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知识产权与遗传资源、传统知识和民间文学艺术政府间委员会

第三届闭会期间工作组会议

2011年2月28日至3月4日，日内瓦

WIPO/GRTKF/IC/9/13: “专利制度与遗传资源”

秘书处编拟的文件

1. 在2010年12月6日至10日举行的第十七届会议上，知识产权与遗传资源、传统知识和民间文艺政府间委员会(“委员会”)“请秘书处为2011年2月28日至3月4日举行的第三届闭会期间工作组会议(IWG 3)提供所有相关文件，其中包括[……]WIPO/GRTKF/IC/9/13［……］”。

2. 根据上述决定，本文件附件中载有文件WIPO/GRTKF/IC/9/13：(“专利制度与遗传资源”)。

3. 请闭会期间工作组注意本文件及其附件。

[后接附件(无中文译文)]

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DATE: April 20, 2006

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Ninth Session
Geneva, April 24 to 28, 2006

THE PATENT SYSTEM AND GENETIC RESOURCES

Document submitted by Japan

1. By a note dated April 20, 2006, the Permanent Mission of Japan to the United Nations Office and Other International Organizations in Geneva request that a documentbe circulated as a working document for the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee") at its ninth session.

2. The text of the document as received is published in the Annex to this document.

3. The Intergovernmental Committee is invited to take note of the contents of the Annex.

[后接附件]

[WIPO/GRTKF/IC/9/13 附件]

The Patent System and Genetic Resources

I. The Relationship between Convention on Biological Diversity (CBD) and the Patent System as for the Premise of Examination

1 The consistency of the Convention on Biological Diversity (CBD) with the patent system has been one of the major points at issue in the recent discussions relating to intellectual property rights, and it is the premise for the examination of various issues concerning the relationship between genetic resources, associated traditional knowledge, and intellectual property rights.

However, as a matter of legal rights and obligations, it is apparent that CBD and the patent system do not conflict with each other and that they are mutually supportive.

A. The Relationship between the CBD and the Patent System

2 Article 22.1 stipulates the following:

> The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

3 Article 16.5 stipulates the following:

> The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

4 First of all, based on Article 22.1 of the CBD, it is clear that the provisions of the CBD do not have the direct influence over the current patent system which has been established according to the existing international agreement.[1] Moreover, although Article 16.5 of the CBD provides the cooperation among countries in order for the intellectual property rights to promote and not to run counter to the objectives of the CBD, the Article also makes clear that such cooperation should take place within the framework of "national legislation and international law", which means within the existing international and national patent system.[2] Therefore, from the legal perspective, it is apparent that existing patent system would not be changed due to the provisions of the CBD and that it is not expected to have such changes.

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[1] As for the proviso on "serious damage or threat" in this provision, it is difficult to judge in which cases "a serious damage or threat to biological diversity" is caused, but it could be considered to be extremely exceptional. In most national legislation and international law that provides protection of international property rights, the possibility of constraints that the intellectual property rights might get in some particular cases as for the sake of public interest has been taken into consideration.

[2] At the drafting stage, this provision was changed from "recognizing that…have an influence on…" to "recognizing that…may have an influence on… [i.e., 'may' was added]," and this showed that a consensus on whether intellectual property rights has an influence on the CBD or not and, if such rights does have an influence, whether the influence was positive or negative, was not obtained in the process of negotiation among the countries.

5 Regarding the impact of the patent system on the CBD, it is necessary to keep in mind that the patent system grants patents that are only for inventions that meet certain requirements such as the requirements of novelty, inventive steps, and industrial applicability, but it does not grant rights for prior art. In other words, what has existed as public domain will remain as it is, and if countries providing/providers of genetic resources and associated traditional knowledge can utilize those in the same manner as usual, and they will not come under the influence of the patent system.

6 The objective of treaties relating to the patent system, such as the TRIPS Agreement, is to protect intellectual property, namely inventions, while the objective of the CBD is to conserve biological diversity; therefore, the objectives, content, and subject matter of the CBD as a treaty differ from those of treaties relating to the patent system.

B. Mutually Complementary Effect of the CBD and the Patent System

7 The objectives of the CBD to be pursued in accordance with its relevant provisions are 1) the conservation of biological diversity, 2) the sustainable use of its components and 3) the fair and equitable sharing of benefits arising out of the utilization of genetic resources, which are accomplished, *inter alia*, by the "appropriate transfer of relevant technology, taking into account all rights over those resources and to technologies" as stipulated in the CBD. In this manner, as emphasis is placed on technological transfer as the means to accomplish the three objectives of the CBD, the patent system is expected to function as an important factor for the technological transfer. For instance, the publication system and the license system under the patent system facilitate the diffusion and transfer of technology. Also, it should be kept in mind that benefits (monetary and non-monetary benefits, including technologies subject to technology transfer), which are subject to benefit sharing, arise from the proper protection of intellectual property rights. To forbid granting of a patent to any living organism will deprive prospective applicants of opportunities to obtain benefits arising from inventions utilizing genetic resources and take away incentives for the technology development which might be subject to transfer, and, consequently, the opportunities for benefit sharing to the countries providing the genetic resources will also be lost.

8 In this way, it is presumable that the patent system may complement the CBD in facilitating the benefit sharing or technology transfer specified in the CBD.

II. Efforts made based on the CBD

A. Obligations under the CBD

9 The CBD aims at i) the conservation of biological diversity, ii) the sustainable use of its components, and iii) the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

10 Article 16 of the CBD, which is related to "patents" or "intellectual property rights", does not require disclosing the source/country of origin of genetic resources and associated traditional knowledge. Therefore, the CBD does not oblige Contracting Parties to disclose the

country of origin, etc., of genetic resources and associated traditional knowledge in patent applications.

11 The CBD leaves the decision to the Contracting Parties' discretion regarding the measures to be taken to accomplish said objectives; therefore, it is permissible for Contracting Parties to implement the Convention by taking other measures than requiring disclosure of the source/country of the origin of genetic resources and associated traditional knowledge in patent applications.

B. Activities in Japan

12 Japan has been a contracting party since the effective date of the CBD; therefore, we think it is very important to accomplish the objectives of the CBD and to realize the sustainable use of genetic resources. Genetic resources are the basic materials for various research activities, including biotechnology, and for industrial applications of the results of such research activities; consequently, such genetic resources are considered to be essential to the sound development of industries in Japan.

13 Therefore, Japan, in "Biotechnological Strategies," aims at the "realization of the collection, acquisition and offer of genetic resources in harmony and cooperation with the countries owning those resources based on the spirit of the Convention of Biological Diversity (the CBD)" and has carried out various activities in accordance with the discretion given to the Parties by the CBD. In steadily advancing our activities, we have come to consider it possible to facilitate smooth access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization based on the CBD.

1. Preparation of "Guidelines on Access to Genetic Resources for Users in Japan"

14 Japan considers it possible for the Contracting Parties of the CBD to facilitate smooth access to genetic resources and fair and equitable benefit sharing arising out of their utilization, which is one of the objectives of the CBD, by fulfilling their obligations in accordance with the discretion given to the CBD Contracting Parties while considering the Bonn Guidelines.

15 Therefore, since the Bonn Guidelines were adopted in 2002, Japan has enlightened Japanese users of genetic resources and has disseminated the necessity to comply with the law of the countries providing said resources and to share benefits arising out of their utilization based on mutually agreed terms with concerned parties when Japanese users have access to genetic resources overseas.

16 Furthermore, "The Guidelines on Access to Genetic Resources for Users in Japan" was prepared in March 2005 based on the opinions of industry representatives and academicians in order to publicize the idea of access to genetic resources and benefit sharing as stipulated in the Bonn Guidelines. From April 2005, the Japanese Government has been disseminating the Guidelines throughout Japan. Japan was the first country to prepare the aforementioned Guidelines for the users of genetic resources in companies and research institutions in Japan. By explaining the necessity of obtaining prior informed consent (PIC) from the governments of the providing countries or parties concerned regarding genetic resources and the necessity

of obtaining mutually agreed terms (MAT) in contracts with the parties concerned, the Guidelines aims at the popularization of the CBD, etc., and serves as a practical guide which explains each step of the procedure involved in accessing genetic resources and benefit sharing.

17 The objective of the Guidelines is to assist both the countries providing genetic resources and the countries utilizing them to enjoy the benefits and to build a win-win relationship between themselves by realizing access to genetic resources and fair and equitable benefit sharing.

2. Activities of the Japan Bioindustry Association (JBA)

18 There are developing countries where rain forests rich in biological diversity have been diminished as a result of development and environmental degradation due to the increase of population or industrial growth, and consequently, many biological species have disappeared, impairing the ecosystem. Under these circumstances, the necessity to “establish and maintain programs for scientific and technical education and training in measures for...the conservation…of biological diversity and its components and provide support for such education and training for the specific needs of developing countries” was provided in Article 12(a) of the CBD in consideration of the needs of developing countries.

19 Against this backdrop, Japan has been providing various research assistance programs and training programs to developing nations in the area of the conservation of biological diversity with an eye to faithfully complying with the CBD and enhancing the CBD’s international presence. As regards the research assistance programs, Japan accepted a total of 591 researchers from Thailand, Indonesia, and Malaysia under the “research partnership program to conserve biological diversity and to use biological resources” during the period from 1993 to 1999. Japan has also dispatched experts to these countries and supported them with the installation of machines and equipment. As for training programs, the JBA has conducted programs for participants from developing countries from all over the world, centering on Asia-Pacific nations. By the end of fiscal 2004, Japan had accepted 159 biotechnology researchers and government officials as trainees from 25 countries. The trainees learned Japan's biotechnology-related policies and an outline of the CBD as well as how genetic resources should be evaluated and applied. They also acquired knowledge and learned to use technology relating to biotechnology through hands-on training.

3. Activities of the National Institute of Technology and Evaluation (NITE)

20 Since the CBD clearly stipulates that the countries providing genetic resources possess sovereign rights over the genetic resources, it became significant to secure the stable and smooth acquisition of genetic resources which is the key to the development of new bio-related technology.

21 Due to this situation, NITE, which is the biological resource center in Japan, deemed it important to comply with the CBD and to secure genetic resources by obtaining consent from the countries producing such resources, and therefore, NITE came to consider it very important, as a national strategy, to forge cooperative relationships relating to access to genetic resources with Asian countries, which have had historically and economically intimate relations with Japan.

22 Thus, NITE has signed memorandums of understanding (MOU) with the relevant government organs in such Asian countries as Indonesia, Vietnam, Thailand and China. Under these MOUs, NITE has been promoting joint projects with these countries to acquire microbiological resources in these countries and taxonomically analyze and utilize such resources. In the joint projects, non-monetary benefits have been shared such as the dispatch of experts and the acceptance of trainees. NITE has also been working to establish an environment which can produce benefits for both parties of a project in accordance with the stage of progress in areas such as basic research and application.

23 Through those activities, NITE has promoted mutual understanding with partner countries and worked to fairly secure genetic resources by introducing the fair and equitable sharing of benefits under the CBD.

III. So-called “erroneously granted patents”

24 Several countries see it as a problem that there are some inventions using genetic resources and related traditional knowledge that have been granted patents erroneously, as the applications have not had novelty and inventive steps and not meet the requirements of patentability. First of all, we would like to point out that, under the present patent system, there is a mechanism in which inventions that have been granted patents may be revoked if they do not meet the requirements for novelty and inventive steps. Nevertheless, we understand that it imposes a burden on third parties if “an erroneous patent” exists even temporarily. In order to deal with and solve these problems, we think it useful to develop a database related to genetic resources and to traditional knowledge accessible by examiners worldwide.

A. Examples of so-called “erroneously granted patents”

25 The cases of Turmeric and Neem are taken up by those who support disclosure obligations as model cases of inventions that utilize genetic resources and related traditional knowledge and have been granted patents erroneously although they do not have novelty and inventive steps and do not meet the requirements of patentability.

26 In the case of Turmeric (United States Patent No.5401504), the patent which had been granted once was later rejected in a reexamination procedure. The opponents insisted while presenting several documents as evidence that the said invention which was granted a patent was an art which had been used for centuries in a certain country. The documents included no-patent documents, literature which had been written more than 100 years ago and literature in local languages. The said invention was finally rejected based on the presented documents for the reason that there was no novelty in it.

27 In the case of Neem (European Patent No.436257), the patent was once granted but later revoked. First, opposition to the granting of the patent was made after the granting of the patent. The opponent to the granting of the patent insisted, while presenting several documents as evidence, that there was neither novelty nor inventive steps. In the opposition procedure, it was judged that there was neither novelty nor inventive steps in the invention. The applicant of the invention, who had an objection to the decision, demanded a trial, but in the trial, the invention was finally revoked for the reason that there was no inventive step,

based on the literature other than the patent documents presented at the time of the opposition phase.

B. The cause for “erroneously granted patents”

28 It is possible to surmise that examiners granted the patents because the examiners could not access the evidence which verified that these inventions had a lack of novelty and/or inventive steps or recognize that the documents referred to prior art.

29 The documents, which were presented when the final decisions of rejection were made, were the documents presented by a third-party, and the examiners had not cited these documents in the list of reference data at the time the patents were granted or cited these documents in the research report, which was produced during the examination process.

30 We now review whether the examiner could access the documents which were referred to at the time the examiners made the final decision in the case along the lines of the examination procedure in Japan.

31 During an examination, examiners investigate the prior art relating to the claimed invention. It cannot be denied that it is extremely difficult even for an examiner who has expert knowledge of the technical field of the claimed invention to investigate all of the available documents, although the examiner is able to review patent documents, the database of technical reports available for commercial purposes, the authoritative science journals, etc. It is impossible to examine any and/or all documents including technical papers and science journals which exist in the world.

32 Examining the above two cases in detail, we could not admit that the said documents could be regarded as (i) patent documents frequently used or (ii) documents in a database of technical papers, since in one of the cases, some of the documents were produced more than 100 years ago, and some of the documents were non-patent documents written in the local language, and it must have been extremely difficult for examiners to examine those old documents or the documents written in local languages. In the other case, we could not deny that it was not an easy task for examiners to find the documents referred to, since the documents referred to at the final decision were not patent documents and probably not included in a database of technical papers.

33 We believe that it is due to many factors such as language barrier and limitations in database facilities, etc, that makes it difficult for the examiners to find access to adequate prior art documents.

C. The solution for the problem of “erroneously granted patents”

34 An effective solution is, from the viewpoint of Japan, to establish a database related to genetic resources and traditional knowledge, which is accessible by examiners in any country, in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge.

35 As mentioned is in section B. above, Japan thinks that the main cause of the erroneous granted of patents is the difficulty due to various restrictions which prevent examiners from

finding documents which verify a lack of novelty and inventive steps in inventions; therefore, we would like to point out that an effective and direct solution is to construct a database, which any examiner can easily access.

36 Examiners have currently been conducting prior art searches with databases. In order to conduct the most efficient prior art search, it is necessary to construct an access friendly database after all. It is extremely difficult for examiners to review all of the available documents, since there are countless documents referring to the genetic resources and related traditional knowledge. Furthermore, it is even more difficult for examiners to review various magazines and old documents. In addition, there might exist prior art only passed down by oral tradition. Therefore, it is highly necessary to construct a database of these documents (and information on the prior art) in order to create an environment which enables examiners to perform efficient searches.

Certain consideration has to be paid to the usage of languages in the creation of the database system, since the database to be created must be easily utilized by examiners in each country.

37 We cannot expect every examiner to be capable of understanding every language in the world since it is natural that language use varies in accordance with each country. Also, we have to recognize that there may be documents described in indigenous languages which are used by indigenous communities. These language barriers have to be removed. One suggestion is that a summary, which has been written in a language which every examiner can understand, be attached to documents written in indigenous languages.

The most efficient approach is for each country to assess and compile the information being integrated in the database.

38 There is a countless amount of information and writings related to genetic resources and traditional knowledge. It is impossible for the newly created database system to provide all information utilized in patent examination or for the database system to store all genetic resources and related traditional knowledge in the world. Also, there might be several documents concerning the same genetic resources and the related traditional knowledge, and there might also be information passed down only by oral tradition concerning genetic resources and the related traditional knowledge. Under these circumstances, it is most efficient way for each country to assess and compile the information concerning genetic resources and the related traditional knowledge under its own responsibility.

The database system thus created should be one which examiners of all countries in the world can utilize on a one-stop-research basis.

39 There are countries which have provided databases of their country’s own genetic resources and related traditional knowledge. Needless to say, the databases thus created should be easily accessible to and utilized by examiners in any country, as applications for patents on genetic resources and related traditional knowledge are not only filed domestically but also internationally.

40 For instance, “camu-camu” is a plant growing not only in one country but also beyond the borders of countries. Therefore, it is not sufficient for examiners to search the database in one particular country, even if that country has its own database. It is necessary for examiners

to investigate the database of each country in which “camu-camu” grows. It really imposes a heavy burden on examiners who have to carry out the investigation within a limited time schedule. Additionally, the search work imposes a heavy burden on examiners if each database requires a different approach or different way of conducting a search, and under such conditions, it is almost impossible for examiners to investigate all databases within a limited time schedule. Consequently, a new system has to be a one-stop system where genetic resources and related traditional knowledge can be searched once and comprehensively and not a system in which each database created by each country has to be searched separately. The one-stop database system thus proposed could be an all-in-one consolidated system or be composed of multiple systems easily searchable with one click. Sufficient discussion has to be conducted to determine how to create the most efficient database in the foreseeable future.

41 The discussion over the creation of such a database has to be done under the initiative of an international organization such as WIPO, which is responsible for administering intellectual property, as the database system should be utilized by examiners of patents in every country.

IV. Disclosure country of origin/providing country/source, evidence of prior informed consent (PIC), evidence of benefit-sharing in patent applications, and prevention of erroneously granted patents

42 Several countries insist that the risk of erroneously granted patents is reduced by disclosing the country of origin/providing country/source, evidence of prior informed consent (PIC), and evidence of benefit-sharing in patent applications because such disclosure provides additional information which patent examiners can use when they conduct prior art search. However, based on the following reasons, we cannot accept this point of view.

A. Information about country of origin/providing country/source of the genetic resources and related traditional knowledge is irrelevant to judgment of novelty and inventive steps by the patent examiner. Similarly, evidence of PIC and evidence of benefit-sharing related to genetic resources and traditional knowledge is irrelevant in judgment of novelty and inventive steps.

43 “Novelty” and “inventive steps (un-obviousness)” are words that are used in the PCT, TRIPS Agreement, etc. There are no clear definitions of these words in the TRIPS Agreement. However, in the PCT, the following definitions are provided.

> PCT Article 33 The International Preliminary Examination
>
> (2) For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations.
>
> (3) For the purposes of the international preliminary examination, a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art.

Regulations under the PCT
Rule 64: Prior Art for International Preliminary Examination
64.1: Prior Art
(a) For the purposes of Article 33(2) and (3), everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) shall be considered prior art provided that such making available occurred prior to the relevant date.

44 Whether only information made available to the public by means of written disclosure is defined as prior art or whether all information (written or verbal) made available to the public is considered to be prior art depends on the IP regulations of each country. Another difference among countries, depending on the regulations of a country, is whether only the prior art of a country is considered or whether the prior art of a country and that of other countries is considered when judging novelty and inventive steps.

45 Let us examine the following hypothetical case, considering all information existing in any place in the world as prior art, which is similar to the definition of prior art in the PCT.

(Hypothetical case)

Suppose that the claimed invention is a 'synthetic resin in which the juice of genetic resource A is mixed with a raw material.'

In the claims of the filed documents, the invention is described as a 'synthetic resin in which the juice of genetic resources A is mixed with raw material,' and there is no description of the country of origin of the genetic resources, etc. in the claims. Suppose that in the filed documents outside of the claims, it is disclosed that the country of origin of genetic resources A is X, and evidence of PIC as well as the sharing of benefits is disclosed.

Additionally, suppose that said invention has the effect that adding the juice of genetic resources A increases the strength of the resin considerably.

The relationship between the effect of an invention and genetic resources

46 Generally, the specific characteristic of genetic resource A will not change regardless of the country in which it was obtained. Therefore, the effect of the invention to increase the strength of the resin is the same, regardless of the country form which resource A that is actually used in the invention was obtained.

47 That is to say, the genetic resource A from the country of origin X has been chosen and utilized in the invention by chance. It is not because the genetic resource A from the country of origin X is especially effective for increasing the strength of the resin. This holds true if the country providing the resource and the source are considered instead of the country of origin.

Additionally, it is needless to say that the obtaining of PIC or the sharing of benefits makes no difference to the effect of invention.

Prior art search by examiners

48 Let us consider how an examiner conducts a search of prior art in this case.

49 The examiner will search the prior art related to the utilization of the genetic resource A, irrespective of the country of origin. There are two meanings in “irrespective of the country of origin”.

50 The first meaning is that the country in which the technical information exists is irrelevant. The technical information related to the usage of genetic resource A produced in the country of origin X may exist not only in said country X, but it is also possible that the technical information related to the usage of genetic resource A produced in the country of origin X exists in the country of origin Y. Therefore, it is necessary to search worldwide for technical information relating to the usage of genetic resource A, even if, in fact, the claimed invention used genetic resource A produced in the country of origin X.

51 The second meaning is that the technical information is irrelevant to the country of origin of the genetic resource A that is actually used in the invention. For example, there may be technical information in which only the use of genetic resource A is clearly specified, but not the country of origin of genetic resource A. Additionally, there may be technical information which describes the use of the genetic resource A from the country of origin X or the use of genetic resource A from the country of origin Y. All technical information is examined as documents of prior art, regardless of whether the country of origin has been clearly specified, or, if it has been clearly specified, regardless of the country of origin of the genetic resource, because the specific characteristics of the genetic resource A do not differ in any country from which it has been obtained. Moreover, in the case where “the juice of genetic resource A,” is only described but the country of origin is not defined in the claims, the claimed invention cannot be interpreted as referring to “the juice of the genetic resource A from the country of origin X,” even though the country of origin X is disclosed in documents filed other than the claims. This is also another reason why the technical information related to the genetic resource A has to be searched, regardless of the country of origin of the genetic resource A.

52 An examiner’s search of the prior art related to genetic resource A is irrelevant to the country of origin, and, therefore, information about the country is not necessary. This holds true if the countries providing the resource and the source are considered instead of the country of origin. Additionally, it is obvious that evidence of PIC and sharing benefits is not necessary information for examiners to search prior art.

In case that the scope of prior art is limited to the prior art in one’s country

53 Not every country has adopted the definition of prior art specified in the PCT. Some countries limit the scope of prior art to the prior art in their own countries. Supposing that country Y has adopted the definition of prior art mentioned above, then a prior art search is conducted as follows.

54 In countries other than country Y, there is technical information related to the use of genetic resource A produced in the country of origin X or technical information related to the use of genetic resource A produced in the country of origin Y. However, in country Y, it is

not permitted to include technical information that exists in the country of origin X in searches of prior art, on the grounds that, in fact, genetic resource A produced in the country of origin X has been used in the invention. Only the technical information that exists in country Y may be searched.

55 In country Y, the technical information on the use of genetic resource A from country X and the technical information on the use of genetic resource A from country Y may possibly exist. As mentioned before, the specific characteristics of the genetic resource A are identical regardless of the country from which the genetic resource A is obtained; therefore, the technical information related to the use of genetic resource A is to be searched, regardless of the country from which the genetic resource A is obtained.

56 Therefore, information about the country of origin of a genetic resource is not necessary in prior art search, even though the scope of the prior art is limited to prior art in one's own country.

Judgment of novelty and inventive steps

57 Let us examine how an examiner makes a judgment about novelty and inventive steps.

58 First, an examiner judges whether a claimed invention is the prior art that was described in documents found in the prior art search; in other words, whether a claimed invention is identical to the prior art. If "a synthetic resin in which the juice of the genetic resource A of the country of origin Y is mixed with raw material" is found in the prior art, the said prior art and the claimed invention are judged to be identical, in this case where the country of origin of the genetic resource A is not recited in the claims. (Supposing there was a description of "the genetic resource A of the country of origin X" in the claim, and the specific characteristics of the genetic resource A were identical regardless of the country from which the genetic resource A had been collected, the said prior art and the claimed invention would be judged to be identical, and the information about the country of origin would have no effect on the judgment of novelty.)

PIn the case that a claimed invention is different from the prior art, it is judged whether the claimed invention involves an inventive step; in other words, if, having referred to the prior art, whether such a claimed invention is obvious to a person skilled in the art. First, an examiner finds the prior art most similar to the claimed invention, compares the said prior art most similar to the claimed invention with the claimed invention, and defines the differences between them. Then, the examiner examines the differences, taking into account not only the said prior art but also other prior art and common general technical knowledge and judges whether the different elements the claimed invention contains are obvious to a person with ordinary creativity and skill in the art, as the result of having referred to the most similar prior art. In other words, the examiner examines whether a person skilled in the art could have easily made the claimed invention based on the most similar prior art by combining other prior art or techniques with the said prior art. This is a technical judgment. If the specific characteristics of the genetic resource A do not differ according to the country from which the genetic resource A was collected, the information about the country of origin does not have an effect on this judgment. (Supposing there were a description of "the genetic resource A of the country of origin X" in the claim, the information about the country of origin would not have an effect on this judgment, and the information about the country of origin would have no

effect on the judgment of inventive steps, if the specific characteristics of the genetic resource A did not differ according to the country from which the genetic resource A had been collected.)

59 In this way, examiners do not utilize information on countries of origin of genetic resources in judging novelty and inventive steps. This holds true if the country providing the genetic resource and the source are considered instead of the country of origin. There are no technical implications in evidence of PIC and evidence of the sharing of benefits; consequently, it goes without saying that examiners do not utilize such information when they make judgments about novelty and inventive steps.

60 In this manner, the judgments of novelty and inventive steps are not associated with information about the country of origin, the country providing the resource, and the sources of genetic resources and related traditional knowledge. Moreover, the judgments of novelty and inventive steps are not associated with evidence based on prior informed consent relating to genetic resources and traditional knowledge or evidence of the sharing of benefits. The erroneous granting of a patent for an invention, which does not meet the requirements for novelty and inventive steps, cannot be prevented if information which is not useful for making judgments about novelty and inventive steps is provided.

B. Even if a genetic resource collected in a specific place has its own specific characteristics, this does not sufficiently explain the necessity of imposing the new obligations of disclosure.

61 Thus far, we have explained on the premise that the specific characteristics of the genetic resource A are identical, regardless of the country in which the genetic resource A is produced, as long as the generally identical genetic resource A is used. However, there is a counterargument that a genetic resource collected in a specific place might have characteristics different from those collected in other places.

62 Even if a genetic resource collected in a specific place has its own specific characteristics, which differ from the characteristics of a resource collected in another place, and an invention was made by utilizing such specific characteristics, this does not sufficiently explain the necessity of imposing a new, additional obligation of disclosure on an applicant.

63 Suppose, for instance, that the genetic resource A of the country of origin X has a specific feature Z. In such a case, the claimed invention might be found to encompass the genetic resource of the country of origin Y, if the claim does not describe the country of origin but only mentions “using the genetic resource A.” Even if the words of “the country of origin X” are written in a part of the filed documents other than the claims, the claimed invention will be found as described in the claims; therefore, it will be found as if the country of origin of the genetic resource were any country. Consequently, if there is a prior art technology using the genetic resource A of the country of origin Y, the novelty and inventive steps of the claimed invention will be judged based on the technology, and as a result, the claimed invention will be rejected. In other words, even if a genetic resource collected in “the country of origin X” has specific characteristics, information which were to be disclosed in accordance with the new obligations of disclosure would not have any effect on the novelty

and inventive steps if the country of origin were to be described in a part of the filed documents other than the claims.

64 If the invention focuses its attention on the characteristic Z, which is specific to the genetic resource A of the country of origin X, and uses the genetic resource A of the country of origin X, the applicant needs to describe the technical matters in the claims in order to clarify the features of the invention which cannot be obtained by using the genetic resource of the country of origin Y and to define the superiority of the invention or to reveal the technical significance of the invention in the filed application. In this instance, it is necessary to describe in the claims, not that "the country of origin is X," but technical matters which directly define the characteristic Z (for example, the specific components, the specific genetic structure, etc.) because it is difficult to say that the phrase, "the country of origin X," distinguishes the characteristic Z from the technical point of view. Even if most genetic resources A of the country of origin X have the specific characteristic Z, there is no guarantee that all of the individual genetic resources A equally have the specific characteristic Z. It is not possible to justify the obligation of disclosing the country of origin within the claims even if the invention focuses its attention on the characteristic Z and uses the genetic resource A of the country of origin X.

65 In addition, we would like to note the enablement requirement in this area. When describing the technical matters which directly distinguish the characteristic Z in the claims, the applicant needs to explain in the filed documents the technical significance of using the genetic resource of the country of origin X or the specific characteristic Z in the genetic resource A of the country of origin X and the technical matters which directly distinguish the characteristic Z so as to make a person skilled in the art understand the invention and make a third party understand and carry out the invention. The applicant also needs to describe how to obtain the genetic resource A which has the specific characteristic Z. It may be required to include in the filed documents descriptive information, namely "the country of origin X," as such information makes it possible to obtain the genetic resource A which has the specific characteristic Z. Although it may be possible to obtain the genetic resource A which has the specific characteristic Z easily if we find the country of origin, it is not always possible. In the case that it is difficult to sufficiently disclose the genetic resource A which has the specific characteristic Z in the specifications in order for a third party to easily obtain the genetic resource, it is necessary to commit the genetic resource A to the care of a deposit organization based on the patent law of each country or the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. Thus disclosing "the country of origin X" does not always fulfill the enablement requirement.

66 Therefore, it is concluded that even in the case that only a genetic resource from a specific place has a specific characteristic, this does not sufficiently justify the necessity to impose the new disclosure obligation.

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