Shook, Hardy & Bacon L.L.P.

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SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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IP NEWS

Indian Supreme Court Rules Novartis Cancer Drug Change Not Patentable

The Supreme Court of India has rejected the patent application filed by Novartis AG for a beta crystalline form of its cancer drug Gleevec, also known as Glivec, finding that the changed form failed "in both the tests of invention and patentability." ***Novartis AG v. Union of India*, Nos. 2706-2716 of 2013 (India, decided April 1, 2013)**.

Recognizing the significance of its ruling, the Court stated that it was "urged to strike a balance between the need to promote research and development in science and technology and to keep private monopoly (called an 'aberration' under our Constitutional scheme) at the minimum. Arguments were made about India's obligation to faithfully comply with its commitments under international treaties and counter arguments were made to protect India's status as 'the pharmacy of the world'." The latter reference is to the nation's apparent role as the world's most significant provider of inexpensive generic drugs.

The Court noted that the patent application was submitted during a transition period between two different patent law regimes, so it discussed at some length the development of patent law protections in India and certain proceedings before the World Trade Organization to explain what led to the most recent statutory amendments that were finalized in 2005. According to the Court, "To anyone going through the debate on the Bill, Parliament would appear keenly alive to national interests, human-rights considerations and the role of India as the producer and supplier of drugs to different parts of the world where impoverished humanity is critically in need of those drugs at cheap and affordable prices. Cutting across party lines, member after member from the Opposition benches highlighted the grave risk in creating private monopolies in an area like pharmaceuticals, the abuses to which product patents in pharmaceutical products were vulnerable, and the ploys used by big companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high." The drug at issue here was apparently referred to specifically during floor debate.

The Court then analyzed the patent application under the amended requirements for an "invention" and, in finding that the drug did not qualify, established an intellectual property benchmark in India that multinational drug makers were expected to view as a setback. A cancer-patient advocate, who argued before the Court on his organization's behalf, reportedly observed that most drugs patented in the United States win patents for minimal discoveries, a practice referred to as "evergreening." He said, "What is happening in the United States is that a lot of money is being wasted on new forms of old drugs. That will not happen in India."

A U.S. trade organization representing the interests of pharmaceutical companies issued a statement, saying that the Pharmaceutical Research and Manufacturers of America (PhRMA) "is very disappointed with the Indian Supreme Court's decision to deny a patent on Glivec. This decision marks yet another example of the deteriorating innovation environment in India. Innovation is critical in meeting unmet needs of patients and is particularly relevant in the context of changing health-care systems." PhRMA President and CEO John Castellani further noted, "It is critically important that India promote a policy environment that supports continued research and development of new medicines for the health of patients in India and worldwide," including patent protection. Castellani said that the industry "is committed to working closely with the Indian Government and other stakeholders to find appropriate solutions to this challenge." *See The New York Times, Reuters* and *PhRMA News Release*, April 1, 2013.

INVESTOR NEWS

UK and India to Fund Genomics and Bioinformatics Tech Research

According to the U.K.'s Biotechnology and Biological Sciences Research Council (BBSRC), up to £10 million has been jointly pledged by the council and India's Department of Biotechnology to fund collaborative research building on the combined strength of researchers in both countries working together on projects involving "sequencing, genomics and bioinformatics for crop improvement." The **call** for research proposals focuses on wheat, brassicas and *Solanaceae*, including tomatoes, potatoes and aubergines. The deadline for receipt of proposals is June 19, 2013, but an intention to submit a proposal must be received no later than April 18. *See BBSRC Press Release*, March 26, 2013.

New Investor Added to Close $25-Million Series A Round for Hepatitis B Treatment

Pennsylvania-based Novira Therapeutics has reportedly added a new investor and raised its Series A funding round to $25 million. The biotechnology company is apparently developing treatments for Hepatitis B, including

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capsid inhibitors that can attack the shell protecting the virus' genetic material, and expects to begin clinical trials in 2014. An early stage antiviral drug discovery company, Novira also focuses on antiviral therapeutics to treat chronic HIV infections. *See MedCity News*, March 25, 2013.

RNA-Targeted Technologies Biotech Secures $26 Million in Funding

RXi Pharmaceuticals Corp. has reportedly raised $26 million from 35 investors to support its work discovering, developing and commercializing therapies for major unmet medical needs based on its "proprietary, next-generation RNAi platform." The Massachusetts-based biotech, apparently spun out of Galena Biopharma Inc., focuses on a self-delivering RNAi compound—sd-rxRNA®--designed to reduce dermal scarring in planned surgeries. According to the company, "there are currently no FDA-approved drugs to prevent scar formation," thus "a therapeutic of this type could have great benefit for trauma and surgical patients." *See Boston Business Journal,* March 26, 2013.

Sepsis Diagnostics Co. Raises $40 Million to Support Clinical Programs and Commercialization

Massachusetts-based biotechnology company T2 Biosystems has reportedly closed a $40-million Series E financing round to support the development of its "flagship molecular diagnostic test panel for the sensitive and rapid identification of species-specific *Candida* fungal infections directly from whole blood." According to Goldman Sachs Managing Director T.J. Carella, "We believe T2 Biosystems' breakthrough T2MR™ technology has the potential to change the clinical diagnostics landscape." The technology apparently uses "miniaturized magnetic resonance to directly detect molecular, immunoassay or hemostasis targets in any clinical sample, including blood, sputum and urine."

Candida, a fungal pathogen that can cause sepsis, is reportedly associated with some 100,000 cases of candidemia in the United States annually, which makes it the fourth leading cause of hospital-acquired infections. Candidemia has a 40 percent mortality rate, but that rate can be reduced to 11 percent with early identification of the specific species. T2 Biosystems President and CEO John McDonough said the company will use the funding to "support the clinical trial and launch of our innovative T2Candida test as well as fund the continued progress of our broad range of molecular, immunoassay and hemostasis products." *See T2 Biosystems News Release*, March 28, 2013.

Reviva Taps Dozens of Investors to Secure $12 Million for CNS Disorder Therapies

Reviva Pharmaceuticals Inc. has reportedly raised $12 million from 82 investors, including doctors and health-care industry executives, to continue developing lead candidate RP5063, a schizophrenia drug that has completed

a global Phase II clinical trial. The San Jose, California-based company describes the drug as "a dopamine-serotonin system stabilizer with a potent partial agonist activity at the dopamine D_2, D_3 and D_4, and serotonin 5-HT_{1A} and 5-HT_{2A} receptors, and antagonist activity at the serotonin 5-HT_6 and 5-HT_7 receptors." It is also apparently intended for use in the treatment of other central nervous system (CNS) disorders, including major depressive disorder, manic-depressive bipolar disorder, autism, and Tourette's syndrome. *See MedCity News*, March 26, 2013.

California Institute Awards Grants for Manufacture and Banking of Stem Cell Lines

The California Institute for Regenerative Medicine has granted two organizations a total of $26 million for stem cell-related research and development. Madison, Wisconsin-based Cellular Dynamics International will receive $16 million to create three induced pluripotent stem cell (iPSC) lines "for each of 3,000 healthy and diseased donors." The latter will include patients with Alzheimer's disease; autism spectrum disorders; liver and cardiovascular diseases; neurodevelopmental disabilities, including cerebral palsy and infantile epilepsy; eye diseases; or respiratory diseases. The Coriell Institute for Medical Research, based in Camden, New Jersey, has apparently received $10 million from the institute "to set up and biobank the iPSC lines" and to "establish a biorepository with proven methods for managing sample collection and tracking, safe storage, and capabilities for worldwide distribution of iPSCs generated by [Cellular Dynamics]." *See Cellular Dynamics International Press Release*, March 21, 2013.

Antibody Discovery Biotech Announces $14-Million Financing Round

Theraclone Sciences, Inc., which focuses on discovering and developing therapeutic antibodies to treat infectious disease and cancer, has reportedly secured $14 million in a Series B extension, which brought the total round to $50 million. According to the Seattle, Washington-based biotech, "Proceeds will help advance Theraclone's clinical programs and support ongoing discovery projects using Theraclone's I-STAR™ technology platform, which is designed for the rapid screening and identification of rare, potent and therapeutically relevant human antibodies." Theraclone CEO Clifford Stocks said that the company "has made significant progress with our lead development programs in flu and CMV [cytomegalovirus]." *See Theraclone Sciences News Release*, March 25, 2013.

BUSINESS CLIMATE

More than 450 Drugs for Chronic Diseases of Aging Now in U.S. R&D Pipeline

According to a new Pharmaceutical Research and Manufacturers of America (PhRMA) **report**, U.S. biopharmaceutical companies are currently developing 465 new medicines that target 10 leading chronic conditions affecting those ages 65 and older. Among the medicines, which are either in human clinical trials or under U.S. Food and Drug Administration review, are treatments for diabetes, rheumatoid arthritis and osteoarthritis, Alzheimer's disease, heart failure, and chronic obstructive pulmonary disease.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Announces Compounding Pharmacy Recall

The U.S. Food and Drug Administration (FDA) has posted on its Website a **letter** from a New Jersey-based pharmaceutical compounding facility recalling all of its compounded products due to their potential contamination with mold. According to the letter, the recall was instituted after Med Prep Consulting Inc. was notified by a Connecticut hospital that it had observed "visible particulate contaminants," confirmed as mold, in 50 ml bags of Med Prep's intravenous solution. FDA Center for Drug Evaluation and Research Director Janet Woodcock said, "We do not have reports of patient infections. However, due to a lack of sterility assurance at the facility and out of an abundance of caution, this recall is necessary to protect patients." FDA has indicated that the investigation is continuing. *See FDA News Release*, March 18, 2013.

Hawaii Senate Shelves Proposal to Require Labels for Imported GE Foods

Three Hawaii Senate committees have deferred consideration of a House bill (**H.B. 174**) that would have prohibited the sale of any "imported genetically engineered [GE] produce intended for human consumption within the State" unless "the fact of genetic engineering is disclosed clearly and conspicuously with a label bearing the words 'genetically engineered' directly on the produce offered for retail sale." Sen. Rosalyn Baker (D-Dist. 6), who chairs the Consumer Protection Committee, reportedly indicated that lawmakers were concerned that the labeling might affect the island's food industry. She also noted that state senators are instead considering a resolution for more research into genetically modified organisms. *See Associated Press*, March 21, 2013.

Virginia Enacts First Biosimilar Substitution Law

Virginia's governor has reportedly signed legislation (**H.B. 1422/S.B. 1285**) that will allow the state's pharmacists to substitute biosimilars for prescribed biologic medicine only if the U.S. Food and Drug Administration has licensed the treat-

ments as functionally "interchangeable." Additional details about other states considering similar measures appear in Issue 51 of this *Bulletin.* Similar bills are also apparently pending in at least five other states, including Indiana, North Dakota, Pennsylvania, Texas, and Washington. *See Law360*, March 21, 2013.

LITIGATION

U.S. Intervenes in False Claims Act Suit Against Biotech Company

The U.S. government has intervened in part of a False Claims Act (FCA) lawsuit against Agave BioSystems, a biotechnology-based small business with laboratories in Ithaca, New York. *United States v. Agave BioSystems, Inc.*, No. 5:10-cv-102 (U.S. Dist. Ct., N.D.N.Y., election to intervene filed March 27, 2013). The court has ordered the government to serve its complaint on the defendants within 30 days. The government declined to participate in that part of the lawsuit alleging retaliation and the submission of false claims by any defendant other than the company and its now-deceased owner Noe Salazar.

According to the original complaint filed by the Ithaca facility's former administrative office manager, the company fraudulently billed the Department of Defense (DOD) for "phantom labor and services which have never been provided, and for phantom expenses which have never actually been incurred in connection with any DOD contract." The manager alleges that the fraud equaled or exceeded $15 million under each "Cost Plus Fixed Fee Contract."

Among other matters, the manager alleges that the defendants represented to DOD that these contracts would involve specified hours of work by a mechanical engineer, electrical engineer and technician—actually "his wife (*a house wife*), his daughter (*a full-time photographer*) and her live-in boyfriend (*a musician*)," who were allegedly placed on the payroll, but did not work on the government contracts. The complaint also alleges that the defendants secured reimbursement from DOD for a down payment on a BMW automobile, contractor bills for work on the owner's personal residence, restaurant meals, and cellular phone bills.

The company's Website indicates that it has expertise in "micro and nanofabrication techniques" and focuses on "the miniaturization of lab-scale diagnostic and analytical instrumentation." It claims that the principal funding for its research and development initiatives is provided by contracts with DOD, the National Institutes of Health, Environmental Protection Agency, and NASA.

Ninth Circuit to Consider Impact of Trial Court Error in Admitting Expert Testimony

In related cases that could have implications for intellectual property, consumer safety and complex litigation where resolution of the dispute relies on factually intensive medical or scientific expert testimony, the Ninth Circuit Court of Appeals has decided to rehear an asbestos injury case en banc to consider

whether trial court error in admitting expert testimony without a *Daubert* hearing requires the case to be retried in its entirety or a new trial only if the *Daubert* determination on remand shows that the testimony was unreliable. *Barabin v. AstenJohnson Inc.*, No. 10-36142 and No. 11-35020 (9th Cir., rehearing order March 25, 2013).

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), imposes on trial courts a "gatekeeping" function whereby they must conduct a hearing to consider whether the challenged testimony of a party's expert witness is relevant and reliable and therefore admissible at trial.

A Ninth Circuit panel decided in November 2012 that the district court abused its discretion by admitting expert testimony without conducting a *Daubert* hearing or making relevance and reliability determinations. The court remanded the matter for a new trial, thus reversing a $9.4-million award to the widow of the asbestos-exposed defendant. Two of the three panel judges concurred to explain that they disagree with the rule in *Mukhtar v. California State University*, 299 F.3d 1053 (9th Cir. 2002), *amended by* 319 F.2d 1073 (9th Cir. 2003), requiring that the judgment be vacated and the case be remanded for a new trial in this instance. Without *Mukhtar* as controlling precedent, the concurring judges would have conditionally vacated the judgment and remanded with instructions to make a new *Daubert* determination. And only if the court finds the testimony unreliable, would a new trial be required. Additional information about the panel's disposition of the case appears in the November 29, 2012, **issue** of Shook, Hardy & Bacon's *Product Liability Litigation Report*.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **issues** draft guidance titled "Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants." According to FDA, "[t]he guidance assists sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products." Comments are requested by May 31, 2013.

The U.S. Food and Drug Administration **extends** the comment period relating to its April 29-30, 2013, public workshop titled "Accessible Standardized Medical Device Labeling." Comments are requested by May 17, 2013.

The U.S. Food and Drug Administration (FDA) **issues** guidance titled "User Fees and Refunds for Premarket Approval Appplications (PMAs) and Device Biologics License Applications (BLAs)." The document is intended to "identify the types of PMAs and BLAs subject to device user fees, including supplements and other submissions, as well as those that do not have an associated user fee. The guidance also identifies industry and FDA actions on these submissions that may result in a refund of the fee."

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The U.S. Patent and Trademark Office **revises** its rules of practice to implement changes to *inter partes* review under the Leahy-Smith America Invents Act. This final rule "eliminates the nine-month 'dead zone' for filing an *inter partes* review petition challenging a first-to-invent patent or reissue patent." Such petitions may now be filed upon patent issuance. The rule took effect March 25, 2013.

The U.S. Patent and Trademark Office **issues** an interim final rule addressing Leahy-Smith America Invents Act revisions to patent term adjustment. Effective April 1, 2013, the changes clarify that "the fourteen-month patent term adjustment period and the three-year patent term adjustment period will be measured from the same date: the date on which an application was filed under 35 U.S.C. 111(a) in an application under 35 U.S.C. 111; or the date of commencement of the national stage under 35 U.S.C. 371 in an international application." Comments are requested by May 31, 2013.

The U.S. Patent and Trademark Office **announces** an April 11, 2013, awards ceremony at the Dirksen Senate Office Building in Washington, D.C., for "patent holders who have made use of patented technologies to address humanitarian challenges." The Patents for Humanity program was launched in February 2012 with the support of the Ewing Marion Kauffman Foundation as "part of an Obama administration initiative promoting game-changing innovations to solve long-standing development challenges."

The U.S. Patent and Trademark Office (USPTO) **schedules** the Kansas Regional Independent Inventors Conference, April 19-20, 2013, in Wichita, Kansas. The event "will feature senior USPTO staff, successful inventors, and seasoned entrepreneurs to provide attendees with expert advice, intellectual property (IP) information and resources."

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