Appeal decision

Appeal No. 2015-16377

Taiwan
Appellant PANION & BF BIOTECH INC

Tokyo, Japan
Patent Attorney HIRAKI, Yusuke

Tokyo, Japan
Patent Attorney FUJITA, Takashi

Tokyo, Japan
Patent Attorney ARAI, Eiichi

Tokyo, Japan
Patent Attorney TANAKA, Natsuo

Tokyo, Japan
Patent Attorney KIKUTA, Naoko

Tokyo, Japan
Patent Attorney HANAI, Hidetoshi

The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2013-103220, entitled "Pharmaceutical-grade ferric organic compound, use of the same, and method of producing the same" (the application published on September 9, 2013, Japanese Unexamined Patent Application Publication No. 2013-177416) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1. History of the procedures

This application is a divisional application filed on May 15, 2013 from Japanese Patent Application No. 2008-527177 with an international filing date of August 18, 2006 (Priority claim under the Paris Convention, August 18, 2005 (US), August 19, 2005 (US)). A Written Amendment was submitted on May 16, 2013 (at the time of request for examination) and in response to the notice of reasons for refusal, a Written Amendment was filed on December 15, 2014. However, the Decision of

Refusal was issued on April 22, 2015. In response to this, the Applicant (Appellant) requested an appeal against the examiner's decision of refusal on September 7, 2015 and filed a Written Amendment at the same time as this Appeal, and subsequently, submitted a Written Statement on September 14, 2015.

No. 2. The examiner's decision to dismiss amendment with respect to the Written Amendment dated September 7, 2015.
[Conclusion of Decision to Dismiss Amendment]

The Written Amendment dated September 7, 2015 (hereinafter referred to as "The Amendment") has been dismissed.

[Reason]
1. Detail of Amendment

The Amendment amends the following Claims before amendment (refer to the Written Amendment dated December 15, 2014) to the following Claims after amendment.

[Claims before Amendment]
"[Claim 1]

A pharmaceutical composition comprising a ferric citrate having a BET active surface area of at least 16.17 sq.m/g and a pharmaceutically acceptable carrier, which is used for the any one of the following uses:
decreasing serum phosphate level of the subject;
inhibiting calcium phosphate deposition;
decreasing calcium-phosphate product ([Ca] x [P]) of the subject;
decreasing serum calcium level of the subject,
and
reversing calcification of soft tissue of the subject.
[Claim 2]

A pharmaceutical composition comprising a ferric citrate having an intrinsic dissolution rate that exceeds 1.88 mg/cm^2/min and a pharmaceutically acceptable carrier, which is used for the any one of the following uses:
decreasing serum phosphate level of the subject;
inhibiting calcium phosphate deposition;
decreasing calcium-phosphate product ([Ca] x [P]) of the subject;
decreasing serum calcium level of the subject,
and
reversing calcification of soft tissue of the subject.

[Claim 3]

An orally administrable form of ferric citrate prepared from a pharmaceutical composition of claim 1 or 2, wherein the form is selected from a tablet, a powder, a suspension, an emulsion, a capsule, a lozenge, a granule, a troche, a pill, a liquid, a spirit, and a syrup.

[Claim 4]

The orally administrable form of ferric citrate of claim 3, wherein the form is a tablet.

[Claim 5]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 2 to 30 grams per day.

[Claim 6]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 4 to 15 grams per day.

[Claim 7]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 2 to 12 grams per day.

[Claim 8]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 2, 4, or 6 grams per day.

[Claim 9]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 500 mg per unit dosage form.

[Claim 10]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the subject has a terminal renal disease.

[Claim 11]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the subject has undergone dialysis.

[Claim 12]

The pharmaceutical composition or the orally administrable form of claim 11, wherein the dialysis is selected from blood dialysis and peritoneal dialysis."

[Claims after Amendment]
"[Claim 1]

A pharmaceutical composition comprising a ferric citrate having a BET active surface area of at least 16.17 sq.m/g and a pharmaceutically acceptable carrier, which is used for the any one of the following uses:
decreasing serum phosphate level of the subject;
inhibiting calcium phosphate deposition;
decreasing calcium-phosphate product ([Ca] x [P]) of the subject;
decreasing serum calcium level of the subject,
and
reversing calcification of soft tissue of the subject,
and wherein the effective amount of the ferric citrate is 2 to 30 grams per day.
[Claim 2]

A pharmaceutical composition comprising a ferric citrate having an intrinsic dissolution rate that exceeds 1.88 mg/cm^2/min and a pharmaceutically acceptable carrier, which is used for the any one of the following uses:
decreasing serum phosphate level of the subject;
inhibiting calcium phosphate deposition;
decreasing calcium-phosphate product ([Ca] x [P]) of the subject;
decreasing serum calcium level of the subject,
and
reversing calcification of soft tissue of the subject,
and wherein the effective amount of the ferric citrate is 2 to 30 grams per day.
[Claim 3]

The orally administrable form of ferric citrate prepared from a pharmaceutical composition of claim 1 or 2, wherein the form is selected from a tablet, a powder, a suspension, an emulsion, a capsule, a lozenge, a granule, a troche, a pill, a liquid, a spirit, and a syrup.
[Claim 4]

The orally administrable form of ferric citrate of claim 3, wherein the form is a tablet.
[Claim 5]

The pharmaceutical composition of claim 3 or 4 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 4 to 15 grams per day.
[Claim 6]

The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 2 to 12 grams

per day.
[Claim 7]
The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 2, 4, or 6 grams per day.
[Claim 8]
The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the effective amount of the ferric citrate is 500 mg per unit dosage form.
[Claim 9]
The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the subject has a terminal renal disease.
[Claim 10]
The pharmaceutical composition of claim 1 or 2 or the orally administrable form of claim 3 or 4, wherein the subject has undergone dialysis.
[Claim 11]
The pharmaceutical composition or the orally administrable form of claim 11, wherein the dialysis is selected from blood dialysis and peritoneal dialysis" (the underline is provided as the original text).

2. The acceptability of the Amendment
When the matters specifying the invention before and after the Amendment are compared, the following changes have been made by the Amendment:
a) With respect to the expression "ferric citrate" in claims 1 and 2, a restriction that "the effective amount is 2 to 30 grams per day" has been added (hereinafter referred to as "Amended Matter 1").
b) Claim 5 before amendment has been deleted, and in accordance to this change, the subsequent claim numbers after claim 6 before amendment have been adjusted (hereinafter referred to as "Amended Matter 2").

Here, the amendment has been made at the same time as the request for Appeal of Article 121(1) of the Patent Act, and the amendment corresponds to the amendment of Article 17-2(1)(iv) of the Patent Act. Such amendment shall be restricted to those made aiming for the matters defined in 17-2(4)(i) to (iv) of the Patent Act before revision, of which the provisions then in force shall remain applicable according to revision of supplement Article 3(1) of the Act No. 55 of 2006 (hereinafter referred to as "The Patent Act before revision of 2006"). The Amended Matter 2 contains a deletion of a claim, and an amendment made for formality required for the other claims in

accordance to the deletion, and then, the amendment corresponds to the deletion of the claims of the above-mentioned 17-2(4)(i).

Note that based on the above-mentioned amendment, an inconsistency arises in claim 11 after amendment, in that the same claim refers to claim 11. In the Written Statement dated September 14, 2015, the Appellant requests to make an amendment to correct such inconsistency; however, regardless of that, for the following reason, the decision of refusal is maintained, and thus, an opportunity for an amendment is not given.

The Amended Matter 1, in claims 1 and 2, restricts the effective amount of "ferric citrate" which is the matter specifying the invention. Here, the field of industrial application and the problems to be solved of the inventions recited in claims 1 and 2 before amendment and claims 1 and 2 after amendment are identical, and therefore, the amendment corresponds to those aiming for the restriction of the Claims of Article 17-2(4)(ii) of the Patent Act before revision of 2006.

Hereinbelow, whether the invention according to claim 2 after the amendment (hereinafter, referred to as "the amended invention") could have been independently patented at the time of filing the patent application (whether it falls under the provisions of Article 126(5) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(5) of the Patent Act before revision of 2006) is examined.

(1) The Amended Invention

The amended invention is as recited in claim 2 after amendment as follows:

" A pharmaceutical composition comprising a ferric citrate having an intrinsic dissolution rate that exceeds 1.88 mg/cm^2/min and a pharmaceutically acceptable carrier, which is used for the any one of the following uses:
decreasing serum phosphate level of the subject;
inhibiting calcium phosphate deposition;
decreasing calcium-phosphate product ([Ca] x [P]) of the subject;
decreasing serum calcium level of the subject,
and
reversing calcification of soft tissue of the subject,
and wherein the effective amount of the ferric citrate is 2 to 30 grams per day."

(2) Described matters of the Cited Documents

International Publication No. WO 2004/074444, which is a publication distributed before the priority date of this application referred in the decision of refusal (hereinafter, referred to as "Cited Document 1"), discloses the following technical

matters along with the Figures. Cited Document 1 is in English, the summarized portion is provided in the Japanese translation with reference to the publication of the National Publication of International Patent Application No. 2006-518391 which is a patent family of the document, and the underlines have been given by the body.

(1-i) "[Claim 37]

A form of ferric citrate having the formula $C_6H_5O_7Fe$ and having physical properties as determined by dissolution rates.

[Claim 38]

A form of ferric citrate according to claim 37 having an intrinsic dissolution rate range, as determined by USP intrinsic dissolution assay in water, between 1.9 and 4.0 $mg/cm^2/min$.

[Claim 39] - [Claim 44] ... Omitted ...

[Claim 45]

A use of the form of ferric citrate according to any one of claims 37 to 42 to treat a person suffering from a disorder responsive to ferric organic compound therapy.

[Claim 46]

A use according to claim 45 wherein the disorder is selected from the group consisting of hyperphosphatemia, and metabolic acidosis.

[Claim 47] - [Claim 48] ... Omitted ...

[Claim 49]

A method of treating a person suffering from a disorder responsive to ferric organic compound therapy comprising administering to the person a therapeutically effective amount of the form of ferric citrate according to any one of claims 37 to 42.

[Claim 50]

A method according to claim 49 wherein the disorder is selected from the group consisting of hyperphosphatemia, and metabolic acidosis.

[Claim 51] ... Omitted ...

[Claim 52]

A form of ferric citrate as claimed in claims 25 and 37 to 42, wherein the form of ferric citrate is in an orally administrable form selected from the group consisting of a tablet, a powder, a suspension, an emulsion, a capsule, a granule, a troche, a pill, a liquid, a spirit, and a syrup.

[Claim 53] ... Omitted ...

[Claim 54]

A pharmaceutical composition comprising the form of claim 24 or 25 or any one of claims 34 to 42 and a pharmaceutically acceptable carrier.

[Claim 55]

A pharmaceutical composition comprising an effective amount of the form of claim 24 or 25 or any one of claims 34 to 42 for treating disorders responsive to ferric organic compound therapy (page 31, line 13 to page 34, line 5, note that [] was added by the body).

(1-ii) "TECHNICAL FIELD

This invention relates to ferric organic compounds, methods of making the ferric organic compounds, and uses of the ferric organic compounds in the treatment of various disorders.

BACKGROUND OF THE INVENTION

Throughout this application, various publications are referenced. Disclosures of these publications in their entireties are hereby incorporated by reference into this application to more fully describe the state of the art to which this invention pertains.

1) Uses of Iron Compounds

Ferric iron containing compounds are useful in the treatment of a number of disorders, including, but not limited to, hyperphosphatemia and metabolic acidosis. Previous studies and inventions have reported the use of ferric compounds in binding with dietary phosphates, and such ferric compounds are potentially useful for the treatment of hyperphosphatemia in renal failure patients (U.S. Patent No. 5,753,706, 1998; CN 1315174, 2001; Yang W. C., et al., Nephrol. Dial. Transplant 17: 265: 270 (2002)). Elevated amounts of phosphate in the blood can be removed by administering compounds such as ferric citrate. Once in solution, the ferric iron binds phosphate, and the ferric phosphate compounds precipitate in the gastrointestinal tract, resulting in effective removal of dietary phosphate from the body. It is also believed that the absorbed citrate from ferric citrate is converted to bicarbonate, which corrects metabolic acidosis, a condition common in renal failure patients. U.S. Patent No. 5, 753,706 discloses the use of ferric containing compounds including ferric citrate and ferric acetate in the crystalline form, in an orally effective 1 gram dosage form, to bind to soluble dietary phosphate, causing precipitation of phosphate as ferric or ferrous phosphates in the gastrointestinal tract, thus preventing oral absorption of soluble phosphates from dietary sources. Since the binding of ferric ions to soluble phosphate in the gastrointestinal tract would require dissolution of the orally administered ferric citrate, and since the rate of dissolution of crystalline ferric citrate is slow (over 10 - 12 hours at 37^{o}C), oral administration of a substantially large dose of 1 g of ferric citrate is required. A related Chinese patent application (CN 1315174) also discloses a similar use of ferric citrate and related compounds in an oral solution dosage form for the treatment of hyperphosphatemia in renal failure patients (page 1, line 11 to page 2, line 27)".

(1-iii) "2. Solubility Profile of Novel Forms of Ferric Organic Compounds

The inventors have found that the novel forms of ferric organic compounds produced according to the methods described above are more soluble than commercially available ferric organic compounds, over a wider range of pH levels. This increase in solubility of the novel ferric organic compounds is believed to be a result of the unique significantly large active surface area of the novel forms of ferric organic compounds.

3. Use of Novel Forms of Ferric Organic Compounds in the Treatment of Disorders

The novel forms of ferric organic compounds are useful in the treatment of hyperphosphatemia, metabolic acidosis, and any other disorders responsive to ferric organic compound therapy. Because the novel forms of ferric organic compounds are more soluble than commercially available ferric organic compounds, smaller amounts of the ferric organic compounds can be used to effectively treat patients suffering from such disorders.

Improved aqueous solubility is particularly relevant to the use of the novel forms of ferric organic compounds in the treatment of disorders responsive to ferric organic compound therapy. Because the novel forms of ferric organic compounds are more soluble, they will be more effective when taken orally, and therefore can be taken in lower doses. The novel forms of ferric organic compounds are more soluble over a wider pH range than commercially available ferric organic compounds, and therefore the novel forms of ferric organic compounds can be more effective by being soluble in the small intestine. As a result, patients can take lower doses of medication with lower incidences of side effects.

In one embodiment of the invention, the novel form of ferric citrate has a significantly higher rate of aqueous solubility under physiological conditions than commercially available forms of ferric citrate, and therefore the novel form is believed to provide a significant improvement in the orally effective use of ferric citrate at a reduced dosage. By reducing the orally effective dose of ferric citrate, it is believed that the novel form of ferric citrate will provide a lower incidence of ulcerative gastrointestinal adverse effects associated with commercially available ferric citrate compounds. In addition, it is believed that the increased rate of dissolution of the novel form of ferric citrate will provide a more rapid onset of action in binding to dietary phosphate.

The novel forms of ferric organic compounds can be administered in a number of forms, including orally administrable forms, which can comprise the novel forms of ferric organic compounds alone or in combination with a pharmaceutically acceptable carrier. The orally administrable form can be selected from the group consisting of a tablet, a powder, a suspension, an emulsion, a capsule, a granule, a troche, a pill, a

liquid, a spirit, and a syrup. The composition can be administered to human beings or other animals suffering from illnesses responsive to ferric organic compound therapy (page 17, line 7 to page 19, line 2)".

(1-iv) "The intrinsic dissolution rates of commercially available ferric citrate were compared with that of the novel form of ferric citrate. The intrinsic dissolution rate is defined as the dissolution rate of pure substances under the condition of constant surface area. The dissolution rate and bioavailability of a drug substance are influenced by its solid state properties: crystallinity, amorphism, polymorphism, hydration, solvation, particle size, and particle surface area. The measured intrinsic dissolution rate is dependent on these solid-state properties and is typically determined by exposing a constant surface area of a material to an appropriate dissolution medium while maintaining constant temperature, stirring rate, and pH. The intrinsic dissolution rates are presented in Table 3.

表 3. pH8 の溶液中 37℃におけるクエン酸第二鉄の固有溶解速度

試料	アセトン添加速度 (mL／分)	固有溶解速度 (mg／cm²／分)	平均固有溶解速度 (mg／cm²／分)
RFS-12 (sigma／市販)	10.0	0.83	0.83
STM-134 (標準物質)	10.0	1.88	3.08
PAN031203A (試験バッチ 1)	10.0	3.82	
PAN031203B (試験バッチ 2)	10.0	4.00	
PAN031203C (試験バッチ 3)	9.5	2.68	
PAN031203D (試験バッチ 4)	40	2.95	
PAN031203E (試験バッチ 5)	4.4	3.13	

表３． ｐＨ８の溶液中の３７℃におけるクエン酸第二鉄の固有溶解速度
Table 3. Intrinsic dissolution rates of ferric citrate at 37ºC in solutions of pH 8

試料 Sample

アセトン添加速度（ｍＬ／分） Rate of Acetone Addition (ml/min)

固有溶解速度（ｍｇ／ｃｍ２／分） Intrinsic Dissolution Rate (mg/cm²/min)

平均固有溶解速度（ｍｇ／ｃｍ２／分） Mean Intrinsic Dissolution Rate (mg/cm²/min)

（ｓｉｇｍａ／市販） (sigma/commercially available)

（標準物質）　(reference material)
（試験バッチ１）　(experimental batch 1)
（試験バッチ２）　(experimental batch 2)
（試験バッチ３）　(experimental batch 3)
（試験バッチ４）　(experimental batch 4)
（試験バッチ５）　(experimental batch 5)

Figure 2 is a graph which compares the dissolution profile of the novel form of ferric citrate to the dissolution profiles of commercially available ferric citrate compounds.

The intrinsic dissolution rate of the novel form of ferric citrate produced by the method of the invention, on average, is approximately 3.8 times greater than that determined for a commercially available ferric citrate material. This increase in dissolution rate of the novel form of ferric citrate is believed to be a result of the significantly large active surface area of the novel form of ferric citrate compared to commercially available materials (page 22, line 13 to page 24, line 6)".

(3) Comparison with the Cited Invention, Judgment

In the above-mentioned summarized matter (1-i), the pharmaceutical composition of claim 55, it is understood that the effective amount effective for treating a disorder responsive to ferric organic compound therapy comprises "A form of ferric citrate between 1.9 to 4.0 mg/cm^2/min" which is specified in claim 38. Moreover, based on the descriptions of claims 46 and 49 which refer to claim 38, a disorder responsive to ferric organic compound therapy may be "hyperphosphatemia", and based on the description of claim 54 which refers to claim 38, it is understood that an embodiment comprising "a pharmaceutically acceptable carrier" may be adopted. These matters can be said to be reasonable based on the knowledge that ferric citrate is effective for the treatment of hyperphosphatemia as shown as prior arts in the summarized matter (1-ii) and based on the descriptions which can be found in the summarized matter (1-iii) stating that (ferric citrate) is more soluble than commercial ferric (organic compounds), and even with a small amount it could be effective for hyperphosphatemia patients and the description that it could be contained together with a carrier.

Note that although Cited Document 1 does not disclose pharmacological data related to a treatment of hyperphosphatemia, descriptions that correspond to pharmacological data can be found in U.S. Patent No. 5,753,706 (hereinafter, referred to as "Reference A"), CN 1315174(hereinafter, referred to as "Reference A"), and Yang

W.C. et al., Nephrol. Dial. Transplant 17:265:270 (2002) (hereinafter, referred to as "Reference C") which are referred to as prior art documents in Cited Document 1 and are recognized by the Applicant of this application, as they are referred to in paragraph [0004] of the Detailed Description of the Invention of the specification of this specification. Then, it is obvious that Cited Document 1 is related to a technique intending to improve the solubility of ferric citrate with the proviso that ferric citrate is effective in the treatment of hyperphosphatemia as mentioned above.

Accordingly, it can be recognized that Cited Document 1 discloses the following invention (hereinafter, referred to "Invention of Cited Document 1").

<The invention of Cited Document 1>

"A pharmaceutical composition for treating hyperphosphatemia comprising a form of ferric citrate having an intrinsic dissolution rate range between 1.9 and 4.0 mg/cm^2/min and a pharmaceutically acceptable carrier."

Now, the amended invention and the invention of Cited Document 1 are compared.

(a) Both the amended invention and the invention of Cited Document 1 achieve a form having a desired solubility by increasing the surface area of ferric citrate being used (refer to the summarized matter (1-iii)). With respect to the intrinsic dissolution rate, the description "an intrinsic dissolution rate range between 1.9 and 4.0 mg/cm^2/min" of the invention of Cited Document 1 coincides with the "intrinsic dissolution rate that exceeds 1.88 mg/cm^2/min" of the amended invention (Table 3 related to a specific intrinsic dissolution rate in Cited Document 1, (refer to the summarized matter (1-iv)) is identical to Table 1 (paragraph [0082]) showing the data of an intrinsic dissolution rate disclosed in the specification of this application). Then, although the beginning of the expression is different, "a form of ferric citrate having an intrinsic dissolution rate range between 1.9 to 4.0 mg/cm^2/min" of the invention of Cited Document 1 corresponds to "a ferric citrate having an intrinsic dissolution rate that exceeds 1.88 mg/cm^2/min" in the amended invention.

(b) The "pharmaceutically acceptable carrier" (*seiyakujyo kyoyousareru tanta*i) of the invention of Cited Invention 1 and the "pharmaceutically acceptable carrier" (*iyakujyo koutekina tantai*) of the amended invention merely differ in terms of expression.

Then, these two inventions coincide in the following point: "A pharmaceutical composition comprising a ferric citrate having an intrinsic dissolution rate range that exceeds 1.88 mg/cm^2/min and a pharmaceutically acceptable carrier" and apparently differ in the following Different Features 1 and 2.

Different Feature 1) With respect to the use of the pharmaceutical composition, the amended invention specifies the following:

"which is used for the any one of the following uses:
decreasing serum phosphate level of the subject;
inhibiting calcium phosphate deposition;
decreasing calcium-phosphate product ([Ca] x [P]) of the subject;
decreasing serum calcium level of the subject,
and
reversing calcification of soft tissue of the subject". On the other hand, the invention of Cited Document 1 defines the following: "for the treatment of hyperphosphatemia".

Different Feature 2)

With respect to the effective amount of the ferric citrate, whereas the amended invention specifies that it is of "2 to 30 grams per day", the invention of Cited Document 1 does not specify such a point.

Herein below, these different features are examined.

(Regarding the different feature 1)

The term "hyperphosphatemia" is recognized to refer to a disease with an indication of a high concentration of phosphoric acid (or phosphate) in blood (blood serum and blood plasma), and then, the treatment of it is nothing but reducing the phosphoric acid level in blood. This is as explained in the explanation of the prior arts in Cited Document 1 (refer to the summarized matter (1-ii)) such that ferric citrate is dissolved and the binding of ferric iron ion and phosphate causes precipitation of phosphate, and thereby, prevents the absorption of phosphate components from dietary sources to the body, and then it is obvious that it would be understood that the phosphoric acid level in the body; i.e., in the blood, would be maintained low. Furthermore, in the originally filed Claims of this application it is recognized that it was acknowledged that "hyperphosphatemia" (Claim 20) is a disorder characterized by a high serum phosphate level (Claim 19).

Then, the "decreasing serum phosphate level of the subject" and "the treatment of hyperphosphatemia" according to Different Feature 1 can be said to be a mere difference in expression, and thus, it cannot be considered to be a substantial different feature even without examining the other uses specified in the amended invention.

(Regarding the different feature 2)

Cited Document 1 does not refer to the dosage per day of the ferric citrate; however, deciding a suitable dosage of a medicine for treatment while verifying the exerted function and effect is mere exertion of ordinary creativity of a person ordinarilyskilled in the art. Moreover, in the prior arts referred in Cited Document 1, it has been shown that a 1 gram dosage form is used (refer to summarized matter (1-ii)), and then, it is obvious that a ferric citrate has been used at least with a dosage equal or higher than that. In fact, it is true that Cited Document 1 does not refer to what maximum quantity (for example, the number of tablets) of dosage form containing a ferric citrate has been used, and therefore, the dosage per day is not necessary clear. Here, References A to C listed as prior arts in Cited Document 1 (refer to summarized matters (1-ii)) have been taken into consideration. Reference A discloses the following: the amount of the ferric containing organic compound to be administered can be altered, if necessary, depending on the level of phosphate binding required in the patient's digestive tract, and a daily dosage of about 5 to about 10 g is effective (3rd column, lines 20 to 24) and it is estimated that a dialysis patient needs 4 to 5 g of ferric citrate, ferric acetate, or a combination thereof, per day, in order to achieve a normal phosphate metabolism (9th column, lines 53 to 56). Reference B discloses that, in view of the phosphoric acid concentration in the digestive tract of the patient, the daily dose of an iron compound of 5 to 10 g is effective (page 3, lines 21 to 23) and that it is necessary to administer a combination of ferric citrate, ferrous acetate, or a combination of them to a dialysis patient with an amount of 4 to 5 g daily (page 13, lines 30 to 32). Furthermore, Reference C indicates Examples using 1 g of ferric citrate per day for 3 times; i.e., 3 g (page 269, bottom left column, line 10 from the bottom to line 7 from the bottom). Then, it has to be said that a dosage of the same degree as in the amended invention has been conventionally conceived.

Then, the dosage "2 to 30 grams per day" specified in the amended invention cannot be recognized to be remarkable, and it is nothing but what could be easily adopted by a person ordinarilyskilled in the art. Moreover, the Applicant/Appellant emphasizes that the effect of the amended invention is that as the (compound) has a high solubility, only a small amount is required to be used; however, Cited Document 1 also clearly indicates a similar function and effect (refer to 3. of the summarized matter (1-iii)), and then, it cannot be said that the effect exerted by the amended invention is remarkable such that is unpredictable to a person ordinarily skilled in the art based on the descriptions of Cited Document 1.

Therefore, the amended invention could have easily been accomplished by a person ordinarily skilled in the art based on the invention disclosed in Cited Document

1, and it cannot be independently granted a patent at the time of filing a patent in accordance with the provisions of Article 29(2) of the Patent Act.

(4) Conclusion of the Amendment

Then, as the amendment fails to meet the provisions of Article 126(5) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(5) of the Patent Act before revision by the Act No. 55 of 2006, whose provisions then in force shall remain applicable according to revision supplement Article 3(1) of the Act No. 55 of 2006, it should be dismissed by the provisions of Article 53(1) of the Patent Act applied mutatis mutandis pursuant to Article 159(1) of the Patent Act.

Therefore, the decision is made in accordance to Conclusion of Decision to Dismiss Amendment.

No. 3. Regarding the Invention

1. The Invention

The amendment dated on September 7, 2015 has been dismissed as above, and therefore the inventions according to claims 1 to 12 of this application are specified by the matters disclosed in claims 1 to 12 of the Claims of the Written Amendment dated December 15, 2014. Then, the invention according to claim 2 (hereinafter, referred to as "the Invention") is as follows:

"[Claim 2]

A pharmaceutical composition comprising a ferric citrate having an intrinsic dissolution rate that exceeds 1.88 mg/cm^2/min and a pharmaceutically acceptable carrier, which is used for the any one of the following uses:

decreasing serum phosphate level of the subject;

inhibiting calcium phosphate deposition;

decreasing calcium-phosphate product ([Ca] x [P]) of the subject;

decreasing serum calcium level of the subject,

and

reversing calcification of soft tissue of the subject."

2. Cited Documents

The Cited Documents referred in the reasons of Decision of Refusal and the described matters are as described in the above-mentioned [Reason] 2.(2) of 2.

3. Comparison and Judgment

The invention is as follows: the matter specifying the invention (only the underlined portion) such as "the effective amount is 2 to 30 grams per day" which is the

restricting matter of "ferric citrate" has been deleted from the amended invention which was examined in the above-mentioned [Reason] 2. of No. 2.

Then, the amended invention corresponding to those comprising all of the matters specifying the invention of the amended invention with other matters specifying the invention being added, as described in the above-mentioned [Reason]2.(3) of No. 2, could have easily been accomplished by a person ordinarily skilled in the art based on the invention disclosed in Cited Document 1. Then, for the same reason, based on the invention disclosed in Cited Document 1, a person ordinarily skilled in the art could have easily accomplished the invention.

4. Closing

As mentioned above, the invention according to claim 2 of this application should not be granted a patent for the invention in accordance with the provisions of Article 29(2) of the Patent Act. Accordingly, this application shall be rejected without examining other claims.

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

August 24, 2016

Chief administrative judge: HATTORI, Satoshi
Administrative judge: MATSUZAWA, Yuko
Administrative judge: FUCHINO, Ruka