

Patent ownership or lack thereof: Lessons learned from *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* and *Edwards Lifesciences AG v Cook Biotech Incorporated*

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The implications of incorrectly drafting agreements to acquire intellectual property rights were once again highlighted by two recent court decisions. A decision from the Court of Appeals for the Federal Circuit and another from the High Court of Justice, Chancery Division Patents Court, United Kingdom demonstrate the importance of correctly determining patent ownership prior to litigation and the role that employment agreements have in determining patent ownership. In both cases, errors in ownership may have cost the respective patentees millions of dollars of revenue from the loss of enforceable patent rights, licensing revenue and/or unsuccessful litigation. More importantly, simple steps on the part of the entities involved, or their respective counsel, could have prevented these losses.

In the first case, *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*,¹ from the Court of Appeals for the Federal Circuit, the Court held that Board of Trustees of Leland Stanford Junior University ("Stanford") lacked standing to assert a claim of infringement against Roche Molecular Systems, Inc. ("Roche"), because Stanford did not possess all ownership interests in the asserted patents.² This was despite the fact that Stanford had obtained and recorded what it believed to be a valid Assignment of rights from all the inventors.³ However, fatally for Stanford's lawsuit, the inventors' employment agreements had not been drafted in light of current Federal Circuit law with the language needed to affectively transfer inventors' rights without further action.⁴ The agreement included an assignment clause; however, the assignment clause included the recital of "I will assign," instead of "I do hereby assign."⁵ The Court interpreted the agreement as a promise to assign the rights in the future rather than an instantaneous transfer of rights.⁶ In fact, prior to Stanford obtaining the Assignment, an inventor of the patents in suit had assigned his rights (possibly unwittingly) through a confidentiality agreement to Cetus Corporation ("Cetus") (which in turn sold the rights to Roche).⁷ As such, when Stanford did obtain an Assignment, the Assignment was ineffective because the inventor did not have any residual rights to transfer, as they had all been transferred to Cetus *via* the confidentiality agreement.⁸ Thus, at the initiation of Stanford's suit against Roche, Roche was in fact the owner of some rights in the asserted patents.⁹ Sadly for Stanford, the rights that Roche now owned had been given up prior to the filing of any patent application, and there was nothing that Stanford could have done to retroactively secure those rights.¹⁰ However, Stanford's rights could have been easily protected by drafting the employment contracts to include a provision for a present assignment of rights (*e.g.*, "I hereby assign").

In a second case, *Edwards Lifesciences AG v Cook Biotech Incorporated*,¹¹ from the United Kingdom, the lack of any agreement between non-employee inventors may have cost Cook Biotech Incorporated ("Cook") patent rights in the UK and quite possibly in any country with Patent Cooperation Treaty membership.¹² Given the increasingly global nature of the economy and the desire of many clients to assert patent rights abroad,

it is becoming increasingly important for practitioners to understand how international patent laws can affect your client's rights, particularly when foreign counsel is not involved, for example when filing an international application with the U.S. receiving office.

In *Edwards Lifesciences AG v Cook Biotech Incorporated*, the Court held that Cook had incorrectly named the applicants when filing an international patent application. Thus Cook was not entitled to claim priority to a previously filed U.S. provisional application.¹³ As a consequence of the loss of priority, intervening prior art became available and several claims of Cook's issued United Kingdom patent were ruled invalid for lack of inventive step over this prior art.¹⁴ In striking similarity to the Stanford case, once Cook had filed the international application with the incorrect applicants listed, there was nothing that they could have done to retroactively correct the situation.¹⁵ However, as in *Stanford v Roche*, it is likely that careful drafting of agreements between non-employee inventors and Cook to include a provision of present assignment would have been sufficient to confer ownership solely to Cook, in which case the correct applicant would have been named on the international application and the priority date of the U.S. provisional application maintained.

Stanford v. Roche

The dispute in *Stanford v. Roche* stems from a patent infringement suit brought by Stanford against Roche for alleged infringement of U.S. Patent No. 5,968,730, No. 6,503,705, and No. 7,129,041, all of which relate to quantifying Human Immunodeficiency Virus ("HIV) in human blood samples, and correlating those measurements to the therapeutic effectiveness of antiretroviral drugs.¹⁶ The claimed methods used the polymerase chain reaction ("PCR")¹⁷ to measure ribonucleic acid ("RNA") from HIV in the blood plasma of infected humans who are taking antiviral drugs.¹⁸ All three patents in suit were descendent from a common parent application and several common inventors, including Dr. Holodniy.¹⁹

A central issue in this case was whether Stanford had standing to bring suit against Roche, as the sole entity that owns or controls all the rights of the patents in suit, because only the "entity or entities that own or control all substantial rights in a patent can enforce rights controlled by that patent, lest an accused infringer be subjected to multiple suits and duplicate liability."²⁰ After initiation of the suit by Stanford, Roche counterclaimed that it in fact owned the rights of one of the inventors (Dr. Holodniy) listed on the patents in question, by virtue of its purchase of the PCR business of Cetus, with which Dr. Holodniy had signed a confidentiality agreement that included a patent assignment clause.²¹

Dr. Holodniy had signed three documents defining his obligations to assign his rights in the subject inventions.²² First, upon joining Stanford, Dr. Holodniy executed a copyright and patent agreement ("CPA") on June 28, 1988.²³ Next, Dr. Holodniy began visits to Cetus, where he signed a visiting scientist confidentiality agreement ("VCA") on February 14, 1989.²⁴ Finally, Dr. Holodniy executed an Assignment of his rights in the subject patent applications to Stanford on May 4, 1995.²⁵

While "the question of who owns the patent rights and on what terms typically is a question exclusively for state courts"²⁶, the Court noted that an exception to this rule is created, when "the question of whether contractual language effects a present assignment

of patent rights, or an agreement to assign rights in the future," further stating "the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is intimately bound up with the question of standing in patent cases. We have accordingly treated it as a matter of federal law."²⁷

At issue was the language of the first two agreements, and what rights Stanford or Cetus had gained when Dr. Holodniy signed the two agreements. Paragraph 2 of the CPA with Stanford recited: "I agree to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in ... such inventions as required by Contracts or Grants."²⁸ Citing its decision in *IpVenture, Inc. v. Prostar Computer, Inc.*, the Court held the language "agree to assign" was only a promise to assign rights in the future not an instantaneous transfer of rights.²⁹ In *IpVenture*, the Court had found identical language as an agreement to conduct future action that required a subsequent action, for example a formal Assignment.³⁰ Therefore, in signing the CPA, "[Dr.] Holodniy agreed only to assign his invention rights to Stanford at an undetermined time."³¹ Stanford may have believed that this subsequent action occurred when it obtained Dr. Holodniy's Assignment of rights on May 4, 1995.³² However, this was not the case, because between the time Dr. Holodniy signed the CPA and the Assignment, he had signed the VCA with Cetus.³³

Turning to the VCA with Cetus, in contrast with the CPA, paragraph 3 of the VCA recited: "I will assign and *do hereby assign* to CETUS, my right, title, and interest in each of the ideas, inventions and improvements."³⁴ The Court concluded that the VCA's language of "do hereby assign" effected a present assignment of Holodniy's future inventions to Cetus.³⁵ Therefore, Cetus immediately gained title to Dr. Holodniy's inventions at the time the VCA was signed.³⁶ Because Cetus' legal title vested prior to Dr. Holodniy executing the Assignment to Stanford, he had no rights left to assign and the Assignment to Stanford had no legal effect.³⁷

Edwards Lifesciences AG v Cook Biotech Incorporated

Edwards Lifesciences AG ("Edwards") sought revocation of EP (UK) Patent 1 255 510 ("the 510 patent"), issued to Cook.³⁸ Cook, in turn, alleged that Edward's SAPIEN artificial heart valve infringed the 510 patent.³⁹ One of the grounds for revocation asserted by Edwards was that priority was improperly granted to a U.S. provisional application, and because the UK patent was not entitled to an earlier priority date, relevant prior art would become available which had the potential to invalidate the claims.⁴⁰

Central to the issue of entitlement of the UK patent to the priority date of the U.S. provisional application was whether the international application, which eventually matured into the UK patent, named the correct applicant.⁴¹ Cook filed a U.S. Provisional patent application, Serial No. 60/179195, January 31, 2000, listing Obermiller, Osse and Thorpe as the joint inventors.⁴² Subsequently, on January 31, 2000, Cook filed an international application (Patent Cooperation Treaty) claiming priority from the earlier U.S. application.⁴³

The international application listed only Cook as the applicant.⁴⁴ Inventor Obermiller was an employee of Cook, and it was not disputed that Obermiller's rights in the invention belonged to Cook; however, Osse and Thorpe were not employees of Cook, and their rights in the invention were only assigned to Cook in September 2002, 21 months after the international application was filed.⁴⁵ Because the international

application was filed only in the name of Cook, the Court held that the international application was not entitled to the January 31, 2000 priority date.⁴⁶ As a result of the loss of the January 31, 2000 priority date, the Pavcnik reference, published in 2000, was determined to be relevant prior art, and several of the asserted claims were found invalid as obvious over this reference.⁴⁷

In finding that the Cook patent was not entitled to the earlier priority date of the U.S. provisional application, the Court relied on its interpretation of Article 4 of the Paris Convention,⁴⁸ which governs the right of priority for international applications. The Court's interpretation of Article 4 was that "[a] person who files a patent application for an invention is afforded the privilege of claiming priority only if he himself filed the earlier application from which priority is claimed or if he is the successor in title to the person who filed that earlier application. If he is neither the person who filed the earlier application nor his successor in title then he is denied the privilege. Moreover, his position is not improved if he subsequently acquires title to the invention. It remains the case that he was not entitled to the privilege when he filed the later application and made his claim."⁴⁹ As the Court notes, this interpretation of Article 4 is also consistent with the European Patent Office's interpretation of Article 4, see decisions J 0019/87 and T 0062/05.⁵⁰

While the Court does not explicitly say so, the loss of priority may have been avoided if an agreement between the non-employee inventors and Cook had been in place. Furthermore, in many instances, European Courts will defer to the law of contract in the jurisdiction of origin to determine if a transfer of rights had occurred. Thus, in applying Federal Circuit law, the UK court likely would have construed an agreement that included a present assignment clause, such as the VCA, between Dr. Holodniy and Cetus, as an immediate assignment of rights. Had such an agreement been in place between the non-employee inventors and Cook, Edwards' challenge to the priority date would have failed.

Conclusion

In sum, assignment provisions in employment agreements should be drafted as present assignments, for example using language such as "I do hereby assign." As a prophylactic measure, it is good practice to execute a formal assignment for each intellectual property development, even where the employment agreement is properly drafted as a present assignment. However, it appears that the problems created by the language in the Stanford's CPA could not be cured after the fact, unless Cetus could have been enticed to relinquish its rights. The damage was done the instant Dr. Holodniy signed VCA with Cetus. This further illustrates the importance of carefully reviewing all agreements signed by inventors with litigation counsel before commencing suit, including agreements with outside entities. Had litigation counsel been properly informed of the CPA and the VCA agreements, it is quite possible that they would have recommended against filing suit, potentially saving Stanford substantial litigation expenses. In addition, entities with substantial collaborations with outside inventors or partners should consider educating their employees about intellectual property rights and the steps for ensuring that intellectual property rights accrue to the employer, for example by requiring all agreement to be reviewed by in house or outside counsel.

While this analysis has been written with an emphasis on employment agreement, it should be noted that other steps could have been taken by Cook to ensure the validity of the priority claim. For example, the initial U.S. provisional application and the subsequent international application could have been filed using the same applicant names. Thus, if it is not possible to transfer rights before the later application is filed, it is important to file the later application in the same names as the priority application, even if this does not accurately reflect the ultimate owner.

As a word of caution to those desiring to fix supplement deficiencies in existing agreements, for example, for current employees or independent contractors. When presenting a new agreement drafted with present assignment language sufficient to satisfy Federal Circuit law, practitioners should consult the local law in which the agreement will be enforced. While the language governing promises to assign versus present assignment is a matter of Federal Circuit law, the law governing contract formation is a matter of state law. This law varies from state to state, but some jurisdictions hold that mere continued employment is inadequate consideration to render such an agreement enforceable. In such jurisdictions, the employee or independent contractor must be provided with adequate additional consideration to make the agreement enforceable.

Ian Griswold is in his third year at Lewis & Clark Law School and is expected to graduate in December 2010. Ian would like to thank Karri Kuenzli Bradley, Ph.D., Attorney at Klarquist Sparkman, LLP, for her contributions to this Article.

Endnotes

¹ *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 583 F.3d 832.

² *Stanford*, 583 F.3d at 848-849

³ *Id.* at 842.

⁴ *Id.* at 841.

⁵ *Id.* at 842.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Edwards Lifesciences AG v Cook Biotech Incorporated* [2009] EWHC 1304 (Pat) (2009).

¹² *Edwards* [2009] EWHC 1304 (Pat) (2009) [199].

¹³ *Edwards* [82]–[100].

¹⁴ Inventive step is similar to obviousness under 35 U.S.C. 103, although the treatment of obviousness in the United Kingdom and other European countries does not mirror obviousness in the United States. "It is helpful to address an allegation of obviousness using the structured approach explained by the Court of Appeal in *Pozzoli v BDMO* [2007] EWCA Civ 588; [2007] FSR 37. This involves the following steps: (1) (a) Identify the notional "person skilled in the art". (b) Identify the relevant common general knowledge of that person. (2) Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it. (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed. (4) Ask whether, when viewed without any knowledge of the alleged invention as claimed: do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?" *Edwards* [111].

¹⁵ *Edwards* [95].

¹⁶ *Stanford*, 583 F.3d at 837

¹⁷ PCR is a biochemical technique that enables measurement of relatively small quantities of nucleic acids by iteratively and exponentially "amplifying" the nucleic acids present in a sample to detectable levels.

¹⁸ *Stanford*, 583 F.3d at 837.

¹⁹ *Id.*

²⁰ *IpVenture, Inc. v. Prostar Computer, Inc.* 503 F.3d 1324 (Fed. Cir. 2007).

²¹ *Stanford*, 583 F.3d at 841-842

²² *Id.*

²³ *Id.* at 841

²⁴ *Id.* at 842

²⁵ *Id.* at 842

²⁶ *Jim Arnold Corp. v. Hydrotech Sys.*, 109 F.3d 1567, 1572 (Fed. Cir. 1997)

²⁷ *Stanford*, 583 F.3d at 841 (and quoting *DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290 (Fed. Cir. 2008)).

²⁸ *Stanford*, 583 F.3d at 841 (emphasis in original)

²⁹ *IpVenture*, 503 F.3d at 1327; *Stanford*, 583 F.3d at 841.

³⁰ *IpVenture*, 503 F.3d at 1327.

³¹ *Id.* at 841.

³² *Id.* at 842.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Edwards* [1].

³⁹ *Edwards* [3]

⁴⁰ *Edwards* [3].

⁴¹ *Edwards* [82].

⁴² *Edwards* [84].

⁴³ *Edwards* [82].

⁴⁴ *Edwards* [85]; Unlike the United States, it is typical to file an application in the name of the entity, rather than the individual inventors.

⁴⁵ *Edwards* [82]-[100].

⁴⁶ *Edwards* [100].

⁴⁷ *Edwards* [100].

⁴⁸ *Edwards* [84].

⁴⁹ *Edwards* [95].

⁵⁰ *Edwards* [95]; Case J 0019/87, *In re Burr-Brown Corporation*, Unpublished (1988); Case T 0062/05, *GE Plastics Japan K.K. v. Koninklijke DSM N.V., Teijin Chemicals, Ltd.*, Unpublished (2006).