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Subject: Docket No. PTO-P-2021-0032 Patent Eligibility Jurisprudence Study

The Japan Patent Attorney Association (JPAA) was established under the Patent Attorneys Act in Japan in May of 1915, and it is the sole professional bar association of patent attorneys in Japan. At present, the JPAA has more than 11,800 members practicing in intellectual property law in Japan. Its members practice in all areas of intellectual property law including patent, design and trademark law as well as copyright and unfair competition law.

The Japan Patent Attorneys Association (JPAA) submits its comments in response to the following questions among those given by the USPTO regarding patent eligibility.

3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas:

b. Artificial intelligence

Examination on inventions created by artificial intelligence (AI-created inventions) is still developing, and it may be more difficult to examine these inventions than those in other technological fields. For example, in examining an AI-created invention, it is necessary to analyze the computer process involved in the invention more accurately and test it in terms of its similarity to a natural phenomenon more deeply and accurately from a mathematical perspective. If a patent examiner fails to understand the essence of artificial intelligence and fully compare an AI-created invention with a natural phenomenon, the examiner might grant a preemptive broad patent protection to the invention.

The two-stage Mayo/Alice test currently adopted in the United States serves to prevent a

patent from being granted for an invention which merely predicts a publicly known natural phenomenon. However, it should be noted that if the two-stage Mayo/Alice test applies, an AI-created invention developed based on a natural phenomenon that an inventor has discovered with effort would be excluded from patent protection and an AI-created invention that is characteristic in its technological feature rather than the natural phenomenon itself would also be rejected due to unclearness of the criteria, which could impede appropriate granting of rights.

d. Diagnostic methods

In Japan, "diagnostic methods" that are regarded as medical activities do not have patent eligibility for humanitarian reasons; however, "test kits" or "testing methods" used in making diagnoses are patentable. For example, a "test kit" for measuring a tumor marker in the blood, which uses a tumor marker control to prepare a calibration curve, is eligible for patent.

However, we heard that in the United States, many inventions relating to such test kits have been determined to lack patent eligibility under Section 101 of the US Patent Act on the grounds that a tumor marker control is a "product of nature." If this practice continues to apply, all test kits used to ascertain the health conditions of humans would not be patented, which would significantly demotivate test kit manufacturers to invent new products. If appropriate test tools are not developed, this would be problematic in maintaining people's health.

e. Pharmaceutical treatments

In the case of creating a pharmaceutical agent by altering an antibody produced by human lymphocytes, for example, an epitope sequence that exists in nature is basically used for binding an epitope to an antibody. In such case, a question arises as to the distinction from a "product of nature." An agent that is effective for animals but not effective for humans cannot be used as a pharmaceutical agent. Therefore, as in the case of test kits mentioned above, the issue of patent eligibility is inevitable when dealing with biotechnology-based pharmaceuticals.

If pharmaceutical manufacturers cannot obtain patents for such inventions, they cannot conclude licensing agreements and recoup development costs, which could affect their pharmaceutical development. Given that today, safety testing takes a huge cost of not less than 100 billion JPY, which cannot be covered by a single company alone, the current practice of the USPTO regarding patent eligibility for these kinds of inventions may have a significant impact on pharmaceutical development in the future.

4. Please explain how your experiences with the application of subject matter eligibility requirements in other jurisdictions, including China, Japan, Korea, and Europe, differ from your experiences in the United States.

(1) Patent eligibility in Japan

According to the Patent Examination Guidelines of Japan Patent Office, the laws of nature as such are patent ineligible, and those set forth in (i) to (v) below are also patent ineligible:

(i) any laws other than the laws of nature (e.g., economic laws);

(ii) arbitrary arrangements (e.g., a rule for playing a game as such);

(iii) mathematical formula;

(iv) mental activities of humans; and

(v) those utilizing only (i) to (iv) (e.g., methods for doing business as such).

However, technology that uses the laws of nature in combination with elements other than the laws of nature is patent eligible in Japan. In the patent eligibility determination, little consideration is given to whether such other elements are well-known. More specifically, a mental process is found to be patent eligible in most cases as long as it is clearly stated that the mental process is realized by computer hardware. Therefore, it is highly likely that the patented inventions disputed in Mayo v. Prometheus would be found to be patent eligible in Japan.

Accordingly, it is presumed that most inventions that have been found to be patent ineligible in the United States would have been found to be patent eligible in Japan.

Meanwhile, the JPO Examination Guidelines include the following provisions concerning the clarity requirement and support requirement, which are not often discussed in the United States.

a. With regard to the problem to be solved by an invention as stated in the description, matters necessary for solving the problem must be described in the claims. Because of this provision, it is highly likely that a claim would be rejected if the important points of the invention recited in the claim are abstract concepts.

b. The technical role of each element of the claimed invention must be comprehensible from the claim language and common general technical knowledge. For example, a claim would be rejected if it is obvious from common general technical knowledge that the claim does not describe a structure necessary for enabling the respective elements to play specific roles; therefore, it is highly likely that an excessively abstract claim would be rejected.

In combination with the inventive step requirement, these provisions may serve to prevent the extensive monopoly of the laws of nature in Japan.

Thus, the approach adopted in Japan enables more consistent determinations on patent

eligibility than the approach adopted in the United States, which considers whether the claimed invention amounts to significantly more than an invention based on natural law itself, focusing on the problem to be solved by the invention and the roles of the elements of the invention.

(2) Comparison with inventions in the pharmaceutical field in Japan

In Japan, inventions relating to test agents are not rejected for a reason that "inventions using proteins in the human body are unpatentable." However, in consideration of the circumstances mentioned in 3. above, we assume that test agent manufacturers in the United States (most of them are biotechnology-based companies) are facing difficulty in obtaining patent rights.

13. Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?

Since the Supreme Court judgment on the Alice Case in 2014 in the United States, the USPTO has modifies its practice, including the MPEP and guidelines, many times, and we consider that the examination has been conducted while the examiners' determinations on patent eligibility have not yet been firmly established. Such situation makes applicants and patent right holders concerned about what types of inventions can be patented or whether their patent rights can be maintained stably. This situation is unfavorable as it would reduce incentives for filing patent applications.

Patent eligibility must be discussed from the global perspective. The reality is, however, that determination on patent eligibility in the United States is made based on the view accepted in the United States, and the same is true of Japan and Europe. Thus, even at a time when technology is used globally, determination on patent eligibility differs under different patent systems, and companies doing business globally may find such patent systems user-unfriendly. To solve this problem, we hope that the United States will coordinate (harmonize) its patent system with those of other countries more actively.

In light of the current practice in the United States in determining patent eligibility for inventions in the fields of biotechnology and pharmaceuticals, there is concern that appropriate protection of patent rights would not be available, as mentioned in 3. above. This could also affect inventions relating to methods for administering drugs among treatment methods.

Thank you for providing the JPAA with the opportunity to comment on the important issues.

Sincerely,

SUGIMURA Junko
President
Japan Patent Attorneys Association