

William Krovatin
Senior Vice President & Assistant General Counsel
INTELLECTUAL PROPERTY

Merck Sharp & Dohme Corp.
126 E. Lincoln Avenue
P. O. Box 2000
R Y86-2011A
Rahway NJ 07065-0900
Fax: 732 594 4005
Tel: 732 594 0221



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VIA E-MAIL ONLY
AIPartnership@uspto.gov

Merck's Comments on "Request for Comments on Patenting Artificial Intelligence Inventions" (Fed. Reg. 84, No. 166; p. 44889, August 27, 2019)

Merck was established in the United States 128 years ago to help address the world's most pressing health challenges. Today, our commitment to be the premier research intensive biopharmaceutical company in the world fuels our pursuit of medical breakthroughs that will benefit patients, our shareholders and society at large for today and for generations to come.

In order to continue to bring the kind of innovation the medical world needs, we recognize that we must incorporate cutting edge technology, such as Artificial Intelligence (AI), into our business model. We believe that it is imperative that inventions (i) utilizing AI or (ii) developed, at least in part, by AI, are afforded some type of protection, either patent or otherwise, to incentivize developers and users of AI to invest in, and advance, the technology. In this regard, we are pleased to participate in the USPTO's request for comments on patenting AI inventions and to help mold the future of how such inventions are protected in the U.S.

In response to the USPTO's request for comments on patenting AI inventions, Merck has copied the 12 questions posed by the USPTO, in the Fed. Reg. 84, No. 166; p. 44889, August 27, 2019, ("Notice") and have included Merck's response below each question.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William Krovatin', written over a white background.

William Krovatin
Senior Vice President and
Assistant General Counsel



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Request for Comments on Patenting Artificial Intelligence Inventions

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.

In the Notice, the PTO defines "AI inventions" as including inventions "that utilize AI" and inventions "developed by AI." Merck suggests that these types of inventions are fundamentally different and should be considered separately. Inventions that "utilize" or use AI are inventions in which some form of AI is an element of the claimed invention (e.g., a claim to a process in which one or more claim elements recite a machine learning step).

In contrast, inventions "developed" by AI are inventions in which the subject matter of the invention is unrelated to AI, but the invention process involved an AI tool (e.g., a machine learning tool was used to sort through a database to select one or more members of the database).

Inventions that utilize AI may include an algorithm as part of the claimed invention. Proposed elements of an invention that utilizes AI can include:

- 1. The problem to be addressed by the AI;*
- 2. The AI algorithm itself;*
- 3. The structure of the database on which the AI algorithm will be trained and/or will act;*
- 4. The training or retraining of the AI algorithm on the data;*
- 5. The policies/weights to be applied to the data that affects the outcome of the results; and*
- 6. The desired solution of the problem being addressed by using the AI invention.*

Elements of an invention that is developed by AI are no different from an invention conceived and developed by a natural person. While inventions developed by AI utilize an algorithm in the development process, the AI algorithm does not need to be included as an element of the claim to the invention itself. For example, an AI algorithm used to develop a patentable compound will not be an element of the claim to the compound itself.

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.



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Merck interprets this question as directed to inventions developed by AI, in which the subject matter of the invention is not directed to AI, but the invention process involved an AI tool. Whether a natural person contributes to the conception of an invention developed by AI will depend on the degree of the inventive contribution of the natural person and should be assessed by a patent attorney according to US inventorship laws. A natural person must make an intellectual contribution to the conception of the invention and not merely be "a pair of hands," contributing only by carrying out the instructions of a person who fully conceived of the invention. Some ways that a natural person can contribute to the conception of an invention that is developed by AI include:

- 1. Identifying a new problem to be solved using an existing AI algorithm;*
- 2. Recognizing an old problem that can be solved by a new or improved AI algorithm;*
- 3. Designing/programming the AI algorithm;*
- 4. Choosing the proper AI algorithm or combination of AI algorithms to use;*
- 5. Weighting adaptations;*
- 6. Structuring the data (choosing the data or choosing the order) on which the AI algorithm is trained;*
- 7. Training and making decisions on retraining the AI algorithm;*
- 8. Evaluating, prioritizing or verifying the results provided by the AI algorithm; and*
- 9. Modifying the results.*

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?

The current US patent law regarding inventorship does not need to be revised to account for an invention that utilizes AI or an invention developed by AI, and the principles behind the current patent law are incompatible with a machine being named as an inventor.

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?

A patent on an invention utilizing AI and/or an invention developed by AI should be owned only by a natural person or a legal entity. Importantly, only natural persons and legal entities can fully participate in the patenting process, transfer rights to other parties, dedicate portions of a patent to the public and enforce patent rights when necessary. Patent rights should only be conferred to natural persons or legal entities that are legally responsible for their decisions.



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In the example provided in the Notice, the company that owns the AI process is not an inventor of an invention that results from running that existing process. However, the individuals selecting the training inputs and otherwise controlling the parameters of the AI process would likely be determined to be inventors (who had conceived of the resulting invention) and, thus, able to convey ownership under US law.

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

None, beyond the current patentability requirements.

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?

Merck does not have an opinion on this question at this time.

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

USPTO guidance on how to comply with the enablement requirement is needed for inventions utilizing AI (in which AI is included as an element of the claims). Some suggestions include providing (1) detailed flow charts and descriptions of computer architecture; (2) a description of pseudo codes; and/or (3) a submission of AI code to a code repository.

In contrast, the enablement requirements for inventions developed by AI do not need to be revised and are the same as for inventions developed without any AI tools (e.g., inventions developed by a natural person).

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?

The "person of ordinary skill in the art" standard, which is codified in 35 U.S.C. § 103 and governed by case law, should not change. Further, the ability of a person of ordinary skill in the art to use AI should not necessarily make obvious any finding in which AI is used.

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



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Merck does not have an opinion on this question at this time.

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

In the event inventions developed by AI are deemed not patent eligible, additional or alternative forms of intellectual property protection should be established.

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

Merck does not have an opinion on this question at this time.

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?

Merck welcomes continued harmonization among international patent offices, specifically within the IP5, regarding the assessment of AI inventions.