Alliance for AI in Healthcare (AAIH)
1340 Smith Ave, Suite 400
Baltimore, MD 21209
Nov 8th 2019

Subject: AAIH Comments on "Patenting Artificial Intelligence Inventions"

Dear USPTO,

The **Alliance for Artificial Intelligence in Healthcare (AAIH)** welcomes the opportunity to comment on the US Patent and Trademark Office's RFI: "**Request for Comments on Patenting Artificial Intelligence Inventions" (Document Citation: 84 FR 51522, Document No: 2019-21190).** Below we provide a brief introduction of who we are followed by abbreviated responses to issues raised.

The AAIH is an **international 501(c)4 not-for-profit multi-stakeholder advocacy organization, launched in 2019 to** promote **scientific, legislative, and regulatory initiatives** necessary for the development, accessibility, and implementation of Artificial Intelligence (AI) powered healthcare solutions. The AAIH mission is to enable the **advancement and responsible use** of AI in healthcare to improve patients' lives by focusing on resolution of the sector's most **pressing and significant issues** for patients and developers. It advances these goals by working collectively to identify and address **industry wide concerns, one of which is the intersection of AI and intellectual property.** AAIH comprises **over 25 organizations [1]** that develop or utilize **AI in biomedical R&D and clinical applications** and that have recognized the need for collaborative engagement to realize common goals for the growth of and reliance upon the AI health sector and to significantly **improve quality of care**. Our members include leading-edge start-ups, biopharma, diagnostics and device manufacturers, academia, and technology and infrastructure developers. We cooperate with *key opinion leaders and with* stakeholders from *government, NGOs, and other international* organizations to support **innovative and thoughtful application of AI.** We are providing our response with diverse input through our primary constituency of **industry and academic** member organizations.

Given that our organizational position is that AI will play a key role in the advance of the bioeconomy, some of the questions you posed respecting intellectual property represent issues of such keen interest to us that they drove our organization's formation. Several thematic areas you cover are echoed in the mandates of our main standing committees: Education and Accreditation, Federal Engagement and Regulatory Affairs, and Technology & Standards Development. We believe that especially in the **highly regulated arena of healthcare**, the establishment, utilization, and relentless improvement of standards, scientific discovery and technological advances, and a well-versed viable and consistent framework for intellectual property, require a multipronged and coordinated approach across the healthcare continuum.

In the following pages, please see our initial brief comments in response to the RFI about patenting AI inventions with a focus on AI in Healthcare. At this critical juncture, as we collectively advance our thinking, we look forward to continued engagement and collaboration with the USPTO in the progress of American leadership in AI.

Respectfully submitted *on behalf of AAIH members*,

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[1] https://www.theaaih.org/members

*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.*

First, it is useful to define AI as the study and use of artificial intelligent agents. An intelligent agent is *an autonomous entity that directs its activities toward accomplishing complex goals by making observations of its environment through sensors, processing the input, and acting on the environment through actuators.* Intelligent Agents may lack certain elements (such as Software-Only Agents considered separate from underlying hardware) and be different in their degree of autonomy. Humans, autonomous drones, machine learning models used to make or support decisions and simple thermostats are examples of intelligent agents.

An "AI invention" or better phrased an "artificial intelligent agent invention" has a number of elements. As the definition states, the intelligent agent could include sensors for input, software and/or hardware for processing input and producing a response to the input, and finally actuators for impacting the environment. The instruction sets encoded in the software and/or hardware can be and often are made up of one or multiple machine learning models in combination with other algorithms. A machine learning model is a function that was generated in turn by a machine learning algorithm from patterns the algorithm "observed" in a training set of data. The training set is represented to the Machine Learning (ML) algorithm as a set of objects, each with a set of features. The ML algorithms select a function of these features from a space of allowable functions. That space of allowable functions is dependent on the planned use of the resulting model function and the algorithm. The algorithm generally selects the function that best minimizes a cost function without overfitting to the training set.

With these principles in mind, let us turn to an analysis of the law's requirements for issuance of patents:

Patents require novelty and non-obviousness. In patenting a specific ML model alone, meeting these requirements can be difficult. For any standard ML problems, including classification or regression, there tend to be multiple similar learning algorithms capable of generating a prediction. A model can be seen as a combination of (1) dataset, (2) specific algorithm, and (3) network architecture/ set of parameters. Often, the selection of items (2) and (3) can be based on trial and error, with the optimal combination edging out alternatives by a small margin. Owing to the abundance of available algorithms and architectures, any patent defending a model through the specified combinations can be easily worked around. **Additionally, models are constantly revisited, and it is not uncommon to update/upgrade often and faster than the overall life-cycle of IP protection.**

Inventiveness, 'the inventive step,' is also a concern in many applications of AI technologies. When specific datasets (database structures) are readily available in tabular form, almost any column (property) can be selected as the target dependent variable to yield a prediction. This process can be fairly obvious, which confounds patent law's inventiveness requirement. Instead, inventiveness is better demonstrated when there is a larger method and system, or process, surrounding the AI model's creation, such as novel data collection methods, complex data transformations, or new abstractions of the objects represented by the data. Meeting the inventiveness criterion, however, should require something beyond applying common techniques for feature engineering / dropping.

Combining novel data types and/or representations in a manner that makes them more suitable to specific algorithms demonstrates an element of a novel, non-obvious inventive step.

True creativity in addressing a real-world AI problem comes when you look at the entire ML lifecycle as a technical process, which includes identification of a problem, data acquisition/transformation, model building, and model evaluation.

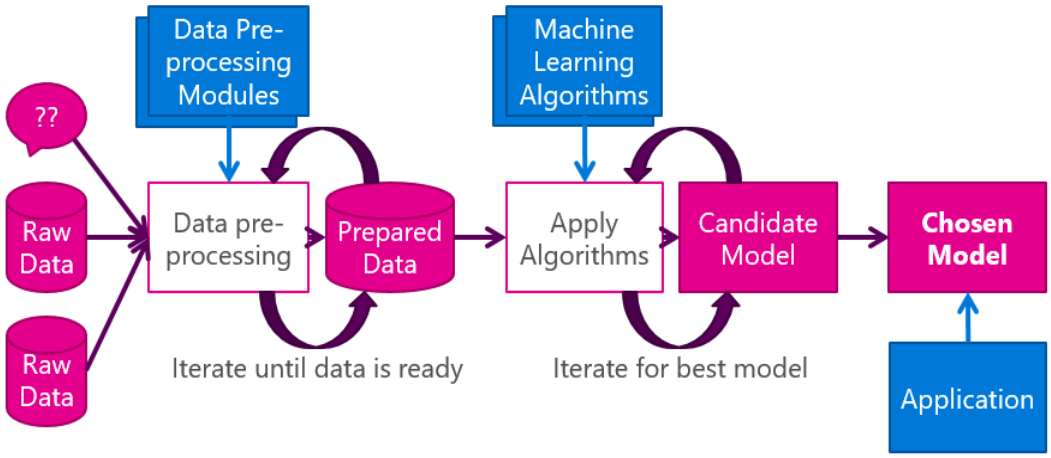

Image From: Steven Taylor, "Data Engineers: Key Players in Machine Learning and Artificial Intelligence," KCAIL, 19 June 2018, available at https://medium.com/kansas-city-machine-learning-artificial-intelligen/importance-of-data-engineers-ddf1ffa4dc86

*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.*

In the same manner as above, simply building or optimizing a model has become very commonplace and obvious. Inventorship should instead be limited to claims relating to the design of an AI solution as a whole in a novel and non-obvious fashion.

A natural person can:

1. Invent a novel use for an intelligent agent
2. Invent and assemble software and hardware parts of a novel intelligent agent
3. Invent a novel intelligent agent that can in turn invent something else
4. Produce a novel machine learning model from a proprietary training set that can be used in an intelligent agent
5. Invent the machine learning algorithm (or parts thereof, such as, the cost function or optimizer) that produces models that can be used as or in intelligent agents

A natural person who accomplishes any of the foregoing can contribute to conception of an AI 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?*

No comments 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?*

Yes. An entity, company or person, should be the owner of the invention if it was operating or training the intelligent agent and can show that the invention was made through its creative and intentional operation and interaction with the intelligent agent.

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

Inventiveness requires creativity and intent (not serendipity). Having an AI agent claim inventorship opens up a host of issues related to Artificial General Intelligence (AGI) and legal interpretations of agency of an AGI or of an intelligent agent. The human trainer(s) of the AI system would need to demonstrate an element of inventiveness in identifying the input data, modifying the source data, and modifying the method of processing the source data in relation to a concrete end product in order to accomplish something sufficiently new to justify recognizing an invention. In that case, the individual(s) would be adhering to the discovery of a new AI process as described in our response to question (1), further reinforcing the notion that, owing to the interchangeable nature of the algorithm component of ML, model creation alone should not constitute inventorship.

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?*

No. A general description of the algorithm suffices for someone skilled in the art to understand and reproduce it. Disclosing the very specific details of a given AI invention, such as the number of layers or weights, is not critical to replicate the invention's behavior. AI technologies are typically patented once they have been developed on simulated validation data (which were withheld from a known dataset). Overall predictive behavior is conserved across a broader range of architectures, algorithms, and hyper-parameters. Small changes in these details typically reflect small changes in predictive performance. Once patented and released for use in the real world, predictive performance almost always changes. When that occurs, it is standard practice to reoptimize hyper-parameters, architectures and algorithms slightly, rendering previously disclosed setups almost meaningless.

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

Exact output metrics and/or optimal setups may be difficult to reproduce numerically. The overall behavior of the predictive system built on ML technologies, however, is not usually difficult to replicate within a reasonable margin of error with independent third party implementations. At AI competitions such as Kaggle, many

successful implementations of different algorithms/parameters applied to the same problem often rank among the top performing results. In this context, enablement should not be seen as reproducing numerical equivalency; rather, it should be considered within a margin of error similar to the outcomes of scientific experiments.

*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?*

No - "Someone skilled in the art" should have both technical expertise in developing/optimizing ML approaches and subject area expertise relevant to the particular disclosure. For instance, an ML expert in the automotive industry should not necessarily be considered 'skilled in the art' for the development of a drug design or for a clinical decision-making ML solution.

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

No comments at this time.

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

ML models themselves should have the same level of IP protection as software. In addition, however, one should be restricted from training a new model by generating a training set from the predictions of an existing model he neither owns not has the owner's express permission to use. Doing so would in effect be copying the model, and thus not creating anything patentable.

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

No comments 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?***

We are aware of the Computer Implemented Inventions guidelines from the EPO which may touch on relevant issues when it comes to AI enabled systems, especially those incorporating hardware components.