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What Every Business Should Know About the Bayh-Dole Act

By Kyle Coleman

Prior to the enactment of Bayh-Dole, the U.S. Government had accumulated and owned nearly 30,000 patents. Astonishingly, only about 5% of those patents were commercially licensed. Today, private ownership of government funded inventions is permitted as a result of the Bayh-Dole Act. Businesses entertaining the assumption of rights or the taking of an interest in government funded projects or inventions from universities, small businesses, federal labs, non-profits or other entities need to be aware of the legal requirements imposed by the regulation. This article identifies and discusses six questions a business should consider and be prepared to handle before committing to a relationship where federal research dollars are involved.

1. WHAT PROJECTS OR INVENTIONS ARE REGULATED BY THE BAYH-DOLE ACT?

The Bayh-Dole Act applies to inventions made by an entity, such as a university, non-profit or business, that received federal money to fund their research only if the invention was "conceived or reduced to practice in the performance of work under a funding agreement." The proportionality between the amount of federal and other monies funding the research is generally not determinative of whether the invention is a "subject invention" or otherwise subject to Bayh-Dole. There are, however, a few notable exceptions to the regulation. For example, one exclusion is where the invention was created in closely related research outside the scope of the federally funded research, only if it can be shown that the non-government research did not "diminish or distract from" the federal research. Research wholly outside the scope of federally funded research that may have involved use of instruments purchased with government funds is excluded as well, if it can be shown that the research was done "without interference with or cost to the government-funded project." Scholarships, fellowships and training grants are also specifically excluded.

Despite these exceptions, businesses should be aware that a significant amount of biomedical and biotechnology research is regulated by the Bayh-Dole Act because the government funds most of this research. The government also heavily funds other areas, such as renewable energy, military and medical research. As such, any business that is interested in a government funded project or invention should be aware of how patent rights and licensing policies are affected by the Bayh-Dole Act, as discussed below.

2. WHAT ACTION MUST A BUSINESS TAKE TO PROTECT THE GOVERNMENT'S INTERESTS?

To comply with the regulation and retain property rights in the "subject invention" certain requirements must be fulfilled. First, the Federal agency funding the research must be notified in a reasonable time after the invention is disclosed to those responsible for patent matters. Notification to all applicable funding agencies should not be done in piecemeal submissions as this has been held to be inadequate disclosure by the Federal Circuit. Businesses should know that if the agency is not notified, the title 'may' pass to the government. Although no Federal agency to this day has exercised its "march-in rights," a business certainly would not want to be the first to test the mettle of this provision. Second, the business must include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention." As part of due diligence, a business should always check for a government support clause in any published or issued patents as this may be an indication that some or all reporting requirements have been overlooked. As a business, if you determine that government funds were received, take steps to ensure that all the disclosure requirements are complete. One way for

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a business to try to limit liability is to require the owner of the patent to affirm in writing that all the disclosure and reporting requirements have been met.

3. CAN A FEDERAL AGENCY GRANT A LICENSE TO A SUBJECT INVENTION ON ITS OWN INITIATIVE?

A business needs to be aware that if certain requirements are not complied with the Federal agency can request the inventor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive or exclusive license in any field of use to a responsible applicant or applicants upon terms that are reasonable under the circumstances. The request can be refused, but the Federal agency has the right to grant a license if it determines that a license is necessary because the inventor has not taken the steps to achieve practical application of the invention within a reasonable time period. Other considerations the agency will review in determining whether its "march-in rights" are justified include action taken to alleviate health or safety needs not taken by the inventor, requirements for public use not reasonably satisfied by the inventor or if the inventor failed to obtain or waive the requirement that the invention be "manufactured substantially in the United States." Although this right, at least in theory, could be devastating to a business that expects and needs an exclusive license to a technology, the government to date has not exercised their "march-in rights."

4. WHAT ONGOING RIGHTS DOES A FEDERAL FUNDING AGENCY HAVE IN AN INVENTION?

The Bayh-Dole Act permits an inventor or contractor to "retain the entire right, title and interest throughout the world to each subject invention," however, the funding agency retains "a nonexclusive, nontransferable, irrevocable, paid-up world-wide license to practice or have practiced for or on behalf of the United States the subject invention." This provision generally only has implications if the government is a primary customer of a business. For example, a business can avoid paying royalties to the patent owner on sales made to the government. One way to ensure that basic research and government funds are kept separate from research leading to product development and patented inventions is to clearly distinguish in writing the work that is covered by the funding agreement from that which is funded by non-federal funds. This is particularly important for companies involved in military R&D where the government may be the primary buyer and where a royalty-free license to use an invention could be economically devastating.

5. CAN BAYH-DOLE IMPACT A BUSINESS'S DISCRETION AS TO ITS BUSINESS DECISIONS OR PARTNERS?

Any business holding an exclusive license to a patent covering a "subject invention" that involves use or sale of a product in the United States must be substantially manufactured in the U.S. Waivers of this rule may be granted by the Federal agency upon a successful showing that reasonable but unsuccessful efforts were made to find a business that would manufacture the product in the U.S., or that manufacture in the U.S. was not economically feasible. Companies should also be aware that one of the strings that attach to the government purse requires patentees to give small business firms preference over other applicants for licenses, provided such firms have the capability and resources to bring the invention to practical application.

6. CAN A GOVERNMENT GRANT PROPOSAL PREVENT GETTING A PATENT?

At least one case concludes that a government grant proposal constitutes prior art against an applicant for a patent. See E.I. du Pont de Nemours & Co., v. Cetus Corp., 1990 U.S. Dist. LEXIS 18382 (N.D. Cal. Dec. 11, 1990). In the DuPont case, the court found the grant proposal at issue (a NSF grant proposal) to be publicly accessible due to the fact that the proposal was: 1) filed, indexed by title, author, institution and grant number; 2) available upon request under the Freedom of Information Act (FOIA); and 3) cited by grant number in a published article written by the author of the proposal. One way to prevent this from happening to you is to mark the relevant portions of the grant proposal as confidential, which may exempt information in the proposal from becoming accessible upon request under the Freedom of Information Act. The better route to avoid this pitfall is to file a patent application on the subject matter of the grant proposal prior to submitting it to a government agency. Businesses should ensure that the attorney prosecuting patents for federally funded inventions knows of this source of potential prior art and take steps to disclose relevant grant proposals to the Patent Office, or to designate relevant portions of a grant application as confidential.

The questions identified above represent only some of the issues businesses may encounter in a relationship where Federal research dollars are involved. Consult your MVS attorney with additional questions or concerns.

Auditing and IP, What You Should Know

By Brad Powers

Every year, companies leave thousands of dollars of assets lying around without proper protection. Although most companies perform annual audits of their finances, they fail to pay similar attention to the intellectual property assets—the same assets which provide the company's competitive advantage and growth.

For those companies that do pay attention to Intellectual Property, the focus remains on R&D rather than the core corporate divisions such as human resources, information technology, and sales/marketing. Failure to take proactive measures to secure these valuable assets can result in costly remedial litigation or - in some cases -complete loss of exclusivity. A healthy focus on IP assets will address patents, copyright, trademark and trade secrets. A short review of some measures to take in each of these areas is provided below.

Trade Secrets:

Virtually all companies have trade secrets which require protection (such as customer lists, supply sources and pricing, marketing strategies and business plans) but many companies fail to take adequate measures to protect them. The initial step is to identify which corporate assets provide a competitive advantage by virtue of not being publicly available.

After identifying the assets, the next step is to secure them. Protection requires (1) the use of written agreements and (2) restricted access to the secret material. Specifically, a company needs to have written confidentiality agreements with all individuals who have access to the trade secret material. This includes employees, contractors and (in some cases) visitors. Without these written agreements, it is very difficult to prove the existence of a trade secret.

The second component of a good trade secret program is to restrict access to the trade secret material. In order to establish and maintain secrecy, access should be restricted to individuals who "need to know" the trade secret information. Examples of adequate measures for restricting access include password protected file servers and locked file cabinets.

Trademark:

Some businesses mistakenly believe that registering their business name with the state provides trademark protection. Registering with a state assumed-business-name registration is not a trademark registration and does not provide the same benefits. Instead, a separate filing is required to enjoy the presumptions and protections afforded to registered marks.

In addition to registration, appropriate use of a mark is essential to obtaining protection. For all marks, care must be taken to use the mark as an identifier of source and avoid using the mark in a descriptive manner. Additionally, for goods, the mark must be affixed to the goods, for services, the mark must be used in advertising for the appropriate services. An audit can review advertising to ensure that mark usage is appropriate.

Copyrights:

The use of contractors for marketing efforts (such as website design and advertising design) can result in the contractor owning the copyright in your website and ads. Many companies mistakenly rely upon the "work made for hire" doctrine, however, a limited number of works actually qualify for this protection. Instead of facing uncertainty over, and possible loss of, ownership of copyright rights, companies should ensure that services agreements include an appropriate copyright assignment provision.

Patents:

The process of securing a company's patent rights does not begin in the research department; instead, the process begins with the human resources department. Without appropriate contractual provisions, ownership of inventions is in question. Without the benefit of contractual language, the end result depends on the relationship between the inventor and the company, or the operation of state law.

For independent contractors, failure to include an appropriate assignment provision will likely result in the contractor owning all rights in the invention. For employees, the answer is more complex. Specifically, the burden is on the employer to prove that the employee was (1) hired to solve a particular problem and (2) that the invention relates to that particular problem. If an employer fails to make this showing, the employee owns the patent and the employer receives a nonexclusive right to practice the invention (a "shop right"). Employers can reduce the risk of costly litigation and loss of rights through a relatively inexpensive assignment provision in employment contracts.

After performing the contractual groundwork, a company should turn to the more traditional tasks of timing patent filings to avoid public disclosure and monitoring competitor's patent filings.

Conclusion:

This article provides an example of some of the issues that are tackled in an IP audit. By proactively identifying and protecting these assets a company can reduce the risk of costly litigation and loss of valuable corporate assets while focusing corporate IP acquisition and enforcement efforts. Contact your MVS attorney if you would like more information about IP audits.

Disclose, Disclose, Disclose – Rule 56 and Beyond

By: Luke Mohrhauser

Everyone who has either worked in patent prosecution, or applied to get a patent has heard of the requirement of disclosing all information which may affect the patentability of an invention. It is one of the give and takes of being granted a limited monopoly over an idea. Disclosure of references which may affect patentability is becoming one of the most scrutinized requirements in obtaining patent protection. In addition, lack of disclosure is being used to combat the enforceability of an issued patent, while also being a way to attack a prosecuting attorney's practice.

THE RULE

The duty of disclosure is found in 37 CFR 1.56 (also known as "Rule 56"), which requires that "each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." The duty has been determined to be an important piece of public interest as the most effective patent examination, and thus it could be argued that the best patent scope, occurs when an examiner is aware of all potential information material to the patent prosecution. In other words, the rationale is that a patent that been examined in light of all material information that could affect the patentability of an invention should be strong enough to not be found invalid or unenforceable in any potential infringement action. The basis of the rule is that the Applicant and anyone else involved in the prosecution may know relevant information about the patent that could affect patentability.

As stated above, the rule extends to each individual associated with the filing and prosecution of a patent application. While clearly the duty extends to the prosecuting attorney and each inventor, it has also been construed rather broadly to include anyone substantively involved with the preparation or prosecution of the application. This could potentially include experts used in preparation or prosecution of the application, any other attorney or clerk involved in the preparation, assignees, and licensees. Additionally, the duty applies while the claims are pending, until issued, canceled, withdrawn, or abandoned.

MATERIALITY

Questions may arise as to what is considered "material to patentability." Rule 56 states that material information is any information that is not cumulative, and either establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability, or (ii) asserting an argument of patentability. The duty includes prior art, information regarding enablement, possible prior public uses, sales offers to sell, derived knowledge, etc. Basically, information should be considered material if it a reasonable examiner would consider the information important in determining the patentability of an application. Such information may be derived from any number of sources, and regardless of the source, it will need to be disclosed.

BREACH OF DUTY

The consequence of not fulfilling the duty of disclosure can be a finding of inequitable conduct. To prove inequitable conduct, a party must show, by clear and convincing evidence, that the patentee intentionally "withheld or misrepresented" information, and that the information was "material." The intent requirement is generally inferred from the facts and circumstances because direct proof of intent is generally not available. While some argue that the more material a reference, the less intent that is required to be shown should be the standard, this argument has not been fully decided upon.

The number of pleadings of inequitable conduct has risen dramatically in the past two decades. According to a recent law review article, in 1991, out of 1,171 patent cases filed, only two cases involved an inequitable conduct pleading. In 2008, out of 2,909 patent cases filed, 1,157 cases involved a pleading of inequitable conduct. The reasoning for the increase in inequitable conduct claims can be seen from the following: (i) it renders unenforceable the entire patent, not just specific claims; (ii) it may render unenforceable entire families of patents; (iii) may allow a finding of attorney's fees ($20 million in one such case); (iv) other reasons such as allowing a defendant to intrude upon attorney-client privilege.

Along with the previous reasons, patent attorneys have a big incentive to disclose and promote disclosure. A pleading of inequitable conduct may allow a defense to characterize the prosecuting attorney as fraudulent or unethical. The mere allegation of inequitable conduct can potentially damage the reputation of an attorney.

Therefore, it is in the best interest of everyone involved in patent prosecution to promote disclosure and disclose to the Patent Office. Contact MVS with any questions or concerns.