How AI-Related Life Sciences Patents Are Examined In Japan

By **Yuki Onoe** (April 22, 2020)

In the midst of the coronavirus outbreak, scientists are working to find ways to utilize artificial intelligence and machine learning techniques to help speed up diagnostic processes, provide predictions, and find a treatment and a cure. While various information and findings should be shared among the scientists to better cope with the crisis, there may be researchers who later seek to patent certain aspects of their new AI- or ML-related inventions.

Patenting AI-Related Inventions

Some patent offices have published comments and discussions on how AI-related inventions are examined in their country or region, while others have not.

For example, the Japan Patent Office has explained its views in its examination handbook, which was revised on Jan. 30,[1] to include case examples pertinent to AI-related technology. The case examples include hypothetical claimed inventions related to AI or ML, and the JPO explains whether those claims satisfy certain patentability requirements, just as the U.S. Patent and Trademark Office provides such explanations in the U.S. Code Title 35 Section 101 subject matter eligibility examples.[2]

The JPO case examples are highly useful and helpful to practitioners, examiners and those who seek to patent their AI-related inventions. Although the patent practice is different, the JPO's case examples may be of interest to U.S. patent practitioners, who may face similar issues raised before the USPTO.

Below is a detailed analysis of the hypothetical examples provided by the JPO where there is an intersection of AI and life sciences.

Obviousness

The JPO handbook includes cases 33-36 to illustrate how the JPO would analyze the issue of inventive step,[3] which is a counterpart of the U.S. Section 103 obviousness.

According to the JPO, Claim 1 of Case 33 directed to "Cancer Level Calculation Apparatus" lacks an inventive step, whereas Claim 1 of Case 36 directed to "Dementia Stage Estimation Apparatus" involves an inventive step.

Case 33, Claim 1	Prior Art
A cancer level calculation apparatus that calculates a possibility that a subject person has cancer, using a blood sample of the subject person comprising a cancer level calculation unit that calculates a possibility that a subject person has cancer, in response to an input of	A cancer level calculation method of calculating a possibility that a subject person has cancer carried out by a doctor, using a blood sample of the subject person comprising a step of cancer level calculation, wherein a possibility that a subject person has cancer is calculated, using measured values of

measured values of A marker and B marker that have been obtained through blood analysis of the subject person, the cancer level calculation unit including a neural network that has been trained through machine learning using training data to calculate an estimated cancer level in response to the input of the measured values of A marker and B marker.	A marker and B marker that have been obtained through blood analysis of the subject person.

Claim 1 of Case 33 lacks an inventive step because it merely recites an application of ML to a conventional method practiced by a doctor. The methods are the same, using the markers A and B to calculate the possibility of a person having a cancer. The use of ML or AI to speed up calculations or improve prediction accuracy may be a common diagnostic application, but if the tool simply implements the method which have been employed by doctors, that would not pass the inventive step test.

According to the JPO, "[i]t is mere the exercise of the ordinary creativity of a person skilled in the art to systemize an estimation method carried out by a doctor in the medical field using a computer or the like."

In addition to the lack of an inventive step, Claim 1 may be viewed as less effective use of ML or AI tools, because these tools are more beneficial when the markers are unknown. The input data or training data are there for ML or AI to learn hidden patterns and find new markers or factors. If one can present Claim 2 reciting such a calculation method based on new markers or factors that a person ordinarily skilled in the art of the invention would not have been able to easily conceive[4], then such a claim may pass the inventive step test.

Claim 1 of Case 36 below does pass the inventive step test. The underlined portions in Claim 1 are features different from the prior art.

Case 36, Claim 1	**Prior Art**
A dementia stage estimation apparatus comprising: a speech information obtainment means for obtaining a speech information on a conversation between a questioner and a respondent; a speech information analysis means for analyzing the speech information, and then specifying a speech section by the questioner and a speech section by the respondent; a speech recognition means for	A dementia stage estimation apparatus comprising: a speech information obtainment means for obtaining a speech information on a conversation between a questioner and a respondent; a speech recognition means for converting the speech information into text through speech recognition and outputting a character string; and a dementia stage determination

converting, through speech recognition, the speech information on the speech section by the questioner and the speech section by the respondent into text and then outputting a character string; a question topic specification means for specifying a question topic by the questioner based on the result of the speech recognition; and a dementia stage determination means for inputting, to a trained neural network, the question topic by the questioner and the character string of the speech section by the respondent to the question topic in an associated manner with each other, and then determining a dementia stage of the respondent, wherein the neural network is trained through machine learning using training data so as to output an estimated dementia stage, in response to an input of the character string of the speech section by the respondent in an associated manner with the question topic by the questioner.	means for inputting, to a trained neural network, the character string that has been converted into text by the speech recognition means, and then determining a dementia stage of the respondent, wherein the neural network is trained through machine learning using training data so as to output an estimated dementia stage in response to an input of the character string.

The first feature missing in the prior art is "a speech information analysis means" that relates to analyzing the speech information and detecting exactly which portions belong to the questioner or the respondent. It is part of pre-processing of the training data.

The second feature is "a question topic specification means" that specifies a question topic (such as food, weather, and family). The specified question topic and a response by the respondent are associated with each other and input to the neural network. The input data in Claim 1 are arranged in a more specific way, which is not described in the prior art.

The JPO states that the first feature, although different from the prior art, may be something that a skilled artisan would have conceived as a modification to improve the estimation accuracy. On the other hand, the second feature contributes to the inventive step, as "it is not a common general technical knowledge at the time of filing," and "it does not seem to be a mere design modification or matter of design choice of an identifier for improving an estimation accuracy."

The JPO further notes the presence of an advantageous effect of the invention, stating "the invention of Claim 1 brings about a significant effect, that is, a highly accurate dementia stage estimation by specifying a question topic by a questioner and a response by a respondent (corresponding character string) to the question topic in an associated manner with each other."

Here, the conclusion could be different under the U.S. practice. A U.S. examiner may argue

specifying a question topic and associating the topic with the response are commonly done in natural language processing, and a skilled artisan would have been motivated to modify the prior art method for better accuracy. The examiner could cite a secondary reference which has nothing to do with assessment of dementia and simply relates to general NLP that shares common issues in speech recognition and analysis. If the input data are arranged in a unique structure or associated with some unique speech patterns or features that doctors would not have found as characteristic to dementia, then a U.S. examiner may find such a method unobvious.

Written Description and Enablement

Cases 46-51 are examples related to the support requirement[5] and the enablement requirement,[6] which are counterparts of the U.S. Section 112(a) written description and enablement requirements.

Notably, Case 50 is directed to a "Method for Estimating Allergy Incidence Rate of Test Substance" and includes claim 1 that fails to satisfy the support requirement and the enablement requirement, and claim 2 that satisfies both requirements according to the JPO.

Case 50	Specification
Claim 1: A method for estimating an allergy incidence rate of a test substance in a human being comprising: inputting a training data to an artificial intelligence model to train the model, the training data including a group of data representing a shape change of a human X cell in culture solution and a scoring data on incidence rates of human allergic reaction caused by each substance, in which each of the substances is separately added to the culture solution and the incidence rates of human allergic reaction caused by each of the substances are already known; obtaining a group of data representing a shape change of a human X cell that has been measured in culture solution to which a test substance is added; inputting, to the trained artificial intelligence model, the group of data representing a shape change of a human X cell that has been measured in the culture solution to which the test substance is added; and causing the trained artificial	An embodiment discloses an experimental result verified by (i) adding each of candidate substances, of which contact dermatitis incidence rate is known, is separately added to culture solution for a human X cell, (ii) obtaining a group of data representing a shape change of a human X cell in the culture solution in an ellipticity, rugosity, and oblateness between before and after the addition; inputting, to a universal artificial intelligence model, a training data to train the model including the above-mentioned 3 types of data in the shape change and a scoring data on incidence rates of contact dermatitis caused by each of the substances so as to train the model; each of substances that has not been used for the training of the artificial intelligence model, of which contact dermatitis incidence rate is known, is separately added to culture solution for a human X cell;

intelligence model to calculate a scoring data of an incidence rate of human allergic reaction. Claim 2: The method for estimating an allergy incidence rate as in Claim 1, wherein the group of data representing a shape change of a human X cell is a combination of a shape change in an ellipticity, rugosity, and oblateness of the human X cell; and the allergic reaction is contact dermatitis.	obtaining a group of data representing a shape change of a human X cell in the culture solution in an ellipticity, rugosity, and oblateness between before and after the addition; inputting the obtained group of data to the trained artificial intelligence model; and calculating a scoring data on contact dermatitis incidence rates that is estimated by the artificial intelligence. The experimental result shows that, for ○% or more of the candidate substances, the difference between the estimated score and the actual score was equal to or less than ○%.

The claims are directed to a method of assessing whether a certain substance could cause an allergic reaction. The specification describes an experiment which assessed the possibility based on the observation of how a certain cell changed its shape in terms of ellipticity, rugosity and oblateness while being cultured with the substance.

The experiment is consistent with claim 2, but claim 1 is not limited to these three factors and more broadly recites "the training data including a group of data representing a shape change of a human X cell in culture solution." The assumption is that change in the cell shape can be measured with various parameters besides ellipticity, rugosity, and oblateness, and no correlation was known between such other parameters and an allergy incidence rate.

Claim 1 is not fully supported by the specification, as it covers estimation based on factors other than ellipticity, rugosity and oblateness, which are not described. The JPO states "it is difficult to presume a correlation or the like between an allergic reaction incidence rate and a cell shape change even if a common general technical knowledge at the time of filing of the present invention is taken into consideration."

Also, claim 1 is not limited to dermatitis, and the JPO notes the existence of various cells associated with different types of allergic reactions, stating "it is a common general technical knowledge that an antibody or cell associated with allergic reaction and a development mechanism varies among many types of allergic reaction including contact dermatitis."

Claim 1 is not enabled, either, because the correlation between the input (shape change

data) and the output (estimate) in the training data is not fully established. In the JPO's explanation, "it does not seem that the invention is sufficiently disclosed for a person skilled in the art to recognize that an allergic reaction incidence rate can be estimated through a method …, which uses a training data including a group of data representing a shape change of a human X cell other than the combination of a shape change in an ellipticity, rugosity, and oblateness, and a scoring data on known incidence rates of human allergic reaction other than contact dermatitis."

Claim 2 is supported and enabled by the experimental result described in the specification. In Case 50, the correlation between the input (shape change in ellipticity, rugosity, and oblateness) and the output (estimate of possibility of causing contact dermatitis) in the training data is verified by the actual experiment on the AI model. But such actual data are not required for establishing the correlation between the input and output in the training data.

The correlation could be based on "common technical knowledge," "supported by statistical information or explanation," or "supported by experimental evaluation of trained AI model."[7] In that sense the JPO does not necessarily require the applicant to describe experimental data obtained by inputting the test data on the AI or ML model. The applicant may establish the correlation between the input and output in the training data by the statistical information as shown below.

Example of statistical information showing existence of a correlation between the input and output data in the training data.[8]

The JPO's requirement for enabling disclosure to show correlation between the input and the output in the training data raises an interesting question. If the specification contains no experimental evaluation of trained ML model and you argue "common technical knowledge" supports a correlation between the input and the output, for example, a certain marker and a disease, would an ML diagnostic method based on such a correlation involve an inventive step?

In the above Case 50, if you argue it was known that dermatitis correlates with certain changes in the cell shape, a U.S. examiner may argue that the AI-based prediction method based on such a correlation would be obvious.

This question related to enablement and obviousness is a familiar issue to U.S. patent practitioners. We have faced the situation where we argue that the specification is

sufficiently enabling the claimed invention (even without the information the examiner claims missing), but taking such a position may weaken the argument of unpredictability to support unobviousness. There is no easy solution in such a situation, and this shows the importance of careful drafting of the first patent application.

The USPTO has not provided any specific guidance on the written description and enablement requirements for AI-related inventions, but the specification should include at least the details necessary for other computer-implemented technologies. Based on the JPO's discussions, there may be ways to satisfy enablement without actual experimental results performed on test data, but at least training data and training protocols should be discussed.

When the AI inventions relate to life sciences, a safer approach in the U.S. may be to include different embodiments and examples and present claims of varying scope in view of how the U.S. Court of Appeals for the Federal Circuit has addressed enablement in the life sciences area.[9]

Conclusion

The JPO's case examples pertinent to AI-related technology in the examination handbook provide an interesting and useful insight into the examination of AI inventions in the life sciences industry. The analyses of hypothetical claimed inventions are helpful also to U.S. practitioners who may face similar issues raised at the USPTO.

To pass the inventive step test or to show unobviousness, the claimed invention cannot be a simple application of AI or ML to a conventional method. It should include, for example, certain unique features learned through the training process or specific input data structures that provide more accurate prediction.

The specification should be carefully drafted to include sufficient information to satisfy written description and enablement requirements to avoid the need to fill the gap with the general knowledge at the time of filing the application, which may undermine the unobviousness argument.

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[1] Case Examples pertinent to AI-related technology, available at https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/handbook_shinsa/document/index/app_z_ai-jirei_e.pdf.

[2] https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.

[3] Japanese Patent Law, Article 29(2).

[4] Japanese Patent Law, Article 29(2). An English translation is available at http://www.japaneselawtranslation.go.jp/?re=02

[5] Japanese Patent Law, Article 36(6)(i).

[6] Japanese Patent Law, Article 36(4)(i).

[7] See the chart on p. 4 of Case Examples pertinent to AI-related technology (English version).

[8] See Case 49.

[9] See Idenix Pharm. v. Gilead Scis. , 941 F.3d 1149 (Fed. Cir. 2019).

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Biography

Yuki Onoe is a partner and Co-Head of the Chemical Practice Group. Ms. Onoe also serves as head of the Tokyo office and is a partner in the Life Sciences and Litigation Practice Groups. Ms. Onoe prepares and prosecutes U.S. patent applications in the areas including pharmaceuticals, diagnostics, nutritional supplements, optical materials, and battery components. She provides legal opinions and counseling, and assists clients in pre-litigation investigations, discovery, and post-grant proceedings.

Ms. Onoe has previously worked at a patent law firm in Osaka, Japan. She also worked at an IP boutique in Chicago where she focused on prosecuting chemistry-related applications.

A Japanese national educated both in Japan and the United States, Ms. Onoe is particularly skilled in communicating with Japanese companies and explaining various issues involving legal and technical matters.