BIOINSIGHTS

SUMMER 2013

We are pleased to share this latest issue of Wiggin and Dana's BioInsights Newsletter. We circulate this newsletter by e-mail periodically to bring to the attention of our colleagues in the biotechnology and life sciences industry reports on recent developments, cases and happenings at Wiggin and Dana. We welcome your comments and questions.

JIM FARRINGTON

PATTI MELICK

About Wiggin and Dana LLP

Wiggin and Dana is a full service firm with more than 140 attorneys serving clients domestically and abroad from offices in Connecticut, New York and Philadelphia. For more information on the firm, visit our website at www.wiggin.com.

FirmNEWS

Wiggin and Dana Expands Biotechnology and Life Sciences Practice Group

Wiggin and Dana is pleased to announce that Lily Wound has joined the firm as Counsel in the firm's Biotechnology and Life Sciences Practice Group.

Lily joins Wiggin and Dana from Kaye Scholer LLP where she was a member of the firm's Corporate Department and Life Sciences Group. She has extensive experience representing pharmaceutical, biotechnology, vaccine and other life sciences clients on a wide range of complex commercial, corporate and licensing transactions. She has worked on transactions at all stages of a product's life cycle.

"Lily is an excellent addition to our team," said Jim Farrington, head of the firm's Biotechnology and Life Sciences practice. "Her science background will give her a unique capacity to communicate with our life sciences clients and understand their technology in connection with their transactions."

Lily's legal career started at Coudert Brothers LLP. She received her J.D. from The George Washington University Law School. She received her Master of Public Health from the Boston University School of Public Health and her B.A., *cum laude*, in the Biochemical Sciences from Harvard University.

IndustryNEWS

TerraLex Life Sciences Newsletter

Industry is increasingly turning to universities and other academic institutions to access innovation. Recent examples include many multiple-party consortiums and multiple-year collaborations with large pharma companies involving funding of $100 million or more. Academic institutions can be a rich source of innovative research, but industrial partners should keep in mind some legal constraints that apply specifically to universities.

CLICK HERE to read a summary of some of the more important issues for academic research in five significant countries. The summary was prepared by partners from the TerraLex Life Sciences Group.

FirmDEALS

Wiggin and Dana Advises Premacure Holding AB on the Sale of Premacure AB to Shire plc

Wiggin and Dana assisted its client, Premacure Holding AB, in the sale of its subsidiary, Premacure AB, to Shire plc for undisclosed financial terms. As announced by Shire on March 12, 2013, the "acquisition underscores and expands Shire's commitment to bringing innovative therapies to patients with rare disorders worldwide."

Premacure, which was launched in 2006 by entrepreneurs and internationally recognized neonatology clinicians, is developing a protein replacement therapy for the prevention of retinopathy of prematurity (ROP), a rare and potentially blinding disorder that inflicts premature infants.

Santaris Pharma A/S and Bristol-Myers Squibb Co. entered into a Collaboration and License Agreement to discover and develop novel medicines using Santaris' proprietary Locked Nucleic Acid (LNA) Drug Platform. Under the terms of the agreement, Santaris will receive an upfront payment of $10 million, up to $90 million in potential milestone payments per product and funding of ongoing discovery and research activities. Santaris will also be eligible to receive royalties on the worldwide sales of all medicines arising from the alliance.

Affibody AB entered into separate License Agreements with **Daiichi Sankyo Co., Ltd.** and **Daewoong Pharmaceutical Co., Ltd.** for the use of Affibody's proprietary Albumod™ platform, which is designed to enhance the efficacy of biopharmaceuticals by extending their circulatory half-life, with undisclosed molecules from Daiich Sankyo's and Daewoong Pharmaceutical's pipelines of proprietary protein therapeutics. Affibody will receive up-front and milestone payments as well as royalties on sales for licensing of the Albumod™ platform pursuant to these agreements. **Affibody AB** also entered into a License Agreement with **AbClon Inc.** regarding the use of Affibody's proprietary technology platforms, Affibody® molecules and Albumod™ for use in combination with AbClon's anti-cancer antibodies to develop a new class of therapeutic molecules, Affimabs.

Swedish Orphan Biovitrum AB (Sobi) entered into an agreement with **Exelixis Inc.** for exclusive distribution rights in the European Union of COMETRIQ® (cabozantinib) for metastatic medullary thyroid cancer, with the potential for such rights in other countries. Under the agreement, Sobi will receive certain pre-determined fixed fees as well as performance-based milestone payments.

Sobi granted **Savient Pharmaceuticals, Inc.** co-promotion rights in the United States for Kineret® (anakinra), a recombinant IL-1 receptor antagonist for the treatment of rheumatoid arthritis and Neonatal-Onset Multisystem Inflammatory Disease.

EffRx Pharmaceuticals SA entered into a distribution agreement with **HIKMA Pharmaceuticals LLC** for Binosto®, EffRx's innovative osteoporosis medication, for the Middle East and North Africa region.

Purdue Pharma L.P. entered into a strategic, multi-year research collaboration with **EIMindA**, the developer of an innovative technology capable of providing drug developers with superior insights into the effect of therapeutic interventions on brain function.

Santaris Pharmas A/S granted **miRagen Therapeutics Inc.** a broad non-exclusive license in the miRNA therapeutics field for therapeutics research and worldwide exclusive rights to research, develop and commercialize LNA drugs against microRNA targets that have been shown to be important in human disease areas of high unmet need. Santaris will receive a combination of cash and equity in consideration for the licenses as well as clinical milestones and royalties on products emerging from the alliance.

BioInvent International AB and **Cancer Research Technology Ltd. (CRT)** entered a collaboration with Queen Mary, University of London, to identify new therapeutic antibodies in oncology. BioInvent and scientists funded by Cancer Research UK at Queen Mary jointly will look for new therapeutic targets by applying BioInvent's F.I.R.S.T.™ technology, a functional approach to therapeutic antibody discovery. The agreement gives BioInvent the option to enter into licenses to bring forward drug candidates beyond lead candidate identification in exchange for milestones and royalties to CRT.

IndustryNEWS

Supreme Court Reviews Patentable Subject Matter in the Biosciences

Under US law, inventors may obtain a US patent for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Since the Supreme Court's 1980 decision in *Diamond v. Chakrabarty* (447 U.S. 303), the US Patent Office has expanded the types of patentable subject matter to include biological materials such as nucleic acids and proteins, as well as methods of using these materials. However, while the scope of patent-eligible subject matter is generally broad, the Supreme Court has also recognized that not everything is a patentable invention under the law. Notable exceptions to patentable subject matter include inventions that cover: (i) laws of nature; (ii) physical phenomena; and (iii) abstract ideas. These inventions have been deemed ineligible for patent protection.

For many years, US patent policy has allowed biological molecules and genetic tests to be patented. Among other requirements, a patent-eligible DNA molecule must be manipulated and isolated through human intervention so as to have a different identity and a distinctive chemical form as compared to naturally occurring DNA. Similarly, diagnostic testing may also be patented, so long as the tests involve clear, tangible steps, chemical transformations, or the use of a specific machine or device. However, the settled understanding that biological molecules and certain diagnostic tests are eligible for patenting was recently called into question in two cases that have significant impact on the biotechnology industry in general and the personalized medicine area in particular.

In *Mayo Collaborative Services et al. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court held that an invention directed to a diagnostic relationship between biological materials was, at its core, a naturally occurring law of nature and hence patent-ineligible. The patent at issue related to methods for determining the ideal dosage of thiopurine drugs for treatment of autoimmune diseases. The inventors discovered that the drug was most effective when the concentration of a particular metabolite in a blood sample fell within a narrow range. The patent covered a diagnostic method in a series of steps: (1) administer the drug, (2) determine the level of the metabolite, and (3) if it falls outside of an optimal range for effectiveness, increase or decrease the dosage to return the level to the optimal range. In holding the invention ineligible for patent protection, the Court said that more than an observation of a relationship was necessary to transform the relationship into a patent-eligible application of a natural law.

In *Association of Molecular Pathology v. Myriad Genetics Inc.*, 569 U.S. ____ (2013) the Supreme Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," but cDNA is patent eligible because it is not naturally occurring. Myriad holds patents on two genes, BRCA1 and BRCA2, which are associated with a heightened risk of breast cancer, and uses these genes to test a patient's cancer risk. The Association challenged these patents alleging that human genes are products of nature and thus unpatentable. The Supreme Court agreed with the Association, reasoning that the mere isolation of a naturally occurring DNA sequence does not satisfy the patent eligibility standard, notwithstanding the fact that isolation of DNA involves breaking the chemical bonds holding the gene in place. On the other hand, the Court also stated that cDNA (synthetic or man-made DNA) did not present the same obstacles to patentability as naturally occurring, isolated DNA segments because "a lab technician unquestionably creates something new when cDNA is made." The Court noted that its decision did not implicate Myriad's ability to exploit claims directed to innovative methods of searching for genes, or for methods of applying knowledge about the BRCA1 and BRCA2 genes, nor did it reach the question of "patentability of DNA in which the order of the naturally occurring nucleotides has been altered."

These decisions will significantly affect subject-matter eligibility for inventions in many areas, but particularly in medical diagnostics and personalized medicine. In *Myriad*, the Court provided some clarity with respect to which types of nucleic acid molecules are eligible for patenting and which are not. In addition, the Court made clear that inventions directed to the application of knowledge regarding naturally occurring DNA sequences may still be patent eligible. What is not clear is how the decision impacts businesses engaged in developing chemical and biological therapeutics, with patents

CONTINUED ON NEXT PAGE

IndustryNEWS CONTINUED

directed to isolated naturally occurring compounds or small molecules. In *Myriad*, the Court stated that merely separating a segment of DNA from its natural surrounding is not an inventive act. How such an analysis could be applied in the chemical and pharmaceutical industries remains to be seen, but will likely be used to attack chemical and pharmaceutical patents directed towards isolated, naturally occurring compounds like proteins, antibodies, and other biomolecules.

After *Prometheus*, the USPTO issued guidelines outlining its approach to examination of method claims. The guidelines describe a three-step test for patent eligibility: (1) determine whether the claim is directed to a process; (2) determine whether the claim focuses on a natural principle; and (3) determine whether the claim includes additional elements or a combination of elements that integrate the natural principle into the invention such that the natural principle is practically applied. With respect to step (3), an invention that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself. According to the guidelines, the analysis turns on whether the invention has added enough to show a practical application of the natural principle. In other words, the invention cannot cover the natural principle itself such that it is effectively standing alone. A bare statement of a naturally occurring correlation, albeit a newly discovered or narrowly defined correlation, would fail the inquiry. Thus it appears clear that diagnostic inventions relating to correlations between biological materials and an outcome will now require more for patent protection than merely a simple observation, application or use of those materials. These guidelines should be taken into account when drafting patent applications in the medical diagnostic or personalized medicine fields.

Thoughtful approaches in the patent drafting process may be helpful to address these new subject matter eligibility standards. Claims for DNA molecules themselves should be focused on synthetic or modified DNAs that do not occur in nature, and inventions directed to the application of knowledge regarding naturally occurring DNA sequences should be claimed if possible. In process inventions, if a step in the invention relies upon an unconventional, novel, or nonobvious technique or reagent (for example, a novel detection agent), the claim could be argued to be a patent-eligible application of a law of nature. Similarly, an invention that includes an unconventional or nonobvious combination of known markers may be sufficient to reach patent-eligible status. Use of a "man-made" sample may also impart patent eligibility, for example, a combination of a marker and a biological sample that would not otherwise exist in nature. Thus, while the *Myriad* and *Prometheus* decisions may impose limits on what can be covered in personalized-medicine or diagnostic medical technologies, it may still be possible to protect much of these inventions through strategic claim drafting and application preparation.

Wiggin and Dana Biotechnology and Life Sciences Practice Group

For more information about this newsletter please contact:

JIM FARRINGTON, Chair
203.363.7614 | Stamford
jfarrington@wiggin.com

PATTI MELICK
203.363.7615 | Stamford
pmelick@wiggin.com

Biotechnology and Life Sciences Attorneys

TOBY BANNON, III
LAURA CHUBB
ALYSSA CUNNINGHAM
MICHELLE WILCOX DEBARGE
JIM FARRINGTON
NORM FLEMING
TODD GARABEDIAN
MERT GOLLAHER
MIKE GRUNDEI
PAUL HUGHES
MARK KADUBOSKI
SCOTT KAUFMAN
BILL KILGALLEN
FRANK MARCO
REBECCA MATTHEWS
PATTI MELICK
JOSEPH SAPHIA
ALAN SCHWARTZ
LILY WOUND