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# Six 'GMP' Tips for On-Going IP Management

## Good manufacturing practice for in-house corporate counsel and managers

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In-house corporate counsel and managers are routinely involved with license agreements, acquisitions, mergers, investments and/or an IPO. All of these transactions will involve intellectual property due diligence—an audit to assess your company's IP assets. Forward-thinking in-house corporate counsel and managers adopt "GMP"—good manufacturing practice. Here, we will discuss six GMP tips for practicing ongoing IP management.

(1) *Review employment and assignment agreements to ensure your company owns all the intellectual property rights.*

GMP requires that your company ensure proper ownership of your IP rights. In a seminal case, *Stanford v. Roche*, the U.S. Supreme Court provided guidance regarding drafting of employment agreements to ensure that your company properly owns all inventions. *Stanford v. Roche*, 131 S. Ct. 2188 (2011).Specifically, the court found that an employment agreement that includes the term "agree to assign … [a] right, title and interest in" an invention is only a "mere promise to assign rights in the future" and thus, does not transfer rights in an invention from an employee to a company. *Stanford*, 131 S.Ct. at 2194, 2202. In contrast, the court held that an employment agreement that includes the term "will assign and do[es] hereby assign" an employee's "right, title and interest in [an invention]" effectively transfer rights in an invention from the employee to an employer. *Stanford*, 131 S.Ct. at 2202. Thus, under GMP, your company should frequently review employment agreements and patent assignments to confirm that the phrase "I hereby assign all right, title and interest" is included, in lieu of the phrase "I promise to assign all right, title and interest" or "I agree to assign all right, title and interest."

(2) *Implement a comprehensive patent monitoring program.*

This year is the third anniversary of the America Invents Act (AIA), which led to significant changes in the United States patent system, which increased the importance of monitoring competitors' patent filings. The AIA changes include new procedures for challenging newly issued patents by filing a request for "post-grant review" with the U.S. Patent and Trademark Office (USPTO), and challenging pending patent applications by confidentially submitting relevant invalidating materials to the USPTO (this is known as a "third-party submission"). The timing for filing the post-grant review and third-party submission are very limited. Hence, an important component of your company's overall business strategy should include a strategy regarding review of patent filings at the USPTO, especially the filings of your company's competitors. Under GMP, to take timely advantage of these new AIA procedures, your company should frequently monitor patent filings and patent activities at the USPTO.

(3) *Evaluate new inventions for patent vs. trade secret protection in view of recent changes to patent-eligible subject matter.*

Over the past few years, three U.S. Supreme Court decisions have been of significant importance to the issue of patent-eligible subject matter: *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S.Ct. 1289 (2012) *("Mayo"); Association for Molecular Pathology v. Myriad Genetics*, 133 S.Ct. 2107 (2013) *("Myriad")*; and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S.Ct. 2347 (2014) ("*Alice*").

In *Mayo*, the court invalidated patent claims directed to a diagnostic method to determine the optimal test for a drug. In invalidating the claims, the court reasoned that the correlation between drug dose and metabolite levels was a law of nature, and the additional claimed steps were considered to be the routine activities of researchers.

In *Myriad*, the court ruled that naturally occurring DNA segments are products of nature even when isolated from an organism's genome and therefore are not patent eligible. In contrast, DNA which is synthesized using RNA as the template was determined to be patentable because it was not naturally occurring.

In *Alice*, the court invalidated claims directed to a method for exchanging financial obligations, a computer used to perform the method and software designed to cause the computer to perform the method. The court reasoned that the claims were

not eligible for patent protection since it was simply an abstract idea implemented using a generic computer system and software.

The ramifications of these cases on what constitutes patentable subject matter are significant. These cases did *not* hold that *all* patents directed to diagnostic tests, nature-based products, or methods that use algorithms, are invalid. On the contrary, it is still possible to obtain claims directed to diagnostic tests, nature-based products, or methods that use algorithms. However, obtaining patent protection for these types of claims is now more difficult. In the wake of *Mayo, Myriad* and *Alice*, and under GMP, your company should critically evaluate new inventions—if the invention does not meet the new standard of patent-eligible subject matter, then the alternative IP protection of maintaining the invention as a trade secret should be evaluated.

(4) *Draft contracts with subcontractors to include sufficient deliverables to meet the increased definiteness standard for patent protection.*

A recent U.S. Supreme Court patent decision changed the way companies should be drafting contracts with subcontractors. On June 2, 2014, the U.S. Supreme Court issued a decision increasing the threshold for determining whether patent claims are sufficiently definite to not be held invalid. *Nautilus v. Biosig Instruments*, 134 S.Ct. 2120 (2014). Essentially, under GMP and under the new definiteness standard, patents are now required to provide *quantitative* results compared to the previous standard of merely requiring *qualitative* results.

Accordingly, the *Nautilus* case had a significant effect on when your company subcontracts with others to provide information for a patent application. For example, a nutritional supplement company will often subcontract with a laboratory to provide data in support of a new formulation subject to potential patent protection. The contract with the laboratory will typically specify that the deliverable includes the analytical data associated with the formulation. The analytical results may then be used in a patent application covering the formulation. Under the new definiteness standard, patent applications require substantially more detail, including the exact test methods used to generate the data included therein. However, unless a subcontractor is contractually obligated to provide detailed test procedures, the subcontractor is often reluctant to provide the exact procedures due to potential trade secret protection. Under GMP, contracts with the subcontracted companies should include multiple deliverables, including the requirement of analytical results and the test methods used to generate those analytical results. This information can then be included in a patent application that will meet the new standard for definiteness.

(5) *When contractually assigning rights to a third party, draft the contract to state your company has no control over the third party's use of those rights.*

A recent U.S. Supreme Court case regarding patent infringement also affects the way a company should draft contracts. *Commil USA v. Cisco Systems*, 135 S.Ct. 1920 (2015). In *Commil*, the court detailed the requirements for a type of patent infringement referred to as "active inducement." Active inducement occurs when a first party knows of a patent and induces a second party to conduct acts that the first party knows constitute infringement. See *Commil*, 135 S.Ct. at 1926. In *Commil*, the court confirmed that the first party must have knowledge of the induced acts that cause infringement to be liable for actively inducing infringement.

The *Commil* case affects companies that contract all rights to provide goods or services to a third party. For example, your company may have rights to provide services to a certain facility. Your company may then subcontract the rights to provide services to a third party. Under GMP, to limit the potential for actively inducing infringement, the contract with the third party should clearly state that your company has no control over the method of delivering the services. Moreover, the contract should make clear that the company provides no input or promotion regarding the third party's method of delivering those services. Thus, the contract will limit your company's exposure to potential liability for induced infringement because the company will *not* have induced the third party to conduct activities that may constitute infringement. Moreover, the appropriately worded third-party contract will facilitate an IP due diligence review and illustrate your company's attempt to reduce potential exposure to patent infringement suits.

(6) *Review trademark portfolio to confirm ownership and validity.*

Unlike patents, trademarks are not freely assignable, but instead are tied to the underlying business and its goodwill with customers. Your company's trademark applications and registrations are owned by your company. Under GMP, if you have multiple parties using trademarks, or a difference between the party using a trademark and the party your company believes is the owner of the trademark, your company will need to make sure to have the appropriate ownership or license agreements in place.

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