JAPAN

ABE & PARTNERS
Osaka

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and
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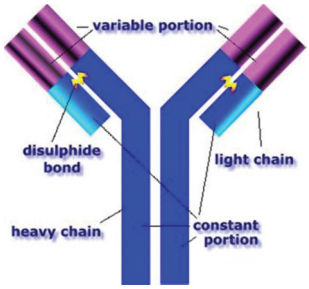
Inventor of an antibody drug

The market for drugs has been shifting from low molecular weight drugs to biotechnology-based drugs such as antibody drugs. Development of biotechnology-based drugs needs the integration of more extensive and sophisticated technology, such as genetic engineering and cellular engineering, than former drug development and cooperation with outside R&D partners becomes more important. Therefore, a dispute over an issues such as the contribution ratio to an invention may arise between R&D partners.



http://en.wikipedia.org/wiki/File:Antibody.jpg

In Japan, very few cases are filed regarding biotechnology-based drugs. This is one of a few cases where a dispute arose among R&D partners regarding the development of antibody drugs.

Summary of the case

Osaka University and BioMedics Japan Inc conducted joint R&D on the anti-CD20 monoclonal antibody for treating malignant lymphoma. The work process of the joint R&D was: (1) prepare mouse antibodies by injecting antigens to mice, (2) chimerise the mouse antibodies (humanise a constant portion of the mouse antibodies), (3) humanise the mouse antibodies (humanise a variable portion other than complementarity-determining region).

This dispute arose from a patent application by BioMedics alone regarding the anti-CD20 monoclonal antibody which was a result of the joint R&D. Osaka University sued BioMedics seeking declaratory judgment on four-fifths of a co-ownership interest in a right to obtain a patent for the invention. Our firm represented Osaka University.

The main issues in this case were who the inventor was and how much the contribution ratio was.

Judgment

In the judgment of October 8 2009, the Osaka District Court found that the co-ownership interest of Osaka University regarding the right to obtain the patent for the invention was two-thirds. Its reasoning is below.

1 Inventor

(1) Creation of technical ideas: Inventor means a person who actually participates in acts of creation regarding technical ideas which are found from a statement of a scope of claims. Preparation of the mouse antibodies is a core of creation of the invention because a series of creation processes regarding the invention begins from obtaining the mouse antibodies. In contrast, chimerisation is not one of the acts of creation of the invention because the work of chimerisation was already a routine work at the time of the patent application. Preparation of the humanised antibodies is a core of creation of the invention because the work of humanisation needs sophisticated technology.

(2) Actual participation in acts of creation: The mouse antibodies are expected to become antibody drugs; however their utility in the future cannot be confirmed at the stage of mouse antibodies. In inventing a mouse antibody, developers shall set out a certain standard based on their expert knowledge regarding which mouse antibody is expected to show utility when it becomes a drug and select antibodies effectively on the basis of that standard. Therefore, regarding an invention of an antibody such as this case, suggesting direction of the work for obtaining antibodies, contriving measurement method for selecting promising antibodies, and setting out a standard for selection are important, and the contribution of these actions is higher than that of obtaining antibodies.

2 Roles played during the joint R&D process

(1) Mouse antibodies:

(a) Preparing the antibodies:

B who is an assistant professor at Osaka University, pointed out that CD20-GST, which had been used as antigen for mouse antibodies, was improper. Following B's suggestion, CD20/CHO came to be used as antigen and thereafter many of mouse antibodies which have CD20 binding activity were able to be obtained. Therefore, direction of the work B suggested contributed to the invention.

G, who is a director of BioMedics, obtained the mouse antibodies by working under a specific immune condition. This can be said to be a direct contribution. However, G's contribution cannot be evaluated highly because the work of G is commonly performed in antibody production.

(b) Selecting the mouse antibodies: Among the prepared mouse antibodies, mouse antibodies that comprise the core of the invention are the selected mouse antibodies only. Thus, selecting the mouse antibodies is an act of creation. Measuring binding affinity by fluorescence centrifugation method which B newly developed and proposed is an important contrivance. Therefore, B contributed to the invention.

(2) Humanised antibodies: Only 1K1791 was humanised among the mouse antibodies. For selecting 1K1791, measuring binding affinity by the fluorescence centrifugation method that B developed contributed as well. Designing for humanised antibody was conducted by M who was entrusted by BioMedics. It needs creativity because universal design does not exist and trial and error is needed for appropriate designing.

3. Inventor of the invention and contribution ratio

In light of the above, the inventor of the invention is B and G regarding the mouse antibodies, and B, G and M regarding the humanised antibody of 1K1791. Calculating the contribution ratio of B,G and M in the entire invention, the co-ownership interest of Osaka University regarding the right to obtain the patent for the invention is two thirds and that of BioMedics is one third.

Practical tips

This judgment provides concrete guidance on how to judge who the inventor of an antibody drug is and how much the contribution ratio is.

At the time of this case, when violation of the joint application or usurped

application happened, a true inventor could seek a declaratory judgment for a right to obtain a patent before the patent was registered, but they could only invalidate the patent after the patent was registered. In 2011, the Patent Act was revised and a true inventor can request a transfer of a patent right after the patent is registered. The concrete guidance given in this judgment could also be applied to future cases of request for transfer of a patent right.