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VEPACHEDU EDUCATIONAL FOUNDATION

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IP and Industry News

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Patent Fees Increase Again

Patent applicants were hit with a 15% surcharge last September as a result of the enactment of the Leahy-Smith America Invents Act (*see* http://www.uspto.gov/aia_implementation/fee_setting_-_ppac_hearing_attachment_1-table_of_patent_fee_changes_7feb12.pdf). The USPTO submitted another set of patent fee changes to the Patent Public Advisory Committee (PPAC) in February (*see* "USPTO

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Proposes Fees Changes"). Another proposed adjustment in fees, which would go into effect on October 1, 2012, is intended to reflect fluctuations in the Consumer Price Index (CPI).
http://www.gpo.gov/fdsys/pkg/FR-2012-05-14/pdf/2012-11649.pdf

Small Entity

Written comments must be received on or before r July 30, 2012, regarding the USPTO notice of proposed rulemaking "**Changes to Implement Micro Entity Status for Paying Patent Fees"**
http://www.gpo.gov/fdsys/pkg/FR-2012-05-30/pdf/2012-12971.pdf

Patentability and the SCOTUS

The Supreme Court of the United States has rejected another Federal Circuit patentable subject matter decision and ordered the appellate court to review its patentability decision with further consideration of *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 566 U.S. ___ (2012). The patent at issue US 7,346,545 claims a particular method for distributing copyrighted products over the Internet. In a nutshell, the invention is a method wherein a consumer receives a copyrighted product in exchange for viewing an advertisement over the internet and with a monetization scheme. In its broadly written opinion, the Federal Circuit (Rader, C.J.) found the claimed invention patentable under Section 101 based upon the requirement that a computer be used to perform the method and the programming complexity required to carry out the claimed elements.

New Sequence Guidelines

The Committee on WIPO Standards (CWS) established a Task Force, led by the European Patent Organization (EPO), to propose a revised standard for the filing of Sequence Listings in XML format, in

October 2010, on which the Office's notice lists six topics on which it is seeking public comment. http://www.gpo.gov/fdsys/pkg/FR-2012-05-15/pdf/2012-11755.pdf

Biosimilars

By 2015, sales of biosimilars are expected to reach between US$1.9-2.6 billion, up from US$378 million for the year to the first half of 2011. The US accounts for most of the global spending on biologics and will be a key driver of long-term biosimilars market potential, while Europe is the most progressive. Devoid of a specific regulatory pathway, the US currently has no established industry for biosimilars. At present, there is only one product on the market that could potentially fit this description – Omnitrope (somatropin/HGH) which was launched by Sandoz in 2007 under a special ruling. (http://www.imshealth.com/ims/Global/Content/Home%20Page%20Content/IMS%20News/Biosimilars_Whitepaper.pdf)

In May, following a 60 day period for comment, the FDA held a public hearing on the Draft Guidance on Biosimilar Development. Researchers, patient and physician groups, and industry advocates provided their thoughts on the FDA's first attempt to clarify the logistics as to the operation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

Representatives of innovators advocated for more clinical studies and stricter standards for identity of products, surprisingly with a strong support from patient groups. Representatives from the National Kidney Foundation, Colon Cancer Alliance, and the Alliance for Safe Biologic Medicines warned that changes in manufacturing, packaging, handling, and storing of biologics can have unintended

consequences and produce drugs that may not work or unsafe. They encouraged the FDA to require unique names for biosimilars, which would help hold manufacturers accountable for their products.

Several biotech and biopharmaceutical companies urged the FDA to put patient safety at the core of its biosimilar policies. FDA must adopt policies that foster manufacturer accountability and supply chain stability, said Senior Vice President Joseph Miletich of Amgen. Sandoz official Mark McCamish said the FDA should use a single, science-based regulatory standard regardless of a developer's business model. The FDA accepted comments from public through May 25.
http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=public hearing biosimilar&utm_content=1
http://www.fda.gov/downloads/Drugs/NewsEvents/UCM302208.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=public hearing biosimilar&utm_content=3

On May 25th, the Senate considered several amendments and passed its version of the user fee provisions, S. 3187. Relevant to the BPCIA is TITLE IV: User Fees for Biosimilar Drugs, which contains several provisions related to various aspects of the nascent biosimilars regime. These include specifically Section 402, which sets forth amendments to the Food, Drug and Cosmetics Act as follows:
http://www.patentdocs.org/2012/05/senate-passes-user-fee-bill.html?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+PatentDocs+%28Patent+Docs%29&utm_content=Yahoo%21+Mail

FDA to Inspect Foreign Manufacturers More

For more than 70 years, the Food and Drug Administration has focused its inspections on U.S. factories. But over time, most companies have moved their operations overseas to take advantage of cheaper labor and materials. Between 2001 and 2008 the number of U.S. drugs made outside of the country doubled, according FDA figures. Today, roughly 80 percent of the ingredients used in U.S. medicines are made overseas.

A Senate bill would do away with a requirement that FDA inspect all U.S. factories every two years, and give the agency more discretion to focus on foreign facilities. Currently, the FDA inspects the average foreign manufacturing facility just once every nine years. Under the bill, FDA inspectors would be instructed to target the most problematic manufacturing sites, regardless of location.
http://www.huffingtonpost.com/huff-wires/20120524/us-fda-bill-senate/

Genetic Diagnostic Tests

The U.S. Patent and Trademark Office had begun to collect information on independent second opinion genetic diagnostic testing where patents and exclusive licenses exist that cover primary genetic diagnostic tests (77 Fed. Reg. 3748). To provide the public with access to comments that were submitted in response to the Office's request, a webpage on genetic diagnostic testing has been established as part of the Office's AIA implementation site.

Intellectual Property Owners Association (IPO) contends that "compelling patent owners to grant licenses for the purpose of permitting third parties to provide second opinion genetic diagnostic tests would have a detrimental effect on the U.S. patent system," by "undermin[ing] the incentive created by the patent system to create new tests, as well as to design around existing patents to provide tests that are comparable to existing tests." The IPO states that "exclusive licenses do not materially reduce the availability of second opinion genetic diagnostic tests, as these tests are usually available from the patent owner or another licensed provider."

Big Pharma Joins Forces with Academia

GlaxoSmithKline and AstraZeneca welcomed the launch of a pioneering approach to antibiotic research in Europe that will see pharmaceutical and biotechnology companies working alongside public partners to tackle the rising threat from antibiotic resistance and address some of the key barriers to the development of effective antibiotics. The objective of the proposed research program is to improve the underlying scientific understanding of antibiotic resistance, design and implement efficient clinical trials and take novel drug candidates through clinical development. The program is part of the European Commission's Action Plan against the rising threats from Antimicrobial Resistance, launched in November last year. http://www.biospace.com/News/drug-giants-such-as-astrazeneca-plc/261459

Indian Compulsory License

Under Section 84 of the Indian Patents Act, any interested person can apply for a compulsory license after the expiry of three years from the date of grant of the patent if reasonable requirements of the public with respect to the patented invention have not been satisfied; the patented invention is not available to the public at a reasonably affordable price or if the patented invention has not worked in the Indian territory.

Indian PTO reviewed, competing claims of Natco (the CL applicant) and Bayer (the patentee):

1) the probable number of patients requiring the drug could lie between 27000 and 70000 bottles per year and that Bayer has made available the drug to only a little above 2% of the eligible patients (Bayer estimated the number of patients eligible for Sorafenib Tosylate as 8842 per year),

2) Bayer's behavior in fulfilling the "reasonable requirements of the public" from the working statement (Form 27) filed by Bayer that showed no logical information about sales in 2009 and import of only 680 units (60 table pack) in 2010,

3) Bayer's conduct of not making the drug available since grant of patent in 2008, as per the requirement of the public in India since the grant of the patent,

And concluded that Bayer actions were not justifiable considering that Bayer was marketing the drug worldwide since 2006 and held that Bayer imported and made available only an insignificant proportion of the reasonable requirement of the patented drug in India, hence the reasonable requirement of the public with respect to the patented invention have not been satisfied. The Controller disregarded Bayer's argument that sales of another Indian generic company, Cipla, should be taken into account in determining whether the Indian market was being reasonably satisfied, noting that Bayer had sued Cipla in Delhi and asked for an injunction to stop these infringing sales.

The Indian PTO decided that failure to manufacture Nexavar in India supported the grant of a compulsory license to Natco (which it termed "reasonable fetter" on Bayer's patent rights). Indian patent law was construed to require that a patentee work a patented invention in India or license another to do so under Section 83(b), which states that "[p]atents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article" and Section 83(c) that "the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology" coupled with the provisions of Section 83(f) that a patent should not be abused.

After reviewing the above, the Indian PTO established the terms of the compulsory license for sorafenib such as:

1. Right to make and sell sorafenib limited to applicant (no sublicensing)
2. Compulsorily licensed drug can be sold only for treatment of liver and renal cancer
3. Royalty shall be paid at a rate of 6%
4. Price set at Rs. 8,800/- for one month treatment;
5. Applicant commits to provide the drug for free to at least 600 "needy and deserving" patients per year
6. Compulsory license not assignable and non-exclusive, with no right to import the drug

7. No right for the licensee to "represent publicly or privately" that its product is the same as Bayer's Nexavar
8. Bayer has no liability for Natco's drug product, which must be physically distinct from Bayer's dosage form

BRIC loses its weight as India's License Raj returns

The grouping of disparate giants known as the BRIC nations — Brazil, Russia, India and China — has, for some reason, lost much of its previous momentum. Last year Brazil grew at only a 2.7 percent rate, down from 7.5 percent, and Chinese and Russian G.D.P. growth are slowing too, to an unknown extent and duration. **India's growth is at 6.9 percent for 2012, estimated by the International Monetary Fund.** On the World Bank's Doing Business Index, the country ranks 132 out of 183 listed countries and regions, behind Honduras and the West Bank and Gaza, and just ahead of Nigeria and Syria. One undercurrent of talk is that the days of "the license Raj" have returned, referring to the country's earlier subpar economic performance under a regime of heavy government regulation.
http://www.nytimes.com/2012/05/06/business/economic-view-forget-europe-worry-about-india.html?_r=1

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!
(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

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