

Use of Bailment in Transferring Technology from a University

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Technology transfer from a university is accomplished in many ways, formal and informal. Publication and professional interactions are two of the informal methods; however, an increasingly traveled route over the last two decades is formal licensing. Most licensing is of patents or of copyrights. Yet during this same time period, technological change has increased the importance of access to tangible personal property as a further means of technology transfer. In the 1980's biotechnology companies solved the tangible material transfer problem through use of the ancient legal tool of bailment, where possession, but not title, of tangible personal property is transferred for a limited purpose and duration. Then universities started utilizing bailment to accomplish transfer of new technology as well. Now bailment is a tool available for use with technology originating at national laboratories run by universities.

Bailment is a useful technology transfer tool in two particular situations. One case arises out of the explosive growth of biotechnology over the last two decades, and the other case is a mechanism to accomplish technology transfer through the use of tangible research products generally. In many instances over the past two decades the traditional patent system has not been able to provide practical or cost-effective protection for a biotechnology invention, if any protection was available at all. Today biotechnology patents are still an evolving area of the law, with court interpretations providing ever narrowing patent protection.

For example, the line of cases of *Amgen, Inc. v Chugai Pharm. Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) (claimed specific biological activity modified by "about" does not satisfy the definiteness requirement of 35 U.S.C. 112, and simultaneous conception and reduction to practice is applied), *Fiers v Revel*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993) (one does not have a DNA-based invention until one has the DNA sequence), and *The Regents of the University of California v Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) (first successful cloning of an important animal hormone in a bacterium using recombinant DNA technology revealing the DNA for making rat insulin provides an inadequate description for a genus claim to vertebrate insulin under 35 U.S.C. 112) apparently take a narrow view of when an inventor is in possession of a DNA-based invention and what the available breadth of patent protection is, even for ground-breaking, early research. Additionally, some early developments of biotechnology, such as hybridomas, became increasingly subject to U.S. Patent and Trademark Office ("PTO") "obviousness" rejections to limit eventual patent coverage.

Increasingly, the early uncertainty in the biotechnology community concerning how patent law would be applied to DNA-based inventions has been converted into concern for the narrowness of court recognized claim coverage after many years of proceedings in the PTO and in court. Uncertainty and narrow patent protection undercut the ability of a company to justify the expense and opportunity choice of bringing a biotechnology invention to the market. Many biotechnology inventions require hundreds of millions of dollars to be commercialized through the FDA licensing process. The lack of predictability of the patent system is illustrated by DNA-based inventions from the 1980's still awaiting the protection of an issued patent.

In the 1980's, the uncertainty over patent protection available after many years of patent prosecution led to employment of an alternate form of protection uniquely suited to the new field of biotechnology. That protection is the bailment contract. In biotechnology, an invention frequently is embodied in biological material and in some cases cannot effectively be separated from or practiced without the tangible embodiment. Even where a biological material can be remade without the original biological material, the new biological material may not have exactly the favorable qualities of the old material and may take significant time, effort, and expense to recreate. Hence, the well- developed law of bailment became a mainstay of biotechnology technology transfer between companies in the 1980's. Universities rapidly followed suit to take advantage of a rapid, cost-effective, and predictable tool in the new technology. In doing so, universities did not give up their traditional devotion to academic publication of research or the preference for patent protection for inventions where appropriate. Academic researchers remain subject to the "publish or perish" imperative of academic advancement.

Turning to the law of bailment, a definition is as follows:

A bailment may be defined as the rightful possession of goods by one who is not the owner. Bailment has also been defined "as a delivery of personality for some particular purpose, or on mere deposit, upon a contract, express or implied, that after the purpose has been fulfilled it shall be redelivered to the person who delivered it, or otherwise dealt with according to his directions, or kept until he reclaims it, as the case may be." (A Treatise on the Law of Contracts, 3rd ed., by Samuel Williston Vol. 9, Ch. 35, Sec. 1030 (1967)) ("Williston")

Note that the bailment definition in an exhaustive work such as Williston does not include a requirement that the bailor be the owner of the property bailed. In most cases the bailor is the owner; hence, a reference in a less complete treatment may appear to make bailor and owner synonymous.

Bailment has a long history to make the protection offered predictable—a requirement for greatly increasing the likelihood of a successful transfer of technology. The fundamental and historic nature of bailment has been expressed as follows:

It is difficult to think of an even moderately organized economic and legal society where problems incidental to bailment transactions would not arise. ... The modern law of bailment has borrowed heavily from the Roman law, and many of the doctrines of the law of bailments today are directly traceable to Roman sources. In the great case of *Coggs v. Bernard* (2 Ld. Raym. (K. B.) 909 (1704)), a simple matter involving the liability of one who gratuitously undertook to transfer certain brandies from one cellar to another and by his negligence damaged them, Lord Holt in 1703, relying upon the Thirteenth Century writer, Bracton, imported into the common law great portions of the Roman law of bailments ... (Brown on Personal Property, 2nd ed., by Ray Andrews Brown Ch. X, Sec. 73 (1936)) ("Brown") (Citation added from footnote)

Use of bailment to protect inventions has a long history as well. Also, protecting an invention by use of bailment does not rely upon maintaining a trade secret, an important consideration for university and national laboratory alike. A university can bail tangible personal property

embodying the invention and still publish a description of an invention without necessarily destroying the contractual protections in a bailment. The California Supreme Court has considered bailment protection of inventions as follows:

... plaintiff is not required to rely upon the secrecy of its invention. We have here a relationship created by contract where the manufacturer took into his custody certain patterns created by the inventor for the purpose of manufacturing castings from them for the inventor. ... Where a bailee of an article has accepted it under definite terms to hold it and use it for the benefit of the bailor, a confidence has been reposed which should remain inviolate. The mere fact that the ingenious principle materialized in the thing bailed may be known to all the world would not depreciate the sanctity of the contract between the bailor and the bailee. (*Hollywood Motion Picture Equipment Co., Ltd. v. Furer* (1940) 105 P.2d 299, 16 Cal.2d. 184 at 188) ("Hollywood")

Also, inventions have a distinct legal existence apart from patent rights. In California the existence, ownership, and transfer of rights in inventions are recognized as follows:

The inventor or proprietor of any invention or design, with or without delineation, or other graphical representation, has an exclusive ownership therein, and in the representation or expression thereof, which continues so long as the invention or design and the representations or expressions thereof made by him remain in his possession. (Cal. Civ. Code Sec. 980(b))

The owner of any invention or design, or any representation or expression thereof, may transfer his property in the same. (Cal. Civ. Code Sec. 982(b))

If the owner of an invention or design does not make it public, any other person subsequently and originally producing the same thing has the same right therein as the prior inventor, which is exclusive to the same extent against all persons except the prior inventor, or those claiming under him. (Cal. Civ. Code Sec. 984)

It is worth noting that the original codification of this invention ownership concept occurred in California in 1872. The distinction between inventions and forms of enforceable protection such as patents was further drawn as follows:

We are dealing here, however, with the inventions before issuance of patent. Under the common law, which has not been changed by statute, an inventor has a natural but not an exclusive right to use and sell his invention independent of any rights conferred by the issuance of a patent. The only effect of a patent is to confer upon the patentee the right to exclude others from the use thereof. (*Summerhays v Scheu* (1936) 52 P.2d 512, 10 Cal.App.2d 574 at 576) ("Summerhays")

The U.S. Supreme Court has considered inventors' rights in the federal context and found the federal government to be no different than private parties:

The government has no more power to appropriate a man's property invested in a patent than it has to take his property invested in real estate; nor does the mere fact that an inventor is at the time of his invention in the employ of the government transfer to it any title to, or interest in it. An employee, performing all the duties assigned to him in his department of service, may

exercise his inventive faculties in any direction he chooses, with the assurance that whatever invention he may thus conceive and perfect is his individual property. There is no difference between the government and any other employer in this respect. (*Solomons v United States*, 137 U.S. 342, 11 S. Ct. 88, 34 L. ed. 667 at 669 (1890)) ("*Solomons*")

Thus, as a matter of law, the federal government is bound by the same common law of invention and patent rights as exists for all others in the society, absent intervening statutory changes since 1890.

Federal preemption does not appear to have destroyed common law (and its codifications) protections for inventions. Of the forms of intellectual property protection (patents, copyrights, trademarks, and trade secrets) available, the U.S. Supreme Court held that federal preemption in patents did not destroy state contract law protection, in that case trade secret:

Our conclusion that patent law does not pre-empt trade secret law is in accord with prior cases of this Court. ... Trade secret law and patent law have co-existed in this country for over one hundred years. Each has its particular role to play, and the operation of one does not take away from the need for the other. Trade secret law encourages the development and exploitation of those items of lesser or different invention that might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement of the Nation. Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the reward of his labor by contracting with a company large enough to develop and exploit it. (*Kewanee Oil Co. v Bicron Corp.*, 416 U.S. 470, 94 S. Ct. 1879, 40 L. Ed. 315 (1974) at 492-493) ("*Kewanee Oil*") (emphasis added)

In 1980, the Congress passed P.L. 96-517 directing the policy choice for nonprofits and small businesses engaged in "the performance of experimental, developmental, or research funded in whole or in part by the Federal Government" (35 U.S.C. 201(b)) that:

Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention ... (35 U.S.C. 202(a)) (emphasis added to P.L. 96-517 text)

... that the Federal Government may receive title to any subject invention in which the Contractor does not elect to retain rights or fails to elect rights within such time. ... (35 U.S.C. 202(c)(2)) (emphasis added to P.L. 96-517 text)

... a contractor electing rights in a subject invention agrees to file a patent application(s) prior to any statutory bar date (within reasonable times) ... and that the Federal Government may receive title to any subject inventions ... in which the contractor has not filed patent applications on the subject inventions within such times. (35 U.S.C. 202(c)(3)) (emphasis for text added by P.L. 98-620 and parenthesis for material deleted then)

... with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments

to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year ... shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility ... (35 U.S.C. 202(c)(7)(E)) (emphasis added)

This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter ... The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act. (35 U.S.C. 210(a)) (emphasis added to P.L. 96-517 text)

The above provisions are fundamentally different from the "shall vest" language mandating title in the federal government in 42 U.S.C. 2182 related to atomic energy and 42 U.S.C. 5908 related to nonnuclear energy. The P.L. 96-517 statutory presumption is a return to invention title being "retained" by the inventor or his/her employer instead of by the federal government. Thus the basic common law understandings in invention rights are operative to the extent of P.L. 96-517 election. Where the contractor does not file for patent rights as the form of protection for an invention, the federal government "may receive title." There is no mandate for the federal government to exercise this right.

Moreover the protections built into P.L. 96-517 are phrased predominantly in terms of the invention, especially: the paid-up license to the federal government at 35 U.S.C. 202(c)(4), the prohibition on a nonprofit assigning title at 35 U.S.C. 202(c)(7)(A), the requirement that net royalties "earned ... with respect to subject inventions ... be utilized for the support of scientific research or education" at 35 U.S.C. 202(c)(7)(C), the small business preference in nonprofit licensing at 35 U.S.C. 202(c)(7)(D), retention of rights by the inventor at 35 U.S.C. 202(d), assignment to the nonprofit or small business of an undivided interest "when a Federal employee is a coinventor of any invention" at 35 U.S.C. 202(e), a bar to a federal agency requiring the licensing of background inventions at 35 U.S.C. 202 (f), all of the march-in-rights at 35 U.S.C. 203, the preference for U.S. industry at 35 U.S.C. 204, the precedence of P.L. 96-517 over other inconsistent laws at 35 U.S.C. 210(a), and education awardee protection at 35 U.S.C. 212. The phrasing of P.L. 96-517 is predominantly in terms of invention rights—not patent rights—and the presumptions are in favor of contractor title to inventions where the common law applies.

The P.L. 98-620 amendments of 1984 to P.L. 96-517 focused on "minor improvements ... to make P.L. 96-517 work even better" for nonprofits and on expansion of such rights to the federal laboratories operated by nonprofits and small businesses. Senate Report No. 98- 662 stated:

After nearly four years of experience with P.L. 96-517, it is clear that the Act is accomplishing what it was intended to do. All of the major research universities appear to agree that the assurance of clear title to Government-funded inventions produced by the Act has led directly to increased patent licensing. Even more important, this assurance has been a major factor in allowing increased business support and collaboration in university research. Universities can negotiate with businesses and reach agreements over who will have what rights to inventions that come from joint efforts when the universities own the basic patents. Experience has shown,

however, that some minor improvements are needed to make P.L. 96-517 work even better. ... (at page 2)

The bill has particular value to the universities that run Federally-owned research facilities under contract to the Government by ensuring that these universities will have the same rights to own inventions that they have under other Federal funding agreements. ... (at page 3) (emphasis added)

S. 2171 repeals the P.L. 96-517 provision excepting inventions made by nonprofit organizations when operating Government-owned laboratory facilities. This provides for uniform treatment of all domestic nonprofit organizations regardless of where they perform their Federally-funded work and is particularly important to organizations that manage Department of Energy laboratories. (at page 8) (emphasis added)

The legislative history in P.L. 98-620 explicitly states that universities are to be given the "same rights to own inventions" arising out of federal laboratories they operate as is practiced on campuses under P.L. 96-517. Again, the statement is made in terms of invention ownership, not ownership of patent rights.

With regard to university practices, the Association of University Technology Managers ("AUTM") published its AUTM Technology Transfer Practice Manual in 1993, illustrating the practice of many universities. Part IV, Chapter 3.2 "Unpatented Tangible Property: Biological Materials" and its Supplementary Material "Biological Licensing" are relevant material. This material is also available at AUTM's web site in AUTM Publications: Journal of the Association of University Technology Managers, Volume IV, 1992, "Biotechnology Licensing," by Annie Yau-Young and Marilyn Ziemer. Comments on bailment are as follows:

A bailment is essentially an agreement under which the bailee/licensee is permitted to use the tangible property of the bailor/licensor under defined terms and conditions. Intellectual property rights such as patent are not involved, though hybrid agreements that include both a bailment and a patent right are not uncommon in biotechnology licensing. These are often quite useful if the licensee wants access to a cell line that is or may in the future be covered by a patent. A bailment agreement can be an exclusive or non-exclusive agreement, and it should have the appropriate clause on product liability, diligence, etc. ... (at page 11)

... It is usually not intended that the licensee be permitted to sell the actual cell line or its progeny or derivative cell lines. Instead, the licensee is permitted to use the cell line and its progeny and perhaps its derivatives to manufacture some component of the product, often a protein. ... (at pages 11 to 12)

... In a university setting, it may be necessary to allow the creators of the tangible material to distribute it to non-profit organizations for internal research use in order to preserve academic freedom. These transfers should be covered by written restrictive agreements and usually do not extend to for-profit organizations. (at page 12)

Many TRP [Tangible Research Property] materials are of interest to companies marketing biological materials to the research community. It, therefore, makes sense to routinely advise such companies of newly disclosed TRP. While research markets are typically much less in sales than pharmaceuticals, they can provide considerable financial return to universities and researchers for their research. Sometimes, the developers are interested in having a convenient source of supply that eliminates the need for growing their own materials for further work; a license to a research reagent marketer may provide for such supply. (at page 4)

In licensing TRP, the licensor's bargaining position may be weak if there are other, equivalent (or at least comparable) materials available from other researchers or universities. In such cases, the licensee does not acquire much protection for his application, but pays for the convenience of getting a largely existing material without having to produce it in-house, or for a better characterized material than others currently available, or perhaps for having TRP provided from a more prestigious laboratory. (at pages 4 to 5)

In the AUTM Technology Transfer Practice Manual, Part IX, Chapter 3.2, a 1991 republished article entitled "The Treatment of Tangible Personal Property in Conjunction with Licensing of Patented Biotechnology" reports the following:

... It cannot be doubted that biotechnology licensing involves consideration of tangible personal property matters to a greater extent than does other technology licensing. This is because of the present inability adequately to describe an invention in words and to reproduce readily that invention from the description using generally available materials. (at page 2)

Biotechnology licensing, like any other technology licensing, requires an accommodation to the needs of the parties. The licensee requires the transfer of sufficient tangible and intangible property to achieve the basic goal of practicing the claimed invention, usually for commercial purposes. On the other hand the licensor desires to confine the property transfer to that calculated to result in the licensee's meeting its contractual obligations and, failing so, to permit effective recovery of that property—both tangible and intangible. Achievement of these respective goals demands that the rights and duties regarding both form of property be fully addressed in the written agreement(s) memorializing the intentions of the parties. (at page 2)

Another potential problem for the intellectual property holder who sells tangible personal property concerns the doctrine of implied license. If the only use of that tangible personal property is to practice a patented invention, the seller may be deemed to have granted the buyer a license to practice the intellectual property. (at page 3)

The thesis of this paper, first presented orally at the American Intellectual Property Law Mid-Winter meeting in 1986, is that licensing of biotechnology inventions often entails the transfer of biological materials, tangible personal property, in addition to patent or trade secret rights, intangible personal property. ... The history of the law of bailments was also reviewed with the conclusion that this ancient form of tangible property transfer was legally, as well as functionally appropriate to biotechnology licensing. Subsequently the transfer of biological materials as a bailment has received widespread approval and use in the biotechnology community. (at page 18 following the text of the Article)

University of California policy is similar to the policies of most universities regarding licensing. Relevant policy statements are as follows:

Tangible research products include a wide range of tangible property resulting from the conduct of research, as distinct from copyrightable expressions and patentable inventions. Tangible research products may confer a public benefit through commercial licensing and may include biological materials, such as cell lines and plasmids; chemical compounds; electrical schematic diagrams; mechanical design drawings; and more abstract products such as detailed descriptions or compilations of laboratory procedures, analytical methods, or other such "know-how." ... (Guidelines on University-Industry Relations, Guideline 10: Tangible Research Products)

In the event that research results are to be licensed, the University prefers that they be patented or copyrighted when possible. When this is not practical, licensing of tangible research products consistent with these Guidelines is permissible. When the University licenses tangible research products, it is willing to restrict commercial availability of such materials, but such agreements must permit the University to retain the discretion to publish any results of research at any time and to disseminate the tangible materials for educational and research purposes. Such publication and dissemination rights are essential to an academic institution of education and research. (Guidelines on University-Industry Relations, Guideline 10: Tangible Research Products) (emphasis added)

It is the intent of the President of the University of California, in administering intellectual property rights for the public benefit, to encourage and assist members of the faculty, staff, and others associated with the University in the use of the patent system with respect to their discoveries and inventions in a manner that is equitable to all parties involved. ... They shall execute such declarations, assignments, or other documents as may be necessary in the course of invention evaluation, patent prosecution, or protection of patent or analogous property rights, to assure that title in such inventions shall be held by the University ... (University of California Patent Policy, October 1, 1997 revision) (emphasis added)

The NIH has decided that contractor licensing of unpatented inventions is acceptable as follows:

... Typically, the Contractor's election not to file a patent application on an invention is an indication that the Contractor is not interested in retaining domain over the invention.

However, this is not necessarily the case with regard to patentable biological materials, which may frequently be licensed for commercial use without patent protection. The policy and procedures established by this notice are intended to simplify: (1) reporting by Contractors of their intention to not file a patent application on the invention but to license the tangible biological materials; and (2) the non-election of title to these inventions by the Federal Government where certain terms and conditions are met.

... To ensure consistency with its public availability goals, ... PHS Grants Policy Statement requires that where the product of research developed with federal funding is a patentable, but unpatented, research product, the terms of a license must be no more restrictive than they would have been if the product had been patented. (NIH Procedures for Handling Non- Election of Title

to Patentable Biological Materials, NIH Guide, Vol. 25, No. 16, May 17, 1996) ("PHS Guide") (emphasis added)

Bailment has been recognized as a technology transfer tool at national laboratories. With respect to the U.S. Department of Energy/University of California operating contracts for Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, and Los Alamos National Laboratory, relevant portions are as follows:

"Laboratory Biological Materials" means biological materials capable of replication or reproduction, such as plasmids, viruses, DNA molecules, RNA molecules, prokaryote or eukaryote cell lines, and the like or associated biological products made under this contract by Laboratory employees or through the use of Laboratory research facilities. (Art. XII, CL. 11, I(a)(5))

"Laboratory Tangible Research Product (TRP)" means tangible material results of research which (i) are provided to permit replication, reproduction, evaluation or confirmation of research effort, or to evaluate its potential commercial utility, (ii) are not materials generally commercially available, and (iii) were made under this contract by Laboratory employees or through the use of Laboratory research facilities. (Art. XII, CL. 11, I(a)(6))

"Bailment" means any agreement in which the University permits the commercial or non-commercial access and use of Laboratory Biological Materials or Laboratory TRP for a specified purpose of technology transfer or research and development, including without limitation evaluation, and without transferring ownership to the bailee. (Art. XII, CL. 11, I(a)(11))

In pursuing the technology transfer mission, the University is empowered to conduct activities including, but not limited, to the following: identification and protection of Laboratory Intellectual Property, ... Bailments ... It is fully expected that the University shall use all of the mechanisms available to it to accomplish this technology transfer mission ... (Art. XII, CL. 11, I(b)(3))

Thus, universities now employ the ancient Roman tool of bailment as an effective means of technology transfer from campuses and national laboratories operated for the federal government. In particular, universities have found bailment provides a vehicle well suited to both a university environment and the demands of modern biotechnology. Educational institutions retain their essential characteristics that publication is an imperative and patent rights are a preferred medium of technology transfer. Bailment provides a complementary alternative for the technology transfer process where patents do not provide adequate protection.

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