Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Free Trade Agreement with Korea Includes IP Provisions

A significant part of the U.S.-Korea Free Trade Agreement ratified by the U.S. Congress on October 12, 2011, is a chapter relating to intellectual property rights. Among other matters, the agreement calls on the parties to "establish a framework for cooperation between their respective patent offices as a basis for progress toward mutual exploitation of search and examination work." It also includes terms relating to making patents available for any invention, providing patent applicants with at least one opportunity to amend or correct their applications, not allowing third-party oppositions to pending patent applications, making civil judicial procedures available to enforce IP rights, and establishing requirements for criminal prosecution of counterfeiting and piracy.

The agreement addresses biosimilar pharmaceutical products by requiring that the signatories may not "authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the marketing approval; or (ii) evidence of the marketing approval based on the new clinical information, for at least three years from the date of marketing approval in the territory of the Party." Ten years of protection are accorded new uses for agricultural chemical products previously approved. The free trade agreements Congress approved with Columbia and Panama also contain IP provisions.

Model Order Would Limit E-Discovery in Patent Litigation

During a recent bench-bar conference in Texas, Federal Circuit Court of Appeals Chief Judge Randall Rader unveiled a set of proposed improvements to patent litigation, including a model order that would place limits on e-discovery. While the court has not yet adopted the order, it was endorsed by the Federal Circuit Advisory Council, which noted in comments accompanying the proposed order, "this Model Order requires a discovery process whereby the parties exchange core documentation concerning the patent,

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the accused product, the prior art, and the finances before making email production requests."

Among other matters, the order would (i) exclude metadata from general electronically stored information (ESI) production requests; (ii) shift costs for disproportionate ESI production requests; (iii) limit e-mail production requests to specific issues only, "rather than general discovery of a product or business," and require that such requests "identify the custodian, search terms, and time frame"; (iv) limit e-mail production requests "to a total of five custodians per producing party for all such requests," unless modified by agreement or court order; (v) limit e-mail production requests "to a total of five search terms per party," unless modified by agreement or court order; and (vi) protect inadvertently produced material by deeming attorney-client privilege or work product not waived in that instance.

Judge Rader pointed to other practices that could help streamline patent litigation, including effective use of summary judgment to narrow issues for trial, careful venue selection, case management improvements, uniform district court procedures, and the imposition of fees and costs on non-practicing entities, or "trolls," attempting to "enforce a patent far beyond its actual value or contribution to the prior art."

NEW BIO BUSINESS VENTURES

Italian Company Announces Alternative Fuels Joint Venture

Italian-based Gruppo Mossi and Ghisolfi (M&G) has announced a joint venture with TPG Capital and TPG Biotech (TPG) to license Proesa® technology, a process that coverts sugar from biomass into bio-ethanol and other chemical products. Called Beta Renewables, the joint venture will work with M&G's wholly-owned subsidiary Chemtex on several Poesa® projects, according to M&G.

Under the agreement, TPG and M&G will invest €250 million in Beta Renewables, with M&G holding a majority stake. M&G will also transfer to Beta Renewables a pilot plant in Tortona, Italy, and a 40-ton industrial-scale cellulosic ethanol plant under construction in Crescentino, expected to open during the first half of 2012. Although Beta Renewables will focus initially on biofuels, "new bio-chemical processes are being developed to replace petroleum-based chemicals used in a large number of applications," according to M&G. *See M&G Press Release,* October 13, 2011.

SemBioSys Enters Agreement with China's Tasly Pharmaceuticals

Canadian agricultural biotech company SemBioSys Genetics has reportedly entered a joint venture agreement with Tasly Pharmaceuticals Ltd. of Tianjin, China, to "develop and commercialize a variety of products including pharmaceutical, functional foods and nutraceuticals for China and the world."

Tasly is purportedly the second largest producer in China of traditional Chinese medicines derived from plants; it will contribute 100 percent of the cost of the venture's global research, development and product marketing. SemBioSys, which claims to use patented plant seed-based oil body and genetic expression technology platforms to develop high value proteins, oils and drug candidates in oil seed-producing plant species, will be entitled to 30-percent ownership and profit sharing in the joint venture. *See SemBioSys Press Release,* October 11, 2011.

Angel Biotechnology Holdings to Form Joint Venture with Russian Pharmaceutical

Biopharmaceutical contract manufacturer Angel Biotechnology Holdings Plc, with facilities in Scotland, has announced that it intends to form a joint venture with Russia-based Materia Medica Holding (MMH). According to the companies, Angel specializes in advanced biologics such as cellular vaccines and stem cells, while MMH's portfolio includes a variety of pharmacological groups such as immunomodulators, antiviral products, anti-inflammatory drugs, and sedatives.

Under the proposal, Angel will own 49 percent of the joint venture, and MMH will own 51 percent, with any profits divided in proportion to shareholdings. The plan calls for Angel to increase the size of its Cramlington facility to customize a new dedicated area that will produce MMH products, while MMH will fund construction and required capital equipment. The joint venture will pay Angel fees for use of the facility. "The arrangement will be reviewed after five years and it is understood that MMH will require a minimum of seven products to be manufactured in the first three to five years," according to Angel. *See Angel Biotechnology Press Release,* October 17, 2011.

INVESTOR NEWS

Cleave Biosciences Lands $42 Million in Funding Round for Cancer Drugs

San Francisco startup Cleave Biosciences has reportedly raised $42 million in Series A financing for novel cancer therapies. The biotech company's investors include U.S. Venture Partners, 5AM Ventures, Clarus Ventures, and OrbiMed Advisors. According to Cleave, the financing will help develop cancer-fighting drugs targeted to specific patients based on pathway-driven strategies.

"We know too much about the biology of cancer to continue to treat each patient without regard for the unique molecular characteristics of their individual tumor, leaving them vulnerable to disease recurrence," said Cleave's CEO Laura Shawver. "We foresee a future when the majority of cancer patients will be treated based on the molecular profile of their tumors, regardless of whether the cancer invades the lung, pancreas, liver or elsewhere." *See Cleave Biosciences Press Release,* October 11, 2011.

DNAnexus Raises $15 Million in Second Financing Round

California-based DNAnexus has reportedly secured $15 million in second-round funding led by Google Ventures and TPG Biotech, with additional participants First Round Capital, SoftTech VC, K9 Ventures, and Felicis Ventures. DNAnexus said it plans to use the new capital for hiring and the development of products to fulfill its mission, described as unlocking "the potential of DNA-based medicine and biotechnology by creating scalable and collaborative data technologies."

"We are at a pivotal time in the field of genomics, with data growing exponentially," said company CEO Andreas Sundquist. "In less than five years, the cost of DNA sequencing will be on par with the cost of other routine lab tests, bringing it in reach of almost everyone in the developed world. DNAnexus will bring together the data and the tools to allow the medical and biotech community to extract meaning." *See DNAnexus Press Release,* October 12, 2011.

Dyadic International Raises $3 Million; Partner Plans Biomass Ethanol Plant

Florida-based Dyadic International, Inc. has apparently raised $3 million from a private placement of convertible subordinated secured promissory notes to five unidentified investors. The global biotechnology company, which focuses on the development of enzyme and protein products for use in the bioenergy, industrial enzyme and biopharmaceutical industries, said the funding will be used for "working capital including continued investments in research and development, new product introductions and general corporate purposes." Maturing on January 1, 2013, unless converted, the notes will pay interest quarterly at 8 percent per year.

According to a news source, the company also said it may collect royalties if its partner, Abengoa Bioenergy, completes plans to build a biomass ethanol plant in Hugoton, Kansas. Abengoa has apparently received a $132.4-million federal loan guarantee to build the plant. *See Dyadic Press Release,* October 5, 2011; *South Florida Business Journal,* October 6, 2011.

Indian Officials to Scrutinize Pharmaceutical M&As

Indian ministry officials have apparently decided that foreign companies may continue to invest in new pharmaceutical industry projects but that foreign proposals for mergers and acquisitions in this sector will have to undergo enhanced scrutiny. Concerns over increasing drug prices, recent foreign takeovers of large Indian drug manufacturers and the potential diversion of Indian-made drugs to more lucrative markets in other countries reportedly led the prime minister to convene a meeting with the ministers of health, commerce and finance. The government rejected proposals to limit foreign investments and will continue to allow 100 percent foreign direct investment.

Foreign takeovers, however, will go before the Foreign Investment Promotion Board for up to a six-month review during which the Competition Commission of India will evaluate the proposed deal. With enhanced powers, the commission is expected to be able to prevent industry cartels, while arbitrary price increases for pharmaceuticals are considered a matter for compulsory licensing and the Drug Price Control Order. *See Pharma Times*, October 11, 2011.

BUSINESS CLIMATE

Tufts Center Roundtable Participants Laud Innovative Partnerships

According to Tufts Center for the Study of Drug Development Director Kenneth Kaitin, pharmaceutical company leaders reported during a recent roundtable that teaming with external partners has allowed them to increase the molecular entities entering Phase I trials while decreasing study times and raising Phase II success rates. Kaitin said, "Drug developers have gotten the message that they need to innovate 'better, faster, and cheaper'—without sacrificing patient safety—and partnering is proving to be an effective strategy. By aligning with others, drug developers are hoping to accelerate the translation of scientific findings into new medicines."

Industry executives also apparently reported that technology scout organizations are helping them identify technologies and platforms that are not currently being commercialized and that "umbrella agreements" with large academic institutions have enabled developers to expand their relationships with individual researchers allowing the identification of scientific advances with marketing potential. Companies are also apparently engaging in trial sharing, that is, two companies share the same Phase I trials, enabling developers to quickly determine "whether joint administration of their compounds can enhance therapeutic outcomes." *See Tufts University News Release*, October 6, 2011.

California BioBusiness Survey Shows Significant Employment Gains

Two California-based life sciences organizations, representing companies throughout the state, have published a survey focusing on the state's industrial biotechnology sector, including biofuel, green industrial chemical and biomaterial production facilities.

While employment in the industry has skyrocketed 632 percent over the past five years, BayBio and BIOCOM, which conducted the survey of 33 companies, caution policymakers and academia that keeping jobs could require some changes. Apparently, industrial biotech companies indicated that tax exemptions and credits as well as a well-prepared workforce would be needed to keep their operations in California. Research and development is apparently robust, but California is evidently lacking in pilot and commercial operations. According to the survey, "[c]ompanies reported difficulty in finding qualified candidates for several highly technical functions, particularly in the areas of chemical engineering, purification, and fermentation."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Lawmakers Introduce Bill to Expedite FDA's Medical Device Review Process

U.S. Senators Amy Klobuchar (D-Minn.), Richard Burr (R-N.C.) and Michael Bennet (D-Colo.) have introduced a bill (S. 1700) aimed at reducing "regulatory burdens that unnecessarily delay new medical devices from reaching the market." The Medical Device Regulatory Improvement Act would, among other things, expedite review times for medical devices by rolling back the conflict-of-interest rules adopted in 2007 for experts serving on the Food and Drug Administration's (FDA's) advisory committees.

According to the lawmakers, FDA's "overly stringent" conflicts rules make it difficult for the agency to find qualified experts to serve on advisory committees, causing delays in the review process. By making FDA committee members subject to the provisions applicable to other federal agencies under the Ethics in Government Act of 1978, the measure would no longer prohibit experts with financial ties to industry from serving on FDA advisory panels without a waiver. Consumer advocates are reportedly concerned that relaxing these rules could jeopardize the panels' independence.

The bill would also (i) amend FDA's premarket approval process to require consideration of "alternative approaches to evaluating device safety and effectiveness in order to reduce the time, effort, and cost of reaching proper resolution of the issue"; (ii) narrow the agency's focus under its "substantial equivalence determination" rules, including a provision that would require FDA to "review the labeling of the device to assess the intended use of the device," while precluding an evaluation of "issues that do not present a major

impact on the intended use as set forth in the labeling"; and (iii) impose a "management and innovation review" 60 days after the bill's enactment under which FDA would contract with an outside entity to review the management and regulatory processes of the agency's Center for Devices and Radiological Health for "potential impacts on innovation with respect to medical devises."

"Recent studies showed that the average time to approve a 501(k) application has increased 43% from the 2003-2007 period to 2010, and the average time to approve a premarket approval (PMA) application has increased 75%," the lawmakers said. "A recent survey of venture capitalist life sciences investors showed that almost 40% of investors are more likely to shift their operations and investments overseas because of FDA's regulatory challenges. . . . These provisions will ensure that when making regulatory decisions on medical devices, FDA focuses only on the relevant information during the decision-making process, considers appropriate alternatives to reduce the time, effort, and cost of reaching regulatory decisions, and uses all reasonable mechanisms to reduce review times when making these decisions." *See Sens. Klobuchar, Burr and Bennet Press Releases* and *Reuters,* October 13, 2011.

USPTO Requests Comments on China's Intellectual Property Enforcement

The U.S. Patent and Trademark Office (USPTO) seeks **written comments** from the public pertaining to China's patent enforcement system. Noting that China's patent and trademark offices are among the world's largest in filings and that its intellectual property (IP) enforcement system is being increasingly used by U.S. patent rights holders, USPTO conducted a series of roundtable discussions in 2011 with the patent community focusing on "the challenges U.S. investors are facing with China's judicial and administrative patent enforcement system."

Preparing to address IP enforcement issues with the Chinese government, USPTO intends to create a report that recommends system improvements. To ensure a wide array of views, USPTO requests comments on (i) "acquisition and enforcement of utility model and design patents," (ii) "evidence collection and preservation in Chinese courts," (iii) "obtaining damages and injunctions," (iv) "enforceability of court orders," and (v) "administrative patent enforcement." Comments are requested by November 4, 2011. *See Federal Register,* October 17, 2011.

European Medicines Agency Considers Changes to Biosimilar Guidelines

The European Medicines Agency (EMA) has published a **concept paper** outlining a number of clinical and non-clinical issues that need revision in its current "Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance." Comments are requested by December 31, 2011.

Among other matters, EMA is re-evaluating "the selection of relevant species for non-clinical studies, need for clinical equivalence studies and other issues [in] the design of the pivotal clinical studies, role of biomarkers, amount of immunogenicity data needed, and the possibility to extrapolate to other indications." According to the concept paper, EMA has prioritized reducing the number animal experiments required. The current guideline took effect in June 2006; experience with that version and rapid advances in the field have apparently led to its re-evaluation. EMA anticipates publishing a draft revised guideline in early 2012.

LITIGATION

Parties to Gene Patent Dispute Change Course by Seeking U.S. Supreme Court Review

After filing petitions for rehearing before the Federal Circuit Court of Appeals panel that split over whether genetic discoveries can be patented, the parties have apparently changed course and indicated their intent to petition the U.S. Supreme Court for review. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office (Myriad Genetics, Inc.),* No. 2010-1406 (Fed. Cir., decided July 29, 2011).

According to a news source, the American Civil Liberties Union and Public Patent Foundation, which brought the suit against Myriad Genetics and the University of Utah Research Foundation on behalf of public, patient and scientific interests, plan to file a petition for *certiorari* by the December 2011 deadline. Myriad is also apparently considering filing its own petition from part of the Federal Circuit's ruling. Additional information about the appellate court decision appears in Issue 18 of this *Bulletin*. *See The Salt Lake Tribune*, October 12, 2011.

Federal Circuit Clarifies Permanent Injunction Standard

The Federal Circuit Court of Appeals has clarified that, while a judgment of patent infringement and validity does not constitute a presumption of irreparable harm "as it applies to determining the appropriateness of injunctive relief," the judgment should not be ignored by the court when weighing the equities involved in deciding whether to impose a permanent injunction. ***Robert Bosch LLC v. Pylon Mfg. Corp.*, No. 2011-1096 (Fed. Cir., decided October 13, 2011)**.

The issue arose in a patent infringement case involving automobile wiper-blade technology. A jury determined that certain of the plaintiff's patent claims were valid and infringed, and the plaintiff sought to permanently enjoin the infringement. The district court denied the plaintiff's motion, finding an absence of irreparable harm.

Interpreting a 2006 U.S. Supreme Court ruling, the Federal Circuit stated, "even though a successful patent infringement plaintiff can no longer rely on presumptions or other short-cuts to support a request for a permanent injunction, it does not follow that courts should entirely ignore the fundamental nature of patents as property rights granting the owner the right to exclude." According to the Federal Circuit, "the record contains no basis on which the district court rationally could have concluded that Bosch failed to demonstrate irreparable harm or that a remedy other than injunction is sufficient to address its harm." Because the district court "made a clear error in judgment in its analysis of the irreparable harm factor," one of four considered in an injunctive-relief analysis, and given the inequities of delaying injunctive relief, the court reversed the lower court's ruling and remanded for entry of an appropriate injunction.

Several other issues the court addressed included the district court's erroneous (i) "conclusion that the presence of additional competitors, without more, cuts against a finding of irreparable harm"; and (ii) reliance on the 'non-core' nature of Bosch's wiper blade business in relation to its business as a whole," to conclude the company had not been irreparably harmed. On the first issue, the court stated, "While the existence of a two-player market may well serve as a substantial ground for *granting* an injunction—e.g., because it creates an inference that an infringing sale amounts to a lost sale for the patentee—the converse is not automatically true, especially where, as here, it is undisputed that the patentee has sought to enforce its rights against other infringers in the market." As to the second issue, the court said, "It is true that some courts have referenced the fact that the patented product is at the core of a party's business when explaining their bases for *granting* an injunction. The trial court's error in relying on these cases again arises from its conclusion that, if a fact supports the granting of an injunction, its absence likely compels denial of one. That is not the law, however."

A dissenting judge would have remanded for the district court to hold a hearing on the matter, disagreeing with the majority that "the record compels the issuance of an injunction." According to this judge, certain factual and evidentiary issues were not clear cut and are for the district court to resolve.

EU Court of Justice Nixes Patents for Stem-Cell Inventions Involving Human Embryo Destruction

The European Union (EU) Court of Justice has determined that EU patent law does not protect neural precursor cells and the processes for their production from embryonic stem cells. ***Brüstle v. Greenpeace e.V.*, Case C-34/10 ECJ (October 18, 2011)**.

Greenpeace, which apparently opposes patents on plants, animals, genes, and smaller parts of DNA, sought to invalidate the German patent held by stem-

cell researcher Oliver Brüstle, contending that such patent protection involves the commercialization of the human body. The basis of the suit was an EU law barring patents on inventions "where their commercial exploitation would be contrary to *ordre public* or morality." According to the court, Brüstle's 1997 patent, "concerns isolated and purified neural precursor cells, processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects."

The court was asked by the referring German court to (i) interpret the term "human embryos" as used in an EU directive (98/44/EC) on the legal protection of biotechnological inventions and (ii) determine whether scientific research is included in the proscription on "uses of human embryos for industrial or commercial purposes." The court was also asked, "Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of the human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching: - because the patent concerns a product whose production necessitates the prior destruction of human embryos, - or because the patent concerns a process for which such product is needed as base material?"

The court ruled that "any human ovum after fertilisation, and non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo,'" and that "it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of Directive 98/44."

The court also determined that the use of human embryos for scientific research is covered by the "exclusion from patentability concerning the use of human embryos for industrial or commercial purposes" under Directive 98/44. Uses of human embryos "for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it" are, however, patentable, according to the court. The court further stated, "Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos."

Brüstle reportedly responded to the legal setback by stating, "Companies now will not invest in these technologies because they cannot safeguard their investment" with patent protections. Still, European inventors may be able to secure patents that would protect their work outside European markets. *See The Wall Street Journal*, October 18, 2011.

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NEWS BYTES

The White House Office of Science and Technology Policy requests public input in the development of a National Bioeconomy Blueprint. Comments are requested by December 6, 2011.

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