

Lietzan, Erika

From: Lietzan, Erika
Sent: Friday, December 23, 2016 7:28 PM
To: 'ST-BIOTECH@MAIL.AMERICANBAR.ORG'
Subject: ABA Biotech Law Committee -- News & Developments

Biotechnology Law Committee, ABA Section of Science & Technology Week of December 18, 2016 to December 24, 2016

**** NO EMAIL NEXT WEEK; HAPPY NEW YEAR ****

Developments of Note.

- **Drug / Device Combination Products.** FDA issued a final rule on December 20 relating to postmarket safety reporting for combination products, which include drugs and biologics that are linked with diagnostics. Here is a link to the final [rule](#), which is not too long but which is surprisingly hard to explain in a few short words. At a very high level, FDA divided the regulated entities into combination product applicants and constituent product applicants; each generally complies with the postmarketing safety reporting requirements applicable to the product based on application type (e.g., NDA); combination product applicants may have additional reporting requirements based on the constituent parts in the combination product; and there are some information sharing requirements.
- **Book Chapter / Journal Article on “Data Generating Patents.”** It seems to have been a slow week for biotechnology law developments, so here’s a [link](#) to a book chapter on what the authors refer to as “biomedical data-generating patents” – which claim inventions that produce valuable data. They mean patents covering genetic diagnostic tests (such as Myriad’s patents) as well as patents covering certain types of implantable devices. They propose a framework for identifying which of these patents are “socially problematic” and evaluate various solutions. It’s a short but thoughtful discussion. They disfavor ex ante solutions, such as limiting the patent term and narrowing patent eligibility. In their view ex post solutions are more promising -- like enhanced independent invention, reverse engineering, and experimental use defenses, as well as mandatory contributions to confidential repositories of data. This article is part of a larger conversation about the intersection of “big data” and “intellectual property” that is inevitably going to lead to some significant shifts in IP doctrine. And the authors seem fairly thoughtful about real world consequences of various possibilities that others are raising. So it may be worth reading.

Committee News.

- **Biotechnology Committee Meeting.** If you plan to attend the ABA Midyear Meeting, please come to the meeting of the biotechnology committee on Friday, February 2, from 2 to 3 pm. I do not have the precise room yet, but the SciTech Section is convening at the Intercontinental Hotel. Information on and registration for the midyear meeting is [here](#).

- **Call for Volunteer.** Does anyone want to work on a “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. Is anyone interested?
-

Committee Network.

- **Introduction: Larry W. Thorpe.** Larry W. Thorpe is a retired litigator and trial lawyer. Currently he is a chair of SciTech’s Committee on the Rights and Responsibilities of Scientists (CORRS), as well as an assistant editor of the SciTech Lawyer. He is also the editor (and article author) of an upcoming special issue of the SciTech Lawyer on gene editing. Prior to his retirement, he was a partner in the firm of Beirne, Maynard and Parsons in Houston, Texas. His litigation practice focused almost exclusively on scientific, medical and expert issues, and he has represented several major pharmaceutical entities, in nationwide product liability lawsuits. Before receiving his law degree (a midlife career change) he was a faculty member in the Department of Human Biological Chemistry and Genetics and Anatomy and Neurosciences at the University of Texas Medical Branch (UTMB) in Galveston, as well as earlier appointments in Pathology and Internal Medicine. He has published numerous papers in several areas of scientific research. He holds a B.S. (Biology) from the University of Oregon, a Ph.D. (Pathology) from the UTMB and a law degree from the South Texas College of Law, Houston.

