Genentech
A Member of the Roche Group

March 8, 2019

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 Electronic Mail to Eligibility2019@uspto.gov (Docket PTO-P-2018-0053)

Dear Director Iancu:

Genentech**,** Inc., and Roche Diabetes Care, Inc., (collectively "Genentech") appreciate the opportunity to submit these comments in response to the United States Patent and Trademark Office's 2019 Revised Patent Subject Matter Eligibility Guidance (2019 Guidance) as set forth in 84 Fed. Reg. 50, published on January 7, 2019.

As a leading biotechnology company with over 15,000 employees dedicated to making life-saving medicine a reality, Genentech has been a consistent stakeholder in the U.S. patent system for over 40 years.[1] This commitment, combined with the dedication of our scientists and researchers, has generated over 20,000 patents. Today, Genentech has 38 medicines on the market and a promising development pipeline. Continuing our search for solutions to the toughest medical challenges depends on a stable, fair, and predictable patent system that rewards innovation and allows companies like Genentech to focus their resources on research and development.

Roche Diabetes Care is dedicated to improving the health and lives of people with diabetes by offering individuals and healthcare professionals innovative products and impactful solutions for convenient, effective, and efficient diabetes management. Our products and services include glucose monitoring devices, insulin delivery systems, and digital health solutions, comprising data management, advice, coaching, and education.

Genentech believes that the 2019 guidance will improve the predictability of patent grants and help insure that applications claiming patentable inventions are less likely to be improperly denied allowance based on section 101. The 2019 Guidance helpfully provides

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[1] Genentech, Inc., *Company Information*, http://www.gene.com/media/company-information (last visited Nov. 19, 2018).

procedures and guidance to "[a]ll USPTO personnel"[2] on how to assess patent subject matter eligibility issues given the complex body of case law that courts have developed over the past several years. Genentech also appreciates the USPTO's reiteration that "an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition" signals integration into a practical application.[3]

Genentech suggests that the USPTO develop updated life sciences examples implementing the new framework, much as the USPTO has already done with the new 2019 Software Eligibility Examples 37-42. In particular, it would be useful if the updated life sciences examples addressed composition claims and different types of method claims, including fact patterns in which a recited judicial exception is integrated into a practical application and fact patterns that show how additional elements might be included to signal integration of the recited judicial exception into a practical application.

Genentech appreciates the USPTO's efforts in the important patent eligibility area. Genentech also appreciates the opportunity to offer its perspective on this important issue. We look forward to continuing this helpful dialogue with the USPTO.

Respectfully submitted,

By: /s/ Laurie L. Hill

Title: Vice President, Intellectual Property
Genentech, Inc.

[2] 84 Fed. Reg. 50-57, 51 (January 7, 2019).

[3] *Id.* at 53 (citing *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066–68 (Fed. Cir. 2011); *Vanda*, 887 F.3d at 1135).