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To: 'ST-BIOTECH@MAIL.AMERICANBAR.ORG'
Subject: ABA Biotech Law Committee -- News & Developments

Biotechnology Law Committee, ABA Section of Science & Technology
Weeks of December 25, 2016 to January 7, 2017

Developments of Note.

- **BPCIA patent litigation provisions; Sandoz v. Amgen, SCOTUS conference January 6.** Sandoz petitioned, and Amgen cross-petitioned, and they were distributed for the conference of January 6. We expect orders from the January 6 conference on Monday morning.
- **Common Rule.** Health and Human Services has sent the final regulations revising the Common Rule to OMB, which suggests the regulations will be released before President Obama leaves office. The Common Rule addresses the protection of human subjects in research, and the Notice of Proposed Rulemaking was published in September 2015. NPRM here, summary of the proposed changes here, summary of public comments from Council on Governmental Relations here. There are some aspects of special interest to folks working in biotech law, including perhaps the expansion of the definition of "human subject" to include non-identified biospecimens.
- **Law Journal Articles.** The latest issue of the Food and Drug Law Journal has two articles that may be of interest to people focusing on biotechnology law: Terry Coleman's history of the 1902 Biologics Control Act, here, and Evita Grant's paper on FDA regulation of clinical applications of CRISP, here. Evita's paper is behind a paywall, Terry's is public access.
- **Patent Owner Appeals of Decisions to Institute IPR; Federal Circuit rehearing relating to scope of Cuozzo, 136 S.Ct. 2131 (2016).** Without getting too much into the patent weeds, the case relates to the scope of section 314(d) of the Patent Act, which states that "the determination by the [PTO] Director whether to institute an inter partes review under this section shall be final and non-appealable." The Federal Circuit interprets this (e.g., in Achates) to mean it cannot hear an appeal from a patent owner challenging a decision to institute IPR on the ground the IPR petition was time barred. Last year in Cuozzo, the Supreme Court considered a different patent owner argument (and still said "no appeal") but included a lengthy discussion about the scope of preclusion under 314(d). That discussion, some believe, leaves open the door for some grounds of appeal. A panel of the Federal Circuit concluded (2:1) in Wi-Fi One that Cuozzo did not overrule its earlier cases, but several judges of the court of appeals have indicated that they want to reconsider Achates. They just decided to rehear the case en banc, and the outcome could be important for biotech patent owners.
- **Biosimilar Guidance.** FDA finalized its guidance document on clinical pharmacology studies for biosimilar applications. Guidance here; FDA explanation of the differences between the draft and final guidance, here; punchline: "These changes are for clarity . . . and are not substantive."

- **But, can they tame them?** Chinese researchers have developed genetically modified tree shrews to use for animal testing of drugs intended for human neurological and infectious diseases; news story here.

Committee News.

- **Biotechnology Committee Meeting.** We are meeting in person on Friday, February 2, at 2pm Eastern at the Intercontinental Hotel in Miami. Information on and registration for the midyear meeting is here.
- **Call for Volunteer: Top 10 List.** We need someone to write a short "top 10 biotech law developments of 2016" piece. This could be an email alert, a short publication, or even perhaps an article (or short piece) for Jurimetrics. I am happy to brain storm and facilitate, but I cannot take this on myself. Some ideas listed below. I am thinking legal developments rather than policy, science, and business developments. Please, someone, don't you want to take this and run with it? Brand a new committee product? The first annual? Does one of our law student members want to take this on, with me editing / helping a bit?
- **Conference on Governance of Emerging Technologies (Call for Abstracts)**. The 5th Annual Conference on Governance of Emerging Technologies: Law, Policy, and Ethics will be May 17–19 in Phoenix, Arizona. By "emerging technologies" they mean, among other things, nanotechnology, synthetic biology, gene editing, biotechnology, genomics, personalized medicine, human enhancement technologies, and robotics. This annual conference is organized by the Sandra Day O'Connor College of Law at Arizona State. SciTech has a close relationship with ASU (and jointly publishes Jurimetrics with ASU). Abstracts are due by January 31, and the sponsors will pay for conference registration (and meals) for one presenter for each abstract. Abstract submission here, more information about the conference here.

Possible Top 10 List.

- Ariosa v. Sequenom (patent eligibility case) certiorari denial
- 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.***

Committee Network.

- **Jorge L. Contreras** is an Associate Professor of Law at the University of Utah, with an adjunct appointment in the Department of Human Genetics (and before that was a partner at Wilmer Cutler). He has written and spoken extensively on the institutional structures of intellectual property, technical standardization and biomedical research. He currently serves as a member of NIH's Council of Councils, the Advisory Council of NIH's National Center for the Advancement of Translational Sciences (NCATS) and the Board of the Cures Acceleration Network (CAN), and previously served as Co-Chair of the National Conference of Lawyers and Scientists (NCLS) and a member of the National Advisory Council for Human Genome Research (NACHGR) and the National Academy of Science's (NAS) Committee on IP Management in Standard-Setting Processes. At the University of Utah, he serves on the Scientific Advisory Board of the Utah Genome Project, the Executive Steering Committee of the Center for Clinical & Translational Science and the Oversight Board of the Veterans Administration Genealogy Project. Professor Contreras's work has appeared in a range of scientific, policy and legal publications including *Science, Nature, Nature Biotechnology, Trends in Genetics, Georgetown Law Journal, North Carolina Law Review, Arizona State Law Journal, American University Law Review, Utah Law Review, Antitrust Law Journal, Berkeley Technology Law Journal,* and *Harvard Journal of Law and Technology*. Together with James Cuticchia, he edited the first text on the law of bioinformatics, *Bioinformatics Law: Legal Issues for Computational Biology in the Post-Genome Era* (Chicago: ABA Publishing, 2013), and has won numerous awards and honors for his scholarship and teaching. He holds degrees from Rice University (B.A., BSEE) and Harvard Law School (JD).