# Some Legal Issues Caused by Identification of Wild Herbal Plants-Interpretation and Perspectives of Patent Law-

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- Interpretation and Perspectives of Patent Law -

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#### 1. Introduction

In 1980 Umberto Eco wrote his best known novel, Il nome della rosa <sup>1</sup>. There are numerous cultivated varieties or hybrids of roses that have unique specification names. Such cultivated roses can be protected as independent species under the laws and regulations of the relevant jurisdiction. Thus, the identifier used to specify a rose is, quite simply, the name of the rose. One of the most famous roses is the Peace Rose which was created by Francis Meilland in 1945 <sup>2</sup>. New hybrids of roses can be created through mating between different roses which could then be distinguished by the name of the roses. A flow sheet of registered roses describes parent roses or offspring roses of a specific hybrid rose. Because the names of hybrid roses are named artificially, the name of the godparent of a specific hybrid rose can be identified and retrievable. Also, there would be a relatively small risk of conflict and confusion if such a registration system of roses functioned normally.

Hybrid orchids can be thought to be a similar example to hybrid roses. But in the case of hybrid orchids, there are some difficulties which are slightly different from those of hybrid roses. Because the mating of roses has continued since long ago, the genes of the rose of the original progenitor are mixed in a complicated way. In fact, to think about the first parent progenitor may be meaningless. Therefore as for the specification name of an artificial hybrid rose, the name of a specific hybrid rose is not a species name but is simply like a name or a nickname attached to each human being which belongs to the species Homo sapiens.

On the other hand, there are many artificial hybrid orchids which have been created in recent years, and in many cases wild orchids discovered newly might be used for plant breeding. To create a new orchid, different species of wild orchids (for

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<sup>&</sup>lt;sup>1</sup> An English translation by William Weaver is "The name of the Rose" in 1983.

<sup>&</sup>lt;sup>2</sup> The Peace rose was created originally as Madame Antoine Meilland rose in 1939. Madame Antoine Meilland was mother's name of Francis Meilland. After World War II, Francis Meilland renamed this rose to Peace and published in the United States in 1945.

instance, Cattleya<sup>3</sup>, Epidendrum, Phalaenopsis, Dendrobium and Paphiopedilum<sup>4</sup>) have been mated with each other. Many people have been enjoying breeding orchids and appreciating them worldwide. As a result, to identify which specific wild orchid is the parent of a specific hybrid orchid can be one of the very important issues in the world of hybrid orchids. However the species belonging to the Orchidaceae family has evolved relatively recently in the history of flora on Earth, and this species has been and will be evolving continuously. <sup>5</sup>Due to this, there are many unknown matters concerning wild orchids, and a lot of undiscovered wild orchid species may be living and flowering somewhere unknown to us. There are also many wild orchids which have not been identified concretely and remain in an ambiguous position in the plant taxonomy field, even if that specific orchid was discovered and well-known as a famous orchid. Theory on the classification of orchids has changed quite frequently and continuously so that any authoritative orchid classification book might become useless after only ten years of its being published. Serious confusion would arise for many people who are enjoying the cultivation of beautiful orchids. In addition, there have been some possibilities that orchid nurseries for commercial purpose might ship an orchid or orchids with labels or name plates attached under the wrong species name. It may cause violation of laws and regulations for consumer protection, of conservation of natural environment or of prohibition of export/import and cultivation of specific protected plants <sup>6</sup>. The threatened plants list under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) <sup>7</sup>has been constructed in accordance with current scientific name (Latin name) of specific plants. However unclearness of scientific name of plants may bring some kind of instability elements into courts' judgment, law enforcement and other related governmental administration.

Moreover, what can be said about ordinary higher plants which have already been thoroughly examined since the times of Carl Linnaeus? Regarding such higher plants, it seems that every scientific name (Latin name) has already been determined and there is no doubt of the name of the plants today. In particular, it has been believed that there was no doubt concerning medicinal herbs (traditional Chinese medicine) which have been widely known in China, Korea, Japan and other Asian countries from years ago. However, this is not correct.

<sup>&</sup>lt;sup>3</sup> Recently, the classification of the genus Cattleya was partly but fundamentally reconsidered and renamed. Orchids which occur in Central America and had been previously classified as genus Cattleya, has been reclassified into the genus Guarianthe. Due to this, the name of many artificial hybrid Cattleya orchids which have been created by breeding with Central American Cattleya orchids shall be renamed in accordance with new classification rule. Similarly the genus Epidendrum and the genus Brassavola were partly reclassified and renamed.

<sup>&</sup>lt;sup>4</sup> See Prof. Summer's Web Garden – World Wild Orchids http://orchids.la.coocan.jp/

For example, See Molecular Phylogeny and Character Evolution of Cymbidium (Orchidaceae) http://ci.nii.ac.jp/naid/110004702089/en/

<sup>&</sup>lt;sup>6</sup> For example on Japanese laws and regulations, See the Ministry of the Environment (the Government of Japan) – Laws http://www.env.go.jp/en/laws/

Onvention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) http://www.cites.org/

For example, there is a well-known plant the extract of which is the raw material for a famous traditional Chinese medicine (dang qui). English common name of this plant is Chinese Angelica. Chinese Angelica is not native to Japan and was introduced from Imperial China in ancient times. The scientific name (Latin name) of Chinese Angelica is Angalica sinensis (Oliver) Diels (Apiaceae (alt. Umbelliferae)) 8. Dang qui, as a traditional Chinese medicine, is the dried root of Angalica sinensis (Oliver) Diels. However, because the dried root of Angalica sinensis was very expensive, other similar Angelica plants which were a species close to Angalica sinensis have been used as a substitute for Angalica sinensis for a long time 9. The name of the substitution root has been dang gui and this substitution root has been sold at relatively high prices in the traditional Chinese medicine markets. Some traditional Chinese medicine merchants have been selling the root of another herbal plant which is not the root of Angalica sinensis as the genuine root of Angalica sinensis (dang gui). However, such activities may be a violation of laws and regulations such as the Drugs, Cosmetics and Medical Instruments Act, or consumer-protection laws and other relevant regulations.

This above mentioned may present similar serious issues that pertain to patent laws. There are various patents which are related to herbal plants (See, Appendix of this article). For instance, a patent on the gene of a plant, a patent on a component itself extracted from a plant, a patent on a method of extraction of such a component, a patent on application of such a component including medical use or cosmetics, a patent on durability of such a component and reinforcement, a patent on cultivation method of a plant, a patent on method of removal or herbicide of the harmful plant, a patent on medical supplies and methods of neutralization of poisonous components of a plant and other related patents. Sometimes these patents may include so-called bio-patents <sup>10</sup>.

Indeed, it is very common that a scientific name (Latin name) of a specific plant is noted to identify the plant described in a patent (as patent names, patent claims, detailed explanations, examples, references or citations and so on). However, if the noted scientific name (Latin name) of the plant is invalid or false then what kind of legal effect or result will be brought about? At least, it may be possible to lose the legal effectiveness of a part of or the whole of the patents, because such an incorrect or false scientific name (Latin name) of the plant serves no function in identifying the plant, to identify any extract or components from the plant, to identify availability or usefulness of such components or to identify related methods described in the patent.

The purpose of this article is to point out some legal issues in the context of the herbal plant patents that can be assumed concerning the above, and I would like

<sup>8</sup> Angelica sinensis (Oliver) Diels in Flora of China http://www.efloras.org/florataxon.aspx?flora\_id=2&taxon\_id=200015389

In Japan, main substitutions of Angelica sinensis are Angelica polymorpha Maximowicz, Angelica keiskei (Miquel) Koidzumi and Angelica pubescens Maximovicz for the example.

See Prof. Summer's Web Garden – Japanese Wild Flowers http://www7a.biglobe.ne.jp/~flower\_world/

<sup>&</sup>lt;sup>10</sup> Noel Cox, Technology and Legal Systems, Ashgate, 2006, pp. 194-209.

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to suggest a possible legal resolution after having clarified the mechanism by which such legal issues would be generated.

#### 2. Mechanisms

There have been many duplicated names, incorrect names, misapplication of names of wild plants. Today, some of such name have been reexamined, denied, removed or changed formally. In this section, I would like to mention about the mechanisms of such duplication and misapplication and so on.

#### 2.1. Popular method - Identification by common name

People have been defining the names of plants in accordance with their physical characteristics, utility or danger of the plant for many years. It seems that the popular name of a plant, which was gradually formed based on experience, was not a name based on scientific inquiry. Generally, such a popular name is called a common name. For example, the English common name "berry" means any plant which have red colored small and sweet fruit such as a strawberry including both herbal plants, tree plants and vine plants. Also "speedwell" is an English common name for small Scrophulariaceae species. This common name would be made based on the fecundity of such tiny weeds. Because such a common name is not based on scientific basis, there are many weeds or trees which have the same or very similar common names, even if such plants could be classified through scientific examination as a different taxonomical family name, tribe name, sub-tribes name or species name. It is very important that the identification of a specific plant by a common name might incur some risks which would cause trouble and confusion. This is because the common name of a plant is not the same from country to country, geographical area, linguistically and other cultural factors.

However, there are not a few patents using the common name to identify a specific plant in claims or detailed explanations of the patent. There are some cases which seem to be doubtful whether or not a specific plant can be identified as described in the patents.

#### 2.2. Modern botanical taxonomy

The Swedish scientist Carl Linnaeus (1707-1778) is called the father of modern animal and plant taxonomy. He has a strong belief that 'all creatures were classified, and it must be named' and established unique classification method for the family, genus or names of animals and plants which was named binomial nomenclature. He applied his method to examine his herbal collection, published some great books <sup>11</sup> illustrating the application of his method. This method became the fundamental basis of current botanical studies. However, the classification of plants by Linnaeus was based mainly on the physical characteristics of plants because Linnaeus lived in an era when modern sciences had not progressed so far. In addition, there were many duplications of classification and sometimes clarified incorrectly or gave different

<sup>&</sup>lt;sup>11</sup> Systema Natured, 1758

names to different plants of the same species. Because his herbal plant specimens were collected in different nations or locations different common names were given to such plants.

Afterwards, German Adolf Engler (1844-1930) and Karl Prantl (1888-1911) made Linnaeus's system more specific and detailed, correcting mistakes and establishing a new classification system of plants. This plant classification system was revised again and was called the Engler's system or the new Engler's system. This method has been used for many years and is still in common use today. Most botanical books, guide books and illustrated books are currently descriptions based on the new Engler's system. On the other hand, George Bentham (1800-1884) and Joseph Dalton Hooker (1817-1911) developed another plant classification system with Engler, and there have been many books based on Bentham's system mainly in the United Kingdom and the United States.

In the history of plants classification before DNA analysis generation, the newest and most correct method is the classification system which American Arthur John Cronquist (1919-1992) established.

However, the systems established by Engler, Bentham and Cronquist were their own theoretical botanical systems. Application of these systems to individual living plants was completed by many scientists who were located in each nation  $^{12}$ . Besides, botanists of each nation had to examine and apply their classification systems by themselves independently because of the physical distance separating them before the age of the Internet. Therefore, much duplication has taken place. For example, while a species might be described as  $Plant\ A$  in the United States, the same species might be described as  $Plant\ B$  in Japan which was a different plant from  $Plant\ A$  in the United States  $^{13}$ .

In addition, generally human society cannot catch up with the newest theories as quickly as modern science progresses. It is impossible to recall all the books written based on an older theory and to rewrite it based on a newer theory. Therefore, there are many cases where description of plant classification in a book is really incorrect under the newest scientific theory, even if the description was once believed correct. In plant patent area, even if a plant name in a patent claim was described correctly based on the correct classification system of the time, such a description became incorrect or wrong in some years later due to the progress or change of scientific theories or newer discoveries. There are a myriad of such issues.

<sup>&</sup>lt;sup>12</sup> Tomitaro Makino (1862 - 1957) examined and classified many plants in Japan based on Engler's system. He published *Illustrated Flora of Japan*.

<sup>13</sup> For example, some Japanese authors believe that Lysionotus pauciflorus like plant in Okinawa and Taiwan should be classified as Lysionotus apicidens (Hance) Yamazaki. Some people and organizations listed up Lysionotus apicidens (Hance) Yamazaki as a threatened species and regarded to be protected. However the flora of China editorial committee judged that Lysionotus apicidens (Hance) Yamazaki is a synonym of Lysionotus pauciflorus Maximowicz. If the opinion of the committee is right then there is no Lysionotus apicidens (Hance) Yamazaki in Japan at all.

See Lysionotus pauciflorus Maximowicz in flora of China

http://www.efloras.org/florataxon.aspx?flora\_id=2&taxon\_id=200021831

#### 2.3. DNA Analysis

The most correct classification method at present is one based on the difference of DNA sequence of plants.

This is called molecule taxonomy. Angiosperm Phylogeny Group (APG)  $^{14}$  promotes this method.

Example: Brassica juncea (Linnaeus) Czernajew 15

According to the knowledge provided by this method, it became clear that there were considerably many mistakes in previous plant classifications. In other words, it suggests that the classification in books based on traditional methods might incorrect.

In fact, recently, some important changes have been taken place in plant classification based on the molecule taxonomy and many plants are now being re-classified. As a result, it has become impossible to correctly identify a specific species based only on the popular common name and even traditional scientific names (Latin names) including family names and genus names of plants.

To identify a specific species or groups of species through plant DNA, it is necessary to use a DNA taxonomical ID which can identify a specific DNA of the plant or groups of plants. However, such a DNA taxonomical ID is more difficult for ordinary people to peruse than the popular common names or traditional scientific names (Latin names). This is closely similar to a relation between an IP address and a domain name on the Internet <sup>16</sup>.

Moreover, a uniform system for such DNA taxonomical ID has yet to be firmly established. In addition, DNA analysis of every plant itself has not been completed yet at present. Many more years are needed to complete DNA analysis of every plant on Earth. Due to this, we have no complete flow sheet of plants based on DNA analysis.

Therefore, it seems to be very difficult to specify a plant through DNA analysis based on taxonomical ID in the case of patents. People may still have to rely on a more incorrect way than DNA based identification in the years to come.

#### 2.4. Nationalism and lack of information

In Asian countries, including Japan, the introduction of modern scientific plants

<sup>&</sup>lt;sup>14</sup> http://www.mobot.org/MOBOT/research/APweb/

<sup>&</sup>lt;sup>15</sup> http://taxon.molgen.mpg.de/getinfo?3707

<sup>&</sup>lt;sup>16</sup> See Chris Reed, Internet Law – Text and Materials (2nd edition), Cambridge University Press, 2004, pp.40-45.

taxonomy was quite late for various historical reasons. In this area, plant classification based on incorrect information has often occurred. At the same time, many domestic plants have been classified as endemic species, due to nationalistic sentiments.

In the case of Japan, the Swedish botanist Carl Peter Thunberg (1743-1828) and German doctor Philipp Franz von Siebold (1796-1866) were the earliest botanists who visited Japan in the Tokugawa era (1603-1867) and examined Japanese wild plants. They visited Japan as Dutch medical doctors. This was a period when Japan was closed to foreign countries except Holland, China and Korea. Their research results have been the starting points of Japanese botanical science and plant taxonomical classification until today. Some years later, many foreign botanists visited Japan especially after Japan had opened to the world. For instance, the Russian Carl Johann Maximowicz (1827-1891) and American Asa Gray (1810-1888) examined Japanese wild plants. However, Japanese scientists had been strictly prohibited from learning modern European science until 1868 when the Tokugawa era came to an end and the Meiji era (1868-1912) began. In the Meiji era, the Japanese government introduced modern European science to make Japan an advanced, modern nation. However, at the same time, nationalism grew in Japan and some botanical scientists began classifying Japanese domestic plants as endemic plants. Many such classifications were not correct, because they were influenced by nationalistic sentiments. The exchange of scientific knowledge between foreign nations and Japan was once again closed until the end the World War II. It had been quite difficult for Japanese botanical scientists to read the latest scientific literature at this time. This period should be thought of as a period of a lack of a flow of information.

Such a phenomenon caused by nationalism can be observed in other countries as well. Today, DNA analysis and other similar new scientific technological methods of analysis have led to many incorrect classifications due to nationalism or the lack of information.

By the way, in many cases, a plant name in a patent used to be written using the scientific name (Latin name) of the plant which was described in the most authoritative books in the country. Due to this, for instance, the name of a plant in Patent X may be described as Plant A in the United Kingdom based on the most reliable botanical book in the United Kingdom, while the name of the same plant in Patent Y may be describes as Plant B in Germany based on the most authoritative book in that country. In such a situation, most people may believe that they are two different patents relating to two different plants. However there is a conflict between these patents, because Plant A and Plant B are actually the same plant. For example, if a European Patent has been issued for Patent X then the validity of Patent Y should be in doubt.

#### 2.5. Misunderstanding or misreading

Over the years there have been numerous incorrect classifications made especially of nationalized plants. This is because correct information of newcomer nationalized plants can not be disseminated from the native country of the plant. This may be

considered another example of a lack of information on plants as mentioned above.

For instance, there have been some nationalized *Oenothera* species in Japan. Some of these species have already been identified (e.g. *Oenothera stricta* Ledebour ex Link, *Oenothera rosea* L'Héritier ex Aiton, *Oenothera laciniata* Hill, *Oenothera speciosa* Nuttall, *Oenothera erythrosepala* (Borbás) Borbás). However, some of them have not been thoroughly identified. Let me present an example of a naturalized herbal plant that exists in Japan. Outlook of this plant has been similar both to *Oenothera stricta* and *Oenothera erythrosepala*, but the plant can not be identified as them. Botanical scientists have been debating what this plant is. However, the argument is not yet settled. This might be due to a misunderstanding or misreading of the description of certain foreign plants.

In such a case, even if a botanical scientist described the plant as having a scientific name (Latin name), the reliability of the identified name is not so clear.

#### 2.6. His/her honor

In the case where a person produces a doctoral thesis based on older theories and receives a doctoral degree and the accompanying honor, such a person may not agree with an opinion which can deny the older theories and the honor of the person.

This is not scientific thought at all. It can be said that a human being is an existence which has an unreasonable emotion.

And if the person has authority and prestige in the botanical science field then new theories (often more correct than the older theories) may occasionally be denied or ignored giving consideration to the honor of the person.

Judgment on the identification of a plant or on a plant patent in a court trial may be influenced by such unreasonable emotion of the person who gives witness or evidence as a famous botanical scientist.

Sometimes it may be the most difficult matter for every specialist to deny the own unique idea made by him/her.

#### 2.7. Judgment and recognition based on subjective observation

On the other hand, there is a fundamental problem for botanical taxonomical science itself.

Generally it seems that the botany constitutes a part of the natural science and based on mathematical accuracy. However, it is not right.

Because a plant is a physical existence, it can be observed objectively and the observation results can be recorded. However, from Linnaeus to Cronquist, the traditional botanical taxonomical science has been based on observation of outlook of plants. Also due to that judgment to classify a specific plant has to be done based on observation of the plant by botanical scientists and that every judgment should be performed as a result of subjective thinking in human brain, the judgment might be subjectivity.

Even in a case of DNA analysis based classification, a part of the classification may be subjective, because only small part of DNA sequence is important to distinguish one genus or species from the other genus of species. For instance, in the case of a human being, details of his DNA structure of a man who has great mustache is not equal to the DNA structure of another man who has no mustache. But such a tiny difference between their DNA sequences has no meaning to judge whether a being is Homo sapiens or other animals.

This is completely same in the botanical taxonomy field. Botanical scientists may be interested only in an important part of DNA sequence of a plant to judge the difference of the family, genus and species of the plant, but not of individuals belong to the same species. The minimum standard which can define the difference of the species may be decided based on the subjective examination by botanical scientists <sup>17</sup>. Therefore if the standard has been changed subjectively then the classification of the plant may be changed too. Thus it should be remarked that plants classification itself is not a physical material but is a changeable description after a subjective examination by human.

Because of that every plant name described in a plant is identified based on such a changeable and subjective classification process, legal validity of the patent may be floating too.

#### 3. Legal issues

There are various types of herbal plant related patents.

For example, Camellia sinensis (Linnaeus) Kuntze was a plant introduced from China in ancient times, and has been regarded as a very useful plant for many years. We know the name Camellia sinensis as Tea tree for green tea and it has been used as a raw material in traditional Chinese medicine. Also, there are a lot of patents related to Camellia sinensis including not only patents on medicine, cosmetics and health food which consist of extracted components from the plant, but also patents on the gene and DNA of the plant and so on <sup>18</sup>.

Issues on identification of a specific plant may affect the legal validity of plant related patent of all these types. These legal issues can be examined in accordance with a difference of patent types. I would like to suggest some issues which may be important for the examination of patent claims and court trials.

#### 3.1. Validity/invalidity of a patent

A specific plant described in a patent should already actually exist on Earth. A patent of no existing plant is wholly meaningless as an application of natural science. Also it is impossible to examine the integrity and utility of the patent. Therefore such a patent is or will be obviously invalid as a plant related patent.

For instance, let's assume that there is a genome patent which patent claim

<sup>&</sup>lt;sup>17</sup> For instance, it is assumed that a scientist (X) classified a hairy type group as a variety of a plant species and another scientist (Y) ignored such a cheap difference to decide what species the plant is which includes both hairy type group and non-hairy type group of the plant. In such a case, it may mean that the scientist X uses his own classification standard which is different from the scientist Y's standard. The selection and application of such a standard takes place inside the scientist's brain subjectively.

<sup>&</sup>lt;sup>18</sup> Camellia sinensis

http://treeflower.la.coocan.jp/Theaceae/Camellia%20sinensis/Camellia%20sinensis.htm

consists of a gene or DNA of a certain herbal plant. In this case, the gene or DNA itself should be specified by an amino acid sequence and the name of the herbal plant is identified by scientific name (Latin name) in general. However, if the description of the scientific name is incorrect or false or if the existence of the plant was denied by new scientific investigation or discovery after the issue of a patent, then the patent would be a curious patent in which no existing plant name is described in the patent at all.

If an amino acid sequence itself described in a patent is correct and identified by the name of the amino acid sequence then the patent may be valid partly as an amino acid sequence patent indeed. However, in this case also, the remaining part of the patent which consists of non-existing plant should be invalid. In the case of a patent on method of a composition (including an amino acid sequence) extraction from a specific plant, if the plant name is incorrect or false then the patent should be wholly invalid. This is also same and true even if the name of composition (or amino acid sequence) is correct and such a composition (or amino acid sequence) actually exists. Because any plant which does not exist can not create any component at all, and can not consist of any method of extraction of the component.

Similarly, on utility of patents, if a plant described in a patent does not exist on Earth then the utility of the plant should be denied. For instance, in a case of herbicidal component patent which is described as effective to kill a specific herbal plant but the described plant does not exist in fact, such a patent has no utility as the described herbicidal product. Such a patent may be invalid wholly or partly.

#### 3.2. Doctrine of equivalents

In the interpretation of patent claims, the doctrine of equivalents can apply to judge whether or not one specific plant and another specific plant are same. This doctrine which was created by the United States courts <sup>19</sup> at the first stage has been accepted by many jurisdictions and enhanced its applicable area to various types of patent trial cases <sup>20</sup>. In such cases, legal issues on the superiority and inferiority between different patents shall be judged by the court.

However, this doctrine may cause some legal issues which are very difficult to be resolved.

For example, I would like to assume a case where one court (X) of a certain jurisdiction judged "the plant using the name of plant A is also effective as the patent on plant C, because the plant named A is the same plant as the plant named C substantially" under the doctrine of equivalents without knowing that there is a patent on a plant with a name called B, while another court (Y) of another jurisdiction judged "the plant using the name of plant B is also effective as the patent on the plant C, because the plant named B is the same plant as the plant named C substantially" under the doctrine of equivalents without knowing that there is a patent on a plant called A. And I assume that both the patent on plant

<sup>&</sup>lt;sup>19</sup> US Supreme Court, Festo Corp. v. Shoketsu Kinzoku Kogyokabushiki Co., 535 U.S. 722 (2002)

<sup>&</sup>lt;sup>20</sup> On similar court judgment, See Japanese Supreme Court, case number 1994 (O) No.1083 http://www.courts.go.jp/english/judgments/text/1998.02.24-1994-O-No.1083.html

A, the patent on plant B and the patent on plant C have substantially equal patent claim descriptions. In such a case, which of the court judgment shall have more authority than another court judgment? Owners of the patent on plant A and the patent on plant B may have to bring action once again more at the X court or the Y court, and have to discuss whether patent on plant A and on plant B is effective.

#### 4. Legislative issues

A similar issue may take place not only with wild herbal plants and their components but also with artificially made plants produced mating or genetic recombination technology.

Concerning the new varieties of plants, the major nations, including the United States and Japan, have agreed with or have ratified the *International Convention* for the Protection of New Varieties of Plants (UPOV, 1961) <sup>21</sup>. The Convention was amended in 1991. After the amendment, double protection of a new variety of plants may be permitted in a particular jurisdiction. For instance, new varieties of plants can be protected both by the Patent Act (35 USC) and the Plant Variety Protection Act (7 USC 2321 et seq.) in the United States, and both by the Patent Act (Act No. 121 of 1959) and the Seeds and Seedlings Act (Act No.83 of 1998) in Japan <sup>22</sup>. These laws have different legislative purposes. The scope and methods of legal protection of these laws are different as well.

However, it should be clearly remarked that double protection on the same new variety of plants may be given in fact under the patent or other intellectual property protection laws. As a matter of possibility, such a double protection may cause unfair trade or other illegal situations mainly on the international level. Only one way to avoid such a double protection is to register and examine the gene information or DNA sequence data of the registered new variety of plants. Also such registered gene information or DNA sequence data has to be able to be easily accessible worldwide.

In addition, in some cases, such duplications may be unavoidable and unable to be detected, even if a gene information registration is established and access is available. For instance, in such cases where a new variety of plant has been protected both by the Patent Act and the Industrial Design Act (artificial outlook of a new variety of plants may be protected.) or the Copyright Act (creative expression of a new variety of plants may be protected.), the patent owner can never know the gene information on the industrial design or copyright of the new variety of the plant. Industrial design protection exists to protect the design of an industrial production but not the right as a new species. And similarly the copyright protection exists to protect the expression of a material but not an identity of a new species. Of course, the industrial design protection and copyright protection have been given mainly to non-living objects such as machines, tools, clothing and books. Thus the industrial

<sup>&</sup>lt;sup>21</sup> UPOV

http://www.upov.int/index\_en.html

<sup>&</sup>lt;sup>22</sup> See Translations of Laws and Regulations in the Web Site of the Japanese Cabinet Office on official English translation of Japanese legislation.

http://www.cas.go.jp/jp/seisaku/hourei/data2.html

design protection and the copyright protection never need any gene information or DNA sequence data of the object matters. In such cases, which of the patent owners, the industrial design right owner or the copyright owner of the same new variety of plants can hold the superior legal status against other rights owners? <sup>23</sup>

I believe that it should be required to register the identification of the new variety of plants (I will mention about the identification later). Also in the case of industrial design protection and copyright protection it would help to avoid conflicts between different legal right owners.

#### 5. How to avoid legal disputes

#### 5.1. Importance of uniform ID system

Today, descriptions using DNA sequence data seem to be the most certain way to identify a living species. It has been believed that DNA sequence is different according to family, genus and species of a living being. Therefore, under this belief, if plant A has the same DNA sequence as plant B then plant A has to be regarded as the same species as plant B, on the contrary, if plant A doesn't have the same DNA sequence as plant B then plant A has to be regarded as a different species from plant B.

However such an explanation is a bit incorrect. Of course, to be more correct, the whole DNA sequence of a specific living plant is a mixture. A part of DNA sequence can be used to identify the family, genus and species of the plant and another part has no relation to identify them. But, the integrated basic scientific theory to separate these parts of DNA sequence of every living being on Earth has not yet been established.

In addition, even if it is possible to use a DNA sequence (an amino acid sequence) as identification for a specific herbal plant, it is reasonable to process such sequence data in computer systems but it is not suitable at all for memorizing and use by human beings. Of course, ordinary people can not imagine physical appearance of a beautiful flower when he/she is informed a description by pure DNA sequence data without any information on common names and scientific names (Latin names) of the plant.

Therefore it seems completely doubtful to believe that DNA sequence can be used to easily identify every specific species on Earth. This has to be clearly remarked.

#### 5.2. Structure of the ID

In general, the identification of a plant has a logical structure which consists of some elements as mentioned below. Of these elements, the description of the DNA structure can not be duplicated, even if other elements may be duplicated. There are many duplications of description on scientific names (Latin names), common names and chromosomal number counts, because they have been named and renamed by

<sup>&</sup>lt;sup>23</sup> J. H. Reichman, Of green tulips and legal kudzu: repacking rights in subpatentable innovation, in David Vaver ed., Intellectual Property Rights – Critical Concepts in Law Vol. V., Routledge, 2006, pp. 248-296.

several different people over many years. Depending on language, social culture, people's preference and the history of the society; there have been numerous duplicated names of plants. However, the DNA sequence is a pure and definitive physical existence.

ID number

Elements
Scientific name (Latin name)
Common name (in English or other languages)
Chromosomal number
DNA structure
Other information

Some database systems may be established by using such identification system in different jurisdictions independently. Therefore the most important matter for the ID system of plants is a relational data linking mechanism to bind any and all element data recorded in such a database which can indicate the correct DNA structure to identify a specific plant correctly. If such a linking mechanism can be established on the Internet then everyone can use this database system to find the common name or scientific name of a plant. The computer system in the database system could thus retrieve and compare every element of relevant data recorded in database systems worldwide through the Internet. Subsequently, the system would provide a linking table based on DNA structure element data of the plant as an internal key to retrieve and sort data. It would thus be able to retrieve every synonym and name using such a database system. In addition, such a linking database system would provide a tree -structured table through which people could identify parent plants or closely relevant plants of a specific plant on the gene level <sup>24</sup>. If such a database system and uniform ID system would be established then no lawyer, judge or patent examiner would misunderstand the name (identification) of the plant <sup>25</sup>. One would thus be able to find the name of the rose correctly.

#### 5.3. Management

If such a uniform ID system can be developed, deployed and used commonly then the most important issue may be who would be responsible in managing this system <sup>26</sup>. If a specific government or private company would manage the ID system, such a management organization might prefer to adopt an unjust management style to ensure their own economic profit or status. In addition, in a worst case scenario, if

<sup>&</sup>lt;sup>24</sup> Due to such important function, such database system can not be used to retrieve human gene data. Human gene data is one of the most important sensitive data to be protected. On human gene data, EU Personal Data Protection Directive (95/46/EC) and other similar international and domestic laws shall apply.

<sup>&</sup>lt;sup>25</sup> New technology has large possibility to change the roll of lawyers. See Richard E. Susskind, The Future of Law: Facing the Challenges of Information Technology, Oxford University Press, 1996, pp. 265-292.

<sup>&</sup>lt;sup>26</sup> See Simson Garfinkel, Database Nation: The Death of Privacy in the 21st Century, Oreilly & Associates Inc., 2000

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such an organization would be able to govern the database systems of the ID system then the organization would be able to succeed in governing every intellectual property right relating to wild herbal plants on Earth. It might be a tradeoff to resolve the critical legal issues mentioned above. However, we have to give careful consideration to and also examine carefully what entity should manage the ID system. It seems that the most suitable way to manage this ID system would be to have it managed by a neutral international organization such as the United Nations or other responsible and relevant international organizations.

#### Appendix A: Examples of Plants related Patents

### 1: Pharmaceutically active plant extract and composition thereof (United States Patent 4352796)

[Abstract]

There discloses a substantially alkaloid-free aqueous extract of an aconite root which is the dried tuberous root of Aconitum japonicum or like plant belonging to Ranunculaceae, which is useful as analgesic and antiphlogistic.

### 2: Method for the treatment of cancer (United States Patent 5366725) [Abstract]

The carcinostatic agent of the present invention is an extract from seeds of Aeginetia indica and has interleukin-2 and interferon- $\gamma$  inducing potency. As shown in FIG. 1, all of the mice, to which this extract was not given, ( $\Delta$ ) died from tumor (6 mice). In contrast, in the mice, to which the extract was given by 0.6 mg/kg (.quadrature.), 1.2 mg/kg (+), and 2.5 mg/kg () intraperitoneally once in every two days from the day of tumor grafting, all mice showed increase in the survival rate. Thus, the extract exhibits excellent carcinostatic effect.

### 3: Herbal compositions for prostate conditions (United States Patent 6790464)

[Abstract]

Methods and compositions are disclosed for prevention or treatment of prostate disorders and ameliorating symptoms thereof, including prostatitis, benign prostate hyperplasia and prostatic carcinoma. The methods comprise administering a composition of matter comprising the following herbal and other components: Radix Asparagi; Radix Angelicae Pubescentis; Radix Trichosanthis; Radix Scuttellariae; Radix Angelicae Sinensis; Radix Dipsaci; Cortex Eucommiae; Medulla Junci; Rhizoma Anemarrhenae; Caulis Akebiae; Herba Dianthi; Semen Plantaginis; Cortex Phellodendri (fried); Radix et Rhizoma Rhei; Rhizoma seu Radix Notopterygii; Olibanum; Fructus Gardeniae; Radix Astragali seu Hedysari; Rhizoma Cimicifugae; Radix Bupleuri; Myrrha; Gypsum Fibrosun; Radix Rehamanniae (crude); Folium Pyrrosiae; Rhizoma Acori Graminei; Rhizoma Dioscoreae Hypoglaucae; Radix Linderae; Herba Cistanche; Radix Paeoniae Rubra; Rhizoma Dioscoreae; Semen Euryales; Cortex Mouton; Polyporus Umbellatus; Radix Rehmanniae Praeparata; Medulla Tetrapanacis; Semen Coicis; Fructus Horedi Germinatus (Poria); Radix Aconiti Praeparata; Rhizoma Alismatis; Cortex Cinnamomi; Herba Asari; Radix Glycyrrhizae; Stigma Maydis; Phaseolus Radiatus L., and optionally, Ganoderma Lucidum.

### 4: Crude drug compositions and the process for preparing them (United States Patent 7247325)

[Abstract]

The present invention provides a crude drug composition comprising extracts of radish and tea leaf and additionally comprising an extract extracted from at least one crude drug selected from a group consisting of Daucus carota var sativa, Aurantii nobilis Pericapium, Aurantii immatri Pericarpium, Ficus carica L., Allium cepa L., Mume Fructus and Prunus armeniaca. Inventive composition induces the functional activation of intestine in the charcoal-administered animal model experiment and constipation-induced animal model and improves the constipation by activating mucus secretion in the intestine. And the composition is confirmed to inhibit the growth of intestinal harmful bacteria without affecting the growth of beneficial bacteria. Therefore, the crude drug composition of the present invention may be useful for the pharmaceutical composition and health care food for preventing, alleviating and treating intestinal disease and constipation.

# 5: Methods of isolating amyloid-inhibiting compounds and use of compounds isolated from Uncaria tomentosa and related plants (United States Patent 7285293)

[Abstract]

Assay-guided affinity fractionation and reverse phase high pressure liquid chromatography (HPLC) methodology to isolate, test and characterize the most active water-soluble ingredients within Cat's Claw, or Uncaria tomentos. These components appear to account for the majority of the amyloid or Aßfibrillogenesis inhibitory activity. Individual fractions and/or compounds as isolated by HPLC are tested in relevant in vitro and/or animal models, and found to consistently demonstrate inhibition of amyloid or Aßfibrillogenesis. Related extraction methods are disclosed.

### 6: Evaporate of Ecbalium elaterium fruit extract for treating viral symptoms (United States Patent 7297350)

[Abstract]

A broad spectrum anti-viral includes a condensate, made by boiling a filtered residue of the Ecbalium Elaterium plant. The condensate, mixed with water, has been successfully used to treat humans for Hepatitis C, Hepatitis B, Influenza, and the Common Cold. The condensate was also subject in vitro assays. These assays showed antiviral activity, with an acceptable level of toxicity.

### 7: Synergistic phytoceutical compositions (United States Patent 7303772) [Abstract]

Phytoceutical compositions for the prevention and treatment of circulatory disorders, feminine endocrine disorders, and dermal disorders. A specific combination of extracts of plants is taught, as well as principles for varying the formulations based on categorizing plants into one of three groups, Energy, Bio-Intelligence, and Organization and selecting several plants from each group. Such combinations have synergistic effects, with minimal side effects.

### 8: Raphanus with increased anthocyanin levels (United States Patent 7304210)

[Abstract]

The present invention relates to plants of the genus Raphanus containing increased levels of anthocyanins. In particular the edible sprouts and turnips of the Raphanus plants contain high levels of anthocyanins and thereby provide health-promoting effects. The anthocyanins in the Raphanus plants are present at a level of at least 100 nmol per gram of fresh weight and have an absorbance maximum at a wavelength in the range of 515 to 550 nm. The invention also provides methods for growing the Raphanus plants as purple sprouts, both in the form of alfalfa-type sprouts as well as in the form of two-leafed plantlets, referred to as cress or micro-vegetables. The invention further provides methods for producing anthocyanins based on growing the Raphanus plants and isolating anthocyanins therefrom.

#### Appendix B: Examples of Genetic Patents and related Patents

### 1: Arabidopsis thaliana derived frigida gene conferring late flowering (United States Patent 7230158)

[Abstract]

Disclosed are isolated nucleic acids obtainable from the FRI locus of plants which encode polypeptides capable of specifically altering, particularly delaying, the flowering time of a plant into which the nucleic acid is introduced. One preferred embodiment is the FRI nucleotide sequence which encodes the polypeptide of FIG. 6 (see the sequence of FIG. 5, particularly bases 362-2188 thereof) or sequences degeneratively equivalent to these. Also provided are variant sequences (e.g. alleles, orthologues, derivatives) and complementary sequences, plus vectors, host cells, plants and associated processes of production and methods of use e.g. for influencing or affecting flowering time in a plant by expression or suppression of FRI or variant sequences.

### 2: Method for modifying plant morphology, biochemistry and physiology (United States Patent 7259296)

[Abstract]

The present invention provides nucleotide sequences and corresponding amino acid sequences for plant cytokinin oxidase proteins. Also provided are vectors, host cells, and transgenic plants comprising such sequences as well as methods for stimulating root growth and/or enhancing the formation of lateral or adventitious roots and/or altering root geotropism using such sequences. Also provided by the present invention are methods for altering various plant phenotypes including increasing seed size and/or weight, embryo size and/or weight, and cotyledon size and/or weight using cytokinin oxidase proteins and/or nucleic acid molecules encoding cytokinin oxidase.

# 3: Nutrition dispensers and method for producing optimal dose of nutrition with the help of a database arrangement (United States Patent 7295889)

[Abstract]

A nutrition dispenser (100) for producing doses of nutrition and/or medication and a method for producing the doses with the help of the nutrition dispenser. A database arrangement is linked to the nutrition dispenser (100), and further, the nutrition dispenser typically includes the user interface (102) for feeding at least the information of the user, and rooms (108) for storing different nutrients and/or medical substances. In addition, the nutrition dispenser is arranged to define the optimal dose of nutrition and/or medication intended for the person consuming the dose, and its ingredients, amounts and proportions of ingredients at least partly with the help of the database arrangement. The nutrition dispenser can further comprise the equipment (110) for measuring out the defined nutrients.

# 4: Authentication of biologic materials using DNA-DNA hybridization on a solid support (United States Patent 7297490) [Abstract]

Provided are a method for preparing an array for authenticating biological samples and a method for authenticating the biological samples based on analysis of variable sequences of ribosomal RNA genes as well as a kit for authentication of the biological samples. The hybridization of probes of the samples to the array of overlapping fragments of authentic variable ribosomal RNA gene regions is quantified. The test enables distinction of species or prokaryotic strains and is unaffected by intra-species or strain polymorphism. The method disclosed is illustrated by authentication of traditional Chinese medicinal materials.

### 5: Method and device for recording sequence information on biological compounds (United States Patent 7308452)

[Abstract]

A method and device for recording sequence information on biological compounds such as nucleotides and amino acids in as small amounts of data as possible are provided. The text data representing the sequence of a series of nucleotides constituting the DNA of the standard sample E is converted into binary data using a conversion table, and the binary data is divided into plural m-bit partial data (A(i,j)) arranged in plural columns and rows  $(m \ge 16)$ . Then a first set of parities  $(B1(i)^*B3(i))$  are computed by applying an operation of Galois field GF(2m) to the partial data (A(i,j)) of each column and a second set of parities  $(C1(j)^*C3(j))$  are computed by applying an operation of Galois field GF(2m) to the partial data (A(i,j)) of each row. The sequence of the nucleotides is represented approximately by the parity information.

### 6: Identification and characterization of an Anthocyanin mutant (ANT1) in tomato (United States Patent 7304207)

[Abstract]

The present invention is directed to a novel plant phenotype, designated Anthocyanin 1 (ANT1), a nucleic acid sequence expressed in plants demonstrating the ANT1 phenotype and the corresponding amino acid sequence. Also provided are plant cells and plants that exhibit modified ANT1 expression.