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Japan: PD-1/PD-L1 related patents: What are the co-inventorship requirements for an invention in the medicine field

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The hurdle for being a co-inventor in a medicine field in Japan might be a little higher than what is expected from precedents. The IP High Court affirmed, in its judgement of 17th March 2021 (2020 (*ne*) No. 10053), the first instance decision of 21st August 2020 (2017 (*wa*) No. 27378) which denied co-inventorship of a graduate student for the patent directed to a cancer treatment comprising an anti PD-L1 antibody which inhibits PD-1's immunosuppression signal. The patent is jointly owned by Ono Pharmaceuticals and Professor Honjo, who is one of co-inventors on the record and a winner of the 2018 Nobel Prize in Physiology or Medicine for his research on PD-1.

The Plaintiff sued the patentees at the Tokyo District Court claiming co-ownership of the patent contending that the patented invention was made based on a scientific paper summarizing results of his experiments and analysis conducted while he was a graduate student at Kyoto University studying in a laboratory led by a professor who was also one of the co-inventors on the record.

PD-L1 had been known as one of molecules which induces inhibition signal from PD-1, and the claimed invention had been made based on a finding that an antibody against PD-L1 inhibits the inhibition signal from PD-1, and as a result, activates immunity against cancer.

The district court first explained in general how to determine an inventor in a field of basic experimental medicine: "in the field of basic experimental medicine, including immunology such as the present invention, in order to materialize a conceived technical idea, it is important to conceive a specific hypothesis to be proven based on the results of prior studies, design and construct an experimental system necessary for demonstrating the hypothesis, and then construct a series of experiments scientifically and logically necessary to prove the hypothesis and eliminate other possibilities."

Applying these to the present case, the district court specified three factors to be comprehensively considered: (1) contribution to the conception of the technical idea that the anti-PD-L1 activates cancer immunity by inhibiting the interaction between PD-1 and PD-L1 molecules; (2) contribution to the creation and selection of an anti-PD-L1 antibody that inhibits the interaction between PD-1 and PD-L1 molecules; and (3) contribution to the design and construction of an experimental system necessary to demonstrate the hypothesis, and the degree of creative involvement in the process of conducting the individual experiment. The first and second factors,

i.e., his involvement in the conception (first factor) and involvement in the creation of antibody (second factor) were denied. Further, the third factor, *i.e.*, his contribution to the design and construction of the experimental system and creative involvement in the design of the experimental system was also denied, despite the fact that the graduate student was named as the first author in the scientific paper showing experiments and results on the effects of anti PD-L1 antibody that were identical with Examples 1 through 3 and 5 in the patent specification. The district court found that the experiments were in fact designed and conceived by the professors and not by the graduate student.

In contrast, the IP High Court found that the graduate student was the one who proposed and conducted the experiments. Nevertheless, the IP High Court still denied his contribution to the design and construction of an experimental system and creative involvement in the process of conducting the experimental system since he lacked an idea on how to conduct actual experiments and post-experimental outlook; "the appellant [the graduate student] actually conducted each of the experiments constituting the subject invention and therefore was more than a mere assistant for Professor A [the professor who led the laboratory] … but his involvement did not correspond to a creative involvement in connection with technical idea of the subject invention.

There are number of court decisions which deny inventorship of a mere assistant or a person whose contribution was something that a POSITA could have easily done. In this case, however, since the IP High Court found that the graduate student planned and conducted the experiments that were not routine and were important to support the claimed invention without professors' direction, there could have been some room to find him as a co-inventor. In fact, however, the Court concluded that the graduate student was not a co-inventor, requiring the knowledge of how to actually conduct experiments and post-experimental outlook in order to be a co-inventor. The hurdle for a co-inventor might be a little heightened because it is inventorship of a pioneer invention in medicine field.

Incidentally, in the U.S., there was a dispute on inventorship for six U.S. patents in the same family. Dana-Farber Cancer Institute sued the patentees claiming a co-ownership in those patents contending that its employee Dr. Freeman should be a co-inventor. The U.S. District Court for the Massachusetts ruled for Dana-Farber[1], and the Court of Appeals for the Federal Circuit agreed with the district court decision that Dr. Freeman was the co-inventor stating "there is no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor."[2]

Moreover, invalidity trials filed by Dr. Freeman against the six Japanese counterpart patents of the six U.S. patents above are currently pending, in which he is likely claiming that he should be a co-inventor. The Japan Patent Office may reach a conclusion sometime this year if the parties do not settle. The decision might be a touchstone for finding whether Japan's inventorship requirements in the medicine field are stricter than those in the U.S.

[1] Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd., 379 F.Supp.3d 53 (D. Mass. 2019).

[2] Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd., 964 F.3d 1365 (Fed. Cir. 2020).

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