



A Member of the Roche Group

January 10, 2020

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 22313-1450

Via AIPartnership@uspto.gov

RE: Docket No. PTO-C-2019-0038, Request for Comments on Intellectual Property Protection for Artificial Intelligence Innovation

Dear Director Iancu:

Genentech, Inc., a member of the Roche Group, is a U.S. company that has been investing in American innovation and delivering on the promise of biotechnology for over 40 years. Roche Diabetes Care is a U.S. company that 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. Roche Molecular Solutions is a U.S. company that develops, manufactures and supplies a wide array of innovative medical diagnostic products with a broad portfolio including oncology, virology, microbiology, and blood screening tests. We are all dedicated to following the science and in doing so, we recognize the significant role that Artificial Intelligence (AI) has and will play in a future of medicine that is much more personalized and tailored to each patient.

We appreciate the U.S. Patent and Trademark Office's (USPTO) continued dedication to promoting the reliability and predictability of intellectual property rights for AI through this second request for comments, and we are grateful for the opportunity to provide our thoughts on this important issue.

As stated in our recent comments to the USPTO on "Patenting Artificial Intelligence Inventions," we firmly believe that the possibilities of AI combined with biotechnology are endless, and any USPTO guidance on AI-based innovation should incentivize further advancement in this field.

In general, as in our patent comments, we think that existing intellectual property laws already provide a workable framework for the majority of AI-based intellectual property at present.

¹ See Comments of Genentech and Roche Diabetes Care to the USPTO in response to the "Request for Comments on Patenting Artificial Intelligence Inventions," Nov. 8, 2019.

Applied properly, these existing tools should ensure that original works of authorship containing AI that are properly fixed in a tangible medium of expression are eligible for copyright protection. That said, we recognize the endless potential that AI has to reshape the intellectual property landscape over time. Accordingly, we generally believe that the USPTO and the Copyright Office should take an incremental approach to dealing with AI-based innovations—one that primarily relies on existing law and uses targeted guidance documents that can be refined to address any novel issues that arise at the outer bounds of common practice.

Before providing our specific answers to the questions that the USPTO posed in the Federal Register Notice, our comments begin with additional information about Genentech, Roche Diabetes Care, and Roche Molecular Solutions, some clarification of terminology, and a discussion of the use of AI-based innovation in the future of medicine. Our unique perspective on the role of AI-based computational modeling in the emerging field of bioinformatics and other biomedical applications informs the responses that follow.

Genentech, Roche Diabetes Care, and Roche Molecular Solutions

At Genentech, we make medicines to treat people living with serious and life-threatening diseases. We are transforming the treatment of serious medical conditions, including cancer, autoimmune conditions, and infectious diseases. Last year alone, 127 million patients worldwide benefited from our medicines.

Genentech has always been at the forefront of the biotechnology revolution. We were the first company to develop recombinant therapeutic human proteins approved by the U.S. Food and Drug Administration (FDA) starting in the 1980s, such as recombinant human growth hormone. Genentech also pioneered the use of revolutionary antibodies to treat various types of cancer, such as HERCEPTIN® for HER2-positive breast cancer; RITUXAN® for chronic lymphocytic leukemia and rheumatoid arthritis, among other indications; and AVASTIN® for certain cancers, including colorectal, glioblastoma, and ovarian cancer. More recently, Genentech received approval for the first antibody treatment for Hemophilia A.

Today, Genentech has over 40 medicines on the market and a promising development pipeline. These medicines represent just the beginning of our journey in finding breakthrough therapies—and indeed, cures—through innovations that build on what we know to push the boundaries of scientific advancement and treatment.

Every day, our teams work to solve some of the hardest biomedical problems, always with the goal of putting patients first. However, the life-changing work of our scientists depends on a stable and predictable intellectual property system that rewards innovation.

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. Roche Diabetes Care is investigating utilizing AI in digital health to interpret and use massive amounts of data to improve efficiency, provide insights, accelerate the pace of innovation and personalize health care.

Roche Molecular Solutions offers comprehensive in vitro diagnostic solutions, covering molecular diagnostics, based on Nobel Prize-winning Polymerase Chain Reaction; Roche Sequencing Solutions, Roche Tissue Diagnostics and IT and Decision support solutions that include NAVIFY Tumor Board. From liquid biopsy to innovative technologies that enable quicker, more effective identification of multidrug-resistant organisms, Roche Molecular Solutions is committed to developing diagnostic solutions that allow clinicians to determine the best possible course of care for individual patients. Roche Molecular Solutions is investigating the potential of AI to improve diagnostic solutions for patients as well.

The Future of Medicine Utilizes Artificial Intelligence

Genentech, Roche Diabetes Care, and Roche Molecular Solutions (collectively referred to as “Genentech”) firmly believe that the possibilities of AI combined with biotechnology are endless. Accordingly, it is critical to ensure a stable and certain environment for investment in the future of innovation, which is likely to include more and more innovation involving AI. The USPTO is taking an important step in soliciting input on the relationship between AI and intellectual property rights. We look forward to working cooperatively in the future to make sure the legal framework for protecting AI provides a solid foundation for the revolution that is coming in medical treatment.

At the outset, we want to clarify that our use of the term “artificial intelligence” is a targeted definition. Specifically, we use the term primarily to refer to computational modeling, such as statistical analyses, neural networks, data science, and machine learning (including deep learning). This is different from the colloquial, all-purpose nature of the term “artificial intelligence” that is used in general parlance. Most notably, our targeted definition is not focused on so-called “artificial general intelligence,” which is a different category of AI relating to self-aware, intelligent machines. In our field, the development of artificial general intelligence remains some way off in the future and is not representative of the current use of AI by Genentech or, for that matter, most companies.

With that definitional clarification in mind, one important transformation underway today is the rise of bioinformatics, in which biotechnology and computational modeling are brought together to inform all stages of personalized medicine. ² Areas of focus include medicine development, diagnostic development, and patient treatment.

² See *Artificial Intelligence: Will It Change the Way Drugs are Discovered?*, The Pharmaceutical Journal (2017), available at www.pharmaceutical-journal.com/news-and-analysis/features/artificial-intelligence-will-it-change-the-way-drugs-arediscovered/20204085.article; Bertalan Mesko (2017) *The role of artificial intelligence in precision medicine*, Expert Review of Precision Medicine and Drug Development, 2:5 (2017),

For example, personalized cancer therapeutics, which are currently in development, are a promising form of treatment that use nucleic acid sequences to encode a portion of a patient's own tumor in order to stimulate the patient's immune system to fight the tumor. These more natural treatments have the potential to be more effective and less harmful than conventional therapies. But such personalized cancer therapeutics would not be possible without the AI-based computational modeling necessary to decode information and determine the personalized composition of the appropriate therapeutic for each patient.

In another area, AI-based technology is now being used to inform clinical trial design, leading to innovative trial designs and analyses that promise to reduce the cost of clinical trials and to expedite product approvals.³

Data representative of real-world patient populations is required to improve clinical outcomes for patients, and we are beginning to aggregate and harness real-world data as a powerful complement to traditional clinical trials.

Personalized medicine has the goal of finding the right treatment for each patient, by analyzing each patient's molecular characteristics and using that information to select the correct treatment for the patient. Bioinformatics, increasingly with the help of AI-based computational modeling, will be an integral, cost-effective tool in making this process possible. Data inputs for this process include, for example, the full genetic makeup of a patient and the patient's tumor, liquid (or non-blood fluid) biopsies, and data acquired in everyday clinical practice, such as diagnostics tests and scans. AI is the critical key in helping to analyze these vast amounts of diverse data inputs and selecting personalized treatments for patients based on such data inputs.

The future of medicine is also likely to include an increase in the use of software in medical devices and consumer- or doctor-facing apps. A variety of intellectual property protection — be it through patents, trademarks, trade dress, copyright, design patents, or trade secrets — is critical to protecting the app design and the underlying software used in such apps. Trademark, trade dress, and design patent protection are especially important for medical devices and consumer- or doctor-facing apps in order to prevent consumer confusion. In the life sciences,

239-241, available at <https://doi.org/10.1080/23808993.2017.1380516>; *Artificial Intelligence In Clinical Development and Regulatory Affairs*, The Regulatory Rapporteur, 15:10 (2018), available at www.topra.org.

³ Roche, *Medical software and the value of digital health*, <https://www.roche.com/about/business/diagnostics/value-of-digital-health.htm> (last visited Dec. 23, 2019); Lee & Park, *Personalizing the Future of Healthcare* (2018), <https://www.gene.com/stories/personalizing-the-future-of-healthcare>; Arnaub Chatterjee et al., McKinsey & Co., *Real-world evidence: Driving a new drug-development paradigm in oncology* (July 2018), <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/real-world-evidence-driving-a-new-drug-development-paradigm-in-oncology>; Elia Stupke, Health Catalyst White Paper, *Extended Real-World Data: The Life Science Industry's Number One Asset* (2019), <https://www.healthcatalyst.com/insights/real-world-data-chief-driver-drug-development>; Jackie Hunter, Drug Target Review, *How artificial intelligence is the future of pharma* (2016), <https://www.drugtargetreview.com/article/15400/artificial-intelligence-drug-discovery/>.

knock-off apps could be extremely dangerous to the health and well-being of the patients relying on such apps.

FLOODLIGHT Open is an example of a Genentech-led study that uses app-based technology to securely aggregate data from multiple sclerosis patients.⁴ By monitoring multiple sclerosis patients all year, instead of two to three days per year, FLOODLIGHT Open is intended to help doctors and researchers see “big picture” trends in the data that could help improve understanding of the disease and how it may lead to disability over time. The data collected are freely available to doctors and researchers to help accelerate further research and inspire collaboration to understand and work toward a cure for multiple sclerosis patients.

Another example is Roche Diabetes Care’s “mySugr,” a diabetes management app and “digital logbook” where patients can directly upload glucose and other data directly from their smart devices.⁵ The mySugr app provides data analysis, therapy advice, game challenges, and coaching services, among other services, to make the lives of diabetes patients easier.

Yet another example is Roche Diagnostics’ NAVIFY Tumor Board, a cloud-based decision support workflow product that securely integrates and displays aggregated data into a single, holistic patient dashboard for oncology care teams to review, align, and decide on the optimal treatment for the patient.⁶

To achieve the level of quality and precision necessary to make bioinformatics tools commonplace technology available for patients, however, we must make significant investment at the outset. Unlike software that can be launched at an early stage and developed, corrected, and extended to an appropriate performance level while in the marketplace through a sometimes endless series of updates, use of bioinformatics to inform serious patient treatment decisions or to design personalized medicines requires precision and more upfront investment at the beginning of the process so that it can receive regulatory approval and perform with stability, accuracy, and predictability from the moment it launches.

In order to protect investment in such technologies, there must be no question that such innovations are eligible for intellectual property protection — be it via copyright or patent laws — and that the USPTO and Copyright Office treat AI-based innovation in a clear and reliable manner.

One of the principal purposes of the intellectual property system is to encourage public disclosure, which enriches the storehouse of common knowledge that others can draw on in creating their own innovations. Ideally, our intellectual property laws will adequately keep pace with AI innovation such that patent and copyright laws, that facilitate public disclosure, can be utilized. However, should AI outpace the intellectual property laws, it could discourage the use

⁴ See *What is Floodlight Open*, <https://floodlightopen.com/en-US/>.

⁵ See <https://mysugr.com/en-us/diabetes-app>.

⁶ See <https://www.navify.com/tumorboard/>.

of the patent and copyright systems and harmfully shift the balance in favor of alternatives such as trade secrets, which do not bring the same public disclosure benefits to society.

1. Should a work produced by an AI algorithm or process, without the involvement of a natural person contributing expression to the resulting work, qualify as a work of authorship protectable under U.S. copyright law? Why or why not?

As noted above, we believe the scenario envisioned by this question assumes a degree of autonomy by a “general AI system” that is more of an aspiration than a present reality in our field.

Accordingly, we believe that existing authorship laws and regulations provide a workable framework for identifying the owners of an AI-based work. Section 305 of the U.S. Copyright Office’s Compendium of U.S. Copyright Office Practices states:

U.S. Copyright Office will register an original work of authorship, provided that the work was created by a human being. The copyright law only protects ‘the fruits of intellectual labor’ that ‘are founded in the creative powers of the mind.’ (citation omitted) Because copyright law is limited to ‘original intellectual conceptions of the author,’ the Office will refuse to register a claim if it determines that a human being did not create the work.

Since all or nearly all copyrighted works containing AI in the life sciences field are still “created by a human being,” such works should be properly eligible for copyright protection under the Copyright Office’s framework. In contrast to *Naruto v. Slater*, better known as the “monkey selfie case,” where the Ninth Circuit held that the “monkey – and all animals, since they are not human – lack[ed] statutory standing under the Copyright Act,” the works in our field must be eligible for copyright protection because human creativity is present in each work. *See Naruto v. Slater*, No. 16-15469 (9th Cir. 2018). However, we agree with the logic of both the Copyright Office and the Ninth Circuit, that if a work lacks human creativity, that work should be ineligible to meet the “authorship” requirements under the existing copyright laws.

Again, we urge the USPTO and the Copyright Office to tread carefully in their assessment of a “computer creator” as we see how the technology develops in this area. The treatment of AI by the USPTO and the Copyright Office on the question of authorship is likely to create incentives that impact AI innovation one way or the other. Accordingly, perhaps continuous evaluation of this question in the short-term makes the most sense, given the aspirational nature of autonomous AI at this time.

⁷ See U.S. Copyright Office, Compendium of U.S. Copyright Office Practices, Copyrightable Authorship, Section 305 <https://www.copyright.gov/comp3/chap300/ch300-copyrightable-authorship.pdf>.

2. Assuming involvement by a natural person is or should be required, what kind of involvement would or should be sufficient so that the work qualifies for copyright protection? For example, should it be sufficient if a person (i) designed the AI algorithm or process that created the work; (ii) contributed to the design of the algorithm or process; (iii) chose data used by the algorithm for training or otherwise; (iv) caused the AI algorithm or process to be used to yield the work; or (v) engaged in some specific combination of the foregoing activities? Are there other contributions a person could make in a potentially copyrightable AI-generated work in order to be considered an “author”?

As per our response to Question 1, we believe that scenarios (i)-(v) could all contain the degree of human contribution necessary to meet the threshold question of authorship under the copyright laws. The Copyright Office would then need to determine whether the other requirements of copyright law are met.

3. To the extent an AI algorithm or process learns its function(s) by ingesting large volumes of copyrighted material, does the existing statutory language (e.g., the fair use doctrine) and related case law adequately address the legality of making such use? Should authors be recognized for this type of use of their works? If so, how?

As per our response to question 1, we believe the scenario envisioned by this question assumes a degree of autonomy by a “general AI system” that is more of an aspiration than a present reality in our field. However, if the AI system is specifically designed by a human to ingest copyrighted material to produce a new work, we urge additional study on the questions of whether and when that use could be considered “fair” under the statute and related case law, as well as whether and when the results produced by such a process would be considered a derivative work.

4. Are current laws for assigning liability for copyright infringement adequate to address a situation in which an AI process creates a work that infringes a copyrighted work?

Please see the response to questions 1 and 2.

5. Should an entity or entities other than a natural person, or company to which a natural person assigns a copyrighted work, be able to own the copyright on the AI work? For example: Should a company who trains the artificial intelligence process that creates the work be able to be an owner?

We believe that existing copyright law provides a workable framework for identifying the owners of an AI-based work.

6. Are there other copyright issues that need to be addressed to promote the goals of copyright law in connection with the use of AI?

Not at this time, however we urge the USPTO and the Copyright Office to tread carefully as we see how innovation develops in this area. The treatment of AI by the USPTO and the Copyright Office on the question of authorship is likely to create incentives that impact AI innovation one way or the other. Accordingly, perhaps continuous evaluation of this question in the short-term makes the most sense, given the aspirational nature of autonomous AI at this time.

7. Would the use of AI in trademark searching impact the registrability of trademarks? If so, how?

We do not have a position on question 7 at this time.

8. How, if at all, does AI impact trademark law? Is the existing statutory language in the Lanham Act adequate to address the use of AI in the marketplace?

We are currently reviewing how AI does and may impact trademark law and whether the existing statutory language in the Lanham Act is adequate to address the use of AI in the marketplace. We look forward to continuing the dialogue with the USPTO on these questions after we conclude our review and as the USPTO continues its exploration of how AI does and may impact trademark law, now and in the future.

9. How, if at all, does AI impact the need to protect databases and data sets? Are existing laws adequate to protect such data?

AI certainly has great potential to impact databases and data sets in the future of the life sciences industry. In our field, meaningful application of data and AI has the potential to address some of the greatest challenges in medicine to the great benefit of our patients.

We urge the USPTO and the Copyright Office to continue to study the impact of AI and the need to protect databases and data sets as this relates to incentivising important innovation, particularly for life sciences and the future of medicine, and we look forward to continuing this discussion as the technology continues to develop in this area.

10. How, if at all, does AI impact trade secret law? Is the Defend Trade Secrets Act (DTSA), 18 U.S.C. 1836 et seq., adequate to address the use of AI in the marketplace?

To the extent that the combination of the patent and copyright systems fail to protect bioinformatics—for example, through overly stringent originality interpretations or an overly broad interpretation of the exceptions to Section 101—trade secret law may be the only viable protection available to ensure that bioinformatics and other practical applications of AI in biotechnology are protected forms of intellectual property. However, trade secret protection over

AI systems may be imperfect if and/or when transparency is too robustly required to secure regulatory approval in the life sciences. Accordingly, if trade secret protection is too difficult to maintain over AI systems for our industry, the Defend Trade Secrets Act would, of course, be inadequate to address the use of AI in the marketplace.

If trade secret protection is insufficient, some alternative, *sui generis* form of protection might be required in order to incentivize the substantial upfront investment required to achieve a system reliable enough to find use in medicine. Such investment is unlikely to happen without some form of protection.

11. Do any laws, policies, or practices need to change in order to ensure an appropriate balance between maintaining trade secrets on the one hand and obtaining patents, copyrights, or other forms of intellectual property protection related to AI on the other?

As noted in our response to question 10, there may be instances, be it through overly stringent originality interpretations or an overly broad interpretation of the exceptions to Section 101, for instance, where the combination of patent and copyright systems fail to protect bioinformatics. Moreover, as also noted in our response to question 10, there may be circumstances that make it difficult to maintain trade secret protection over aspects of AI systems in the life sciences space as well. Although we are still evaluating how the technology is developing in this area, we urge the USPTO and the Copyright Office to proceed cautiously and deliberately so that innovation in AI, including exploration of AI in the life sciences field is incentivized, and not inadvertently left unprotected. If copyrights, patents, and/or trade secrets fail as viable intellectual property protections, perhaps robust regulatory exclusivity through the FDA or a new form of intellectual property right specific to AI may be required, complete with equally robust enforcement provisions as exist for other forms of intellectual property.

We urge the USPTO and the Copyright Office to continue to evaluate such potential protection gaps as AI innovation continues to develop, so as to ensure that the intellectual property laws are applied equitably among all industries. Possible “gaps” in protection risk discouraging advancement of AI-based innovation, just as we are at the cusp of realizing the potential AI-based computational modeling holds for improving medicine. Several life sciences companies are already exploring how digital therapeutics can make a meaningful difference in the lives of people diagnosed with Autism or for individuals diagnosed with post-traumatic stress disorder. Other companies, as well as Genentech, are investing to embed AI-based techniques in all aspects of drug discovery, development, and personalized medicine and diagnostics, as discussed in the personalized cancer therapeutics examples above. Any categorical cutoff of what can be protected would impinge on all companies’ ability to advance development for patients in these promising innovative areas.

12. Are there any other AI-related issues pertinent to intellectual property rights (other than those related to patent rights) that the USPTO should examine?

We do not have a position on questions 12 and 13 at this time.

13. Are there any relevant policies or practices from intellectual property agencies or legal systems in other countries that may help inform USPTO's policies and practices regarding intellectual property rights (other than those related to patent rights)?

Please see response to question 12.

Conclusion

We applaud the USPTO for requesting stakeholder input on such important questions to assess the existing intellectual property protections for AI-based inventions, and explore gaps that may need protection in the future. We believe AI is and will be instrumental in achieving a future of medicine that is better tailored to each individual patient. Intellectual property protection for such AI-inventions is absolutely critical to advancing these overall goals and we thank you for your leadership on this issue.

Sincerely,

/Laurie L. Hill/

Laurie L. Hill

Vice President, Intellectual Property
Genentech, Inc., A Member of the Roche Group