While the overall pace of venture capital investing slowed during Q1 2010 when compared to Q4 2009, the Life Sciences sector continued to lead the way according to the most recent PriceWaterhouseCoopers MoneyTree™ report. While both the number of deals and the dollar amount invested dropped when compared with Q4 2009, Life Sciences led in both number of deals and funds raised. Life Science firms completed a total of 160 deals that raised $1.3 billion, representing a 21 percent drop in number of deals and a 26 percent decline in dollars raised from Q4 2009. The Software industry group was second in both categories during Q1, with 144 deals that raised $681 million. The MoneyTree™ report defines the Life Sciences sector to include firms in the Biotechnology industry group and the Medical Devices industry group. New England led the way in terms of both number of deals and dollars raised among the various regions represented in the Life Sciences sector. New England saw 32 completed deals that raised a total of $412 million, or almost one third of all dollars raised in the Life Sciences sector nationwide.

Two of the largest deals completed during Q1 2010 were biotech deals. On March 31, Achaogen, Inc., of San Francisco, CA, completed a Series C round of $56 million. Achaogen is focused on the discovery and development of innovative broad-spectrum antibiotics to treat life-threatening, multi-drug resistant bacterial infections. The round was led by new investor Frazier Healthcare Ventures, and also included new investor Alta Partners and current investors 5 AM Ventures, ARCH Venture Partners, Domain Associates, Venrock Associates, Versant Ventures and the Wellcome Trust. The funds raised will be used to advance multiple clinical programs, including conducting a Phase 2 study in complicated urinary tract infections of ACHN-490, Achaogen’s lead candidate for multi-drug resistant bacterial infections.

On April 8, SAGENT Pharmaceuticals, Inc., a privately held specialty pharmaceutical company based in Schaumburg, IL, announced that it had raised $40 million through two tranches of a strate-
The field of life sciences has always been faced with ethical questions. Biotechnology, in particular, is repeatedly confronted with controversial issues resulting from discoveries that appear to push the envelope of man’s power over nature.

It is therefore useful to understand the policies of different patent offices addressing these contentious subjects. These policies affect not only what innovations you can protect through patents but also how you can protect them.

Europe has generally shown great concern with ethical issues, particularly in biotechnology, and has implemented means to address such concerns within the EPC (European Patent Convention) patent system. From its inception, the EPC has prohibited, for example, morally offensive subject-matter from patent protection through Article 53(a).

In 1999, the EPC was amended to incorporate provisions from European Community Directive (98/44/EC), the “Biotechnology Directive”. These rules provide guidance as to how to interpret “morality” in the field of biotechnology. Rule 28 provides a non-exhaustive list of four categories of biotechnological inventions that are excluded from patent protection as being considered contrary to morality.

A recent case decided by the EPO’s Enlarged Board of Appeal (Wisconsin Alumni Research Foundation, G 2/06) discusses the legal affect of Art. 53(a) and Rule 28 in the field of stem cell patents. The Wisconsin Alumni Research Foundation (WARF) filed a PCT application in 1996 related to a pioneering new technique to isolate and culture human embryonic stem cells that can be grown in vitro. Stem cells hold great promise as a therapy for a variety of human disorders including diabetes, Parkinson’s disease, muscle damage, and spinal cord injuries. They have the ability to divide and differentiate into a number of other cell types and may be derived from adult tissue, embryonic tissue, or umbilical cord blood. Embryonic stem cells are often considered to have the widest application, as these cells can theoretically differentiate into every type of cell in the human body. Unfortunately, embryonic stem cells are usually only obtainable from the destruction of embryos. The use of human embryos for this purpose has gained the attention of a number of public organizations concerned with the protection of human dignity and wish to prevent the commercialization of embryos.

The patent claims in the WARF application were directed to a cell culture comprising primate (including human) embryonic stem cells which are capable of proliferation in vivo. The Examining Division refused the application for not complying with the requirements of Art. 53(a) and Rule 28(c). Although the claims themselves were not directed to the use of a human embryo, at the time the application was filed, the only source of the stem cell cultures resulted in the destruction of an embryo.

WARF naturally appealed the decision. One of the questions ultimately referred to the Enlarged Board of Appeal was whether Rule 28(c) prohibits the patenting of product claims (such as stem cell cultures) which at the filing date of the application can only be prepared by the destruction of human embryos. The Enlarged Board answered the question with a resounding ‘yes’. The Board concluded that the invention (the stem cell culture) concerns the use of human embryos for an industrial or commercial purpose. The Board further stated that it is irrelevant whether technical developments achieved after the filing date of

**Rule 28**: Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
the patent application make it possible to make or practice the claimed product without the destruction of human embryos. Thus, the critical date by which the “morality” of the invention is assessed appears to be that of the filing date.

The Enlarged Board of Appeal was careful to note that its decision was not concerned with the patenting of human stem cells generally, but only of products that are obtained exclusively by the destruction of human embryos. Since the decision was issued, at least two other stem cell cases have been brought before the Technical Board of Appeal (T 0522/04 and T 0329/06). In both cases the claims were determined to violate Rule 28(c) since the invention at the time of filing was only described through the use of human embryos. The Board did, however, allow claims that specifically excluded human stem cells. As one can imagine, the commercial relevance of such claims may be significantly decreased by such a disclaimer.

Although it may become possible in the future to isolate embryonic stem cells without destroying the embryo, this would still likely be regarded as a use for an industrial purpose and a violation of Rule 28(c). Members of the EPO Examining Division have indicated, however, that methods that utilize already existing embryonic stem cell lines would not contravene Rule 28(c), even though the already existing cell lines themselves were obtained from the use of an embryo.

Through technological advancements it is believed that pluripotent stem cells can now be obtained from non-embryonic source material. While the term “pluripotent stem cell” arguably encompasses embryonic stem cells, other methods which are not contrary to morality could also be used to produce such cells (e.g., reprogramming adult stem cells). Therefore, in stem cell inventions it would seem wise to claim pluripotent instead of embryonic stem cell subject-matter and to include in the patent application various methods and sources for obtaining stem cells.

Although rejection of the early stem cell applications in Europe may seem disheartening for those in biotechnology, applicants should not be discouraged. With the help of thoughtful claim-drafting and awareness of the potential pitfalls, patents can be granted on novel and inventive, albeit controversial subject matter.

For more information, please contact:
Tamara Elmore
Vereenigde
United States Patent Agent
European Patent Attorney Trainee
t.elmore@vereenigde.com

Does a Technology License Necessarily Include a License to All Licensor IP?

If your company receives a license to use or commercialize another company’s technology or know-how, does that license include the right to practice all subsequently acquired intellectual property that covers that technology and know-how?

It is natural to assume yes, since it would be odd for the law to allow a business to say: “I granted you rights to my technology, but since I didn’t specifically include patents [I later acquire], I can still enforce those against you (and, in essence, defeat the license).” Yet that’s largely what happened in State Contracting & Engineering Corporation and State Paving Corporation v. State of Florida (Fed. Cir. 2001).

The plaintiffs (“State”) were successful bidders on a contract to build a sound barrier wall for the Florida Department of Transportation (“Florida”). During construction, State proposed using a cost-saving design, which involved positioning a column in a cement pile. Florida accepted this proposal (the Value Engineering Change Proposal or “VECP”) and signed a Supplemental Agreement. State later patented this new technology. When it learned that Florida was negotiating with other contractors to use data from the VECP, it sought a patent royalty, then sued Florida and 7 contractors for patent infringement, unconstitutional “ takings,” and breach of contract.

The infringement and taking claims against Florida were dismissed on “sovereign immunity” grounds (another lesson here: often you can sue a state government for infringing your IP). The focus became the infringement claims against the contractors, who argued they couldn’t be liable for patent infringement because they were acting under the license to Florida, which included the later-acquired State patents that covered the licensed technology and data.

The court disagreed, pointing out that the agreement “did not explicitly convey any patent rights, require the contractor [State] to surrender its rights to the technology, or bar the contractor from securing a patent on the invention…. The contract’s failure to explicitly provide for the licensing of patent rights is a glaring omission.”

The moral? Don’t assume that a license to use certain technology secures your rights under patents or other IP acquired by your licensor. Therefore, when you (or your client) licenses that technology, be sure the license expressly covers not only the technology (and related know-how) to be used, but also existing intellectual property, and any IP subsequently acquired by your licensor, that covers or is embodied in that
technology and know-how.

For more information, please contact Howard Zaharoff at hzaharoff@mbbp.com.

Small Business Jobs Act Encourages Investment

President Obama has signed the Small Business Jobs Act of 2010 (the “Act”) into law. The Act includes a number of provisions intended to encourage investments in certain types of depreciable assets and in “qualified small business stock.”

Expanded Section 179 Expensing

Section 179 of the Internal Revenue Code provides a limited exception to the general rule that the cost of property acquired for use in a business must be capitalized and recovered in the form of depreciation over a prescribed recovery period that extends beyond the year of acquisition. Instead, Section 179 permits a taxpayer to expense a portion of the cost of qualifying property placed in service in any year, subject to a cap that is reduced on a dollar-for-dollar basis by the cost to the taxpayer of qualifying property placed in service during the year to the extent in excess of a phase-out amount. In general, qualifying property is tangible, depreciable property acquired by purchase for use in the active conduct of a trade or business. Qualifying property need not be new. For a limited period of time, qualifying property also includes certain “off-the-shelf” software that is readily available for purchase by the general public subject to a non-exclusive license without modification.

Before the enactment of the Act, the cap on the amount that could be expensed was $250,000 for tax years beginning in 2010 and $25,000 for tax years beginning in 2011 or thereafter. The phase-out amount was $800,000 for tax years beginning in 2010 and $200,000 for tax years beginning in 2011 or thereafter. Thus, a taxpayer placing $225,000 or more of qualifying property into service in 2011 would not have been able to expense any portion of the cost of the qualifying property under Section 179.

Under the Act, but only for tax years beginning in 2010 and 2011:

- the cap on the amount that may be expensed under Section 179 has been increased to $500,000, and the phase-out amount has been increased to $2,000,000 (thus, for each of 2010 and 2011, a taxpayer may expense under Section 179 up to $500,000 of the cost of qualifying property placed in service, and will not begin to lose the benefit of the full deductible amount until placing more than $2,000,000 of qualifying property into service);
- qualifying property continues to include off-the-shelf software; and
- qualifying property will include certain “qualified real property” (subject to a cap of $250,000).

After 2011, the cap and phase-amount amounts are scheduled to revert to $25,000 and $200,000, respectively, and qualifying property will cease to include off-the-shelf software and qualified real property.

Extended Bonus Depreciation

The post-9/11 stimulus provisions that Congress added to the Internal Revenue Code included Section 168(k). In general, Section 168(k) allowed a taxpayer acquiring and placing certain qualifying property in service by a deadline date to claim a percentage of the cost of the property as “bonus” depreciation for the year in which the property was placed in service. Most recently, the percentage of the cost that was allowed as bonus depreciation was 50%. Qualifying property, for purposes of Section 168(k), was generally new, depreciable, tangible personal (i.e., not real estate) property with a recovery period of 20 years or less. Qualifying property also included computer software not subject to 15-year amortization under Section 197 of the Internal Revenue Code, certain “water utility property” and certain “qualified leasehold improvement property.” Before the enactment of the Act, the deadline date before which qualifying property had to be acquired and placed in service was January 1, 2010 (or January 1, 2011 for certain transportation property, aircraft or property with a recovery period of at least 10 years).

The Act has extended the deadline date before which qualifying property has to be acquired and placed in service to January 1, 2011 (or January 1, 2012 for certain transportation property, aircraft or property with a recovery period of at least 10 years).

Increased Exclusion Amount for Qualified Small Business Stock Gains

Section 1202 of the Internal Revenue Code allows a non-corporate taxpayer who has held “qualified small business stock” (or “QSBS”) for more than five years to exclude a portion of the gain recognized on a sale of the stock. For stock to be QSBS, it must have been acquired upon original issuance (or by inheritance, gift or, under certain circumstances, distribution from another who acquired the stock upon original issuance) from a C corporation that, among other things, satisfies certain “qualified small business” and “active business” requirements. The “qualified small business” requirement limits the applicability of Section 1202 to stock issued by corporations with aggregate gross assets of $50 million or less. The “active business” requirement limits the
applicability of Section 1202 to corporations most of whose assets are used in one or more “qualified trades or businesses” (which exclude, among other things, providing professional services such as law, engineering, accounting and actuarial science). In addition, the corporation may not have redeemed more than de minimis amounts of its outstanding stock within specified periods of time before or after the issuance of the stock in question. “Look-through” rules can allow an S corporation or partnership to pass the benefits of Section 1202 through to its owners.

From the enactment of Section 1202 in 1993, the maximum excludible portion was 50%. Unfortunately, the non-excluded portion has generally been taxed since 2001 at a 28% rate. In addition, a portion of any excluded gain has generally been a preference item under the alternative minimum tax. Given the rate at which the unexcluded portion is taxed, Section 1202 lost much of its luster in 2003 when the maximum rate generally applicable to long-term capital gains from stock sales was reduced to 15%.

The American Recovery and Reinvestment Tax Act of 2009 breathed some new life into Section 1202 by increasing the maximum excludible portion to 75% for QSBS acquired after February 17, 2009 and before January 1, 2011.

Under the Act, the maximum excludible portion of the gain on the sale of QSBS acquired before January 1, 2011 and held for more than five years has been increased to 100%. In addition, no portion of the excluded gain is a preference item under the alternative minimum tax. Thus, gains of eligible taxpayers on sales of QSBS acquired before January 1, 2011 and held for more than five years will not be subject to tax under the regular federal income tax or under the federal alternative minimum tax.

For more information, please contact Chip Wry at cwry@mbbp.com.

Advertising Mine Fields Abound in Life Sciences

In the old days, before high-speed Internet access, America’s airwaves were largely free of advertising for medical devices and pharmaceuticals. That all changed in 1997, when the Food & Drug Administration (“FDA”) loosened its rules on direct-to-consumer advertising for prescription drugs. Since then, many consumers would probably say we’ve gone too far in the other direction. What convinced them? Maybe it was watching football on Sundays, seeing the gray-haired man in the Levitra® ad throwing a football through a tire swing. But what the ad lacked in subtlety of metaphor, it made up for in effectiveness. Levitra® sales topped $300 million per year.

The easing of restrictions on advertising in the life sciences field mirrors a broader trend of allowing more types of advertising across many industries, including in the legal field. This is logical in a free market economy. Truthful advertising allows consumers to make informed decisions and therefore creates more efficient markets. There are many laws and regulations in place to protect consumers from false or misleading advertising, and thus many pitfalls for life sciences companies trying to spread the word about their services and products. Just a few of the most important regulations include:

New FTC Guidelines for Endorsements and Testimonials

In October 2009, the Federal Trade Commission (“FTC”) announced that it had approved new guidelines for advertisers on how to comply with the FTC Act for endorsement and testimonial ads. The FTC guidelines had not been updated since 1980. For the miracle weight-loss pill, it’s no longer enough to flash “before” and “after” photos of the customer who lost 100 pounds. The advertiser must clearly disclose the results that consumers can generally expect. The new guidelines also make clear that “material connections” between advertisers and endorsers (usually monetary payments or free products) must be disclosed. In addition, the guidelines now explicitly provide that both advertisers and endorsers may be liable for false or unsubstantiated claims made in an endorsement, or for failure to disclose material connections. The endorser’s duty to disclose material connections applies even outside the context of traditional ads, such as on talk shows or in social media.

Attorney General Enforcement Actions

In addition to the federal FTC Act (15 U.S.C. § 45), almost every state has its own deceptive trade practices act. These are commonly called “little FTC” acts, and usually allow Attorneys General to bring enforcement actions against false or deceptive advertisements. In 2009, Massachusetts Attorney General Martha Coakley announced that Massachusetts and 26 other states had reached an agreement with Bayer Corporation regarding the marketing of an oral contraceptive called “Yaz®.” The lawsuit accused Bayer of failing to identify the uses the FDA had approved for the drug, and required Bayer to submit all television advertisements for “Yaz®” to the FDA for pre-approval. Bayer was also required to conduct a $20 million corrective advertising campaign to remedy the alleged misinformation from the prior ads.

Private Lawsuits

Consumers and competitors can also sue for false advertising. Consumers often seek class action status for their claims, which creates potentially huge exposure. In 2007, consumers began suing Canadian companies NxCare, NxLabs, and WellNx (and some of
orders, which were initially granted but overturned a few days later. The case remains pending in the Eastern District of Tennessee.

Advertising is an essential component of most life science companies’ marketing efforts. Ensuring compliance with federal regulations—as well as the accuracy of factual claims made in advertising—is crucial not only to avoiding liability, but also to building and maintaining the consumer trust that is essential to success in today’s hyper-competitive marketplace.

For more information, please contact our Trademark Practice Group.

U.S. Supreme Court Weighs in on Patent-Eligible Subject Matter in Bilski Decision

In a decision by the U.S. Supreme Court, the requirements for patent eligibility of business methods, software, biotech diagnostics, and other process-based inventions have been clarified, and the Court confirmed that patents claiming these types of technologies are not categorically precluded. Specifically, the Court recognized that these types of inventions can qualify as patentable subject matter so long as they are not claimed as merely “abstract ideas”.

The Bilski patent claims were actually deemed not to qualify as a “process” because they claimed an abstract idea relating to the concept of hedging risk and the application of that concept to energy markets through use of a mathematical formula.

In its analysis, the Court indicated that a more restrictive test (the machine-or-transformation test) that has been relied upon most recently as determinative of patentability “is not the sole test for patent eligibility under §101”, but that it is merely a “useful and important clue or investigative tool” for deciding whether an invention is patent-eligible.

The Court stated that when looking at inventions relating to statistical analyses and mathematical calculations, a limiting principle should instead be the unpatentability of abstract ideas. The Court provided examples of precedent where inventions were deemed to be claimed as abstract ideas (an algorithm for converting binary-coded decimal numerals into pure binary code, and a procedure for monitoring the conditions during the catalytic conversion process relying upon a mathematical algorithm). The Court then provided an example precedent where an invention was deemed to be a patent eligible process and not merely an abstract idea (an application of a mathematical formula to a known structure or process in the form of a claim to a method for molding raw, uncured synthetic rubber into cured precision products, the method relying upon a mathematical formula executed by a computer to complete some of the several method steps).

To read the full decision, please visit the Supreme Court online at http://www.supremecourt.gov/opinions/09pdf/08-964.pdf.

For more information, please contact Sean Detweiler at sdetweiler@mbbp.com.
Pharmalucence, Inc. is a privately-held, employee-owned company specializing in the production and marketing of radiopharmaceuticals and the furnishing of contract drug formulation, analytical methods development and production services. Pharmalucence traces its roots to CIS-US, Inc. CIS-US was incorporated in 1985 to commercialize medical applications from isotopic technologies developed by its European parent company. In mid-2007, Pharmalucence was created via the management buy-out of CIS-US by three long-term employees who shared the vision to become the leading company in radiopharmaceutical supply and, in so doing, establish an advanced drug production capability that could be leveraged as a contract manufacturing organization.

Pharmalucence currently makes eight compounds used in the diagnosis of illnesses like cancer or heart disease. The company sells its excess production capacity to other pharmaceutical companies that need production support. Pharmalucence received approval of its first new product, the hepatobiliary imaging agent generic Mebrofenin, in 2008. In July 2009, the company was notified of FDA approval for its generic Sestamibi, an agent used in the majority of heart imaging studies.

With its new product line additions and the on-going demand for its traditional products, Pharmalucence has initiated investment in its production infrastructure during 2010. The company has announced its plan to construct a state-of-the-art, 70,000 square foot pharmaceutical production facility and new corporate headquarters at 29 Dunham Road, Billerica, MA. The company expects to create 25 to 30 new jobs as a result of this expansion. The project is supported by the first Recovery Zone Facility Bond issued in Massachusetts. The $20 million bond was issued on the company’s behalf by MassDevelopment and purchased by TD Bank.

This new facility will support Pharmalucence product supply and provide the foundation to make the organization a key source of contract production of injectable drugs. The facility will feature advanced automation and use methods that isolate manufacturing within an aseptic envelope to enhance cleanliness and regulatory compliance. This facility will be among the first of its kind available to contract manufacturing customers. It will support small clinical trial lots to full commercial scale production for markets worldwide. Construction will commence during the summer of 2010 with full operation expected by the end of 2012.

For more information on Pharmalucence products and services, visit http://www.pharmalucence.com.