Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Business Interests Call for "Patent Troll" Demand-Letter Registry

During a **hearing** before a U.S. Senate subcommittee considering consumer-protection issues purportedly raised by the demand letters disseminated by non-practicing entities (NPEs, also known as "patent trolls")—those patent owners that allegedly exist to demand payments in lieu of bringing patent infringement litigation—several witnesses called for the federal government to establish a registry where NPEs would be required to post information about their activities.

Counsel for the Electronic Frontier Foundation, which has set up a database of demand letters, testified at the November 7, 2013, hearing before the Subcommittee on Consumer Protection, Product Safety, and Insurance of the Senate Committee on Commerce, and said, "Companies that actually create products, services, and jobs find themselves under siege by trolls who purchase vague and overbroad patents to launch or threaten lawsuits." She claimed that "many demand recipients are often not willing or inclined to publicly share their letters" over concerns about adverse publicity, but suggested that the U.S. Patent and Trademark Office or Federal Trade Commission (FTC) could require patent holders to report how many demand letters they have sent, the identity of all parties who would benefit from any resulting license and how often the patent holder has filed a lawsuit based on the patent at issue.

Counsel for Cisco Systems testified that a number of its customers have "received licensing demands from many of these shake down campaigns. In each case, the campaigns are inherently deceptive. The patents are often invalid or irrelevant to their targets or already licensed." He also called for legislation to "require anyone sending patent demand letters to more than ten entities who are NOT the manufacturers of the accused products to file the letters in an on-line registry to be maintained by the FTC." He also suggested that NPEs be required to provide specific information in their demand letters, such as "a list of products which are deemed to infringe, including the manufacturer and model number, and [information about] the right to have the manufacturer defend the case."

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SHB offers expert, efficient and innovative representation to life sciences clients facing complex biotech litigation and intellectual property and regulatory protocols. We know that the successful resolution of biotech-related matters requires a comprehensive strategy developed in partnership with our clients.

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Nebraska Attorney General Jon Bruning, currently engaged in a campaign to address allegedly deceptive demand letters under the state's consumer protection laws, called on Congress "to use its subpoena powers to bring the most egregious patent trolls and the lawyers who enable them to account." Bruning highlighted the experience of a state resident who was the recipient of a demand letter claiming that he was infringing on the NPE's scan-to-email patent through his work for Phelps County Emergency Management. According to Bruning, this resident "never worked" for that entity; he is, rather "an elderly gentleman living in a nursing home in Holdrege, Nebraska, and who once served on the Phelps County Board many years ago." Bruning claimed that this is just one story of many.

George Mason University School of Law Professor Adam Mossoff testified to the contrary that the "patent licensing business model" is essential to the distribution of patented innovation through the marketplace. He cautioned, "Whether there are benefits or harms from specific commercial and legal practices in the innovation economy is an important empirical and policy question, but such benefits or harms should no more be based on rhetoric, anecdotes, and incorrect claims about historical practices than they should be based on 'nonrandom and nongeneralizable' studies. Congress should exercise restraint, avoid '[a]ttempting to label and then discriminate based on identity,' and be cautious in accidentally killing 'the goose laying our golden egg.'"

INVESTOR NEWS

Biopharmaceutical Sets $150-Million IPO Terms

According to a news source, Redwood City, California-based Relypsa, Inc. seeks to raise $150 million by offering more than 7.87 million shares priced at $16 to $19 in a deal that includes an over-allotment of more than 1 million shares. Relypsa, which develops drugs to treat cardiovascular and renal disease, filed an initial public offering (IPO) to raise $126.5 million in September 2013 and increased the offering to $138 million in October. The company reportedly plans to use the funds to develop and produce Patiromer, a treatment for hyperkalemia—a potentially deadly condition in which blood potassium levels become elevated.

Sources indicate that a two-part, Phase III trial has been completed and Relypsa plans to submit Patiromer for Food and Drug Administration approval in 2014. The company is also reportedly developing a preclinical drug candidate, RLY-6002, to treat adults with type 2 diabetes. *See San Francisco Business Times,* November 1, 2013; *Silicon Valley Business Journal,* November 4, 2013.

Antibiotic Developer Announces $45-Million Offering

Tetraphase Pharmaceuticals, Inc., which develops and markets tetracycline-based drugs to treat drug-resistant infectious diseases, inflammation and cancer, has priced an underwritten offering of 4.5-million shares of common stock at $10 per share with the goal of raising $45 million to fund ongoing clinical development of Eravacycline, the company's lead drug treatment for complicated urinary tract infections.

According to a news source, in addition to funding a second Phase 3 trial for Eravacycline, the Watertown, Massachusetts-based biopharmaceutical plans to seek Food and Drug Administration approval for the drug, which the agency has apparently designated as a Qualified Infectious Disease Product. Tetraphase is reportedly one of a few companies developing new drugs to treat the antibiotic-resistant *Enterobacteriaceae*, a type of superbug that the Centers for Disease Control and Prevention warned about earlier this year when it called for urgency in developing drugs to fight the disease. *See Boston Business Journal,* November 5, 2013; *Tetraphase Pharmaceuticals, Inc. News Release,* November 7, 2013.

Israeli Science Institute to Establish Personalized Medicine Center

With a $50-million pledge from a San Francisco-based couple and an additional $70 million from private donations and philanthropic foundations, the Weizmann Institute of Science in Rehovot, Israel, will establish the Nancy and Stephen Grand Israel National Center for Personalized Medicine on its campus. The center's four units, now operating in temporary laboratories, will be housed within the next year in the former "Solar Tower," which is undergoing a major renovation. Headed by Weizmann alumna Berta Strulovici, the center will "serve Israel's entire life sciences and biomedical research community" to conduct the research and develop the technology needed to create medical treatments prescribed according to an individual's unique genetic makeup, "so as to attain the best possible outcome with the fewest side effects." *See Weizmann Institute of Science News Release*, November 11, 2013.

Ultragenyx Files with SEC to Raise $86.25 Million in IPO

Orphan disease drug developer Ultragenyx Pharmaceutical Inc. has filed a registration statement with the U.S. Securities and Exchange Commission (SEC) indicating its intent to raise $86.25 million through an initial public offering (IPO). Information about the company's recently finalized licensing agreement with a Tokyo-based drug developer appears in Issue 64 of this *Bulletin.* According to a news source, Novato, California-based Ultragenyx has attracted considerable attention by moving swiftly into the orphan disease space and has several drugs moving through Phase

I and II clinical trials. In its prospectus summary, the company reports that its "current pipeline consists of two product catergories: biologics, including a monoclonal antibody and enzyme replacement therapies; and small-molecule substrate replacement therapies" for use in the "treatment of rare and ultra-rare diseases." *See Ultragenyx Pharmaceutical SEC Form S-1* and *San Francisco Business Times*, November 8, 2013.

BUSINESS CLIMATE

Boston Region Surges Ahead in Biotech IPOs

According to an analysis of initial public offering (IPO) data from 2013, *xconomy's* National Biotech Editor Luke Timmerman has concluded that Boston is the clear biotech-cluster winner, with eight completed IPOs raising $769.6 million. Combining data for New York and New Jersey, an equal number of companies completed IPOs this year, but raised less at $668.2 million. Noting that 15 more biotech companies are currently scheduled to go public, based on U.S. Securities and Exchange Commission filings, Timmerman suggests that the ranking could change given that just one more Boston company is "in the queue," while San Diego and Philadelphia have the most in line. So far this year, 45 life sciences companies have raised a combined $3.9 billion through IPOs. *See xconomy.com*, November 4, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Compounding-Pharmacy Legislation Awaits President's Signature

The U.S. Senate has approved by voice vote a bill (**H.R. 3204**) that would broaden federal oversight of compounding pharmacies; it now awaits President Barack Obama's signature. Drafted in response to last year's fatal outbreak of fungal meningitis reportedly traced to contaminated vials of an injectable painkilling steroid from a New England compounding pharmacy, the bill would bar compounding pharmacies from copying drugs approved by the U.S. Food and Drug Administration (FDA) and marketed by other pharmaceutical companies. It would also create a national system for tracking prescription drugs from manufacturers to retail pharmacies.

The new law would establish a category of "outsourcing facilities," under which pharmacies conducting large-scale drug compounding could opt for federal oversight, and FDA would conduct risk-based inspections of such facilities. The bill would also require detailed compounded drug

labeling and fees to pay for the oversight. Traditional compounding pharmacies would continue to be regulated by the states, and the decision to opt into the category and its associated FDA regulations would be voluntary. Entities that do not stay within the limits of a traditional pharmacy and fail to register as an outsourcing facility would be deemed to be selling drugs illegally.

Noting that the bill is not as comprehensive as FDA would have hoped, Commissioner Margaret Hamburg reportedly called it "a step in the right direction." Hamburg also explained that although the agency is concerned with current regulatory oversight of compounding pharmacies in general, its chief concern is with large volume drug compounders shipping high-risk products, such as sterile injectables, across state lines—not with compounding in traditional "mom and pop" pharmacies. *See CQ Roll Call,* November 12 and 18, 2013; *ABC News.com,* November 13, 2013; *American Pharmacists Association,* November 15, 2013; *CQ News*, November 18, 2013.

FTC to Conduct Workshop on Biosimilar Issues

The U.S. Federal Trade Commission (FTC) has **scheduled** a December 10, 2013, public workshop in Washington, D.C., "to explore competition issues involving biologic medicines and follow-on biologics. The workshop will focus on the potential impact of state regulations and naming conventions on such competition, including how regulations may be structured to facilitate competition while still protecting patient health and safety." The workshop will be Webcast, and comments are requested by March 1, 2014.

FTC notes that some states have adopted laws regulating "the substitution of biosimilars or interchangeable biologic products for reference biologic products." How these initiatives may affect competition is among the matters that will be addressed during the workshop. It will also explore the effects of allowing biosimilars to have the same nonproprietary names as reference products, as well as approaches taken in other countries to biosimilars. *See Federal Register*, November 15, 2013.

In a related development, six bipartisan senators and congressional representatives have addressed the issue of biosimilar naming in a November 13 letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg. They assert that it was Congress's intent, when enacting the Biologics Price Competition and Innovation Act, "to provide the FDA with the flexibility to establish a science-based policy for non-proprietary naming of drug substances, and not to encourage the FDA to adopt a policy of either identical or differentiated naming. It is not the role of Congress to predetermine decisions that should be based on scientific evidence."

FDA Issues Personalized Medicine Report

The U.S. Food and Drug Administration (FDA) has issued a **report** titled "Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development." It outlines the steps FDA has taken to support the development of "tailored medical products," i.e., those "drugs, biologics and medical devices targeted to particular sub-populations together with genetic or other biomarker tests for use in identifying appropriate patients for those treatments." The report also includes a table of select agency guidances that relate to personalized medicine. Citing specific examples, the report illustrates how efforts have been made to streamline the approval process for these therapeutics.

Biosimilar-Substitution Proposal Moves to PA Senate

The Public Health and Welfare Committee of Pennsylvania's Senate has approved a bill (**S.B. 405**) that imposes certain requirements on the substitution of biosimilars for a "prescribed brand name biological product." The bill will next go to the full senate for a vote. The bill's core provision, like its counterparts in other states, allows pharmacists to substitute biosimilars for a pioneer biologic only when the U.S. Food and Drug Administration deems the treatments functionally interchangeable. Biosimilars, also known as follow-on biologics, serve as the generic equivalent of biologic drugs, which are either made by, or derived from, living organisms. Under current Pennsylvania law, pharmacists may treat biosimilars like any other generic drug, with substitution permitted unless a doctor specifies that the brand-name drug is medically necessary.

Sponsored by Sen. Patricia Vance (R-Cumberland), the bill also requires pharmacists to notify patients and physicians of the substitutions and to maintain such records. Evidently, the rationale for notification is that biosimilars, unlike traditional generics, may not function exactly like their brand-name versions. Bill proponents maintain that doctors should be aware when biosimilars are used so they can be alert for diminished safety or effectiveness. Similar bills have reportedly flooded statehouses around the country this year, although only a few have become law. These measures have reportedly been approved in North Dakota, Oregon, Utah, and Virginia, although sunset provisions were adopted in the latter three. *See Law 360,* November 15, 2013.

LITIGATION

Federal Circuit Refuses to Rehear Ruling on the Finality of Patent Infringement Determinations

The Federal Circuit Court of Appeals has denied a petition for panel rehearing and rehearing en banc in 10-year-old litigation that concluded with the court allowing a U.S. Patent and Trademark Office (USPTO) reexamination to decide patent-infringement issues pending in district court. ***Fresenius USA, Inc. v. Baxter Int'l, Inc.*, Nos. 2012-1334, 1335 (Fed. Cir. Nov. 5, 2013)**. The *Fresenius* chronology and the implications of the court ruling to which the petition pertains are detailed in Shook, Hardy & Bacon's *IpQ* **newsletter**, prepared by IP Partner **Peter Strand**. Several jurists penned dissenting statements to the latest ruling, complaining that the lower court's resolution of validity issues was final and should not have been disturbed as to these litigants by the later USPTO determination.

Exhaustion Doctrine Applied to Method Patent

A divided Federal Circuit Court of Appeals panel has determined that a method patent holder that gave away 60 percent of the blood-glucose testing equipment it manufactured could not enjoin the sale of competing test strips used with the equipment, finding the patent exhaustion doctrine applicable. ***LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, No. 2013-1271 (Fed. Cir., decided November 4, 2013)**. So ruling, the court reversed a district court order enjoining the defendant from selling competing test strips.

According to the court, the innovation that LifeScan Scotland patented was a method of testing that could reveal whether blood-glucose test results should be discarded as unreliable and not the test strips used with the company's meter. The company sued Shasta Technologies, alleging that its manufacture and distribution of test strips indirectly infringed its patent. Shasta argued that the sale and distribution of LifeScan's meter exhausted its rights under its method patent because the meter substantially embodies the invention. The Federal Circuit ruled that the exhaustion doctrine applies to method patents regardless whether the patent holder gives away or sells its patented product. In the court's view, "[r]ejecting a claim of exhaustion in this case would be particularly problematic because LifeScan would be permitted to eliminate competition in the sale of the strips even though the strips do not embody the claimed invention and are themselves not patentable. Allowing LifeScan to control the sale of the strips would be akin to allowing a tying arrangement whereby purchasers of the meters could be barred from using the meters with competing strips."

A dissenting judge concluded that the test strips, and not the meters, embody the patent's essential features. "The majority's holding in this case will unquestionably cause LifeScan's patented method to plummet in value and result in its exclusive rights over the method lasting only one transaction," the dissenter said.

NEWS BYTES

The U.S. Patent and Trademark Office **extends** the 60-day comment period relating to the paperwork burdens for Initial Patent Applications. Written comments are requested by December 16, 2013.

The U.S. Patent and Trademark Office **schedules** a December 11, 2013, roundtable in Alexandria, Virginia, "to obtain additional public input regarding the burden associated with the Initial Patent Applications collection and ways to potentially reduce it." Registration is requested by December 4, and those wishing to speak must submit their final presentation materials by that date. The roundtable will be available via Webcast.

The U.S. Patent and Trademark Office (USPTO) **announces** a charter agreement placing regional pro bono programs in the hands of a newly-formed advisory council. More than 30 representatives from regional inventor assistance programs, intellectual property (IP) law associations and IP law school programs recently participated in a ceremonial signing with Federal Circuit Court of Appeals Chief Judge Randall Rader. USPTO hopes to have regional pro bono programs covering all 50 states by 2015; currently, seven regional programs cover more than 20 states that offer pro bono assistance to "financially under-resourced independent inventors and small businesses."

The U.S. Food and Drug Administration (FDA) **seeks** comments on a proposed rule that would speed the dissemination of new safety information about generic drugs to health professionals and patients by allowing generic drug makers to use the same process as brand-name drug manufacturers to update product label safety information; they would be permitted to update product labeling with newly acquired safety information before FDA reviews the change. The rule would also require generic manufacturers to inform the brand-name manufacturers about the change. Under the new rule, "brand and generic drug products would ultimately have the same FDA-approved prescribing information." Comments are requested by January 13, 2014.

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UPCOMING CONFERENCES AND SEMINARS

The Product Quality Research Institute, U.S. Pharmacopeial (USP) Convention and American Association of Pharmaceutical Scientists have **scheduled** a nanotechnology workshop for January 14-15, 2014, at the USP Meeting Center in Rockville, Maryland. Titled "Nanomaterial Drug Products: Current Experience and Management of Potential Risks," the workshop will feature presentations by industry representatives, academics and government regulators.

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