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Collaboration and Joint Inventorship: Who Invented this Biologic?

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Background

The patent statute recognizes that an invention may be jointly invented, however, there is no definition of inventorship in the patent statute. For this reason, the courts have been left to determine what constitutes sufficient contribution to an invention to qualify one for inventorship. 35 U.S.C. § 116 (2018) states:

> Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type of amount or contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Thus, the statute sets out elements not required for joint inventorship but fails to "set forth the minimum quality or quantity of contribution required for joint inventorship."[1]

The threshold question in determining inventorship is who conceived of the invention. "[E]ach person claiming to be a joint inventor must have contributed to the conception of the invention."[2] "Unless a person contributes to the conception of the invention, he is not an inventor. Insofar as defining an inventor is concerned, reduction to practice per se is irrelevant."[3] In other words, once the invention is conceived, inventorship should be fully established, without consideration for those who reduced the invention to practice.

But, conception requires more than formulating a goal to be reached. Conception requires formation in the mind of the person claiming to be the inventor of both the desired outcome and the means of reaching that outcome.[4] The greater the degree of conceptual specificity in a participant's intellectual contribution to the idea and the means of putting the idea to use, the more likely his or her contribution will rise to the level of inventorship. Furthermore, the means of accomplishing the purpose of the invention must be visualized in sufficient detail that it may be reduced to practice through the exercise of "ordinary skill." [5] The conceptual contribution cannot be "insignificant in quality, when . . . measured against the dimension of the full invention." [6] Likewise, the contribution must do "more than merely explain to the real inventors well-known concepts and/or the current state of the art."[7]

Conception Of A Biologic

In *Dana-Faber Cancer Institute, Inc. v. Ono Pharmaceutical Co. Ltd.*,[8] the Federal Circuit affirmed a district court ruling that two collaborators should be added to patents claiming methods of treating cancer by administering antibodies that target T cell receptor-ligand interactions, specifically, the interaction between PD-1 and PD-L1 or PD-L2, which inhibits T cell attack on cancer cells. The case was an appeal from the District of Massachusetts following a bench trial ordering Drs. Freeman and Wood to be named co-inventors on six patents.[9] Dr. Honjo, a professor at Kyoto's medical school who won the Nobel Prize for the invention, originally discovered the PD-1 receptor and its DNA sequence.[10] His laboratory created a knock-out mouse and determined PD-1 was involved in inhibition of the immune system.[11] Dr. Honjo subsequently began to collaborate with Drs. Freeman and Wood, who determined that PD-1 bound to a molecule subsequently named PD-L1.[12] Drs. Freeman and Wood filed a patent application directed to modulation of the immune response by activating or blocking the PD-1/PD-L1 pathway, without naming Honjo as an inventor. Dr. Honjo, in turn, filed applications without listing Drs. Freeman or Wood as inventors.[14] Dana-Farber, Dr. Freeman's employer, brought suit against Ono, Dr. Honjo's assignee, to add Drs. Freeman and Wood as inventors.[15]

In an opinion by Judge Lourie, the Court noted "[a]n inventor need not know . . . that an invention will work for its intended purpose in order for conception to be complete, as verification that an invention actually works is part of its reduction to practice."[16] The court further reasoned that "[i]nventorship of a complex invention may depend on partial contributions to conception over time, and there is no principled reason to discount genuine contributions made by collaborators because portions of that work were published prior to conception for the benefit of the public."[17] Of particular relevance, the court reasoned that, even though Honjo's claims were directed to the use of PD-1 antibodies, "[u]nless one also knows that the PD-1 receptor binds to at least one ligand that inhibits the immune response, such as PD-L1, there would be no reason to use anti-PD-1 antibodies to treat tumors."[18] The Court concluded "the district court did not err in holding Drs. Freeman and Wood should be included as joint inventors," and Drs. Freeman and Wood should have been listed as inventors in view of their contributions to the blockade of the PD-1/PD-L1 interaction.[19] Ono's requests for panel and en banc rehearing were denied by the Federal Circuit.[20]

Petition For Writ of Certiorari

On March 8, 2021, Ono filed a petition for a writ of certiorari.[21] "The question presented is: Whether the Federal Circuit erred in adopting a bright-line rule that the novelty and non-obviousness of an invention over alleged contributions that were already in the prior art are 'not probative' of whether those alleged contributions were significant to conception."[22] Ono states that the issue of joint inventorship has not been addressed by the Supreme Court "in more than 100 years" and "has become 'one of the muddiest concepts in the muddy metaphysics of patent law'."[23] Ono argues the district court credited Dr. Freeman and Dr. Wood "as having made certain significant contributions even though those alleged contributions had already been disclosed in

the prior art before Dr. Honjo conceived of the patented methods of treating cancer."[24] Ono further argues that the Federal Circuit's decision would "undermine collaboration and create windfalls for individuals who contributed only ideas that are already covered by prior art."[25]

On April 20, 2021, Dana-Farber filed its brief in opposition to Ono's petition for a writ of certiorari. [26] Dana-Farber argued that, although Dr. Honjo identified the PD-1 receptor, he failed to identify its ligand, instead learning of the ligand from Dr. Freeman and Dr. Wood.[27] Dana-Farber argues that, "[f]or inventorship, ideas may be found to have contributed significantly to conception if they were not publicly known *at the time they were shared with a collaborator*," and, "[t]o the extent [Ono] challenges the inventorship test applied by the Federal Circuit, it conflates two distinct concepts in patent law, inventorship and patentability."[28] Dana-Farber further argues that the Federal Circuit applied settled law in upholding the district court's determination that Drs. Freeman and Wood should be named as co-inventors.[29]

Takeaways

As the *Dana Farber* case is very fact specific, the Supreme Court may not grant Ono's petition for writ of certiorari. However, the Federal Circuit opinion provides lessons. *Dana-Farber* suggests that claims to use of a biologic agent, such as a receptor-blocking antibody, do not necessarily exclude those who contributed to identification of other aspects of the biologic pathway, such as the receptor ligand. Thus, as a matter of practice, an inventorship analysis should be completed upon filing a patent application, with careful attention to the scope and nature of the claims and to the contribution of any collaborators to the conception of the claimed invention. Failure to properly name inventors may lead to actions in district court to correct inventorship under 35 U.S.C. § 256, which authorizes courts to direct the USPTO to issue a certificate to correct inventorship. If an outside collaborator is determined to be co-inventor, the right to assign or license the patent rights should be addressed contractually so as to avoid compromising the value of the patent rights.

Please, contact the authors with any questions, and stay tuned for updates regarding this important topic.

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Footnotes

[1] *Burroughs Wellcome Co. v. Barr Labs, Inc.*, 40 F.3d 1223, 1227 (Fed. Cir. 1994).

[2] *Acromed Corp. v. Safamor Danek Grp., Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001).

[3] *In re Hardee*, 223 U.S.P.Q. 1122, 1123 (Comm'r Pat. & Trademarks 1984) (citation omitted).

[4] *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985).

[5] *Ethicon v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) (citation omitted).

[6] *Acromed*, 253 F.3d at 1379 (quoting Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998)).

[7] *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).

[8] 964 F.3d 1365, 1372 (Fed. Cir. 2020) (Lourie, J.), *petition for cert. docketed*, No. 20-1258 (U.S. Mar. 11, 2021).

[9] *Id*. at 1367.

[10] *Id*. at 1368-1370.

[11] *Id*. at 1368.

[12] *Id*.

[13] *Id*.

[14] *Id*. at 1369.

[15] *Id*. at 1370.

[16] *Id*. at 1372.

[17] *Id*. at. 1372-73.

[18] *Id*. at 1373.

[19] *Id*.

[20] *See Ono Pharm. Co. Ltd. v. Dana-Faber Cancer Institute, Inc.*, No. 20-1258 (U.S. Mar. 11 2021), https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/20-1258.html (docket entry).

[21] *Id*.

[22] Brief for Petitioner at i, *Ono Pharm. Co., Ltd. v. Dana-Farber Cancer Inst., Inc.*, No. 20-1258 (U.S. Mar. 8 2021), https://www.supremecourt.gov/DocketPDF/20/20-1258/171211/20210308155833592_20-__%20Ono%20Pharmaceutical%20Co.%20et%20al.%20-%20Petition%20for%20a%20Writ%20of%20Certiorari.pdf.

[23] See *id*. at 1 (citation omitted).

[24] *Id*.

[25] *Id*. at 2.

[26] See Brief in Opposition, *Ono Pharm. Co., Ltd. v. Dana-Farber Cancer Inst., Inc.*, No. 20-1258 (U.S. Apr. 20, 2021), https://www.supremecourt.gov/DocketPDF/20/20-1258/176205/20210420195805572_Brief%20in%20Opp.%20--%20Ono%20Pharm.%20v.%20Dana-Farber%20Cancer%20Inst.%20--%20No.%2020-1258.pdf.

[27] *Id*. at 2.

[28] *Id*.

[29] *Id*. at 18.