

The importance of getting inventorship right

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Errors in inventorship can invalidate a patent, rendering it unenforceable.

In the United States, individuals, not companies or institutions, must be named as inventors on patent applications. Being named as an inventor confers ownership, and can bring prestige and financial rewards as well. Those named as inventors on an issued patent possess property rights in the invention as a matter of law. More particularly, this means that they have the right to exclude others from practicing the patented invention.

Most inventions are made in the context of the inventor's employment, and employees are typically required to assign to the employer all ownership rights in any invention made on the job. Hence, filed patent applications frequently are accompanied by a document assigning to the employer all rights in the described invention. Once such an assignment is recorded in the patent office, the employer becomes the owner of record, though the inventors' names will remain on the patent document. The owner of a patented invention may license to third parties the right to use the invention, and can do so on an exclusive or nonexclusive basis. If a product or process protected by a patent should reach the market, sales or royalties can be substantial, making it a matter of great importance to ensure that these benefits accrue to the rightful owner.

Errors in inventorship not only can confer ownership on the wrong party, but can invalidate a patent, rendering it unenforceable. This type of error is rarely fatal to the validity of a patent, as the law allows inventorship to be corrected, provided there was no deceptive intent in naming the wrong inventors¹. Given that



only a patent with correctly named inventors is enforceable, names cannot be included merely to acknowledge a technician's long hours in conducting experiments or a colleague's moral or financial support.

Conception

The proper criteria for determining inventorship have been set forth in US patent law and by the federal courts. The inventive process involves designing or 'conceiving' the invention, and then creating the invented item or carrying out the invented method, referred to as 'reduction to practice.' Yet identification of inventors focuses entirely on determining who conceived the invention.

Conception of an invention has been defined as "the complete performance of the mental part of the inventive act" and is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention"². Moreover, conception is established "when the invention is made sufficiently clear to enable one skilled in the

art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill"³. In some instances, particularly in the mechanical arts, conception is complete when the invention is so well described that another person could build the invention from the designs, and thus no separate reduction to practice is required to complete the inventive process. In the biotechnology field, it is generally established that the conception of a DNA or RNA molecule is not complete until the nucleotide sequence itself is known, and in this instance, conception and reduction to practice are conflated⁴.

Obviously, more than one person can contribute to the conception of a single invention, thus joint inventors may be named on a patent application. The contributions of joint inventors do not have to be equal, nor do the joint inventors necessarily have to work in the same laboratory or even at the same institution. Furthermore, their contributions to the invention do not have to be made at the same time. Joint inventors each enjoy the same inventorship rights in the entire invention, regardless of the relative amount each actually contributed. Thus, each of them, or their respective assignees, can market or license the invention without obligation to share their profits with the other.

The claim's the thing

Because an invention is defined by its 'claims,' the inventive entity of a given patent application may change during prosecution, that is, during the time when the application is being evaluated for patentability by a patent examiner. Claims are numbered statements at the end of a patent application or patent in which precise language is used to set forth the exact metes and bounds of an invention. The often lengthy descriptions, explanatory materials and examples preceding the claims are called the 'specification.' Regardless of who contributed

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material in the specification, inventorship is based solely on the subject matter encompassed by the claims. Each person named as an inventor must have made an inventive contribution to at least one, but not necessarily more than one, of the claims.

At times, the inventive entity in a patent application has to be changed. Let's consider a hypothetical patent application that describes newly cloned recombinant DNA encoding protein ABC, purified recombinant ABC protein and methods for treating acne by administering ABC. Let's assume further that John cloned and sequenced the ABC DNA with the help of his technician, Lois, who had creatively overcome an unexpected technical roadblock that otherwise would have sabotaged the cloning project. John's colleague Sharon discovered that ABC was useful for treating acne. The claims section of this patent application includes one or more separate claims for each of these three aspects of the invention, that is, the DNA, the protein and the use of the protein for treating acne. When the application is first filed, John, Lois and Sharon are named as inventors. However, the patent examiner notifies them that he regards the DNA claims, the protein claims and the method of use claims as 'separate inventions,' and requires the restriction of the claims to one of these categories. The applicants are permitted to pursue the other categories of claims in separate 'divisional' applications based on the same specification. If the claims for treating acne are withdrawn in response to the examiner's restriction requirement, the attorney or agent prosecuting the case must remove Sharon's name from the inventive entity. Similarly, if a divisional application is filed claiming only the method of treating acne, then Sharon should be named as the sole inventor.

Throughout the prosecution of any patent application, claims often are amended in order to satisfy concerns about patentability raised by the patent examiner. Thus, if the claims are amended so that an inventor's contribution is entirely eliminated from the claims, the inventive entity must be corrected to remove that person's name.

When a player is not an inventor

Imagine a hypothetical scenario featuring Sally, a postdoctoral fellow, and two of her coworkers. Sally worked in a lab headed by Dr. Bob, who was widely known for his discovery of compound X. Through a collaboration with a large drug company, Bob had demonstrated the usefulness of compound X for treating kidney stones. Until Sally arrived in his laboratory, neither Bob nor anybody else had ever postulated the use of compound X for treating diseases other than kidney stones. Nonetheless, after her work with cell cultures uncovered previously unknown pharmacologic properties of compound X, Sally proposed that compound X would be effective in treating obesity.

Sally wished to confirm her hypothesis using certain mice that are regarded as a well-established animal model for testing drugs that induce weight loss. She wrote a protocol for a controlled experiment using these mice and gave it to Dr. Bob for review. The next day, she took a temporary leave of absence for a long-planned trip around the world. After Sally had left, Bob concluded that the basis for her prediction was convincing. Impatient to see whether the drug truly would induce weight loss, he ordered the special strain of mice and assigned his lab technician, Tommy, the task of conducting the experiment Sally had designed. Bob helped Tommy choose which syringes to use and how to graph the data comparing the weights of the test mice and control mice. When the experiment yielded positive results, Bob drafted a paper for a medical journal, naming himself and Tommy as authors and thanking Sally for suggesting the experiment.

Fully aware of the commercial value of a new obesity treatment, Dr. Bob contacted his university's technology transfer department about filing a patent application. The university in turn engaged a patent attorney to draft and file a patent application claiming the use of compound X to induce weight loss. Upon investigation of the circumstances, the attorney had to conclude that only Sally should be named as an inventor, not Tommy or Bob. Sally was an inventor because she had conceived the idea

for the new treatment, and implementation of the experiment she designed required only skills that were common knowledge in her field of research. Tommy was not an inventor because he was just 'a pair of hands,' merely carrying out routine procedures that required no inventive contribution. And Bob was not an inventor because he did not participate in the conception of the invention, but merely acted as a catalyst for the execution of Sally's experiment. The guidance that Bob provided to Tommy did not amount to an inventive contribution.

Were the circumstances somewhat different, Tommy or Dr. Bob might also have qualified as inventors. This would be so, for example, if one of them had determined that weight loss could be greatly enhanced if a second active agent were administered in combination with compound X, and claims to this effect were included in the patent application.

Summary

To be valid and enforceable, a patent must correctly identify the inventors who conceived of the subject matter claimed. Not all participants in an inventive effort meet the legal standard for inventorship, which focuses on the mental act of conception rather than on technical contributions. Correction of inventorship is possible when errors in inventorship are discovered, or when changes in inventive entity are necessitated by amendment of the claims in a pending patent application. With significant marketing or licensing revenue potentially at stake, the accurate identification of inventors is imperative. The task of identifying the correct inventive entity is often complex, and is best left to a professionally qualified patent agent or patent attorney.

1. Title 37 §1.48 of the Code of Federal Regulations provides instructions for how to correct the inventive entity of a pending patent application, and Title 37 §1.324 sets forth the procedure for correcting inventorship in an issued patent.
2. *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1930).
3. *Hiatt v. Zeigler*, 179 USPQ 757, 763 (Bd. Pat. Inter. 1973).
4. *Amgen v. Chugai*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991); *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993).

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