

William Krovatin
Senior Vice President & Assistant General Counsel
INTELLECTUAL PROPERTY

Merck Sharp & Dohme Corp.
126 E. Lincoln Avenue
P. O. Box 2000
RY86-2011A
Rahway NJ 07065-0900
Fax: 732 594 4005
Tel: 732 594 0221



February 14, 2020

VIA E-MAIL ONLY

ai2ip@wipo.int

Merck's Comments on "Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/GE/20/1) December 13, 2019

Merck was established 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 WIPO's request for comments on patenting AI inventions and to help mold the future of how such inventions are protected.

WIPO has requested comments on the following six areas: Patents, Copyright, Data, Designs, Technology Gap and Capacity Building, and Accountability for IP Administrative Decisions. In response to WIPO's request for comments on patenting AI inventions, Merck takes this opportunity to raise additional considerations in the following three areas: Patents, Data and Accountability for IP Administrative Decisions. For ease of reference, we have reproduced WIPO's questions posed in the Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/GE/20/1), December 13, 2019 ("Paper"), and have included Merck's additional considerations in italics. The numbering used corresponds to the paragraph number used in the Paper.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'William Krovatin', is written over a faint, larger version of the same signature.

William Krovatin
Senior Vice President and
Assistant General Counsel

PATENTS

Issue 1: Inventorship and Ownership

6. In most cases, AI is a tool that assists inventors in the invention process or constitutes a feature of an invention. In these respects, AI does not differ radically from other computer assisted inventions. However, it would now seem clear that inventions can be autonomously generated by AI, and there are several reported cases of applications for patent protection in which the applicant has named an AI application as the inventor.

7. In the case of inventions autonomously generated by AI:

(i) Should the law permit or require that the AI application be named as the inventor or should it be required that a human being be named as the inventor? In the event that a human inventor is required to be named, should the law give indications of the way in which the human inventor should be determined, or should this decision be left to private arrangements, such as corporate policy, with the possibility of judicial review by appeal in accordance with existing laws concerning disputes over inventorship?

(ii) The inventorship issue also raises the question of who should be recorded as the owner of a patent involving an AI application. Do specific legal provisions need to be introduced to govern the ownership of autonomously generated AI inventions, or should ownership follow from inventorship and any relevant private arrangements, such as corporate policy, concerning attribution of inventorship and ownership?

If an AI application is named as an inventor, can an AI application also sue an infringer, or can an AI application also be an infringer?

If an inventor, can an AI application assign its IP rights? Would rights to an AI application's invention reside in the creator of the associated AI algorithm, the developer that funded the initial AI work, the owner of the AI application or the owner of the computer on which the AI application is run?

(iii) Should the law exclude from the availability of patent protection any invention that has been generated autonomously by an AI application? See also Issue 2, below.

Issue 2: Patentable Subject Matter and Patentability Guidelines

8. Computer-assisted inventions and their treatment under patent laws have been the subject of lengthy discussions in many countries around the world. In the case of AI-generated or -assisted inventions:

(i) Should the law exclude from patent eligibility inventions that are autonomously generated by an AI application? See also Issue 1(iii), above.

(ii) Should specific provisions be introduced for inventions assisted by AI or should such inventions be treated in the same way as other computer-assisted inventions?



Merck's Comments on "Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/GE/20/1) December 13, 2019

(iii) Do amendments need to be introduced in patent examination guidelines for AI assisted inventions? If so, please identify which parts or provisions of patent examination guidelines need to be reviewed.

(iv) Should there be a standard definition of what constitutes an AI invention? What are the features of an AI invention?

Issue 3: Inventive Step or Non-Obviousness

9. A condition of patentability is that the invention involves an inventive step or be nonobvious. The standard applied for assessing non-obviousness is whether the invention would be obvious to a person skilled in the relevant art to which the invention belongs.

(i) In the context of AI inventions, what art does the standard refer to? Should the art be the field of technology of the product or service that emerges as the invention from the AI application?

(ii) Should the standard of a person skilled in the art be maintained where the invention is autonomously generated by an AI application or should consideration be given to replacing the person by an algorithm trained with data from a designated field of art?

(iii) What implications will having an AI replacing a person skilled in the art have on the determination of the prior art base?

(iv) Should AI-generated content qualify as prior art?

What constitutes AI-generated content? How would AI-generated content differ from traditional prior art?

Issue 4: Disclosure

10. A fundamental goal of the patent system is to disclose technology so that, in the course of time, the public domain may be enriched and a systematic record of humanity's technology is available and accessible. Patent laws require that the disclosure of an invention be sufficient to enable a person skilled in the relevant art to reproduce the invention.

(i) What are the issues that AI-assisted or AI-generated inventions present for the disclosure requirement?

(ii) In the case of machine learning, where the algorithm changes over time with access to data, is the disclosure of the initial algorithm sufficient?

If the initial algorithm is insufficient, how would reasonable equivalents to the initial algorithm be determined? That is, when would an evolved algorithm cease to be covered by or equivalent to the initial algorithm disclosed?



Merck's Comments on "Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/GE/20/1) December 13, 2019

(iii) Would a system of deposit for algorithms, similar to the deposit of microorganisms, be useful?

(iv) How should data used to train an algorithm be treated for the purposes of disclosure? Should the data used to train an algorithm be disclosed or described in the patent application?

(v) Should the human expertise used to select data and to train the algorithm be required to be disclosed?

(vi) What should be the standard of disclosure for an AI invention? How much information is needed in the specification?

(vii) Are functional descriptions of an AI invention sufficient or would disclosure of actual code be required?

Issue 5: General Policy Considerations for the Patent System

11. A fundamental objective of the patent system is to encourage the investment of human and financial resources and the taking of risk in generating inventions that may contribute positively to the welfare of society. As such, the patent system is a fundamental component of innovation policy more generally. Does the advent of inventions autonomously generated by AI applications call for a re-assessment of the relevance of the patent incentive to AI-generated inventions? Specifically,

(i) Should consideration be given to a sui generis system of IP rights for AI-generated inventions in order to adjust innovation incentives for AI?

(ii) Is it too early to consider these questions because the impact of AI on both science and technology is still unfolding at a rapid rate and there is, at this stage, insufficient understanding of that impact or of what policy measures, if any, might be appropriate in the circumstances?

ISSUES 6-9 WILL NOT BE ADDRESSED IN THESE COMMENTS.

DATA

Issue 10: Further Rights in Relation to Data

Merck's Comments on "Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/GE/20/1) December 13, 2019

(i) Should IP policy consider the creation of new rights in relation to data or are current IP rights, unfair competition laws and similar protection regimes, contractual arrangements and technological measures sufficient to protect data?

(ii) If new IP rights were to be considered for data, what types of data would be the subject of protection?

(iii) If new IP rights were to be considered for data, what would be the policy reasons for considering the creation of any such rights?

(iv) If new IP rights were to be considered for data, what IP rights would be appropriate, exclusive rights or rights of remuneration or both?

(v) Would any new rights be based on the inherent qualities of data (such as its commercial value) or on protection against certain forms of competition or activity in relation to certain classes of data that are deemed to be inappropriate or unfair, or on both?

(vi) How would any such rights affect the free flow of data that may be necessary for the improvement of AI, science, technology or business applications of AI?

(vii) How would any new IP rights affect or interact with other policy frameworks in relation to data, such as privacy or security?

(viii) How would any new IP rights be effectively enforced?

(ix) Irrespective of the protection regime, should there be exceptions, e.g. use of another's safety data to obtain government approval of a product?

(x) Are there data protection laws from other jurisdictions that should be considered, such as EU sui generis rights in databases or regulatory data protection?

ISSUES 11-12 WILL NOT BE ADDRESSED IN THESE COMMENTS.

ACCOUNTABILITY FOR IP ADMINISTRATIVE DECISIONS

Issue 13: Accountability for Decisions in IP Administration

(i) Should any policy or practical measures be taken to ensure accountability for decisions made in the prosecution and administration of IP applications where those decisions are taken by AI applications (for example, the encouragement of transparency with respect to the use of AI and in relation to the technology used)?



Merck's Comments on "Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/GE/20/1) December 13, 2019

(ii) Do any legislative changes need to be envisaged to facilitate decision-making by AI applications (for example, reviewing legislative provisions on powers and discretions of certain designated officials)?

(iii) What parts of the patent prosecution process should or could AI be applied to?

(iv) Should unity of invention/restriction practice be eliminated if AI tools are incorporated into patent prosecution? It is foreseeable that application of AI in this space could moot the "undue burden" consideration considered by examiners when conducting prior art searches.