

PATENTS

Protecting the patentability of your collaborative research

Collaborations are great. But who gets the patent rights?

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Whether an invention is patentable depends—among other things—on its novelty and nonobviousness in view of the prior art¹. Prior art for an invention is generally the published information available before the date of filing the patent application. The significance of publications as prior art is, in general, well understood in the scientific community.

What is often unappreciated, however, is what constitutes prior art among collaborating researchers. In collaborations, there are separate rules for defining prior art, depending on who was participating in the project, when they became actively involved, and what agreements were in place at the commencement of their collaboration. As joint research products between academic institutions and industry increase, one is well advised to understand the nuances of prior-art rules for these collaborations. Unfortunately, failure to be forewarned may defeat the patentability of your promising invention.

The inventive entity

We habitually think of an “inventor” as a single individual. But, in the eyes of the US Patent and Trademark Office (PTO; Washington, DC), “an inventor” can be an individual, two persons working in collaboration, or even a group of collaborators. For the purposes of patent law, then, it is more helpful to think of an “inventive entity” rather than a solo inventor when considering authorship of a patent².

Inventive entities, unlike individuals, change every time their participating members increase or decrease in number. Thus, the work of professors Able and Baker constitutes the work of one inventive entity (A+B). But when Dr. Crane joins the project, an entirely new inventive entity (A+B+C) is created³. In the same manner, if Dr. Crane left the project and was replaced by Dr. Doom, a new inventive entity would be created (A+B-C+D).

Understanding this definition of inven-

tive entity is important in assessing the patentability of a new invention, because the PTO can use the work of a first inventive entity to deny a patent to a second inventive entity, even when there is overlap among the membership of the two inventive groups.

How is this possible? Take for example our hypothetical professors, Able and Baker. Together, they identify a mutated form of a gene. They then invite Dr. Crane, an expert from a neighboring medical center, to join in their research. Together, the three researchers confirm an association between the mutant allele and a particular cancer, and develop diagnostic assays based on these findings. A patent application is filed claiming both the isolated DNA having the mutant sequence and the diagnostic assays.

Now, in the eyes of the PTO, the isolated DNA mutant was invented by the first inventive entity—Able and Baker (A+B). The diagnostic assays, on the other hand, were subsequently invented by Drs. Able, Baker, and Crane (A+B+C)—a completely different inventive entity. As a result, when examining the patent application, the PTO may decide that the work of inventive entity A+B makes the later work of A+B+C obvious and, therefore, not patentable³.

Yes, it is true that Able and Baker never published their findings before bringing in Dr. Crane to work on the project. But the PTO views this type of work as “secret prior art”⁴—secret because it has not been published or otherwise publicly disclosed, yet still “prior art” available to the patent office. It does not matter that the prior work was never published, or that the patent application in question describes and claims the work of A+B as well as A+B+C. In this hypothetical situation, collaboration with a colleague from a neighboring institution turned existing work into prior art against any new invention arising from the inter-institutional collaboration⁵.

Avoiding the “secret” pitfall

How can one avoid this potential PTO rejection without being forced to do all the work by yourself? In the hypothetical example discussed, Able and Baker might have eliminated this possible rejection, if instead of inviting Dr. Crane from a neighboring uni-

versity, they had invited Dr. Doom—a member of their own institution. Why?

Most employment agreements include the obligation to assign inventions to the employer. Since Professors Able and Baker and Dr. Doom are all employed by University Xenophobe, they were contractually obligated to assign their inventions to the university. If at the time the subsequent invention is made, the common ownership (or common obligation to assign ownership) exists among all the members of the inventive entity—the previous work cannot serve as prior art against the later invention⁶.

Professors Able and Baker got into trouble in the hypothetical example because their work is owned by University Xenophobe, whereas the later invention arising out of the collaboration with Dr. Crane of Zenith University will be owned jointly by Universities Xenophobe and Zenith. Because the inventorship of the previous invention is different from that of the later invention, the previous work of A+B can properly be cited by the PTO as prior art against the collaborative invention of A+B+C. Furthermore, because there was no common ownership or duty to assign at the time the A+B+C invention was made, the A+B+C invention must be shown to be patentable (novel and nonobvious) over the work of A+B.

It is important to note that, in the eyes of the PTO, a transfer of ownership rights after the invention in question is made will not be sufficient to disqualify previous work of a different inventive entity as prior art.

A question many inventors in this situation have is, “If secret prior art is defined by who owned what invention and when, how does the patent office ever discover secret prior art in the first place?”

Patent applications that list joint inventors also typically list a multitude of claims. These claims do not indicate which inventors contributed to which claim, or the timing of invention. Indeed, where a patent application names joint inventors, the PTO presumes that the claimed inventions were commonly owned at the time they were made. But when common ownership is not the case, it is the patent applicants’ duty under the law to disclose the inventors and invention dates of any claimed invention

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that was not commonly owned at the time a later claimed invention was made⁷. If one does not perform this duty, the patent may later be invalidated during infringement litigation where potentially millions of dollars could be at stake.

An insurance policy against this outcome is the daily documentation of progress in witnessed laboratory notebooks. Well-kept notebooks allow the determination of dates and inventorship with a of time and expense⁸.

Planning your collaboration

Obviously, the best way to avoid creating "secret prior art" by collaboration is to take steps before the start of any collaborative work. As the moment of invention can only be seen in hindsight, the obligation to assign to the same institution must be in place when collaboration begins.

But what happens if it is absolutely necessary to make a collaboration outside your institution? One common mistake is to assume that in industry–university, or university–university collaboration, "secret" prior art objections can be overcome by having an agreement in place at the outset that any or all patent applications will be assigned to a particular institution. The problem with this is that by the time a patent application is prepared the invention has already been made, and the secret prior art invalidation may already be in effect.

One way around this is that collaborating inventors from different institutions agree to assign all inventions to a joint venture created especially for the project at the beginning of the project. Alternatively, they may agree to assign all inventions arising out of the project to a single institution. All collaborators joining the project at a later date would then similarly agree to assign to the same entity.

Another way to handle this is to create an obligation to assign joint owners. For example, consider a first inventive entity consisting of researchers from two institutions, who are obligated to assign ownership to their respective institutions who own the invention jointly. If these individuals are later joined by additional inventors from either (or both) of these institutions, the obligation to assign has not changed, as the second inventive entity is obligated to assign to the same two institutions as the first inventive entity⁹.

Should this law be changed?

Many inventors, particularly those that have seen their invention invalidated through this secret prior art invalidation, wonder how the US patent laws evolved to this seemingly strange result? Why should "collaborations" within an institution be protected, and collaborations between institutions penalized? Surely, no one

would argue that cooperation between institutions should be hindered, or that patent laws should as a matter of policy discourage efforts to more rapidly advance science through these means. Why do the US patent laws seem to protect certain types of collaboration, but not others?

The ability to disqualify the previous "secret" work of another as prior art by showing common ownership became part of US patent law in 1984. It was intended to alleviate the burden placed on industry where ongoing research within a single corporate entity may be started by one employee and continued by another. Why would they need this type of special protection? The requirement for common ownership at the time a later claimed invention is made is intended to prevent a company or institution from "buying up" prior work in order to disqualify it as prior art¹⁰. Such "buying up" could result in information that would otherwise enter the public domain becoming the proprietary property of the purchaser. The law was designed to require assignments of these rights to be sufficient to establish that the invention resulted from an ongoing internal research project. Collaborating researchers from different institutions can also use these standards to avoid the creation of certain types of prior art, but the rules are not specifically tailored to use in interinstitutional settings.

Critics of the law suggest that the law is misguided in that such protected intrainstitutional work is not a true collaboration in the first place. Furthermore, they claim that the requirement of common ownership does comport with both the definition of joint inventors, and the "first-to-invent" policy underlying the US patent system.

The fundamental requirement for joint inventors is that there be some form of collaboration. Under this definition, two researchers can be joint inventors only by having collaborated on the claimed invention. The inventors need not "physically work together or at the same time, . . . make the same type or amount of contribution, or . . . make a contribution to the subject matter of every claim of the patent"¹¹.

However, if two inventors simultaneously but independently invent the same product, under the "first to invent" policy, they cannot—upon discovering each other's work—agree to file a single patent application naming both individuals as inventors. Under US patent law, patents issue only to the true first inventor¹². Two simultaneous, but independent, inventors who find themselves in this situation must each file their own patent applications and then file an interference to determine who was the first inventor.

Should the ability of the PTO to use "secret prior art" in rejecting inventions as

obvious¹³ be changed? This situation could be negated by simple amendment of the patent laws. Supporters of such an amendment say that this would bring US patent law into line with the European model in this regard. Opponents suggest that this would encourage the purchase of "prior-art" information—removing it from the public domain—and therefore would be at odds with the purpose of the patent system. A compromise position has been suggested in creating a protected category of academic research or collaboration among nonprofit institutions that would be defined by law. However, the complexity of implementing such legislation over the objection of the current law's supporters makes this an unlikely event in the near future. For now, the best course of action is to understand existing law, and use it to your advantage.

1. Johnson, E.A. 1996. A benchside guide to patents and patenting, *Nature Biotechnology* 14:228–291. This discusses four criteria by which patentability is assessed: Novelty, nonobviousness, sufficiency of the disclosure, and utility. See also Linck, N.J. and Chambers, S.A. 1995. Utility in biotech patent applications, *Bio/Technology* 13:962.
2. Naming correct inventors on a patent application can require its own investigation. "Inventor" is a legal category; authorship on a publication does not necessarily establish inventorship. We do not mean to imply herein that membership in a research group automatically confers inventorship status. See Rzuicido, E.C. and Auth, D.R. Will the real inventor please stand up?, *Nature Biotechnology* 14:358–359.
3. What is prior art is defined by 35 USC. §102; prior art is used by the PTO in rejecting claims as obvious under 35 USC. §103.
4. The term "secret prior art" is not a term of art. It is most often used to refer to patent applications pending in the PTO, which are not published. Once a patent issues on an application, however, that patent is effective prior art as of the application filing date, even though a member of the public could not have gained access to the United States application before issuance of the patent. See 35 USC §102(e). In contrast, most other countries publish patent applications at some set time after the filing date.
5. The previous work may be defined as prior art under 35 USC. §102(f) (subject matter invented by another) or §102(g) (the invention was made in the US by another before the applicant's date of invention).
6. 35 USC. §103(c) states: "Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."
7. See MPEP §706.02(m).
8. See Superko, C. Habits of highly successful international patent applicants. *Bio/Technology* 14:41–42.
9. See MPEP §706.02(i), which states that "the terms 'person' and 'organization' in [37 CFR §1.104] would include circumstances where the ownership resided in more than one person and/or organization as long as the applications are owned jointly by the same owners."
10. MPEP §706.02(j).
11. 35 USC. §116.
12. The "first-to-invent" system of the United States contrasts with most foreign countries, where the first inventor who files a patent application is entitled to the patent which issues for that invention, even where another person independently invented the same item at an earlier date, but filed a later application.
13. I.e., the ability to use 35 USC §102(f), (g) and (e) prior art in making §103 obviousness rejections.