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# Asamura NEWS

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## Recent remarkable court's decisions in Japan in the chemical and pharmaceutical fields



## 1. Second Medical Uses
## *–How is it judged that prior art disclose a medical use?*
### Hei26(Gyo Ke)10182: IP High Court Decision, Aug. 20, 2015

### Summary of Facts

This reports the Intellectual Property High Court Decision rescinding the trial decision on the inventive step regarding the invention which is characterized by the second medical use.

The present invention is related to "pharmaceutical composition ***for ameliorating depressive symptoms***, which contains triglycerides in which part or all of the constituent fatty acids is (are) arachidonic acid".

The Appeal Board denied the inventive step of the present invention based on reference 1 which describes "a pharmaceutical formulations prepared by combining: eicosapentaenoic acid or any appropriate derivative (EPA) with arachidonic acid or any appropriate derivative (AA) ***for the treatment of any psychiatric, neurological or other central or peripheral nervous system disease, in particular schizophrenia, depression, bipolar disorder and degenerative disorders of the brain including Alzheimer's disease and other dementias and Parkinson's disease***". Only the difference between the present patent and reference 1 was found by the Board in that the former recited "***depressive symptoms***" while the latter stated "***depression***". However, the Board concluded that such difference was not substantial since if the depression was successfully treated, the depressive episodes would be also treated well.

In addition, the board denied the inventive step of the present invention based on reference 2 which describes "a composition having ***preventive or ameliorative action on symptoms or diseases caused by decreased brain function including depression or dementia***, which comprises arachidonic acid and/or a compound having arachidonic acid as a constituent fatty acid, wherein the compound is an alcohol ester of arachidonic acid or a triglyceride, phospholipid or glycolipid in which all or a portion of the constituent fatty acids are arachidonic acid". Only the difference between the present patent and reference 2 was acknowledged by the Board in that the former identified the use as "***ameliorating depressive symptoms***" while the latter ***did not***. However, the Board concluded that the depression was clearly specified as one of diseases caused by decreased brain function in reference 2 and that ameliorating effects on depressive symptoms could

be presumed from the results of the Morris water maze test as exemplified in reference 2.

The appellant filed a lawsuit to revoke the above appeal board's decision of rejection.

## Summary of Court's Decision

The Intellectual Property High Court states:

Reference 1 describes the intended indications of the formulation as the very wide range of diseases including any psychiatric, neurological or other central or peripheral nervous system disease, in particular schizophrenia, depression, bipolar disorder and degenerative disorders of the brain including Alzheimer's disease and other dementias and Parkinson's disease. However, the results of working examples of reference 1 in which the effects on schizophrenia was only confirmed cannot be extrapolated to the treatment of depression or bipolar disorders. In other words, reference 1 does not describe nor imply that the depressive symptoms are ameliorated by the formulation of reference 1.

Reference 2 discloses the Morris water maze test wherein the preventive or ameliorative action on decreased memory or learning ability by use of the triglyceride in which all or a portion of the constituent fatty acids were arachidonic acid was confirmed. However, it cannot be recognized from such result of the Morris water maze test that depression is also treated by such compound.

Based on the findings of fact, the IP High Court revoked the appeal decision.

## Comments

In prosecution of a patent application directed to second medical use, an applicant sometimes receive an office action which rejects the application based on all-inclusive description found in prior art. However, in view of the above decision, it should be noted that if the prior art does not specifically exemplify usefulness of specific disease, the patentability of the invention directed to treatment of such specific disease may not be denied.

**(by Mari YUGE)**

# 2. Failure of Injunction by Patent with Too Narrowly Limited Claims Defining Crystalline Material

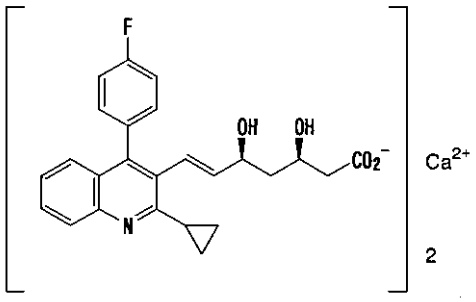
### Hei25(wa)33993: IP High Court Decision, Jan. 27, 2015

## Summary of Facts

The plaintiff is the patentee of Japanese Patent No. 5186108. Claim 1 of the patent recites:

"A crystal form of pitavastatin calcium salt,

wherein the crystal form of pitavastatin calcium salt is composed of a compound represented by the following formula (1):




( 1 )

wherein the crystal form of pitavastatin calcium salt has a water content of 7 to 13%;

wherein the crystal form of pitavastatin calcium salt has, according to X-ray powder diffraction using CuKα radiation, peaks at diffraction angles (2 thetas) of 4.96°, 6.72°, 9.08°, 10.40°, 10.88°, 13.20°, 13.60°, 13.96°, 18.32°, 20.68°, 21.52°, 23.64°, 24.12° and 27.00° and

wherein the crystal form of pitavastatin calcium salt has a peak at a diffraction angle (2 thetas) of 30.16° that is a relative strength of greater than 25% based on 100% being the peak at the diffraction angle (2 thetas) of 20.68°,

provided that a crystal having a melting point of 95°C according to differential scanning calorimetry excluded therefrom."

Claim 1 as originally filed did not recite the underlined matters, in particular the fifteen (15) diffraction angle peaks (to the second decimal place) of X-ray powder diffraction, but they were added to the original claim 1 in order to overcome the prior art rejections raised in the examination before the JPO.

The plaintiff filed an injunction against the defendant to discontinue manufacturing and selling the defendant's product. During the court proceedings, the plaintiff submitted experimental results of determination of X-ray diffraction angle peaks for the defendant's product by using each of five measurement methods, which are shown below.

The results of the column indicated by the mark "①" represent diffraction angle peaks of the subject patent measured at a wavelength of 1.54 angstroms; and the results of the column indicated by the mark "②" represent diffraction angle peaks of the subject product converted from the values of "①" under a wavelength of 0.75 angstroms. "(イ)" to "(オ)" represent diffraction angle peaks of the accused products. The mark "○" represents that the two values are identical to each other (to the second decimal place) whereas the mark "×" represents that the two values are different from each other.

| ピーク | ① | ② | (ア) | | (イ) | | (ウ) | | (エ) | | (オ) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 4.96 | 2.41 | 2.41 | ○ | 2.42 | × | 4.96 | ○ | 2.45 | × | 2.44 | × |
| 2 | 6.72 | 3.27 | 3.27 | ○ | 3.30 | × | 6.75 | × | 3.31 | × | 3.30 | × |
| 3 | 9.08 | 4.41 | 4.41 | ○ | 4.43 | × | 9.05 | × | 4.43 | × | 4.41 | ○ |
| 4 | 10.40 | 5.05 | — | | — | | — | | — | | 5.09 | × |
| 5 | 10.88 | 5.29 | 5.27 | × | 5.31 | × | 10.80 | × | 5.34 | × | 5.29 | ○ |
| 6 | 13.20 | 6.41 | 6.38 | × | 6.43 | × | 13.20 | ○ | 6.48 | × | 6.41 | ○ |
| 7 | 13.60 | 6.60 | 6.58 | × | 6.64 | × | 13.57 | × | 6.69 | × | 6.63 | × |
| 8 | 13.96 | 6.78 | 6.75 | × | 6.81 | × | 14.08 | × | 6.85 | × | 6.82 | × |
| 9 | 18.32 | 8.88 | — | | — | | — | | — | | 8.88 | ○ |
| 10 | 20.68 | 10.02 | — | | — | | 20.72 | × | — | | 10.02 | ○ |
| 11 | 21.52 | 10.42 | — | | — | | — | | — | | 10.45 | × |
| 12 | 23.64 | 11.44 | — | | — | | — | | — | | 11.44 | ○ |
| 13 | 24.12 | 11.67 | — | | — | | 24.19 | × | 11.59 | × | 11.65 | × |
| 14 | 27.00 | 13.04 | — | | — | | 26.97 | × | 12.98 | × | 13.03 | × |
| 15 | 30.16 | 14.54 | — | | — | | 30.20 | × | 14.47 | × | 14.59 | × |

(UNIT:°)

## Outline of IP High Court Decision

It was submitted by the plaintiff that, according to the sixteenth revised Japanese Pharmacopoeia, a plurality of crystal forms of a pharmaceutical can be decided to be satisfactorily identical to each other when there are 10 or more peaks matching at an accidental error of ± 0.2° or less by using an X-ray powder diffraction method and the identicalness may be sometimes decided positively even when there are less than 10 peaks meeting these criteria. As a result of the experiments conducted by the plaintiff, the claimed requirements of X-ray diffraction angle peaks of the subject patent should be met by the defendant's product, because the defendant's product had 10 or more peaks matching at an accidental error of ± 0.2° or less or otherwise comparable values by using each of the five X-ray powder diffraction methods.

However, the IP High Court dismissed the plaintiff's claim for the following reasons.

Firstly, claim 1 of the subject patent was amended to add thereto the fifteen (15) diffraction angle peaks (to the second decimal place) of X-ray powder diffraction in response to an Office Action issued during the examination before the JPO. It was not submitted in an Argument filed that a certain degree of accidental error of diffraction angle peak values should be accepted and a crystal meeting only a part of the claimed fifteen diffraction angle peaks could be encompassed within the scope of the claimed invention. The specification of the subject patent does not refer to the acceptance of a certain degree of accidental error of diffraction angle peak values or the permission of meeting only a part of the claimed fifteen diffraction angle peaks, either.

Secondly, there are many patent applications relating to a pharmaceutical compound having a specific crystal form by specifying diffraction angle peak values of X-ray powder diffraction, which defines an accidental error ± 0.1 to 0.2° to be accepted for each peak. However, the claim of the subject patent does not define any accidental error for each peak of diffraction angle. Therefore, the claimed invention of the subject patent should be construed to require for the defendant's product to completely match the fifteen (15) diffraction angle peaks (to the second decimal place) of X-ray powder diffraction in order to decide whether the defendant's product is included in the scope of protection sought by the claim.

Thirdly, the Japanese Pharmacopoeia is considered to be guidelines for judging the identicalness of a plurality of pharmaceutical products from the viewpoint of public interest of health and hygiene, which has been regulated by the Health, Labor and Welfare Ministry. In contrast, the scope of protection sought by a claim of a patent relating to a pharmaceutical product should be unambiguously construed by the recitation of the claim in view of the specification and drawings rather than by the Japanese Pharmacopoeia.

Finally, the IP High Court dismissed the plaintiff's claim as mentioned above.

### Comments

In this case, the main claim of the subject patent was amended in a too narrow manner in order to dodge the teaching of the prior art documents cited during the examination before the JPO. Consequently, the scope of protection sought by the claim was construed in an unduly narrow manner and the patent was then decided not to be infringed due to the narrowly construed scope of the claimed invention.

If the presence or acceptance of an accidental error of the diffraction angle values had been originally mentioned in the specification or was referred to in an Argument during the examination, a different conclusion of court decision might be reached.

In a case where claims are restricted by numerical ranges of physical or chemical properties (e.g., by results of an instrumental analysis), it would be preferred for applicants to try to make the restriction at a minimum as far as possible.

**(by Mikio KAMAOKA)**

## 3. Patent Battle between Two Measure Beer Makers

### Hei27(wa)1025: Tokyo District Court Decision, Oct. 29, 2015

### Summary of facts

The plaintiff (Suntory Holdings Ltd.) is the patentee of Japanese Patent No. 5382754 which has a priority date of November 22, 2011. Claim 1 of the patent (hereinafter referred to as "the patented invention") recites:

"A non-alcoholic beer-taste beverage whose total amount of an extract component(s) is 0.5% by weight or higher and 2.0% by weight or lower, having a pH of 3.0 or higher and 4.5 or lower, and having a saccharide content of 0.5g/100ml or lower."

The plaintiff began to sell a commercial product named "Suntory ALL-FREE" (hereinafter referred to as "ALL-FREE"), which is a non-alcoholic beer-taste beverage, on August 3, 2010 that is before the priority date of the patent.

The defendant (Asahi Brewery Ltd.) also began to sell a commercial product named "Asahi W-ZERO" (hereinafter referred to as "W-ZERO"), which is a non-alcoholic beer-taste beverage, on August 3, 2010 that is before the priority date of the patent (Note: "W-ZERO" can be actually pronounced as "double-zero"). The defendant is then selling a commercial product named "DRY ZERO", which is a non-alcoholic beer-taste beverage from early part of September, 2013.

The plaintiff Suntory Holdings Ltd. and the defendant Asahi Brewery Ltd. are both big beer manufacturers which are very famous in Japan.

The plaintiff filed an injunction against the defendant to discontinue manufacturing and selling the defendant's product.

There has been no dispute between the plaintiff and the defendant in the fact that both "ALL-FREE" and "W-ZERO" are not encompassed within the scope of the patented invention. The defendant just submitted a patent invalidation defense to argue that the subject patent should be decided to be invalid for several reasons, i.e. not meeting the support and enablement requirements; not meeting the requirements of prevention of new-matter introduction; the lack of inventive step of the patented invention due to the fact that **"ALL-FREE" was publicly worked in advance of the priority date** and due to the fact that **"W-ZERO" was also publicly worked in advance of the priority date** ("ALL-FREE" and "W-ZERO" are hereinafter referred to as a "Publicly Worked Invention 1" and a "Publicly Worked Invention 2", respectively); the lack of inventive step of the patented invention over U.S. Patent No. 3,717,471; and the lack of novelty over JP-A-2013-21944 that was filed before the priority date and then published thereafter.

The main issue of this court decision resides in whether or not the patented invention is considered to involve an inventive step over the Publicly Worked Invention 1 that is "ALL-FREE" (i.e. the commercial product of the plaintiff Suntory); and whether or not the patented invention is considered to involve an inventive step over the Publicly Worked Invention 2 that is "W-ZERO" (i.e. the commercial product of the defendant Asahi Brewery).

## Outline of Tokyo District Court Decision

From the evidences submitted, the Publicly Worked Invention 1 is recognized as a non-alcoholic beer-taste beverage whose total amount of an extract component(s) is 0.39% by weight, having a pH of 3.78, and having a saccharide content of lower than 0.5g/100ml. The patented invention only differs from the Publicly Worked Invention 1 in that the former requires for the beverage to have the "total amount of an extract component(s) is 0.5% by weight or higher and 2.0% by weight or lower", whereas the latter has the total amount of an extract component(s) of 0.39% by weight.

It was submitted by the plaintiff that the patented invention is characterized by **the combination per se of** the claimed three parameters of total amount of an extract component(s), pH and saccharide content, whereas the Publicly Worked Invention 1 does not relate to such a unique technical idea of the characteristic combination and a skilled person in the art could never consciously select these three parameters alone from an enormous number of lists of beverage properties so as to arrive at the patented invention. However, such arguments by the plaintiff are not persuasive in consideration the common general knowledge in the art conceivable from the evidences and the disclosure of the present specification. The difference between the patented invention and the Publicly Worked Invention 1 should be identified as mentioned above.

As of the priority date of the subject patent, consumers had gotten an impression such as not being very rich in taste or being poor in drinking sensation for the Publicly Worked Invention 1. And, as of the priority date of the subject patent, because non-alcoholic beer-taste beverages has been generally evaluated as being unsatisfactory with richness in taste, strong drinking sensation or the like, techniques of using various additives (e.g. extract components as presently claimed) in the beverages for the improvement of these factors had been well known in the art.

The skilled person, trying to improve the defect of not being very rich in taste for the Publicly Worked Invention 1, would be naturally motivated to add an extract component(s) thereto. Therefore, it would be obvious for him or her to boost the amount of an extract component(s) of the Publicly Worked Invention 1 from 0.39% by weight to the presently claimed "0.5% by weight or higher and 2.0% by weight or lower" while controlling the pH and saccharide content as appropriate. In addition, any unexpectedly advantageous effects over the Publicly Worked Invention 1 could not be seen by the patented invention.

In conclusion, the patented invention should be decided to be invalid as not being considered as involving an inventive step over the Publicly Worked Invention 1.

From the evidences submitted, the Publicly Worked Invention 2 is recognized as a non-alcoholic beer-taste beverage whose total amount of an extract component(s) is 1.07% by weight, having a pH of 3.05, and having a saccharide content of 0.9g/100ml. The patented invention only differs from the Publicly Worked Invention 2 in that the former requires for the beverage to have "a saccharide content of 0.5g/100ml or lower", whereas the latter has a saccharide content of 0.9g/100ml.

It was submitted again by the plaintiff that the patented invention is characterized by **the combination per se of** the claimed three parameters of total amount of an extract component(s), pH and saccharide content, whereas the Publicly Worked Invention 2 does not relate to such a unique technical idea of the characteristic combination and a skilled person in the art could never consciously select these three parameters alone from an enormous number of lists of beverage properties so as to arrive at the patented invention. However, such arguments by the plaintiff are not persuasive again as discussed above.

As of the priority date of the subject patent, due to ground swell of health tread, the label "Saccharide Zero" on containers of non-alcoholic beer-taste beverages (which means a saccharide content of less than 0.5g/100ml) had become widely popular among consumers.

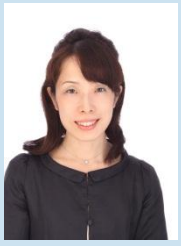
Apparently, the skilled person, looking to the Publicly Worked Invention 2, would be strongly motivated to reduce the saccharide content to less than 0.5g/100ml. Moreover, it would be easy for the skilled person to make the saccharide content smaller while controlling the pH and amount of an extract component(s) as appropriate. In addition, any unexpectedly advantageous effects over the Publicly Worked Invention 2 could not be seen by the patented invention.

In conclusion, the patented invention should be decided to be invalid as not being considered as involving an inventive step over the Publicly Worked Invention 2.

## Comments

The plaintiff Suntory has indicated their intension to appeal the decision to the Intellectual Property High Court. As long as any correction is not made to the patented invention and the difference identification is not reversed by the IP High Court, there is only one difference between the patented invention and the Publicly Worked Invention 1 or 2 in the amount of an extract component(s) or saccharide content. Attention of consumers and other beer-manufacturers will be attracted to how the lack of an inventive step of the patented invention over the Publicly Worked Invention 1 or 2 could be rebutted by the plaintiff (or appellant).

**(by Mikio KAMEOKA)**

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