Shook, Hardy & Bacon L.L.P.

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IP NEWS

Fewer Patent Cases Filed Before ITC in FY2012

According to a news source, 30 percent fewer intellectual property cases were filed before the U.S. International Trade Commission (ITC) in fiscal year (FY) 2012 than were filed in FY2011. Just 48 cases were apparently filed in FY2012, while 70 cases, a record, were filed in FY2011. ITC administers section 337 of the Tariff Act of 1930 under which U.S. companies can sue, among other matters, for unfair methods of competition from importers that infringe a valid and enforceable U.S. patent, or registered copyright or trademark. As noted in Issue 10 of this *Bulletin*, the pharmaceutical sector rarely chooses this forum for its disputes. And, not surprisingly, commentators attribute the drop in IP-related cases before the ITC to changes in the "smartphone patent wars" that have pitted domestic interests against foreign phone makers in a variety of forums. *See The Blog of Legal Times*, October 5, 2012.

"Patent Trolls" Filed 40 Percent of All Patent Infringement Suits in 2011

According to research conducted at the request of the U.S. Government Accountability Office (GAO), "patent monetization entities," otherwise known as patent trolls or non-practicing entities, have increased their litigation activity from 22 percent of patent cases filed five years ago to nearly 40 percent of cases filed in 2011. **Feldman, et al., "The America Invents Act 500: Effect of Patent Monetization Entities on US Litigation," *Duke Law & Technology Review* (forthcoming)**. Congress required under the America Invents Act that GAO gather information on this type of litigation. GAO turned to the authors of this analysis to compile data on a random sampling—100 cases per year for five years—that GAO would use for its report to Congress.

The researchers, who decided that the term "patent monetization entities" better described parties that sue to generate income from patent rights separated from any product, conducted their own analysis. They concluded that (i) the impact of these "entities on patent litigation is both dramatic and growing across time; (ii) "of the five litigants who filed the most patent infringement claims in the period covered by the data, four were monetizers and only one was an operating company," i.e., an entity whose main source of income is

selling a product or providing a service unrelated to patent monetization; (iii) universities, which do not typically make or sell products, "barely registered on the scale, filing only 0.2 percent of the lawsuits in our sample"; and (iv) cases filed by patent monetization entities are "unlikely to advance very far in the trial process and generally settle[] early in the litigation."

On the basis of their analysis, the researchers suggest that "lawsuits filed are only the tip of the iceberg, and a major operating company may face hundreds of invitations to license for every lawsuit. Much of the bargaining, posturing, and payment concludes without any party filing suit. Thus, one can only imagine the magnitude of the impact that patent monetization has on the patent system, and on the economy, as a whole." They acknowledge limitations in their data, noting that the small sample size may affect any broad conclusions about case outcomes and that they excluded cases lacking sufficient electronically available information.

NEW BIO BUSINESS VENTURES

Indian Biotech Association Signs MOU with U.S.-Based Association

The Association of Biotechnology Led Enterprises (ABLE), representing biotechnology interests in India, has reportedly signed a memorandum of understanding (MOU) with the Washington Biotechnology and Biomedical Association (WBBA), Washington state's life-sciences trade association. The MOU will apparently enable wide-ranging cooperation to support biotechnology discoveries in health care, agriculture and clean energy.

ABLE President P.M. Murali said of the agreement, "The collaboration aims to achieve breakthrough discoveries to provide affordable solutions for critical diseases, important challenges in agriculture and energy on mutually agreed topics." WBBA President Chris Rivera was quoted as saying, "We see India as the growth engine of tomorrow and one of the fastest growing economies in the world. The collaboration with ABLE is significant to facilitate best of research in biotechnology from both countries."

Among other matters, the collaboration could involve investment and business partnering, as well as internships, exhibitions, workshops, seminars, capacity building, and market research. With some 500 member organizations, WBBA claims to have mentored more than 100 unique life-science startup companies since 2009. It brings investors together with promising companies and advocates for policies at the federal and state levels to advance members' interests. *See The Hindu Business Line*, October 7, 2012.

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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INVESTOR NEWS

Developer of Drug to Reduce Double Chin to Raise $70.4 Million in IPO

A California-based biopharmaceutical company that develops products for the "aesthetic medicine market" has reportedly offered 4.4 million shares in an initial public offering (IPO) priced at $16 per share for a total of about $70.4 million. KYTHERA® Biopharmaceuticals expected to close the offering on October 16, 2012. As of October 15, KYTHERA shares had reached $19.10. The company reportedly has a product candidate, ATX-101, currently in Phase III clinical development. It is an injectable synthetic formulation of a human bile component that breaks down fat and is intended for use as a double-chin treatment. *See KYTHERA® Biopharmaceuticals Press Release*, October 11, 2012; *Xconomy*, October 15, 2012.

Clinical-Stage Vaccine Developer Secures $30 Million in Series C Financing

With participation by new investor The Bill and Melinda Gates Foundation, Genocea Biosciences, Inc. has reportedly closed a $30-million Series C financing round. According to Genocea CEO Chip Clark, "We have made strong progress in our effort to create a new class of vaccines capable of combating serious infectious diseases that current vaccine discovery technologies cannot address." The Cambridge, Massachusetts-based clinical-stage company will use the funds to continue developing GEN-003, "a clinical-stage therapeutic vaccine candidate designed to reduce the frequency and severity of clinical outbreaks associated with moderate-to-severe Herpes Simplex Virus type 2," and GEN-004, "a preclinical vaccine candidate to prevent infections caused by *Streptococcus pneumonia*." In collaboration with the Foundation, the company will also expand its malaria program. *See Genocea Biosciences News Release*, October 10, 2012.

Company Raises Funding to Advance Autoimmune and Cancer Therapeutics

Gliknik, Inc. has reportedly raised $4.9 million in a Series B financing to further develop new therapies for patients with cancer and immune/inflammatory disorders. From its Baltimore, Maryland, headquarters, the company indicated that it would use the funds to study its IVIG-mimetic lead compound, GL-2045, "in autoimmune conditions, including initially Myasthenia gravis (a neuromuscular disorder) and a variety of other neurological indications." According to the privately held biopharmaceutical company, IVIG "is produced through fractionated human plasma rather than by recombinant methods." Gliknik will also use the funds "to advance its clinical immunomodulator compounds, which are currently in multiple-dose studies in patients with advanced cancers, including multiple myeloma and head and neck cancers." *See Gliknik News Release*, October 8, 2012.

Synovex Raises $3.5 Million in Series B Funding to Advance Fibrotic Disease Treatment

According to a Securities and Exchange Commission filing, a company that has developed highly specific Cadherin-11 antagonists to treat rheumatoid arthritis and fibrotic diseases, such as pulmonary fibrosis and skin fibrosis, has raised the first half of a new $7-million financing round, the first since it closed a 2008 Series B round for a total of $12 million. Cambridge, Massachusetts-based Synovex Corp. is reportedly entering human clinical trials this year. The company holds a portfolio of patents relating to the use of Cadherin-11 antagonists. Derived from a skin and lung protein that acts as an adhesive between cells, Cadherin-11 can apparently influence the cellular environment by causing cells to produce proteins. *See Mass High Tech*, October 11, 2012.

BUSINESS CLIMATE

Biotech Investment Undergoes Innovations

With the "slow and painful death" generally acknowledged for biotech venture capital, new funding models are emerging even while a handful of traditional biotech venture capital firms are expected to survive. According to *Xconomy's* National Biotech Editor Luke Timmerman, "[t]he dropoff in biotech venture financing this year has been so dramatic that only about a dozen firms in the U.S. are left who can credibly claim that they are still active early-stage life science investors." Still, with potential returns high and 11 of the 12 biotech IPOs filed this year going up, Timmerman believes that as the IPO market moves closer to balance, i.e., not too hot or cold, the biotech venture capital firms still active should be able to "keep doing what they do for a long time." He predicts that the venture investors that survive "will surely be well positioned for years to cherry-pick the best company ideas."

Meanwhile, *Nature Biotechnology* focuses in its current issue on non-traditional options for funding biomedical innovation, including corporate venture funds and mechanisms that spread risk, such as a megafund model attracting investors with varying risk tolerances funding development within a multi-billion dollar portfolio of assets with dependable returns, citizen funding through the Internet, and social networking that links researcher information to advance investigational networking as well as provide a knowledge base for investors.

Studying biotech deals funded at least in part by corporate venture funds, Georg von Krogh and others identified six principles for successful corporate venturing in their article "The changing face of corporate venturing in biotechnology." They include (i) a strong mandate for corporate venture units from the top of the organization; (ii) the adoption of investment objectives that follow a disciplined execution approach; (iii) autonomy for the

venture unit to limit internal conflicts of interest and short-term performance requirements; (iv) the development of sustained relationships in the venture capital investor community; (v) the creation of value-based incentives, i.e., performance-related compensation schemes; and (vi) the use of performance metrics for financial and strategic returns.

The megafund model, advanced in the article "Commercializing biomedical research through securitization techniques," would involve portfolios with "a large number of biomedical programs at various stages of development" and a range of returns to satisfy equity holders and others, such as pension funds, insurance companies and large institutional investors, tolerant of lower returns. The authors describe their concept as funding of biomedical innovation through the use of "financial engineering," in which "mathematical and statistical models for structuring and pricing various financial securities" are used "to achieve specific objectives." These megafunds would combine equity and securitized debt to "access much larger sources of investment capital." By investing in dozens of drug-development programs instead of just one, "the likelihood of at least one hit is dramatically increased, reducing the risk of the entire portfolio." The authors contend that this may be the best way to address the growing need for innovative life-saving pharmaceuticals at a time when the risks of developing them have never been greater.

An article titled "Social networks attempt to spark academic-university collaborations" discusses the launch of Knode, an Internet service that aims to "help industry scientists interact with and identify partners in academic labs." As a social networking tool, the service will enable industry to provide funding for specific research programs or help create the formation of consultant-type interactions. It will also allow "industry executives looking for a specific expertise or capability" to locate the scientists they need. Knode co-founder Brigham Hyde said, "One component is social network mapping. We have metrics that enable our users to identify who the most successful collaborators might be. It's not just about who has the most papers on PubMed. We look at qualitative aspects such as grant funding and whether their research is translational, basic, or clinical." Similar models that can provide a way for nonprofit organizations to support academic scientists are also apparently underway. *See Xconomy*, October 15, 2012; *Nature Biotechnology*, October 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Bioethics Commission Issues Report on Genome Sequencing and Privacy

The Presidential Commission for the Study of Bioethical Issues has issued a **report** "Privacy and Progress in Whole Genome Sequencing," one in a series that the commission will produce as it identifies and promotes "policies and

practices to ensure that scientific research, health care delivery, and technological innovation are conducted by the U.S. in a socially and ethically responsible manner." The commission has previously advised the president about the risks and benefits of synthetic biology and existing rules that protect human subjects in research. It has also conducted an independent investigation into the U.S. Public Health Service's socially transmitted disease experiments in Guatemala in the 1940s.

Concluding that whole genome sequencing holds "enormous promise" for advancing clinical care and the greater public good, the commission cautions that individual privacy interests must be protected. To that end, the commission proposes proactive measures that government can take to "help craft policies that are flexible enough to ensure progress and responsive enough to protect privacy." Among other matters, the commission urges federal and state governments "to develop a process for ensuring a consistent floor of protections covering whole genome sequence data regardless of how they were obtained. These policies should protect individual privacy by prohibiting unauthorized whole genome sequencing without the consent of the individual from whom the sample came." Specific protections would include informed consent as well as guarantees of confidentiality, anonymity or data security. *See Presidential Commission for the Study of Bioethical Issues News Release*, October 11, 2012.

ANSI Nanotechnology Standards Panel to Convene October 30

The American National Standards Institute's (ANSI's) Nanotechnology Standards Panel will meet in Washington, D.C., on October 30, 2012. Formed in 2004, the panel "serves as the cross-sector coordinating body and works to provide a forum for standards developing organizations (SDOs), government entities, academia, and industry to identify needs and establish recommendations for the creation or updating of standards related to nanotechnology and nanomaterials." During its meeting, the panel will "consider whether current nanotechnology standards activities meet existing stakeholder needs, as well as discuss the impact of existing standards on research and development and possibilities for greater collaboration between stakeholders in this area." Confirmed speakers include representatives of ANSI, the Consumer Product Safety Commission, National Institute of Standards and Technology, and Personal Care Products Council.

European Commission Proposes Regulation on Access to Genetic Resources

To carry out European Union (EU) obligations under the Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing, the European Commission (EC) has **proposed** a regulation that would ensure that only legally acquired genetic resources and associated traditional knowledge are used in the EU and that such resources are fairly and equitably shared.

According to the EC, a broad array of interests throughout the EU, including plant and animal breeding, biocontrol, cosmetics, food and beverage, horticulture,

industrial biotechnology, and pharmaceutical, uses resources found in "biodiversity hotspots in the developing world." For example, 26 percent of all new drugs approved during the past 30 years "are either natural products or have been derived from a natural product." In the absence of clear rules on acquisition and benefit sharing, European researchers and companies have apparently "been accused of 'biopiracy' by countries claiming a violation of their sovereign rights." The Nagoya Protocol, expected to take effect in 2014, will require signatories to follow certain procedures so that the rights of countries and of indigenous and local communities are protected while researchers in Europe are also given "improved, reliable access to quality samples of genetic resources at low cost with high legal certainty."

If adopted, the proposed regulation will impose obligations on users of genetic resources, establish an EU register of trusted collections, require member states to designate competent authorities to oversee its implementation and monitor user compliance, and provide for penalties, such as fines, suspension of specific use activities and confiscation of illegally acquired genetic resources, for transgressions. *See European Commission Press Release*, October 4, 2012.

LITIGATION

SCOTUS to Determine Where Patent Lawyers May Be Sued for Legal Malpractice

The U.S. Supreme Court has decided to review a Texas Supreme Court decision that found lower courts had erred in ruling on legal malpractice claims arising from patent-infringement litigation on the ground that federal courts have exclusive jurisdiction over patent-law matters. ***Gunn v. Minton*, No. 11-1118 (U.S., *certiorari* granted October 5, 2012)**.

The lower courts had agreed with the attorney-defendants that the matter belonged in state court and granted their motion for summary judgment, effectively dismissing on the merits the disappointed client's claims of legal malpractice for his attorneys' alleged mishandling of patent-infringement litigation. In a split ruling, the state supreme court determined that the federal patent issue underlying the state legal-malpractice lawsuit was "necessary, disputed, and substantial," and thus that federal jurisdiction was exclusive. The court relied on the "arising under" federal-question jurisdiction standard established in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), and the Federal Circuit's application of that standard in reaching its decision.

Thus, the issue presented to the U.S. Supreme Court is whether the Federal Circuit has departed from the *Grable* standard by holding that "state law legal malpractice claims against trial lawyers for their handling of underlying patent matters come within the exclusive jurisdiction of the federal courts." Recent divided Federal Circuit rulings on the issue are discussed in issues **34** and **35** of this *Bulletin*.

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NEWS BYTES

The U.S. Patent and Trademark Office **reopens** the comment period on its proposed rulemaking and proposed examination guidelines, published on July 26, 2012, "to implement the first-inventor-to-file provisions of the Leahy-Smith America Invents Act." Comments may now be submitted until November 5.

The U.S. Patent and Trademark Office **launches** a new Patent Prosecution Highway (PPH) with the Czech Republic's patent office and plans to launch two additional PPHs with its counterparts in the Philippines and Portugal in January 2013. The office claims that the expedited examinations provided by its PPHs "will allow applicants to obtain corresponding patents faster and more efficiently" thus improving the international patent system.

The Presidential Commission for the Study of Bioethical Issues **plans** to convene its 11th meeting November 5-7, 2012, in Chicago, to "continue discussing topics related to the ethical issues associated with the development of medical countermeasures for children." Written comments will be accepted at the registration desk, and the public is invited to participate. The meeting will be webcast at **www.bioethics.gov**.

The U.S. Food and Drug Administration's (FDA's) Risk Communication Advisory Committee is **scheduled** to meet November 2, 2012, to "discuss general factors in risk communication about FDA regulated products, including approaches to avoid message fatigue and related communication barriers such as prevention or warning fatigue or inaccurate risk perception." Those wishing to speak must notify FDA by October 25, and written comments are due by that date.

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