Appeal decision

Appeal No. 2017-16402

Appellant Medasani, Munisekhar

Patent Attorney OZAKI, Takahiro

The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2015-209566 titled "PICRORHIZA KURROA EXTRACT FOR PREVENTION, ELIMINATION, AND TREATMENT OF INFECTION OR DISEASES" (the application published on February 12, 2016, Japanese Unexamined Patent Application Publication No. 2016-26203) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

1. History of the procedures

The present application is a patent application filed on October 26, 2015, which is a divisional of Japanese Patent Application No. 2012-527450 with an international filing date of September 2, 2010 (claiming priority under the Paris Convention with a priority date of September 4, 2009 in India (IN)), for which a notice of reasons for refusal was issued on August 12, 2016, a written opinion and a written amendment were submitted on February 14, 2017, and a decision of refusal was issued on June 29, 2017. In response, an appeal against an examiner's decision of refusal was filed on November 6, 2017, and an amendment to amend the grounds for appeal in the Appeal Brief was made by a written amendment received on December 12, 2017.

2. The Invention

The inventions according to Claims 1 to 24 of the present application are as per the recitation of Claims 1 to 24 of the scope of claims in the written amendment received on February 14, 2017. Of these, the invention according to Claim 1 of the present application (hereinafter referred to as "the Invention") is set forth as below:

"A medicinal or nutraceutical composition for use in the prevention, elimination, treatment, and management of viral infections, disorders, and diseases in human and animal subjects and for use in other applications as hepatoprotective and antihyperlipidemic agents, comprising one or more of the terpenes found in one plant of Picrorhiza kurrooa Royle, Picrorhiza scrophulariflora Pennell, and Neopicrorhiza scrophulariiflora or any mixture thereof and one or more of the fatty acids found in said plants."

In addition, a composition "comprising one or more of the terpenes found in one plant of Picrorhiza kurrooa Royle, Picrorhiza scrophulariflora Pennell, and Neopicrorhiza scrophulariiflora or any mixture thereof and one or more of the fatty acids found in said plants" is simply referred to as "the composition of the present

invention".

Further, the use of "for use in the prevention, elimination, treatment, and management of viral infections, disorders, and diseases in human and animal subjects and for use in other applications as hepatoprotective and antihyperlipidemic agents" of the present invention is simply referred to as "the use of the present invention".

3. Judgment by the body

(1) The requirement as provided in Article 36(4)(i) of the Patent Act (enablement requirement)

A Article 36(4)(i) of the Patent Act specifies that the Detailed Description of the Invention of the specification should "disclose definitely and sufficiently to the extent that allows those who have expert knowledge in the technical field to implement the invention". The "implementation" in this provision is make, use, etc. of a product according to the invention in an invention of the product. Thus, in order to satisfy the enablement requirement, the Detailed Description of the Invention of the specification should be described to the extent that allows a person skilled in the art to make and use the product according to the invention. Further, in a use invention of pharmaceuticals, it is generally difficult to predict the effectiveness of the use and the effective amount of the pharmaceutical only from a substance name, a chemical structure, etc. and it is almost impossible to use the pharmaceutical according to the invention for the use. Therefore, it is essential that the Detailed Description of the Invention describe to the extent that allows a person skilled in the art to recognize the utility as a pharmaceutical as well as the producibility of the pharmaceutical in light of the common general knowledge as of the filing in order to conform to the enablement requirement in an invention of pharmaceutical use.

Further, consideration is given hereinafter as to whether the Detailed Description of the Invention of the specification of the present application might be described to the extent that allows a person skilled in the art to recognize the utility of the present invention as a pharmaceutical; i.e. whether the composition of the present invention shows the utility of the use of the present invention.

B Descriptions of Detailed Description of the Invention

(A) The Detailed Description of the Invention of the specification of the present application has the following descriptions (Underlined by the body.):

"[Background Art]

[0002]

The plants of the order Scrophulariaceae are known to possess medicinal properties as reported in traditional medicine systems. The medicinal efficacy of these plants arises from the numerous glycosides present in the plants of this order. The more accessible of Scrophulariaceae plants are the plants in the genus Picrorrhiza. Three members of this genus are of particular interest because of their safety and absence of toxicity. They are Picrorhiza kurrooa Royle, Picrorhiza scrophulariflora Pennell, and Neopicrorhiza scrophulariiflora.

[0003]

Picrorhiza kurrooa (known as Katuka in India) is widely found in India. It grows in the Himalayas at an altitude of about 3000 to 5000 meters. The extract is known for its properties as a liver protector and an immune modulator. Roots of the

plant have been traditionally used in the Indian Ayurvedic system of medicine for asthma, bronchitis, malaria, chronic dysentery, viral hepatitis, upset stomach, and scorpion stings, as a bitter tonic for stimulating the appetite, and for improving digestion. It is known for its therapeutic value as a hepato-protectant and for relief in fevers, but there is no disclosure or evidence in the prior art as to whether it acts against hepatitis or other viruses or is a mere liver rejuvenant.
[0004]

The plant also grows in China, Nepal, Bhutan, and other regions, where roots and rhizomes thereof have been traditionally used for dysentery, jaundice, steaming of bone, hepatoprotection, and immuno-modulation function. The plant, particularly the roots, is known to be rich in terpenoids and glycosides."

"[Problem to be solved by the Invention]
[0006]
... The species name Picrorhiza kurrooa is referred to hereinafter as PK for short in the interests of conciseness. In this specification, the initials 'PK' refer to said Picrorhiza species. Depending on the context, said initials may refer to just one of the species or to more than one simultaneously. ..."
"[0009]

The active principle in PK is referred to in the prior art as kutkin, which comprises kutkoside, a glycoside. It further comprises iridoid glycosides named Picroside I, II, and III, and other picrosides. Several other principles have been identified such as apocynin, drosin, and nine cucurbitacin glycosides, the first-named being a potent antiinflammatory agent and the other two also being reported to have medicinal properties. These medicinal factors occur uniformly across the entirety of said order (the Scrophulariaceae family) and in particular in all the plants of the P. genus. Thus far, said medicinal efficacy of PK extracts has not been attributed to specific active principles (factors) in the prior art.
[0010]

It is now known that plant matter of the P. genus in particular and the Scrophulariaceae family (S. family for short) in general comprise both lipophillic and non-lipophillic constituents. The lipophillic compounds and constituents of said family are referred to further herein as LCs for short, and similarly the non-lipophillic constituents and compounds of the family are referred to as NLCs. This is in the interest of conciseness and without any limitation to the scope of the invention."
"[0012]

The inventors observe that the above-named medicinal factors of PK that have been reported, discussed, or investigated either in the traditional medicine practices or in the modern prior art are mainly NLCs. It may be noted that prior art (including traditional medicine practices) has confined itself to use of only water and alcohols (methanol and ethanol) as extracting solvents. The inventors note that said solvents generally speaking, extract said NLCs, and leave out almost all the LCs. Consequently, the attention of the prior art has been placed solely on the NLCs and their medicinal properties and has not extended to these other components.
[0013]

The chief NLC in P. plant matter are the glycosides thereof. In modern times, a wide range of medicinal properties of the various plant glycosides have come to light.

They extend over a wide range of diseases and disorders. Different types of glycosides are found in the plant world. The focus and spotlight in the prior art, at least as far as medicinal properties and effects are concerned, has been totally on the P. glycosides. Prior art appears to be unaware of the nature and extent of the other constituents in the S. family of plants, namely said LCs and their medicinal significance. This is understandable, as the prior art has substantially excluded other solvents from their studies, solvents that would have also extracted the LCs to a greater or lesser extent and exposed them to research, study, and medicinal scrutiny. Presumably, prior art would then have explored the nature and extent of their medicinal efficacies. Perhaps because the water and alcohol extracts exhibited considerable medicinal efficacy and offered sufficient scope for investigations, attention did not extend to the other extracting solvents and thereby to the lipophillic constituents of the S. family."

"[0014]

Through their experimental observations, the inventors have established that the medicinal activity of said LCs (lipophillic compounds of the S. family) is of a very high order. As first observed by the inventors, the range and quantum of the medicinal effect of said LCs in contrast to said glycosides is considerably and surprisingly higher and wider. This invention is the first to consider said LCs and to verify their quite extraordinary medical significance, for example, as anti-viral compounds. This invention has also established for the first time that the presence of NLCs tends to impair and reduce the medicinal efficacy of the LCs and that it is therefore important to produce P extracts that contain the LCs substantially exclusively or with minimal NLC content. To this end, the inventors provide a novel process and have identified appropriate solvents that preferentially extract said LCs and whose extraction profile is such as to substantially keep out said NLCs or minimize their extraction into the extract.

[0015]

The inventors observe that the NLCs mask the medicinal effects of the LCs. The presence of any NLCs in an extract containing said LCs has the effect of reducing the medicinal efficacy of the latter. It may be that some of the NLCs of the S. family have an action opposite to that of the LCs. Whatever the mechanism, this invention has experimentally established that the LCs have pronounced medicinal effects and that LC-extracts are preferably substantially free of NLCs so as to realize their full medicinal efficacy.

[0016]

The novel PK extract of the invention therefore differs in a very fundamental way from the PK extracts of prior art in that the medicinal principles in the former are different from those in the latter. The medicinal principles of the former are substantially absent in the latter and the medicinal principles in the latter have been substantially avoided in the former for reasons elaborated hereinbelow. The medicinal principles in the former are the LCs of the S. family of plants and not the S. family glycosides as is the case with the latter.

[0017]

The chief medicinal factors in the former are the fatty acids and terpenes found in the S. family of plants followed by the aglycons arising from the S. family glycosides. Said fatty acids, terpenes, and aglycons extracted out in the extract in the process are absent in the latter. As is known, the glycosides in PK plants are the picrosides I, II, III etc. The latter therefore consists mainly of said picrosides and a compound named

apocynin, while the former is substantially free of both said picrosides and other glycosides, and also apocynin. Rather than said picrosides present in the original plant matter, what we have in the extract of the invention are aglycons derived therefrom.
[0018]

It may therefore be noted that the process of the invention is not merely a physical process of extraction but also incorporates chemical changes. The inventors observe that hydrolysis and esterification reactions occur during the process of extraction resulting in the release of said aglycons in the extract. This hypothesis is submitted without commitment, as the higher medicinal efficacy stands established by the experimental investigations of the inventors. This invention provides experimental proof that chemical reactions are occurring during extraction so that the extraction process of the invention involves a combination of physical and chemical changes. This invention prepared a hexane extract and also an extract wherein the first solvent was ethanol and the second was hexane. The yield in the former procedure was found to contain about 35% more LCs. HPLC analysis indicates the presence of aglycons, steroidal terpenes, and long chain fatty acids structures in the extract. It is inferred that the extra yield corresponds to the existence of these aglycons, steroidal terpenes, and long chain fatty acids in the hexane extract. These compounds, which are either originally present in the S family plant matter or are reaction products involving some of said originally present compounds, are substantially absent in the extract obtained by the ethanol-hexane solvent system. The ethanol-hexane solvent system leaves out these components during extraction.
[0019]

The extract of the invention further contains the fatty acids found in the S. family plants. The S. family glycosides are highly bitter compounds that make the prior art PK extracts unpalatable. In contrast, the PK extract of the invention is highly palatable being almost free of bitterness factors. A number of odor factors come out in water and alcohol extracts, and consequently the prior art PK extracts have a strong unpleasant odor that reduces their acceptability for human and animal consumption. Said picrosides and other glycosides in the S. family are highly bitter compounds. Smaller quantities of other bitter principles are also found in PK plants. On the other hand, the extract of the invention is substantially odorless. All in all, the extract of the invention is a distinct and different paradigm from the prior art extracts.
[0020]

The mechanism of the medicinal action of the terpenes and other components of the extract of the invention is not known, nor is there an explanation of the superiority of their medicinal action vis-a-vis the prior art extract components. The inventors again observe that said superior medicinal activity is experimentally established by their experimental work.
[0021]

The drawbacks of the prior art extracts are therefore the presence of the glycoside components that are of considerably lesser medicinal efficacy than said terpenes and other LCs of the S. family of plants. The range of medicinal effectiveness of the glycosides is also considerably lesser than that of said terpenes and other LCs. Although they are reported to be hepatoprotective, said glycosides do not possess anti-viral activity (Herbal medicines for liver diseases in India, SP Thyagarajan, S Jayaram, V Gopalakrishnan, R Hari, P Jeyakumar, MS Sripathi, Journal of

Gastroenterology and Hepatology Volume 17, pages S370-S376, December 2002). On the other hand, said LCs exhibit strong anti-viral activity against both DNA and RNA viruses and their action is therefore much wider than the reported limited liver-protective and regenerative action of said NLCs. The prior art extracts are highly bitter such as to be almost unpalatable, and their unacceptability extends further to their strong unpleasant odor components.

[0022]

The drawbacks of the prior art processes of extraction are that they are confined to water and the two alcohols, ethanol and methanol, and do not extend to a whole range of solvents that yield novel and better and medicinally more useful effective extracts containing the LCs of the S. family.

[0023]

The inventors have experimentally established through cell lines that the use of P extracts mainly comprising said lipophillic components actively inhibits the action of hepatitic and other viruses of the DNA and RNA types. It further destructs the viral structures, providing confirmation that it is a highly effective anti-viral composition.

[0024]

As is known, phospholipids involved the structure of cell membranes comprise two highly lipophilic (fat-loving) alkyl chains and a highly hydrophilic (water-loving) ionic group at the other end, typified by choline phosphate. The inventors believe that this allows the lipophillic moieties and other structures in PK extracts to be more active pharmacologically in the treatment of viral diseases. The in vitro investigations by the present inventors have been confirmed by independent labs. They confirm that PK lipophillic compounds have very high anti-viral properties against DNA and RNA viruses including Hepatitis B, influenza, retroviruses such as HIV, and other viruses.

[0025]

The inventors observe that a combination (mixture) of one or more of the terpenes found in said S. family of plants with one or more of the fatty acids found in said family of plants is a novel, potent anti-viral composition that is highly effective against a number of viral, fungal, bacterial, parasitic, and protozoal infections, disorders, and diseases. Said novel composition is effective against both DNA and RNA viruses. In view of that, it has applications in biochemical and biotechnical processes in research and industry, in particular the technical fermentation industry. The novel composition of the invention may further comprise one or more of the aglycons of the glycosides found in said family of plants. The constituents of the composition of the invention may be of plant origin, or synthetic or part-synthetic origin. Said composition may be made by a process of admixture of said constituents or obtained partly or fully from plant matter.

[0026]

This invention has extracted said S. family plant matter in general and plant matter of the P. genus in particular. These extracts were fractionated by HPLC (High Performance Liquid Chromatography) to yield several fractions. It is observed that said fractions also constitute compositions of the invention, as each of them comprises said terpenes and fatty acids of the S. family plants. Said fractions are elaborated further hereinbelow.

[0027]

The inventors have discovered that when a human or animal subject is

administered said extract or composition of the invention, antigens and antibodies are produced by the body's immune processes. Although the mechanism of this process is not fully known, the inventors have established that antibodies and allied species and substances such as antigens, immunogens, immune sera, anti-serum, serum, and immunoglobins are produced in said subjects and can be isolated from the serum of human, animal, bird, or aquatic animal subjects employed; that is, subjects that have been administered the extract or the composition of the invention. Antibodies and allied species thus isolated may be used to formulate vaccines, adjuvants, and other formulations for administration to subjects who are in need of prevention or treatment. Said antibodies, allied species, and substances are collectively referred to herein as 'immune system related species'.
[0028]

It is therefore an object of this invention to provide a composition comprising a mixture of the terpenes and fatty acids found in the plant matter of the Scrophulariaceae family(order) of plants."

" [Means for solving the problem]
[0038]

To achieve the goal, the present invention provides a medicinal, nutraceutical or food composition for use in the prevention, elimination, treatment, and management of viral, fungal, bacterial, parasitic, and protozoal infections, disorders, and diseases in human and animal subjects and for use in other applications as hepatoprotective, anti-hyper-lipidemic, anti-diabetic, and kidney- protective agents, comprising one or more of the terpenes found in Scrophulariaceae and one or more of the fatty acids found in said plants."
"[0044]

The composition of the invention and the PK extract of the invention therefore essentially comprise the terpene constituents of the S. family of plants. In the description further hereinbelow, references to the composition of the invention may also be considered to be references to the extract of the invention and vice versa, unless repugnant to the context. They may comprise one said terpene or any mixture of the terpenes of the S. family. They further essentially comprise one or more of the fatty acid(s) of the S. family of plants. The combination of said terpenes and fatty acids exhibits therapeutic synergy. Such synergy is also exhibited by the three component system: said terpenes, fatty acids, and aglycons. Preferably, the terpenes are the single major LC component, and the terpenes and fatty acids together form the major part of said lipophillic components in the composition/extract. Said extract and composition also preferably comprise the aglycons of the glycosides present in the S. family plants. These glycosides undergo reactions (such as hydrolysis) and/or decomposition under the extraction conditions and yield their respective aglycons that are then extracted out by the solvents of the invention into the extract. Preferably, the combined amount of said terpenes, fatty acids, and aglycons; that is, the combined amount of the LCs as a whole, is 80% by weight or more. Preferably, the extract of the invention is free of said bitter glycosides, and the amount of the other NLCs in the extract is between 0.01 % by wt. and 20% by wt. of the extract as a whole. Preferably, the amount of said glycosides, kutkisides, picrosides, and apocynin and drosin together does not exceed 20% by wt. of the extract. Preferably less than 10% of the extract is water

soluble. The parameters given hereinabove are applicable to both said composition and extract of the invention unless otherwise required by the context."
"[0047]

Within the scope of the invention, said PK extract of the invention may be the extract of any species in said S. family of plants. It will be noted that the process of extraction of the invention is easily and simply extensible to any said plant species or other plant matter. Equally easily and simply, said process is adaptable to any mixture of said species. Preferably, the extract is from a mixture of the three species mentioned hereinabove: Picrorhiza kurrooa Royle, Picrorhiza scrophulariflora Pennell, and Neopicrorhiza scrophulariiflora. These three species are favored from the point of view of toxicity."

"[Description of Embodiments]
[0065]

In order to provide a clearer understanding of the invention, some of the embodiments thereof are described hereinbelow without limitation to the scope of the invention.
[Embodiment 1]
[0066]
1. Roots and rhizomes of said PK plants were procured and sun-dried. Manual picking of foreign particles was carried out.
2. The plant matter was subjected to water washing by means of sprinklers to remove sand and dirt.
3. The plant matter was then air dried under vacuum to bring down the moisture.
4. The plant matter was then ground manually and the ground matter air dried to remove traces of moisture.
5. A batch of this matter was weighed and charged into the reactor (extraction vessel).
6. Hexane was added and the solid-liquid mixture heated. (Alternatively any other non-polar solvent).
7. The heated mixture was continuously stirred.
8. The extraction process including said reactions was allowed to proceed for a period of about 24 hours.
9. The plant matter and the solution were separated.
10. The solution was transferred to another vessel under vacuum.
11. The solution was filtered thrice to remove suspended matter and undissolved matter and thereafter the solution was sent to a reaction vessel (evaporator) where the solvent was evaporated under vacuum. The temperature was maintained below 70°C during evaporation.
12. The solvent was recovered and sent for re-use in the extraction.
13. The solid residue resulting from evaporation was air dried under vacuum in a controlled atmosphere. The dried material is the extract product of the invention and the same was sent for testing.
[Embodiment 2]
[0067]
1. Steps 1 and 2 as in embodiment 1 were carried out.
2. The P plant matter was ground into small pieces by mechanical means.
3. A batch was measured out and loaded into the reactor (extraction vessel).

4. A mixture of solvents, pentane, and ethyl acetate was charged to the reactor. (Alternatives: Any mixture of pentane, ethyl acetate, acetone, n-hexane, ether, chloroform, and tetrahydrofuran).
5. Reactor contents were heated and stirred continuously. Extraction was carried out for about 36 hours.
6. Separation of the plant matter and solution was carried out.
7. The solution was transferred to another vessel under vacuum.
8. The solution was filtered thrice and the clear liquid was evaporated at about 80°C under vacuum.
9. Solvent was recovered.
10. The solid residue from the evaporation was collected and subjected to air drying under vacuum in an atmosphere of nitrogen (alternatively carbon dioxide).
11. The dried product is the product extract of the invention and was sent for testing.
[Embodiment 3]
[0068]
1. Steps 1 and 2 as in embodiment 1 were carried out.
2. The PK plant matter was mashed into a paste and mixed with a sufficient quantity of water.
3. Organic acid (alternatively an inorganic acid) was added to bring down the pH so as to initiate the esterification reaction of the glycosides.
4. Stirring continued for about 24 hours.
5. At this stage, the n-hexane solvent was added (alternatively petroleum ether) and extraction continued for about 4 hours with stirring.
6. The solution was moved (decanted) and filtered.
7. The solvent was evaporated from the solution under vacuum by heating at about 75°C.
8. The semi-solid residue was collected and lypolised at about minus 80°C under vacuum and further process to obtain it in a powdered form.
9. The powder is the extract product of the invention and was sent for testing.
[Embodiment 4]
[0069]
1. Steps 1 and 2 as in embodiment 1 were carried out.
2. The PK plant matter was ground into a paste and steam distilled.
3. The steam was condensed and the residual solution after steam distillation was collected.
4. Enzyme esterase was added. pH and temperature were adjusted and the solution stirred for about 6 hours.
5. The temperature was raised to about 100°C to under vacuum to denature the enzyme.
6. The solution was then cooled.
7. Petroleum ether was added and the mixture stirred for about 4 hours.
8. The solution was filtered to remove the enzyme debris and un-dissolved particles.
9. The solution was separated into a petroleum ether layer and an aqueous layer.
10. The petroleum ether was heated to evaporate the solvent under vacuum.
11. The solid residue was collected, being the extract product of the invention.
12. The extract product was air dried and sent for testing.
13. The water was evaporated from the aqueous layer. The evaporation was under vacuum. The residue contained the water soluble components in the PK plant matter.
[Embodiment 5]

[0070]
1. Same as steps 1, 2, and 3 of embodiment 1 were carried out.
2. The PK plant matter was ground into small pieces by mechanical means.
3. A batch was measured out and loaded into the extractor reactor.
4. A measured quantity of solvent ethanol (alternative: methanol) was charged to the reactor.
5. Reactor contents were heated to the required level while stirring and were maintained at those conditions for about 24 hours.
6. The solution was transferred to another reactor vessel under vacuum.
7. The solution was filtered three times.
8. Water was added to the solution and stirred for about 1 hour.
9. Solvent n-hexane (alternatively pentane) was added and the contents stirred for about 6 hours.
10. The solution was allowed to settle for about 4 hours.
11. Evaporation under vacuum was carried out to distill off the solvent to recover the extract product of the invention in a solid or semi-solid form.
12. Balance liquid containing water and alcohol was distilled to recover the solvent.
13. Product air was dried under vacuum in nitrogen atmosphere (alternatively CO2 atmosphere) and sent for testing and microbial examination.
[Embodiment 6]
[0071]
1. Steps 1 to 3 same as in embodiment 1 were carried out.
2. Step 2 same as in embodiment 5 was carried out.
3. A batch of the PK plant matter was measured out and loaded into the extractor reactor.
4. The reactor was charged with the required quantity of n-hexane (alternative solvents for this embodiment: pentane, 1,4-di-oxane, di-ethyl ether, and petroleum ether.
5. The reactor contents were heated to the required level and stirred for about 24 hours.
6. The solution was transferred to another vessel under vacuum and filtered three times.
7. The solution was heated to evaporate the solvent under vacuum to obtain the extract product of the invention in solid or semi-solid form.
8. Residual solvent was removed from product by air drying under vacuum in a nitrogen atmosphere (alternatively a CO2 atmosphere).
9. Product was sent for testing for physical properties and microbial evaluation."

(B) According to the above (A), the Detailed Description of the Invention of the specification of the present application discloses that Picrorhiza kurrooa Royle, Picrorhiza scrophulariflora Pennell, and Neopicrorhiza scrophulariiflora (hereinafter these three species are collectively referred to as "PK") are known to possess medicinal properties as reported in traditional medicine systems ([0002]), and conventionally attention was paid only to "non-lipophilic component" extracted with an extraction solvent of water and alcohols and its pharmacological effect (a liver protector and an immune modulator) ([0003], [0012], [0022]). The present inventors have clarified through experimental observation that the pharmacological activity of "lipophilic compound (component)", which is different in active ingredient from the conventional PK extract, is at an extremely high level ([0010], [0014] to [0016]). It is described that "the present invention" is the first invention which has considered "lipophilic compound (component)" and confirmed its extraordinary medical significance, for example, as an

anti-viral compound ([0014]).

Further, the chief medicinal factors are a novel PK extract of the "present invention" are the fatty acids and terpenes aglycons arising from plant glycosides ([0017], [0044]), The inventors have experimentally established through cell lines that the use of P extracts mainly comprising said "lipophillic components" actively inhibits the action of hepatitic and other viruses of the DNA and RNA types ([0023]), and the in vitro investigations by the present inventors have been confirmed by independent labs, and they confirm that PK "lipophillic compounds (compound)" have very high anti-viral properties against DNA and RNA viruses ([0024]).

Furthermore, Embodiments 1 to 6 disclose that the extract product obtained by use of extraction solvents such as hexane, pentane, and ethyl acetate and petroleum ether from PK plants was sent for microbial examination ([0065] to [0072]).

B The Detailed Description of the Invention of the specification of the present application discloses in Embodiments 1 to 6 that the extract product obtained by use of extraction solvents such as hexane, pentane, and ethyl acetate and petroleum ether from PK plants was sent for microbial examination ([0065] to [0072]); however, its test result was not specifically described. Further, it is not specifically described that, in many components that may be contained in the resultant extract product, the combination of "terpene" and "fatty acids", which may include various structures, shows antiviral effect, etc. without regard to the specific structure.

Further, the Detailed Description of the Invention other than Embodiments describes that "Through their experimental observations, the inventors have established that the medicinal activity of said LCs (lipophillic compounds of the S. family) is of a very high order." ([0014]), "The inventors have experimentally established through cell lines that the use of P extracts mainly comprising said lipophillic components actively inhibits the action of hepatitic and other viruses of the DNA and RNA types." ([0023]), "The in vitro investigations by the present inventors have been confirmed by independent labs. They confirm that ... have very high anti-viral properties." ([0024]). It describes that the pharmacological activity such as antiviral effect was experimentally confirmed; however, the result of the experiment is not at all described specifically.

Furthermore, the Detailed Description of the Invention discloses that "The mechanism of the medicinal action of the terpenes and other components of the extract of the invention is not known" ([0020]), "The inventors believe that this allows the lipophillic moieties and other structures in PK extracts to be more active pharmacologically in the treatment of viral diseases." ([0024]). The mechanism that the composition of the present invention has eventually achieved the utility of the use of the present invention is not specifically described.

Consequently, a person skilled in the art could not specifically recognize from the description of the Detailed Description of the Invention of the specification of the present application that PK extract product mainly comprising a "lipophilic component"; specifically, the composition of the present invention comprising terpenes and fatty acids present in PK, which is novel due to the difference in active ingredient from PK extract product for which a drug efficacy was conventionally known as a liver protective agent and an immune modulator, shows an antiviral effect, a liver protective effect, or an antihyperlipidemic effect; i.e., shows the utility of the use of the present invention.

C Further, it was not common general knowledge as of the original application date that "terpenes and fatty acids" present in PK show antiviral effects, liver protection effect, or antihyperlipidemic effect without regard to the specific structure.

D Therefore, it cannot be said from the common technical knowledge as of the original filing date that the Detailed Description of the Invention of the specification of the present application might be described to the extent that allows a person skilled in the art to recognize that the composition of the present invention shows the utility of the use of the present invention.

(2) The requirement as provided in Article 36(6)(i) of the Patent Act (support requirement)

A The determination of whether or not the recitation of the Claims might comply with the support requirement of the specification should follow the steps of: comparing the recitation of the Claims and the descriptions of the Detailed Description of the invention; and considering whether or not the invention recited in the Claims might fall within the scope in which person ordinarily skilled in the art could recognize that a problem to be solved by the invention might be solved by the description of the Detailed Description of the Invention, or considering whether or not the invention recited in the Claims might fall within the scope in which a person ordinarily skilled in the art could recognize without such description or suggestion in view of the common technical knowledge as of the filing that the problem to be solved by the invention might be solved.

Therefore, consideration is given as to whether or not the present invention might be supported by the Detailed Description of the Invention, or might fall within the scope that a person skilled in the art could recognize that the problem to be solved by the invention might be solved by the description of the Detailed Description of the Invention.

B The Detailed Description of the Invention of the specification of the present application describes the following matters:

"[0024]

As is well known, phospholipids involved in the structure of cell membranes comprise two highly lipophilic (fat-loving) alkyl chains and a highly hydrophilic (water-loving) ionic group at the other end, typified by choline phosphate. The inventors believe that this allows the lipophillic moieties and other structures in PK extracts to be more active pharmacologically in the treatment of viral diseases. The in vitro investigations by the present inventors have been confirmed by independent labs. They confirm that PK lipophillic compounds have very high anti-viral properties against DNA and RNA viruses including Hepatitis B, influenza, retroviruses such as HIV, and other viruses."

"[0028]

It is therefore an object of this invention to provide a composition comprising a mixture of the terpenes and fatty acids found in the plant matter of the Scrophulariaceae family (order) of plants."

Combining these descriptions and the recitation of Claim 1 of the present application, the problem to be solved by the present invention (hereinafter referred to as "a problem to be solved by the invention") is to provide a medicinal or nutraceutical composition for use in the prevention, elimination, treatment, and management of viral infections, disorders, and diseases in human and animal subjects and for use in other applications as hepatoprotective and antihyperlipidemic agents, comprising one or more of the terpenes found in one plant of Picrorhiza kurrooa Royle, Picrorhiza scrophulariflora Pennell, and Neopicrorhiza scrophulariiflora or any mixture thereof and one or more of the fatty acids found in said plants.

C On the other hand, as discussed in the above item (1), the Detailed Description of the Invention of the specification of the present application does not describe any pharmacological test result in which the composition of the present invention shows the utility of the use of the present invention, nor does it describe the mechanism that the composition of the present invention has eventually shown the utility of the use of the present invention.

Further, as is discussed in the above item (1), it was not a matter of common general knowledge as of the original application date that "terpenes and fatty acids" present in PK show antiviral effects, liver protection effect, or antihyperlipidemic effect without regard to the specific structure.

Consequently, a person skilled in the art could not recognize that the composition of the present invention showed the utility for the use of the present invention, and could solve the problem to be solved by the present invention.

Therefore, it cannot be said from the common general knowledge as of the original filing date that the present invention might fall within such a scope that allows a person skilled in the art to recognize that the problem to be solved by the invention might be solved by the description of the Detailed Description of the Invention.

(4) Appellant's allegation

A The Appellant alleges in the statement of the request of the written amendment received on December 12, 2017:

"Regarding the enablement requirement, the Detailed Description of the Invention discloses the Embodiments of [0066] to [0071] by taking the common general knowledge as of the filing into account. As a use invention of pharmaceuticals, it discloses definitely and sufficiently to the extent that allows a person skilled in the art to implement the invention according to the claims. According to the common knowledge of a person skilled in the art as of the filing, the respective examination notices of two United States applications corresponding to the present invention ... do not make a reference to the enablement requirement and the support requirement, and the examination notice of the corresponding European application makes a reference to the nonconformance to the enablement requirement and the support requirement, but an opposing opinion was submitted thereto with a response communication. Thus, comprehensively taking into account the Embodiments of the specification of the present application, the prosecution of the corresponding foreign applications, and the pharmacological test result, the original decision made an error in the common general knowledge as of the filing, thereby making an erroneous construction of 'enable' of

'enablement requirement'. Thus, of course, the enablement requirement is established with respect to the present invention.

Regarding the support requirement, similarly to the above, the original decision made an error in the finding of the scope of the common general technical knowledge as of the filing, thereby making an erroneous construction of 'the scope in which one can recognize that the problem to be solved by the present invention may be solved' in the 'support requirement', and with respect to the present invention, the support requirement is established."

B However, in the prosecution of the corresponding foreign applications in US and Europe as the Appellant alleges has no direct relationship with this case.

Further, the Appellant alleges that "the original decision made an error in (the scope of) the common general knowledge as of the filing"; however, the Appellant fails to present any specific allegation of the error of the original decision with respect to "the common general knowledge", and thus it cannot be recognized from the above Appellant's allegation that the original decision is erroneous.

Furthermore, the "pharmacological test results" in the Appellant's allegation are construed as referring to the pharmacological test results as shown in the attached documents 1 to 6 of the written opinion received on February 14, 2017. As aforementioned, the Detailed Description of the Invention of the specification of the present application fails to describe any pharmacological test result of the composition of the present invention. Under such circumstances, it is obvious that the pharmacological test results submitted later may not complement the description of the specification of the present application. Further, documents 1 to 6 do not support the common general knowledge as of the filing. Therefore, the pharmacological test results shown in documents 1 to 6 cannot be taken into account in considering the enablement requirement and the support requirement.

Therefore, the above Appellant's allegation does not affect the Judgment by the body with respect to the enablement requirement and the support requirement.

4. Closing

As described above, the Detailed Description of the Invention of the specification of the present application does not conform to the provision of Article 36(4)(i) of the Patent Act, and the scope of claims does not conform to the provision of Article 36(6)(i) of the Patent Act, and thus the present application should be rejected.

Therefore, the appeal decision shall be made as described in the conclusion.

October 23, 2018

Chief administrative judge: MURAKAMI, Kimitaka
Administrative judge: FUJIWARA, Hiroko
Administrative judge: ASANO, Mina