GETTING INVENTORSHIP RIGHT: WHY THE BIG DEAL?

Decisions attributing authorship of a scientific publication involve a myriad of factors that are inappropriate for consideration when deciding who is an inventor on a patent application. Politics, professional courtesy, the desire to reward hard or tedious work all play a hand in the authorship decision and typically result in the identification of all who participated in or contributed to the work in some way. Research directors, principle investigators, and laboratory technicians are often named as authors. If a mistake is made, absent fraud, no great, long-term, harm results.

In contrast, incorrectly naming inventors on a patent application can have devastating consequences; the named inventor and possibly the patent owner can lose the patent and all rights associated with it, including the right to the royalty stream generated from any patent licensing.[1] Courts also award unjust enrichment damages and punitive damages against a party that has misappropriated another's invention by failing to attribute inventorship accurately.[2]

Attributing correct inventorship involves an intensive factual analysis that results in a legal determination. Each person named on a patent must have contributed to the "conception" of the invention described in the patent claims.[3] Conception has a well established meaning in patent law: it is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is to be applied in practice.[4] To the courts, this means that the idea must be laid out in such detail that another person of ordinary skill in that field would be able to reduce the invention to practice from the laid out details; i.e., all of the parts or elements of the invention must be known and described and how they are interrelated to one another and operate together must be delineated. "Reduction to practice", the second element of the invention equation, refers to the physical making of the invention and the demonstrating that it works for its intended purpose. [5]

Under these rules, the lab technician who performs, but does not design or modify, experiments is not an inventor, regardless of the amount of tedious, hard work contributed. The laboratory technician is the inventor's "pair of hands" in carrying out the reduction to practice of the invention. The provider of material to another researcher does not contribute to the researcher's invention unless the provider also provides specific

---

[1] In *Yeda Res. & Dev. Co. v. ImClone Systems Inc*., the court removed all of the named ImClone inventors from the patent and substituted Yeda inventors, which in effect converted ImClone's only product from being patent protected to patent infringing. ImClone's stock value dropped by 37% on the news.

[2] *Univ. of Colo. Found., Inc. v. American Cyanamid Co.*, 974 F. Supp. 1339, 1355 (D. Colo. 1997), rev'd on other grounds, 196 F.3d 1366 (Fed. Cir. 1999). *Richardson v. Suzuki Motor Co., Ltd*., 868 F.2d 1226 (Fed. Cir. 1989), cert. denied, 493 U.S. 853 (1989).

[3] The invention must be a new and useful process, machine, article of manufacture, or composition of matter, including a new use of a known process, machine, article of manufacture, or composition of matter, or any useful improvement on an old process, machine, article of manufacture, or composition of matter. An invention does not include or comprise the discovery of how or why something works the way it works.

[4] *Hybritech Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

5 There are really two types of reductions to practice: actual and constructive. Actual is the physical making and demonstration of operability referred to here. Constructive reductive to practice occurs with the filing of a patent application meeting all the statutory requirements for patentability. Either actual or constructive reduction to practice + conception = invention.

suggestions or instructions for experiments or uses for the material and the invention arose as a result of those suggestions or instructions. But if the provider's instructions are such that the researcher is acting as the provider's "pair of hands", then the provider is the inventor and not the researcher.[6] The supervisor of an experiment or project is not an inventor unless s/he makes a specific creative contribution to one or more of the invention's elements, for example by designing or suggesting experiments or by suggesting materials or processes that end up as part of the invention.

Under U.S. patent law, attribution of inventorship is so important that any claim of inventorship must be corroborated by evidence from either contemporaneous documents or the testimony of non-inventors. Standing in the research community, reputation, past accomplishments are not considered. Scientists, whether in industry or in academia, are taught, and are expected, to maintain careful records of their ideas, the progress of their research, and their research results in laboratory notebooks that are signed, dated and witnessed. If this is done, evidence of conception of the invention can be produced if any question arises relating to the correct naming of the inventors. Others claiming they contributed to the inventive concept claimed in the patent application will have a difficult time proving their claim.

Most recent case in point: Yeda Research v. ImClone. In that case, the claimed invention was a method of treating cancer using, in combination, ImClone's proprietary antibody and a chemotherapeutic agent. ImClone scientists had made the antibody and then sent it to scientists at Yeda's academic research institute. These scientists tested the antibody with various chemotherapeutic agents and found that certain combinations of antibody and agent were more effective against cancer than the agents alone. They drafted a manuscript detailing how the antibody could be employed in an antibody-based combination therapy for cancer and as a courtesy shared it with ImClone. ImClone filed a patent application on both the antibody and on the combination antibody-based therapy described in the manuscript, naming only the ImClone scientists who had made the antibody as inventors. The application issued with claims only to the combination antibody-based therapy, not to the antibody itself. When the Yeda scientists learned of the issued patent, they sued ImClone in U.S. Federal Court asking that the name inventors be removed from the patent and that they be added. In deciding whether to grant the relief requested, the Court looked at all of the written and oral evidence available. ImClone could produce no documentary evidence that its scientists had conceived of employing the antibody in combination with any chemotherapeutic agent, only the oral testimony of one of its named inventors. The Yeda scientists presented contemporaneous, written evidence documenting all of their oral testimony: that they had been given the antibody with no information or suggestion about how the antibody should be used. The documentation corroborating their oral testimony was decisive. The ImClone inventors were removed from the patent and replaced by the Yeda scientists.

---

[6] See *Burroughs-Wellcome v. Barr Labs., Inc*., 40 F.3d 1223, 1228 (Fed. Cir. 1994). BW wanted to test AZT as an AIDS treatment and contracted with the NIH to perform blind experiments on HIV-infected cells, which were restricted in their availability. Because the NIH scientists were not aware of the identify of the test drug until later verification testing and BW had filed a patent application upon receiving the results of the blind tests, BW had conceived the invention before the verification testing so that NIH could not have contributed to the initial and complete conception of the invention by BW.

ImClone no longer owned the patent; Yeda became the owner. In order to market their antibody as an anticancer combination therapy, ImClone would have to obtain a license from Yeda. Hence, the big deal.

In conclusion, failing to acknowledge the correct inventive contributions to an invention will eventually be discovered, and the potential consequences can be severe: reassignment of ownership of the patent at the very least, and if the misidentification occurred through deliberate deception, invalidity and unenforceability, in other words, a court enforced dedication of the patent property to the public. Unlike authorship, inventorship is not intended to offer credit to all who may have contributed in some way to a project's success. It is a strict legal mandate that requires an actual creative involvement in the conception of the invention as claimed in the patent application. The applicant for the patent, whether it be the inventors themselves or the owner to whom the inventors have or will assign their rights, must be certain that the inventors are correctly named and must maintain corroborating documentary evidence in case a dispute over inventorship arises. It is for these reasons that Brown Technology Partnerships urges its researchers to follow the guidelines discussed in the document "Keeping Lab Notebooks" on the BTP website and use the Invention Disclosure Form located on that site when documenting any developments.