

# Incomplete Invention of Drugs

Tomoyuki Hisa\*

University of Tokyo, Rm670, Bldg4, RCAST, 4-6-1 Komaba, Meguro, Tokyo, 153-8904, Japan

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**Abstract:** Scientists seldom know the differences between "rejected invention", "non-invention", "incomplete invention", "invention yet to be completed" and "defective invention". The Japanese Supreme Court appointed me as a specialist member (Article 92-2, Code of Civil Procedure) of intellectual property division for medical and biological patents. Herein, I present scientists to the differences and which of them are patentable. In order to prevent oneself from being taken for granted for the scientists' noblesse oblige by clever business administrations, the scientists must know the borderline between patentable or non-patentable.

**Keywords:** Rejected invention, non-invention, incomplete invention, invention yet to be completed, defective invention.

## INTRODUCTION

The definition of the term "invention" in the Patent Law in Japan is said to be synonymous with the definition proposed by Josef Kohler. Article 2, Paragraph 1 of the law stipulates that invention means "highly advanced creation of technical ideas by which a law of nature is utilized."

The Supreme Court decision on January 28, 1969 says that it is appropriate to understand that the technical content of "invention" in Article 2, Paragraph 1 of the Patent Law must have concrete and objective constituent features to the extent that a person having ordinary knowledge about the technical field in question may repeatedly use such technical content and achieve the intended technical effect. It states that any invention having technical content with no such constituent features to that extent is an incomplete invention and should not be regarded as an "invention" as set forth in Article 2, Paragraph 1 of the Patent Law.

Thus, the Supreme Court decision on October 13, 1977 in a drug product case says that the rejection of a patent application based on the grounds of its being an "incomplete invention" should be based on the provisions of the main paragraph of Article 29, Paragraph 1 of the Patent Law. In other words, it states that while one of the requirements of patentability is the fact that an invention for which a patent has been applied should be an industrially applicable one, "invention" here should be understood to mean an "invention" as stated in Article 2, Paragraph 1 of the Patent Law. Thus, if an invention for which a patent has been applied is an incomplete one, such an application shall be rejected for the reason that the invention is not an "invention" as defined in the main paragraph of Article 29, Paragraph 1 of the Patent Law.

However, the definition of an "invention" in Article 2, Paragraph 1 of the Patent Law is that of an "invention" in general and is not that of a "patented invention." "Patented

invention" is defined in Article 2 Paragraph 2 of the Patent Law, and the concept of invention in general and that of patented invention differs from each other. The Tokyo High Court decision on February 28, 1989 says that Article 2, Paragraph 1 of the Patent Law is a very general definition of the concept of invention and that the term "invention" specified in Article 2, Paragraph 1 of the Patent Law also includes those inventions rejected on the grounds that they do not fulfill the requirements for patentability.

Based on the above discussion, it is my opinion that an "invention" that has been subject to a patent rejection because it has not been completed, whereby the main paragraph of Article 29, Paragraph 1 of the Patent Law was used as the reason for the rejection, should be considered as a "patented invention" as set forth in Article 2, Paragraph 2 of the Patent Law.

## REJECTED INVENTION (NON-INVENTION AND INCOMPLETE INVENTION)

With regard to the completion of an invention, in the U.S., a mere conception is regarded only as a first stage, and a second stage, which is a tangible stage, is required for the completion of the invention. The idea adopted in Japan is itself similar to this American idea [1].

The general examination standards in 1972 said that there are two types of "rejected inventions", which do not meet the requirements for invention and have not been completed. According to the standards, they are a "non-invention" and an "incomplete invention;" while the former includes the laws of nature themselves, a mere discovery, an invention against the laws of nature and an invention using no law of nature, the latter includes cases where it is doubtful, based on the laws of nature, that the disclosed technical means can attain its purpose and cases where the alleged invention does not express any perfect technical idea. Therefore neither of these two types is an "invention."

The examination standards in 1993 abolished the distinction between "non-invention" and "incomplete invention" and said that what does not fall under the category of "invention" are the laws of nature themselves, a

\*Address correspondence to this author at the University of Tokyo, Rm670, Bldg4, RCAST, 4-6-1 Komaba, Meguro, Tokyo, 153-8904 Japan; Tel: +81-3-5452-5436, Fax: +81-3-5452-5436; Email: pa2022@art.osaka-med.ac.jp

mere discovery that is no creation, an invention against the laws of nature, an invention using no law of nature, an invention that is not a technical idea (a skill, a mere presentation of information, a mere esthetic creation, a computer program-ming language, or a computer program itself), an invention lacking all the means to attain its purpose and an invention that does propose the means to attain its purpose but is, however, clearly unable to attain that purpose.

As a result of the above-mentioned revision of the examination standards, judgment of whether the applied invention uses a law of nature or not is now made on the basis of all claims. In addition, the term "incomplete invention" is no longer used in the examination standards for patents and utility models. However, the Tokyo High Court decision on January 18, 2005 in the case of an external preparation for the treatment of atopic dermatitis, including nitroimidazole-based compounds, stated that the invention is an "invention yet to be completed (incomplete as an invention)" because it is impossible to presume that the technical content (technical means) of the invention in the present case can attain the technical effect the invention intends.

I think that the distinction between an "incomplete invention" before 1993 and an "invention yet to be completed" in and after 1993 is unclear. But I consider it possible to ensure the consistency of the meaning of these terms if we understand, based on the context of the precedent in 2005 referred to above, that we should reword a "defective invention," which is discussed in Section 3 below, into a "defective invention in a narrow sense (an invention that is insufficient but has been completed as invention)" and call this "defective invention in a narrow sense" and an "invention yet to be completed (an invention that has not been completed because it is insufficient) a "defective invention in a broad sense" collectively.

## DEFECTIVE INVENTION

Neither a "non-invention" nor an "incomplete invention," the two types of "rejected inventions" mentioned above, on patentable on the grounds that they are not regarded as an "invention." By contrast, a "defective invention" has patentability.

While an "incomplete invention" means an invention that shows some objective working effect but does not attain its purpose at all, a "defective invention" refers to an invention that cannot be regarded as having fully attained the purpose stated in the specification or it is one that has some problems in terms of its working. Because a "defective invention" is insufficient but has been completed as an invention, it has patentability.

One of the well-known cases of a "defective invention" is the case of the invention of a wind power generator for wireless communications with specification lacking any description of a device for eliminating the risk of short circuits. This was in the trial decision on October 5, 1925.

As already stated above, an example of an "incomplete invention" is the Supreme Court decision on October 13, 1977 in a drug product case. More famous, however, is the

Supreme Court decision on January 28, 1969 in the case of an energy generating device. In this case, the court ruled that, considering the fact that the risk of reactors is a unique one that is uncontrollable by any ordinary means, unlike in the case of common power plants, the invention had to be regarded as incomplete as the invention of a reactor. This is because the specification did not specify the method for controlling fission energy and for preventing the risk of radioactivity, even though the basic structure of the reactor had been completed.

I probably do not need to discuss this case here because there have been many criticisms about it, but I consider that this may be a "defective invention" rather than an "incomplete invention." Could this decision be considered similar to the trial decision on October 5, 1925 referred to above?

In this case, the application for a patent for the invention was filed in 1940, ruled invalid due to the outbreak of World War II but then recovered its validity as a result of postwar measures. In 1962, the application was given a decision of rejection, followed by a demand for an appeal, an appeal decision, a suit against the appeal decision and a final appeal. The Patent Law applied to this case was the Patent Law of 1921 and its provisions governing the term of a patent differed from those of the postwar Patent Law. Because of this, if the application had been patented as a "defective invention," there is no doubt that an unnatural situation would have arisen whereby this case of an invention, whose patent right had already expired in other countries, but remained valid only in Japan. Therefore, it can be supposed that a political judgment lay behind the fact that the invention was not patented. However, the invention should have originally been patented, and I think that if the authorities did not want to patent the invention, they should have used public order or other general clauses as the basis of rejection instead of regarding the invention as an "incomplete invention."

What would happen if these ideas were applied to drugs? In the case of drugs that may produce harmful side effects, what corresponds to the device for eliminating the risk of short circuits mentioned in the trial decision in the case of a wind power generator for wireless communications and to the method for preventing the risk of radioactivity referred to in the case of an energy generating device could be considered to be another drug for curbing side effects or a method for preventing them. In this case, a drug having a specified side effect would be patented, after considering that the invention of the drug is a "defective invention" even though it has a side effect, and another drug for curbing the side effect would be patented as a new invention.

Needless to say, it would be natural that the above-mentioned Tokyo High Court decision on January 18, 2005 in the case of the external preparations for the treatment of atopic dermatitis, including nitroimidazole-based compounds, stated that because it was impossible to presume that the technical contents (technical means) of the invention in the present case could attain the technical effect the invention intended, the invention was an "invention yet to be completed (incomplete as an invention)."

Also, no drug is allowed to be distributed on the market as a drug without approval for production from a government agency. Thus, a drug that has not yet been given such approval for production by a government agency may be regarded as a defective invention, too. As stated before, however, one cannot deny that this invention is an "industrially applicable invention" as set forth in the main paragraph of Article 29 of the Patent Law. In other words, one can say that an invention has industrial applicability even if it is virtually in no industrially applicable state.

In addition, genetic information lacks the requirements for patentability because it has no utility itself, but genetic information with a specified function has patentability because it is presumed that such information has utility. I myself applied for a patent for genetic information with a specified function first in 2005 (June 2, 2005) and then filed an international patent application for the function lately (June 2, 2006) (PCT/JP2005/311119) [2]. I am now looking forward to the outcome of these applications.

### INVENTION YET TO BE COMPLETED

An invention with an abstract technical idea and being void of concreteness is considered to be an "incomplete invention/invention yet to be completed." However, whether the invention is an "incomplete invention/invention yet to be completed" or a technically completed one is determined only based on the specification, that is, the filing document presented by the applicant. Because of this, the distinction between the disclosure requirements for an invention in the filing document and the completion or non-completion of the invention is unclear, and as a result, cases arise where the invention is considered not as an "incomplete invention/invention yet to be completed" but as a "deficiency in the description of the specification."

By contrast, there are also cases where because of a deficient description of the specification, the constitution of the invention is not specific or objective enough for a person skilled in the art to work the invention repeatedly and attain the intended purpose. In these cases, the invention may be regarded as an "incomplete invention/invention yet to be completed" rather than as a "deficiency in the description of the specification."

In this connection, there are two types of "deficiency in the description of the specification:" (i) the case where the "invention" has been "completed" but the "description" is "deficient;" and (ii) the case where the "invention" is "incomplete" and so the "description" is inevitably "deficient."

In the past, the amendment rules were more flexible and the strategy of filing an application first and then amending any deficiency later was adopted in some cases. In these cases, no amendment was possible for an "incomplete invention/invention yet to be completed" because the invention had not been completed, while a "deficiency in the description of the specification" could be amended. At present, however, no large difference exists between an "incomplete invention/invention yet to be completed" and a "deficiency in the description of the specification" because the amendment rules are stricter now.

The differences between the case where the patent application is considered as an "incomplete invention/invention yet to be completed" and the case where it is regarded as a "deficiency in the description of the specification" are outlined below:

\* Effect of excluding a later application for a prior invention

It is stipulated that a patentable invention must have been completed at the time of its application. This rule is important in relation to a later application. If the practice of applying an incomplete invention first and making an amendment to the invention later is allowed, the first-to-file system will be destroyed. The Tokyo High Court decision on April 25, 2001 in the case of grain flour for frozen instant noodles stated that a prior invention that is an "invention yet to be completed," which cannot be considered as an "invention" under the Patent Law, has no effect in terms of excluding any later application. This means that no later application is permitted on account of the problem of novelty if the prior invention is an "invention," while a later application may be allowed if the prior application is no "invention" because no problem of novelty arises.

\* Cited invention in the decision on unobviousness

The Tokyo High Court decision on September 29, 1998 in the case of pancreatic alpha-amylase said that no "invention yet to be completed" can be cited as an invention.

\* First applied invention used as the basis of a claim of priority

The Tokyo High Court decision on October 20, 1993 in the case of an antilipotropic drug stated that the U.S. patent application, which was used as the basis of a claim of priority, was unable to claim priority because it was an "invention yet to be completed."

\* Completion of an employee's invention

The Nagoya District Court decision on September 2, 1996 in the case of a multi-storey car park where the time of completion of an invention was the problem involved in determining in whom the right to an employee's invention should vest recognized that when the working plan had been completed, the invention of the multi-storey car park had been completed.

\* Non-exclusive license resulting from prior use

The Supreme Court decision on October 3, 1986 in the case of a walking beam-type heating furnace stated that for an invention to be completed, its technical means should have a concrete and objective constitution that is sufficient for a person of average knowledge in the technical field in question to apply the technical means repeatedly and attain the intended purpose and that this is a sufficient condition for a completed invention. This standard was used to establish the prior user's right.

In the Supreme Court decision on February 29, 2000 in the case of a new variety of peach, the point at issue was the fact that reproducibility was low when the invention was carried out repeatedly. The decision said that the invention could not be regarded as an invention yet to be completed

because it should be considered that the possibility of carrying out the invention repeatedly could not be denied for the reason that it had low reproducibility.

#### **CURRENT & FUTURE DEVELOPMENTS**

However, I am of the opinion that the frequency of the reproducibility of the repeated working is a matter of degree. I think that while the invention has the possibility of repeated working to a certain level of low reproducibility, one will be unable to say that it has such a possibility if the reproducibility goes down below such a level. In other words, if the invention has reproducibility so low that a new invention would be needed to have reproducibility, such an invention would not be patentable because it could no longer be considered to be an invention (or because it has only insufficient descriptions concerning repeated working). Actually, the Tokyo High Court decision on September 29, 1998 in the case of the experimental method for saliva alpha-amylase stated that the invention was an invention yet to be completed because the description of the sample experiments in the specification was not concrete and because the three double-checkers for the quoted sample experiments who had skill and experience in the preparation of monoclonal antibodies failed to reproduce the invention.

In my own case, I believe that I gave careful consideration to avoid my invention being regarded as an invention yet to be completed by depositing cells producing monoc-

lonal antibodies themselves with the International Patent Organism Depository on June 1, 2006 (FERM ABP-10615, 10616, 10617, 19618).

I took part on May 17, 2006 as a specialist member (Article 92-2, Code of Civil Procedure) in the suit against the appeal decision No.10820 of 2005 (Gyo Ke) as to the case where the patent application No. 507654 of 1992 was rejected in accordance with Article 36, Paragraphs 5 and 6 of the Patent Law and the petition for the appeal No. 2003-24255 was not approved. The point at issue in this case was whether the "method for producing activated complex" was an invention, an invention yet to be completed or a deficiency in the description of the specification, and I thought that the case would be that of a deficiency in the description of the specification. This was because the invention had so many uncertain factors that no activated complex could be obtained unless a person skilled in the art worked on all of the factors, although the invention could be carried out. Such a method would be insufficient as a method for producing any activated complex when paying attention to the producing function.

#### **REFERENCES**

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