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CASE STUDY

Inventor of anti-PD-L1 antibody patent

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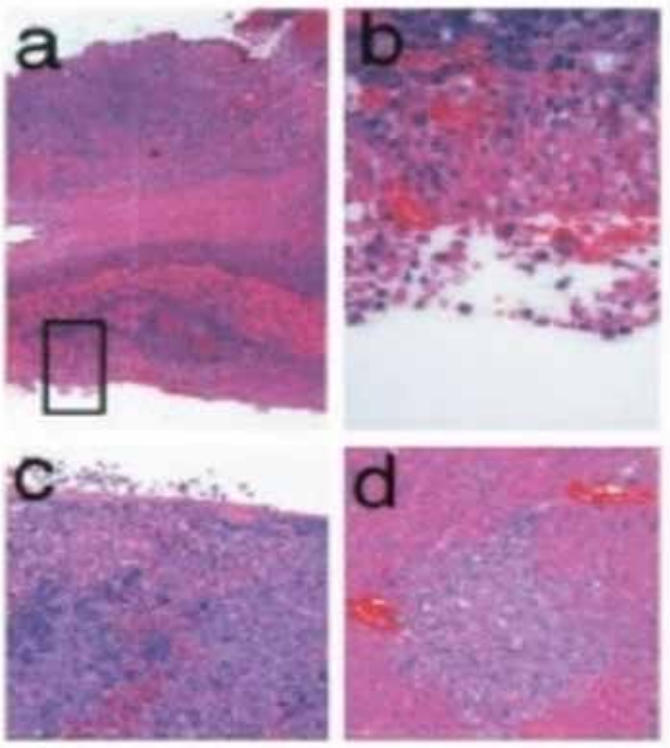
Abe & Partners report on a significant case of disputed inventorship regarding the invention of an anti-PD-L1 antibody patent.

In a dispute over inventorship, evaluation of the degree of contribution is directly linked to the sense of pride of the individuals concerned, and the conflict between the parties tends to be extremely intense. In this case, inventorship was disputed by the first author of the relevant paper, regarding the invention of an anti-PD-L1 antibody patent.

Tasuku Honjo, a distinguished professor of the Faculty of Medicine at Kyoto University, awarded the Nobel Prize in Physiology or Medicine 2018, is one of the inventors of the invention.



Summary of the case

The plaintiff X was enrolled in the master's course at the Graduate School of Biostudies, Kyoto University (Field of Bioimaging and Cell Signaling), Professor Z's laboratory, from April 2000 to March 2002. X sought confirmation that he is the inventor of the invention, and sought a registration of transfer for each quarter of the patent right as a share based on article 74 , paragraph (1) of the Patent Act of Japan against the defendants, Ono Pharmaceutical

"The experiment conducted by X was evaluated as being carried out merely within the framework of the experimental system designed and constructed by Professor Z."

and Professor Honjo (Y), who jointly owning the patent right alleging that X is one of the inventors of the invention since the invention of patent right titled "Cancer treatment agent" (JP 5885764) is based on a *Proceedings of the National Academy of Sciences of the USA (PNAS)* paper summarising the results of experiments conducted by X and the findings obtained from the analysis while enrolled in the graduate school.

In addition, X claimed for compensation for damages of 10 million yen in total based on joint tort (2 million yen for economic damages, 3 million yen for mental damages and 5 million yen for legal fees) and delay damages, alleging that X suffered damages because the defendants intentionally or negligently failed to file an application with X as a co-inventor.

Judgment of August 21 2020, Tokyo District Court

On August 21, 2020, the Tokyo District Court (presiding Judge Sato) dismissed confirmation of X's being an inventor, and rejected the remaining part of X's complaint, holding as follows.

Criteria of inventor

An invention means a highly advanced creation of technical ideas utilising the laws of nature (article 2, paragraph[1] of the Patent Act), and the technical scope of a patented invention must be determined based upon the statements in the claims. Therefore, an inventor needs to conceive a characteristic part of the technical idea defined in the claims and to actually participate in the reduction to practice.

Even if he or she has been involved in acts of creation, conducted experiments for the inventor, and collected and analysed data, if he/she played only a subsidiary role of the inventor, it cannot be said that he/she actually participated in creative activities.

For determining the inventorship of the invention, the following facts must be taken comprehensively in consideration: (i) contribution in idea of the technical ideas that anti-PD-L1 antibody activates cancer immunity by inhibiting the interaction of PD-1 molecule and PD-L1 molecule; (ii) contribution in production and selection of anti-PD-L1 antibody that inhibits the interaction of PD-1 molecule and PD-L1 molecule; (iii) contribution in design and construction of experimental systems necessary for demonstrating hypotheses, as well as the degree of creative involvement in the process of performing individual experiments, etc.

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Contribution of X in idea of technical ideas of the invention

Before X entered Professor Z's laboratory, Y and Z shared the technical idea that anti-PD-L1 antibody activates cancer immunity by inhibiting the interaction of PD-1 molecule and PD-L1 molecule, and started concrete experiments to prove it.

On the other hand, X was not aware that the interaction of PD-1/PD-L1 was studied in relation to cancer immunity when the experiment was started, and he did not think of a possibility that the experiments was for cancer until this was pointed out at a subsequent group meeting. Therefore, it cannot be admitted that X was involved in the idea of the technical ideas that the anti-PD-L1 antibody activates cancer immunity by inhibiting the interaction of PD-1 molecule and PD-L1 molecule.

Contribution of X in production of anti-PD-L1 antibody

The experiment conducted by X can be recognised as meaningful in the final selection of the 1-111 antibody. However, considering that it was recognised that the production itself of 1-111 antibody and 1-167 antibody had been completed by April 22, 2000, immediately after X entered Z's lab, and no promising antibodies could be found in X's search for anti-PD-L1 antibodies other than 1-111 antibody and 1-167 antibody, it should be said that even if X was partially involved in the production and selection of anti-PD-L1 antibody, the degree of his contribution was very limited.

Who contributed to the production and selection of the anti-PD-L1 antibody of the invention were Z and assistant professor W, and although X can be said to have played a certain role under the guidance of Z and others, the degree of his contribution was very limited.

Contribution of X in conception and reduction to practice of individual experiments constituting the invention

Although X actually worked regarding the individual experiments constituting the invention, it was Z who designed and constructed each experimental

"X's contribution in the execution process of each experiment should be regarded as limited."

system, so X's contribution in the execution process of each experiment should be regarded as limited. The ingenuity regarding the type of experiment, selection of experimental materials, and experimental method, claimed by X, is merely an ingenuity or a trial and error on experimental technique in the execution process of experiments, and it cannot be said that X was creatively involved in the experiment.

Inventor of the invention

According to the foregoing, it is acknowledged that (i) it was Y and Z who conceived the technical idea of the invention; (ii) those who contributed to the production of the anti-PD-L1 antibody were Z and W; and (iii) it was Z who designed and constructed the individual experiments constituting the invention. Although X made a certain contribution in the invention including the implementation of experiments, the degree of contribution is limited, and it was not sufficient to recognise him as the inventor of the invention. Therefore, X cannot be recognised as the inventor of the invention.

Argument of X

There is no dispute between the parties regarding the fact that X conducted almost all the experiments, and X argued that in the field of chemistry, those who actually conducted and examined the experiments underlying invention should be recognised as the inventor.

However, in order to be recognised as an inventor, it is necessary for him/her to conceive a characteristic part of the technical idea defined based on the claims and to actually participate in the reduction to practice. It should be understood that even if he/she actually conducts experiments for the inventor, and collects and analyzes data, if he/she played only a subsidiary role of the inventor, he/she cannot be said to be the inventor.

As stated previously, X was not involved in the technical idea of the invention and X's contribution to the production and selection of the anti-PD-L1 antibody and the design and construction of the experiments constituting the invention was very limited, so X's role in the invention should be said to be subsidiary.

X pointed out that in the *PNAS* paper, X was specified as the co-first author and that the footnote (page 1) stated that "A and X contributed equally to this study", and argued that since Y was in a position to submit the paper, Y had acknowledged X's contribution. However, as stated previously, whether he/she is the inventor of the invention should be determined from the perspective

of (i) contribution in the conception of the idea of the technical ideas; (ii) contribution in production and selection of anti-PD-L1 antibody; and (iii) contribution in design and construction of experimental systems necessary for demonstrating hypotheses, as well as the degree of creative involvement in the process of performing individual experiments, etc, based on the specific facts leading up to the background of the invention.

Therefore, even if there is a statement that X is the co-first author in the paper and contributed equally to the study, it cannot be immediately inferred that the co-first author of the paper is the inventor.

Practical tips

In this case, the graduate student who actually conducted the experiment and became the co-first author of the paper was not recognised as the inventor and decided to play only a subsidiary role of the inventor. Why did the first author of the paper receive the same appraisal as a technician in recognition as an inventor of patent?

Where is the watershed that separates an inventor and a subsidiary? A major factor may be that the experiment conducted by X was evaluated as being carried out merely within the framework of the experimental system designed and constructed by Z. In other words, a person working according to the instructions from another person will be judged that he/she is not involved in the creation and not the inventor.

In order to be recognised as an inventor, it is necessary to be involved in creation initiatively. However, there is an example from 2014 when Hiroshi Amano was awarded the Nobel Prize in Physics because he was judged to be not just a subsidiary of Isamu Akasaki when he had been a graduate student.

As a method of proving inventorship, a testimony is used in addition to documentary evidence such as lab notebooks, etc. It is necessary to prove closely who did what and when by this evidence. In this case, the research

“It cannot be immediately inferred that the co-first author of the paper is the inventor.”

activities in the world's top laboratories are portrayed frankly by the detailed proof of the parties concerned.

Compared to the patent infringement lawsuits where little testimony is used, a testimony is a major feature in dispute regarding the inventorship. In a testimony, the attitude in the witness or the party him/herself as well as the content of the testimony and statement may affect the credibility of testimony, etc, and affect the judge's impression.

In the witness testing (article 85 of the Rules of Civil Procedure), it is important to convey that witnesses should understand of necessity to pay attention not only to the content of the testimony but also to the attitude in the court. The testimony must resonate with the judge.

The judgment also found that "even in light of Z's testimony content and attitude, it is not recognised that the relationship between Z and Y influenced Z's testimony, and there is not enough evidence to admit that Kyoto University to which Z belongs received benefit from Ono Pharmaceutical."

In a dispute over the inventorship, it is difficult to reach a settlement due to the extremely intense emotional conflict between the parties. This is probably because the evaluation of the degree of contribution is directly linked to the individual's sense of pride. There are many similar examples among Nobel Prize winners.

In 1923 Frederick G. Banting was furious when he and John Macleod won the Nobel Prize in Physiology or Medicine but his colleague Charles Best missed out; Banting shared the prize money with Best. The order of the authors Satoshi Mizutani and Howard M. Temin was changed on a paper.

Shuji Nakamura argued that the method of Akasaki/Amano could only produce very dark LEDs, and the bright LEDs he made were a breakthrough, which he complained was not stated in the reason for the award. ●

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