

Mr. Andrei Iancu
The Director of the U.S. Patent and Trademark Office

November 5th, 2019

Comments on "Patenting Artificial Intelligence Inventions"

Dear Mr. Andrei Iancu,

The Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary organization established in 1968, and represents the R&D-oriented pharmaceutical companies in Japan. Counting about 72 leading R&D-oriented pharmaceutical companies as members (as of April, 2019), the JPMA is devoted to contribute to the promotion of the health and welfare in the global population through development of innovative medicines prescribed in medical facilities including hospitals and clinics.

The Intellectual Property Committee of JPMA submits recommendations and proposals to the relevant authorities and organizations with regard to the establishment and improvement of intellectual property systems for the pharmaceutical industry.

As for your invitation for the public to comment on "Patenting Artificial Intelligence Inventions", we submit our comments especially on the important issues for JPMA's member companies. Your deep consideration on these matters would be appreciated.

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I. Regarding points 1 to 4 below from USPTO

- 1. What are elements of AI inventions?
- 2. What are the different ways that a natural person can contribute to conception of AI invention and be eligible to be a named invention?
- 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?
- 4. Should an entity of 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?

AI inventions would be mainly consisted of (1) AI core inventions: inventions characterized by the basic technology for AI such as mathematical or statistical information processing technology (for example, inventions related to various machine learning technologies including neural networks, deep learning, etc.) and (2) Inventions to apply AI: inventions characterized by applying AI core invention to various technologies such as image processing, sound processing, natural language processing, device control / robotics, diagnosis / detection / prediction / optimization system, etc.

It is not included in (1) and (2) as the above mentioned that an result is obtained by applying AI as just a tool (for example, invention of the optimal parameter value output by AI, selection of development candidate compounds and / or optimal compounds in pharmaceutical development, identification of new uses of existing compound (drug repositioning) and the case where AI is applied as a tool to screen for the optimal compound). Particularly in the fields of chemistry and pharmaceutical where the effect of the invention is supported by verification of specific experimental results, AI learning alone would be insufficient for completion of the invention because the results (effects) foreseen by AI is not necessarily consistent with actual results (effects) and the predictability and reliability of AI learning are not credible. However, in this document, we comment below including such inventions into scope of examination.

When an invention is obtained by someone based on a certain idea by applying AI as a tool, it should be considered whether he/she contributes to the conception of the claimed invention itself under the provisions for the "inventorship" of the current patent law, regardless whether he/she contributes or not to the development of AI such as creation of a program related to a learning model.

Even when AI proposes a result while learning spontaneously through deep learning, the AI itself that is not a natural person or the corporation that owns the AI should not be considered as an inventor under the provisions for the "inventor" of the current patent law. In such a case, it should be examined whether the person who input the specific instruction to AI or the person who conducted the prelearning and verified enablement of the idea could be "inventor" or not.

II. Regarding point 5 below from USPTO

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

There would be a possibility that an AI invention is judged as patent ineligible, since it is just an abstract idea. However, it is necessary to carefully consider whether patent ineligibility for the AI invention could be acknowledged as just an abstract idea, because, sometimes, there could be no choice but to explain AI technology in an abstract expression (for example, we cannot specifically describe the inner working of AI when it brings a result, so called black box). Not only patent eligibility under section 101 but also other requirements for patentability should be fully considered to decide whether a patent can be granted for an AI invention.

III. Regarding points 6 and 7 below from USPTO

- 6. Are there any disclosure-related considerations unique to AI inventions?
- 7. How can patent applications for AI inventions best comply with the enablement requirement, particularly given the degree of unpredictability of certain AI systems?

Patent office examiner should consider how and what kind of invention AI is applied to when

they examine whether the requirements of written description and enablement are satisfied for a patent application including an AI invention. For example, an application claiming a specific compound designed by applying AI invention as a tool without disclosing any actual experimental data, which will be frequently filed in the future in the fields of chemical and pharmaceutical industry, should not be easily granted, because current AI technology cannot always correctly predict actual effect. Such patent application not disclosing actual experimental data would be granted only in a case that it is widely recognized by a skilled person in the art that the outcome from AI technology at the time of invention is fully predictable and consistent with actual effect.

IV. Regarding points 8 and 9 below from USPTO

- 8. Does AI impact the level of a person of ordinary skill in the art?
- 9. Are there any prior art considerations unique to AI inventions?

When considering the requirements of non-obviousness and enablement for AI invention, it may be judged that the effect of the invention can be easily predicted by using AI without experimental data. However, it should be carefully determined whether an effect of invention is easily predicted by "person skilled in the art" using AI technology, because AI technology does not always give him/her the foreseeable result and requires him/her to verify the obtained result through actual experiments, especially, in chemical and pharmaceutical field.

Patent office examiner should very carefully review especially an invention claiming a compound designed by applying AI as a tool, which will be frequently filed in the future in the fields of chemistry and pharmaceutical, and such an invention should not be easily granted without experimental data, because, under the current situation, the accuracy of AI technology will depend on each prior art regarding AI technology. In the case that a former patent application, which claims an invention supported by the optimal parameters generated by applying AI without actual wet data, is first filed and then a later application claiming the same invention with experimental data is filed, there is a concern that the novelty and non-obviousness of the later application will be denied as a reference of the previous application. As for inventions related to chemistry, and pharmaceuticals, it should be carefully examined whether the prior art disclosing the invention designed by applying AI technology without actual wet data could be cited, considering whether reliability of the result by applying AI technology in the cited prior art is widely recognized at the time of invention, or not etc.

V. Regarding point 10 below from USPTO

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

The data input to AI is extremely important for AI invention, and it is expected that the right and legal position related to such data will become more complex in the future. From the perspective of proactively creating AI inventions, it is desirable to actively promote the utilization of data. If there is any legally supported contract which allows to access and use data, we should respect such right to

handle the data with emphasis as a "right to use the data", but not an issue of ownership of the data.

VI. Regarding points 11 and 12 below from USPTO

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

In 2018, JPO announced "Examination standards for IoT-related technologies". They determine patent eligibility as following:

whether "structured data" and "data structure" are equivalent to program, or, in other words, whether or not they have similar properties to programs in that the structure of data prescribes computer processing. If the "structured data" and "data structure" are equivalent to programs, they are determined to be (computer) software. And "trained model" is also "program" if it is clear to be a program. This is considered one of the effective policies from the perspective to create AI inventions actively.

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JPMA appreciates this opportunity to submit comments and to provide feedback on the important issues raised by USPTO.

Very truly yours,

Yohei Ishida, Ph.D.

Chairperson

Intellectual Property Committee

Japan Pharmaceutical Manufacturers Association