May 15, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property
and Director U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

Submitted via: https://www.regulations.gov

Re: Request for Comments Regarding Artificial Intelligence and Inventorship (Docket No. PTO–P–2022–0045)

Dear Director Vidal:

The Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the ***Request for Comments Regarding Artificial Intelligence and Inventorship*** published in the Federal Register on February 14, 2023 ("Notice").

IPO is an international trade association representing a "big tent" of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO's vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO's mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO provides written responses to questions posed by the USPTO below. IPO is grateful for this opportunity to share feedback.

Responses to Questions for Public Comment

Question 1: How is AI, including machine learning, currently being used in the invention creation process? Please provide specific examples. Are any of these contributions significant enough to rise to the level of a joint inventor if they were contributed by a human?

Response: Examples of how AI is currently being used in the invention creation process include being used to create synthetic training data, use in drug development and testing/virtual patients, digital twins, and identifying second medical uses and candidate drugs. In none of these situations do we believe AI is currently involved in "conception" and therefore the AI's contributions do not rise to the level of joint inventor. However, there are situations where it can be difficult to identify the proper human to name as the inventor and USPTO guidance would be helpful in this regard.

Question 2: How does the use of an AI system in the invention creation process differ from the use of other technical tools?

Response: IPO does not believe that the use of an AI system in the invention creation process currently differs from the use of other technical tools, except that technical efficiency may be improved.

Question 3: If an AI system contributes to an invention at the same level as a human who would be considered a joint inventor, is the invention patentable under current patent laws? For example:

a. Could 35 U.S.C. 101 and 115 be interpreted such that the Patent Act only requires the listing of the natural person(s) who invent(s), such that inventions with additional inventive contributions from an AI system can be patented as long as the AI system is not listed as an inventor?

b. Does the current jurisprudence on inventorship and joint inventorship, including the requirement of conception, support the position that only the listing of the natural person(s) who invent(s) is required, such that inventions with additional inventive contributions from an AI system can be patented as long as the AI system is not listed as an inventor?

c. Does the number of human inventors impact the answer to the questions above?

Response:

IPO's response to Question 3 is subject to two assumptions:

- Because Question 3 requests analysis "under current patent laws," IPO's response is governed by the laws as they exist on the date of this response. This includes the Federal Circuit's decision in *Thaler v. Vidal*, where the Federal Circuit held that "inventors," as described in the Patent Act, "must be human beings."[1]
- Because the question refers to joint invention, IPO's response is limited to human/AI system cooperative contributions, and thus, it does not separately address situations where all contributions are provided by an AI system.

Response to Question 3(a):

IPO believes that 35 U.S.C. §§ 101 and 115 support the position that the Patent Act only requires the listing of natural persons as inventors.

[1] *Thaler v. Vidal*, 43 F.4th 1207, 1212 (Fed. Cir. 2022), cert. denied --- S.Ct. ---- (Apr. 24, 2023).

35 U.S.C. § 115 requires that an application for a patent must include "the name of the ***inventor*** for any invention claimed in the application."[2] And that "each individual who is the ***inventor*** or a ***joint inventor*** of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application."[3]

The Federal Circuit in *Thaler v. Vidal* held that the Patent Act's recitation of "inventor" was limited to human beings. In particular, the court recognized that the Patent Act defines an "inventor" as an "*individual*" or "*individuals*" (in the context of joint inventions).[4] While the term "individual" is not defined in the Patent Act, *Thaler* recognized that the term is ordinarily used to denote a human being.[5] *Thaler* also found that 35 U.S.C. § 115 uses the pronouns "himself" and "herself" to refer to "individuals," further indicating a lack of intent by Congress to "permit non-human inventors."[6] As a result, *Thaler* held that "the Patent Act . . . confirms that 'inventors' must be human beings."[7]

Thus, 35 U.S.C. § 115 supports the position that only humans who have provided an inventive contribution to an application need be named on an application, even where an AI system has contributed to the application.

While 35 U.S.C. § 101 provides fewer guideposts on this issue, it is consistent with the above position. In particular, 35 U.S.C. § 101 recites that "*[w]hoever* invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[8] The Federal Circuit in *Thaler* noted that, while the Patent Act broadly uses the term "whoever" to refer to "corporations and other non-human entities," the statute also recites that any patent grant is also "subject to the conditions and requirements of this title."[9] Those requirements include the Patent Act's definition of "inventor," which is limited to a human being, and 35 U.S.C. § 115's use of that term.[10]

Thus, 35 U.S.C. § 115 supports the position that the Patent Act only requires the naming of at least one human being inventor in a patent application. And, even where an AI system contributes to such a disclosure, § 115 does not apply to the AI system because it is not an "inventor" as defined by the Patent Act and interpreted by *Thaler*.

Response to Question 3(b):

Yes, current jurisprudence supports the position that only humans can invent, and existing case law on conception supports the notion of inventorship to humans who participate in the inventive process, even when additional contributions to the invention are made by AI systems in much the same manner as other tools of innovation.

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[2] 35 U.S.C. § 115 (emphasis added).
[3] *Id.*
[4] *Thaler v. Vidal*, 43 F.4th at 1211 (quoting 35 U.S.C. § 100(f) and § 100(g).
[5] *Thaler v. Vidal*, 43 F.4th at 1211.
[6] *Id.*
[7] *Id.* at 1212.
[8] 35 U.S.C. § 101 (emphasis added).
[9] *Thaler v. Vidal*, 43 F.4th at 1212 (quoting 35 U.S.C. § 101).
[10] *Thaler v. Vidal*, 43 F.4th at 1212.

As recently solidified by the Federal Circuit's decision in *Thaler v. Vidal* and the Supreme Court's subsequent denial of certiorari, the Patent Act unambiguously defines "inventors" as exclusively natural persons.[11] Indeed, the Federal Circuit's decision did not hinge upon the degree of contribution of the AI system or other "metaphysical matters" and, instead, concluded that non-persons are categorically excluded from inventorship under U.S. Law.[12] Other portions of the Patent Act and the related caselaw on inventorship similarly exclude AI systems from consideration as anything more than a tool.

Much of the current jurisprudence on conception stems from case law on conflicting inventorship claims between two or more human inventors otherwise known as joint inventors, rather than direct discussions of AI inventorship. Nonetheless, recent decisions on AI inventorship in cases like *Thaler* in combination with this earlier precedent lay a sufficient framework for addressing the contributions of AI systems. The established rules of inventorship and conception can be applied to AI-related inventions in a straightforward fashion. "The threshold question in determining inventorship is who conceived the invention" as claimed in a patent.[13] Conception is a legal, rather than philosophical determination, and under current precedent, AI systems cannot legally "conceive" of an invention because the "question of conception is properly directed to whether there was 'formation [ ] ***in the mind of the inventor*** of a definite and permanent idea of the complete and operative invention.'"[14] Applied with the *Thaler* decision, it is clear from this earlier precedent on conception that no AI system can establish legal conception of the invention because an AI system does not have a human mind and therefore cannot be an "inventor" under the Patent Act, and only an "inventor" is legally capable of legal conception.

Additionally, current precedent requires "contemporaneous recognition and appreciation of the invention for there to be conception."[15] The decisions in *Silvestri* and *Invitrogen* suggest that an invention can be entirely duplicated prior to legal conception by an inventor if the invention is unrecognized and unappreciated in the first instance.[16] The requirement for recognition and appreciation suggests that an AI system preparing certain aspects of an invention prior to legal conception by a human inventor does not preclude later patenting by the human inventor. This requirement of recognition and appreciation also suggests that some level of human activity outside of the reach of current AI systems is required before conception is complete. Many modern AI systems are generally considered sophisticated statistical inference engines that many would argue are unable to independently differentiate between a "good" and "bad" solution absent some human involvement, such as a predetermination of "good" and "bad" or a subsequent recognition of the value and significance of the output from the AI system. Given the legal jurisprudence prohibiting AI systems from being inventors or conceiving of inventions, we do not reach a conclusion on this issue here, but the requirement for

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[11] *Thaler v. Vidal*, 43 F.4th at 1213.
[12] *See id.* at 1209.
[13] *See* MPEP 2137.01 (citing *Fiers v. Revel*, 984 F.2d 1164, 1168 (Fed. Cir. 1993)).
[14] *Bosies v. Benedict*, 27 F.3d 539, 543 (Fed. Cir. 1994) (citing *Coleman v. Dines*, 754 F.2d 353, 359 (Fed.Cir.1985)); see also MPEP 2138.04(I) (citing *Bosies*) (emphasis added).
[15] MPEP 2183.04(III) (citing *Silvestri v. Grant*, 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974); and *Invitrogen, Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1064, 77 USPQ2d 1161, 1169 (Fed. Cir. 2005)).
[16] *See id*.

recognition and appreciation suggests that many current AI systems lack the capability of conception in either event.

The instant question asks us to determine whether an AI system could provide an "additional inventive contribution" with one or more natural persons, and the jurisprudence on joint inventorship is similarly restrictive. Under current precedent, for multiple parties (e.g., an AI system and human) to qualify as joint inventors, each must contribute to the conception of the invention.[17] Given that an AI system cannot legally "conceive" of an invention, or portion thereof, an AI system cannot be a joint inventor on any patent application under current U.S. jurisprudence.

This raises the question of whether a human inventor or group of human inventors can lawfully establish ***sole*** conception of an invention to which an AI system contributed. Current precedent distinguishes between those who suggest results and those who contribute to conceiving of the means to accomplish the result, with the Board of Patent Appeals and Interferences (BPAI), for example, noting that "one who suggests an idea of a result to be accomplished, rather than the means of accomplishing it, is not a coinventor."[18] However, this precedent is based on the existence of another human who provides additional conception and the question before the tribunal was ***which*** human was properly considered the inventor. In contrast, because AI cannot legally perform an act of conception, AI systems are more properly considered tools which ***help*** the human inventor conceive and refine the invention rather than independent inventors whose contributions must be weighed against those of the human inventors.

The comparative efforts of the AI system and human inventor is akin to the interplay between natural forces and human inventors in *Dunn v. Ragin*. In *Dunn*, the BPAI found that "the creation of the bud sport so far as is known is the result of natural forces alone," but nonetheless the "new variety may popularly be said to be conceived or discovered when an individual becomes aware of its existence."[19] Accordingly, even a human's recognition and appreciation of the product of purely natural forces in *Dunn* has been held sufficient conception to qualify the discoverer for inventorship, assuming all other statutory requirements are satisfied. While various aspects of the creation, operation, and downstream usage of the results of an AI system may raise additional questions about ***which*** particular human qualifies as an inventor, the framework established in other uncertain fields of technology suggests that non-human contribution, even at the level described in *Dunn*, does not preclude a finding of complete inventorship for the humans associated with the process.

35 U.S.C. § 101 supports this interpretation, noting that "[w]hoever invents ***or discovers*** any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor" (emphasis added). As interpreted in *Thaler*, 35 U.S.C. 101 refers only to humans that "invent or discover" such patent eligible subject matter. Thus, the Patent Act and current jurisprudence suggest that a human inventor may establish sole conception of an invention to which an AI system contributed, and the human's contribution may be limited in cases where the field of

[17] MPEP 2137.01(V) (citing *Ethicon Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460-63, 45 USPQ2d 1545, 1548-1551 (Fed. Cir. 1998)).
[18] *Ex parte Smernoff*, 215 USPQ 545, 547 (Bd. App. 1982).
[19] 50 USPQ 472, 475 (Bd. Pat. Inter. 1941).

technology is unpredictable and substantial non-human factors are necessary to ultimately create the invention. AI has been used as a tool for many years without affecting the ability of human inventors to seek, receive, and enforce patents. While current AI tools are more sophisticated than ever, this is a difference in degree rather than kind from past AI systems, and AI contributions to inventorship are properly seen as tools used by human inventors to facilitate human conception rather than independent contributions of the AI system.

Response to Question 3(c):

The number of human inventors does not impact the answer to the questions above.

Question 4: Do inventions in which an AI system contributed at the same level as a joint inventor raise any significant ownership issues? For example:

a. Do ownership rights vest solely in the natural person(s) who invented or do those who create, train, maintain, or own the AI system have ownership rights as well? What about those whose information was used to train the AI system?

b. Are there situations in which AI- generated contributions are not owned by any entity and therefore part of the public domain?

Response: IPO believes that this question is not yet ripe, because AI's contributions do not currently rise to the level of joint inventor.

Question 5: Is there a need for the USPTO to expand its current guidance on inventorship to address situations in which AI significantly contributes to an invention? How should the significance of a contribution be assessed?

Response: IPO does not believe that there is a need for the USPTO to expand its current guidance on inventorship to address such situations because the "significance" of the AI contribution is irrelevant, as AI cannot currently be an inventor. The inventors are the humans who contributed to at least one claim.

Question 6: Should the USPTO require applicants to provide an explanation of contributions AI systems made to inventions claimed in patent applications? If so, how should that be implemented, and what level of contributions should be disclosed? Should contributions to inventions made by AI systems be treated differently from contributions made by other (*i.e.*, non-AI) computer systems?

Response: IPO believes that further study would be needed before deciding whether or not to implement such a requirement. IPO understands and appreciates why such a requirement might be considered, but IPO also believes that careful analysis is needed of the potential burden and expense this would create for innovators, the potential difficulties associated with how such a requirement would be implemented, and whether or not such a requirement would be consistent with the practices of other jurisdictions. IPO also currently believes that contributions to inventions made by AI systems should not be treated differently from contributions made by other (*i.e.*, non-AI) computer systems, because these are all tools from the standpoint of the patent law.

Question 7: What additional steps, if any, should the USPTO take to further incentivize AI-enabled innovation (*i.e.,* innovation in which machine learning or other computational techniques play a significant role in the invention creation process)?

Response: IPO and AIPLA have adopted the attached Category Definitions for AI-Related Inventions to try to help frame the discussion surrounding AI policy issues. To be clear, these definitions do not attempt to provide any guidance on the substance of the law (including that they do not address patent eligibility), but provide categories that can help facilitate discussion of AI policy issues by allowing participants to "speak the same language" regarding AI-related inventions. IPO believes that, the more these terms are used in AI policy discussions, the more transparent and clear the resulting AI policies will be, which could help facilitate AI-enabled innovation.

IPO also believes that, with respect to "category two" AI inventions, which are inventions on specific applications of core AI technology, it would be helpful to have guidance regarding the naming of human inventors and guidance regarding sufficiency of disclosure.

Question 8: What additional steps, if any, should the USPTO take to mitigate harms and risks from AI-enabled innovation? In what ways could the USPTO promote the best practices outlined in the *Blueprint for an AI Bill of Rights* and the *AI Risk Management Framework* within the innovation ecosystem?

Response: IPO believes that this is an important issue and that the best practices outlined in the *Blueprint for an AI Bill of Rights* and the *AI Risk Management Framework* should be included in the USPTO's educational efforts related to AI and IP.

Question 9: What statutory changes, if any, should be considered as to U.S. inventorship law, and what consequences do you foresee for those statutory changes? For example:
a. Should AI systems be made eligible to be listed as an inventor? Does allowing AI systems to be listed as an inventor promote and incentivize innovation?
b. Should listing an inventor remain a requirement for a U.S. patent?

Response: IPO does not currently believe that any statutory changes are needed to U.S. inventorship law. It will, however, continue to analyze this issue with respect to this rapidly developing area of technology.

Question 10: Are there any laws or practices in other countries that effectively address inventorship for inventions with significant contributions from AI systems?

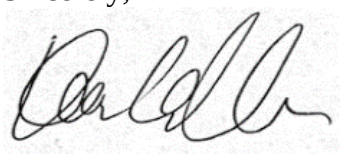
Response: IPO understands that the vast majority of countries address this issue by treating only the human as the inventor.

Question 11: The USPTO plans to continue engaging with stakeholders on the intersection of AI and intellectual property. What areas of focus (*e.g.*, obviousness, disclosure, data protection) should the USPTO prioritize in future engagements?

Response: IPO suggests that the USPTO prioritize guidance regarding sufficiency of disclosure.

IPO thanks the USPTO for its attention to IPO's comments submitted herein and welcomes further dialogue and opportunity to provide additional comments.

Sincerely,



Karen Cochran
President

Enclosure

IPO/AIPLA Category Definitions for AI-Related Inventions
(August 2022)

INTRODUCTION

This document provides **proposed category definitions for inventions relating to Artificial Intelligence (*i.e.*, AI-related inventions)** as well as corresponding examples for each category.

To ensure a better understanding of the category definitions and promote coherent conversations, we have provided a high-level, non-controversial description of AI technologies below. We have taken pains to avoid taking a position on an explicit definition for AI due to the term's inherent amorphousness and many interpretations. Instead, we believe defining categories of inventions relating to AI will provide a sufficient framework to facilitate continued work on AI policy issues.

For most contexts, AI in contemporary parlance is essentially synonymous with automation. From a theoretical standpoint, AI comes in three flavors: narrow AI (or weak AI), general AI (or strong AI), and super AI. Of these categories, it is only narrow AI that exists today and, by most accounts, is the only type of AI that will exist for the foreseeable future.[1]

Narrow AI involves only inductive inferences, whereas general and super AI involve deductive and abductive inferences—skills which are presently only possessed by humans. Narrow AI describes a computer program that is good at performing a defined set of tasks (*e.g.*, tasks associated with playing chess or Go or making purchase suggestions, sales predictions, or weather forecasts).

In the broadest sense, today's AI includes non-learning systems that automate traditional human tasks (*e.g.*, rule-based expert system). Machine learning is a subset of current AI where hard coded algorithms are replaced by models trained on example input-output pairs to predict outputs for previously unseen inputs. Deep learning is a subset of machine learning that employs vast networks of artificial neurons. General AI is a *purely hypothetical* computer program that can understand and reason its environment as a human would. Also *purely hypothetical*, super AI describes a computer program that is much smarter than the sum of all human intelligence in practically every field.

[1] *See, e.g.,* Dilmegani, Cem (2021) "Will AI reach singularity by 2060? 995 experts' opinions on AGI," AIMultiple. Available at: https://research.aimultiple.com/artificial-general-intelligence-singularity-timing/.

PROPOSED CATEGORY DEFINITIONS FOR AI-RELATED INVENTIONS

Preamble: The following category definitions are based on what is claimed, evaluated on a claim-by-claim basis, but not intended to preclude a claim from falling into multiple categories (*i.e.*, one claim can fall within the scope of multiple definitions).

#1 **Inventions on Core AI Technology ("Core AI Technology")**: Products, designs, processes, computer programs, or other types of material artifacts that have general applicability (*i.e.*, are not limited to specific problem domains) and are the building blocks for application-specific tools. Examples include:

(a) Software-based AI technology such as AI training, architectures, and methodologies; or
(b) Hardware-based AI technology such as AI accelerator chips, neuromorphic chips, and improvements in graphics processing units (GPUs).

#2 **Inventions on Specific Applications of Core AI Technology ("Applications of Core AI Technology")**: Products, designs, processes, computer programs, or other types of material artifacts employing Core AI Technologies as one component in a larger context to perform tasks more intelligently. In other words, this type of AI-related invention applies one or more Core AI Technologies to a specific problem or task domain. Application Specific AI inventions typically integrate the Core AI Technologies with domain specific systems that provide input data (*e.g.*, sensors) or use the outputs of the Core AI Technology for a specific end goal (*e.g.*, to control the path of a robot).

#3 **Inventions Generated By or Using AI:** Products, designs, processes, computer programs, or other types of material artifacts that are:

(a) Conceived of or devised by a human with the assistance of an AI technology (AI is a tool of innovation);
(b) Conceived of or devised by a human in collaboration with AI where the activity of the AI, if done by human, would be considered co-inventorship (AI is co-inventor with a human inventor); or
(c) Conceived of or devised by an AI system under circumstances in which no person traditionally qualifies as an inventor (AI is only inventor; no human inventors).

With inventions generated by or using AI, the resulting material artifacts may or may not relate to AI technology.

EXAMPLES:

Because of the significant differences among these categories of AI-related inventions, there is no one set of elements common to all AI-related inventions. Due to the diversity of implementation and application, identifying the range of possible elements in each category of AI-related inventions would require a lengthy and detailed treatment that is not likely to be valuable in the context of this question. Further, an attempt to distill common elements of all AI-related inventions would necessitate creating broad general features that are not beneficial to understanding the differences between AI-related inventions for considering issues such as inventorship, enablement, eligibility, non-obviousness, and so forth.

Nevertheless, we discuss and provide examples regarding elements of the above categories of AI-related inventions for clarity. The elements depend on the subtype of AI being used and the application domain in which the AI is deployed.

#1 Core AI Technology: Elements depend on the subtype of AI technology being considered. Thus, the elements of a new type of artificial neural network (NN) architecture will be different from the elements of a new type of expert system, evolutionary algorithm, or AI accelerator chip.

Given the current interest in neural networks (NN) and machine learning (ML), the following features may be part of a Core AI invention for a new NN architecture:

- General objective, such as classification, prediction, translation, content generation;
- Data representation and pre-processing;
- Node ("neuron") definition (internal structure, activation function, output function);
- Layer definitions, including layer function (*e.g.*, input, convolution, normalization, pooling, hidden layer, output layer, connections, weighting, etc.), layer shape and interconnectivity, organization and sequencing of layers; and
- Hyperparameters, optimization, regularization, loss function, training algorithm.

This list is illustrative and not meant to suggest that every feature must be expressly discussed in a patent application for a NN architecture. Rather, the list identifies various aspects of a NN architecture that may be part of a Core AI invention.

> Example: A training technique that vastly reduces the training time of ML models for very- high-dimensionality data sets, such as population-wide medical studies, by using a new loss function and training algorithm. The ability to train or retrain ML models rapidly may be extremely important, such as where conventional training models require significant amounts of time to complete even on the fastest supercomputers, and where the new training process may complete the same training within several hours. This training technique is an improvement in the functionality of the ML model. The elements

of the AI-related invention here would be the loss function and the steps of the training algorithm and the selection of the relevant hyperparameters.

#2 **Applications of Core AI Technology**: Elements can be similar to those of Core AI Technologies but applied for a particular application domain.

Example: A factory assembly line including a machine vision system that visually inspects a manufactured part for defects. The system is configured to inspect the part for potential defects using infrared and ultraviolet light at a point in the manufacturing process during which the part is not visible to humans, such as within a mold, where early detection may permit an adjustment of the manufacturing process that compensates for the defect and salvages the part. In this example, the machine vision system includes a conventional convolutional NN that is trained in a typical manner to detect a simple feature, such as color, shape, orientation, or alignment of the part. The training data is specific to infrared and ultraviolet images of the part being manufactured under various conditions, and the output layer is configured to provide a classification signal as to the type of defect. Thus, the ML component is integrated into a specific application using domain specific data to provide domain specific outputs.

#3 **Inventions Generated By or Using AI**: Elements depend on what is invented. For instance, if the invention is a beverage container, the elements will be associated with the beverage container (*e.g.*, shape, material, etc.). If the invention relates to an improvement in AI, the elements will be associated with Core AI Technologies described above. There are no elements specific to the fact that the invention was generated by AI as opposed to a human.

Example: A synthetic protein that binds to a receptor to provoke an immune system response. The selection of the protein may involve the simultaneous consideration of many properties, such as the shape and physical chemistry of the amino acid sequence that exclusively binds to this receptor; the synthesis pathway to produce this protein from a DNA sequence, including how it is assembled and folds into an active conformation; and compatibility with other co-factors or pharmaceuticals. The protein may be primarily or even solely designed by a conventional ML algorithm; however, the elements of the claimed invention would be directed to the structure of the protein itself, such as the nucleic acid or amino acid sequences that encode it, without regard to the manner in which it was identified by the ML system.