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Federal Circuit Confirms Adding Co-Inventors to Cancer Treatment Patents

By Marc Richards, Jason Jang

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Properly determining inventorship on collaborative projects between two organizations can be difficult and have very important consequences. In *Dana-Farber Cancer Inc., v. Ono Pharm. Co., Ltd. et al.,* 2019-2050 (Fed. Cir. July 14, 2020), the Federal Circuit confirmed the legal standards for determining joint inventorship by holding that the law does not require: (1) physically working on the invention together or at the same time, or making the same type or amount of contribution[1]; or (2) obviousness of the combined invention over an individual's contribution. The Court confirmed that the conception of an invention is complete when an idea is definite and sufficiently permanent that one of ordinary skill in the art could understand it, and a joint inventor need not have known that the invention would work for its intended purpose.

Determining Joint Inventorship

It is important to ensure that only the true inventors are named in a patent application to avoid potential disputes on inventorship and invalidation of a patent. The patent statute provides that "whoever invents or discovers" any patentable subject matter "may obtain a patent therefor."[2] "Conception is the touchstone of the joint inventorship inquiry." If[3] more or fewer than the true inventors are named with deceptive intent, a patent may be found invalid or unenforceable.

U.S. patent statutes require that when two or more persons jointly invent, they must jointly apply for a patent even though they did not physically work together or at the same time, each did not make the same type or amount of contribution, and each did not contribute to the subject matter of every claim of the patent as long as each joint inventor contributes in some significant manner to the conception or reduction to practice of the invention.[4] A joint inventor needs only contribute to the conception of a single claim in a patent.

However, one does not qualify as a joint inventor when merely assisting the actual inventor after conception of the claimed invention, or when simply providing the inventor with well-known principles or explaining the state of the art without ever having a firm and definite idea of the invention. Thus, the critical question for joint conception is who conceived the subject matter of the claims of the patent.[5]

District of Background Facts of *Dana-Farber Cancer Inc., v. Ono Pharm. Co., Ltd. et al.*

In 1998, Dr. Gordon Freeman at the Dana-Farber Cancer Institute, Dr. Clive Wood at the Genetics Institute in the U.S., and Dr. Tasuku Honjo at Kyoto University in Japan began sharing information and eventually biological materials, while remotely collaborating on anti-cancer research involving antibodies binding to PD-1 receptors that played a role in fighting cancer. The three scientists conducted further research sharing their separate results that disclosed such matters as the antibodies'

structure, function of inhibiting interaction, and experimental knockout mouse data relating to the immune response. The three also co-authored journal articles documenting their discoveries concerning PD-L1 inhibiting an anti-tumor immune response. In 1999, Drs. Freeman and Wood filed a provisional patent application on their independent discoveries involving PD-1 and PD-L1 without including Dr. Honjo. In 2002, Dr. Honjo filed his own patent applications in Japan with his Japanese colleagues and without including Drs. Freeman and Wood. Dr. Honjo's patents claim methods of treating cancer by administering antibodies targeting specific receptor-ligand interactions on T cells. The claims recite "uses of antibodies that target either the PD-1 receptor or its PD-L1 ligand[6], blocking the receptor-ligand interaction." Dr. Honjo would later go on to win the Nobel Prize in 2018.

Dana-Farber Cancer Institute, the assignee of Dr. Freeman's inventions, filed suit in the district court of Massachusetts against the assignees of Dr. Honjo's patents, alleging that Drs. Freeman and Wood should be added as inventors. The district court ruled Drs. Freeman and Wood were co-inventors of the patents. Ono Pharm. Inc. et al. (collectively "Ono") appealed.

Finding A Contribution Significant To Inventorship

On appeal, Ono argued that Drs. Freeman and Wood "failed to participate in certain experiments that led to the conception of the claimed invention," and that the three scientists' "collaboration was too speculative until the 2000 knockout mice studies" performed in Japan.

In addition, Ono argued that Drs. Freeman's and Wood's alleged contributions to the inventions should be deemed irrelevant to inventorship because their work with Dr. Honjo was published in October 2000 in a scientific journal prior to the filing of Dr. Honjo's patent applications.

Rejecting Ono's various arguments, the Federal Circuit pointed out that a "joint invention is simply the product of a collaboration between two or more persons working together to solve the problem addressed," and "[t]here is no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor."

The Federal Circuit determined that Drs. Freeman and Wood contributed to finding features essential to all the claimed inventions, and the later knockout mice experiments by Dr. Honjo and his Japanese colleagues did not negate the prior conception to which Drs. Freeman and Wood contributed.

The Federal Circuit also clarified that "joint inventorship does not depend on whether a claimed invention is novel or nonobvious over a particular researcher's contribution." The Federal Circuit concluded that "[c]ollaboration and concerted effort are what result in joint inventorship."[7]

Practice Tips

This decision illustrates the challenges faced by counsel in properly determining inventorship, and how that determination can be challenged years after the patents issue. It is important to prepare contemporaneous records of decisions on joint inventorship, especially where the inventors work for different organizations. It is likely better to err on the side of including collaborators as inventors, because the Federal Circuit stated there is "no explicit lower limit on the quantum or quality of inventive contribution." Ownership of an invention in the U.S. originates with the inventor and each joint inventor has an independent right to the whole invention. Therefore, identifying possible inventors is important so that ownership of an invention may be determined and the parties may promptly agree to the transfer and licensing of the patent rights well in advance of significant investments in the invention or its commercialization. Having an unnamed inventor appear after a patent issues gives that unnamed inventor or any assignees full independent rights in the patent without any duty to account to the owners of record, thus diminishing the exclusivity and value of the patent rights to the patentee.

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[1] Citing *Burroughs Wellcome Co. v. Barr Labs., Inc.,* 40 F.3d 1223, 1227 (Fed. Cir. 1994).
[2] 35 U.S.C. §101

[3] *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994).
[4] 35 U.S.C. §116; *Burroughs Wellcome*, 40 F. 3d at 1227
[5] *Ethicon Inc. v. United States Surgical Corp*., 135 F. 3d 1456, 45 (Fed. Cir. 1998).
[6] A ligand is a molecule that binds to another molecule.
[7] Citing *Eli Lilly & Co. v. Aradigm Corp*., 376 F.3d 1352, 1359 (Fed. Cir. 2004).