



JAPAN PATENT ATTORNEYS ASSOCIATION

3-4-2, Kasumigaseki Chiyoda-ku, Tokyo 100-0013, JAPAN
Telephone: + 81-3-3581-1211 / Facsimile: +81-3-3581-9188
<http://www.jpaa.or.jp>

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United States Patent and Trademark Office
myriad-mayo_2014@uspto.gov

Re: Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products

Dear Sirs:

The Japan Patent Attorneys Association (JPAA) is a professional association of more than 10,000 patent attorneys practicing in intellectual property law in Japan. Its members practice in all areas of intellectual property law including copyright and unfair competition as well as patent, trademark and design laws. Many are capable of representing clients in infringement lawsuits. The JPAA would like to submit comments on the proposals.

The USPTO issued and published on March 4, 2014, examination guidance titled "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products."

The content of the guidance intends to broaden the meaning of the Supreme Court decision on the Myriad case "*Association for Molecular Pathology et al. vs Myriad Genetics Inc.*" from the field of genes in the human genome to a wide range of natural products.

We, however, consider that the guidance should not make it so that the Myriad case – a judgment on genes in the human genome – is broadly applied to all other natural products. Our opinion is as follows.

1. Distinctiveness or particularity

The guidance does not fully consider the distinctiveness of the Myriad case.

The Myriad case was a lawsuit contesting the subject matter eligibility of genes in the human genome. The Supreme Court decision judged that isolated DNA is not markedly different from a human genomic sequence, and the judgment is understandable from the statements of the decisions as cited below:

(Supreme Court decision, Syllabus, p.2, L31-L36, Statement of Decisions p.14,



L13~L16)

"Myriad's claims are not saved by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together. The claims are not expressed in terms of chemical composition, nor do they rely on the chemical changes resulting from the isolation of a particular DNA section."

(Statement of Decisions, p.12, L2-L3)

"Nor did Myriad create or alter the genetic structure of DNA."

(Statement of Decisions, p.12, L23-24)

"Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."

In many cases of practical application of genes, the worth or essential quality of a gene is generally its base sequence and the genetic information encoded by that sequence. Accordingly, a fair comparison of the isolated DNA with the genomic sequence of a gene is able to be made via the sole aspect of the base sequence in many cases.

As well, the gene in the human genome, a naturally occurring product, which was compared with the isolated DNA in the Myriad case, is distinctive in that 99% of its genetic information has been analyzed and made publicly available.

The Myriad case possesses the distinctiveness as described above.

On the other hand, p.7 of the guidance describes Example B that explains purified amazonic acid. Amazonic acid is a natural product, but its entire structure has not been analyzed nor made public, and this situation of amazonic acid is different from that of genes in the human genome. That is to say, in order to determine a claim regarding amazonic acid to be not patent eligible, there must be a "template" of a naturally occurring product that should be used for making a structural comparison with amazonic acid. Despite the absence of such template, however, Example B asserts that amazonic acid is not eligible due to the simple reason that it is present in a naturally occurring product.

That assertion can only be made by broadening the meaning of the Supreme Court decision on the Myriad case.

If such an approach for determining the eligibility as subject matter as described in Example B were applied to a broad range of natural products, there is a concern that many chemical substances whose structures have not been elucidated, including even antibiotics and proteins with sugar chains, could be determined to be not eligible for a product claim by reason that the claimed chemical substance is a natural product.

In addition, the Supreme Court decision on the Myriad case states, in its conclusion, that genes and the information encoded by the genes are not patent eligible under §101 simply because they have been isolated from the surrounding genetic



material.

(Statement of Decisions, p.18, L2~L9)

"Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of §101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."

For the Myriad case, the Supreme Court decision itself restricts the object to be judged to a matter of genes in the genome and information encoded by the genes.

The guidance should more carefully consider the distinctiveness of the Myriad case. We are concerned that if the guidance is applied to a whole range of natural products, it is likely that it would fail to accomplish the intention of the Supreme Court decision on the Myriad case, that is, to keep a balance between prohibition against monopolization of a fundamental tool of scientific or engineering technology that should be put in the public domain and the creation of incentives for discovery, creation and invention.

2. Inventions not implicated by decision in the Myriad case

The Supreme Court decision on the Myriad case states that this decision does not affect certain kinds of inventions. The guidance, however, describes that those inventions are not eligible. That assertion in the guidance is problematic.

The Supreme Court decision on the Myriad case states as follows.

(Statement of Decision, p.17, L14~16)

"It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court."

The above statement means that a method claim is excluded from the effective range of the Supreme Court decision.

Besides method claims, the Supreme Court decision further declares the same for a composition claim, as follows.

(Statement of Decision, p.17, L25~ p.18, L1)

"Similarly, this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, '[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.'"



The above statement mentions that a claim reciting genes accompanied by a new application is not included in the range of objects for judgment. This includes Claims 16 and 17 of the Myriad patent (USP5747282) concerned with two primers.

(Claim 16)

"A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene."

(Claim 17)

"The pair of primers of claim 16 wherein said BRCA1 gene has the nucleotide sequence set forth in SEQ ID NO: 1."

The Supreme Court decision accordingly means the primer is patent eligible. On the other hand, Example E, p.11 of the guidance simply describes that a primer of Claim 1 is not eligible, and that means the guidance goes further than the Supreme Court decision on the Myriad case.

The guidance should more clearly explain that there may be a case where the primer is found to be eligible.

3. Supreme Court decision on Funk Brothers

Our opinion is that the reason why the Supreme Court decision on the Funk Brothers case denies the eligibility of the claimed invention of the Funk Brothers' patent is not because the claimed invention is a natural product.

The claimed invention of the Funk Brothers' patent is a product that packages plural sorts of known bacteria together. The Supreme Court decision on the Funk Brothers case judged that the claimed invention is not eligible by reason that the claimed invention is an application of a natural principle and it is not a product of invention.

Therefore, it should be noted that the criterion taken up by the Supreme Court decision on the Funk Brothers case in order to judge whether the subject matter of the claimed invention falls under 'the product of invention' is to estimate whether the action to make the subject matter is a merely trivial or nominal action, and the criterion in the Funk Brothers case is different from that of judging whether the claimed invention is obvious under 35 USC §103.

The Supreme Court decision on the Funk Brothers states as follows:
(333 U.S. 131)

"The aggregation of select strains of the several species into one product is an application of that newly discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants."



(333 U.S. 132)

"But once nature's secret of the non-inhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention."

(333 U.S. 133.)

"But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery."

What is more, the Supreme Court decision on the Funk Brothers case simply states that the discovery of a phenomenon of nature is ineligible; the decision does not directly state that a natural product is ineligible.

(333U.S.130)

"[The patentee] does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature."

The Supreme Court decision in the Funk Brothers case accordingly judged that if the substantial content of a claimed invention merely describes phenomena of nature, the invention is not eligible under 35 USC §101.

Our opinion is that the Supreme Court decision in the Funk Brothers case did not create grounds for considering the issue of whether a structural difference from a naturally occurring product should be included in the requirements for eligibility under 35 USC §101, the issue relating to Factor (a) of the guidance.

4. Legal stability of patent rights

The guidance describes that a product made by artificially changing a natural product is patent eligible. Example B, for example, shows the relationship between amazonic acid as a natural product applicable to curing cancer and 5-methyl amazonic acid as an artificial derivative applicable to stimulating hair growth in addition to curing cancer.

However, evidence to show whether the claimed product is a natural product is not restricted to the matters known before filing the patent application, but includes those found after the patent application is filed. Thus, even if a chemically synthesized product is filed as a product claim in a patent application and is considered to be a markedly different product at the time when the patent application was filed, the patent right on the product claim may be invalidated upon discovery of the fact that the patented product may be rare but is actually found to be present in nature due to progress in science after the filing of the patent application. We are therefore concerned



Page 6 of 6
June 2014

that the legal stability of patent rights may be deteriorated.

5. Patent harmonization

The so-called “substance patent system” has been adopted in major jurisdictions including Japan. A substance isolated from a natural product, for example, a microorganism, antibiotic, or a protein with a sugar chain, is eligible as an invention of a product in these jurisdictions. On the other hand, substances isolated from natural products are not eligible in the U.S. according to this guidance. The guidance goes against the effort to internationally harmonize patent system requirements.

Our opinion is therefore that the guidance should not make it so that the Myriad case – a judgment on genes in the human genome – is broadly applied to all other natural products.

Best Regards,

Fumio Furuya

President

Japan Patent Attorneys Association