on the Eligibility of Nature-Based Products

As discussed above, Supreme Court jurisprudence underscores that there is no one-size-fits-all approach for satisfying § 101. Yet, the USPTO’s current patent eligibility guidance includes only one test for nature-based products—the markedly different test—and excludes from eligibility all nature-based product claims that do pass that test. BIO urges the USPTO to revise its patent eligibility guidance and MPEP § 2106 to indicate that the patent eligibility of a nature-based product can be assessed by alternative approaches.

One alternative approach supported by Supreme Court decisions would ask whether the inventor(s) created “something new.” Such an approach was taken by the Supreme Court in *Myriad*, when it found claims to non-naturally occurring cDNA to be patent-eligible. The Court did not implement a *Mayo* analysis in doing so, but instructed that the key to its analysis was that the lab technician “unquestionably create[d] something new when cDNA [was] made.” 596 U.S. at 595. Such an approach also is consistent with *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). There, in finding claims to a modified naturally occurring organism patent-eligible, the Court asked whether the claimed subject matter constituted a “manufacture” or “composition of matter,” distinct from subject matter found in nature.⁴ *Id.* at 307. The Supreme Court’s long-standing approach to these types of claims is instructive: composition of matter claims requiring the work of laboratory technicians are unlikely to run afoul of § 101.⁵

In view of the Supreme Court guidance, BIO believes the USPTO should revise its patent eligibility guidance to include alternative ways to establish patent eligibility

⁴ This approach also is consistent with the “different in kind” concept Judge Learned Hand articulated in *Parke-Davis & Co. v. H. K. Mulford Co*, 189 F. 95 (SDNY 1911), and the Fourth Circuit’s focus on the strikingly advantageous properties of the claimed enriched vitamin B12 preparations in *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958).

⁵ In contrast, *Funk Bros.* tells us that a simple mixture (“aggregation”) of naturally occurring products may not amount to the creation of something new. 333 U.S. at 131. See also *Hailes & Treadwell v. Van Wormer*, 87 U.S. 353, 368 (1873) (“Merely bringing old devices into juxtaposition, and there allowing each to work out its own effect without the production of something novel, is not invention.”); *Reckendorfer v. Faber*, 92 U.S. 347, 357 (1875) (“There must be a new result produced by [the] union [of the lead pencil and the india rubber]: if not so, it is only an aggregation of separate elements.”).

of claims that include a nature-based product, such as providing for eligibility based on the creation of “something new.”

III. The *Berkheimer* Memo

The *Berkheimer* Memo provides patent eligibility guidance in view of the Federal Circuit decision in *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018), which addressed the determination of whether certain claim limitations represent “well-understood, routine, and conventional activity.” As discussed above, the Supreme Court has taken different approaches when it explored the patent-eligibility of processes on the one hand, and compositions and articles on the other. As noted above, none of the Supreme Court cases that addressed compositions and manufactures applied an “inventive concept/significantly more” analysis.⁶ Thus, BIO does not believe *Berkheimer* is particularly relevant to nature-based product claims, except to the extent it highlights that patent eligibility is a fact-intensive, case-specific inquiry. As such, BIO provides here its comments on *Berkheimer* and the *Berkheimer* Memo in the context of claims that implicate other judicial exceptions to patent eligibility, such as so-called abstract ideas, laws of nature, and natural phenomenon.

A. The *Berkheimer* Decision

The *Berkheimer* decision addressed the “well-understood, routine, and conventional” test that can arise under the second step of the *Mayo/Alice* framework (the USPTO’s Step 2B). As the court noted, “[t]he second step of the *Alice* test is satisfied when the claim limitations ‘involve more than performance of ‘well-understood, routine, [and] conventional activities previously known to the industry.’” 881 F.3d at 1367. The Federal Circuit explained that, “[w]hile patent eligibility is ultimately a question of law ... [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. The court also emphasized that “[w]hether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.” *Id.*

B. The *Berkheimer* Memo

The *Berkheimer* Memo updates the USPTO’s patent eligibility guidance by emphasizing that a determination that “an element (or combination of elements) represents well-understood, routine, conventional activity ... must be based upon a factual determination that is supported as discussed in section III [of the Memo].” BIO agrees that a determination of “well-understood, routine, and conventional

⁶ If *Mayo* and *Alice* apply to compositions and manufactures, then the “inventive concept” must be satisfied by the “markedly different characteristics” and “potential for significant utility” that were displayed by Chakrabarty’s bacterium.

activity” must be based on facts, but disagrees with many of the options outlined in section III.A for supporting such a determination. Instead, the determination should be based only on facts that are supported by substantial evidence of record, and made in the context of the claimed subject matter as a whole.

For similar reasons, and as explained in more detail below, BIO disagrees that a determination should be upheld over an applicant’s response if the element(s) have been shown to be well-understood, routine, and conventional “in the relevant field,” rather than in the context of the claimed invention in particular. BIO also disagrees with guidance invoking enablement standards as a proxy for a well-understood, routine, and conventional determination. There are many situations where an element is not well-understood, routine, and conventional in the specific context of the claimed invention but does not require a detailed description for enablement.

1. Applicant Statements

The *Berkheimer* Memo provides that a determination that element(s) represent well-understood, routine, and conventional activity (hereinafter, a “determination”) can be supported by “citation to an express statement in the specification or to a statement made by an applicant during prosecution that demonstrates the well-understood, routine, conventional nature of the additional element(s).” The Memo explains further, “A specification demonstrates the well-understood, routine, conventional nature of additional elements when it describes the additional elements as well-understood or routine or conventional (or an equivalent term), as a commercially available product, or in a manner that indicates that the additional elements are sufficiently well-known that the specification does not need to describe the particulars of such additional elements to satisfy 35 U.S.C. § 112(a).” BIO has a number of concerns with this guidance.

First and foremost, this specific guidance incorrectly does not require the determination that the element(s) represent well-understood, routine, and conventional activity be made in the context of the claimed invention as a whole. Thus, the guidance could lead examiners to incorrectly reject claims that recite element(s) that are not well-understood, routine, and conventional in the context of the claimed invention on the basis that they are well-understood, routine, and conventional in some other context. Just because an application teaches that an inventive method can be implemented with a commercially available product does not mean that it was well-understood, routine, and conventional to use that commercially available product to carry out the method. Likewise, just because an element is “sufficiently well-known that the specification does not need to describe the particulars of such additional elements to satisfy 35 U.S.C. § 112(a)” does not mean that it was well-understood, routine, and conventional to use that element in the context of the invention.

Claim 7 of the USPTO’s Subject Matter Eligibility Example 28 (Vaccines) illustrates the problem with this new guidance. That example notes that “Prior to applicant’s invention, and at the time the application was filed, coated microneedle arrays were

known to most scientists in the field, but were not routinely or conventionally used to administer vaccines.” Thus, that example illustrates a situation where an additional element could be implemented with a “commercially available product” and/or where the specification need not describe “the particulars” in order to satisfy enablement, and yet the element was not “well-understood, routine, and conventional” in the context of the claimed invention, such that it supported eligibility.

Second, BIO has concerns about the USPTO’s extrapolation of the enablement standard to the patent eligibility context. The Supreme Court and Federal Circuit have been careful to draw a line between §§ 102/103 and § 101. Against that backdrop the USPTO should not of its own initiative blur the line between § 112 and § 101. The *Berkheimer* Memo cites no precedential court decisions supporting its assertion that “the analysis as to whether an element (or combination of elements) is widely prevalent or in common use is the same as the analysis under 35 U.S.C. § 112(a) as to whether an element is so well-known that it need not be described in detail in the patent specification.”

Although the Memo cites *Genetic Techs. Ltd v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016), as supporting a convergence of § 112(a) and § 101, the Federal Circuit’s decision that “amplifying genomic DNA with a primer pair” was well-understood, routine, and conventional in that case was not based on a finding of enablement, but rather on its finding that the “claimed step of ‘amplifying’ genomic DNA with a primer pair was indisputably well known, routine, and conventional in the field of molecular biology” as of the priority date. That finding was supported by evidence of record including statements made by the patentee to the court, in the application, and during examination (in support of enablement). Indeed, the patentee had not relied on the “amplifying” step in its arguments for patent eligibility. Thus, while *Genetic Techs.* may indicate that facts supporting enablement also can support a determination that an activity was well-understood, routine, and conventional, it does not indicate that the inquiries are “the same.”

Still further, BIO is concerned that this guidance could lead to Examiners to put Applicants in a §101/§112 “squeeze” where arguments for eligibility might be used against enablement and *vice versa*. There is no authority for such a tension between patent eligibility and enablement.

2. Court Decisions

The *Berkheimer* Memo provides that a determination can be supported by “citation to one or more of the court decisions discussed in MPEP § 2106.05(d)(II).” BIO strongly objects to this guidance because it improperly turns findings of fact made on the specific records of the listed cases into rulings of law with general applicability. As such, this guidance is directly contrary to *Berkheimer*, which underscores that a determination is a question of fact. BIO therefore respectfully urges the USPTO to retract this aspect of the *Berkheimer* Memo and reiterate that the cases discussed in MPEP § 2106.05(d)(II) merely illustrate determinations that

were made on specific records, and acknowledge that similar elements could be found to not be well-understood, routine, and conventional in the context of a different invention and different evidentiary record.

3. Publications

The *Berkheimer* Memo provides that a determination can be supported by “citation to a publication that demonstrates the well-understood, routine, conventional nature of the additional element(s).” The Memo explains further, “[t]he nature of the publication and the description of the additional elements in the publication would need to demonstrate that the additional elements are widely prevalent or in common use in the relevant field, comparable to the types of activity or elements that are so well-known that they do not need to be described in detail in a patent application to satisfy 35 U.S.C. § 112(a).” BIO disagrees with this guidance for several reasons.

First, BIO believes that a publication would support a determination only if the publication demonstrates the well-understood, routine, and conventional nature of the additional element(s) in the specific context of the claimed invention, not just the “relevant industry” or “relevant field.” As discussed above, Claim 7 of the USPTO’s Subject Matter Eligibility Example 28 (Vaccines) illustrates a situation where an additional element was “known to most scientists in the field,” but still not “well-understood, routine, and conventional” in the context of the claimed invention, such that it supported eligibility.

Second, BIO disagrees with the conflation of the enablement inquiry with the “well-understood, routine, and conventional” inquiry for the reasons discussed above. BIO urges the USPTO to recognize and explain in its patent eligibility guidance that an element that is known *per se* may not need to be described in detail in order to satisfy enablement, but also may not be “well-understood, routine, and conventional” in the context of the claimed invention.

IV. The *Vanda* Memo

BIO commends the USPTO on its issuance of the June 7, 2018 memorandum regarding the *Vanda Pharm. Inc. v. West-Ward Pharm.* patent eligibility decision (the “*Vanda* Memo”). The *Vanda* Memo aptly conveys the Federal Circuit’s determination that the method claims at issue were not “directed to” a judicial exception but rather are patent-eligible method of treatment claims that apply observed natural relationships. BIO believes that the *Vanda* Memo accurately reflects the Supreme Court’s guidance regarding method of treatment claims provided in *Mayo* and additionally affords a useful reminder that claims should be analyzed as a whole when patent-eligibility is assessed. This guidance will help promote uniform, predictable, and reliable assessment of method of treatment claims, which will help the biopharmaceutical industry continue investing in this important area of research and development.

V. Conclusion

BIO thanks the USPTO in advance for its consideration of our comments and recommendations. We believe the matters raised above would benefit from further public dialogue with the USPTO before the guidance set forth in the *Berkheimer* Memo is finalized, and look forward to working with you further on this difficult but critically important subject.

Respectfully submitted,

/s/ Hans Sauer

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