AIPLA
FDA COMMITTEE FLASH

2015 Summer Issue

Events at the AIPLA Annual Meeting

1. **Joint Presentation from the FDA and Patent Litigation Committees**

Roughly four years after the passage of the Biosimilars Price Competition and Innovation Act ("BPCIA"), the action in the US biosimilars arena is heating up. A panel of experts will discuss "Biosimilars are Off and Running: A Litigation and Regulatory Update" on **October 23, 2015, 3:30-5:30 PM**, exploring what can be gleaned about the regulatory pathway from the approvals to date and discussing the latest litigation developments.

2. **Joint Presentation from the Biotech and ITC Committees**

On **October 22, 2015, 3:30-5:30 PM**, the Biotech and ITC Committees will jointly examine the patents of Soteria Biosciences, a hypothetical biotech company, which grew from a small agro-bio startup into a multidisciplinary global giant. The presentations will focus on whether to pursue enforcement of Soteria Bioscience's patents before the ITC as opposed to a district court, and preparing for PTAB challenges to Soteria's Pre-AIA and Post-AIA Patents.

3. **Patent Prosecution – A "101 Special" Session**

On **October 23, 2015, 8:45-11:45 AM**, experts will take a comprehensive look at the current status of the subject matter eligibility issue. Topics include:

- A Look at the Numbers: A statistical analysis and overview of metrics including allowance rates and filing volumes before and after *Alice*.
- Legislative Logistics: What can be done by the legislature to separate the subject matter debate from troll concerns?
- Allowed, but Enforceable? A review of litigation and post-grant proceedings to see how courts are applying *Alice* and Progeny.
- The Details: Practical Advice on how to work with the current 101 regime: An

interactive discussion of patent application preparation and prosecution of both Electrical/Software and Chem/Bio technologies.

AIPLA FDA Committee News

From Elise, the FDA Committee Recruiter:
World IP Day was launched in 2000 by the World Intellectual Property Organization (WIPO) to promote and protect creative ideas. The Public Education Committee of the AIPLA has been working with local IP law associations, Chambers of Commerce, cities, and law schools to celebrate World IP Day nationwide. Are you interested in being involved in 2016? Contact Elise Selinger at eselinger@dfw.conleyrose.com.

From Tony and Li, FDA Flash Editors:
If anyone is interested in writing articles for upcoming issues of the FDA Flash, then please contact Tony Orsi (torsi@bereskinparr.com) or Li Feng (li.feng@finnegan.com).

Articles

Linda Pissott Reig (Buchanan Ingersoll & Rooney PC): For years, the pharmaceutical industry has complained about the extraordinary restrictions that limit dissemination of important data about FDA-approved prescription drugs. Recently, however, an important court decision has called into question the long-standing prohibition against prescription drug companies engaging in promotion of "off-label" information about their drugs.

Relying on First Amendment principles, a District Court (Southern District of New York) agreed that FDA's rules prohibiting off label promotion are simply too restrictive. It was of no matter to the court that the company had only recently been denied an expanded indication for the product and that the information the company wanted to share (and that the court agreed that it could share) was "off-label."

The pharmaceutical industry is now abuzz with excitement about the *Amarin v. FDA*

decision. The excitement is warranted but there are a few caveats that must be kept in mind. These include that it is a decision that is only binding on one jurisdiction (i.e. Southern District of New York), it relates to a very safe product that is available in high dosage forms by prescription (but that, in much lower doses, is sold over-the-counter), and the ruling is solely a "preliminary" one. Even with such caveats, the ruling is an important one for First Amendment advocates and for the pharmaceutical industry. Read more here.

Laura W. Smalley (Harris Beach PLLC): Amgen has apparently filed one of the first complaints alleging compliance with the "patent dance" provisions of the BPCIA in the United States District Court for the Southern District of Florida. Amgen seeks to enjoin the manufacture and distribution of a version of Amgen's Neulasta® (pegfilgrastim) by Apotex, claiming that such actions would infringe the patents-in-suit and that Apotex has not provided an effective notice of commercial marketing under the BPCIA. Read more here.