

Appeal decision

Appeal No. 2015-3177

USA

Appellant THE UNITED STATES OF AMERICA AS REPRESENTED BY THE
SECRETARY FOR THE DEPARTMENT OF HEALTH & HUMAN SERVICES

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The following appeal decision has been made with respect to the case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2012-512066 "AKT phosphorylation at SER473 as an indicator for taxane-based chemotherapy" (International Publication Date: November 25, 2010, WO2010/135671, November 8, 2012, National Publication, National Publication of International Patent Application No. 2012-527631).

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

This application is a PCT patent application in foreign language filed with an

international filing date of May 21, 2010 (priority claim under the Paris Convention: May 22, 2009, USA). On February 14, 2014, a Reason for Rejection was notified with 3 months of allowance for responding from the dispatch date (February 25, 2014) as a reasonable period for the submission of the Written Opinion. The Applicant (Appellant of the present appeal case) requested an extension of term within the designated period; however, no response was made by the Applicant during the designated period which had been extended upon the request, and thus, the Decision for Refusal was made on October 16, 2014 after the expiration of the designated period. In response to this, on February 19, 2015 the Applicant (Appellant) filed an appeal against the examiner's decision of refusal, and filed a Written Amendment at the same time.

No. 2 The examiner's decision to dismiss amendment with respect to the Written Amendment dated February 19, 2015.

[Conclusion of Decision to Dismiss Amendment]

The Written Amendment dated February 19, 2015 (hereinafter referred to as "The Amendment") has been dismissed.

[Reason]

The Amendment amends the entire Claims, and claims 1 to 34 before this Amendment (which are provided in the translation of the claims attached to the Written submission of translation submitted on January 20, 2012 and which are considered the Claims submitted along with the application under the provision of the Patent Act Article 36(2) defined in Article 184(6)(ii), hereinafter the same) are amended to claims 1 to 18 after amendment.

1 Regarding the matters of the amendment according to claims 10 to 14

(1) The description of claim 10 after the amendment is as follows:

"Claim 10

A pharmaceutical composition comprising a taxane compound for treating a tumor in a subject having breast cancer, which is administered to the subject after the subject is predicted to be sensitive to the treatment of a taxane compound by a prediction method comprising:

(a) performing at least one immunohistochemical assay of a sample for obtaining physical data in relation to the expression state of a phosphorylated Akt-Ser473 (pAkt) protein in the sample of the tumor; and

(b) when the expression state of the pAkt protein in the physical data sample is indicated to be positive, the tumor is predicted to be sensitive to the treatment of a taxane compound". (The underline indicates the amended parts based on the description

of claim 11 before the amendment asserted by the Appellant).

(2) The invention according to claim 10 after the amendment, as being obvious from the beginning of the description, is recognized to be an invention according to "a pharmaceutical composition". The Claims before the amendment only define inventions according to "A method of determining whether a subject having cancer is likely to benefit from a treatment regimen that includes treatment with a taxane compound" in claims 1 to 10, inventions according to "A method of treating a cancer in a subject" in claims 11 to 16, inventions according to "A kit for determining whether a patient is likely to benefit from treatment with a taxane compound" in claims 17 to 27, and inventions according to "a method of treating cancer in a patient" in claims 28 to 34. Here, no claims defining an invention according to "a pharmaceutical compound" are found.

(3) Here, for the invention according to claim 10 defined as the invention according to "a pharmaceutical composition" after the amendment to correspond to those which aim for the restriction of the scope of claims defined in the Patent Act Article 17-2(5)(ii) (hereinafter referred to as "restriction by limitation"), it is required that the invention recited in any of the claims before the amendment be restricted by limitation.

Nonetheless, as mentioned above in (2), the Claims before the amendment do not define an invention according to "a pharmaceutical composition" corresponding to an invention according to claim 10 after the amendment, and thus, it is obvious that the description of claim 10 after the amendment cannot be said to aim for restricting and limiting the invention defined in any of the claims before the amendment.

Furthermore, in view of the fact that the invention corresponding to the invention according to claim 10 after the amendment is not substantially defined in the claims before amendment, it can be assessed that the invention according to claim 10 has been newly added by the amendment.

Then, it is obvious that the amendment for such claim 10 does not correspond to those aiming for the matters provided in each item of the Patent Act Article 17-2(5).

(4) Moreover, for the same reason, it is obvious that the amendment for claims 11 to 14 after the amendment which directly or indirectly refer to claim 10 after the amendment does not correspond to those aiming for the matters provided in each item of the Patent Act Article 17-2(5).

(5) In the Written demand for trial, the Appellant asserts the following: "(6) In previous claim 11, the subject matter of the invention is modified to 'a pharmaceutical composition' based on 'a preparation' of paragraph [0020], for example, of the specification of this application, and the same amendment which was made to previous claim 1 has been made. In the same way, the subject matters of previous claims 12 to 16 have been modified", and asserts that claims 10 to 14 after the amendment amend the

descriptions of claims 11 to 16 before the amendment.

However, claim 11 before the amendment, as examined above, is an invention of a method according to "A method of treating a cancer in a subject" given as follows:

"A method of treating a cancer in a subject, comprising:

- (a) determining whether said cancer is pAkt positive;
- (b) upon a determination that said cancer is pAkt positive, indicating that the subject is likely to benefit from treatment with a taxane compound".

Such an invention of a method and an invention of a product as in "a pharmaceutical composition" according to claim 10 after the amendment belong to a different category of invention, and it cannot be said that the field of industrial applicability and the problem to be solved are identical between those inventions belonging to different categories before the amendment and after the amendment.

Then, as the Appellant asserts, although the matter of the amendment according to claim 10 is formally an amendment based on claim 11, the purpose of the amendment cannot be said to correspond to those aiming for restricting and limiting the Claims, and thus, the assertion made by the Appellant has no grounds.

2 Regarding the matters of the amendment according to claims 15 to 18

The description of claim 15 after the amendment is as follows:

"Claim 15

A pharmaceutical composition comprising an anthracycline, a cyclophosphamide, and a taxane compound for treating a tumor in a patient having breast cancer, which is administered to the patient after the patient is predicted to be sensitive to the treatment of an anthracycline, a cyclophosphamide, and a taxane compound by a prediction method comprising:
(a) performing at least one immunohistochemical assay of a sample for obtaining physical data in relation to the expression state of a phosphorylated Akt-Ser473 (pAkt) protein in the sample of the tumor; and
(b) when the expression state of the pAkt protein in the physical data sample is indicated to be positive, the tumor is predicted to be used in chemotherapy with an anthracycline and cyclophosphamide and to be sensitive to the subsequent treatment of a taxane compound". (The underline indicates the amended parts based on the description of claim 28 before the amendment asserted by the Appellant).

The inventions according to claims 15 to 18 after the amendment, as in the invention according to claim 10 after the above-mentioned amendment, are inventions according to "a pharmaceutical composition". For the same reason as already examined in the above-mentioned "1 Regarding the matters of the amendment according to claims

10 to 14", the matters of the amendment according to claims 15 to 18 after the amendment do not correspond to those aiming for any of the matters provided in each item of the Patent Act Article 17-2(5).

Furthermore, the Appellant asserts that claims 15 to 18 after the amendment amend claims 28 to 32 before the amendment; however, as the inventions of a method according to claims 28 to 32 and the inventions of a product such as "a pharmaceutical composition" according to claims 15 to 18 after the amendment belong to a different category of invention, it cannot be said that the field of the industrial applicability and the problem to be solved are identical between those inventions belonging to different categories before the amendment and after the amendment. Moreover, although the matters of the amendment according to claims 15 to 18 are formally an amendment based on claims 28 to 32, the purpose of the amendment cannot be said to correspond to those aiming for restricting and limiting the Claims.

3 Conclusion of the Decision to dismiss the amendment

As stated above, the amendment fails to comply with the provision under Patent Act Article 17-2(5), and thus, the amendment shall be dismissed by the provision under the same Act Article 53(1), which is applied mutatis mutandis pursuant to the same Act Article 159(1).

Accordingly, in conclusion, the above-mentioned decision to dismiss the amendment has been made.

No. 3 Regarding the invention

1 The Invention

As mentioned above, the Written Amendment dated February 19, 2015 has been dismissed, and then, the inventions according to claims 1 to 34 of this application (hereinafter, referred to as "Inventions 1 to 34 of this application" and the like) are those provided in the translation of the Claims attached to the Written submission of translation submitted on January 20, 2012 and they are those as specified by the matters provided in claims 1 to 34 which are considered the Claims attached to the application for submission under the provision of the Patent Act Article 36(2) defined in Article 184(6)(ii).

2 Regarding the inventions 28 to 34 of this application

(1) Invention 28 of this application is provided as follows (the body has added the underline):

"Claim 28

A method of treating cancer in a patient that comprises the use of chemotherapy

with an anthracycline and cyclophosphamide followed by treatment with a taxane compound, comprising the step of obtaining a determination of whether said cancer is pAkt positive".

(2) Invention 28 of this application, as its matter specifying the invention, defines "the use of chemotherapy with an anthracycline and cyclophosphamide"; i.e., "the use of chemotherapy with a specific drug", followed by "a method of treating cancer in a patient" comprising a successive procedure such as the "treatment with a taxane compound". Then, Invention 28 of this application is nothing but a method comprising a procedure for treating a cancer in a patient who is a human, and thus, it corresponds to "methods of surgery, therapy or diagnosis of humans".

Then, Invention 28 of this application does not correspond to an industrially applicable invention.

Moreover, in the same way, inventions 29 to 34 of this application which directly or indirectly depend from Invention 28 of this application do not correspond to an industrially applicable invention.

3 Regarding Inventions 11 to 16 of this application

(1) Invention 11 of this application is provided as follows:

"Claim 11

A method of treating a cancer in a subject, comprising:

- (a) determining whether said cancer is pAkt positive;
- (b) upon a determination that said cancer is pAkt positive, indicating that the subject is likely to benefit from the treatment with a taxane compound".

(2) The "subject" in Invention 11 of this application does not exclude humans, and as the invention encompasses a method of treating cancer in a human, it is nothing but those corresponding to "methods of surgery, therapy or diagnosis of humans".

Then, Invention 11 of this application also does not correspond to an industrially applicable invention.

Moreover, in the same way, Inventions 12 to 16 of this application which directly or indirectly refer to Invention 11 of this application do not correspond to an industrially applicable invention.

4 Closing

As mentioned, none of Inventions 11 to 16 and 28 to 34 of this application corresponds to an industrially applicable invention, and as they do not fulfill the requirement provided in the Patent Act Article 29(1) main paragraph.

Accordingly, without referring to the other claims, this application should be rejected.

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

March 7, 2016

Chief administrative judge: KORIYAMA, Jun
Administrative judge: OZAKI, Atsushi
Administrative judge: MATSUMOTO, Takahiko