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Florida's Innovation Boom
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Florida has rapidly built a reputation as a thriving center for life sciences, an established leader in the medical device and information technology industries, and a growing center for the digital media and simulation industry. In Central Florida, the Burnham Institute for Medical Research, the Nemours Children's Hospital, the University of Central Florida (UCF) Medical School, and a new Veteran's Administration hospital will all be built in the next two years. In South Florida, hundreds of scientists are already in residence at the Scripps Research Institute Florida headquarters in Palm Beach County, and Germany's Max Planck Society recently announced that it will establish its first U.S. institute, a bio-imaging center, next to Scripps Florida at the Jupiter campus of Florida Atlantic University (FAU). In early 2009, the Torrey Pines Institute for Molecular Studies will be opening its east coast headquarters in Port St. Lucie, and the University of Miami is in the midst of expanding its medical campus and bioscience research cluster in the City of Miami's Health District. In Tampa, the H. Lee Moffitt Cancer Center & Research Institute continues to expand its efforts in research and biotechnology. With the arrival of these various institutes, the growth of technology transfer centers at Florida universities, and a focused effort to attract capital and nurture the leadership and workforce needed to grow these various industries, there is no doubt that Florida is serious about growing a knowledge-based economy.

At the forefront of this economy is the creation, protection, and enforcement of IP and, in particular, patents. Patents are the driving force for innovation and progress in the United States and provide the incentives for private sector investment and development of new products and discoveries. The market exclusivity afforded by U.S. patent protection motivates entrepreneurs and scientists to expend great resources to develop and produce cutting-edge life sciences, medical device, and information technology products. The protection offered trademarks, copyrights, and trade secrets likewise provides the incentive to invest in innovation and development.

Protecting Certain Inventions and Preserving Patent Rights When Working With the Federal Government

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The exponential growth in Central Florida's Modeling, Simulation, and Training Industry (MSTI) has been fueled in large measure with investment by the federal government. Federal agencies such as the U.S. Departments of Defense, Homeland Security, and Energy have awarded a multitude of government contracts in the region and dedicated significant resources to satisfying its MSTI requirements. Primary by-products of these activities are the valuable inventions that are created by contractors during the performance of a government contract. Such IP often is the "crown jewel" of a company and must be protected from unauthorized use.

The federal government has unique requirements concerning the rights to such inventions, and treatment of these inventions generally occurs under what has commonly become known as the "Bayh-Dole" system (based on the Bayh-Dole Act, 35 U.S.C. § 200, et seq.). Although Bayh-Dole enables U.S. contractors to obtain title to the particular invention conceived or first actually reduced to practice during the performance of a government agreement (Subject Invention), such contractors must provide the federal government with a non-exclusive license that may unwittingly have a potentially broad application. These issues must be recognized and understood by contractors and their investors when working with the government. In fact, with the ability to

navigate this system, inventors and investors may have the opportunity to take advantage of certain "carve-outs" that current law has made to Bayh-Dole.

Current regulations implementing Bayh-Dole are found under Part 27 of the Federal Acquisition Regulation (FAR). The FAR's corresponding patent clauses require, among other things, that contractors disclose their Subject Inventions to the government in a timely manner. Failure to comply with these strict notice and election obligations, for example, could lead to the government taking title to the Subject Invention — an onerous, but possible, outcome. However, once the applicable disclosure requirements have been satisfied, the contractor may elect to retain title to the patent with the understanding that the government will be provided its standard Bayh-Dole license.

Extravagant Arrangements With Physicians Get Device Makers in Big Trouble

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Device makers, like pharmaceutical manufacturers, have long-recognized that their success depends upon making their products known to physicians who will prescribe or recommend the use of their particular product. In addition to their ability to influence current product use, physicians also are in the best position to conduct or oversee research which may expand future market share, including identifying additional clinical uses or adaptations for a product (some of which may not yet be approved by the U.S. Food and Drug Administration (FDA)). With respect to many devices, physicians may not be the actual purchaser of the product; rather, a hospital or surgery center, or even a group purchasing organization, may be the actual purchaser for use in facility procedures. Nonetheless, physicians often serve as thought leaders who can directly and indirectly influence product selection by the actual purchaser.

Recent enforcement activity by the United States Department of Justice (DOJ) and the Office of Inspector General of the Department of Health and Human Services (OIG) demonstrates the government's commitment to limiting manufacturer contacts with physicians that may skew independent medical decision making. The federal Anti-Kickback Statute (AKS) is a criminal prohibition against improper remunerations (broadly defined to include virtually anything of value) to referral sources. In addition, enforcement activity may be premised upon the federal Civil False Claims Act (FCA), even though the device manufacturer does not bill the federal health care programs and the physician may not purchase the product. The requisite "link" is that the FCA can be violated if an individual or entity either submits a false claim, or *causes* a false claim to be submitted, seeking reimbursement from a federal health care program. "Kickbacks" may be alleged to "taint" a claim giving arguable rise to civil false claim liability even if there is no evidence to support the criminal intent required for an AKS violation.

As part of a settlement with the DOJ involving a health care entity, a Corporate Integrity Agreement (CIA) often is required. This is the OIG's contract with the entity with respect to future performance, and reciprocates for the OIG's relinquishment of its option to exclude (debar) the entity from participation in federal health care programs (e.g., Medicare and Medicaid). CIAs also provide the industry with guidance as to the operational monitoring the OIG would like, or expect, to see from similarly situated entities. For example, the September 2007 CIA with Smith & Nephew, Inc., requires the creation of a database for all its arrangements (including those with physicians) with eight required categories of information, including the methodology for determining compensation. This CIA also requires tracking of all remuneration to and from parties to these arrangements.

In a new twist, the DOJ recently required public disclosure of physician arrangements as part of a Deferred Prosecution Agreement to resolve AKS allegations. The device maker (Company) was required to prominently feature on its Web site the name, city, and state of residence for each of the Company's consultants (defined to include physicians), along with the payments made to each consultant.

Best Practices
Best practices for device manufacturers to consider to avoid the enforcement trap include the following:

- Manufacturers should have an effective compliance program, including adequate resources to support it. Some states may require a compliance plan as a condition for doing business in the state (e.g., California's SB 1765). Codes of ethics or conduct and similar guidance published by trade associations like AdvaMed, PhrMA, NEMA, and the American Medical Association (and others), provide basic guidance on contacts with physicians, and should be considered to represent "industry standard."

- Manufacturers should critically review all existing arrangements with physicians including, but not limited to, the following:
    - Vendor-sponsored product training and education
    - Support for third-party educational conferences
    - Sales and promotional meetings with physician participation
    - Consulting arrangements
    - Gifts, paid entertainment, recreation, and meals
    - Charitable donations
    - Research grants
    - Preceptorship agreements

- Policies and procedures should be designed — and followed — for approval of future arrangements with physicians. It is particularly important to document all terms of such arrangements, including the services to be provided (and proof that they were provided) and the methodology for compensation. "Safe harbors" specified in the regulations may provide protection against AKS allegations if all requisite conditions are met.

- Sales and marketing staff must be trained on the risks associated with basic marketing practices that may be fully acceptable — or even considered key strategies — in non-health care lines of business.

Conclusion
Device manufacturers, following pharmaceutical manufacturers who, in turn, followed direct health care providers, are now the subjects of government enforcement activity. An initial enforcement focus is the manufacturers' relationships with physician thought leaders. Due care must be taken to assure compliance with all laws and regulations regarding such arrangements.

Catalyst for Growth: The Role of Incubators and Other Support Entities in the Lives of Start-Ups and Emerging Companies in Florida

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The formation and operation of start-up companies is a fast-growing avenue of technology transfer in Florida, particularly for commercialization of technologies in the life sciences, medical device, and biotechnology areas. University technology transfer and licensing offices as well as technology "incubators" and other entities increasingly are nurturing and supporting the growth of such start-ups.

While university technology transfer and licensing offices traditionally work with academic researchers to provide resources and support for the identification, marketing, and licensing of their innovations, technology incubators are focused on providing an environment conducive to the growth of start-up companies, which often requires access to capital and business-related services, particularly at the early product and customer development stage. Incubators such as those at the University of Florida, University of Central Florida, and Florida Atlantic University, can help fill the gap by leasing customizable office space and research facilities such as "wet labs." This may attract partners such as angel investors, venture capitalists, and providers of business services such as legal and accounting, especially in connection with the protection and management of IP and the procurement of funding, the lifeblood of emerging companies.

In addition to incubators, industry and even regional geographic communities have aggregated resources to create environments conducive to start-up growth. For example, in San Diego, CONNECT, a "public benefits organization" founded by the University of California, San Diego in 1985, catalyzes, accelerates, and supports the growth of promising life sciences businesses by facilitating networking between start-ups and CONNECT "partners" that are able to provide high-level expertise in the fields of life sciences, law, accounting, investment banking, marketing, and communications.

An important aspect of incubators and entities such as CONNECT, in general, is the networking opportunities that they provide, particularly with business service providers. Start-ups and their financiers face a number of significant events and milestones early in the existence of an emerging company. Start-ups must be careful to avoid losing or damaging their existing or potential IP rights, which can result from taking an action without the knowledge and consideration of the consequences. Likewise, it is important for start-ups to consider how IP portfolios will be protected and managed as a start-up grows, especially in light of financing transactions, potential public offerings, or merger, acquisition, and licensing transactions. In addition to these types of events, start-ups must consider how to set up corporate governance and structures and funding agreements as well as employee and confidentiality agreements to protect IP. Identifying experienced and knowledgeable advisors and counselors can smooth the path of rapid start-up growth.

Incubators and "incubator-like" entities can help get start-ups "over the hump," particularly by offering physical research facilities and access to business support and development networks. To be successful, Florida technology start-up companies require capital and related corporate services such as accounting and legal. Incubators and other support entities are set up to provide resources needed by start-up companies as well as an environment conducive to growth.

Florida's Personalized Medicine Industry: Patentability

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Personalized medicine applies information about a person's unique genetic makeup and environment when treating and preventing diseases. The field frequently takes advantage of diagnostic kits, tools, and molecular screening methods for biomarkers. In recent years, Florida has positioned itself to become a leader in this field. For example, H. Lee Moffitt Cancer Center & Research Institute has extensively engaged in relevant research and development, and has partnered with companies and universities.

Florida's personalized medicine sector can benefit greatly from patent protection. Relevant legal issues — such as those relating to "subject matter" patentability — have a bearing. Courts have clarified that patentable subject matter, while broad in scope, does not include laws of nature, natural phenomena, or abstract ideas.

In *Laboratory Corp. v. Metabolite*, the U.S. Supreme Court addressed subject matter patentability of diagnostic methods and kits. The claim at issue read: "*A method for detecting a deficiency of cobalamin or folate ... comprising ...: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine ... with a deficiency of cobalamin or folate.*" The "correlating" step, not the "assaying" step, provided the novel component.

The Supreme Court initially agreed to address whether the claim corresponded patentable subject matter, but later dismissed the case. Several Justices wrote an opinion, however, indicating that the claim was "not a process for transforming blood or any other matter," but rather "instructs the user to (1) obtain test results and (2) think about them." The fact that the assaying step involved the transformation of blood through an unpatentable (known) procedure was unavailing. As stated by Justice Breyer, the "correlation is an unpatentable 'natural phenomenon'."

Federal Circuit decisions also may be relevant. Although relating to computers and/or "business methods," recent cases may impact subject matter patentability in the field of personalized medicine.

For example, *In re Comiskey* addressed the patentability of a business method patent. The court noted that if an abstract concept has a practical application in a process, a process claim is patentable only if the abstract idea "is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter." Here, however, claims merely added a known computer/device to an otherwise unpatentable mental process. The court stated that "[t]he routine addition of modern electronics to an otherwise unpatentable invention typically creates a prima facie case of obviousness."

A pending case, *In re Bilski*, also relates to a business method patent. The Federal Circuit recently decided to rehear this case en banc to address issues such as when a claim containing both mental and physical steps creates unpatentable subject matter, and whether a method must result in a physical transformation of an article or be tied to a machine to be patentable.

Florida's personalized medicine industry should take care when preparing and pursuing patent applications — especially considering recent court decisions. By understanding legal requirements such as subject matter patentability, innovative groups in Florida can obtain maximum benefit from patenting efforts.

If you have any questions about this issue or would like to discuss these topics further, please contact your Foley attorney or the following individual:

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