Corey Salsberg
Vice President,
Global Head IP Affairs

Novartis Services Inc.
801 Pennsylvania Ave. N.W., Ste 700
Washington, DC 20004 USA
T: +1 (202) 662-4369
corey.salsberg@novartis.com

Dr. Leslie Fischer
Principal Patent Attorney,
I&D Patent Group
E. Hanover Site Head,
R&D IP Unit

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
T +1 (862) 778-9308
leslie.fischer@novartis.com

March 7, 2019

VIA E-MAIL ONLY
Eligibility2019@uspto.gov

Novartis Comments on "2019 Revised Patent Subject Matter Eligibility Guidance" (Fed. Reg. 84(4); p. 50-57, January 7, 2019)

Novartis is a global healthcare company whose mission is to reimagine medicine to improve and extend people's lives. In pursuit of our mission, we use innovative science and the latest technologies to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. As one of the world's top spenders on innovative R&D, we rely on the patent system to enable our work, and to sustain the extraordinary investments and effort needed to conduct the type of cutting-edge R&D that leads to breakthrough innovations that transform patients' lives. For this reason, the health and direction of the patent system are of paramount importance to us, and to the patients who ultimately benefit from our treatments and cures.

Sadly, over the last several years, we have been firsthand witnesses to the weakening of the US patent system, at a time when the need for strength and predictability has never been greater. As we charge ahead with our mission and work at this time of rapid technological change, making big bets in emerging fields like advanced cell therapy (e.g. CAR-T), gene replacement therapy, complex biologics and digital medicine, subject matter eligibility law in the US has cast an ever-expanding shadow of uncertainty across the US patent system, even as other countries who aspire to lead in innovation have bolstered their systems. To cite some specific examples, in the last year alone, Novartis has faced Section 101 rejections on patent claims covering new digital microscopes, methods of using lasers to monitor gas concentrations in tissue in surgery, and new non-naturally occurring peptides, to name but a few. At the same time, despite some helpful guidance from the Courts and this Office as to how to apply certain aspects of eligibility law to certain types of claims—e.g. *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018)'s recognition of the factual nature of Step 2 of the *Mayo* test, *Vanda v. West-Ward,* 887 F.3d 1117 (Fed. Cir. 2018)'s distinction between methods of treatment and certain diagnostic methods, and the Office's related guidance—eligibility doctrine continues to expand, moving dangerously close to encompassing many of the emerging technological fields that hold the most promise for medical as well as general human progress.

Against this troubling backdrop, Novartis is deeply encouraged by the Office's issuance of its 2019 Revised Patent Subject Matter Eligibility Guidance (Revised Guidance). The Revised Guidance provides much needed direction and clarity to examiners and the PTAB on a subject over which the courts themselves continue to struggle substantially. *See, e.g., Athena v. Mayo,* No. 17-2508, 2019 U.S. App. LEXIS 3645 (Fed Cir. Feb. 6, 2019) (Newman, J., dissenting) ("This court's decisions on the patent-ineligibility of diagnostic methods are not consistent, and my colleagues today enlarge the inconsistencies and exacerbate the judge-made disincentives to development of new diagnostic methods, with no public benefit."). At the same time, while we acknowledge that it is not always clear how to apply the Supreme Court's eligibility framework, we believe the approach set forth in the Revised Guidance at minimum correctly reflects the key principles of the Court's controlling precedents, including the need to consider patent claims as a whole without ignoring any elements (*See Diamond v. Diehr*, 450 U.S. 175 (1981)), and the need to "tread carefully" and apply subject matter exclusions narrowly, "lest [they] swallow all of patent law." *Alice Corp. v. CLS Bank,* 134 S. Ct. 2347, 2354 (2014).

Below, we are pleased to provide more specific comments, which we hope will help the Office in further developing the Revised Guidance and in adding still further clarity to this critical issue.

I. The Revised Guidance improves certainty and increases clarity by limiting the further expansion of the judicial exceptions and drawing clearer distinctions between the exceptions and practical applications thereof

Novartis appreciates the Office's efforts to bring greater certainty to the scope of the judicial exceptions and to the application of the Supreme Court's eligibility framework by dividing the Office's current "Step 2A" into two new prongs. At least insofar as method claims are concerned, we believe the Office's approach provides clear and practical guidance to examiners as to how to apply the Supreme Court's two-step *Mayo* test, and will help to keep the judicial exceptions from spreading further beyond the bounds of the relatively narrow categories of "abstract ideas" "laws of nature" and "natural phenomena" that the Supreme Court's jurisprudence intended.

Specifically, new "Prong One" helpfully limits "abstract ideas" to the three types of subject matter embodied in the case law ("mathematical concepts," certain methods of organizing human activity," and "mental processes,") and allows other subject matter to qualify only in "rare circumstances" that require further review. We believe this approach correctly focuses examiners on applying current law, and will help to curtail the inadvertent expansion of eligibility doctrine into new categories of subject matter that the Supreme Court never intended to exclude from the patent system. By adding additional layers of scrutiny to cases involving new categories of abstract ideas, and making clear how exceptional these should be, we believe the Revised Guidance gives proper deference to the Supreme Court's admonition to "tread carefully," *Alice Corp.* 134 S. Ct. at 2354, and to apply the "exclusionary principle" narrowly, lest it "eviscerate patent law." *Mayo v. Prometheus*, 566 U.S. 66, 71 (2012).

Likewise, we believe that new "Prong Two," which makes an important and correct distinction between claims that are truly "directed to" a judicial exception, and those that merely "recite" and integrate one into a practical application, will help to significantly clarify the exceptions and prevent their further expansion beyond the controlling case law. The distinction between a claim that is "directed to" (i.e. *claims*) an abstract idea, law of nature or natural phenomenon, and one that merely "recites" one goes to the very heart of the matter of eligibility, as the Supreme Court aptly recognized in its statement that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. Despite the critical importance of this distinction, current Office guidance incorrectly advises examiners that "[a] claim is **directed** to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is **recited** (i.e., **set forth or described**) in the claim." (emphasis in original). MPEP 2106.04. The Revised Guidance effectively repudiates this incorrect equation of "directed to" with "recited" by establishing a "practical application" test that we believe aligns with a key principle of Supreme Court eligibility jurisprudence—namely, that only patent claims that effectively encompass a judicial exception as such should be excluded from the system.

We further agree with and support the Office's framing of its "practical application" test as an inquiry into whether a claim, either through additional elements, ***or*** through such elements *in combination* with any judicial exceptions, evaluated as a whole, integrates the exception into a practical application. The importance of evaluating a claim "as a whole," ***without excising or ignoring the judicial exception or any other element,*** cannot be stressed enough, and reflects the Supreme Court's longstanding precedent set forth in *Diamond v. Diehr*, 450 U.S. at 188 and reaffirmed in *Mayo*. *See Mayo,* 132 S. Ct. at 1298 (referring to *Diehr* as "controlling precedent" and a case "most directly on point."). In this regard, we believe one of the most critical aspects of the Revised Guidance is the paragraph advising examiners that sometimes "it is the combination of elements that provide the practical application" rather than an "additional element" alone, and that "examiners should give careful consideration to both the element and *how it is used or arranged in the claim as a whole*." Revised Guidance at 55 (emphasis added). Given the importance of the legal principle that this instruction reflects, we would welcome additional efforts to emphasize it in the MPEP. As further practical guidance, we also recommend that the Office consider supplementing the Revised Guidance to instruct examiners to consider affirmative statements in the specification, or other factual evidence, demonstrating that the invention reflects a new *application* of known elements as highly relevant to the eligibility inquiry and, barring contrary evidence, sufficient to overcome a rejection.

Last, we agree with the Office that it is consistent with case law, and in fact imperative, to examine the claims for a practical application as part of a *Mayo* Step 1 inquiry, without regard to whether the claim employs an "inventive concept," which applies only in *Mayo* Step 2. The Federal Circuit has held as much in several exemplary cases, including *Vanda*, 887 F.3d 1117 and *Rapid Litig. Mgmt. v. CellzDirect, Inc.,* 827 F.3d 1042 (Fed. Cir. 2016), where the Court determined, respectively, that the method of treatment claims and the claims to novel techniques

for freezing hepatocytes, were not "directed to" a patent ineligible concept and thus immediately eligible under *Mayo* Step 1 without inquiry under *Mayo* Step 2. We thus agree with the Revised Guidance's clear statement that "a claim that includes conventional elements may still integrate an exception into a practical application, thereby satisfying the subject matter eligibility requirement of Section 101," which again is consistent with *Diehr*, and will help to ensure that examiners do not inappropriately import a novelty or obviousness analysis (35 U.S.C. §§102 or 103) into a subject matter eligibility inquiry under 35 U.S.C. §101.

II. The Office should provide additional direction regarding how the Revised Guidance applies to nature-based product claims.

While Novartis fully supports the Revised Guidance, one area that could benefit from further clarity is how it—specifically new Prong Two of Step 2A— will be applied to claims that are directed to nature-based products (implicating natural phenomena). While the Guidance is clear that the revised procedures of Prong Two are intended to apply to all judicial exceptions, it is not entirely clear how a natural phenomenon will be treated in terms of the new "practical application" analysis, since claims to compositions of matter and manufactures do not reflect "applications" in the same way that process claims do. Complicating matters further, the Office's current eligibility framework (set forth in MPEP 2106.4) approaches nature-based product claims differently from other claims, instructing examiners to apply the "markedly different characteristics" analysis of *Association for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107 (2013). Under that 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." MPEP 2106.04(c) further provides that, as a general rule, process claims are not subject to the markedly different analysis based upon the use of a nature-based product in a claimed process.

Given that the Office's current practice treats nature-based product claims very differently from process claims, the Revised Guidance will apparently impact the former quite significantly, yet it contains little guidance as to how to apply a "practical application" inquiry to these claims. For this reason, we request that the Office provide some guidance and examples of how examiners should approach composition of matter and manufacture claims that involve natural phenomena and/or otherwise cover nature-based products. One way of approaching these types of claims would be to maintain the current "markedly different structural or functional characteristics" test (MPEP 2106.4(c)) and to instruct examiners to perform both this analysis and a practical application analysis under Prong Two. As with claims reciting abstract ideas, the "practical application" analysis of such claims should, under this or any alternative approach, be undertaken without any "inventive concept" analysis. Further guidance, in any event, is needed in this area to improve examination clarity and consistency for both applicants and examiners.

NOVARTIS

III. The Office should clarify that *Alice Corp.*'s "technological solution" test may be used to analyze all technologies in Prong Two

We last wish to suggest that the Office clarify that the "technological solution" test[1] set forth in *Alice Corp.* applies equally to all technologies. The Revised Guidance currently refers to the "technological solution" test as a way of approaching the new practical application analysis of Step 2A Prong Two, but it does so mainly in the context of the computer arts. In *CellzDirect*, however, the Federal Circuit applied *Alice Corp.*'s technological solution test to claims covering novel techniques for freezing hepatocytes, upholding the clams under *Mayo* Step 1 on the basis that the claims were not to the discovery of a natural law, but reflected the application of "their natural discovery to create a new and improved way of preserving hepatocyte cells for later use."[2] We therefore suggest that the Revised Guidance add this example as an application of the "technological solution" test to the life sciences, and clarify that the test is technology-neutral.

Novartis thanks the Office for its Revised Guidance 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,

/s/ Corey Salsberg
Corey Salsberg
Vice President, Global Head IP Affairs

/s/ Leslie Fischer
Dr. Leslie Fischer
Principal Patent Attorney, E. Hanover Site Head, R&D IP Unit

[1] A detailed analysis of the "technological solution" test may be found in our prior submissions. *See*, e.g., "Novartis Comments on 'Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products'," dated July 31, 2014, p. 10-11 available at https://www.uspto.gov/sites/default/files/patents/law/comments/mm-e-novartis20140731.pdf

[2] Notably, the Federal Circuit made clear that *Alice Corp.*'s technological solution test would also apply under *Mayo* Step 2: "Even if LTC were correct that the '929 patent is 'directed to' hepatocytes' natural ability to survive multiple freeze-thaw cycles, and that we must proceed to step two, we would find the claims patent-eligible at that point as well. Under step two, claims that are 'directed to' a patent-ineligible concept, yet also 'improve[ ] an existing technological process,' are sufficient to 'transform[ ] the process into an inventive application' of the patent-ineligible concept."