

## Lietzan, Erika

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**From:** Lietzan, Erika  
**Sent:** Friday, December 9, 2016 11:03 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 4, 2016 to December 10, 2016

Check out the slowly improving [Committee Website](#)

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#### Developments of Note.

- **Biosimilars.** The Solicitor General [finally weighed in](#), on the question whether the Supreme Court should grant certiorari in the Amgen/Sandoz dispute over interpretation of the patent litigation provisions in the BPCIA cases. The questions presented in the cert petition are (a) whether notice of commercial marketing under 42 U.S.C. 262(l)(8)(A) is legally effective if it is given before FDA approval of the biosimilar application, and, if not, (b) whether 42 U.S.C. 262(l)(8)(A) is a stand-alone requirement that may be enforced by means of an injunction that delays the marketing of the biosimilar until 180 days after FDA approval. The question presented in the conditional cross-petition is whether 42 U.S.C. 262(l)(2)(A) creates a binding disclosure obligation that a court may enforce by injunction, or whether the sponsor's sole recourse for the applicant's failure to disclose the information is the right, prescribed elsewhere in the BPCIA, to commence an immediate action for patent infringement. The SG has recommended that both petitions be granted, which increases the chances that certiorari will be granted.
- **21<sup>st</sup> Century Cures Act.** The Senate passed the bill this week; the House passed it last week; President Obama is slated to sign it into law on December 13. There is a lot in here to unpack. [Here](#) is a nice summary of the provisions related to medical devices. Join us on the 14th for a 30-minute tour of the highlights that will affect biotech (see below).

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#### Committee News.

- **Lunchtime Lightning Round.** Please join us on Wednesday, December 14, at 11am central for 30 minutes, to hear Professor Rachel Sachs of Washington University School of Law explain what's significant for biotech in the 21<sup>st</sup> Century Cures Act. Wednesday, December 14, 11am central, (866) 646-6488, Conference Code: 956 115 8534.
- **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](#).

- **Hot Topics.** Committee member Andrew Varcoe (featured below) gave a brief presentation mid-week to Division and Section Leadership within the ABA regarding recent developments affecting agricultural biotechnology. He addressed three topics. First was the recently enacted National Bioengineered Food Disclosure Law, which charges the Agricultural Marketing Service of USDA with developing a mandatory national system for disclosing the presence of bioengineered food. There will be rulemaking, and [this](#) is the website to watch. Second was the possibility of revision to the 7 C.F.R. part 340, through which APHIS (part of USDA) implements the Plant Protection Act. Under this authority, APHIS regulates certain genetically engineered organisms. Whether USDA will issue a proposed rule to revise these regulations seems a bit uncertain now, but [this](#) would be the web page to watch. Third was the recent 9th Circuit decision in [Atay v. Maui](#). The case related to a Maui ordinance banning the cultivation and testing of genetically engineered plants. The court found the ordinance expressly preempted by the Plant Protection Act to the extent it bans genetically engineered plants that APHIS regulates as plant pests. As to genetically engineered crops that APHIS has deregulated, the ordinance is not preempted by the Plant Protection Act, but it is impliedly protected by Hawaii state law.
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### Committee Network.



- **Introduction: Andrew Varcoe.** Andy Varcoe is Deputy General Counsel for Agriculture and Environment at BIO. Andy provides legal counsel, and manages legal projects and support, for BIO's Food and Agriculture Section and Industrial and Environmental Section. He focuses heavily on environmental law issues, and on legal and regulatory issues relating to agricultural and industrial biotechnology. Between 2007 and 2014, Andy served as in-house agency legal counsel at the Office of the General Counsel of USDA, helping to manage the agency's appellate litigation nationwide in a wide range of mission areas. Before that, he was a litigator at WilmerHale and before that a law clerk for the Honorable Edith H. Jones of the U.S. Court of Appeals for the Fifth Circuit and the Honorable Francis X. Spina of the Massachusetts Supreme Judicial Court. He graduated with honors from Harvard Law in 1999 and received his undergraduate degree with honors from the University of Chicago in 1995.