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Electronic Lab Notebooks as Evidence in Interference Proceedings

By William A. Holtz, Ph.D.

In the United States, the first to invent is entitled to obtain a patent on an invention. When more than one patent application is filed by different inventors or groups of inventors claiming an identical invention, the U.S. Patent Office may hold an interference proceeding to determine the first inventor(s). This determination focuses on the date of invention by establishing the competing inventors' dates of conception and reduction to practice, and potentially, the diligence of the parties to reduce their invention to practice following conception. Similarly, establishing the date of invention to determine the first to invent or to antedate prior art may be required in litigation.

Paper lab notebooks have long been accepted as evidence of invention in interference proceedings at the Patent Office. Properly kept paper lab notebooks are well suited as evidence of conception, reduction to practice, and diligence, and as proof of the contribution of parties to an invention because they provide a complete, continuous record on consecutively numbered pages containing data and results, narrative, names, dates, and signatures. Paper lab notebooks can be signed and dated by non-inventor witnesses, which is important because as a matter of law, one cannot establish the date of invention without corroboration. Further, paper lab notebooks can be stored for decades and can be authenticated by ink and paper dating.

Although paper lab notebooks will continue to be well accepted for Patent Office purposes, in many cases the advance of technology is making them obsolete for their primary purpose, that is, for use by researchers to record their results. Paper lab notebooks are not well suited to storing large data sets, are limited as to the types of graphical representations that can be included, cannot be easily shared over the Internet, and are not electronically searchable. To overcome these drawbacks, electronic notebooks are increasingly replacing paper lab notebooks.

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According to the United States Patent Office, electronic records are admissible in patent interferences: "To the same extent that electronic records are admissible under the Federal Rules of Evidence," which requires authentication by sufficient evidence that the record in question is what its proponent claims it to be. Thus, admitting into evidence electronic lab notebooks that haven't been prepared with authentication in mind may be difficult. Unless a system is in place that rules out uncontrolled access, system errors, hacking, etc., electronic lab notebooks may be subject to accusations of tampering or other alteration of files, date changes, and difficulty in proving the authenticity of signatures. In view of these potential problems in authenticating electronic records, the Court in *Lorraine v. Markle Am. Ins.*, 241 F.R.D. 534 (D. Md. 2007) warned "If it is critical to the success of your case to admit into evidence computer stored records, it would be prudent to plan to authenticate the record by the most rigorous standard that may be applied." Therefore, a custodian of electronic records should be able to establish the trustworthiness of the records being submitted by testifying to details of the computer system and software, computer policy, control of access to the system, recording and logging of changes, backup practices, and audit procedures. In short, one must provide evidence that the electronic records being submitted have not been altered from the original records, that signatures are authentic, and that dates are accurate.

Technologies have been developed to support the verification of electronically stored information and thereby satisfy the rigorous requirements of authentication. For example, the Public Key Infrastructure (PKI) uses cryptographic keys to apply authenticable digital signatures and digital time stamps to electronic documents. Also, the SAFE-BioPharma Association protocol is an example of an industry-developed standard for applying digital signatures and timestamps to electronic documents (www.safe-biopharma.org).

The switch to electronic lab notebooks appears inevitable, if it has not already occurred, in most areas of research. Although the path to widespread acceptance of the use of electronic notebooks as evidence has seen many questions raised about the reliability of computer stored records, if properly authenticated, electronic lab notebooks are admissible in patent interference proceedings and in court proceedings. However, to guarantee that electronic lab notebooks can be relied upon as admissible evidence in the future, careful thought must be given now about how to create, store, and authenticate the records, including providing foundational testimony as to the trustworthiness of the electronic records, to satisfy potential future scrutiny.

About the Author

William A. Holtz earned both his J.D. and Ph.D. from Washington University in St. Louis. As a doctoral candidate, he studied molecular mechanisms of cell death in a model of Parkinson's disease. Additionally, he has research experience working for a major biotechnology company. Dr. Holtz has published in peer reviewed scientific journals such as Journal of Biological Chemistry, Journal of Neurochemistry, Neurobiology of Disease, and Antioxidants & Redox Signaling. He uses his extensive experience in molecular cloning, DNA and RNA purification, cell culture, immunohistochemistry, protein expression, protein purification, quantitative PCR, gene array analysis, and microscopy in the preparation and prosecution of biotechnology and pharmaceutical patent applications. He can be reached at 314-552-6512 or at wholtz@thompsoncoburn.com

Supreme Court to Decide Technology Transfer Dispute Calling into Question Inventors' Rights Under the Bayh-Dole Act Thirty Years After Its Enactment

By Pamela M. Miller

This year will mark 30 years since the passage of the Bayh-Dole Act, arguably one of the most significant pieces of legislation that most Americans have never heard of[1]. The Act created a uniform patent policy among the many federal agencies that fund research[2]. The goal was to promote the utilization of inventions arising from federally funded research and to ensure that the government obtained sufficient rights in such inventions, if it so elected[3]. Since its enactment, small businesses and non-profit organizations, including universities, have been able to retain title to inventions made under federally funded research via technology transfer activities. As a result, thousands of companies have been formed generating billions of dollars of direct benefit to the U.S. economy[4]. The U.S. is currently the global leader in biotechnology in part due to the Bayh-Dole Act.

Although the Act contemplates that title allocation decisions are to be made by the universities and the government, with the inventor only being able to retain title afterwards in certain circumstances, it fails to address what happens when an inventor assigns rights in the invention to a third-party prior to title vesting in either the university or the government. This is precisely what happened in *Stanford v. Roche*, a case that will soon be decided by the Supreme Court[5]. In *Stanford*, an inventor executed the university's standard Copyright and Patent Agreement, in which he agreed "to assign" to Stanford any future rights to inventions developed from his federally funded research[6]. With Stanford's knowledge, the inventor then began working with Cetus, a company that partnered with Stanford for research and whose assets (including agreements with Stanford and its researchers) were subsequently purchased by Roche[7]. At Cetus, the inventor signed a Visitor Confidentiality Agreement, where language was used to effectuate an assignment to Cetus of any future inventions that the inventor may devise as a consequence of his work at Cetus[8]. Once the inventions based on the research at Stanford and Cetus were complete, the inventor and his co-inventors (three other Stanford researchers) disclosed the inventions to Stanford. Under the Bayh-Dole Act, Stanford applied for and received three patents covering the subject inventions. All of the inventors assigned their rights in the patents to Stanford[9].

Believing that it was the sole owner of the patented technology, Stanford offered to license the technology to Roche because it had begun selling products based on the subject technology after it acquired Cetus[10]. When Roche refused to take a license, claiming that it also owned the patents at issue, Stanford sued Roche[11]. The district court held, in part, that the Bayh-Dole Act negated the inventor's assignment to Cetus because it empowered Stanford to take complete title to the inventions[12]. On appeal, the Federal Circuit disagreed and held that the agreement between the inventor and Cetus resulted in a present assignment of future inventions and vested equitable title in Cetus prior to any title being vested in Stanford once the inventions were created[13]. Therefore, the Bayh-Dole statutory scheme did not automatically void the inventor's prior assignments to the third-party and thus Roche is a co-owner

of the patents[14]. The Federal Circuit further held that Stanford's inability to establish that it possessed the inventor's interest in the patents-in-suit defeats its right to assert its infringement cause of action against Roche[15].

The Supreme Court will soon weigh in on this issue, which could significantly impact the manner in which universities and other organizations structure their technology transfer agreements, especially when third-parties are involved. In the meantime, entities utilizing the Bayh-Dole Act should examine their contracts with their inventive employees to ensure that the present conveyance "hereby assign" language is used, instead of a mere promise to assign such rights in the future. By carefully crafting the language in written agreements, it may be possible to prevent the patent ownership issue that arose in Stanford.

[1]Press Release 10-64, United States Patent and Trademark Office, USPTO Marks 30th Anniversary of Bayh-Dole Act (Dec. 12, 2010), http://www.uspto.gov/news/pr/2010/10_64.jsp (hereinafter "Press Release 10-64"); Sean O'Connor, Stanford v. Roche: the U.S. Bayh-Dole Act and Inventors' Rights (Jan. 24, 2011), http://www.iposgoode.ca/2011/01/stanford-v-roche-bayh-dole-act-and inventors-rights/.
[2]Press Release 10-64.
[3]35 U.S.C. §§ 200 and 202 (2006).
[4]Press Release 10-64.
[5]See Bd. of Trustees of Leland Stanford Jr. Univ. v. Roche Molecular Sys., Inc., 583 F.3d 832 (Fed. Cir. 2009), cert. granted, 131 S. Ct. 502 (2010).
[6]Id. at 837.
[7]Id. at 837-38.
[8]Id. at 837.
[9]Id. at 837-38.
[10]Id. at 838.
[11]Id.
[12]Id. at 844.
[13]Id. at 844-45.
[14]Id. at 845.
[15]Id. at 848.

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Pamela Miller specializes in intellectual property law, representing clients in actions involving patent and trademark infringement, unfair competition, and media law issues. She has experience in all phases of litigation and has litigated complex patent infringement and unfair competition cases. Prior to law school, she worked as a Research and Development Chemist designing environmentally-friendly, water-based emulsions for application as plastic and electrical insulation coatings. Additionally, her undergraduate research focused on the synthesis of radiopharmaceuticals for potential use in cancer treatment. Pamela's chemistry background allows her to assist clients in actions involving chemical patents and technology. She can be reached at 314-552-6322 or at pmiller@thompsoncoburn.com.

Divorce and IP: Untying the Knot May Tie Up Patent Rights

By Jason M. Schwent

Divorce is not normally something that IP lawyers consider in their day-to-day work. Recent case law, however, has shown that divorce should, perhaps, be given greater thought. Counsel, whether in-house or outside counsel, must account for the possible impact of divorce on patent ownership rights or face potentially disastrous consequences. The Federal Circuit recently dealt with the issue of divorce and patent ownership in the case of *Enovsys, LLC v. Nextel Comm'n., Inc*[1]. The plaintiff in Enovsys narrowly avoided losing an almost $3 million infringement judgment when the Federal Circuit found that the patents-in-suit were marital community property. In light of the Federal Circuit's findings in *Enovsys*, it would behoove

all counsel to account for the effect of divorce on the ownership of intellectual property rights in both patent right transfers and litigation or face potentially dire consequences.

In the *Enovsys* case, Enovsys sued Sprint-Nextel for allegedly infringing two patents co-invented by one of Enovsys' owners, Mundi Fomukong. Among the usual defenses of invalidity and non-infringement, Sprint-Nextel claimed that the case should have been dismissed for a lack of standing because Enovsys had failed to join Fomukong's ex-wife—a party Sprint-Nextel regarded as a part owner of the patents-in-suit.

At the time he filed the patent applications for the patents-in-suit, Fomukong was married to Fonda Whitfield. After divorcing his wife, Fomukong and his co-inventor assigned their rights in the two patents-in-suit to Enovsys. Sprint-Nextel claimed that the patents-in-suit were community property created during the marriage and, under California law, Fomukong's ex-wife was a joint owner of those patents. According to Sprint-Nextel, by bringing suit without joining all holders of legal title, Enovsys lacked standing. The district court disagreed and Sprint-Nextel was ultimately found liable for patent infringement.

On appeal, the Federal Circuit, applying California law, concluded that, because the patents were marital property acquired during the marriage, they were presumptively jointly owned by Fumokong and his wife.

Had there been no further facts, Fomukong's wife would have held an undivided ownership interest in the patents-in-suit. And because his ex-wife assigned her interest in the patents to Sprint-Nextel, Enovsys would have been out the $2.78 million it had been awarded for Sprint-Nextel's infringement.

Unfortunately for Sprint-Nextel, there were additional facts. During Fomukong's summary divorce proceedings[2], both Fomukong and his wife affirmed that they had no joint marital property. Thus, the California divorce judgment had concluded that there was no marital community property. Fomukong's wife was therefore estopped from later arguing that she was a joint owner of the patents-in-suit and Sprint-Nextel (in privity thanks to the agreement with Fomukon's ex-wife assigning her patent rights) was barred by res judicata from relitigating Fomukong's ex-wife's property rights in the Enovsys patent litigation.

While Enovsys ultimately prevailed in its litigation with Sprint-Nextel, the more important takeaway from the case is that the result could have been far different. In community property states[3] like California, Fomukong's ex-wife gained an undivided ownership interest in his patents simply by being married to him at the time the patent applications were filed. Had she not later chosen to pursue a California quickie divorce—a divorce which did not specifically address any patent ownership rights—she could have easily retained that ownership interest.

At a minimum, counsel would be wise to consider community property rights as they relate to patent ownership. In community property states (or when dealing with inventors from community property states), counsel should inquire with assignors about the marital status of inventors before executing assignments and require assignments from not just inventors but also inventor spouses. Counsel should also ensure that marital status is investigated prior to (or during) litigation to make sure that the plaintiff has the patent rights it claims. Ultimately, an ounce of investigation and due diligence will be worth far more than a pound of effort in trying to clean up a patent ownership issue during litigation or a merger or acquisition.

[1]614 F.3d 1333 (Fed. Cir. 2010).

[2]In California, couples may obtain a streamlined summary dissolution of their marriage if they meet certain requirements. Specifically, the couple must either (1) have no community property, or (2) have signed a property settlement agreement listing and dividing all community assets and liabilities. In such a summary proceeding, there is no hearing or trial before a judge and both parties give up their rights to appeal.

[3]There are only 9 community property states: Arizona, California, Idaho, Louisiana, New Mexico, Nevada, Texas, Washington, and Wisconsin.

About the Author

Jason Schwent's practice is centered on the litigation of intellectual property matters, licensing technology and advising clients on intellectual property protections. He has experience in litigating complex patent, trademark, and copyright matters in both administrative proceedings (like interferences, reexaminations, oppositions, and cancellations) as well as in state and federal courts. He also is experienced in drafting and reviewing open source and proprietary software licenses, counseling clients regarding media licensing and technology transfer, and advising clients about maximizing the protection for their intellectual property assets. Jason has substantial experience representing and advising established and emerging technology companies, multi-state and multi-national manufacturing companies, as well as large fortune 500 corporations. Jason can be reached at 314-552-6291 or at jschwent@thompsoncoburn.com

A Practical Primer for Patenting Genes Amid Myriad Uncertainties

By Charles P. Romano, Ph.D.

Since the courts have long held that products of nature are patentable once isolated or manipulated by man, the District Court decision of Judge Sweet in the "Myriad" case[1] that isolated or manipulated genes are not patentable and the subsequent appeal of that decision to the Court of Appeals for the Federal Circuit (CAFC) [2] has prompted considerable legal debate. While the CAFC should issue its decision shortly, there is every expectation that the *Myriad* case will be appealed to the Supreme Court, further prolonging current uncertainties as to the patentability of isolated and manipulated genes. Given this uncertainty, those who seek or hold patents directed to isolated or recombinant nucleic acids should adopt strategies to protect their intellectual property irrespective of what the courts ultimately decide.

In developing strategies for patenting genes post-*Myriad*, potential Court holdings ranging from the most to least restrictive can be anticipated and addressed. Patent applicants have a wide array of options for meeting post-*Myriad* patentability criteria that might be imposed by the courts while preserving their rights to pre-*Myriad* claims if patentability of isolated or manipulated genes is ultimately maintained. At one extreme of the spectrum of potential outcomes is a scenario where the District Court decision is upheld in full, rendering claims to both genes in general and "isolated" genes in particular unpatentable. If the District Court decision is upheld and composition claims to genes are held to be unpatentable, methods of using genes should still be patentable if they meet the *Bilski*[4] requirements (i.e. the methods

do not comprise "abstract ideas" or "mental steps"). Applicants should thus be certain to claim any methods of using genes or portions of genes to make therapeutic proteins, to diagnose conditions or select traits, to confer useful properties on non-human transgenic organisms, and the like using concrete language that provides for "transformations of matter" or otherwise meets *Bilski*[4] requirements. Non-human transgenic organisms should also be claimed since their patentability was upheld in the Supreme Court's *Chakrabarty*[5] decision. Another potential outcome is that the Courts will hold that claims to genes that have been engineered or otherwise manipulated by man are patentable while genes that are simply "isolated" are unpatentable as advocated by the US Department of Justice in its Amicus Brief[3]. If this occurs, properly crafted claims to recombinant DNA molecules or cDNAs can distinguish the claimed gene from its naturally occurring form. An additional advantage of claims to recombinant DNA molecules is that they are not subject to the limitation of being "isolated." However, applicants must distinguish the claimed recombinant DNA molecules from potential prior art recombinant molecules such as clones used in whole genome sequencing projects. At the other extreme of this spectrum of outcomes is the possibility that the lower court decisions are overturned in full, rendering claims to isolated and manipulated genes patentable as per pre-*Myriad* case law. Claims to isolated DNA may be useful and should thus be maintained in pending applications in the event that *Myriad* is overturned in full and for any foreign patent application filings.

Holders of issued U.S. patents with claims directed to isolated or recombinant genes will also need to carefully monitor *Myriad* and consider seeking reissue of those patents if a ruling adverse to the patentability of such genes is ultimately handed down by the CAFC or the Supreme Court. Reissue provides for correction of patents that are wholly or partly inoperative or invalid when the patentee claims more or less than he or she had a right to claim in the patent under 35 USC §251. Since reissue entails the surrender of the original patent and subsequent examination of the reissue application in the same manner as a non-provisional application, the pros and cons of seeking reissue must be carefully weighed for each case. Furthermore, reissue applicants are only entitled to seek amendments that would broaden claim scope within two years of the grant of the original patent. After two years from grant, reissue applicants can only seek amendments that would maintain or limit claim scope. Turning to a scenario where a patent has claimed "an isolated nucleic acid sequence" and an adverse ruling is ultimately handed down by the appellate courts in *Myriad*, any amendment that strikes the term "isolated" would likely be viewed as a broadening amendment and thus prohibited after two years from grant of the original patent. Nonetheless, amendments where the term "isolated" is retained but other limitations that further distinguish the claimed nucleic acid from its form as found in nature are added would not likely be viewed as "broadening" the claims and should be permitted.

Although the ultimate outcome of *Myriad* may not be decided for some time, those seeking or holding patents directed to isolated or manipulated genes do have a number of viable options for protecting their intellectual property. To paraphrase Samuel L. Clemens' retort to those who prematurely reported his demise, blanket statements that "gene patents are dead" are an exaggeration. Nonetheless, the potential impact of any decision adverse to the patenting of such genes merits close observation and prudent precautionary actions.

[1] Association For Molecular Pathology v. U.S.P.T.O. and *Myriad* Genetics, Inc., 702 F.Supp.2d 181 (S.D.N.Y. 2010)

[2] Association For Molecular Pathology v. U.S.P.T.O. and *Myriad* Genetics, Inc, WL 3275970 (Fed. Cir. 2010)

[3] Brief For The United States As Amicus Curiae In Support Of Neither Party, WL 3275970 (Fed. Cir. 2010)

[4] *Bilski* v. Kappos, 130 S.Ct. 3218 (2010).

[5] Diamond v. Chakrabarty, 447 S.Ct. 303 (1980)

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Dr. Charles Romano is a Senior Patent Agent in the firm's intellectual property practice area. As a former research Director at Monsanto and Apath, Charles has over fourteen years of experience in the biotech industry. He is a named inventor on sixteen issued United States patents in molecular biology, agricultural biotechnology and pharmaceutical discovery and has published in peer-reviewed scientific journals such as Genes and Development, The Plant Cell, EMBO Journal and PNAS-USA.

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