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New Rules — What Now?

Immediate Steps to Address the New USPTO Claims and Continuations Rules

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What do you need to be doing now with your pending patent applications? The United States Patent and Trademark Office (USPTO) has finalized new rules that will substantially impact the way some patent applications will be prepared and the options available for all currently pending and future applications. In summary, the new rules limit the number of applications that can be filed within a patent family and the number of claims that may be filed on a particular invention, regardless of the number of separate applications directed to that invention.

Because the effective date of the rules is November 1, 2007, every medical device company should be aware of options they have now that disappear on the effective date as well as steps they should be taking now to best preserve their rights.

As with any new government rules package that occupies more than 125 pages in the Federal Register, there are numerous options and exceptions that apply to any attempt at a concise explanation of the rules. Therefore, those having pending patent applications at the USPTO are encouraged to consult with their patent counsel regarding how the rules impact their currently pending applications.

File Any Desired Applications That May Be Impossible to File as of November 1, 2007

The strategy of keeping one application pending in a chain of related applications, in order to keep options open, will soon be severely limited. The new rules establish a limit of two continuation applications and one request for continued examination (RCE) per patent family (defined by U.S./PCT non-provisional priority date) as a matter of right. Divisional applications, filed in response to a restriction requirement, do not count as part of the parent's patent family. The divisional application is directed to a different invention and therefore starts a new family with respect to the new continuation, RCE, and claim limits.

The new rules prohibit filing a continuation-in-part (CIP) application claiming priority to a divisional application. However, this option remains available before November 1, 2007.

Consider filing an RCE before November 1, 2007. If an RCE has already been filed in the family (including parent, sister, or child cases), no further RCEs are permitted as a matter of right as of November 1, 2007.

Despite the limits on continuations noted above, the rules provide for one more continuation across the family on or after August 21, 2007, which can be filed anytime, including after November 1, 2007. However, if you would like to file more than one continuation per family, or have already filed a continuation in the family on or after August 21, 2007, you may want to consider filing other continuation application(s) or CIP(s) before November 1, 2007.

Claim Limits for Patent Families

The new rules establish a limit of 5 independent and 25 total claims per application, but the USPTO may count claims in other applications toward the 5/25 limit if any claims between the applications are not "patentably distinct." This 5/25 limit applies to any case without a first Office Action mailed by November 1, 2007 that has not received a Notice of Allowance, and applies after any Restriction Requirement. The 5/25 claim limit is waived in an application if a new Examination Support Document (ESD) is filed before the first Office Action on the merits.

To reduce the effective claim count of an application without canceling claims, applicants can encourage, and simultaneously commit to, a Restriction Requirement and election by filing a new Suggested Restriction Requirement (SRR) document.

Any unclaimed embodiments are best addressed and claimed now, to permit a CIP if needed. Earlier action also can give more time to prompt a restriction requirement and/or factor new claims into the 5/25 claim limits.

Office Action and Restriction Responses

Consider the new rules, and their limits on claims and further application/RCE filings, in any Office Action response or plan to file a continuation or RCE in current negotiations with examiners. Any pending or newly filed application is subject to the claim limits, unless a first Office Action on the merits, or allowance, is mailed before November 1, 2007.

There is a benefit to not traversing restriction requirements in order to permit filing of divisional applications.

Gather Application Data for Reporting Obligations and to Determine Patent Families

There will be mandatory reporting obligations for pending cases generally, not just new or recently filed cases, that are: (1) commonly owned, co-pending applications with a common inventor and any priority dates within two months of each other, regardless of application content; or (2) commonly owned, co-pending applications with a common inventor, any same priority date, and overlapping content. There also are reporting obligations for CIP applications.

Companies who use in-house and outside counsel, or who use more than one outside counsel for patent prosecution, should start gathering information now, and may need to establish information-sharing procedures to ensure compliance.

Start your planning now and involve your entire IP team, including outside counsel, that have a role in filing cases.

Recent U.S. Regulatory Developments Herald Increasing FDA Regulation of Laboratory-Developed Diagnostic Tests and Services

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Recent regulatory developments continue to signal that, barring congressional or judicial intervention, the U.S. Food and Drug Administration (FDA) intends to bring many more diagnostic test products and systems under regulation as "medical devices" under the Food, Drug, and Cosmetic Act (FDCA).[1] The specific class of products are those classified as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs),which include many genetic-based tests as well as many diagnostic test systems/services developed and marketed by clinical laboratories. While many such products are on the market or currently under development, as a matter of traditional FDA enforcement policy very few have been regulated as medical devices to date.[2] However, FDA's current — and still evolving — policy signals a strong possibility that previously unregulated diagnostics could require FDA approval or clearance prior to marketing as well as being subject to other medical device requirements under the FDCA, including compliance with FDA's Quality Systems Regulations (QSRs), product listing and facility registration, and adverse event reporting.

The specific class of products to be regulated as IVDMIAs was recently redefined by FDA as part of a revised draft guidance document, *Draft Guidance for Industry, Clinical Laboratories, and FDA Staff – In Vitro Diagnostic Multivariate Index Arrays* (July 26, 2007) (Revised Guidance).[3] The Revised Guidance replaces an earlier version issued in September 2006.[4] Both versions of the guidance represent a significant shift from traditional FDA enforcement policy, under which FDA did not consider it necessary as a matter of public health and safety to regulate various diagnostic tests and test components, including those now defined as IVDMIAs.

As newly redefined, an IVDMIA is a medical device that (1) combines the values of multiple variables using an interpretation function (algorithm) to yield a single, patient-specific result (e.g., a "classification," "score," "index," and so forth) that is intended for use in the diagnosis of disease or other conditions; and (2) provides a result whose derivation is non-transparent and cannot be independently derived or verified by the end user.[5] Examples of IVDMIAs identified in the guidance include gene expression profiling assays for breast cancer prognosis; products/systems that predict disease risk by integrating results from multiple immunoassays; and those that predict risk or diagnose disease by integrating age, sex, and genotype of multiple genes.[6] The Revised Guidance also provides multiple examples of devices that are not considered to be IVDMIAs.[7] While the Revised Guidance provides a general overview of medical device requirements and their potential application to IVDMIAs,[8] it anticipates a transition period of 12 months following the issuance of additional and more detailed guidance on the application of particular device requirements such as QSRs.[9]

The draft IVDMIA policy was widely opposed by diagnostic test manufacturers and clinical laboratories as unnecessarily burdensome, confusing, and detrimental to the development and commercialization of needed diagnostic technologies.[10] Preliminary comments indicate that the Revised Guidance will be equally controversial, and that many details remain to be resolved before it can effectively be implemented. For example, the newly added definitional provision that IVDMIA results are "non-transparent" and "cannot be independently derived and verified by the end user" appear potentially subject to debate, as does the application of various examples newly added to the Revised Guidance. As the guidance itself recognizes, still further detailed guidance will need to be developed in order to apply the medical device QSR regulations to

laboratory-developed IVDMIAs, and to resolve potential overlap or conflict with separate regulations applicable to clinical laboratories under the Clinical Laboratories Improvements Act of 1988 (CLIA). Finally, there may be grounds for potential legal challenges to FDA's interpretation of its "medical device" jurisdiction as well as its use of non-binding guidance documents rather than notice-and-comment rulemaking to impose the requirements at issue.[11]

In addition to FDA's ongoing guidance process, a separate but related development has been unfolding at the Center for Medicare Services (CMS), which is responsible for the regulation of clinical laboratories under CLIA. Many comments on FDA's regulatory policies involving IVDMIAs and other diagnostics not historically regulated as medical devices have argued that such products are already adequately regulated under CLIA. Additionally, parties across the spectrum of public debate about genetic-based testing have proposed that such products and services should primarily be regulated by CMS under a new CLIA "specialty" for genetic testing, and in 2002 CMS announced plans to do so. In August, 2007, however, CMS formally declined to proceed with such rulemaking at this time.[12]

In summary, as matters now stand, it is clear that many questions about the appropriate role of federal agencies in regulating genetic testing and other innovative diagnostic products and technologies remain to be fully identified, much less resolved. Based upon recent events, however, it appears that FDA is poised to take a far more active role than it has in the past.

[1] FDCA § 201(h).

[2] Specifically, FDA did not think it necessary as a matter of public health or safety to regulate either the active components of diagnostic tests ("analyte specific reagents" or ASRs), or "home brew" tests developed and marketed by clinical laboratories using commercially marketed ASRs. Most IVDMIAs are considered to be a subset of laboratory-developed test.

[3] Available at http://www.fda.gov/cdrh/oivd/guidance/1610.pdf.

[4] Available at http://www.fda.gov/cdrh/oivd/guidance/1590.pdf.

[5] Revised Draft Guidance at 5.

[6] Id. at 5-6.

[7] Id. at 6-7.

[8] Id. at 7-9.

[9] Id. at 10.

[10] For a summary of public comments on the 2006 Draft IVDMIA Guidance, see www.dnapolicy.org/resources/FDAIVDMIAcommentchart.pdf.

[11] For more detail on these and other points, see American Clinical Laboratory Associations, Comment to FDA Docket No. 2006D-0347 (Aug. 24, 2007), available at http://www.clinical-labs.org/documents/ACLACommentstoFDAonIVDMIARevisedDraftGuidanceAugust2007_000.pdf.

[12] This position was stated in response to a 2006 Citizen Petition submitted to CMS by the Genetics and Public Policy Center, asking CMS to develop a CLIA specialty regulation and proficiency standards for genetic testing. See http://www.dnapolicy.org/resources/CMSresponse8.15.07.pdf (Petition Denial Letter, Aug. 15, 2007); http://www.dnapolicy.org/resources/Petition_For_Rulemaking_September_2006.pdf (Citizen Petition). Key reasons cited by CMS for denying the petition were a lack of evidence that the requested regulation would significantly advance the resolution of key issues in genetic testing, the current adequacy of general CLIA requirements without an addition specialty regulation, and an unfavorable balance of costs versus benefits.

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

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Entrepreneurship, as channeled into the formation and operation of start-up companies, is a fast-growing avenue of technology transfer, particularly for commercialization of technologies in the life sciences and biotechnology areas. Traditionally, university-developed technologies have been developed for commercialization through licenses to government or corporate entities for applied research directed to specific commercial uses. However, the increasing importance of technology as a component of corporate/enterprise value (as opposed to the traditional emphasis on tangible assets) has fueled an increase in entrepreneurial activity directed to start-up companies. Government, industry, universities, and their surrounding communities also are paying attention to the related economic potential, by materially supporting the development of emerging companies. For example, university technology transfer and licensing offices are increasingly providing business-related support such as business planning and marketing directly to start-ups companies focused on commercializing technology developed in the university's labs. In addition, technology "incubators" and other entities such as Technology Ventures Corporation, and San Diego's CONNECT organization (which receive state, university, and corporate support), nurture and support the growth of start-ups. This article explores the role of incubators and these types of organizations as well as related legal considerations.

To be sure, the concept of technology incubators is not new. Many have been founded as outgrowths of the support provided to university start-up companies by university technology transfer and licensing offices. Traditionally, university technology transfer and licensing offices have worked with academic researchers to provide resources and support for the identification, marketing, and licensing of their innovations. In contrast to these broader duties and responsibilities of university licensing and technology transfer offices, incubators are focused on providing an environment conducive to the growth of start-up companies. Start-ups often require access to capital and business-related services, particularly at the early product and customer development stage. Incubators can help fill the gap by leasing customizable office space and research facilities such as "wet labs." In addition to physical facilities, incubators attract partners such as angel investors, venture capitalists, and providers of business services such as legal and accounting (which start-ups require), especially in connection with the protection and management of intellectual property (IP) and the procurement of funding, the lifeblood of emerging companies. The close-knit nature of an incubator environment allows for ease of networking between start-ups, technologists, investors, and service providers throughout the life cycle of a start-up company.

This type of environment provides other benefits as well. Many incubators are located in close proximity to university research facilities, thus allowing for useful intellectual exchange during the innovation process, and the sharing of services. University technology transfer and licensing offices also can provide marketing support by showcasing technologies and companies that are "in the pipeline." Numerous universities have been involved in founding and operating incubators. Examples include: the IC[2] Institute in Austin, near the University of Texas, the University of Florida's Sid Martin Biotechnology Incubator,[1] and the Entrepreneurial Research Laboratory (ERL) at Boston University. The ERL offers a unique program under which it provides free incubator space to young entrepreneurs who give back to the school by presenting guest lectures on their innovative work.[2] Many states also have taken notice of the potential for regional economic benefits provided by incubators, and thus provide financial and other support to such incubators. Additional support/partnership often is provided by industry, venture capitalists, and business service providers, thus rounding out the start-up support network that incubators provide.

In addition to incubators, industry and even regional geographic communities have aggregated resources to create environments conducive to start-up growth. For example, the San Diego area's CONNECT, which describes itself as a "public benefits organization," specifically catalyzes, accelerates, and supports the growth of promising life sciences businesses.[3] CONNECT facilitates 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. Interestingly, CONNECT was founded by the University of California, San Diego, in 1985, and due to its success, has been replicated in other cities, such as St. Louis, and other countries, such as Scotland, Denmark, Norway, Sweden, and Taiwan.

Technology Ventures Corporation (TVC) is an example of industry playing a role in start-up support. It provides training and support to start-up companies in connection with forming, planning, financing, operating, and expanding technology-based businesses.[4] TVC also has developed a unique model to connect inventors, entrepreneurs, and investors for the purpose of creating companies and taking laboratory inventions to the marketplace.[5] TVC was founded by Lockheed Martin Corporation in 1993, in conjunction with a proposal to manage the U.S. Department of Energy's Sandia National Laboratories. TVC has certainly proven its unique technology commercialization model: since 1993, TVC has been involved in funding events totaling $817 million, and the formation of 93 new businesses.[6] More specifically, it has helped start-up companies such as Arcxis,[7] a privately held biomedical device firm, and VeraLight,[8] a privately held medical device company, raise multiple millions of dollars in financing. These resources are invaluable to emerging companies in the development, testing, and introduction of new products based upon technology.

An important aspect of entities such as CONNECT, TVC, and incubators, 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 should be careful to avoid losing or damaging their existing or potential intellectual property rights, which can result from taking an action without the knowledge and consideration of the consequences. It also is important 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 should carefully 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.

In conclusion, entrepreneurship in the life sciences and medical device industries, particularly as embodied in start-up companies, has become a significant mode of commercializing technology products in the industries. 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, 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.

[1] The Sid Martin Biotechnology Incubator is a 40,000 square foot facility with 19 "wet" laboratories, and $1,000,000 in equipment. It is presently fully occupied by 12 start-ups, including Banyan Biomarkers, Pasteuria Bioscience, and AxoGen Nerve Regeneration. *Source: Business Week*, May 21, 2007, Innovation: "MIT, Caltech-And The Gators?"

[2] *Computerworld*, June 26, 2007: "Boston University Unveils Technology Incubator With a Twist"

[3] www.connect.org/about/index.htm

[4] www.techventures.org/whatwedo/entrepreneurs.php

[5] www.techventures.org/whatwedo/index.php

[6] www.techventures.org/

[7] www.techventures.org/news/index.php?releaseID=065

[8] www.techventures.org/news/index.php?releaseID=063

KSR v. Teleflex — Are Medical Device Patents at Risk?

The Supreme Court Rejects the Federal Circuit's Rigid Approach to Obviousness Determinations

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In patent law it is not always obvious, or easy, to determine what is an "obvious" invention. Lawyers, judges, inventors, and business executives continue to struggle with this seemingly simple issue.

On April 30, 2007, the U.S. Supreme Court gave us its current guidance on the subject when it unanimously reversed the U.S. Court of Appeals for the Federal Circuit in *KSR International Co. v. Teleflex Inc*. The Supreme Court's opinion fundamentally changes the law regarding obviousness in a manner that is likely to make patents on medical devices harder to obtain and enforce.

The *KSR* case concerns a basic issue of whether or not a claimed invention is patentable. The invention in this case was a mechanism that combined an electronic sensor with an adjustable automobile pedal so that the pedal's position can be transmitted to a computer that controls the throttle in the vehicle's engine. However, the principles of the *KSR* case would apply equally as well to an electronic sensor that controls a pump drive used, for example, in a heart-lung machine.

Obvious Inventions Are Not Patentable

An applicant is not entitled to a patent if the differences between the invention sought to be patented and prior patents, prior publications, or other prior information are such that the invention as a whole "would have been obvious" at the time the invention was made to a person having ordinary skill in the technology to which the invention pertains. In applying this standard, the Federal Circuit has held that even if all of the elements of an invention can be found somewhere in prior patents, publications, or other available information, the invention still is not obvious unless there is a "teaching, suggestion, or motivation" to combine the prior information to create the claimed invention, with the "teaching, suggestion, or motivation" found in some place other than the inventors' disclosure.

The Supreme Court opinion reversed the Federal Circuit's "rigid approach" in analyzing the question of obviousness. In so doing, the Supreme Court's opinion re-emphasized that an obviousness determination required a "broad inquiry."

Are Medical Device Patents at Risk?

In the *KSR* opinion, the Supreme Court re-emphasized some old principles that likely will make medical device patents harder to obtain and easier to invalidate. Many medical device inventions, like almost all inventions, are combinations of elements and components — for example, pumps, filters, needles, prostheses, or electrical components — that are well-known and commonly used. In the *KSR* case, the Supreme Court stated a need for caution in granting a patent based upon a combination of elements found in the prior art, particularly when the invention only unites old elements with no change in their respective functions. The Supreme Court stated that a combination of familiar elements "is obvious," and thus not patentable, if the combination does no more than "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement." Those seeking to obtain or enforce medical device patents can expect to face some form of this logic applied to conclude their invention is "obvious."

Yet, as a practical matter, most inventions in most technologies are made of old or familiar elements. As Judge Learned Hand observed almost 50 years ago, "substantially every invention" is a "combination[] of old elements." *Reiner v. I. Leon Co.*, 285 F.2d 501 (2d Cir. 1960) More recently, the Court of Appeals for the Federal Circuit wisely noted that in making inventions "Men [and women] must work with old elements." *Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985). Nobel laureate Albert Szent-Gyorgyi observed, "Discovery consists of seeing what everybody has seen and thinking what nobody has thought." However, if what everybody has seen are old or familiar elements, this may be "discovery," but the Supreme Court may have some doubts as to whether it is a patentable invention.

The Supreme Court's opinion states that the obviousness inquiry "must ask whether the improvement [represented in the claimed invention] is more than the predictable use of prior art elements according to their established functions." If it is, the invention likely will be found to be not "obvious."

Aircraft or Heart Valves — What's the Problem?

The Supreme Court identified three errors in the Federal Circuit's obviousness analysis. First, the Supreme Court held that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." This is in contrast to the Federal Circuit's rule that only problems addressed by the patentee could be considered as the source of a motivation to combine references. Thus, for example, under the logic of *KSR*, a prior patent seeking to solve a problem involving turbulent flow of air over the wing of an aircraft may be used against a medical device invention seeking to solve a problem involving turbulent flow of blood over a heart valve, since both arguably relate to the same problem — turbulence — and the same field of endeavor — fluid flow.

A Person of Ordinary Skill Is Not an Automaton

Second, the Supreme Court held that the Federal Circuit had adopted too constricted a view of the person of ordinary skill in the art. Because "[a] person of ordinary skill also is a person of ordinary creativity, not an automaton," the fact that an invention is obvious to try may suffice to establish unpatentability.

Common Sense and the "Obvious to Try" Standard

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not one of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious.

Third, the Supreme Court explained that the Federal Circuit had overemphasized the risk that patent examiners and courts would fall prey to hindsight bias.

The Supreme Court's opinion revised the tests for obviousness and did so in a manner that is likely to make medical device patents harder to obtain and easier to invalidate. Indeed, recent cases following *KSR* have indicated this is what is happening. In making decisions about obtaining or enforcing medical device patents, inventors and business executives need to thoroughly understand the new "obviousness" analysis.

The High Cost of Being a Public Company Under the Sarbanes-Oxley Act

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In January of 2003, Foley began an annual study of the corporate governance compliance costs associated with the Sarbanes-Oxley Act (Act), a then-new phenomenon in the business world that has since become a household name. While our methodology evolved over the years as we learned how best to gather and analyze our data, one element remained constant: Corporate governance reform comes with a heavy financial burden for today's public companies.

Even now, more than five years after the Sarbanes-Oxley Act's initial implementation, costs associated with corporate governance compliance continue to rise. The question "corporate governance at what cost?" remains as relevant as ever.

Cost of Being Public

What we have found in the fifth year of our study is that companies are still paying millions of dollars to comply with the Act and related governance reforms. Specifically, the 2007 edition of our study, "The Cost of Being Public In the Era of Sarbanes-Oxley," determined that the average cost of compliance for companies with under $1 billion in annual revenue has increased more than $1.7 million to approximately $2.8 million since the enactment of the Act. This represents a 171 percent overall increase between fiscal years 2001 and 2006.

Notwithstanding the large cumulative increase since 2001, this year's study found only a slight increase in overall corporate governance compliance costs (one percent) in fiscal year 2006. This slight increase followed a 19 percent decrease in fiscal year 2005.

The 2005 decrease resulted primarily from a 46 percent decrease in lost productivity reported in fiscal year 2005. Lost productivity decreased another 48 percent in fiscal year 2006. Other studies have concluded that the realization of efficiencies after the initial phase-in of Section 404 in fiscal year 2004 have driven down costs, and the reductions we have seen in lost productivity in 2005 and 2006 are consistent with that conclusion. Nevertheless, these decreases in lost productivity in 2005 and 2006 have not reversed the extraordinary increases in lost productivity seen in 2002 (102 percent increase), 2003 (72 percent increase), and 2004 (556 percent increase), and lost productivity in fiscal year 2006 was $290,000, a 530 percent increase from $46,000 in fiscal year 2001.

While overall costs associated with Act compliance have "plateaued," the out-of-pocket costs facing public companies have increased between fiscal years 2005 and 2006. Out-of-pocket costs associated with Act compliance were up 13 percent in fiscal year 2006 from fiscal year 2005 for public companies with annual revenue of under $1 billion, and they were up 12 percent over the same period for public companies with annual revenues over $1 billion. The increased cost of audit fees, board compensation, and legal fees has driven these out-of-pocket increases.

Quality Directors in Short Supply

This year's study also confirms that it continues to be increasingly expensive for companies of all sizes to attract and retain qualified directors. Annual director fees increased steadily and consistently for each category of company analyzed. Overall, annual director fees have increased an average of 70 percent for small-cap companies, 98 percent for mid-cap companies, and 93 percent for S&P 500 companies between fiscal years 2001 and 2006. We believe changes in the accounting rules requiring the expensing of stock options contributed to this trend, as many corporations reduced their grants of stock options to directors and increased cash compensation after these rules phased-in in 2006.

Going Private

This year's study found nearly one in four survey respondents, or 23 percent, are considering going-private transactions as a result of the corporate governance and public disclosure reforms, which is consistent with respondents from previous years. Additionally, respondents to our

2007 survey continued to consider other options, including selling the company (16 percent) and merging with another company (14 percent). It is no surprise that respondents, who are asked to check all options that apply for this question, are increasingly seeking alternatives to going private. We believe this is driven by increased awareness among the business community of the attractive prices being paid in 2006 and early 2007 by private equity funds in the mergers and acquisitions market.

Study Methodology

In 2007, Foley worked with national research firm, KRC Research, to conduct its fifth annual study designed to gauge the true financial impact of corporate governance reform on public companies. Due to the complexities of current reforms and the myriad of governance issues facing companies today, a multi-tiered approach was used to gather the necessary data. The study consisted of a survey designed to measure attitudes toward current reform among top executives and a comprehensive review of a database compiled by Standard and Poor's Investment Services Custom Business Unit from proxy statements filed in 2007 for certain S&P Small-Cap, S&P Mid-Cap, and S&P 500 companies. A copy of the study, including a more thorough description of the study methodology, can be found online at www.foley.com/files/tbl_s31Publications/FileUpload137/3736/Foley2007SOXstudy.pdf.

Thomas E. Hartman has served as director of Foley's annual study: "The Cost of Being Public in the Era of Sarbanes-Oxley" since 2003.

The rapidly changing legislative, reimbursement, regulatory, and technology landscapes, coupled with increasing civil and criminal liability, have posed significant challenges and offered tremendous opportunities for medical device manufacturers.

To help you address these developments, the Medical Device attorneys of Foley & Lardner LLP provide fully integrated experience in U.S. Food and Drug Administration (FDA) and health care regulatory issues, reimbursement, intellectual property law, business law, litigation, and public affairs, enabling us to collaboratively craft effective strategies and implement them with clients.

To learn more, visit ***Foley.com/medicaldevices***.

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