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Sent: Tuesday, January 17, 2017 12:26 PM
To: 'ST-BIOTECH@MAIL.AMERICANBAR.ORG'
Subject: ABA Biotech Law Committee -- News & Developments

**Biotechnology Law Committee, ABA Section of Science & Technology
Week of January 8, 2017 to January 14, 2018
Plus January 15 & 16, 2018**

Developments of Note.

- **Certiorari Grant: Sandoz v. Amgen.** On January 13, the Court granted certiorari in [15-1195](#) and [15-1039](#). The cases are consolidated. The issues, in brief, though stated differently in the petitions, are (1) whether the 180 day notice of commercial marketing by a biosimilar applicant may be given before approval of the biosimilar application is effective, (2) whether a biosimilar applicant must provide the reference product sponsor a copy of its marketing application and manufacturing information (and participate in the information exchange process that leads to premarket patent litigation as described in section 351(k)(6) of the PHSA), or, colloquially, whether the “patent dance” is mandatory or optional.
- **Biosimilar Guidance.** FDA is kicking out a lot of guidance. Today they released draft guidance on the [Considerations in Demonstrating Interchangeability with a Reference Product](#), and on the 12th they released final guidance on [Nonproprietary Naming of Biological Products](#).
- **Combination Products Guidance.** FDA released final guidance on CGMP requirements for [combination products](#) (e.g., drug plus diagnostic). This describes and explains the regulation that was issued in 2013 (21 CFR part 4), and it works through three hypothetical scenarios (prefilled syringe, drug-coated mesh, drug-eluting stent).
- **Injunction in Amgen v. Sanofi (Civ. No. 14-1317-SLR).** This was a patent infringement case brought by Amgen, which holds approval for Repatha (evolocumab), against Sanofi, which launched Praluent (alirocumab). The defendants stipulated to infringement of certain claims, trial was held on validity, and the jury found the asserted claims valid. Applying eBay, the district court (D. Del., Judge Robinson) [granted](#) Amgen’s motion for a permanent injunction. The permanent injunction caught a lot of people by surprise.

Committee News.

- **Biotechnology Committee Meeting.** We are meeting in person on Friday, February 2, at 2pm Eastern in the Palm Isle Room at the Intercontinental Hotel in Miami.
 - **Call for Volunteer: Top 10 List.** We need someone to write a short “top 10 biotech law developments of 2016” piece.
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Top 10 Biotech Law Developments of 2016

- Ariosa v. Sequenom (patent eligibility case) certiorari denial
 - Enactment of bioengineered food disclosure law
 - Enactment of 21st Century Cures
 - FDA's Biosimilar Labeling guidance
 - Approval of Sarepta's Exondys 51 (eteplirsen) for Duchenne muscular dystrophy
 - Enactment of Defend Trade Secrets Act of 2016
 - ***What else? Email me back.***
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Committee Network.

- **Krista Carver.** Krista is the past-chair of this committee and a member of the Section Council. She is a partner at Covington & Burling, focusing on FDA regulatory and legislative matters for companies in the biotechnology, pharmaceutical, medical device, and cosmetic industries and on related transactional matters. She assisted biotechnology innovators in legislative matters leading up to enactment of the BPCIA and has deep experience with biosimilars issues. She also counsels clients on an array of regulatory issues including orphan drug, Hatch-Waxman, and pediatric exclusivities and life cycle management strategies; priority review vouchers; breakthrough and fast track status; product jurisdiction; human cells, tissues, and cellular and tissue-based products (HCT/Ps); clinical trial data confidentiality and transparency; proprietary naming of pharmaceuticals; and medical device and diagnostic regulation. Ms. Carver also assists clients with advocacy before FDA, including formal dispute resolution requests and citizen petitions, and with legislative issues surrounding potential amendments to the Federal Food, Drug, and Cosmetic Act and related laws.