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Who Owns That Patent? Do Your Interactions with Others Jeopardize Your Patent Ownership?

Landslide
Vol. 12, No. 2
November/December 2019

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Patent rights form the backbone of many companies' business plans, and yet companies often do not adequately consider the risks to their patent estate when they interact with third parties. This article will discuss how third-party interactions can jeopardize a company's exclusive patent ownership.

Companies often hold pre-agreement technical discussions that do not end in a formal collaboration agreement. These initial technical discussions may follow a nondisclosure agreement (NDA). But NDAs too often do not include patent ownership or control provisions. What happens when these initial technical discussions spark an innovation? Companies may also receive feedback from customers on their products. Who owns an invention when a customer makes an impactful product-improvement suggestion? Or when a peer at a scientific meeting gives feedback on a poster presentation that changes the direction of the research? Finally, scientists themselves change jobs and might have the germ of an idea developed before leaving a first employer to join a second. When does conception occur?

In today's innovation culture and dynamic business environment, scientists from different organizations participate in intellectual exchanges that can lead to new inventions. This can result in unintended consequences for patent ownership. Many practitioners incorrectly believe that they can rely on contract solutions to address all third-party inventorship problems. While most practitioners include patent ownership and prosecution control clauses in formal collaboration agreements with academic groups or other companies, few practitioners include these terms in agreements governing all potential interactions with third-party scientists.

Patent validity requires correctly naming inventors, and ownership generally follows inventorship (at least initially). Companies, both large and small, need to avoid, whenever possible, third-party inventors without adequate patent ownership agreements in order to prevent a potential loss of full rights to their inventions.

Most companies recognize collaborative relationships with third parties as valuable, even essential, but potential patentees need to more carefully consider both contractual solutions and the nature of third-party interactions in order to avoid future ownership disputes.

Reviewing recent inventorship case law shows the complexity of third-party interactions and their impact on inventorship. The case law also hints at the potential for different inventorship determinations and the potential for both inventorship confusion and unintended ownership consequences. As seen in the cases discussed below, preliminary collaborative discussions between parties can spur an invention. Disputes about the exact timing of an invention follow inventor job changes because both the former employer and the current employer want to own the invention in question. Even a seemingly simple suggestion may rise to the level of inventorship. Finally, disputes over inventorship have unpredictable outcomes, and a resulting loss of exclusive ownership can lead to a significant loss of revenue for a company.

Risks from Early Discussions: *Eli Lilly v. Aradigm*

Eli Lilly & Co. v. Aradigm Corp.[1] demonstrates the potential hazards of engaging in preliminary discussions prior to a collaboration focused on improving insulin administration.

When a patient injects human insulin subcutaneously, it does not start working for up to 30 minutes.[2] Lilly had developed a human insulin analog with faster bioavailability, called lispro. Aradigm, meanwhile, developed aerosols for drug delivery to the lungs. During several preliminary meetings, scientists from Lilly and Aradigm discussed the possibility of delivering insulin to the lungs using Aradigm's aerosol technology.[3] In these meetings, Lilly discussed using the lispro form of insulin in the aerosolized delivery system. Lilly and Aradigm, however, did not enter a formal collaboration, and went their separate ways.

Aradigm then filed a patent application claiming methods for improving bioavailability of insulin delivered to the lung using an aerosolized insulin analog (identified as lispro in a dependent claim). After the patent issued, Lilly sued, seeking to have two of its scientists who participated in the precollaboration meetings named as joint inventors on the patent. The claim at issue required that a method of aerosolized delivery produce a relative bioavailability of lispro that is greater than twice that of aerosolized human insulin. Although Lilly's scientists discussed using lispro in general during the precollaboration meetings, Aradigm argued that only its scientists found that using aerosolized lispro provides a twofold or greater bioavailability compared to insulin.[4] Lilly failed to show that its scientists communicated a relative bioavailability of lispro that is greater than twice that of aerosolized human insulin.

The court stressed the need for actual collaborative efforts in joint inventorship under 35 U.S.C. § 116, pointing to "some open line of communication during or in temporal proximity to their inventive efforts."[5] Here, Lilly merely provided a suggestion to try lispro in Aradigm's inhalation devices, and therefore the Federal Circuit concluded that the Lilly scientists were not inventors.[6]

This case provides a cautionary tale about transferring information or ideas without a concrete agreement in place or without exerting appropriate control over the flow of information between parties. Collaborators frequently resist addressing patent ownership in an NDA or other early stage collaborative agreement. Some assume that no patentable inventions will arise from the collaboration, while others believe that they will

1. 376 F.3d 1352 (Fed. Cir. 2004).
2. *Id.* at 1355.
3. *Id.* at 1356–57.
4. *Id.* at 1364.
5. . *Id.* at 1359.
6. *Id.* at 1363–64.

enter into a more formal agreement to address patents and other intellectual property issues at a later stage, should the collaboration proceed. *Lilly* shows the pitfalls of this approach because the parties might not enter into a more formal agreement and may, in fact, discuss patentable ideas at the NDA stage. *Lilly* also shows that the failure to sufficiently address inventorship opens a company up to the risk that a third party will proceed with a patent on its own. Practitioners can prevent these potential disputes by handling ownership up front and before any collaborative efforts begin. Companies should, as early as possible in any collaborative process, execute agreements defining patent ownership and control, including assignment obligations, cost burdens, and prosecution cooperation clauses.

Establishing When Conception Occurs: *Dawson v. Dawson*

Even in the best of situations, practitioners cannot create contract solutions to all third-party inventorship problems. In *Dawson v. Dawson*,[7] the inventor changed employers during the process of making a new invention, leading to an inventorship dispute arising from his work allegedly done *prior* to joining a company. While at a first employer, the University of California, San Francisco (UCSF), Dawson proposed topically treating trachoma, an eye infection, with the azalide antibiotic azithromycin. Dawson presented his proposal at a World Health Organization (WHO) meeting, and the WHO subsequently released a WHO report containing a discussion of the proposal. The report pointed out challenges in identifying an appropriate delivery vehicle, and listed several possibilities, including a topical ophthalmic ointment called Durasite. This report further noted that dosing, efficacy, toxicity, and pharmacokinetics required further study.[8] Dawson allegedly continued some efforts to develop a formulation, including reaching out to Bowman of InSite, an ophthalmic drug company.

Later, Dawson joined InSite, where he worked with Bowman on developing an azithromycin ophthalmic ointment. Dawson and Bowman filed two applications covering their formulations. The specifications of both patents highlight the challenges faced in developing topical eye treatments. UCSF filed a substantially identical application, thereby provoking two interferences. One interference count was directed to treating eye infections with a topical antibiotic at a specific dose, and the other count was directed to "topically applying an azalide antibiotic to an eye in an amount effective to retard or suppress infection in a tissue of the eye."[9]

In considering when Dawson invented and who was a coinventor, the court pointed out that the WHO report merely "announce[d] a general idea, acknowledge[d] many of the difficulties associated with making that idea operative, and offer[ed] some thoughts on how one might proceed (including by listing a few potential delivery vehicles)."[10] The court considered that the potential use described in the WHO report "falls short of a 'definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'"[11] UCSF produced no evidence that Dawson had determined the specific dosages recited in the first interference count, nor "an amount effective to treat infection in a tissue of the eye" in the second interference count. Accordingly, the court found that Dawson had only a general idea or a research plan during his UCSF employment; therefore, UCSF was not entitled to ownership. Instead, the Federal Circuit concluded that Dawson and Bowman developed the dosage aspects of the invention during their work together at InSite.

Judge Reyna's dissent in this case, however, shows the challenges in differentiating between a research plan and a conception. Judge Reyna concluded that Dawson had completed the conception of the invention by

7. 710 F.3d 1347 (Fed. Cir. 2013).
8. *Id.* at 1348.
9. *Id.* at 1351.
10. *Id.* at 1353.
11. *Id.* (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)).

the time of his WHO presentation, while still employed by UCSF.[12] Specifically, Dawson had "a settled idea to solve a particular problem" and had decided to administer topical azithromycin in one of several vehicles that are administered as a drop and persist in the eye, including the vehicle Durasite.[13] Judge Reyna also concluded that Dawson had identified a dosage for azithromycin by suggesting to use the same dosage as an alternative antibiotic for treating the eye, noting that this was, in fact, one of the dosages recited in the patent specification. Because invention is the work of the mind and does not require a physical embodiment of the invention, Judge Reyna's dissent found that Dawson had completed his invention while at UCSF.[14] Judge Reyna further explained that the "WHO presentation manifested an inventive embryo which thereafter sought deliverance [and] . . . [a]ll that was left was the work of the mechanic—that is, reduction to practice."[15] This dissent illustrates the challenge in interpreting when conception has occurred and the risks the parties have that a court will make an unexpected decision.

Dawson shows both the risks inherent in changing employment affiliations and the importance of diligence in filing applications, particularly in the post-America Invents Act world. If UCSF had obtained an invention disclosure before Dawson left the university and filed an application based on that disclosure before he became employed by InSite, UCSF may have been able to obtain rights in the invention. Employers should carefully conduct exit interviews with their departing scientists to ensure they have obtained all possible invention disclosures and should file patent applications based on those invention disclosures. Having a fully developed record of the scope of an inventor's idea before his or her departure for a new employer can also help to demonstrate that the idea was, in fact, a complete conception instead of simply a research plan. Filing the patent application not only beats the next employer to the patent office, but it also provides substantially better evidence of conception than many other types of documents.

Turning to the new employer or collaborator, practitioners should carefully assess what aspects of an invention might have predated a new employment or collaboration relationship. To maintain ownership and control of a patent application, the new employer should ensure that the patent application contains claim limitations that go beyond the original idea. In order to establish that an invention differs from a mere idea or research plan, applicants can use the specification to explain the challenges inventors overcame between the initial research plan and actual conception. Applicants can differentiate a conception from a research plan by describing what was missing from the research plan, such as method steps, reagents, reaction conditions, structural features, amounts, or dosing. Additionally, negative data can show that the inventor, subsequent to joining the new institution, faced challenges implementing the idea or research plan. Thus, the specification can tell the story of initial failures and eventual success on the road to a complete conception. Adding limitations to an invention can change the date of conception. Of course, in some instances, a new employer will have to decide whether claim breadth and a possible license provides more benefit than narrower claims. Because employees frequently change jobs, employers at all stages need to watch for the potential impact on patent ownership.

Merely Suggesting Can Rise to the Level of Inventorship: *In re VerHoef*

In re VerHoef[16] shows how a simple suggestion can rise to the level of inventorship, changing the ownership of a patent. Lamb, a veterinarian, was treating VerHoef's dog for difficulty walking, known as "knuckling," in which a dog drags a back paw, thereby placing weight on the knuckle. Lamb recommended a commercially available harness that supports the hind leg, but it still did not prevent knuckling in VerHoef's dog. VerHoef believed that if the harness could connect to the dog's toes instead of the ankle, it would work. During a

12. *Id.* at 1357 (Reyna, J., dissenting).
13. *Id.* at 1357–58.
14. *Id.* at 1359.
15. *Id.* at 1360.
16. 888 F.3d 1362 (Fed. Cir. 2018).

therapy session with the dog, VerHoef told Lamb "[t]here has to be a way to connect the cord to the toes."[17] Lamb then recommended arranging a strap in a figure eight to fit around the toes and wrap around the lower part of the leg, above the paw. VerHoef then proceeded to make a harness including Lamb's suggested figure eight strap and ultimately designed a harness that successfully prevented the knuckling problem.[18]

VerHoef engaged a patent attorney to file an application directed to the harness, listing himself and Lamb as joint inventors. Thereafter, their relationship soured, and VerHoef's attorney abandoned the joint application and refiled a substantially identical application listing VerHoef as the sole inventor. VerHoef's application included the recitation of the figure eight strap. Lamb also filed her own application.

The examiner rejected VerHoef's application under § 102(f) for failing to name Lamb as an inventor, and VerHoef ultimately appealed this decision. In reviewing joint inventorship, the court observed that a joint inventor must:

1. contribute in some significant manner to the conception or reduction to practice of an invention;
2. make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention; and
3. do more than merely explain to the real inventors well-known concepts and/or the current state of the art.[19]

The Federal Circuit concluded that both VerHoef and Lamb were inventors of the claimed invention because the figure eight loop was an essential feature of the invention expressly recited in the claims, meaningfully distinguishing the invention from the prior art.[20]

Furthermore, the Federal Circuit clarified that joint inventors do not have to contribute equally to a claimed invention.[21] *VerHoef* demonstrates the potential consequences of an unplanned third-party interaction that leads to a potentially patentable product. In instances when a third party makes a valuable contribution to the conception of an invention, practitioners may wish to obtain an assignment of rights for appropriate compensation or an exclusive license as soon as possible while the parties still have a positive relationship. In situations where companies seek feedback on products from customers, they may wish to consider including assignment-of-invention clauses in shrink-wrap labels that assign rights to any inventions a customer submits to the company as a product suggestion.

Financial Repercussions of Inventorship Disputes: *Dana-Farber v. Ono Pharma*

As seen in the recently decided *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co.*[22] case in the U.S. District Court for the District of Massachusetts, inventorship suits can have significant financial repercussions. In the *Dana-Farber* case, scientists from three organizations collaborated together to make an immuno-oncology invention. Honjo (from Ono Pharma), Freeman (from Dana-Farber), and Wood (formerly of Genetics Institute) worked together to characterize the relationship between cancer and two proteins (PD-1 and PD-L1).[23] The parties initially had a positive relationship and executed some written material transfer agreements and collaboration agreements between their organizations, but the relationships

17. *Id.* at 1364.
18. *Id.*
19. *Id.* at 1366 (citing *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998)).
20. *Id.*
21. *Id.*
22. 379 F. Supp. 3d 53 (D. Mass. 2019).
23. *Id.* at 80.

took a turn for the worse over the filing of patent applications and who was named an inventor.[24] The district court opinion does not elaborate on whether the agreements failed to address ownership or had different ownership terms for joint vs. sole inventions.

Patents issuing from applications filed by Ono Pharma naming Honjo (but not Freeman and Wood) as an inventor were issued and licensed by a company later acquired by Bristol-Myers Squibb Co. (BMS).[25] This license ultimately led to the marketing of anti-PD-1 monoclonal antibodies as treatments for cancer.[26] BMS launched Opdivo (nivolumab), which had sales of $4.9 billion in 2017 and $6.7 billion in 2018.[27] Other pharmaceutical companies, including major players, also have targeted this lucrative market with their own anti-PD-1 and anti-PD-L1 antibodies, including Merck, Regeneron, Novartis, Tesaro, Roche Genentech, and AstraZeneca, and have been subject to patent infringement lawsuits by BMS.[28]

The district court found that Freeman and Wood should, in fact, have been named as inventors on the patents in question. While Pfizer (the successor in interest to Genetics Institute) settled with Ono Pharma,[29] Dana-Farber now has rights to make, use, and sell the patented inventions (or, more significantly, to license these rights). And because Dana-Farber has a policy of not granting exclusive licenses,[30] it may now license its rights to the multiple companies that have developed anti-PD-1 and anti-PD-L1 antibodies, potentially eviscerating all of the exclusivity that BMS licensed from Ono Pharma. Thus, this inventorship decision has the potential to dramatically change the commercial landscape for this technology and result in a significant loss of revenue for BMS.

Conclusion

These real-world scenarios demonstrate some of the risks to patent ownership that may arise during third-party interactions, and also provide guidance for protecting a company's interests. Practitioners should carefully consider the implications of interactions with third parties that might lead to an invention, evaluating risks from inadequate agreements and patent application filing practices. Practitioners should also ensure their clients have agreements addressing patent ownership and control before any exchange of ideas occurs. Ideally, ownership results should adequately address a client's business needs irrespective of who gets named as an inventor on any resulting patent applications. Companies that solicit feedback on products from customers may wish to include assignment clauses in agreements with their customers. Scientists should also limit interactions between third parties and their own corporate invention team, closing lines of communication and avoiding using third parties as sounding boards.

When drafting an application, the specification should delineate the conception from any earlier research plans proposed by third parties (or when employees were working for a prior employer). The specification should outline any missing elements in the research plan, ensure that the claims recite these missing elements, and explain any challenges the inventors overcame between the original tentative idea and the complete conception of the invention. Finally, practitioners should ensure that each independent claim has a feature developed solely by their client and that the application claims retain this element throughout prosecution.

Innovation benefits when scientific teams can exchange ideas and work together, but in this increasingly collaborative environment, practitioners must carefully guard against unexpected surprises for patent

24. *Id.* at 60, 70, 76.
25. *Id.* at 77.
26. *Id.*
27. *Id.*
28. *Id.* at 77–78.
29. *Id.* at 87.
30. *Id.* at 78.

inventorship and ownership.