Genentech
A Member of the Roche Group

November 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 22313-1450

Via AIPartnership@uspto.gov

RE: Request for Comments on Patenting Artificial Intelligence Inventions

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. We are 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) dedication to promoting the reliability and predictability of patenting AI, and we are grateful for the opportunity to provide our comments on this important issue.

We firmly believe that the possibilities of AI combined with biotechnology are endless, and any USPTO guidance on AI-based inventions should incentivize further innovation in this field. In general, we think that existing laws, including inventorship law and the current version of Section 112, provide a workable framework for AI-based inventions at present. Applied properly, these existing tools should ensure that practical applications of AI are patent eligible, but that claims provide sufficient detail to make clear what has been invented without being unduly vague, or sweeping far beyond an inventor's contribution. Accordingly, we generally believe that the USPTO should take an incremental approach to dealing with AI-based inventions—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 and Roche Diabetes Care, some clarification of terminology, and a discussion of the use of AI-based inventions in the future of medicine. Our unique perspective on the role of AI-based

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computational modeling in the emerging field of bioinformatics and other biomedical applications informs the responses that follow.

Genentech and Roche Diabetes Care

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 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 patent 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.

The Future of Medicine Utilizes Artificial Intelligence

Genentech and Roche Diabetes Care (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 the patent system, and we look

forward to working cooperatively in the future to make sure the legal framework for patenting 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. The development of artificial general intelligence generally 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. Areas of focus include medicine development, diagnostic development, and patient treatment.[1]

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 treatment regimens 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.[2] Data representative of real-world patient populations is required to

[1] *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), 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.

[2] Roche, *Medical software and the value of digital health*, https://www.roche.com/about/business/diagnostics/value-of-digital-health.htm (last visited Oct. 24, 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),

improve clinical outcomes for patients, and we are beginning to harness and aggregate 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 use of software in medical devices and consumer- or doctor-facing apps. FLOODLIGHT Open is an example of a Genentech-led study that uses app-based technology to securely aggregate data from multiple sclerosis patients.[3] 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.

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 patent eligible and that the USPTO treats claims to AI-based inventions in a clear and reliable manner. One of the principal purposes of the patent system is to encourage public disclosure, which enriches the storehouse of common knowledge that others can draw on in creating their own innovations. Failure to achieve a system of strong, stable protection will discourage use of the patent system in favor of alternatives such as trade secrets, which do not bring the same benefits in terms of public disclosure.

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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/.

[3] *See What is Floodlight Open*, https://floodlightopen.com/en-US/.

Responses to Questions

1. *Inventions that utilize AI, as well as inventions that are developed by AI, have commonly been referred to as ''AI inventions.'' What are elements of an AI invention? For example: The problem to be addressed (e.g., application of AI); the structure of the database on which the AI will be trained and will act; the training of the algorithm on the data; the algorithm itself; the results of the AI invention through an automated process; the policies/weights to be applied to the data that affects the outcome of the results; and/or other elements.*

   We want to applaud the USPTO for asking these important questions, which we believe identify many elements of AI-based inventions.[4] Differences in these elements, and others identified below, can have a big effect on the performance of AI-based computational modeling. A substantial amount of experimentation to select the right mix of inputs, models, weights, and other elements goes into the creation of AI-based inventions.

   In addition to the factors listed above, the type and representation of data used for every model should be considered as an element of an AI invention. The categories of data used with a particular model and the way a particular model captures data can be quite different and nuanced and this can impact performance of the model.

   The specific algorithm used in a computational model is also a relevant consideration, along with the other factors considered in the question. The field of AI involves many techniques, and new ones are rapidly being invented. Examples include various types of regressions; tree-based models, such as random forest classifiers; and neural network-based architectures, including convolutional neural networks and reinforcement learning models. Some models may be more appropriate to the data available in a particular technology area over others. For example, a classifier that determines the progression of a neurological condition in patients may perform better with some types of data (*e.g.*, age, smoking status), while performing worse with others (*e.g.*, weight, geographic place of residence). These choices of algorithm, along with the type and representation of the data and other factors, may make the difference in designing a clinically relevant tool versus one that does not provide useful information to patients.

   Additionally, the process by which a computational model is trained to make a prediction may make a further difference. For example, the performance of a neural network depends not only on the number of nodes in the network and how they are interconnected, but also on weights initially attributed to each node and each interconnection. As the neural network gets exposed to and learns from more and newer data, how the algorithm adjusts the weights dictates the accuracy of the prediction.

   In our experience, these details matter to the performance of the resulting tool and the ultimate outcome for the personalized medicine examples discussed above. Although not

[4] For this discussion, we set aside the issue of inventions developed by forms of artificial general intelligence that largely remain in the future, as discussed *supra*.

every element may be as important for every claim, the claims should provide enough detail on these types of factors that is clear what has been invented.

2. *What are the different ways that a natural person can contribute to conception of an AI invention and be eligible to be a named inventor? For example: Designing the algorithm and/or weighting adaptations; structuring the data on which the algorithm runs; running the AI algorithm on the data and obtaining the results.*

   The following answer addresses both questions 2 and 4.

   We believe that existing inventorship law provides a workable framework for identifying the inventors of an AI-based invention. Although the law can require judgment calls in close cases, several high-level principles appropriately guide the analysis.[5]

   First, current law requires that there be collaboration for someone to be considered a joint inventor. *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1307-1308 (Fed. Cir. 2010) ("[A] group of co-inventors must collaborate and work together to collectively have a definite and permanent idea of the complete invention."); *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1227 (Fed. Cir. 1994) ("A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed."). This limits the scope of who can be considered an inventor and helps ensure that only contributions to the invention that are fairly direct will qualify someone as a joint inventor.

   Second, merely "teaching skills or general methods that somehow facilitate a later invention, without more, does not render one a coinventor." *Board of Educ. ex rel. Bd. of Tr. of Florida State Univ. v. American Bioscience, Inc.*, 333 F.3d 1330, 1342 (Fed. Cir. 2003). Instead, "each joint inventor must contribute in some significant manner to the conception of the invention." *BJ Services Co. v. Halliburton Energy Services, Inc*., 338 F.3d 1368, 1373 (2003).

   Third, current law focuses on exactly what is claimed. Not every point on which parties cooperate will necessarily be reflected in the claims of an issued patent, so it is important to focus on the claimed invention when assessing whether a party has made an inventive contribution. Moreover, alleged contributions must be significant when "measured against the dimension of the full invention." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Not all contributions must be equal, but contributions that are minor or insignificant in quality do not make someone a joint inventor.

   Fourth, current law considers what makes a claim inventive. "A contribution of information in the prior art cannot give rise to joint inventorship because it is not a contribution to conception." *Eli Lilly & Co. v. Aradigm Corp*., 376 F.3d 1352, 1362 (Fed. Cir. 2004). Likewise, "the basic exercise of ordinary skill in the art, without an inventive act, does not make one a joint inventor." *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1302 (Fed.

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Cir. 2002). For example, one who merely works as a "pair of hands" at the direction of another or exercises ordinary skill to reduce an invention to practice is not generally credited as a joint inventor.

These established principles help ensure that inventorship roughly follows investment and is not allocated too far upstream or downstream. The idea is to reward investment in unproven ideas and recognize that such investments are often the result of many people's efforts, without spreading credit for inventorship so thin that the incentive is diminished.

Applying these principles to AI-based inventions, the provider of off-the-shelf software should not normally be considered an inventor of innovative new uses of that software by its customers because there will not normally be the requisite degree of collaboration on the conception of the new invention and the software itself may be in the prior art. A person who is just using ordinary skill (*e.g.*, training a particular AI model according to the design and at the direction of someone else) should not normally qualify either.

In contrast, someone who links a particular algorithmic technique to the problem and technology area to be addressed, modifies the design of the algorithm (*e.g.*, through the selection of features to be included in the model or the architecture of the processing to performed, for example by changing the layers of a neural network), or trains the algorithm in a way that requires more than just the exercise of ordinary skill would normally be considered an inventor.

3. *Do current patent laws and regulations regarding inventorship need to be revised to take into account inventions where an entity or entities other than a natural person contributed to the conception of an invention?*

We appreciate the interesting issue posed by Question 3 and recognize that the USPTO is grappling with this question in a pending patent application. That said, we believe that the scenario envisioned by this question assumes a degree of autonomy by a "general AI system" that is generally more of an aspiration than a present reality and so we do not have a position on Question 3 at this time. It would seem that if a company uses a system that genuinely makes contributions to an invention, there should be a mechanism for any resulting rights to be assigned to the company.

We urge the USPTO to tread carefully in its assessment of a "computer inventor" as we see how the technology develops in this area. As noted in our response to Question 2, the treatment of AI by the Office on the question of inventorship is likely to create incentives that impact AI innovation one way or the other. Accordingly, perhaps temporary guidance and continuous evaluation of Question 3 in the short-term makes the most sense, given the aspirational nature of autonomous AI at this time.

4. *Should an entity or entities other than a natural person, or company to which a natural person assigns an invention, be able to own a patent on the AI invention? For example:*

Should a company who trains the artificial intelligence process that creates the invention be able to be an owner?

Please see the response to question 2.

5. *Are there any patent eligibility considerations unique to AI inventions?*

We appreciate the Office's proactive patent eligibility guidance that was published in January 2019 and updated in October 2019, and we believe that practical applications of AI should be patent eligible. This does not necessarily require the creation of new principles unique to AI. But given the confusion in the case law, it is important to ensure that the judicially-created exceptions to Section 101 do not broadly preclude patents on inventions that apply AI-based computer modeling in a new and useful way.

For example, an algorithm that supports clinical oncology decisions by analyzing patient computed tomography (CT) images in a specific, novel way to determine whether or not a tumor is responding to treatment is a practical application of AI and should therefore be eligible, assuming it is properly supported under Section 112 and meets all other statutory requirements. Such a claim is not directed to an abstract idea or natural law, but rather is directed to a series of specific steps that achieve the useful result of improving medical treatment.

We are merely 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 patented would impinge on all companies' ability to protect and advance development for patients in these promising innovative areas.

6. *Are there any disclosure-related considerations unique to AI inventions? For example, under current practice, written description support for computer-implemented inventions generally require sufficient disclosure of an algorithm to perform a claimed function, such that a person of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention. Does there need to be a change in the level of detail an applicant must provide in order to comply with the written description requirement, particularly for deep-learning systems that may have a large number of hidden layers with weights that evolve during the learning/training process without human intervention or knowledge?*

The following answer addresses both questions 6 and 7.

We appreciate the Section 112 guidance that the USPTO issued in January 2019. We agree that concerns about purely functional limitations "are particularly relevant to computer-implemented functional claims." 84 Fed. Reg. 57, 57 (Jan. 7, 2019). We also agree that "the scope of protection sought by the claims" should remain "commensurate with what the applicant described and enabled." *Id*. at 62. Existing tools should be sufficient to achieve these goals, but there may need to be changes in the way those tools are applied to account for the differences between the relative predictability of traditional software and the relative unpredictability of AI-based inventions.[6]

The biotechnology industry has long been familiar with the robust application of Section 112 tools in an unpredictable art. These tools may be less familiar or less rigorously applied in the world of traditional software patents where inventions have traditionally involved claims consisting of rigid logical operations on data. With the increasing shift to the use of AI, however, Section 112 principles developed in less predictable arts such as the life sciences may play a useful role, because AI-based computational modeling introduces greater uncertainty and experimentation than traditional software patents.

This may require a change in how the data processing and software art units within the USPTO handle AI-based patent applications. When considering software patents in these traditionally "predictable arts," mere disclosure of an algorithm along with a statement of the utility of that algorithm is often enough to satisfy both the written description and enablement prongs of Section 112. The algorithm may be expressed "in any understandable terms including as a mathematical formula, in prose, or as a flow chart." *Finistar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008). There may also be heavy reliance on the background skill in the art given the "high level of predictability in generating programs to achieve an intended result without undue experimentation." 84 Fed. Reg. at 62.

AI-based computational modeling is different. It substitutes logic grounded in probability for the rigid logical operations seen in traditional software. As discussed in response to question 1, differences in numerous factors—including the type of data selected, the way the data is represented, the models used, the weights selected, and the training process—can all affect the performance of the modeling. The creation of AI-based inventions thus tends to be far more experimental than traditional software development.

The greater degree of unpredictability associated with AI-based inventions makes it appropriate to apply the written description requirement and the enablement factors from *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), more like they have been applied in the life sciences. As the USPTO has recognized, "[t]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." 84 Fed. Reg. at 61. Similarly, the quantity of experimentation necessary (*Wands* factor 1), the nature of the invention (*Wands* factor 4), the state of the prior art (*Wands* factor 5), and the predictability or unpredictability of the art (*Wands* factor 7), should all inform the USPTO's assessment of the amount of

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direction or guidance presented (*Wands* factor 2), the presence or absence of working examples (*Wands* factor 3), and the breadth of the claims (*Wands* factor 8).

None of this requires the creation of new tools. But it may require additional training to ensure that those less familiar with applying existing Section 112 tools in an unpredictable art do not approach AI-based inventions in the same way as traditional software patents.

7. *How can patent applications for AI inventions best comply with the enablement requirement, particularly given the degree of unpredictability of certain AI systems?*

Please see the response to question 7.

8. *Does AI impact the level of a person of ordinary skill in the art? If so, how? For example: Should assessment of the level of ordinary skill in the art reflect the capability possessed by AI?*

AI is a tool that may be available to a person of ordinary skill in the art, just like any other tool. But the USPTO must be very cautious in assessing which uses of that tool are considered merely the exercise of ordinary skill in the art for purposes of challenging an invention as obvious based on the possibility that the claimed invention could have been achieved with the use of artificial intelligence. There is a serious risk that AI will be used to short-circuit a proper obviousness analysis based on unduly optimistic assumptions about what could have been achieved with AI. Factoring AI into the level of ordinary skill would thus require constant vigilance against hindsight.[7]

As an initial matter, careful consideration should be given to the field in which the AI is being applied. AI-based techniques remain beyond the skill level of ordinary artisans in many fields. Careful consideration also should be given to how the AI-based tool is used. To the extent using the tool to reach a particular outcome would itself have required innovation, that outcome should not be treated as obvious.

For example, an invention could contain a connection between particular features of data and some aspect of a disease's biology. AI may be the specific tool through which the invention is physically implemented, and the claim may include steps about AI's use in the diagnosis, prognosis, or treatment. However, the connection between the data and a particular outcome achieved by an AI model in this instance would itself require innovation beyond the skill level of an ordinary artisan in the field, as the outcome was not a given at the beginning of the inventor's effort. In this scenario, that outcome should not be treated as obvious, regardless of the use of AI in the invention.

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9. *Are there any prior art considerations unique to AI inventions?*

Ordinary prior art rules should apply to AI just as they apply to other technologies. AI may create challenges in identifying prior art and may increase reliance on the on-sale and public bars to the extent prior art AI references do not disclose complete information. But both of those challenges are already familiar from the field of software.[8]
One issue that may arise with some frequency is the question of which improvements in accuracy should be considered a non-obvious improvement over the prior art. In general, we believe that merely achieving a marginal increase in accuracy by having better data would not normally be considered a patentable invention. Materially improving accuracy by using different types of data or adjusting the features/parameters of a model, however, could be the type of improvements that might be considered non-obviousness.

10. *Are there any new forms of intellectual property protections that are needed for AI inventions, such as data protection?*

Our experience with AI is that there is a division of labor between patent and trade secret, and possibly copyright protection. We believe that both patent and trade secret protection have valid roles and that the two can easily co-exist, with patent protection being used to claim particular techniques and applications, while trade secret protection protects aspects such as the underlying data. Copyright protection may also be used to protect certain data sets or other original fixed works of authorship that meet the requirements of the copyright laws.

However, to the extent the patent system fails to protect bioinformatics—for example, through an overly broad interpretation of the exceptions to Section 101—some alternative, *sui generis* form of protection might be required to ensure that bioinformatics and other practical applications of AI in biotechnology are protected forms of intellectual property. The upfront investment required to achieve a system reliable enough to find use in medicine can be huge, and the transparency required for regulatory approval may make it hard to maintain trade secret protection over AI systems. Such investment is not going to happen without some form of protection. If patents fail here, perhaps robust regulatory exclusivity through the FDA or a new form of intellectual property right specific to AI may be required.

11. *Are there any other issues pertinent to patenting AI inventions that we should examine?*

The nature of AI-based claims, particularly the ease of portability of a trained AI model which may be stored in a simple flash drive and run on a server from any country, can make them uniquely vulnerable to circumvention through divided infringement and cross-border infringement. Some of these problems can be addressed through the use of system claims, for which some protection is provided by the definition of "use" applied in *NTP, Inc. v. Research in Motion, Ltd*., 418 F.3d 1282 (Fed.Cir.2005), and *Centillion Data Systems v. Qwest Communications*, 631 F.3d 1279 (2011). There remains a risk, however, that copiers

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will structure their operations so they practice AI-based inventions in jurisdictions with weaker protection and send results back to places with more robust patent protection. This will undermine the competitiveness of U.S. companies.

Accordingly, we kindly request that as the USPTO provides input on projects related to foreign patent protection, it should advocate for closing loopholes that would permit U.S. patent protection to be circumvented. We also request that the USPTO avoid examples that would create obvious divided infringement problems in any guidance or training materials on AI that it prepares.

12. *Are there any relevant policies or practices from other major patent agencies that may help inform USPTO's policies and practices regarding patenting of AI inventions?*

We appreciate the USPTO's wisdom in exploring any relevant policies or practices from other jurisdictions, and we are glad to provide our perspective of interactions with the European Patent Office (EPO) regarding patenting of AI inventions.

Our experience is that the EPO does not treat AI inventions differently from other types of computer-implemented inventions. There is no separate consideration of "super intelligent machines" or the like – a philosophy that is and should remain the standard in the U.S. as well. In the EPO, as long as the invention contains an *application* of AI to a field of technology (*e.g.*, bioinformatics, diagnostics, personalized therapeutics, etc.), the invention meets the EPO's "technical nature" requirements, and a patent will be granted if the invention is novel and involves an inventive step. Such application demonstrates the value that the EPO places on these types of AI inventions; a value that we believe the USPTO shares as well.

The case law has developed a large number of examples of valid technical purposes (*see* again Guidelines of Examination of the EPO, G-II, 3.3 for the full list). A few notable examples in the medical and bioinformatics area are:

- providing a genotype estimate based on an analysis of DNA samples, as well as providing a confidence interval for this estimate so as to quantify its reliability; and
- providing a medical diagnosis by an automated system processing physiological measurements.

Conclusion

Again, we applaud the USPTO for requesting stakeholder input on such important questions regarding the elements of AI-based inventions. We believe AI is and will be instrumental in achieving a future of medicine that is better tailored to each individual patient. Patent protection for such AI-inventions is absolutely critical to advancing these overall goals.

We welcome the opportunity to continue this valuable dialogue on AI. We would be glad to provide any additional information, and welcome any questions or comments that you may have.

Sincerely,

/Laurie L. Hill/

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