AMGEN

Amgen Inc.
Thousand Oaks, CA 91320
www.amgen.com

March 8, 2019

Submitted Via email: Eligibility2019@uspto.gov and 112Guidance2019@uspto.gov

Attention: **The Honorable Andrei Iancu, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office**

Re: **Amgen's Comments on the 2019 Revised Patent Subject Matter Eligibility Guidance; Fed. Reg. Vol. 84, No. 4 (January 7, 2018), Docket Number PTO-P-2018-0053**

Amgen's Comments on the Guidance for Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. §112; Fed. Reg. Vol. 84, No. 4 (January 7, 2018), Docket Number PTO-P-2018-0059

Dear Director Iancu:

Amgen Inc. provides the following comments in response to the notices identified above and thanks the United States Patent and Trademark Office ("the USPTO" or "the Office") in advance for its thoughtful consideration of these comments.

Amgen supports patent rules that provide certainty, uniformity, and predictability to the public, and for these reasons, Amgen supports both the 2019 Revised Patent Subject Matter Eligibility Guidance and the Guidance for Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. §112. The proposed guidance provides helpful direction for patent applicants and examiners, and will yield a more predictable outcome for the patent applicant and the public.

About Amgen

Established in 1980 as a biotech start-up, Amgen became a pioneer in the biotechnology industry and has grown to be one of the world's leading biopharmaceutical companies. Amgen has developed many first-in-class, breakthrough therapies used to treat millions of patients around the world. Amgen continues its commitment to serve patients by researching human biology to invent and develop new therapeutic products for the benefit of patients suffering from serious illness in areas of high unmet medical need. As one example, Amgen recently launched a new, first-in-class product to treat migraines that acts on a different biological pathway than prior treatments, bringing new hope to those patients suffering the debilitating effects of migraines.

Amgen holds over a thousand U.S. patents directed to a wide array of inventions in many different areas of scientific research. Similar to other companies in our industry, Amgen's business model

Amgen Inc.
Thousand Oaks, CA 91320
www.amgen.com

depends on securing patents to protect the large investment of time and resources to discover, develop, and bring to market new breakthrough therapies. Amgen's success would not have been possible without a strong, reliable patent system to protect its inventions.

We provide comments on both of these proposals together, as §101 and §112 work in concert with the rest of the patent statute, and it appears that the Director is attempting to address existing issues through a careful, yet measured approach that attempts to keep the overall balance and interplay of the patent statute intact.

Amgen's comments in response to the 2019 Revised Patent Subject Matter Eligibility Guidance

The proposed subject matter eligibility (SME) guidance provides a revised examination procedure with regard to application of the *Alice/Mayo* test.[1] In the proposed guidance, step 2A of this existing test is further broken down to two prongs. In Prong 1 the examiner determines whether the claim is directed to a judicial exception. In Prong 2, if the claim is directed to a judicial exception, the examiner determines whether this exception is integrated into a practical application of that exception in the claim language. To assist this analysis, in addition to laws of nature and natural phenomena the guidance now also provides three explicit categories of judicial exceptions for abstract ideas: mathematical concepts, certain methods of organizing human activity, and mental processes. This guidance is helpful in that it distills relevant caselaw into an easier to follow format for examiners, patent applicants, and the public.

Amgen supports this guidance. Early drug discovery is increasingly more complex and in many cases focused on narrow indications and distinct patient populations. Moreover, drug research and development does not end at product launch. A biopharmaceutical may behave differently from person to person, or in certain disease states a biopharmaceutical will only be an effective treatment for those patients having a particular genetic profile, property, or biomarker. In some instances, these behaviors and properties will be studied early on in the R&D process. In other instances, some of these more targeted indications —potentially more impactful for specific patient groups—are not realized until the later phases of clinical trials.

Whether during early stages of research or during later clinical trials, realization of these differences and then practical application in treatments is driving a new class of precision therapeutics. The time and resources necessary to perform this work increases with each year. These inventions must be protected in order to appropriately incentivize this R&D and the tremendous investment required to eventually get the product to patients.

In apparent recognition of this need and seizing on language regarding the application of natural phenomena to methods of treatment in the *Mayo* decision, the Federal Circuit in *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals*[2] distinguished the majority holding in *Mayo* and the

---

[1] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (S.Ct. 2012); Manual of Patent Examining Procedure, 9th Ed., Rev. 08.2017, §2106.

[2] *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.* (Fed. Cir. 2018)

Amgen Inc.
Thousand Oaks, CA 91320
www.amgen.com

Office promptly put forth a memorandum for examiners taking this decision into account[3]. The new guidance builds upon the *Vanda* decision and Office memorandum, adding more detailed instruction for a fact-based analysis under Step 2A. Among other things, the guidance reasserts that method of treatment claims that are a practical application of a natural phenomenom should be considered patent eligible under this modified analysis. This type of clear and concise guidance, grounded in court decisions, is very much appreciated by Amgen and the public at large.

We do have some suggestions to provide additional clarity. Although the new examples 37-42 are useful in providing context and practical application in certain technology areas, the Office should now provide additional examples with fact patterns more relevant to biopharma patents. Additional examples that are supported by the *Vanda* decision and the more recent *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*[4] decision would provide helpful direction for the biopharma industry. The Office should also reevaluate and revise any of the existing prior examples that now may have a different outcome. Finally, and if not already planned, the Office should provide more examiner training based on the new guidance so that uniformity of examination within and across art units occurs. All of this, of course, with the caveat that the *Vanda* case has a Supreme Court *certiorari* petition pending and timing for any additional examples and training should take this into account[5].

Amgen's comments in response to the Guidance for Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. §112

Although computer-implemented patents may not immediately be associated with the biopharma industry, we briefly wish to provide comments on this new guidance. From computer implemented dosing methods to artificial intelligence in molecule selection to automation of manufacturing processes, there is a confluence of technologies driving the next wave of innovation. The patent statute's many sections are designed to work in concert, assuring uniformity and predictability in the patent grant. §112 is an integral part of this, but it has not been consistently applied across all technologies. Accordingly, Amgen appreciates the Director's attempts to unify application of the law across differing technologies.

The §112 guidance addresses two issues related to examination of computer-implemented inventions: 1) examination of computer-implemented functional claims having means-plus-function claim limitations, and 2) written description and enablement issues related to the examination of computer-implemented functional claims. Amgen's views on the state of §112 case law are well known[6].

---

[3] June 7, 2018 USPTO Memorandum, Recent Subject Matter Eligibility Decision: Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals.
[4] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, (Fed. Cir. 2019)
[5] *Hikma Pharmaceuticals USA Inc. v. Vanda*, Petition for a Writ of Certiorari (December 2018), conference scheduled for March 15, 2019.
[6] see, for example, *Amgen Inc., Amgen Manufacturing Limited, and Amgen USA, Inc. v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals, Inc., and Sanofi-Aventis U.S., LLC*, Petition for a Writ of Certiorari (July 2018), cert. denied (Jan. 2019) ("*Amgen v. Sanofi* cert. petition").

Regardless of where the §112 patentability analysis lies, however, it should be applied with the same rigor across all technology areas.

Innovators like Amgen can drive the forefront of biopharma discovery, clearly satisfy the judicially created onerous written description and enablement tests, yet still be challenged for not providing enough[7]. In stark contrast, some computer-implemented patents can seemingly provide the barest shell of an outlined process, utterly devoid of "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."[8] Yet these sorts of computer-implement patents have been granted.

The current guidance appears to be a necessary attempt to address this disparate treatment between different technology areas. Not only will this result in more predictability in the patent grant, it should also result in fewer "bad patents" that have generated so much of the negative public discourse about our patent system. This serves the best interests of all innovative industries and the public. Amgen agrees with this new guidance and it is a welcome move to apply §112 more fairly across all technology areas.

Conclusion

Amgen again commends the Office for its continued efforts to improve our patent system, most recently with these two proposed sets of guidance. In tandem, these sets of guidance should work towards a goal of providing certainty, uniformity, and predictability to the public. Amgen believes that these proposals will help further this goal. We again thank the Director and the Office for the opportunity to provide comment, we hope these comments are useful, and we look forward to working with the Office in the future to continue to help in improving and optimizing our patent system.

Respectfully Submitted,

for Stuart L. Watt 3/8/19

Stuart L. Watt
Vice President, Law & Intellectual Property Officer
Amgen Inc.

3/8/19

Michael G. Penn
Principal Counsel
Amgen Inc.

[7] *Amgen v. Sanofi* cert. petition
[8] 35 U.S.C. 112(a) (2011)