Appeal decision

Appeal No. 2017-2278

Switzerland
Appellant NOVIMMUNE SA

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The case of appeal against the examiner's decision of refusal for Japanese Patent Application No. 2013-548613 "ANTI-TLR4 ANTIBODIES AND METHODS OF USE THEREOF" [International Publication: July 19, 2012 as WO2012/096917, National Publication: February 27, 2014 as National Publication of International Patent Application No. 2014-505056, The number of claims: 10] has resulted in the following decision.

Conclusion

The examiner's decision is revoked.

The invention of the present application shall be granted a patent.

Reason

No. 1 History of the procedures

The application is an application with an international filing date of January 10, 2012 (claiming priority under the Paris Convention with a priority date of January 10, 2011 in the United States (US)), for which a notice of reason for refusal was issued on October 30, 2015, a written opinion and a written amendment were submitted on May 6, 2016, and the Examiner's decision of refusal (original decision) was issued on October 13, 2016. In response, a notice of appeal was filed on February 17, 2017 with a written amendment on the same date.

No. 2 Summary of the original decision for refusal

The outline of the original decision of refusal (decision of refusal on October 13, 2016) is set forth as below:

The inventions according to Claims 1 to 10 and 14 of the present application were easily conceivable on the basis of the invention described in Cited Documents 1 and 2 and the inventions according to Claims 11 to 13 and 15 were easily conceivable on the basis of the invention described in Cited Documents 1 to 3 by a person who had ordinary knowledge in the art to which the inventions belong (hereinafter referred to as "a person skilled in the art"). Thus the appellant should not be granted a patent for the inventions under the provision of Article 29(2) of the Patent Act.

List of Cited Documents, etc.

1. FASEB Journal, 2007, Vol. 21, pp. 2840-2848
2. National Publication of International Patent Application No. 2009-509540
3. National Publication of International Patent Application No. 2010-526868

No. 3 Amendment as of the demand for appeal

It cannot be said that the amendment as of the demand for appeal conforms to the requirement of 17-2(3) to (6) of the Patent Act.

Regarding an amendment as of a demand for appeal, it is considered as to whether the amendment of incorporating the matter of

"a drug wherein the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (i), the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (iii), or the antibody or immunologically active fragment thereof that specifically binds to TLR4 in steps (i) and (iii) comprises a heavy chain amino acid sequence ... (SEQ ID NO:9) and a light chain amino acid sequence (SEQ ID NO:10)." into "an antibody or immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide" in Claim 1 is aiming at the restriction of the scope of claims in a limited way (hereinafter referred to as "restriction in a limited way") as specified in Article 17-2(5)(ii) of the Patent Act.

It is recognized that the above amendment restricts "an antibody or

immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide" of Claim 1 to include one where a specific heavy chain amino acid sequence and a light chain amino acid sequence recited in Claim 13 before the amendment, and an industrially applicable field of the invention and a problem to be solved by the invention are not changed before and after the amendment. Thus the amendment corresponds to a restriction of the scope of the claims in a limited way.

Further, the amendment is supported by the matters described in the translation of the specification or the drawings (limited to the explanation in the drawings) of the International Patent Application as of the international filing date, the translation of the scope of claims of the International Patent Application as of the international filing date, or the drawings of the International Patent Application as of the international filing date (excluding the explanation in the drawings.) (paragraphs [0006] and [0009], paragraph [0020] etc.). Thus the amendment does not incorporate new matter.

Further, as shown in "No. 4 The Invention" to "No. 6 Comparison / judgment," the above inventions according to Claims 1 to 10 after the Amendment are independently patentable.

No. 4 The Invention

The inventions according to Claims 1 to 10 of the present application (hereinafter referred to as "the present invention 1" to "the present invention 10," respectively) should be specified by the matters recited in Claims 1 to 10 of the scope of the claims that have been amended by the written amendment on February 17, 2017 in the following:

"[Claim 1]

A drug for inhibiting rejection of or prolonging survival of transplanted biological material in a subject, comprising an antibody or immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide, wherein the biological material to be transplanted is islet cells,
wherein said drug is used for a method comprising the steps of:
(i) contacting said antibody or immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide with said islet cells to be transplanted to produce a transplantable composition;
(ii) implanting the transplantable composition at a desired location in the subject; and
(iii) administering to the subject one or more additional doses of an antibody or immunologically active fragment thereof that specifically binds to TLR4, wherein the antibody is administered in an amount sufficient to prevent transplant rejection or prolong survival of the transplanted islet cells in the subject,
wherein the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (i), the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (iii), or the antibody or immunologically active fragment thereof that specifically binds to TLR4 in steps (i) and (iii) comprises a heavy chain amino acid sequence

MGWSWIFLFLLSGTAGVHCQVQLQESGPGLVKPSDTLSLTCAVSGYSITGGYSWHWI
RQPPGKGLEWMGYIHYSGYTDFNPSLKTRITISRDTSKNQFSLKLSSVTAVDTAVYY
CARKDPSDAFPYWGQGTLVTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYFP
EPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKPSNT
KVDKRVEPKSCDKTHTCPPCPAPELLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVS
HEDPEVKFNWYVDGVEVHNAKTKPREEQYNSTYRVVSVLTVLHQDWLNGKEYKC
KVSSKAFPAPIEKTISKAKGQPREPQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVE
WESNGQPENNYKTTPPVLDSDGSFFLYSKLTVDKSRWQQGNVFSCSVMHEALHNH
YTQKSLSLSPGK (SEQ ID NO: 9)

and a light chain amino acid sequence

MEWSWVFLFFLSVTTGVHSEIVLTQSPDFQSVTPKEKVTITCRASQSISDHLHWYQQ
KPDQSPKLLIKYASHAISGVPSRFSGSGSGTDFTLTINSLEAEDAATYYCQQGHSFPLT
FGGGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNAL
QSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQGLSSPVTKSFNR
GEC (SEQ ID NO: 10)

.

[Claim 2]

The drug of Claim 1, wherein the subject is human.

[Claim 3]

The drug of Claim 1 or 2, wherein said islet cell to be transplanted is an allogeneic islet cell.

[Claim 4]

The drug of Claim 1, wherein the antibody or immunologically active fragment thereof that specifically binds to TLR4 in steps (i) and (iii) is the same antibody or immunologically active fragment.

[Claim 5]

The drug of Claim 1, wherein the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (i) and the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (iii) are different antibodies or immunologically active fragments.

[Claim 6]

The drug of Claim 1, wherein the antibody or immunologically active fragment thereof that specifically binds to TLR4 is administered in step (iii) in combination with one or more additional agents.

[Claim 7]

The drug of Claim 6, wherein the one or more additional agents is one or more immunosuppressive agents.

[Claim 8]

The drug of Claim 6, wherein the one or more additional agents is selected from methotrexate, cyclosporin A, tacrolimus, sirolimus, everolimus, a corticosteroid, anti-thymocyte globulin, Infliximab, Etanercept, and Adalimumab.

[Claim 9]

The drug of Claim 1, where the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (i), the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (iii), or the antibody or immunologically active fragment thereof that specifically binds to TLR4 in steps (i) and (iii) is a monoclonal antibody.

[Claim 10]

The drug of Claim 1, where the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (i), the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (iii), or the antibody or immunologically active fragment thereof that specifically binds to TLR4 in steps (i) and (iii) is mouse, chimeric, humanized, fully human monoclonal antibody, domain antibody, single chain, Fab, Fab', or F(ab')2 fragments, scFvs, or an Fab expression library."

No. 5 Cited Document, Cited Invention, and the like

1. Regarding Cited Document 1

Cited Document 1 cited in the reasons for refusal stated in the examiner's decision discloses the following matters.

(1) Described matter 1-1

"Blocking TLR4 with an anti-TLR4 antibody prolongs C57BL/6 islet allograft survival in BABL/c recipients

We tested whether blocking TLR4 in isolated islets in vitro with an anti-TLR4 antibody would prevent islet allograft from immune rejection after transplantation. Freshly isolated islets precultured with the anti-TLR4 antibody (25 μg/ml) or normal rat IgG2a control were transplanted into diabetic recipients. As shown in FIG. 5, islets cultured with control rat IgG2a were rejected in 18.0+-3.1 days (n=5). Preincubation of islets with the anti-TLR4 antibody significantly prolonged islet allograft survival for up to 30.6 + - 12.6 days (n=5, P<0.05 v.s. control)."

(page 2844, right column, lines 1 to 13. The description of the above underlined portion is respectively "C57BL6/recipients" and "BABL/c islet," but it is obviously a typo of "C57BL/6 islet" of "BALB/c recipient" in view of the whole disclosure of Cited Document 1 including the following described matter 1-2. Thus it is translated as in the above underlined portion.)

(2) Described matter 1-2

"

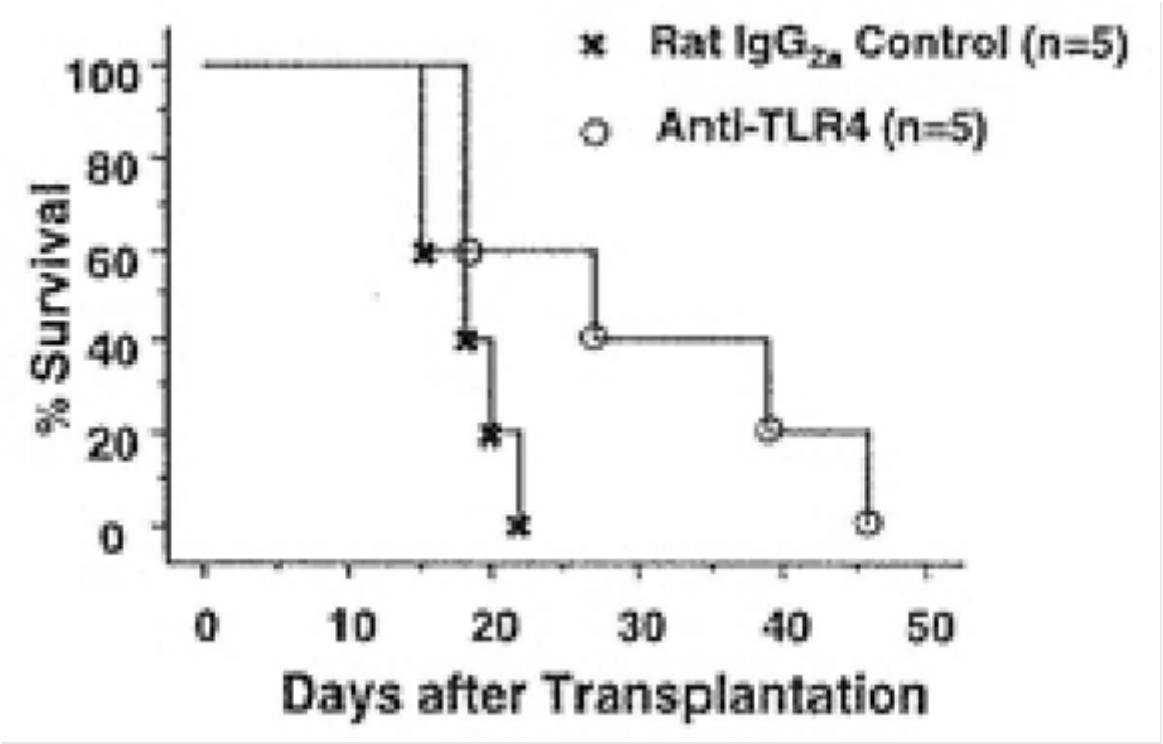


FIG. 5 Survival of C57BL/6 islets incubated with the anti-TLR4 antibody in BALB/c recipients. C57BL/6 islets precultured with the anti-TLR4 antibody or control IgG were transplanted into BALB/c recipients. Grafts precultured with anti-TLR4 antibody (○, n=5) survived significantly longer in BALB/c recipirnts than islets precultured with nomal rat IgG2a (×, n=5, P<0.05 v.s. control)."
(page 2844, right column, FIG. 5)

(3) Described matter 1-3
"Use of the anti-TLR4 antibody was far less effective, but islets treated with the antibody showed showed significantly prolonged, although not long-term survival."
(page 2846, right column, lines 9 to 12)

(4) The invention described in Cited Document 1 (hereinafter referred to as "Cited Invention 1")

It is recognized that Cited Document 1 describes the following inventions.

"Anti-TLR4 antibody subjected to preculture with isolated islets graft, which are then transplanted into a recipient."

2. Regarding Cited Document 2

Cited Document 2 cited in the reasons for refusal stated in the examiner's decision discloses the following matters:

(1) Described matter 2-1
"[Claim 1]

A method for increasing the efficiency of lymphoid cell engraftment after

transplantation comprising inhibiting one or more toll-like receptor (TLR) pathways of hematopoietic stem cells through contact with a TLR pathway antagonist.

[Claim 2]

The method of Claim 1, wherein said cells are obtained from a patient, treated ex vivo with said antagonist, and returned to said patient.

[Claim 3]

The method of Claim 1, wherein said cell is obtained from an allogeneic donor, treated ex vivo with said antagonist, and transplanted to said patient.

...

[Claim 18]

The method of Claim 1, wherein a transplantation patient is treated in vivo with said TLR pathway antagonist at the time of transplantation."

([Claim 1] to [Claim 18] of [Scope of Claims])

(2) Described matter 2-2

"In still yet another embodiment, there is provided a method for increasing the efficiency of lymphoid cell engraftment after transplantation into a patient comprising inhibiting one or more toll-like receptor (TLR) pathways of hematopoietic stem cells through contact with a TLR pathway antagonist. The cells may be obtained from said patient, treated ex vivo with said antagonist, and returned to said patient. The cell may be obtained from an allogeneic donor, treated ex vivo with said antagonist, and transplanted to said patient. The TLR pathway may be inhibited with a TLR2 or TLR4 antagonist. The antagonist may be a soluble TLR, an anti-TLR antibody, or a soluble TLR dimerization mimic. The antagonist may be an siRNA, ribozyme, morpholino oligo, or an scFv or scAb. The TLR pathway may be inhibited through inhibition of MyD88 expression or through inhibition of MyD88 function, such as by use of a MAL/TIRAP antagonist. The antagonist may act on an MyD88-independent pathway, such as an antagonist that acts on TRAM or TRIF. The patient may be immunocompromised or immunodeficient, may be being treated with chemotherapy, and/or may be undergone an organ transplant. The patient may be being or have been administered an immunosuppressant. The patient may suffer from an autoimmune disorder, or from another disorder or disease with an autoimmune component. The patient may be a human. The transplantation patient may be treated in vivo with said TLR pathway antagonist at the time of transplantation."

(Paragraph [0015])

(3) Described matter 2-3

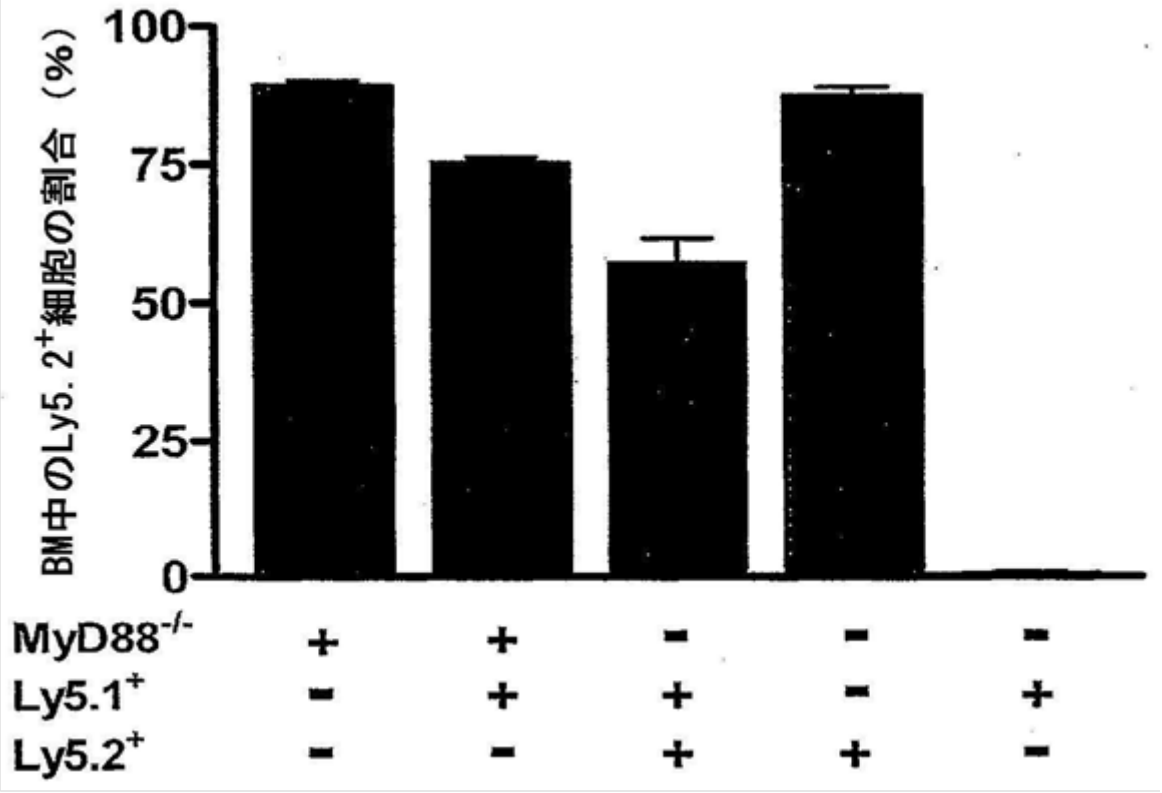
"Example 4-Stem Cell Engraftment

Bone marrow transplantation experiments were conducted to learn how hematopoietic progenitor cells of MyD88-/- mice function relative to those of normal mice. Bone marrow from MyD88-/- mice was transplanted along with bone marrow from MyD88+/+ mice (2×10^6 cells total) in a 1:1 ratio into C57BL/6 (Ly5.1) mice that had been given a lethal dose of irradiation (650Rx2). The degree of chimerism was determined by flow cytometry. Three months after the transplantation, most of the blood-producing cells in the recipient bone marrow derived from the MyD88-/- cells (FIG. 16). Specifically, thymocytes and peripheral blood granulocytes were preferentially produced by MyD88-/- cells. The percentage of MyD88-/- lymphocytes

in the spleen was closer to a 1:1 ratio, possibly because lymphocytes have long half lives, and their survival could partially depend on effective TLR signaling."
(paragraph [0207])

(4) Described matter 2-4
"FIG. 16 - MyD88-/- stem cells engraft better than those from normal mice. C57BL/6 (Ly5.1) mice were given a lethal dose of irradiation (650R x 2) and then transplanted with a total of 2 x 10^6 bone marrow cells. Two of the five groups of experimental animals received a 50:50 mixture as indicated. The degree of chimerism in the marrow recipients was determined by flow cytometry 3 months following transplantation."
(Explanation part of [FIG. 16] of paragraph [0214])

(5) Described matter 2-5
"[FIG. 16]



ＢＭ中のＬｙ５．２$^+$細胞の割合（%）　　% Ly5.2$^+$ cells in BM
"
(FIG. 16)

3. Regarding Cited Document 3
Cited Document 3 describes an anti-TLR4 antibody and a method for producing the same.

No. 6 Comparison / judgment

1. Regarding the invention 1

(1) Comparison with Cited invention 1

"Anti-TLR4 antibody," "recipient," and "islets graft" of Cited Invention 1 respectively correspond to "an antibody specifically binding to Toll-like receptor 4 (TLR4) polypeptide," "subject," and "islet cell" of Invention 1. Further, the method for using anti-TLR4 antibody "which are then transplanted into a recipient" of Cited Invention 1 corresponds to "implanting the transplantable composition at a desired location in the subject;" of Invention 1.

Further, the method for using anti-TLR4 antibody, the method comprising the step of "subjecting to preculture with isolated islets graft" of Cited Invention 1 corresponds to "contacting said antibody or immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide with said islet cells to be transplanted to produce a transplantable composition;" of Invention 1. Further, it can be said that the step is aiming at "producing a transplantable composition," since the step precedes the transplantation.

Furthermore, according to the described matters 1-1 and 1-2 of Cited Document 1, it is obvious that the contact of an anti-TLR4 antibody with islets graft allows the survival of the islets graft transplanted into a recipient to extend as compared to a control.

Therefore, it can be said that there are the following common points and different features between Invention 1 and Cited Invention 1.

(Corresponding features)

"A drug for prolonging survival of transplanted biological material in a subject, comprising an antibody specifically binding to a Toll-like receptor 4 (TLR4) polypeptide (hereinafter also referred to as "Anti-TLR4 antibody") wherein the biological material to be transplanted is islet cells, and the drug is used for a method comprising the steps of:

(i) contacting said anti-TLR4 antibody with said islet cells to be transplanted to produce a transplantable composition; and

(ii) implanting the transplantable composition at a desired location in the subject."

(Different feature 1)

The drug of Invention 1 is used for a method including the steps of: "(iii) administering to the subject one or more additional doses of an antibody or immunologically active fragment thereof that specifically binds to TLR4, wherein the antibody is administered in an amount sufficient to prevent transplant rejection or prolong survival of the transplanted islet cells in the subject" in addition to the above paragraphs (i) and (ii), whereas Cited Invention 1 does not specify such provision.

(Different feature 2)

The antibody used for the above steps (i) and/or (iii) of the present Invention 1 binding to TLR4 is specified as specifically binding to human TLR4 and comprising a specific heavy chain amino acid sequence and light chain amino acid sequence, whereas Cited Invention 1 fails to specify them.

(2) Judgment about the different features with Cited Invention 1

When it comes to the above different feature 1, Cited Document 1 only discloses that anti-TLR4 antibody is used for the preculture of islets graft. It neither discloses nor teaches administering an additional dose of further anti-TLR4 antibody in an amount sufficient to prevent rejection of islets graft or prolong survival of the transplanted islet cells for a transplanted subject after the transplantation of graft in the subject.

In this regard, Cited Document 2 discloses not only contacting hematopoietic stem cells with a TLR4 pathway antagonist of anti-TLR4 antibody prior to transplantation for increasing the efficiency of engraftment after transplantation in transplanting hematopoietic stem cells into a subject, but also treating the subject with anti-TLR4 antibody during transplantation (Described matters 2-1 and 2-2), however, the transplanted cell raised in Cited Document is exclusively a hematopoietic stem cell. Cited Document 2 is silent about islet cells. In addition, the experimental results of transplantation specifically described in Cited Document 2 only mention that MyD88-/- stem cells, specifically hematopoietic stem cells derived from knockout mice in which TLR4 pathways are shut down, showed excellent efficiency of engraftment after transplantation as compared to hematopoietic stem cells derived from normal mice (Described matters 2-3 to 2-5). There are no specific experimental results to show that the treatment of a subject after transplantation with anti-TLR4 antibody allows for the improved efficiency of engraftment of hematopoietic stem cells after transplantation. Thus it cannot be confirmed that such treatment improves the efficiency of engraftment of hematopoietic stem cells. Consequently, it cannot be recognized that a person skilled in the art could have easily conceived of further administering anti-TLR4 antibody against a transplanted subject on the basis of the description of Cited Document 2 in Cited Invention 1 directed to the transplantation of an islet cell, which is not a hematopoietic stem cell.

Further, Cited Document 3 does not disclose that the administration of anti-TLR4 antibody after transplantation can extend survival of a graft, nor can it be recognized as a common technical knowledge as of the filing. Thus it cannot be recognized that a person skilled in the art could conceive of administering an additional dose of anti-TLR4 antibody in an amount sufficient to prevent transplant rejection or prolong survival of the transplanted islet cells in the subject in Cited Invention 1.

Further, when it comes to the effects of Invention 1, the present application discloses in FIGS. 5 and 6 that the administration of anti-TLR4 antibody to a subject twice a week for 28 days after transplantation may extend the survival of islet cells at least for 60 days, whereas Cited Document 1 discloses that the survival of islets graft was only extended up to 50 days in the case where an antibody is not administered after transplantation (Described matter 1-2). This is recognized as a significant effect that goes beyond the expectation of a person skilled in the art.

Therefore, without considering the above Different feature 2, it cannot be said that a person skilled in the art could have easily conceived of Invention 1 on the basis of Cited Invention 1 and the description of Cited Documents 2 and 3.

(3) Summary

Therefore, it cannot be said that a person skilled in the art could have easily conceived of Invention 1 on the basis of Cited Invention 1 and the description of Cited Documents 2 and 3.

2. Regarding Inventions 2 to 10

Inventions 2 to 10 further confine the scope of Invention 1, and comprise the step of "(iii) administering to the subject one or more additional doses of an antibody or immunologically active fragment thereof that specifically binds to TLR4, wherein the antibody is administered in an amount sufficient to prevent transplant rejection or prolong survival of the transplanted islet cells in the subject" of Invention 1. Therefore, for a reason similar to that for Invention 1, it cannot be said that a person skilled in the art could have easily conceived of the inventions on the basis of Cited Invention 1 and the description of Cited Documents 2 and 3.

No. 7 Original Decision

1. As for Reason (Article 29(2) of the Patent Act)

Due to the amendment as of the demand for appeal, Inventions 1 to 10 have the matter of

"A drug for inhibiting rejection of or prolonging survival of transplanted biological material in a subject, comprising an antibody or immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide, wherein the biological material to be transplanted is islet cells,

wherein said drug is used for a method comprising the steps of:

(i) contacting said antibody or immunologically active fragment thereof that specifically binds to a Toll-like receptor 4 (TLR4) polypeptide with said islet cells to be transplanted to produce a transplantable composition;

(ii) implanting the transplantable composition at a desired location in the subject; and

(iii) administering to the subject one or more additional doses of an antibody or immunologically active fragment thereof that specifically binds to TLR4, wherein the antibody is administered in an amount sufficient to prevent transplant rejection or prolong survival of the transplanted islet cells in the subject,

wherein the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (i), the antibody or immunologically active fragment thereof that specifically binds to TLR4 in step (iii), or the antibody or immunologically active fragment thereof that specifically binds to TLR4 in steps (i) and (iii) comprises a heavy chain amino acid sequence

MGWSWIFLFLLSGTAGVHCQVQLQESGPGLVKPSDTLSLTCAVSGYSITGGYSWHWI
RQPPGKGLEWMGYIHYSGYTDFNPSLKTRITISRDTSKNQFSLKLSSVTAVDTAVYY
CARKDPSDAFPYWGQGTLVTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYFP
EPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKPSNT
KVDKRVEPKSCDKTHTCPPCPAPELLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVS
HEDPEVKFNWYVDGVEVHNAKTKPREEQYNSTYRVVSVLTVLHQDWLNGKEYKC
KVSSKAFPAPIEKTISKAKGQPREPQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVE
WESNGQPENNYKTTPPVLDSDGSFFLYSKLTVDKSRWQQGNVFSCSVMHEALHNH
YTQKSLSLSPGK (SEQ ID NO: 9)

and a light chain amino acid sequence

MEWSWVFLFFLSVTTGVHSEIVLTQSPDFQSVTPKEKVTITCRASQSISDHLHWYQQ
KPDQSPKLLIKYASHAISGVPSRFSGSGSGTDFTLTINSLEAEDAATYYCQQGHSFPLT
FGGGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNAL
QSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQGLSSPVTKSFNR
GEC (SEQ ID NO: 10)
."

It cannot be said that a person skilled in the art could have easily conceived of the Invention on the basis of Cited Documents 1 to 3 cited in the original decision of refusal.

Therefore, the reason for the original decision may not be maintained.

No. 8 Closing

As described above, the application cannot be rejected due to the reasons of the examiner's decision.

Further, no other reason for rejection is found in the present application.

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

December 21, 2017

Chief administrative judge: TAMURA, Kiyoko
Administrative judge: SEINO, Chiaki
Administrative judge: TOMINAGA, Midori